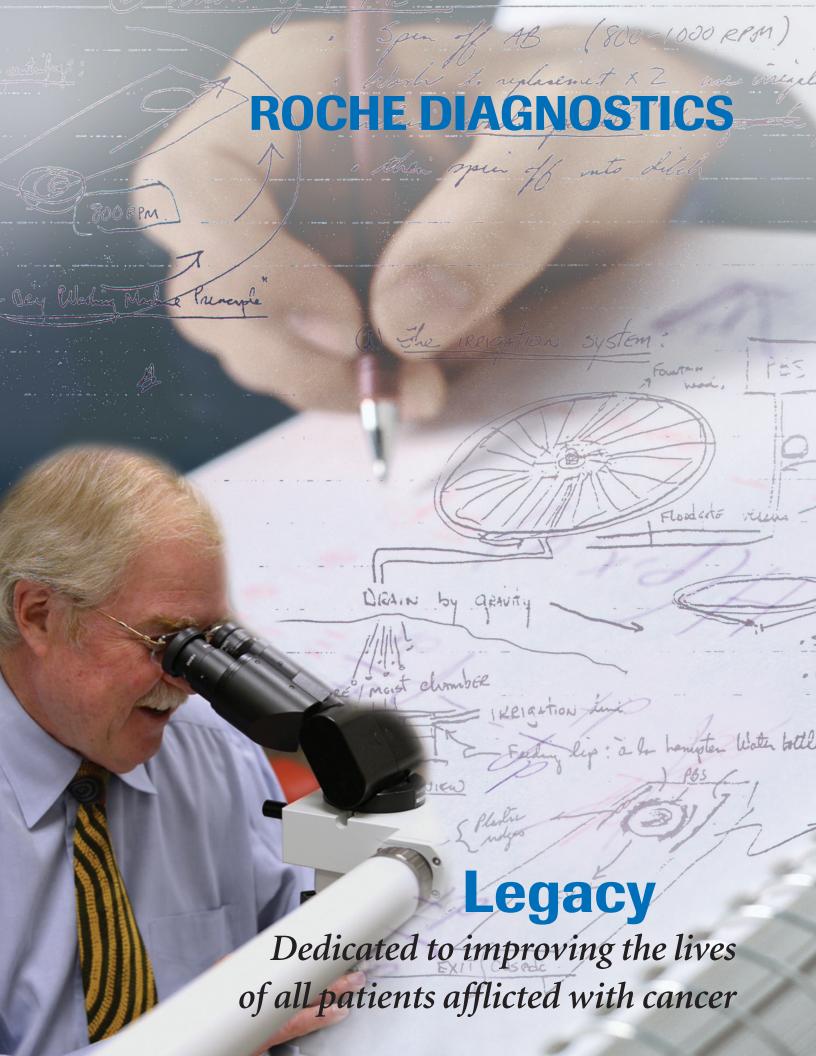


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### **Roche Diagnostics**

### Delivering medical value and testing efficiency

Roche is a global pioneer in pharmaceuticals and diagnostics, focused on advancing science to improve people's lives. This combination of strengths has made Roche the leader in personalized healthcare—a strategy that aims to fit the right treatment to each patient in the best way possible.

The world's largest biotech company, Roche is also the global leader in in vitro diagnostics and tissue-based cancer diagnostics.

#### **Combined strengths of the Roche Group**



**Personalized Healthcare** 

#### **Spanning the entire spectrum of diagnostics users**

#### Research

#### **Clinical Applications**













Academia

Pharma

Reference Lab Ho

Hospital

**Doctor's Office** 

**Patient Homes** 

**Diabetes Care** 

Sequencing Solutions

Molecular Diagnostics

**Tissue Diagnostics** 

Centralized Solutions

Point of Care Solutions

### **Tissue Diagnostics**

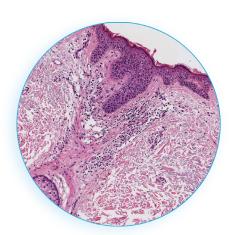
### Solutions to help your lab advance patient care

Like you, we're passionate about the patient behind every slide. We're committed to transforming cancer diagnosis with solutions that address the needs of anatomic pathology labs and healthcare professionals to help them improve the lives of the patients they serve.

### **Empowering your lab from sample accessioning through case sign-out**

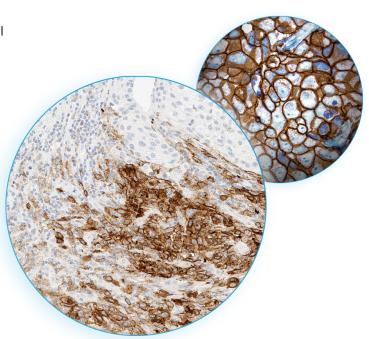
Our broad portfolio includes VENTANA integrated staining and workflow management platforms, digital pathology solutions and a robust menu of high-medical value assays that help labs increase efficiency, improve patient safety and deliver medical value.

From the time a patient specimen arrives to delivery of test results, Roche solutions enable your lab to provide accurate and reliable results in a timely manner. This helps patients get the right test, for the right treatment, at the right time.



#### Pathologist founded, patient focused

Building on the vision of Dr. Thomas Grogan, Roche continues to drive tissue diagnostics innovation that transforms the practice of medicine to improve patients' lives.



### **What's New**

### Improving lives through ongoing innovation

As part of Roche, we're continuously investing in diagnostic tools that address unmet medical needs and provide information to help advance patient care.

#### anti-p504s (SP116) Rabbit Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 08035130001** 790-6011

See complete product details on page 93.

#### **VENTANA DLL3 (SP347) Assay**

**50 tests Ordering Code Cat. No. 08416931001** 790-7016

See complete product details on page 55.

#### **VENTANA HA Assay**

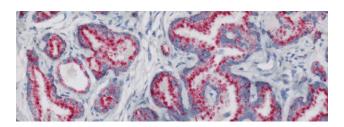
**50 tests Ordering Code Cat. No. 08289018001** 790-6074

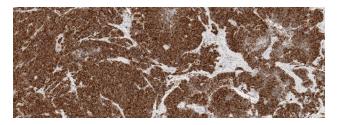
See complete product details on page 69.

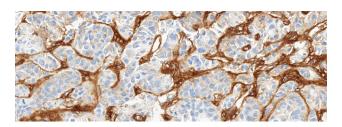
#### **VENTANA MSLN (SP74) Assay**

**50 tests Ordering Code Cat. No. 08508011001** 790-7028

See complete product details on page 84.









## See more with the VENTANA MMR IHC Panel

# Stratify colorectal cancer patients at risk for Lynch syndrome

The Class II IVD detects deficiency of any of the four mismatch repair (MMR) proteins as an aid in identifying probable Lynch syndrome in patients diagnosed with colorectal cancer (CRC).



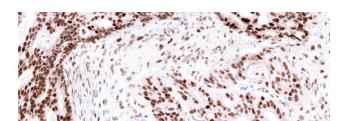
Inclusion of the VENTANA BRAF V600E (VE1) antibody helps refine the number of patients who receive additional testing for Lynch syndrome by identifying sporadic CRC in the absence of MLH1 expression.

The ready-to-use panel is optimized for use with the VENTANA OptiView DAB IHC Detection Kit on the fully automated VENTANA BenchMark ULTRA instrument.

### **VENTANA** anti-MLH1 (M1) Mouse Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 07862237001** 790-5091

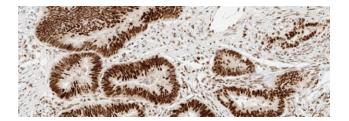
See complete product details on page 82.



#### **VENTANA** anti-MSH2 (G219-1129) **Mouse Monoclonal Primary Antibody**

**50 tests Ordering Code Cat. No. 07862253001** 790-5093

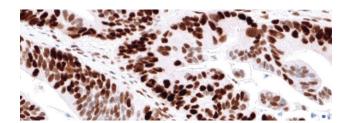
See complete product details on page 83.



### **VENTANA** anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 07862245001** 790-5092

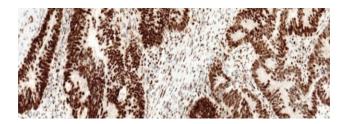
See complete product details on page 84.



### **VENTANA** anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 07862261001** 790-5094

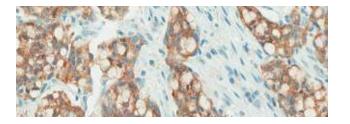
See complete product details on page 99.



#### **VENTANA** anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 07862270001** 790-5095

See complete product details on page 28.



### Carbonic Anhydrase IX (EP161) Rabbit Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 08313466001** 760-6080

See complete product details on page 34.

#### Inhibin, alpha (MRQ-63) Rabbit Monoclonal Primary Antibody

**50 tests Ordering Code Cat. No. 08313474001** 760-6081

See complete product details on page 74.

### **MUM1 (EP190) Rabbit Monoclonal Primary Antibody**

**50 tests Ordering Code Cat. No. 08313482001** 760-6082

See complete product details on page 86.

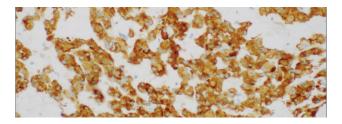
### **PSMA (EP192) Rabbit Monoclonal Primary Antibody**

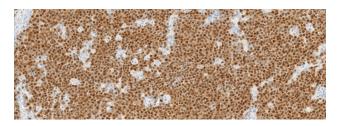
50 tests Ordering Code Cat. No.

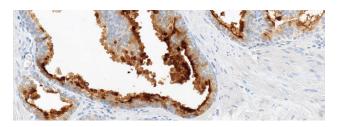
**08313423001** 760-6076

See complete product details on page 102.









#### **VENTANA DP 200 Slide Scanner\***

Robust, reliable, high-speed scanning for research

Advance your pathology research with high-quality, high-resolution digital imaging. Introducing the latest in brightfield scanners for research from Roche.

See complete product details on page 142.

\* For research use only. Not for use in diagnostic procedures.







# **Transformative**

Pioneering solutions that drive personalized healthcare

### **Companion Diagnostics**

### Because your assay choice matters

#### A call to personalize the practice of medicine

"Personalized healthcare is not holding a patient's hand. It's holding the intimate details of a patient's test results to a brighter light and asking, 'What am I missing?"

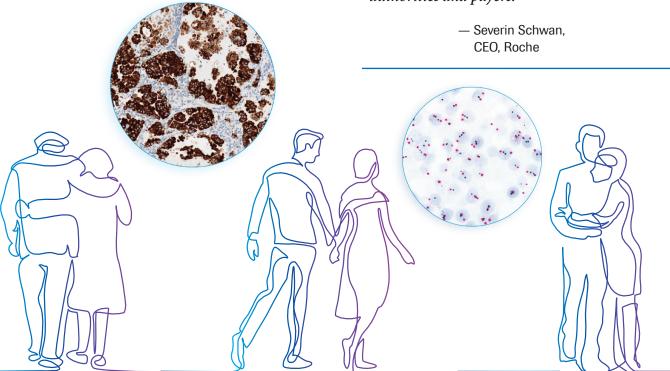
 Tom Grogan, M.D., pathologist and founder of Ventana Medical Systems, Inc.

Linking the most accurate diagnosis with the most targeted and relevant therapeutic is the essence of personalized healthcare, offering the potential for more positive outcomes for the patient—saving lives and improving the quality of life.

### Our commitment to helping you deliver personalized healthcare

In our mission to improve the lives of all patients afflicted with cancer, our goal is to empower you with the highest quality, most innovative tools to help deliver on the promise of personalized diagnostics and treatment. We're committed to accelerating the development of new cancer tests that can help improve and extend patients' lives by spanning the gap between generic and personalized treatment.

"Targeted diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers."



#### **VENTANA** companion diagnostics

Selective and predictive assays essential for personalized healthcare

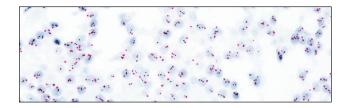
VENTANA companion diagnostics are fully automated to help improve quality and standardize testing, and can easily fit into your current workflow.



### VENTANA PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody

Aids in the assessment of breast cancer patients for whom Herceptin® (trastuzumab) treatment is considered.

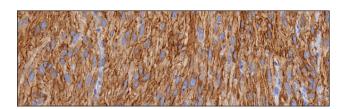
For more information on the VENTANA PATHWAY anti-HER-2/neu (4B5) primary antibody, see page 71.



#### **VENTANA INFORM HER2 Dual ISH Assay**

The only fully automated PMA-approved HER2 molecular assay that allows evaluation of HER2 gene status with morphological context using brightfield microscopy.

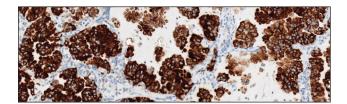
Catalog Number: 780-4422 Ordering Code: 05586640001



#### **VENTANA PATHWAY Anti-c-KIT (9.7)**

Aids in the selection of gastrointestinal stromal (GIST) patients who may qualify for Gleevec®/Glivec® (imatinib mesylate) therapy.

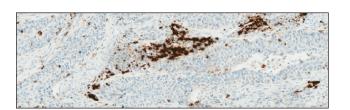
For more information on the PATHWAY anti-c-KIT (9.7) primary antibody, see page 29.



#### **VENTANA ALK (D5F3) CDx Assay**

Fully automated, easy-to-score, 4-hour ALK IHC test that provides same-day results to aid in identifying non-small cell lung cancer (NSCLC) patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib).

For more information, see page 23.



#### **VENTANA PD-L1 (SP142) Assay**

The first and only FDA-approved test predictive for TECENTRIQ® (atezolizumab) in urothelial carcinoma (UC) patients.

For more information on the VENTANA PD-L1 (SP142) Assay, see page 97.

### **Complementary Diagnostics**

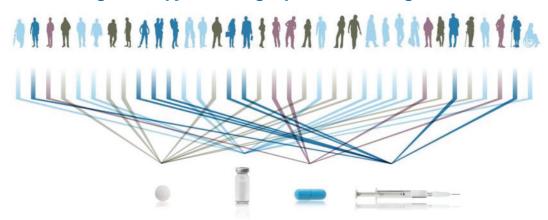
### Important information for drug-benefit decisions

#### Insights to guide immunotherapy decisions

Complementary diagnostic assays expand the array of tools available to help drive personalized healthcare and enable better outcomes for patients. While not required for safe and effective use of a therapeutic drug, complementary diagnostic assays may provide

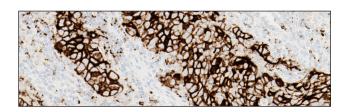
additional information that helps physicians make informed treatment decisions. By helping identify patients that are more likely to benefit from a specific therapy, complementary diagnostics aid in the choice of specific therapies for each patient.

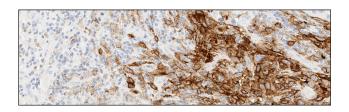
#### Right therapy, for the right patient, at the right time



#### **VENTANA** complementary diagnostics

The VENTANA PD-L1 (SP142) Assay is fully automated to help provide reliable, accurate results to enable timely diagnostic decisions and therapeutic choices.





#### **VENTANA PD-L1 (SP142) Assay**

FDA approved to assess non-small cell lung cancer (NSCLC) patient treatment benefit from TECENTRIQ® (atezolizumab).

For more information on the VENTANA PD-L1 (SP142) Assay, see page 97.

#### **VENTANA PD-L1 (SP263) Assay**

Identify urothelial carcinoma (UC) patients most likely to benefit from IMFINZI® (durvalumab).

For more information on the VENTANA PD-L1 (SP263) Assay, see page 97.

### **Regulatory Classifications**

### What do they mean?

At Roche Diagnostics, we develop and manufacture a variety of in vitro diagnostic (IVD) products, including reagents, instruments and systems. IVDs that are classified as a medical device for clinical diagnostics fall under FDA regulations.

#### In vitro diagnostic (IVD) products

In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its consequences. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.<sup>†</sup>

### FDA-regulated in vitro diagnostics are composed of non-clinical and clinical-use reagents

#### Non-clinical reagents include:

- Research Use Only (RUO)
- Investigational Use Only (IUO)

RUOs and IUOs are not intended for clinical diagnostic use.

#### Clinical reagents include:

FDA Cleared

- Class I, including analyte specific reagents (ASRs)
- Class II (510(k) and de novo status)
- Class III (Premarket Approval (PMA), companion and complementary status)

### **IVD Assay Classifications:**

		510(k) / de novo	FDA Approved / PMA
Regulatory Classification		<b>II</b> >	<b>III</b>
Risk to Public Health	Low	Moderate	High
Clinical Utility	Adjuvant test	Standalone assay	Predictive / Selective Diagnostic
Characteristics	Established in literature	Well-characterized tissue controls	Claims supported by clinical trials data submission
Examples	CD3	ER, PR (breast), CINtec <sup>®</sup> Histology, MMR IHC Panel	HER2, ALK, PD-L1

As device class increases from Class I to Class III, the regulatory controls also increase, with Class I devices subject to the least regulatory control, and Class III devices subject to the most stringent regulatory control.

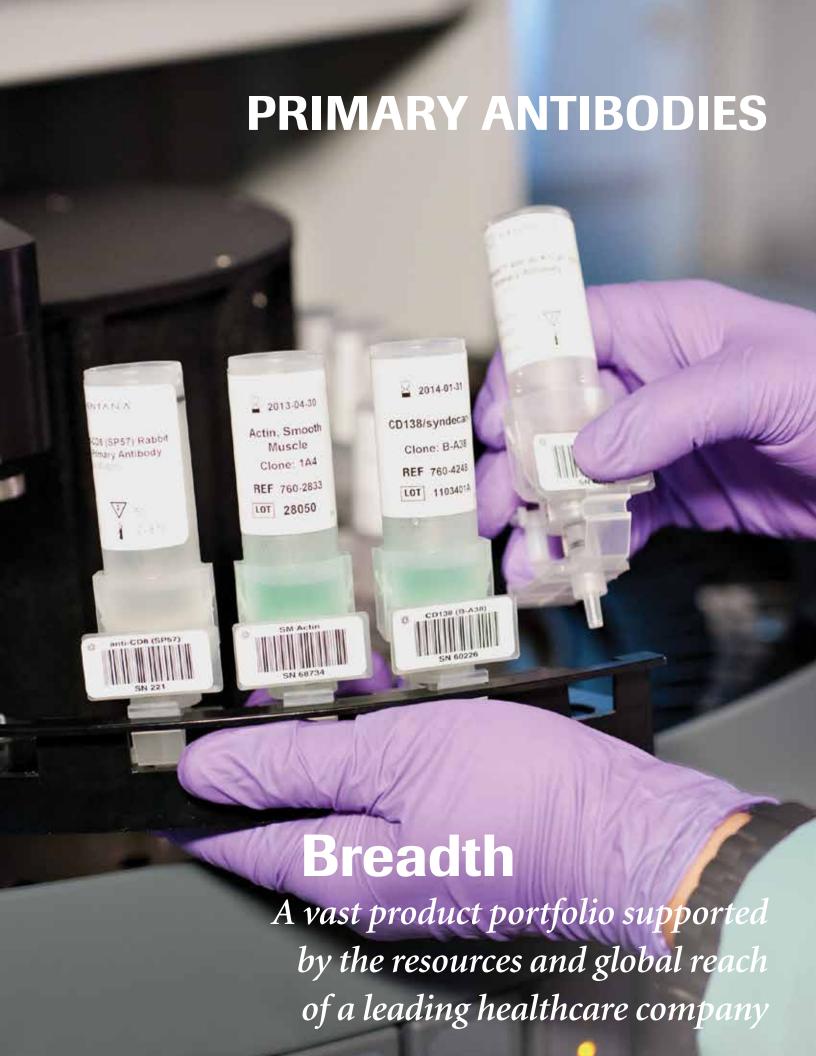
<sup>†</sup> https://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm123682.htm#1

### The regulatory controls for each device class include:

- RUO/IUO (Research Use Only/Investigational Use Only)
  - RUO and IUO devices are not intended for clinical diagnostic use.
- Class I (low to moderate risk): General controls
  - Class I devices are typically an adjuvant test, low risk and therefore subject to the least regulatory controls.

- Class II (moderate to high risk): General controls and special controls
  - Class II products are standalone, moderate-risk assays, requiring greater regulatory controls to provide reasonable assurance of safety and effectiveness.
- Class III (high risk): General controls and Premarket Approval (PMA)
  - Class III products are used as predictive or selective diagnostic assays, and have the highest risk. They are therefore subject to the highest level of regulatory control. These devices must be approved by the FDA prior to being promoted or sold in the U.S.

	Product Classification:	RUO	Class I	Class II	Class III
	FDA submission	No	No	Yes	PMA
	Immunoreactivity (ToT ToB)	No	Yes	Yes	Yes
performed	Robustness	No	Yes	Yes	Yes
rfor	Repeatability	No	Yes	Yes	Yes
	Pre-analytical (fixatives, etc)	No	Yes	Occasionally	Yes
dies	Stability studies	No	Yes	Yes	Yes
stu	Design validation	No	Yes	Yes	Yes
tion	Reader precision	No	No	Yes	Yes
rizat	Inter-laboratory reproducibility or repeatability	No	No	Yes	Yes
cte	Proof of utility in detecting a disease	No	No	Occasionally	Yes
Characterization studies	Clinical utility proving device performance in relation to drug outcome or potential misdiagnosis	No	No	Occasionally	Yes
	Cut off	No	No	Yes	Yes
	Clinical application:	None	Biomarker detection	Aids in treatment decisions	Linked to a therapy (Companion/ Complementary

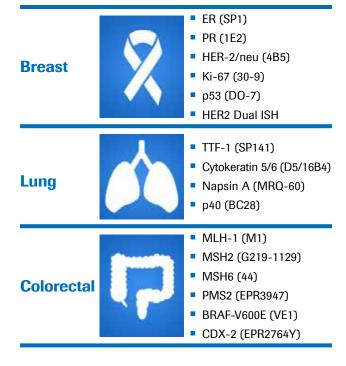


### **Ready-to-Use Primary Antibodies**

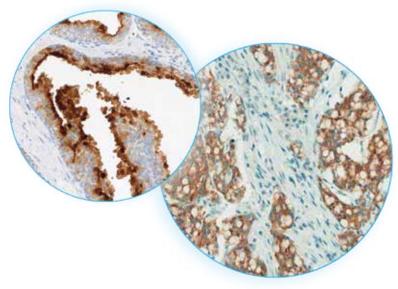
# More than 250 prediluted antibodies, optimized for use on VENTANA staining platforms

Featuring a world-class breast panel as well as cornerstone and emerging markers for lung diagnostics and other disease states, our comprehensive portfolio of high-value assays empowers pathology labs to deliver accurate, timely results with clinical confidence.

- Improve testing efficiency: Our prediluted antibodies are optimized for use on the fully automated VENTANA BenchMark staining platforms, reducing time-to-result and the resources required with manual or semi-automated solutions.
- Count on consistent performance: Roche antibodies have consistently demonstrated (via in-house validation) superior performance when compared to concentrated antibodies that require manual dilution.<sup>1</sup>
- Choose from a comprehensive portfolio:
   We offer more than 250 ready-to-use Class I assays, including the largest menu of rabbit monoclonal IVD antibodies available.



Our broad portfolio includes sensitive, specific assays for key markers. Turn the page for a complete listing of our primary antibodies and other IHC/ISH reagents by disease state.



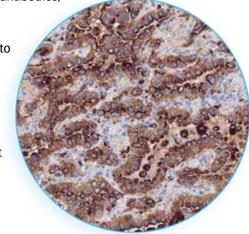


#### The rabbit monoclonal difference

Superior sensitivity and specificity for consistent, high-quality staining<sup>2</sup>

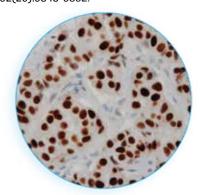
Demonstrating a better signal-to-noise ratio compared to mouse monoclonal and rabbit polyclonal antibodies, rabbit monoclonals:

- Provide broader diagnostic potential due to recognizing antigens and epitopes that are not immunogenic in rodents
- Reduce background for cleaner slides
- Provide greater consistency from lot to lot



#### **References:**

- Assessment Run B13 2012. Estrogen receptor (ER). NordiQC. http://www.nordiqc.org/Run-35-B13-H1/ Assessment/assessment-B13-ER.htm. Updated July 10, 2012. Accessed May 23, 2013.
- Spieker-Polet H, Sethupathi P, Yam PC, Knight KL. Rabbit monoclonal antibodies: Generating a fusion partner to produce rabbit-rabbit hybridomas. Proc Natl Acad Sci U S A. 1995; 92(20):9348-9352.



### **IHC/ISH Reagents by Disease State**

Extensive menu of ready-to-use clinical reagents, optimized for use on VENTANA BenchMark IHC/ISH staining platforms



#### **Breast**

#### **Typical Breast Panel Assays**

Estrogen Receptor (ER) (SP1), CONFIRM
Progesterone Receptor (PR) (1E2), CONFIRM
HER-2/neu (4B5), PATHWAY
HER2 Dual ISH DNA Probe Cocktail, INFORM
Ki-67 (30-9), CONFIRM
p53 (DO-7), CONFIRM

Calponin-1 (EP798Y)
Cytokeratin 14 (SP53)
Cytokeratin 5/6 (D5/16B4)
Cytokeratin 5/14 (EP1601Y/LL002)
E-cadherin (36), CONFIRM
E-cadherin (EP700Y)
FOXA1 (2F83)
GATA3 (L50-823)
GCDFP-15 (EP1582Y)
Mammaglobin (31A5)
p120 (98)
Topoisomerase IIa (JS5B4), CONFIRM



#### **Prostate**

#### **Typical Prostate Panel Assays**

Basal Cell Cocktail (34βE12+p63), VENTANA Cytokeratin 5/6 (D5/16B4) p504s (SP116) p63 (4A4), VENTANA PSA, CONFIRM PSAP (PASE/4LJ)

Androgen Receptor (SP107)
Cytokeratin (34βE12)
Cytokeratin 7 (SP52), CONFIRM
Cytokeratin 20 (SP33), CONFIRM
ERG (EPR3864)
EZH2 (SP129)
NKX3.1 (EP356)
PSMA (EP192)
PTEN (SP218)
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#### Lung

#### **Typical Lung Panel Assays**

Cytokeratin 5/6 (D5/16B4)

Napsin A (MRQ-60)

p40 (BC28)

Thyroid Transcription Factor-1 (SP141)

ALK (D5F3)	ΑL	_K	(I	Э5	F3)	)
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c-MET Total (SP44), CONFIRM

Calretinin (SP65), CONFIRM

Carcinoembryonic Antigen (CEA) (TF3H8-1)

Caveolin-1 (SP43)

CD56 (123C3), CONFIRM

CD56 (123C3), CONFIRM

CD56 (MRQ-42)

Chromogranin A (LK2H10)

Cytokeratin (CAM 5.2)

Cytokeratin 5 (SP27)

Cytokeratin 5/14 (EP1601Y/LL002)

Cytokeratin 7 (SP52), CONFIRM

Cytokeratin 17 (SP95)

Cytokeratin 20 (SP33), CONFIRM

Desmoglein 3 (5G11)

DLL3 (SP347)

E-cadherin (36), VENTANA

E-cadherin (EP700Y)

EGFR E746-A750 del (SP111)

EGFR (5B7), CONFIRM

EGFR (3C6), CONFIRM

EGFR L858R (SP125)

EMA (E29), CONFIRM

Epithelial-Related Antigen (MOC-31)

Ep-CAM (Epithelial Specific Antigen) (Ber-EP4)

IGF-1R(G11), CONFIRM

Mesothelial Cell HBME-1 (HBME-1)

MUC1 (H23)

NSE (MRQ-55)

p63 (4A4), VENTANA

PD-L1 (SP142)

PD-L1 (SP263)

SOX-2 (SP76)

Synaptophysin (MRQ-40)

Synaptophysin (SP11), CONFIRM

TAG-72 (B72.3)

WT1 (6F-H2)

### **IHC/ISH Reagents by Disease State** (continued)



### **Colorectal and Gastrointestinal**

#### **Typical Colorectal Panel Assays**

MLH-1 (M1)

PMS2 (A16-4)

MSH2 (G219-1129)

MSH6 (SP93)

BRAF-V600E (VE1)

Beta-catenin (14)

Cadherin 17 (SP183)

CEA (TF3H8-1)

COX-2 (SP21)Cytokeratin 19 (A53-B/A2.26)

Glutamine Synthetase (GS-6)

MUC1 (H23)

**MUC2 (MRQ-18)** 

#### **Typical Gastrointestinal Panel Assays**

c-KIT (9.7), PATHWAY

CDX-2 (EPR2764Y)

DOG1 (SP31)

CD34 (QBEnd/10), CONFIRM

Smooth Muscle Actin (1A4)

Cytokeratin 7 (SP52), CONFIRM

Cytokeratin 20 (SP33), CONFIRM

Helicobacter pylori (SP48), VENTANA



### **Dermatopathology**

#### **Typical Melanoma Panel Assays**

MART-1/melan A (A103), CONFIRM

Melanoma Associated Antigen (KBA.62)

Melanoma Associated Antigen (PNL2)

Melanosome (HMB45), CONFIRM

MITF (C5/D5), CONFIRM

Nerve Growth Factor Receptor (MRQ-21)

S100 (4C4.9), CONFIRM

S100 (Polyclonal), CONFIRM

SOX-10 (SP267)

Tyrosinase (T311), CONFIRM

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a-1-Antichymotrypsin (A	١U	)
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a-1-Antitrypsin (AAT)

CEA (TF3H8-1)

CD2 (MRQ-11)

CD3 (2GV6), CONFIRM

CD31 (JC70)

CD34 (QBEnd/10), CONFIRM

CD63 (NKI/C3)

Cytokeratin (AE1), CONFIRM

Cytokeratin 8 & 18 (B22.1 & B23.1)

Desmin (DE-R-11), CONFIRM

EMA (E29), CONFIRM

Ep-CAM (Epithelial Specific Antigen) (Ber-EP4)

Factor VIII Related Antig	en
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Factor XIIIa (AC-1A1)

Factor XIIIa (EP3372)

C1q, FITC

C3, FITC

Fibrinogen, FITC

Kappa, FITC

Lambda, FITC

HHV-8 (Human Herpes Virus Type 8) (13B10)

IgA (Immunoglobulin A)

IgA (Immunoglobulin A), FITC

IgG (Immunoglobulin G)

IgG (Immunoglobulin G), FITC

IgM (Immunoglobulin M)

IgM (Immunoglobulin M), FITC

Macrophage (HAM-56)

Melanoma Triple Cocktail (A103, HMB45, T311)

Neurofilament (2F11)

p53 (DO-7), CONFIRM

p53 (Bp53-11)

Podoplanin (D2-40)

Synaptophysin (MRQ-40)

Synaptophysin (SP11), CONFIRM

Tryptase (G3)

Vimentin (V9), CONFIRM

Vimentin (Vim 3B4), CONFIRM

### **IHC/ISH Reagents by Disease State** (continued)



### Hematopathology

#### **Typical Hematopathology Panel Assays**

bcl-2 (SP66)

c-Myc (Y69)

CD3 (2GV6), CONFIRM

CD5 (SP19), CONFIRM

CD10 (SP67), VENTANA

CD20 (L26), CONFIRM

CD23 (SP23), CONFIRM

CD30 (Ber-H2)

Cyclin D1 (SP4-R)

Ki-67 (30-9), CONFIRM

MUM-1 (EP190)

PAX5 (SP34), CONFIRM

ALK1 (ALK01) CONEIDM
ALK1 (ALK01), CONFIRM
Annexin A1 (MRQ-3)
bcl-2 (124), CONFIRM
bcl-6 (Gl191E/A8)
BOB.1 (SP92)
CD1a (EP3622)
CD2 (MRQ-11)
CD4 (SP35), CONFIRM
CD7 (SP94)
CD8 (SP57), CONFIRM
CD13 (SP187)
CD14 (EPR3653)
CD15 (MMA), CONFIRM
CD16 (SP175)
CD22 (SP104)
CD25 (4C9)
CD31 (JC70)
CD33 (SP266)
CD34 (QBEnd/10), CONFIRM
CD43 (L60)
CD45 (LCA) (2B11 & PD7/26)
CD45 (LCA) (RP2/18), CONFIRM
CD45R (MB1)
CD45RO (UCHL-1), CONFIRM

CDEC (100CO), CONICIDIA
CD56 (123C3), CONFIRM
CD56 (MRQ-42)
CD57 (NK-1)
CD61 (2f2)
CD68 (KP-1), CONFIRM
CD71 (MRQ-48)
CD79a (SP18), CONFIRM
CD99 (O13), CONFIRM
CD138 (Syndecan-1) (B-A38)
Fascin (55k-2)
Galectin-3 (9C4)
Glycophorin A (GA-R2)
Granzyme B
Granzyme B Hemoglobin A (SP212)
Hemoglobin A (SP212)
Hemoglobin A (SP212) HGAL (MRQ-49)
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A)
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D)
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D) IgG (Immunoglobulin G)
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D) IgG (Immunoglobulin G) IgM (Immunoglobulin M)
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D) IgG (Immunoglobulin G) IgM (Immunoglobulin M) Kappa, CONFIRM
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D) IgG (Immunoglobulin G) IgM (Immunoglobulin M) Kappa, CONFIRM Lambda, CONFIRM
Hemoglobin A (SP212) HGAL (MRQ-49) IgA (Immunoglobulin A) IgD (Immunoglobulin D) IgG (Immunoglobulin G) IgM (Immunoglobulin M) Kappa, CONFIRM Lambda, CONFIRM LMO2 (1A9-1), CONFIRM

Myeloperoxidase
Neutrophil Elastase (SP203)
Oct-2 (MRQ-2)
PD-1 (NAT-105)
SOX-11 (MRQ-58)
Spectrin (RBC2/3D5)
T-bet (MRQ-46)
TdT
TRAcP (9C5)
ZAP-70 (2F3.2)

#### A-1-Antichymotrypsin (polyclonal)

 Catalog Number:
 760-2604

 Ordering Code:
 05267196001

 Quantity:
 50 tests

Controls: Histiocytic Tumors

Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

A-1-Antichymotrypsin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the alpha-1 antichymotrypsin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### A-1-Antitrypsin (polyclonal)

 Catalog Number:
 760-2605

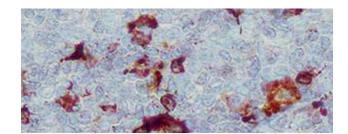
 Ordering Code:
 05267200001

 Quantity:
 50 tests

Controls: Appendix, Lymph Node, Tonsil

Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD

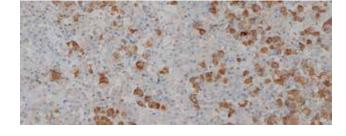
INTENDED USE



A-1-Antitrypsin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the A-1-Antitrypsin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **ACTH (polyclonal)**

**Catalog Number:** 760-2708 **Ordering Code:** 05268176001 Quantity: 50 tests Normal Pituitary **Controls: Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD



#### **INTENDED USE**

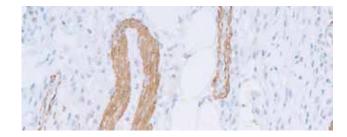
ACTH Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the ACTH protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **Actin, Muscle Specific (HHF35)**

Catalog Number:760-2601Ordering Code:05267161001Quantity:50 testsControls:Skeletal Muscle

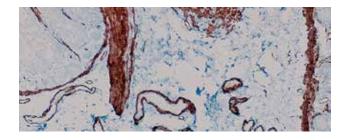
 $\begin{tabular}{lll} Isotypes: & IgG_1/K \\ Clone Name: & HHF35 \\ Species: & Mouse \\ Localization: & Cytoplasmic \\ \end{tabular}$ 

Regulatory Status: IVD



#### **INTENDED USE**

Actin, Muscle Specific (HHF35) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the actin, muscle-specific protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### Actin, Smooth Muscle (1A4) Mouse Monoclonal Antibody

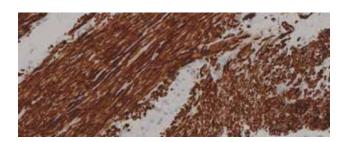
Catalog Number:760-2833Ordering Code:05268303001Quantity:50 tests

Controls: Appendix, Uterus

Isotypes:IgGClone Name:1A4Species:MouseLocalization:CytoplasmicRegulatory Status:IVD

#### **INTENDED USE**

Actin, Smooth Muscle (1A4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the smooth muscle actin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### anti-Actin, Muscle (HUC1-1) Primary Antibody

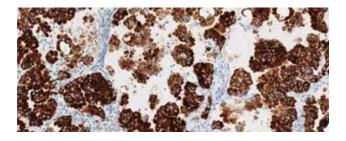
Catalog Number: 760-2502
Ordering Code: 05266882001
Quantity: 50 tests
Controls: Skeletal Muscle

 $\begin{array}{lll} \textbf{Isotypes:} & & \text{IgG}_1 \\ \textbf{Clone Name:} & & \text{HUC1-1} \\ \textbf{Species:} & & \text{Mouse} \\ \textbf{Localization:} & & \text{Cytoplasmic} \\ \end{array}$ 

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) anti-Actin, Muscle (HUC 1-1) may be used to aid in the identification of cells of normal and abnormal myocytic lineage as an aid in diagnosis of anaplastic tumors. Anti-Actin, Muscle (HUC 1-1) specifically binds to antigens located in the cytoplasm of myocytic cells. This antibody is intended for laboratory use to qualitatively identify by light microscopy muscle actin in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



#### **VENTANA ALK (D5F3) CDx Assay**

Catalog Number: 790-4796
Ordering Code: 06687199001
Quantity: 50 tests
Controls: Appendix
Isotypes: IgG
Clone Name: D5F3

**Species:** Rabbit Monoclonal **Localization:** Cytoplasmic

Regulatory Status: IVD, FDA Approved (PMA)

#### **INTENDED USE**

VENTANA ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

#### **CONFIRM anti-ALK1 (ALK01) Primary Antibody**

Catalog Number: 790-2918 **Ordering Code:** 05278147001 Quantity: 50 tests

**Controls:** Anaplastic Large Cell Lymphoma

Isotypes: IgG<sub>3</sub>/K **Clone Name:** ALK01 Species: Mouse

Localization: Nuclear, Cytoplasmic

**Regulatory Status:** IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-ALK1 (ALK01) Primary Antibody is a mouse monoclonal antibody directed against p80 protein present in human tissue. This antibody is intended for laboratory use to qualitatively stain sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



**Catalog Number:** 760-2603 **Ordering Code:** 05267188001 Quantity: 50 tests **Controls:** Fetal Liver **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic

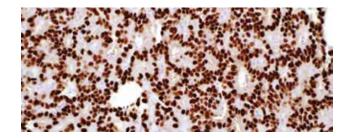
**Regulatory Status:** IVD

#### **INTENDED USE**

Alpha-Fetoprotein Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of Alpha-Fetoprotein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

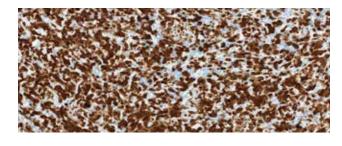


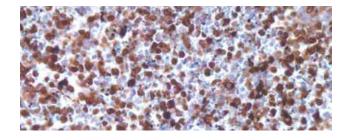
**Catalog Number:** 760-4605 **Ordering Code:** 06523838001 Quantity: 50 tests **Controls:** Prostate Isotypes: IgG SP107 **Clone Name:** Species: Rabbit Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

Androgen Receptor (SP107) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of androgen receptor in formalinfixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





#### **Annexin A1 (MRQ-3)**

 Catalog Number:
 760-4435

 Ordering Code:
 05973945001

 Quantity:
 50 tests

Controls: Hairy Cell Leukemia

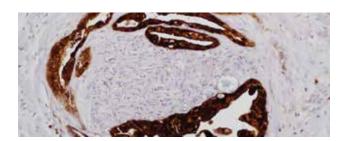
Isotypes:IgG1Clone Name:MRQ-3Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Annexin A1 (MRQ-3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Annexin A1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### anti-S100P (16/f5) Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4620

 Ordering Code:
 06523935001

 Quantity:
 50 tests

**Controls:** Placenta, Pancreatic Ductal Adenocarcinoma,

Urinary Carcinoma

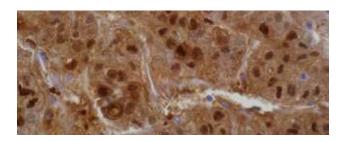
Isotypes:IgGClone Name:16/f5Species:Mouse

Localization: Cytoplasmic, Nuclear

Regulatory Status: IVD

#### **INTENDED USE**

S100P (16/f5) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the S100P protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### anti-Arginase-1 (SP156), Rabbit Monoclonal Primary Antibody

Catalog Number:760-4801Ordering Code:06732348001Quantity:50 tests

Controls: Hepatocellular Carcinoma, Normal Liver

**Isotypes:** IgG **Clone Name:** SP156

**Species:** Rabbit Monoclonal **Localization:** Cytoplasmic, Nuclear

Regulatory Status: IVD

#### **INTENDED USE**

Arginase-1 (SP156) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Arginase-1 enzyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### VENTANA Basal Cell Cocktail (34βE12+p63)

 Catalog Number:
 790-4536
 790-1010

 Ordering Code:
 06364497001
 06419445001

 Quantity:
 50 tests
 250 tests

Controls: Normal Basal Cells in Prostate Tissue

 $\begin{array}{lll} \textbf{Isotypes:} & & \lg G_{2a}/K \\ \textbf{Clone Name:} & & 34\beta E12 + 4A4 \\ \textbf{Species:} & & Mouse \\ \end{array}$ 

**Localization:** Cytoplasmic (34βE12), Nuclear (4A4)

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA Basal Cell Cocktail (34βE12+p63) is an antibody cocktail of anti-p63 (4A4) and anti-keratin (34βE12). Anti-p63 (4A4) reacts with the p63 molecule in the nuclei of human prostatic basal cells and urothelial tissues. Anti-keratin (34βE12) reacts with cytokeratins 1, 5, 10 and 14, and stains the cytoplasm of human prostatic basal cells. This antibody cocktail may be used to aid in the differentiation of benign and malignant prostatic lesions. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **BCA-225 (Cu-18)**

 Catalog Number:
 760-2607

 Ordering Code:
 05267226001

 Quantity:
 50 tests

Controls: Breast Carcinoma

Isotypes:IgG1Clone Name:Cu-18Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD

#### INTENDED USE

BCA-225 (Cu-18) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the BCA-225 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **CONFIRM** anti-bcl-2 (124) Mouse Monoclonal **Primary Antibody**

 Catalog Number:
 790-4464

 Ordering Code:
 05986826001

 Quantity:
 50 tests

Controls: Interfollicular T Cells in Tonsil,

B Cells of the Mantle Zone

 Isotypes:
 IgG1

 Clone Name:
 124

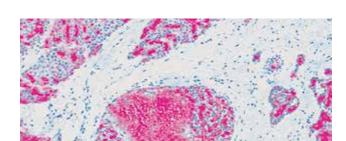
 Species:
 Mouse

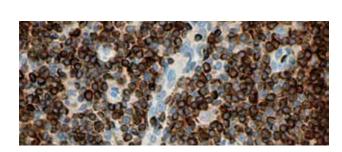
 Localization:
 Cytoplasmic

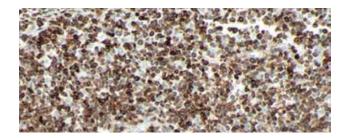
Regulatory Status: IVD

#### INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-bcl-2 (124) Mouse Monoclonal Primary Antibody (CONFIRM anti-bcl-2 (124)) is directed against human bcl-2 expressed by B cells of the mantle zone and interfollicular T cells. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of follicular lymphomas and diffuse large cell lymphomas, and to differentiate follicular lymphomas from reactive lymph nodes. CONFIRM anti-bcl-2 (124) is designed to qualitatively detect the presence of cells expressing bcl-2 protein via light microscopy in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.







### anti-bcl-2 (SP66) Rabbit Monoclonal Primary Antibody

Catalog Number:790-4604Ordering Code:06446329001Quantity:50 tests

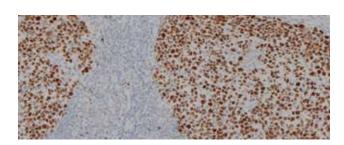
Controls: Interfollicular T Cells in Tonsil, B Cells of the Mantle Zone

Clone Name: SP66
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-bcl-2 (SP66) Rabbit Monoclonal Primary Antibody is directed against human bcl-2 expressed by B-cells of the mantle zone and interfollicular T cells. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of follicular lymphomas and diffuse large cell lymphomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### bcl-6 (GI191E/A8)

 Catalog Number:
 760-4241

 Ordering Code:
 05269008001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 Isotypes:
 IgG1

 Clone Name:
 GI191E/A8

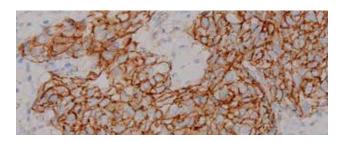
 Species:
 Mouse

 Localization:
 Nuclear

 Regulatory Status:
 IVD

#### **INTENDED USE**

bcl-6 (GI191E/A8) Mouse Monoclonal Antibody is intended for laboratory use in the detection of the bcl6 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **Beta-Catenin (14)**

 Catalog Number:
 760-4242

 Ordering Code:
 05269016001

 Quantity:
 50 tests

Controls: Fibromatosis of Breast or Abdomen

#### **INTENDED USE**

Beta-Catenin (14) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Beta-Catenin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### BG8, Lewis<sup>y</sup> (F3)

 Catalog Number:
 760-4450

 Ordering Code:
 05973767001

 Quantity:
 50 tests

Controls: Lung Adenocarcinoma

 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & & \\ \textbf{Species:} & & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \end{tabular}$ 

Regulatory Status: IVD

#### **INTENDED USE**

BG8, Lewis<sup>y</sup> (F3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of BG8 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **BOB.1 (SP92)**

 Catalog Number:
 760-4593

 Ordering Code:
 06433308001

 Quantity:
 50 tests

 Controls:
 Tonsil

 Clone Name:
 SP92

**Species:** Rabbit Monoclonal **Localization:** Nuclear, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

BOB.1 (SP92) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of BOB.1 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **VENTANA** anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody

#### For use with VENTANA MMR IHC Panel

 Catalog Number:
 790-5095

 Ordering Code:
 07862270001

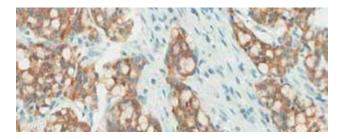
 Quantity:
 50 tests

**Controls:** Pre-qualified case of CRC that is positive for

the VENTANA anti-BRAF V600E (VE1) antibody

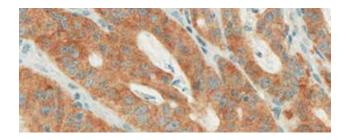
 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & & & & & \\ \textbf{Species:} & & & & & & & & & & & \\ \textbf{Localization:} & & & & & & & & & & & \\ \textbf{Cytoplasmic} & & & & & & & & & \\ \hline \end{tabular}$ 

Regulatory Status: IVD



#### **INTENDED USE**

The VENTANA MMR IHC Panel is a qualitative immunohistochemistry (IHC) test intended for use in the light microscopic assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) and BRAF V600E proteins in formalin-fixed, paraffin-embedded colorectal cancer (CRC) tissue sections. The OptiView DAB IHC Detection Kit is used with MLH1, MSH2, MSH6 and BRAF V600E, and the OptiView DAB IHC Detection Kit with OptiView Amplification Kit is used for PMS2 detection. The VENTANA MMR IHC Panel is for use on the VENTANA BenchMark ULTRA instrument. The VENTANA MMR IHC Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody and VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody. The VENTANA MMR IHC Panel is indicated in patients diagnosed with colorectal cancer (CRC) to detect mismatch repair (MMR) proteins deficiency as an aid in the identification of probable Lynch syndrome and to detect BRAF V600E protein as an aid to differentiate between sporadic CRC and probable Lynch syndrome. Results from the VENTANA MMR IHC Panel should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. The clinical performance of this device to guide treatment of MMR deficient patients has not been established. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.



#### anti-BRAF V600E (VE1) Mouse Monoclonal **Primary Antibody**

**Catalog Number:** 790-4855 **Ordering Code:** 06918727001 Quantity: 50 tests

Controls: Appropriate positive tissue controls include

colorectal adenocarcinoma or thyroid papillary

carcinoma with the BRAF V600E mutation

 $\mathsf{IgG}_{\mathsf{2a}}$ Isotypes: **Clone Name:** VE1

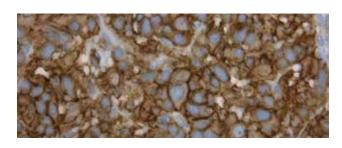
Species: Mouse monoclonal antibody

Localization: Cytoplasmic

**Regulatory Status:** IVD

#### **INTENDED USE**

Anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody (antiBRAF V600E (VE1)) may be used to aid in the identification of the mutant protein, BRAF V600E. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### PATHWAY Anti-c-KIT (9.7) **Primary Antibody**

**Catalog Number:** 790-2951 **Ordering Code:** 05278317001 Quantity: 50 tests

Controls: Breast, GIST, Skin

Isotypes: IgG **Clone Name:** 9.7 Species: Rabbit

Localization: Cytoplasmic, Membranous IVD - FDA Approved **Regulatory Status:** 

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use.

Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody is intended for laboratory use, via light microscopy, for the qualitative detection of KIT protein in formalin-fixed, paraffin-embedded gastrointestinal stromal tumors (GISTs) using either an automated immunohistochemistry staining system or a manual assay. It is indicated as an aid in the diagnosis of GIST within the context of the patient's clinical history, tumor morphology and other diagnostic tests evaluated by a qualified pathologist. It may be used after the diagnosis of GIST as an aid in the selection of GIST patients who may qualify for imatinib mesylate (Gleevec®/Glivec®) therapy.

PATHWAY Anti-c-KIT (9.7) Primary Antibody is optimized for use on a VENTANA Automated Slide Stainer and for manual application in combination with Ventana Medical Systems' iVIEW™ DAB Detection Kit and accessories. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

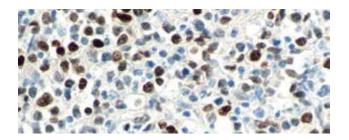
Note: The test is not intended as the sole basis for making the diagnosis of GIST and is not intended as the sole basis for selecting Gleevec/Glivec therapy. The proportion of c-KIT negative GIST patients who can respond to Gleevec/Glivec has not been established. A negative result would not necessarily exclude the diagnosis of GIST, nor should it preclude treatment with Gleevec/Glivec. 14, 34, 39

All of the subjects in the Novartis Gleevec/Glivec clinical trials were selected using an investigational immunocytochemical antibody (ICA). None of the subjects in those trials were selected using the VENTANA PATHWAY Anti-c-KIT (9.7) Primary Antibody. The VENTANA PATHWAY Anti-c-KIT (9.7) Primary Antibody was compared to the ICA on independent sets of samples and found to provide acceptably concordant results.

- 14. Heinrich, M., Corless, C., Duensing, A., McGreevey, L., Chen, C-J., Joseph, N., Singer, S., Griffith, D., Haley, A., Town, A., Demetri, G., Fletcher, C., and Fletcher, J. PDGFRA Activating Mutations in Gastrointestinal Stromal Tumors. Science. 229:708-710, 2003.
- 34. Taniguchi, M., Nishida, T., Hirota, S., Isozaki, K., Ito, T., Nomura, T., Matsuda, H., and Kitamura, Y. Effect of c-KIT mutation on prognosis of gastrointestinal stromal tumors, Cancer Res. 59: 4297-300, 1999.
- 39. Medeiros, F., Corless, C.L., Duensing, A., Hornick, J.L., Oliveira, A.M., Heinrich, M.C., Fletcher, J.A., Fletcher, C.D. KIT-negative gastrointestinal stromal tumors: Proof of concept and therapeutic implications. Am J Surg Pathol. Jul 28(7): 889-894, 2004.

#### anti-c-MYC (Y69) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-4628 **Ordering Code:** 06504612001 Quantity: 50 tests **Controls:** Skin Isotypes: IgG **Clone Name:** Y69 Species: Rabbit Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

Anti-c-MYC (Y69) Rabbit Monoclonal Primary Antibody (anti-c-MYC (Y69)) is directed against the transcription factor c-MYC, an important factor in cell cycle regulation. The anti-c-MYC (Y69) antibody exhibits a nuclear staining pattern and may be used to aid in the characterization of lymphoma. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **C3d Rabbit Polyclonal Antibody**

Catalog Number:760-4522Ordering Code:06419143001Quantity:50 tests

Controls: Acute Rejected Kidney Transplant

Isotypes:IgGClone Name:PolyclonalSpecies:Rabbit

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

C3d Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the C3d protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### C4d (polyclonal)

 Catalog Number:
 760-4436

 Ordering Code:
 05973937001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil, Kidney (Reject Transplant)

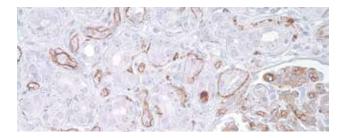
Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit

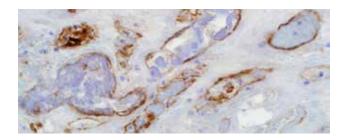
Localization: Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

C4d Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the C4d protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





#### C4d (SP91)

 Catalog Number:
 760-4803

 Ordering Code:
 06732364001

 Quantity:
 50 tests

Controls: Acute Rejected Kidney Transplant,

Tonsil/Lymph Node

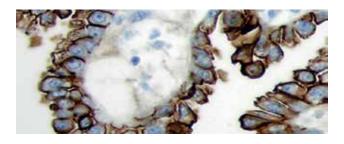
**Isotypes:** IgG **Clone Name:** SP91

**Species:** Rabbit Monoclonal **Localization:** Membranous

Regulatory Status: IVD

#### **INTENDED USE**

C4d (SP91) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the C4d protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **CA-125 (OC125)**

 Catalog Number:
 760-2610

 Ordering Code:
 05267269001

 Quantity:
 50 tests

Controls: Ovarian Carcinoma

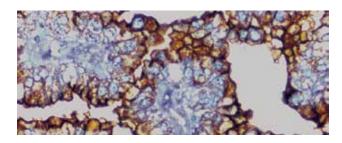
Isotypes: $lgG_1/K$ Clone Name:OC125Species:Mouse

Localization: Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

CA-125 (OC125) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CA 125 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### CA19-9 (121SLE)

 Catalog Number:
 760-2609

 Ordering Code:
 05267242001

 Quantity:
 50 tests

Controls: Colon, Salivary Gland

Isotypes:IgMClone Name:121SLESpecies:MouseLocalization:CytoplasmicRegulatory Status:IVD

#### **INTENDED USE**

CA19-9 (121SLE) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CA19-9 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Cadherin 17 (SP183) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4865

 Ordering Code:
 07047703001

 Quantity:
 50 tests

Controls: Colorectal Carcinoma

**Isotypes:** IgG **Clone Name:** SP183

**Species:** Rabbit Monoclonal **Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Cadherin-17 (SP183) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cadherin-17 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



 Catalog Number:
 760-2611

 Ordering Code:
 05267277001

 Quantity:
 50 tests

Controls: Medullary Carcinoma of Thyroid

Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD

#### INTENDED USE

Calcitonin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the calcitonin hormone in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



 Catalog Number:
 760-4705

 Ordering Code:
 06586554001

 Quantity:
 50 tests

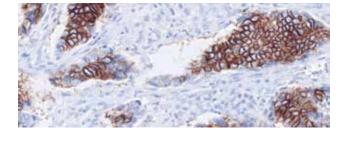
Controls: Medullary Carcinoma of Thyroid

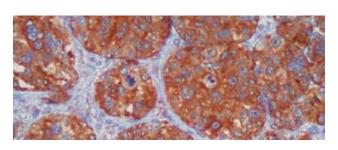
Isotypes:IgGClone Name:SP17Species:RabbitLocalization:Cytoplasmic

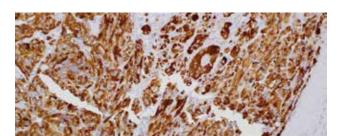
Regulatory Status: IVD

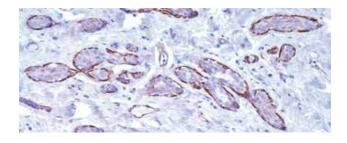
#### **INTENDED USE**

Calcitonin (SP17) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Calcitonin polypeptide in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.









### Caldesmon (E89)

 Catalog Number:
 760-4375

 Ordering Code:
 05463459001

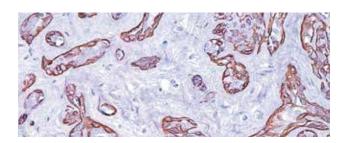
 Quantity:
 50 tests

Controls: Esophagus, Smooth Muscle from Bowel, Uterus

Isotypes:IgGClone Name:E89Species:RabbitLocalization:CytoplasmicRegulatory Status:IVD

#### **INTENDED USE**

Caldesmon (E89) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Caldesmon protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

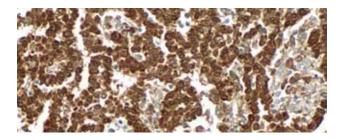


# Calponin-1 (EP798Y)

Catalog Number: 760-4376 **Ordering Code:** 05435684001 Quantity: 50 tests **Controls:** Appendix Isotypes: lgG **Clone Name:** EP798Y Rabbit Species: Localization: Cytoplasmic **Regulatory Status:** IVD

### **INTENDED USE**

Calponin-1 (EP798Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Calponin-1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM Calretinin (SP65) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4467

 Ordering Code:
 05992184001

 Quantity:
 50 tests

Controls: Mesothelioma, Normal Appendix

Clone Name: SP65 Species: Rabbit

**Localization:** Cytoplasmic, Nuclear

Regulatory Status: IVD

#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-Calretinin (SP65) Rabbit Monoclonal Primary Antibody (CONFIRM anti-Calretinin (SP65)) is directed against the calcium-binding protein, calretinin, expressed by normal and reactive mesothelium, eccrine glands of skin, Sertoli cells of the testis, ovarian stromal cells and adrenal cortical cells. This antibody exhibits a nuclear and cytoplasmic staining pattern and may be used to aid in the identification of mesothelioma, and in distinguishing mesothelioma from adenocarcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Carbonic Anhydrase IX (EP161) Rabbit Monoclonal Primary Antibody

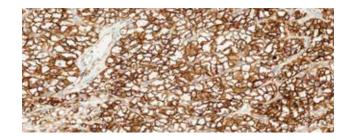
 Catalog Number:
 760-6080

 Ordering Code:
 08313466001

 Quantity:
 50 tests

Controls: Clear Cell Renal Cell Carcinoma, Gall Bladder

Isotypes:IgGClone Name:EP161Species:RabbitRegulatory Status:IVD



### **INTENDED USE**

Carbonic Anhydrase IX (EP161) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Carbonic Anhydrase IX protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Caveolin-1 (SP43) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4951

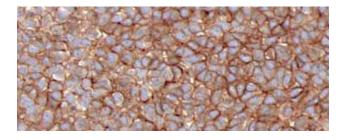
 Ordering Code:
 07391439001

 Quantity:
 50 tests

Controls: Ewings Sarcoma, Mesothelioma

Isotypes:IgGClone Name:SP43Species:RabbitLocalization:Membranous

Regulatory Status: IVD



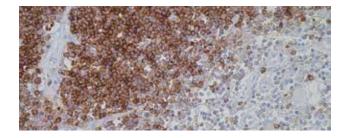
#### **INTENDED USE**

Caveolin-1 (SP43) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Caveolin-1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# CD1a (EP3622)

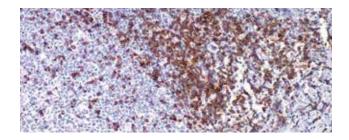
**Catalog Number:** 760-4525 **Ordering Code:** 06419160001 Quantity: 50 tests Thymus **Controls: Isotypes:** IgG<sub>1</sub> **Clone Name:** EP3622 Species: Rabbit Localization: Membranous

Regulatory Status: IVD



#### **INTENDED USE**

CD1a (EP3622) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD1a glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **CD2 (MRQ-11)**

Catalog Number:760-4377Ordering Code:05463467001Quantity:50 tests

Controls: Lymph Node, Tonsil

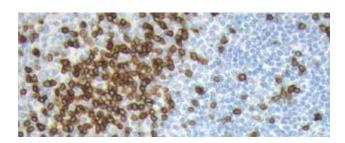
 $\begin{array}{ll} \textbf{Isotypes:} & \text{IgG}_1/K \\ \textbf{Clone Name:} & \text{MRQ-11} \\ \textbf{Species:} & \text{Mouse} \\ \end{array}$ 

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD2 (MRQ-11) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody**

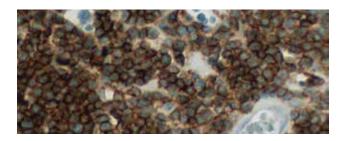
Catalog Number:790-4341Ordering Code:05278422001Quantity:50 testsControls:Spleen, TonsilClone Name:2GV6Species:Rabbit

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody (CONFIRM anti-CD3 (2GV6) antibody) is a rabbit monoclonal antibody (lgG) directed against the nonglycosylated epsilon chain of the human CD3 molecule.1 CONFIRM anti-CD3 (2GV6) antibody is intended for use to qualitatively identify T cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA BenchMark IHC/ISH series of automated instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-CD4 (SP35) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 790-4423 **Ordering Code:** 05552737001 Quantity: 50 tests **Controls:** Liver, Tonsil Clone Name: SP35 Species: Rabbit Localization: Membranous **Regulatory Status:** IVD

# **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD4 (SP35) Rabbit Monoclonal Primary Antibody is intended for the qualitative detection of CD4 in sections of formalin-fixed, paraffin-embedded normal and neoplastic human tissues. CD4 is present on helper-inducer T lymphocytes that recognize antigen in the context of MHC class 2 molecules. CD4 positive staining results may aid in identifying T-cell lymphomas and in identifying the T helper-inducer cell subset of T lymphocytes in normal tissues. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# **CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody**

Catalog Number: 790-4451
Ordering Code: 05929903001
Quantity: 50 tests
Controls: Tonsil, Lymphoma

Clone Name: SP19 Species: Rabbit

**Localization:** Cell Membrane, Cytoplasmic

Regulatory Status: IVD

### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody is directed against human CD5 expressed on the plasma membrane of virtually all human T cells and the B1a subset of human B cells found in the follicular mantle zones, bone marrow and peripheral blood. Staining CD5 is commonly used as part of several IHC panels to determine T cell and B cell subclassifications. CD5 may be used to aid in the identification of T-cell lymphomas and certain B-cell lymphomas, including mantle cell lymphoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-4558 **Ordering Code:** 06537847001 Quantity: 50 tests **Controls:** Thymus, Tonsil Isotypes: Rabbit Ig SP94 **Clone Name:** Species: Rabbit Localization: Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody (anti-CD7 (SP94)) is directed against the 40kD transmembrane glycoprotein, CD7 which is present in thymocytes and mature T cells. Anti-CD7 (SP94) may be used to aid in the identification of T-cell lymphomas. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-CD8 (SP57) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4460

 Ordering Code:
 05937248001

 Quantity:
 50 tests

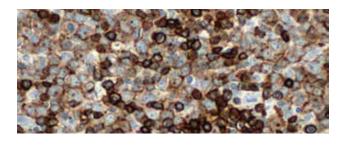
Controls: Tonsil, T Cell Lymphoma

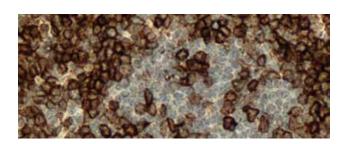
Clone Name: SP57
Species: Rabbit
Localization: Cell Membrane

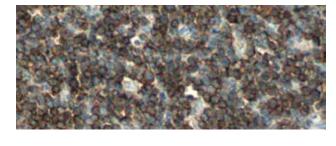
Regulatory Status: IVD

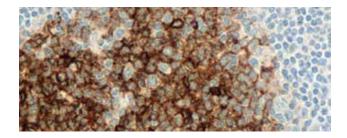
#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-CD8 (SP57) Rabbit Monoclonal Primary Antibody (CONFIRM anti-CD8 (SP57)) is intended for the qualitative detection of CD8 in sections of normal and neoplastic human tissues. The CD8 glycoprotein is present on cytotoxic/suppressor T lymphocytes that recognize antigen in the context of MHC class 1 molecules. CD8 positive staining results may aid in identifying T-cell lymphomas and in identifying the T cytotoxic/suppressor cell subset of T lymphocytes in normal tissues. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.









# **VENTANA** anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody

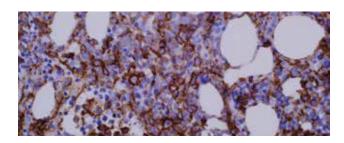
Catalog Number: 790-4506
Ordering Code: 05857856001
Quantity: 50 tests
Controls: Tonsil
Isotypes: Rabbit Ig
Clone Name: SP67
Species: Rabbit

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody is directed against the CD10 molecule, or common acute lymphoblastic leukemia antigen (CALLA), expressed on the surface of early lymphoid cells, and on various nonlymphoid tissues including breast myoepithelial cells, bile canaliculi, fibroblasts, kidney tubular brush borders and small intestine epithelium. This antibody exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of Burkitt's lymphoma and follicular germ cell lymphoma, and in the classification of some carcinomas such as renal cell carcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CD13 (SP187) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4862

 Ordering Code:
 07047673001

 Quantity:
 50 tests

 Controls:
 Liver

 Isotypes:
 IgG

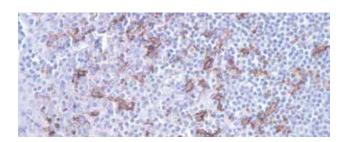
 Clone Name:
 SP187

**Species:** Rabbit Monoclonal **Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD13 (SP187) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD13 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CD14 (EPR3653) Rabbit Monoclonal Antibody

Catalog Number:760-4523Ordering Code:06419151001Quantity:50 testsControls:TonsilIsotypes:IgGClone Name:EPR3653Species:Rabbit

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

CD14 (EPR3653) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD14 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody**

 Catalog Number:
 760-2504

 Ordering Code:
 05266904001

 Quantity:
 50 tests

Controls: Hodgkin's Lymphoma

Isotypes:IgMClone Name:MMASpecies:Mouse

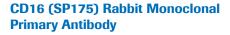
**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgM, kappa) directed against a carbohydrate epitope present on most granulocytic cells. This antibody is intended for use to qualitatively identify CD15 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on the VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

1. Pinkus GS., P. Thomas, and J.W. Said. Leu-M1 — A Marker for Reed-Sternberg Cells in Hodgkin's Disease: An Immunoperoxidase Study of Paraffin-Embedded Tissues. Am. J. Pathol. 1985; Vol. 119, p. 244-252.



Catalog Number:760-4863Ordering Code:07047681001Quantity:50 testsControls:TonsilIsotypes:IgGClone Name:SP175

Species: Rabbit Monoclonal
Localization: Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

CD16 (SP175) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD16 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



Catalog Number:760-2531Ordering Code:05267099001Quantity:50 tests

Controls: Lymph Node, Tonsil

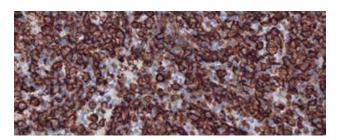
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{2a}/\textbf{K} \\ \textbf{Clone Name:} & \textbf{L26} \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Membranous} \\ \end{array}$ 

Regulatory Status: IVD

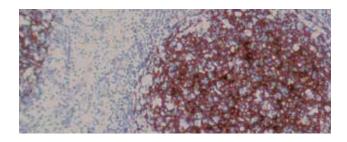
# **INTENDED USE**

CONFIRM anti-CD20 (L26) Primary Antibody (CONFIRM anti-CD20 (L26) antibody) is a mouse monoclonal antibody (IgG2a, kappa) directed against an epitope present on human B lymphocytes. CONFIRM anti-CD20 (L26) antibody is intended for use to qualitatively identify cells of B lymphocytic lineage<sup>1</sup> by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA BenchMark IHC/ISH series automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

1. Mason DY, Comans-Bitter WM, Cordell JL, Verhoeven MA, van Dongen JJ. Antibody L26 recognizes an intracellular epitope on the B-cell-associated CD20 antigen. Am J Pathol. 1990;136(6):1215-1222.







### CD21 (2G9)

Catalog Number:760-4245Ordering Code:05269059001Quantity:50 tests

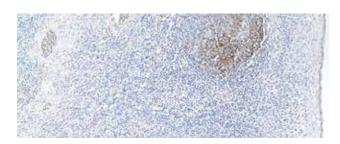
Controls: Lymph Node, Tonsil

Isotypes:IgG2aClone Name:2G9Species:MouseLocalization:Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD21 (2G9) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CD21 (EP3093)

Catalog Number:760-4438Ordering Code:05973902001Quantity:50 tests

Controls: Lymph Node, Tonsil

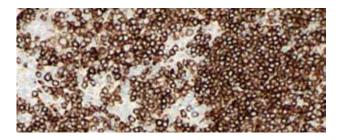
Isotypes:IgG1Clone Name:EP3093Species:Rabbit

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

### **INTENDED USE**

CD21 (EP3093) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-CD22 (SP104) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4588
Ordering Code: 06391117001
Quantity: 50 tests
Controls: Tonsil
Clone Name: SP104

Species: Rabbit Monoclonal
Localization: Membranous, Cytoplasmic

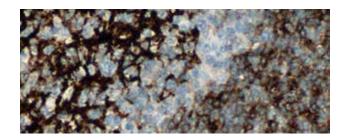
Regulatory Status: IVD

#### **INTENDED USE**

Anti-CD22 (SP104) Rabbit Monoclonal Primary Antibody (antiCD22 (SP104)) is directed against the type 1 integral membrane glycoprotein, CD22. Anti-CD22 (SP104) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of B-cell lymphomas. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-CD23 (SP23) Rabbit Monoclonal Primary Antibody**

Catalog Number: 790-4408
Ordering Code: 05479258001
Quantity: 50 tests
Controls: Tonsil
Clone Name: SP23
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD



### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD23 (SP23) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of CD23 expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining may be useful in classifying small lymphocytic lymphoma/leukemia from other small B-cell lymphomas including mantle cell and marginal zone lymphoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

### CD25 (4C9)

 Catalog Number:
 760-4439

 Ordering Code:
 05973899001

 Quantity:
 50 tests

Controls: Lesions of Mastocytosis, Small Bowel

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{2b} \\ \textbf{Clone Name:} & \textbf{4C9} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

# **INTENDED USE**

CD25 (4C9) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of CD25 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-4858

 Ordering Code:
 07007841001

 Quantity:
 50 tests

**Controls:** Positive control tissue: Lymphoma or Tonsil

Negative control tissue: Tonsil Germinal

Center B-cells

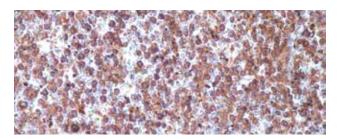
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{1}/\textbf{K} \\ \textbf{Clone Name:} & \textbf{Ber-H2} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

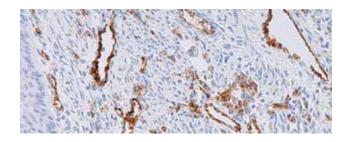
**Localization:** Cell Membrane, Cytoplasmic, Golgi

Regulatory Status: IVD

#### **INTENDED USE**

The anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody (anti-CD30 (Ber-H2)) is intended for laboratory use in the detection of the CD30 protein in formalin-fixed, paraffin-embedded tissue stained with BenchMark IHC/ISH instruments. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.





### **CD31 (JC70)**

 Catalog Number:
 760-4378

 Ordering Code:
 05463475001

 Quantity:
 50 tests

Controls: Appendix, Placenta, Tonsil

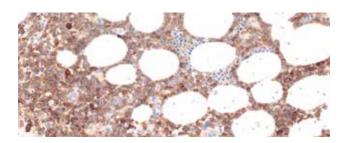
Isotypes: $IgG_1/K$ Clone Name:JC70Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD31 (JC70) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD31 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CD33 (SP266) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4952

 Ordering Code:
 07391447001

 Quantity:
 50 tests

**Controls:** Acute Leukemia, Placenta Syncytiotrophoblasts

 Isotypes:
 IgG

 Clone Name:
 SP266

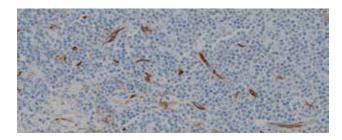
 Species:
 Rabbit

 Localization:
 Membranous

Regulatory Status: IVD

### **INTENDED USE**

CD33 (SP266) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD33 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-CD34 (QBEnd/10) Primary Antibody**

 Catalog Number:
 790-2927

 Ordering Code:
 05278210001

 Quantity:
 50 tests

Controls: Appendix, Placenta, Tonsil

 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \end{tabular}$ 

Regulatory Status: IVD

# **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD34 (QBEnd/10) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against human CD34. This antibody is intended for use to qualitatively identify CD34 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# anti-CD43 (L60) Mouse Monoclonal **Primary Antibody**

**Catalog Number:** 760-2511 **Ordering Code:** 05266980001 Quantity: 50 tests

**Controls:** Lymph Node, Tonsil

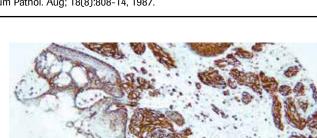
Isotypes: IgG, **Clone Name:** L60 Species: Mouse Localization: Membranous

**Regulatory Status:** IVD



This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) Anti-CD43 (L60) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody directed against an epitope present on human monocytes, granulocytes and lymphocytes. This reagent may be used to aid in the identification of cells of lymphoid and myelomonocytic lineage. Anti-CD43 (L60) is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

1. Strickler JG, Weiss LM, Copenhaver CM, Bindl J, McDaid R, Buck D, Warnke R. Monoclonal antibodies reactive in routinely processed tissue sections of malignant lymphoma, with emphasis on T cell lymphomas. Hum Pathol. Aug; 18(8):808-14, 1987.



# anti-CD44 (SP37) Rabbit Monoclonal **Primary Antibody**

Catalog Number: 790-4537 **Ordering Code:** 06364985001 Quantity: 50 tests Controls: **Normal Tonsil** Isotypes: IgG **Clone Name:** SP37 Species: Rabbit Localization: Membranous

**Regulatory Status:** IVD

#### **INTENDED USE**

Anti-CD44 (SP37) Rabbit Monoclonal Primary Antibody is directed against the CD44 protein. CD44 is a type I transmembrane receptor protein expressed in several cell types including T and B lymphocytes, monocytes, granulocytes, erythrocytes, fibroblasts, epithelial and mast cells. This antibody exhibits a membraneous staining pattern and may be used to detect the CD44 standard and variant proteins in a variety of neoplastic tissues, including squamous cell and urothelial carcinoma. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# CD45 (LCA) (2B11 & PD7/26)

**Catalog Number:** 760-4279 **Ordering Code:** 05269423001 Quantity: 50 tests

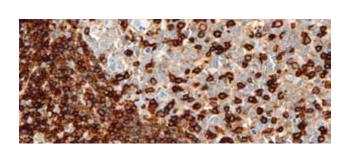
**Controls:** Lymph Node, Tonsil

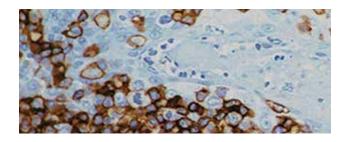
Isotypes: IgG<sub>1</sub>/K 2B11 & PD7/26 **Clone Name:** Species: Mouse Localization: Membranous

**Regulatory Status:** IVD

#### **INTENDED USE**

CD45 (LCA) (2B11 & PD7/26) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD45 (LCA) protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





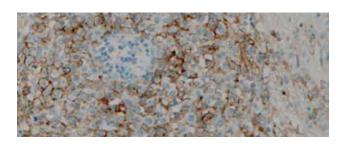
# **CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody**

Catalog Number: 760-2505 **Ordering Code:** 05266912001 Quantity: 50 tests Controls: Tonsil Isotypes: IgG₁/K Clone Name: RP2/18 Species: Mouse Localization: Membranous

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against CD45. CONFIRM anti-CD45, LCA (RP2/18) may be used in immunocytochemical methods to aid in the identification of normal and abnormal cells of leukocytic lineage and as an aid in the diagnosis of anaplastic tumors. CONFIRM anti-CD45, LCA (RP2/18) specifically binds to antigens located on the membrane of leukocytes. Staining is most consistent for lymphocytic cells with less consistent reaction in other leukocytes (macrophages/histiocytes/myeloid cells). The epitope recognized by the antibody is LCA-RB. CONFIRM anti-CD45, LCA (RP2/18) is intended for laboratory use to qualitatively stain leukocytes in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. Light microscopy is used to detect the staining of cell components. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



### **CD45R (MB1)**

 Catalog Number:
 760-2624

 Ordering Code:
 05267340001

 Quantity:
 50 tests

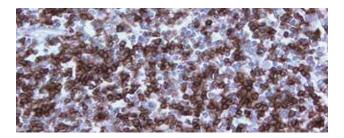
Controls: Lymph Node, Tonsil

 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{IgG}_1 & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \end{tabular}$ 

Regulatory Status: IVD

# **INTENDED USE**

CD45R (MB1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD45R protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CONFIRM anti-CD45RO (UCHL-1) Primary Antibody

Catalog Number:790-2930Ordering Code:05278244001Quantity:50 tests

Controls: Lymph Node, Tonsil

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-CD45RO (UCHL-1) Primary Antibody is a mouse monoclonal antibody (IgG2a) directed against CD45RO. This antibody is intended for use to qualitatively identify CD45RO by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

# **CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody**

 Catalog Number:
 790-4465

 Ordering Code:
 05878519001

 Quantity:
 50 tests

**Controls:** Brain, Normal Pancreas

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & 123\text{C3} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

Localization: Membrane, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody (CONFIRM anti-CD56 (123C3)) is directed against the CD56 molecule or neural cell adhesion molecule expressed by most neuroectodermally derived cell lines, tissues and neoplasms. It is also expressed on some mesodermally derived tumors, on natural killer cells and NK cell lymphomas. This antibody exhibits a membrane/cytoplasmic staining pattern and may be used to aid in the identification of small cell carcinomas, neuroblastoma and rhabdomyosarcoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



 Catalog Number:
 760-4596

 Ordering Code:
 06433359001

 Quantity:
 50 tests

Controls: Pancreatic Islet Cells, Pancreatic Endocrine

Cells, Neuroblastoma

Clone Name: MRQ-42

Species: Rabbit Monoclonal
Localization: Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD56 (MRQ-42) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD56 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



Catalog Number:760-2626Ordering Code:05267366001Quantity:50 tests

Controls: Lymph Node, Tonsil

 Isotypes:
 IgM/K

 Clone Name:
 NK-1

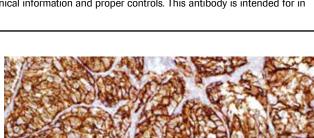
 Species:
 Mouse

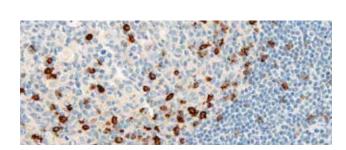
 Localization:
 Membranous

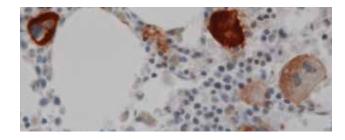
Regulatory Status: IVD

#### **INTENDED USE**

CD57 (NK-1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of CD57 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.







### CD61 (2f2)

 Catalog Number:
 760-4249

 Ordering Code:
 05269091001

 Quantity:
 50 tests

 Controls:
 Bone Marrow

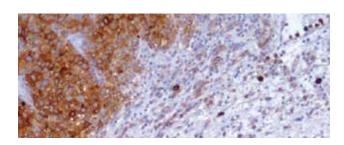
 Isotypes:
 IgG<sub>1</sub>

Clone Name: 2f2
Species: Mouse
Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

CD61 (2f2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD61 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **CD63 (NKI/C3)**

 Catalog Number:
 760-4379

 Ordering Code:
 05463483001

 Quantity:
 50 tests

Controls: Malignant Melanoma

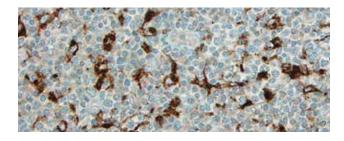
Isotypes: $IgG_1/K$ Clone Name:NKI/C3Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD63 (NKI/C3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD63 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-CD68 (KP-1) Primary Antibody**

 Catalog Number:
 790-2931

 Ordering Code:
 05278252001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Isotypes: $lgG_1/K$ Clone Name:KP-1Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana®) CONFIRM anti-CD68 (KP-1) Primary Antibody is a mouse monoclonal antibody, class IgG1 kappa. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-CD68 reacts with a 110 KD intracellular glycoprotein associated with the cell membrane of macrophages and some myeloid elements. 1.2.3.4 Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained tissue or cells will show immunoreactivity. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

- 1. Herman GE, Elfont EA. The taming of immunohistochemistry: the new era of quality control. Biotech Histochem 66(4): 194-199, 1991.
- 2. Omata M, Liew CT, Ashcavai M, Peters RL. Nonimmunologic binding of horseradish peroxidase to hepatitis B surface antigen. A possible source of error in immunohistochemistry. Am J Clin Pathol 73(5): 626-32, 1980.
- 3. Nadji M, Morales AR. Immunoperoxidase: part 1. The technique and its pitfalls. Lab Med 14: 767, 1983.
- 4. Taylor RT, Cote RJ. Immunomicroscopy: A Diagnostic Tool For The Surgical Pathologist, 2nd Edition. W.B. Saunders Company, Philadelphia, 1994.

### **CD71 (MRQ-48) Mouse Monoclonal Antibody**

Catalog Number:760-4589Ordering Code:06433162001Quantity:50 testsControls:Bone Marrow

**Isotypes:** IgG **Clone Name:** MRQ-48

**Species:** Mouse Monoclonal **Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

CD71 (MRQ-48) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of CD71 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM** anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4432

 Ordering Code:
 05640296001

 Quantity:
 50 tests

Controls: Tonsil, B Cell Lymphoma

Clone Name: SP18 Species: Rabbit

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody is intended for the detection of CD79a in normal and neoplastic human tissues. Anti-CD79a is directed against a protein expressed on the surface of B lymphocytes at all stages of maturation, from B lymphocyte precursors through plasma cells. Expression of CD79a may aid in the identification of B cell lineage in malignant lymphomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-CD99 (O13) Mouse Monoclonal Primary Antibody**

 Catalog Number:
 790-4452

 Ordering Code:
 05913594001

 Quantity:
 50 tests

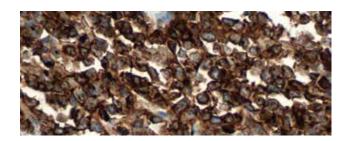
Controls: Pancreatic Islet Cells, Sertoli Cells of the Testis

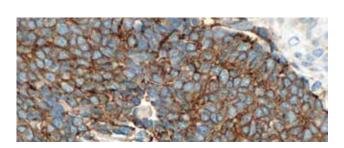
 $\begin{tabular}{lll} \textbf{Isotypes:} & & lgG_1\\ \textbf{Clone Name:} & & O13\\ \textbf{Species:} & & Mouse\\ \textbf{Localization:} & & Membranous\\ \end{tabular}$ 

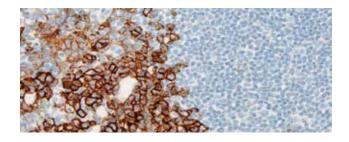
Regulatory Status: IVD

### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-CD99 (O13) Mouse Monoclonal Primary Antibody (CONFIRM anti-CD99 (O13)) is directed against human CD99 expressed on T lymphocytes, cortical thymocytes, granulosa cells of the ovary, pancreatic islet cells, CNS ependymal cells and Sertoli's cells. CD99 shows a plasma membrane location. This antibody may be used as part of a panel to aid in the identification of Ewing's sarcoma and related peripheral neuroectodermal tumors. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.







# CD138/syndecan-1 (B-A38)

 Catalog Number:
 760-4248

 Ordering Code:
 05269083001

 Quantity:
 50 tests

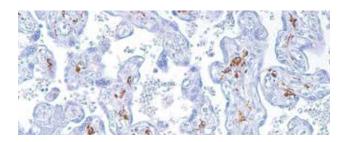
Controls: Plasmacytoma, Tonsil

Isotypes:lgGClone Name:B-A38Species:MouseLocalization:Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD138/syndecan-1 (B-A38) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD138/syndecan-1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### CD163 (MRQ-26)

Catalog Number: 760-4437
Ordering Code: 05973929001
Quantity: 50 tests
Controls: Inflamed Tissue
Isotypes: IgG,

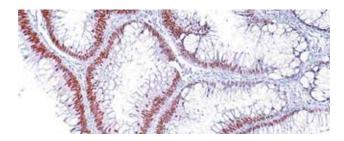
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{MRQ-26} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

CD163 (MRQ-26) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD163 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CDX-2 (EPR2764Y)**

Catalog Number:760-4380Ordering Code:05463491001Quantity:50 tests

Controls: Adenocarcinoma of Colon, Normal Colon

 $\begin{array}{lll} \textbf{Isotypes:} & \text{IgG}_1/K \\ \textbf{Clone Name:} & \text{EPR2764Y} \\ \textbf{Species:} & \text{Rabbit} \\ \textbf{Localization:} & \text{Nuclear} \\ \textbf{Regulatory Status:} & \text{IVD} \\ \end{array}$ 

# **INTENDED USE**

CDX-2 (EPR2764Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CDX-2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **CEA (CEA31) Mouse Monoclonal Antibody**

 Catalog Number:
 760-4594

 Ordering Code:
 06433316001

 Quantity:
 50 tests

Controls: Adenocarcinoma of Colon, Colon Mucosa

**Isotypes:**  $IgG_1$  **Clone Name:** CEA31

**Species:** Mouse Monoclonal **Localization:** Cytoplasmic

Regulatory Status: IVD

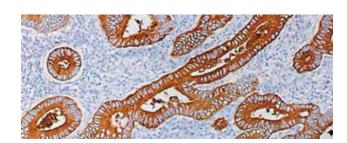
#### **INTENDED USE**

CEA (CEA31) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CEA glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **Anti-CEA (TF 3H8-1) Primary Antibody**

**Catalog Number:** 760-2507 **Ordering Code:** 05266947001 Quantity: 50 tests **Controls:** Colon Isotypes: IgG<sub>1</sub> **Clone Name:** TF3H8-1 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



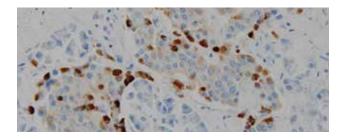
#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana) CEA (TF 3H8-1) Primary Antibody may be used to aid in the identification of cells of normal and abnormal epithelial lineage as an aid in diagnosis of anaplastic tumors. CEA (TF 3H8-1) Primary Antibody specifically binds to antigens located in the plasma membrane and cytoplasmic regions of normal simple epithelial cells. CEA (TF 3H8-1) is a mouse monoclonal antibody (IgG1) directed against carcinoembryonic antigen (CEA). The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

# anti-Chromogranin A (LK2H10) Primary Antibody

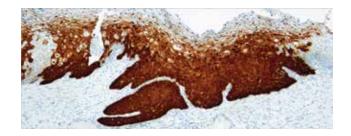
**Catalog Number:** 760-2519 **Ordering Code:** 05267056001 Quantity: 50 tests Controls: **Pancreas** Isotypes: IgG₁/K **Clone Name:** LK2H10 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

Anti-Chromogranin A (LK2H10) Primary Antibody is directed against the chromogranin A protein found in the secretory granules of most neuroendocrine cells. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of tumors of neuroendocrine origin. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CINtec®** Histology

 Catalog Number:
 705-4793
 725-4793

 Ordering Code:
 06680003001
 06680011001

 Quantity:
 50 tests
 250 tests

 Controls:
 Cervical Carcinoma, CIN2, CIN3,

Normal Cervix

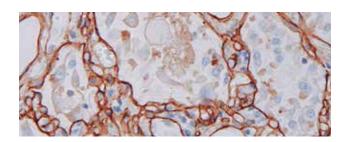
 $\begin{array}{ll} \text{Isotypes:} & \text{IgG}_{2a} \\ \text{Clone Name:} & \text{E6H4}^{\text{\tiny TM}} \\ \end{array}$ 

**Species:** Mouse monoclonal

Regulatory Status: IVD

#### **INTENDED USE**

CINtec® Histology is a qualitative immunohistochemistry (IHC) test using mouse monoclonal anti-p16 antibody clone E6H4, and is intended for use in the light microscopic assessment of the p16INK4a protein in formalin-fixed, paraffin-embedded (FFPE) cervical punch biopsy tissues using OptiView DAB IHC Detection Kit on a VENTANA BenchMark ULTRA instrument. The test is indicated as an adjunct to examination of hematoxylin and eosin (H&E) stained slide(s), to improve consistency in the diagnosis of cervical intraepithelial neoplasia (CIN). Diagnosis of CIN presence or level should be based on H&E stained slide(s) and other clinical and laboratory test information. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.



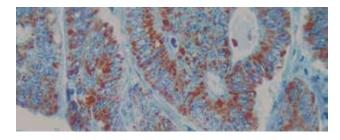
# **Collagen Type IV (CIV22)**

**Localization:** Basement Membrane

Regulatory Status: IVD

### **INTENDED USE**

Collagen Type IV (CIV22) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Collagen Type IV protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### COX-2 (SP21)

 Catalog Number:
 760-4254

 Ordering Code:
 05269148001

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

Isotypes:IgGClone Name:SP21Species:RabbitLocalization:CytoplasmicRegulatory Status:IVD

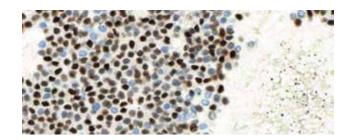
#### **INTENDED USE**

COX-2 (SP21) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the COX-2 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA** anti-Cyclin D1 (SP4-R) Rabbit Monoclonal Primary Antibody

Catalog Number:790-4508Ordering Code:05862949001Quantity:50 testsControls:Normal Tonsil

Isotypes:IgGClone Name:SP4-RSpecies:RabbitLocalization:NuclearRegulatory Status:IVD



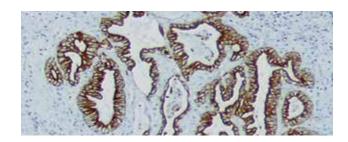
#### **INTENDED USE**

VENTANA anti-Cyclin D1 (SP4-R) Rabbit Monoclonal Primary Antibody (VENTANA anti-Cyclin D1 (SP4-R)) is directed against the Cyclin D1 molecule, a key cell cycle regulator, expressed primarily during the G1 phase of the cell cycle. This antibody exhibits a nuclear staining pattern, and may be used to aid in the identification of mantle cell lymphoma and breast carcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Cytokeratin (35betaH11)

**Catalog Number:** 760-2637 **Ordering Code:** 05267471001 Quantity: 50 tests **Controls:** Prostate Isotypes: IgM/K **Clone Name:** 35betaH11 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

Cytokeratin (35betaH11) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the cytokeratin 8 and 18 proteins in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-Cytokeratin (AE1) Primary Antibody**

 Catalog Number:
 760-2521

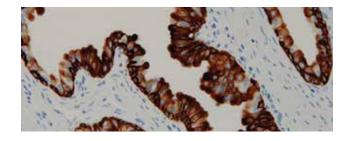
 Ordering Code:
 05267064001

 Quantity:
 50 tests

**Controls:** Prostate, Salivary Gland

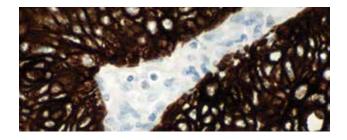
 $\begin{array}{lll} \textbf{Isotypes:} & & \text{IgG}_1 \\ \textbf{Clone Name:} & & \text{AE1} \\ \textbf{Species:} & & \text{Mouse} \\ \textbf{Localization:} & & \text{Cytoplasmic} \\ \end{array}$ 

Regulatory Status: IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) CONFIRM anti-Cytokeratin (AE1) is intended for laboratory use to qualitatively stain cytokeratin in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Cytokeratin (AE1) may be used to aid in the identification of cells of normal and abnormal epithelial lineage as an aid in diagnosis of anaplastic tumors. CONFIRM anti-Cytokeratin (AE1) specifically binds to antigens located in the cytoplasmic regions of normal epithelial cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



# anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-4555

 Ordering Code:
 06478425001

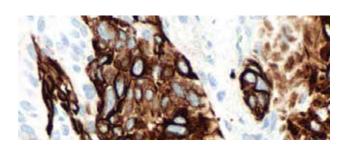
 Quantity:
 50 tests

Controls: Pancreatic Carcinoma and Colon

Isotypes:IgGClone Name:Cam 5.2Species:MouseLocalization:CytoplasmicRegulatory Status:IVD

#### **INTENDED USE**

Anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody (anti-Cytokeratin (CAM 5.2)) is directed against cytokeratin 7 and cytokeratin 8 present on secretory epithelia but not on stratified squamous epithelia. This antibody may be used to aid in the identification of tumors of epithelial origin such as colorectal, pancreatic and non-small cell lung cancer and in distinguishing carcinomas from other malignant tumors of non-epithelial origin. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4935

 Ordering Code:
 07292821001

 Quantity:
 50 tests

**Controls:** Mesothelioma, Prostate

Isotypes: IqG

Clone Name: Cytokeratin 5 (SP27) Rabbit Monoclonal

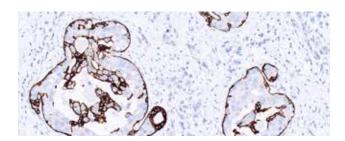
Primary Antibody

**Species:** Rabbit **Localization:** Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 5 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody

Catalog Number:790-4554Ordering Code:06478441001Quantity:50 tests

Controls: Prostate and Tonsil

 $\begin{array}{lll} \textbf{Isotypes:} & & \textbf{IgG}_1 \\ \textbf{Clone Name:} & & \textbf{D5/16B4} \\ \textbf{Species:} & & \textbf{Mouse} \\ \textbf{Localization:} & & \textbf{Cytoplasmic} \end{array}$ 

Regulatory Status: IVD

#### **INTENDED USE**

Anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody (anti-Cytokeratin 5/6 (D5/16B4)) detects cytokeratins 5 and 6. Cytokeratin 5 is expressed in various epithelia and mesothelial cells, while cytokeratin 6 is expressed by proliferating squamous epithelium. This antibody exhibits a cytoplasmic staining pattern and may be used to aid in the identification of squamous cell carcinoma and in distinguishing malignant mesothelioma from lung adenocarcinomas. The detection of cytokeratin 5 in myoepithelial cells with this antibody may also be used to aid in the determination of breast and prostate malignancies. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4939

 Ordering Code:
 07292864001

 Quantity:
 50 tests

Controls: Esophagus, Squamous Carcinoma

**Isotypes:** IgG

Clone Name: Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and

Mouse Monoclonal Primary Antibody

Species: Rabbit and Mouse Monoclonal

**Localization:** Cytoplasmic **Regulatory Status:** IVD

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Cytokeratin 5/14 (EP1601Y/LL002) Rabbit and Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 5 & 14 proteins in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4462

 Ordering Code:
 05986818001

 Quantity:
 50 tests

Controls: Breast, Salivary Gland, Glandular and

**Ductal Epithelium of Lung** 

Clone Name: SP52
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD

### INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody (CONFIRM anti-Cytokeratin 7 (SP52) antibody) is directed against a type II cytokeratin protein expressed by most ductal, glandular and transitional epithelia. Cytokeratin 7 exhibits a cytoplasmic localization. This antibody may be used to aid in the identification of normal and neoplastic cells of ovary, lung and breast epithelial origin which express Cytokeratin 7, and those of colonic and prostate epithelial lineage which lack Cytokeratin 7 production. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Cytokeratin 8 & 18 (B22.1 & B23.1)

 Catalog Number:
 760-4344

 Ordering Code:
 05269776001

 Ouantity:
 50 tests

Controls: Pancreas, Prostate, Salivary Gland

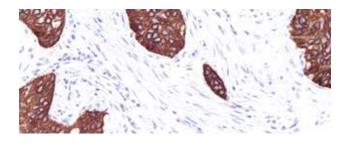
**Isotypes:** IgG<sub>1</sub>

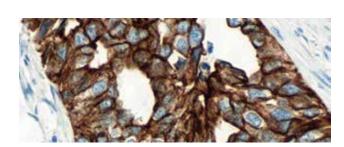
Clone Name: B22.1 & B23.1 Species: Mouse Localization: Cytoplasmic

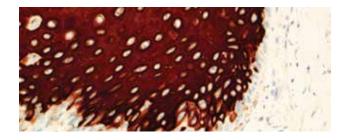
Regulatory Status: IVD

#### **INTENDED USE**

Anti-Cytokeratin 8 & 18 (B22.1 & B23.1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the cytokeratin 8 & 18 proteins in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





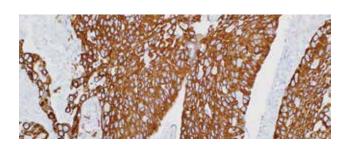


# anti-Cytokeratin 10 (SP99) Rabbit Monoclonal Primary Antibody

Catalog Number: 790-4562 **Ordering Code:** 06425135001 Quantity: 50 tests Controls: Skin Isotypes: Rabbit Ig Clone Name: SP99 Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Anti-Cytokeratin 10 (SP99) Rabbit Monoclonal Primary Antibody (anti-Cytokeratin 10 (SP99)) is directed against the 56.5kD member of the type 1 cytokeratin family, cytokeratin 10. Cytokeratin 10 is expressed in keratinizing stratified epithelia, but is absent from the basal layer, in various organs including the skin. AntiCytokeratin 10 (SP99) exhibits a cytoplasmic staining pattern and may be used to aid in the identification of well differentiated squamous carcinomas of the cervix and anus. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### Cytokeratin 14 (LL002)

 Catalog Number:
 760-4251

 Ordering Code:
 05269113001

 Quantity:
 50 tests

 Controls:
 Squamous Ca

Controls: Squamous Carcinoma, Squamous Mucosa

 Isotypes:
 IgG<sub>3</sub>

 Clone Name:
 LL002

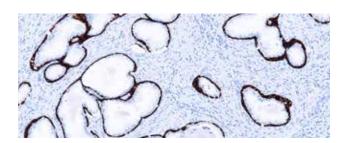
 Species:
 Mouse

 Localization:
 Cytoplasmic

 Regulatory Status:
 IVD

### INTENDED USE

Cytokeratin 14 (LL002) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 14 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4805

 Ordering Code:
 06732429001

 Quantity:
 50 tests

**Controls:** Prostate, Skin, Squamous Carcinoma

**Isotypes:** IgG **Clone Name:** SP53

Species: Rabbit Monoclonal Localization: Cytoplasmic Regulatory Status: IVD

#### **INTENDED USE**

Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 14 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-Cytokeratin 17 (SP95) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4560

 Ordering Code:
 06373658001

 Quantity:
 50 tests

Controls: Normal Skin, Cervical Carcinoma

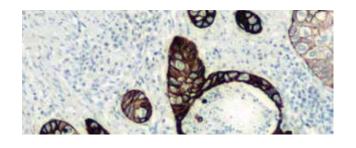
Isotypes:Rabbit IgClone Name:SP95Species:Rabbit

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-Cytokeratin 17 (SP95) Rabbit Monoclonal Primary Antibody (anti-Cytokeratin 17 (SP95)) is directed against Cytokeratin 17 expressed in basal cells of complex epithelia, glandular epithelium with myoepithelial component, and transitional and pseudostratified epithelia. This antibody may be used to aid in the identification of squamous cell carcinomas in various tissues including the cervix, lung and oral cavity. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **Cytokeratin 19 (A53-B/A2.26)**

 Catalog Number:
 760-4281

 Ordering Code:
 05269440001

 Quantity:
 50 tests

Controls: Colon Carcinoma, Thyroid

Isotypes:IgG1Clone Name:A53-B/A2.26Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Cytokeratin 19 (A53-B/A2.26) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 19 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM** anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4431

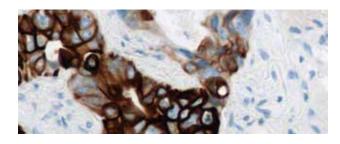
 Ordering Code:
 05587760001

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

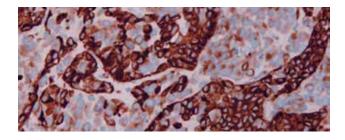
Clone Name: SP33
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody (CONFIRM anti-Cytokeratin 20 antibody) is directed against a type I cytokeratin protein of mature enterocytes and goblet cells of the gastric and intestinal mucosa. This antibody produces a cytoplasmic staining pattern, and may be used to aid in the identification of normal cytokeratin 20 expressing cells and neoplastic cells of colonic epithelial lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

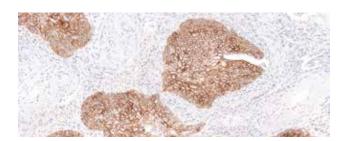


# **CONFIRM anti-Desmin (DE-R-11) Primary Antibody**

Catalog Number: 760-2513 **Ordering Code:** 05267005001 Quantity: 50 tests Controls: Intestine Isotypes: IgG₁/K **Clone Name:** DE-R-11 Species: Mouse Localization: Cytoplasmic **Regulatory Status:** 

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Desmin (DE-R-11) Primary Antibody is a mouse monoclonal antibody (IgG1, light chain kappa) directed against desmin. This antibody is intended for use to qualitatively identify desmin in myocytic cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Desmin (DE-R-11) may be used to aid in the identification of cells of normal and abnormal myocytic lineage as an aid in diagnosis of anaplastic tumors. CONFIRM anti-Desmin (DE-R-11) specifically binds to antigens located in the cytoplasm of myocytic cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

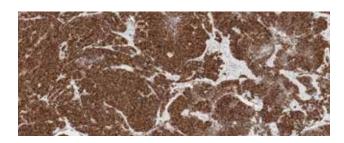


# Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody

Catalog Number: 760-5060 Ordering Code: 07709447001 Quantity: 50 tests Isotypes: IqG Clone Name: 5G11 Species: Mouse Localization: Membranous **Regulatory Status:** IVD

#### **INTENDED USE**

Desmoglein 3 (5G11) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the desmoglein 3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **VENTANA DLL3 (SP347) Assay**

 Catalog Number:
 790-7016

 Ordering Code:
 08416931001

 Quantity:
 50 tests

Controls: Small Cell Lung Carcinoma (positive),

Normal Lung tissue (negative)

Isotypes:IgGClone Name:SP347Species:Rabbit

**Localization:** Membranous and/or Cytoplasmic Staining

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA DLL3 (SP347) Assay (DLL3 (SP347) Assay) is intended for laboratory use in the detection of Delta-like protein 3 (DLL3) in sections of formalin-fixed, paraffin-embedded (FFPE) tissue when stained on BenchMark IHC/ISH instruments using the OptiView DAB IHC Detection Kit. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **DOG1 (SP31) Rabbit Monoclonal Antibody**

 Catalog Number:
 760-4590

 Ordering Code:
 06433189001

 Quantity:
 50 tests

 Controls:
 GIST

 Isotypes:
 Rabbit Ig

 Clone Name:
 SP31

**Species:** Rabbit Monoclonal **Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

DOG1 (SP31) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the DOG1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA** anti-E-cadherin (36) Mouse Monoclonal **Primary Antibody**

 Catalog Number:
 790-4497

 Ordering Code:
 05905290001

 Quantity:
 50 tests

Controls: Ductal Breast Carcinoma

 $\begin{tabular}{lll} \textbf{Isotypes:} & \textbf{IgG}_{2a}/\textbf{K} \\ \textbf{Clone Name:} & 36 \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Membranous} \\ \end{tabular}$ 

Regulatory Status: IVD

### **INTENDED USE**

VENTANA anti-E-cadherin (36) Mouse Monoclonal Primary Antibody (VENTANA anti-E-cadherin (36)) is directed against the cytoplasmic domain of the human transmembrane protein E-cadherin expressed as a part of the cell-cell adhesion complex in epithelial tissues. Reduction or loss of expression is associated with invasive carcinoma and possibly metastasis in a variety of carcinomas. This antibody may be used to aid in the differentiation of in situ and/or invasive lobular carcinoma from in situ and/or invasive ductal carcinoma of the breast. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. Test results should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# E-Cadherin (EP700Y)

 Catalog Number:
 760-4440

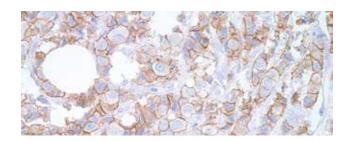
 Ordering Code:
 05973872001

 Quantity:
 50 tests

Controls: Breast, Lung Adenocarcinoma, Pancreas

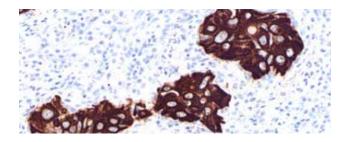
Isotypes:IgGClone Name:EP700YSpecies:RabbitLocalization:Membranous

Regulatory Status: IVD



#### **INTENDED USE**

E-cadherin (EP700Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the E-cadherin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CONFIRM anti-Epidermal Growth Factor Receptor (3C6) Primary Antibody

 Catalog Number:
 790-2988

 Ordering Code:
 05278341001

 Quantity:
 50 tests

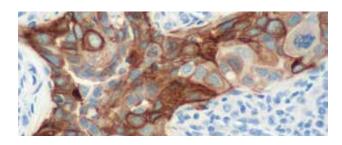
Controls: Colorectal Adenocarcinoma, Skin

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & 3C6 \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Membranous} \end{array}$ 

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Epidermal Growth Factor Receptor (EGFR) (3C6) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against the extracellular domain of human EGFR protein of 170kD. The antibody also recognizes the type III variant of 145kD. This antibody is intended for laboratory use, via light microscopy, for the qualitative detection of EGFR in formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



# **CONFIRM anti-EGFR (5B7) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4347

 Ordering Code:
 05278457001

 Quantity:
 50 tests

Controls: Non-Small Cell Lung Carcinoma, Placenta, Skin

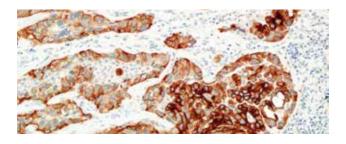
Clone Name: 5B7 Species: Rabbit

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-EGFR (5B7) Rabbit Monoclonal Antibody is a primary antibody designed to qualitatively detect the presence of the internal domain of EGFR via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. This antibody is directed against the internal domain of the human Epidermal Growth Factor Receptor (also called EGFR, ErbB1 or HER 1). The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.



# anti-EGFR E746-A750 del (SP111) Rabbit Monoclonal Primary Antibody

Catalog Number:790-4650Ordering Code:06521932001Quantity:50 tests

Controls: EGFR E746-A750 Deletion-Positive Lung

Adenocarcinoma Tissue

Isotypes: IgG Clone Name: SP111

Species: Rabbit Monoclonal
Localization: Cytoplasmic, Membranous

Regulatory Status: IVD

### **INTENDED USE**

Anti-EGFR E746-A750 del (SP111) Rabbit Monoclonal Primary Antibody (anti-EGFR E746-A750 del (SP111)) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of the Epidermal Growth Factor Receptor mutant protein, EGFR E746-A750 del. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-EGFR L858R (SP125) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4649

 Ordering Code:
 06521924001

 Quantity:
 50 tests

Controls: Lung Adenocarcinomas that are positive for

the L858R mutation

**Isotypes:** IgG **Clone Name:** SP125

**Species:** Rabbit Monoclonal **Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-EGFR L858R (SP125) Rabbit Monoclonal Primary Antibody (anti-EGFR L858R (SP125)) exhibits a cell membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of the Epidermal Growth Factor Receptor mutant protein, EGFR L858R. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



 Catalog Number:
 790-4463

 Ordering Code:
 05878900001

 Quantity:
 50 tests

Controls: Normal Pancreas

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{2a} \\ \textbf{Clone Name:} & \textbf{E29} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-EMA (E29) Mouse Monoclonal Primary Antibody (CONFIRM anti-EMA (E29)) is directed against epithelial membrane antigen expressed on the apical surface of glandular epithelia. This glycoprotein is primarily membrane localized on normal and tumor tissue, although it may exhibit a cytoplasmic localization in less differentiated carcinomas. This antibody may be used to aid in the identification of epithelial membrane antigen in adenocarcinomas derived from secretory epithelia, malignant mesothelioma, renal cell carcinomas and meningiomas. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **Ep-CAM (Ber-EP4)**

 Catalog Number:
 760-4383

 Ordering Code:
 05435676001

 Quantity:
 50 tests

**Controls:** Adenocarcinoma, Columnar Epithelium

 Isotypes:
 IgG<sub>1</sub>/K

 Clone Name:
 Ber-EP4

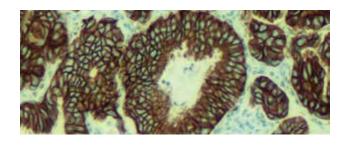
 Species:
 Mouse

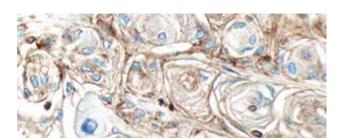
 Localization:
 Cytoplasmic

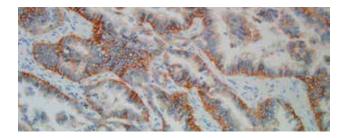
Regulatory Status: IVD

#### **INTENDED USE**

Ep-CAM/Epithelial Specific Antigen (Ber-EP4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Ep-CAM glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.







# anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-4561

 Ordering Code:
 06374409001

 Quantity:
 50 tests

Controls: Breast, Colon, Kidney, Lung

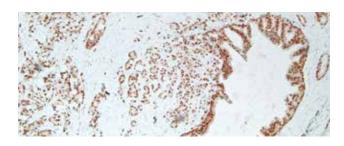
 $\begin{array}{lll} \textbf{Isotypes:} & & \textbf{IgG}_1 \\ \textbf{Clone Name:} & & \textbf{MOC-31} \\ \textbf{Species:} & & \textbf{Mouse} \\ \end{array}$ 

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody (anti-Epithelial Related Antigen (MOC-31)) is directed against the 40kD epithelial cell adhesion molecule, Epithelial Related Antigen. Epithelial Related Antigen is expressed in most normal epithelial cells in tissues including lung, breast, pancreas and colon. This antibody exhibits a membranous and/or cytoplasmic staining pattern in neoplastic and normal tissue. Anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody may be used as an aid in the differentiation of lung adenocarcinoma and mesothelioma. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody

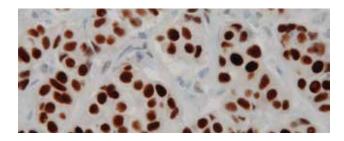
Catalog Number: 790-4576
Ordering Code: 06478450001
Quantity: 50 tests
Controls: Spleen
Clone Name: EPR3864
Species: Rabbit

Localization: Nuclear, Cytoplasmic

Regulatory Status: IVD

#### INTENDED USE

Anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody (anti-ERG (EPR3864)) is directed against the C-terminus of the ETS transcription regulator, ERG, and is capable of detecting both wildtype ERG and truncated ERG resulting from ERG gene rearrangement. This antibody exhibits a nuclear staining pattern and may be used to aid in the identification of prostate adenocarcinomas through the detection of truncated ERG. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-(ER) (SP1) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4325
 790-4324

 Ordering Code:
 5278414001
 05278406001

 Quantity:
 250 tests
 50 tests

Controls: Breast Isotypes: IgG Clone Name: SP1 Species: Rabbit Localization: Nuclear Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody is intended for laboratory use for the qualitative detection of estrogen receptor (ER) antigen in sections of formalin-fixed, paraffin-embedded breast tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-ER (SP1) is directed against an epitope present on human ER alpha protein located in the nucleus of ER positive normal and neoplastic cells. CONFIRM anti-ER (SP1) is indicated as an aid in the management, prognosis and prediction of hormone therapy for breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. Prescription use only.

# anti-EZH2 (SP129) Rabbit Monoclonal **Primary Antibody**

**Catalog Number:** 790-4651 **Ordering Code:** 06522858001 Quantity: 50 tests **Controls:** Tonsil Isotypes: IgG **Clone Name:** SP129

Species: Rabbit Monoclonal

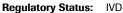
Localization: **Regulatory Status:** IVD

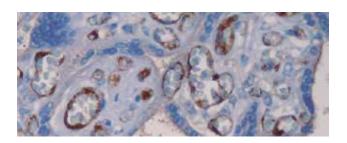
### **INTENDED USE**

Anti-EZH2 (SP129) Rabbit Monoclonal Primary Antibody (antiEZH2 (SP129)) is directed against human EZH2 expressed by cancer cells and lymphocytes. This antibody exhibits a nuclear staining pattern and may be used to aid in the identification of prostate cancer, breast cancer and bladder cancer. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Factor VIII-R Ag. (polyclonal)

**Catalog Number:** 760-2642 **Ordering Code:** 05267528001 Quantity: 50 tests **Controls:** Placenta, Skin **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic





### **INTENDED USE**

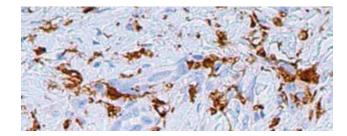
Factor VIII-R Ag. Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the Factor VIII-R Ag. protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Factor XIIIa (AC-1A1)

**Catalog Number:** 760-4384 **Ordering Code:** 05435692001 Quantity: 50 tests Dermatofibroma **Controls:** 

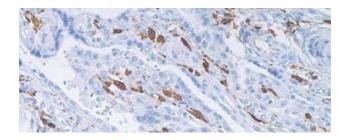
Isotypes: lgG1 **Clone Name:** AC-1A1 Mouse Species: Localization: Cytoplasmic

**Regulatory Status:** IVD



# **INTENDED USE**

Factor XIIIa (AC-1A1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of Factor XIIIa in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### Factor XIIIa (EP3372)

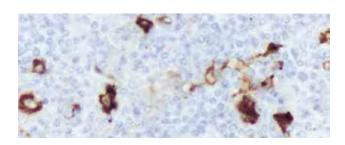
Catalog Number:760-4441Ordering Code:05922470001Quantity:50 testsControls:Dermatofibroma

Isotypes:IgGClone Name:EP3372Species:RabbitLocalization:Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Factor XIIIa (EP3372) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of Factor XIIIa in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### Fascin (55k-2)

 Catalog Number:
 760-2702

 Ordering Code:
 05268117001

 Quantity:
 50 tests

Controls: Hodgkin's Lymphoma, Lymph Node

 Isotypes:
 IgG1

 Clone Name:
 55k-2

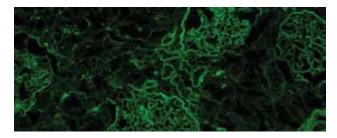
 Species:
 Mouse

 Localization:
 Cytoplasmic

Regulatory Status: IVD

### **INTENDED USE**

Fascin (55k-2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the fascin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **FITC anti-Albumin Primary Antibody**

Catalog Number:760-2699Ordering Code:05268087001Quantity:50 tests

**Controls:** Frozen, Diseased Skin or Diseased Renal Tissue

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-Albumin Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human albumin. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of human albumin in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Albumin is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

# FITC anti-C1q Primary Antibody

 Catalog Number:
 760-2688

 Ordering Code:
 05267994001

 Quantity:
 50 tests

Controls: Frozen, Diseased Skin or Diseased Renal Tissue

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) Systems FITC anti-C1q (complement 1q) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human C1q. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of complement 1q in C1q target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-C1q is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

# FITC anti-C3 Primary Antibody

 Catalog Number:
 760-2686

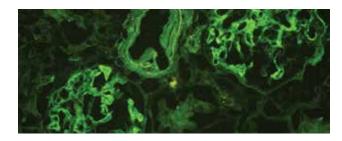
 Ordering Code:
 05267978001

 Quantity:
 50 tests

**Controls:** Frozen, Kidney or Skin from Lupus Cases

Containing C3 Deposits

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) FITC anti-C3 (complement 3) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human C3. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of complement 3 in C3 target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-C3 is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# **FITC anti-Fibrinogen Primary Antibody**

 Catalog Number:
 760-2685

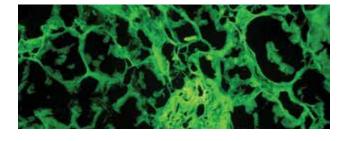
 Ordering Code:
 05267960001

 Quantity:
 50 tests

Controls: Frozen, Placenta or Tissue Containing

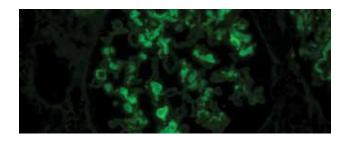
Clotted Blood

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) FITC anti-Fibrinogen Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human fibrinogen. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of fibrinogen in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Fibrinogen is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



### FITC anti-IgA Primary Antibody

 Catalog Number:
 760-2681

 Ordering Code:
 05267927001

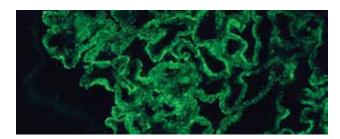
 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-IgA (immunoglobulin A) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgA. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin A in IgA target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgA is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



### FITC anti-IgG Primary Antibody

 Catalog Number:
 760-2680

 Ordering Code:
 05267919001

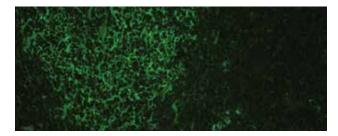
 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node Clotted Blood

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-IgG (immunoglobulin G) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgG. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin G in IgG target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgG is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



# **FITC anti-IgM Primary Antibody**

Catalog Number:760-2682Ordering Code:05267935001Quantity:50 tests

Controls: Frozen, Tonsil or Lymph Node

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

# INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-IgM (immunoglobulin M) Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human IgM. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of immunoglobulin M in IgM target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-IgM is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

### **FITC anti-Kappa Primary Antibody**

 Catalog Number:
 760-2683

 Ordering Code:
 05267943001

 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node Clotted Blood

Clone Name: Polyclonal Species: Goat Regulatory Status: IVD

#### INTENDED USE



This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-Kappa Primary Antibody is a goat derived polyclonal antibody labeled with fluorescein and specifically directed against human kappa immunoglobulin light chains. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of kappa in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Kappa is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

# **FITC anti-Lambda Primary Antibody**

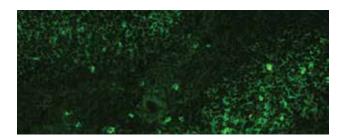
 Catalog Number:
 760-2684

 Ordering Code:
 05267951001

 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node

Clone Name: Polyclonal Species: Burro Regulatory Status: IVD



### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Systems FITC anti-Lambda Primary Antibody is a burro derived polyclonal antibody labeled with fluorescein and specifically directed against human lambda light chains. This reagent should be used in conjunction with a panel of antibodies to aid in the identification of lambda light chains in target tissue (e.g., in the diagnosis of renal or dermal pathologies). FITC anti-Lambda is intended for laboratory use to qualitatively stain sections of frozen tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

# FOXA1 (2F83) Mouse Monoclonal Primary Antibody

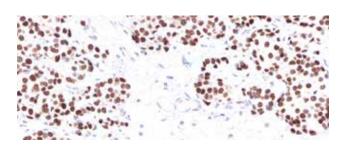
Catalog Number: 760-4937
Ordering Code: 07292848001
Quantity: 50 tests
Controls: Breast Carcinoma

**Isotypes:** IgG

Clone Name: FOXA1 (2F83) Mouse Monoclonal

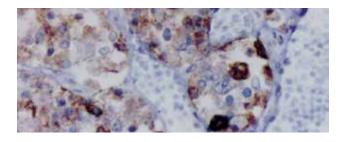
Primary Antibody

Species: Mouse
Localization: Nuclear
Regulatory Status: IVD



### INTENDED USE

FOXA1 (2F83) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the FOXA1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

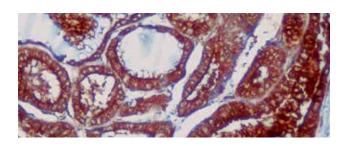


# **FSH** (polyclonal)

**Catalog Number:** 760-2710 **Ordering Code:** 05268192001 Quantity: 50 tests **Controls:** Normal Pituitary **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

FSH Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of FSH in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### Galectin-3 (9C4)

 Catalog Number:
 760-4256

 Ordering Code:
 05269164001

 Quantity:
 50 tests

**Controls:** Papillary or Follicular Carcinoma of Thyroid

 Isotypes:
 IgG₁

 Clone Name:
 9C4

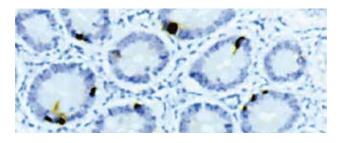
 Species:
 Mouse

 Localization:
 Cytoplasmic

 Regulatory Status:
 IVD

#### **INTENDED USE**

Galectin-3 (9C4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the galectin-3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

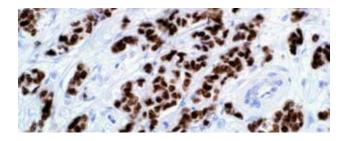


### **Gastrin (polyclonal)**

Catalog Number: 760-2643 **Ordering Code:** 05267536001 50 tests Quantity: **Controls:** Stomach **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD

#### **INTENDED USE**

Gastrin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the gastrin hormone in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# GATA3 (L50-823) Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4897

 Ordering Code:
 07107749001

 Quantity:
 50 tests

Controls: Ductal Carcinoma in situ

Isotypes:IgGClone Name:L50-823Species:MouseLocalization:NuclearRegulatory Status:IVD

### **INTENDED USE**

GATA3 (L50-823) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the GATA3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **GCDFP-15 (EP1582Y) Rabbit Monoclonal Antibody**

 Catalog Number:
 760-4386

 Ordering Code:
 05463530001

 Quantity:
 50 tests

Controls: Breast, Breast Carcinoma

Isotypes:IgGClone Name:EP1582YSpecies:RabbitLocalization:Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

GCDFP-15 (EP1582Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the GCDFP-15 glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **GH** (polyclonal)

Catalog Number:760-2804Ordering Code:05268257001Quantity:50 testsControls:Normal PituitaryClone Name:PolyclonalSpecies:RabbitLocalization:Cytoplasmic

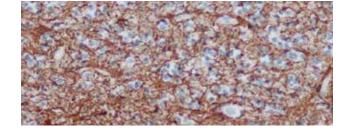
Regulatory Status: IVD

### **INTENDED USE**

GH (Growth Hormone) Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the growth hormone in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

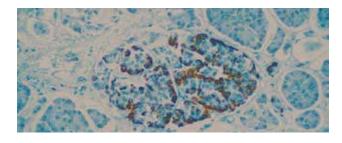
# **Glial Fibrillary Acidic Protein (GFAP) (EP672Y)**

**Catalog Number:** 760-4345 **Ordering Code:** 05269784001 Quantity: 50 tests **Controls:** Brain Isotypes: IgG **Clone Name:** EP672Y Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD



# **INTENDED USE**

Glial Fibrillary Acidic Protein (EP672Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Glial Fibrillary Acidic Protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use..

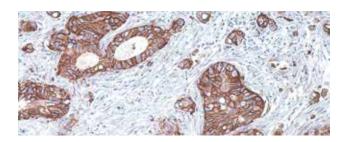


### **Glucagon Rabbit Polyclonal Primary Antibody**

**Catalog Number:** 760-2644 **Ordering Code:** 05267544001 Quantity: 50 tests Controls: Pancreas **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Glucagon Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the glucagon hormone in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **GLUT1 Rabbit Polyclonal Antibody**

 Catalog Number:
 760-4526

 Ordering Code:
 06419178001

 Quantity:
 50 tests

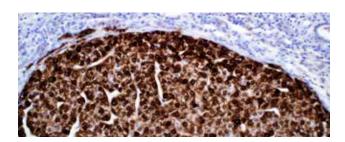
Controls: Malignant Mesothelioma, Colorectal Carcinoma

Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit
Localization: Membranous

Regulatory Status: IVD

#### **INTENDED USE**

GLUT1 Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the GLUT1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4898

 Ordering Code:
 07107757001

 Quantity:
 50 tests

Controls: Hepatocellular Carcinoma

 Isotypes:
 IgG

 Clone Name:
 GS-6

 Species:
 Mouse

 Localization:
 Cytoplasmic

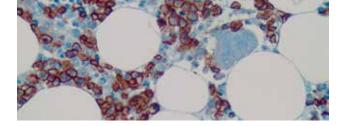
 Regulatory Status:
 IVD

#### **INTENDED USE**

Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the glutamine synthetase in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **Glycophorin A (GA-R2)**

**Catalog Number:** 760-4257 **Ordering Code:** 05269172001 Quantity: 50 tests **Controls:** Bone Marrow Isotypes: IgG<sub>2a</sub>/K **Clone Name:** GA-R2 Species: Mouse Localization: Membranous



Regulatory Status: IVD

#### **INTENDED USE**

Glycophorin A (GA-R2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Glycophorin A protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Glypican-3 (1G12)

 Catalog Number:
 760-4442

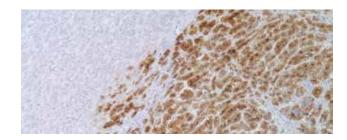
 Ordering Code:
 05973864001

 Quantity:
 50 tests

Controls: Hepatocellular Carcinoma

Isotypes:IgG1Clone Name:1G12Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

Glypican-3 (1G12) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Glypican-3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-Glypican 3 (GC33) Mouse Monoclonal Primary Antibody

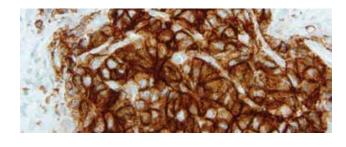
Catalog Number:790-4564Ordering Code:06483186001Quantity:50 tests

Controls: Placenta, Hepatocellular Carcinoma

 $\begin{array}{lll} \textbf{Isotypes:} & \lg G_{2a} \\ \textbf{Clone Name:} & GC33 \\ \textbf{Species:} & \textit{Mouse} \\ \end{array}$ 

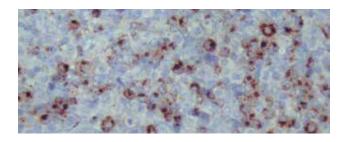
**Localization:** Granular Cytoplasmic/Membrane

Regulatory Status: IVD



# **INTENDED USE**

Anti-Glypican 3 (GC33) Mouse Monoclonal Primary Antibody (antiGlypican 3 (GC33)) is directed against the heparan sulfate proteoglycan, glypican 3. This antibody may be used to aid in the differentiation of hepatocellular carcinoma from normal liver or benign lesions. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



## **Granzyme B (polyclonal)**

Catalog Number: 760-4283
Ordering Code: 05269466001
Quantity: 50 tests
Controls: Tonsil
Clone Name: Polyclonal
Species: Rabbit

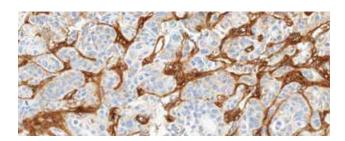
**Localization:** Granular 2, Cytotoxic Thymphocytes,

Natural Killer Cells

Regulatory Status: IVD

#### **INTENDED USE**

Granzyme B Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the Granzyme B protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **VENTANA HA Assay**

 Catalog Number:
 790-6074

 Ordering Code:
 08289018001

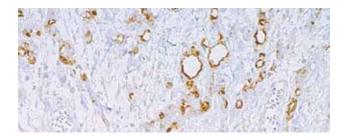
 Quantity:
 50 tests

Controls: Normal Human Skin

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA HA Assay is intended for laboratory use in the detection of hyaluronan in sections of formalin-fixed, paraffin-embedded tissue when stained on BenchMark IHC/ISH instruments using the OptiView DAB IHC Detection Kit and target retrieval with Protease 1. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



# HBME-1 (HBME-1)

 Catalog Number:
 760-4445

 Ordering Code:
 05973813001

 Quantity:
 50 tests

Controls: Mesothelioma, Thyroid Carcinoma

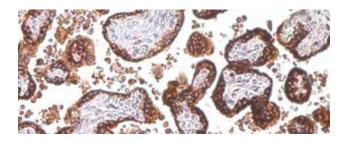
Isotypes:IgM/KClone Name:HBME-1Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

# **INTENDED USE**

Mesothelial Cell (HBME-1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the HBME-1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### hCG (polyclonal)

Catalog Number: 760-2650
Ordering Code: 05267617001
Quantity: 50 tests
Controls: Placenta
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

### **INTENDED USE**

hCG Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of hCG (human chorionic gonadotropin) in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA** anti-*Helicobacter pylori* (SP48) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-1014
 790-1015

 Ordering Code:
 06425607001
 6425623001

 Quantity:
 50 tests
 250 tests

Controls: Helicobacter pylori-Infected Stomach

Clone Name: SP48 Species: Rabbit

**Localization:** Whole *Helicobacter pylori* Organism

Regulatory Status: 510(k)

#### **INTENDED USE**

VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody (VENTANA anti-H. pylori (SP48)) is designed to qualitatively detect the presence of Helicobacter pylori in formalin-fixed, paraffin-embedded gastric biopsy tissue via light microscopy. Immunohistochemical staining with this antibody product may aid in the diagnosis of Helicobacter pylori infection. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody

Catalog Number:760-4936Ordering Code:07292830001Quantity:50 testsControls:Bone Marrow

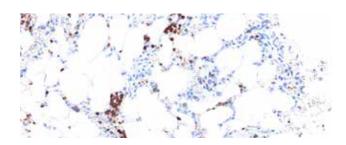
**Isotypes:** IgG

Clone Name: Hemoglobin A (SP212) Rabbit Monoclonal

Primary Antibody

**Species:** Rabbit **Localization:** Cytoplasmic

Regulatory Status: IVD



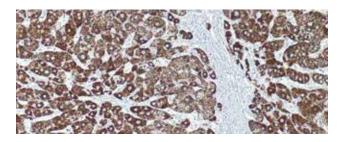
### **INTENDED USE**

Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the hemoglobin A protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **Hepatocyte Specific Antigen (OCH1E5)**

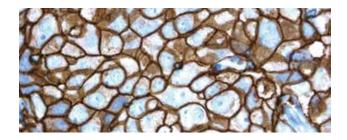
**Catalog Number:** 760-4350 **Ordering Code:** 05269792001 Quantity: 50 tests **Controls:** Liver **Isotypes:** IgG₁/K 0CH1E5 **Clone Name:** Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



# INTENDED USE

Hepatocyte Specific Antigen (Hep Par-1) (OCH1E5) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of mitochondrial antigen in hepatocytes in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-100

 Ordering Code:
 05278368001

 Quantity:
 50 tests

10 PATHWAY HER-2 4in1 Control Slides

Interpretation Guide

Controls: Breast Carcinoma

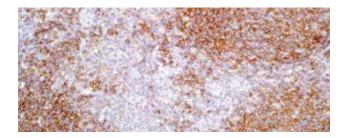
Clone Name: 4B5
Species: Rabbit
Localization: Membranous
Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems, Inc.'s (Ventana) PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY HER2 (4B5)) is a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue on a VENTANA automated immunohistochemistry slide staining device. It is indicated as an aid in the assessment of breast cancer patients for whom Herceptin treatment is considered.

Note: All of the patients in the Herceptin clinical trials were selected using a clinical trial assay. None of the patients in those trials were selected using PATHWAY anti-HER-2/neu (4B5). PATHWAY anti-HER-2/neu (4B5) was compared to PATHWAY HER-2 (clone CB11) Primary Antibody on an independent sample set and found to provide acceptably concordant results. The actual correlation of PATHWAY anti-HER-2/neu (4B5) to clinical outcome has not been established.

The VIAS Image Analysis System is an adjunctive optional computer-assisted image analysis system functionally connected to an interactive microscope. It is intended for use as an aid to the pathologist in the detection, classification and counting of cells of interest based on marker intensity, size and shape using appropriate controls to assure the validity of the VIAS scores. Prescription use only.



# **HGAL (MRQ-49) Mouse Monoclonal Antibody**

 Catalog Number:
 760-4597

 Ordering Code:
 06433375001

 Quantity:
 50 tests

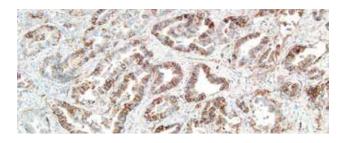
Controls: Lymph Node, Tonsil

 $\begin{tabular}{ll} Isotypes: & IgG_{2a}/K \\ \begin{tabular}{ll} Clone Name: & MRQ-49 \\ \end{tabular}$ 

Species: Mouse Monoclonal Localization: Cytoplasmic Regulatory Status: IVD

#### **INTENDED USE**

HGAL (MRQ-49) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of HGAL in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Human Equilibrative Nucleoside Transporter 1 (SP120) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4852

 Ordering Code:
 06903444001

 Quantity:
 50 tests

**Controls:** Adrenal Cortex, Kidney, Thyroid, Tonsil,

Normal Pancreas

**Isotypes:** IgG **Clone Name:** SP120

**Species:** Rabbit Monoclonal **Localization:** Membranous, Cytoplasmic

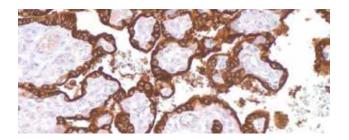
Regulatory Status: IVD

### **INTENDED USE**

Anti-hENT1 (SP120) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of hENT1 in formalin-fixed, paraffin-embedded tissue. This antibody exhibits a membranous and/or cytoplasmic staining pattern and may be used to detect hENT1 protein in benign and neoplastic human pancreatic, breast, lymphoid or lung tissue stained with a VENTANA immunohistochemical automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **Human Placental Lactogen (hPL) (polyclonal)**

**Catalog Number:** 760-4443 **Ordering Code:** 05973830001 Quantity: 50 tests **Controls:** Placenta Isotypes: IgG **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic



#### **Regulatory Status:** IVD

# **INTENDED USE**

Human Placental Lactogen (hPL) Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the hPL protein in formalinfixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

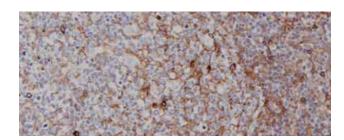
# **IgA** (polyclonal)

**Catalog Number:** 760-2652 **Ordering Code:** 05267625001 Quantity: 50 tests

**Controls:** Lymph Node, Tonsil

**Clone Name:** Polyclonal Rabbit Species: Localization: Cytoplasmic

**Regulatory Status:** IVD



#### **INTENDED USE**

IgA Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of IgA in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

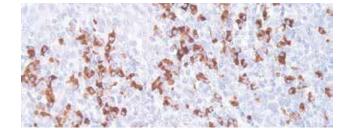
# **IgD** (polyclonal)

**Catalog Number:** 760-4444 **Ordering Code:** 05973821001 Quantity: 50 tests

**Controls:** Lymph Node, Tonsil

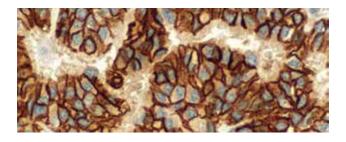
Isotypes: IgG **Clone Name:** Polyclonal Rabbit Species: Localization: Cytoplasmic

**Regulatory Status:** IVD



# **INTENDED USE**

IgD Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of IgD in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CONFIRM anti-IGF-1R (G11) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4346

 Ordering Code:
 05278449001

 Quantity:
 50 tests

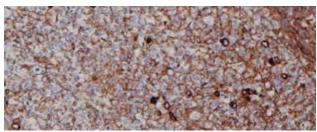
Controls: Breast Carcinoma, Placenta

Clone Name: G11
Species: Rabbit
Localization: Membranous

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-IGF-1R (G11) Primary Antibody is a rabbit monoclonal antibody directed against IGF-1R. This antibody is intended for use to qualitatively identify IGF-1R positive cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.



#### IgG (polyclonal)

 Catalog Number:
 760-2653

 Ordering Code:
 05267633001

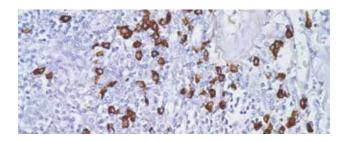
 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD

# INTENDED USE

IgG Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of IgG in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **IgG4 (MRQ-44) Mouse Monoclonal Antibody**

 Catalog Number:
 760-4614

 Ordering Code:
 06523854001

 Quantity:
 50 tests

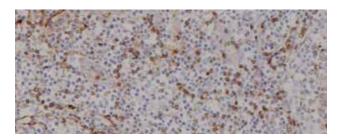
Controls: Tonsil, Plasma Cells

Isotypes:IgG1/KClone Name:MRQ-44Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD

### **INTENDED USE**

IgG4 (MRQ-44) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of IgG4 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### IgM (polyclonal)

Catalog Number: 760-2654
Ordering Code: 05267641001
Quantity: 50 tests

Controls: Lymph Node, Tonsil

Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD

#### **INTENDED USE**

IgM Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of IgM in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Inhibin, alpha (MRQ-63) Rabbit Monoclonal **Primary Antibody**

**Catalog Number:** 760-6081 **Ordering Code:** 08313474001 Quantity: 50 tests

**Controls:** Adrenal Cortex, Placenta, Testis

Isotypes: IgG **Clone Name:** MRQ-63 Species: Rabbit **Regulatory Status:** 

#### **INTENDED USE**

Inhibin (MRQ-63) Rabbit Monoclonal Antibody is intended for laboratory use in the detection of the Inhibin protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

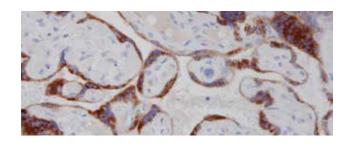
# Inhibin, alpha (R1)

**Catalog Number:** 760-2834 **Ordering Code:** 05268311001 Quantity: 50 tests

**Controls:** Adrenal Cortex, Placenta, Testis

IgG<sub>2a</sub> Isotypes: **Clone Name:** R1 Species: Mouse Localization: Cytoplasmic

**Regulatory Status:** IVD



#### **INTENDED USE**

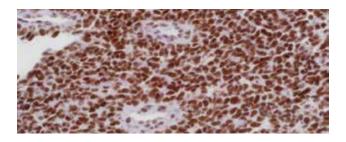
Inhibin, alpha (R1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the inhibin alpha protein in formalinfixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-INI-1 (MRQ-27) Mouse Monoclonal **Primary Antibody**

**Catalog Number:** 760-4615 06523862001 **Ordering Code:** Quantity: 50 tests

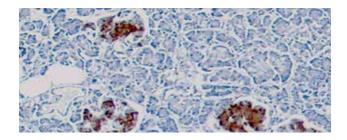
**Controls:** Brain, Endothelial Cells, Astrocytoma

MRQ-27 **Clone Name:** Species: Mouse Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

INI-1 (MRQ-27) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the INI-1 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

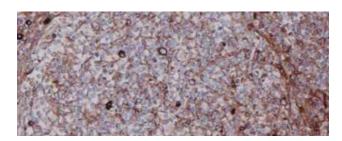


# **Insulin (polyclonal)**

Catalog Number: 760-2655 **Ordering Code:** 05267650001 Quantity: 50 tests **Controls:** Pancreas Clone Name: Polyclonal Species: Guinea Pig Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Insulin Guinea Pig Polyclonal Primary Antibody is intended for laboratory use in the detection of Insulin hormone in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM** anti-Kappa Rabbit Polyclonal **Primary Antibody**

 Catalog Number:
 760-2514

 Ordering Code:
 05267013001

 Quantity:
 50 tests

**Controls:** Lymph Node, Tonsil **Clone Name:** Polyclonal

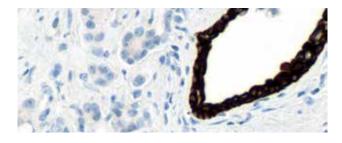
Species: Rabbit

**Localization:** Surface Membrane, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Kappa Rabbit Polyclonal Primary Antibody is directed against kappa immunoglobulin light chains. Staining for kappa light chains can be used to aid in the identification of cells of normal and abnormal B cell lineage. This antibody is intended for laboratory use to qualitatively stain B cells and plasma cells expressing kappa light chain immunoglobulins in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Kappa Rabbit Polyclonal specifically binds to antigens located in the cell membrane and cytoplasmic regions of normal B cells and plasma cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription use only.



# **CONFIRM** anti-Keratin (34βE12) Mouse Monoclonal Primary Antibody

Catalog Number: 790-4373 Ordering Code: 05479266001 Quantity: 50 tests **Controls:** Prostate Isotypes: IgG<sub>1</sub> **Clone Name:** 34BE12 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD

# INTENDED USE

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' CONFIRM® anti-Keratin (34βE12) Mouse Monoclonal Primary Antibody recognizes cytokeratins 1, 5, 10 and 14, and is used as an aid in the identification of basal cells in prostate and myoepithelial cells in breast, via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# **CONFIRM anti-Keratin (AE3) Primary Antibody**

 Catalog Number:
 790-2909

 Ordering Code:
 05278040001

 Quantity:
 50 tests

Controls: Bladder, Prostate, Salivary Gland

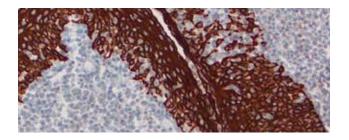
 Isotypes:
 IgG1

 Clone Name:
 AE3

 Species:
 Mouse

 Localization:
 Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana) CONFIRM anti-Keratin (AE3) is a mouse monoclonal antibody (IgG1, kappa) directed against basic cytokeratins of h 65-67, 64, 59, 56 and 52 kD.<sup>1,2,3,4</sup> Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained tissue or cells will show immunoreactivity. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

- 1. Pinkus GS, O'Connor EM, Etheridge CL, Corson JM. Optimal immunoreactivity of keratin proteins in formalin-fixed, paraffin-embedded tissue requires preliminary trypsinization. An immunoperoxidase study of various tumors using polyclonal and monoclonal antibodies. The Journal of Histochemistry and Cytochemistry 33(5): 465-473, 1985.
- 2. Weiss RA, Eichner R, Sun TT. Monoclonal antibody analysis of keratin expression in epidermal diseases: a 48- and 56-KD keratin as molecular markers for hyperproliferative keratinocytes. The Journal of Cell Biology 98(4): 1397-1406, 1984.
- 3. Tseng SC, Jarvinen MJ, Nelson WG, Huang JW, Woodcock-Mitchell J, Sun TT. Correlation of specific keratins with different types of epithelial differentiation; monoclonal antibody studies. Cell 30(2): 361-372, 1982.
- 4. Woodcock-Mitchell J, Eichner R, Nelson WG, Sun TT. Immunolocalization of keratin polypeptides in human epidermis using monoclonal antibodies. The Journal of Cell Biology 95(2 pt 1): 580-588, 1982.

# **CONFIRM anti-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody**

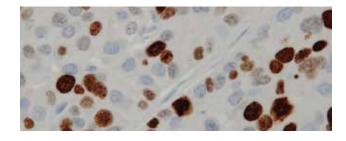
 Catalog Number:
 790-4286

 Ordering Code:
 05278384001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

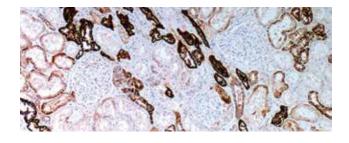
Clone Name: 30-9
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD



#### INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Ki-67 (30-9) Primary Antibody is a rabbit monoclonal antibody (IgG) directed against C-terminal portion of Ki-67 antigen. Staining for Ki-67 can be used to aid in assessing the proliferative activity of normal and neoplastic tissue.<sup>1,2,3</sup> This antibody is intended for use to identify stained proliferating cells by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

- 1. Keng PC, Siemann DW. Measurement of proliferation activities in human tumor models: a comparison of flow cytometric methods. Radiatn Oncol Investig, 6(3):120-7, 1998.
- 2. Rey A Lara PC. Ki67 proliferation index in tumors of the upper urinary tract as related to established prognostic factors and long-term survival. Arch Esp Urol, 51(2): 204-10, 1998.
- 3. Bacchi CE, Gown AM. Detection of cell proliferation in tissue sections. Braz J Med Biol Res, 26(7): 677-87, 1993.



# Ksp-cadherin (MRQ-33)

 Catalog Number:
 760-4387

 Ordering Code:
 05463548001

 Quantity:
 50 tests

Controls: Chromophobe Renal Cell Carcinoma, Kidney

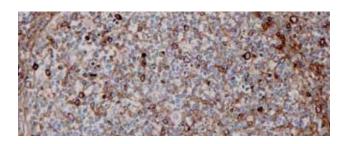
 $\begin{array}{lll} \textbf{Isotypes:} & & \text{IgG}_1 \\ \textbf{Clone Name:} & & \text{MRQ-33} \\ \textbf{Species:} & & \text{Mouse} \\ \end{array}$ 

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Ksp-Cadherin (MRQ-33) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of Ksp-Cadherin in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **CONFIRM anti-Lambda Rabbit Polyclonal Primary Antibody**

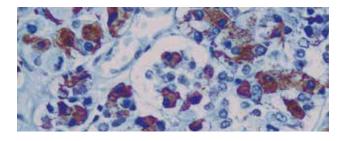
Catalog Number:760-2515Ordering Code:05267021001Quantity:50 testsControls:TonsilClone Name:PolyclonalSpecies:Rabbit

**Localization:** Surface Membrane, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Lambda Rabbit Polyclonal Primary Antibody is directed against lambda immunoglobulin light chains. Staining for lambda light chains can be used to aid in the identification of cells of normal and abnormal B cell lineage This antibody is intended for laboratory use to qualitatively stain B cells and plasma cells expressing lambda light chain immunoglobulins in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. CONFIRM anti-Lambda Rabbit Polyclonal specifically binds to antigens located in the cell membrane and cytoplasmic regions of normal B cells and plasma cells. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription use only.



## **LH** (polyclonal)

Catalog Number:760-2802Ordering Code:05268222001Quantity:50 tests

Controls: Lymph Node, Tonsil

Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

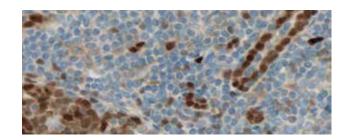
LH Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the LH glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-LMO2 (1A9-1) Mouse Monoclonal Primary Antibody**

Catalog Number:790-4368Ordering Code:05479274001Quantity:50 tests

Controls: Lymph Node, Tonsil

Isotypes:IgG1/KClone Name:1A9-1Species:MouseLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-LMO2 (1A9-1) Mouse Monoclonal Primary Antibody is designed to qualitatively detect the presence of LMO2 expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining results may aid in the classification of B-cell lymphomas. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

#### LM02 (SP51)

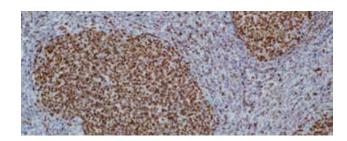
 Catalog Number:
 760-4704

 Ordering Code:
 06586546001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil, Follicular Lymphoma

Isotypes:IgGClone Name:SP51Species:RabbitLocalization:NuclearRegulatory Status:IVD



## **INTENDED USE**

anti-LMO2 (SP51) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the LMO2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### Lysozyme (polyclonal)

 Catalog Number:
 760-2656

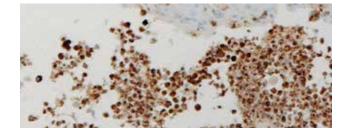
 Ordering Code:
 05267668001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

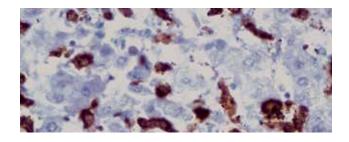
Clone Name:PolyclonalSpecies:RabbitLocalization:Cytoplasmic

Regulatory Status: IVD



# **INTENDED USE**

Lysozyme Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of lysozyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Macrophage (HAM-56)

Catalog Number:760-2657Ordering Code:05267676001Quantity:50 tests

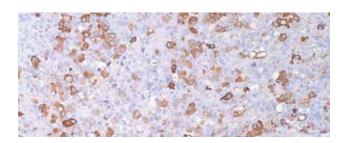
Controls: Lymph Node, Tonsil

Isotypes:lgM/KClone Name:HAM-56Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Macrophage (HAM-56) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of HAM-56 in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Mammaglobin (31A5)

Catalog Number:760-4263Ordering Code:5269253001Quantity:50 tests

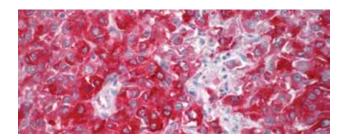
Controls: Breast Carcinoma

Clone Name: 31A5
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Mammaglobin (31A5) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the mammaglobin glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-2990

 Ordering Code:
 05278350001

 Quantity:
 50 tests

Controls: Melanoma, Normal Skin

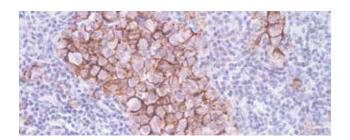
Regulatory Status: IVD

### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems, Inc.'s (Ventana) CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgG1) directed against melan A. This antibody is designed to qualitatively detect the presence of melan A by light microscopy in sections of formalin-fixed, paraffin-embedded tissue. Positive staining may aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# Melanoma Associated Antigen (KBA.62) Mouse Monoclonal Antibody

**Catalog Number:** 760-4527 **Ordering Code:** 06419186001 Quantity: 50 tests **Controls:** Melanoma Isotypes: IgG₁ **Clone Name:** KBA.62 Species: Mouse Localization: Cytoplasmic **Regulatory Status:** 



#### **INTENDED USE**

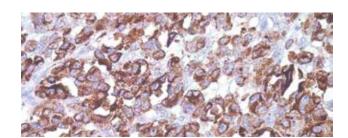
Melanoma Associated Antigen (KBA.62) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of an unidentified melanoma associated antigen in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Melanoma Associated Antigen (PNL2) Mouse Monoclonal Antibody

**Catalog Number:** 760-4528 **Ordering Code:** 06419194001 **Quantity:** 50 tests **Controls:** Melanoma **Isotypes:** IgG<sub>1</sub> **Clone Name:** PNL<sub>2</sub> Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD



**INTENDED USE** 



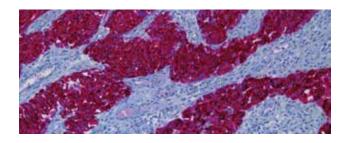
Melanoma Associated Antigen (PNL2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of PNL2 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Melanoma Triple Cocktail (HMB45+A103+T311) Primary Antibody

Catalog Number: 790-4677
Ordering Code: 06527787001
Quantity: 50 tests
Controls: Melanoma

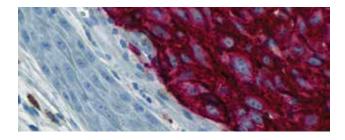
Clone Name: HMB45+A103+T311

Species: N/A
Localization: Cytoplasmic
Regulatory Status: IVD



#### **INTENDED USE**

Melanoma Triple Cocktail (HMB45+A103+T311) is an antibody cocktail of anti-Melanosome (HMB45), anti-MART-1/melan A (A103) and anti-Tyrosinase (T311) mouse monoclonal antibodies. This antibody cocktail demonstrates cytoplasmic staining and may be used to aid in the identification of melanoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



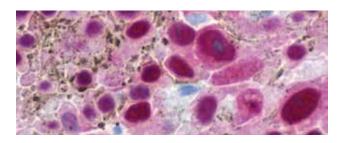
# **CONFIRM anti-Melanosome (HMB45) Mouse Monoclonal Primary Antibody**

Clone Name: HMB45
Species: Mouse
Localization: Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana) CONFIRM anti-Melanosome (HMB45) is a mouse monoclonal antibody (IgG1, kappa) directed against an oncofetal antigen present within immature melanosomes in the cytoplasm of activated and neoplastic melanocytes. CONFIRM anti-Melanosome (HMB45) is intended for laboratory use to qualitatively detect, via light microscopy, cells containing immature melanosomes in sections of formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.



# **CONFIRM anti-MITF (C5/D5) Mouse Monoclonal Primary Antibody**

**Catalog Number:** 790-4367 **Ordering Code:** 05549175001 Quantity: 50 tests Controls: Melanoma Isotypes: IgG, C5/D5 **Clone Name:** Species: Mouse Localization: Nuclear **Regulatory Status:** IVD

### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-MITF (C5/D5) Mouse Monoclonal Primary Antibody is a mouse monoclonal cocktail. This antibody cocktail reagent detects microphthalmia transcription factor (MITF) proteins 52-56KD of MITF expressing cells in normal and neoplastic tissues. This antibody is used in the identification of melanotic lesions such as malignant melanoma and melanotic neurofibroma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining or absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

# **VENTANA** anti-MLH1 (M1) Mouse Monoclonal Primary Antibody

#### For use with VENTANA MMR IHC Panel

 Catalog Number:
 790-5091

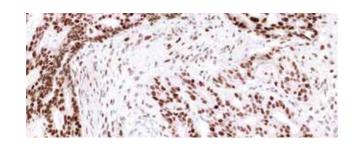
 Ordering Code:
 07862237001

 Quantity:
 50 tests

Controls: CRC tissue with an MLH1 Clinical Status of

Intact or normal colon tissue pre-qualified with VENTANA anti-MLH1 (M1) antibody

Isotypes:IgGClone Name:M1Species:MouseLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

The VENTANA MMR IHC Panel is a qualitative immunohistochemistry (IHC) test intended for use in the light microscopic assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) and BRAF V600E proteins in formalin-fixed, paraffin-embedded colorectal cancer (CRC) tissue sections. The OptiView DAB IHC Detection Kit is used with MLH1, MSH2, MSH6 and BRAF V600E, and the OptiView DAB IHC Detection Kit with OptiView Amplification Kit is used for PMS2 detection. The VENTANA MMR IHC Panel is for use on the VENTANA BenchMark ULTRA instrument. The VENTANA MMR IHC Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody and VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody. The VENTANA MMR IHC Panel is indicated in patients diagnosed with colorectal cancer (CRC) to detect mismatch repair (MMR) proteins deficiency as an aid in the identification of probable Lynch syndrome and to detect BRAF V600E protein as an aid to differentiate between sporadic CRC and probable Lynch syndrome. Results from the VENTANA MMR IHC Panel should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. The clinical performance of this device to guide treatment of MMR deficient patients has not been established. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.

# anti-MLH-1 (M1) Mouse Monoclonal Primary Antibody

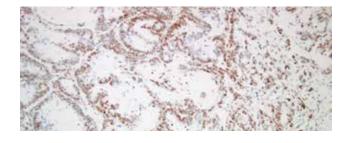
 Catalog Number:
 790-4535

 Ordering Code:
 06472966001

 Quantity:
 50 tests

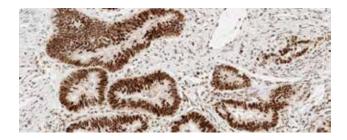
Controls: Appendix, Breast, Colon, Testis, Ovary

Isotypes:IgGClone Name:M1Species:MouseLocalization:NuclearRegulatory Status:IVD



### **INTENDED USE**

Anti-MLH-1 (M1) Mouse Monoclonal Primary Antibody (anti-MLH-1 (M1)) is used to qualitatively identify human DNA mismatch repair (MMR) protein MLH1, expressed in the nucleus of normal proliferating cells. Deficient or low levels of MLH1 are associated with colorectal and other cancers. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# VENTANA anti-MSH2 (G219-1129) Mouse **Monoclonal Primary Antibody**

#### For use with VENTANA MMR IHC Panel

**Catalog Number:** 790-5093 **Ordering Code:** 07862253001 Quantity: 50 tests

CRC tissue with an MSH2 Clinical Status of Controls:

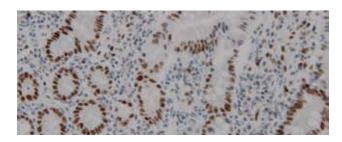
Intact or normal colon tissue pre-qualified with

VENTANA anti-MSH2 (G219-1129) antibody

Isotypes: IgG₁ **Clone Name:** G219-1129 Mouse Species: Localization: Nuclear Regulatory Status: IVD

#### **INTENDED USE**

The VENTANA MMR IHC Panel is a qualitative immunohistochemistry (IHC) test intended for use in the light microscopic assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) and BRAF V600E proteins in formalin-fixed, paraffin-embedded colorectal cancer (CRC) tissue sections. The OptiView DAB IHC Detection Kit is used with MLH1, MSH2, MSH6 and BRAF V600E, and the OptiView DAB IHC Detection Kit with OptiView Amplification Kit is used for PMS2 detection. The VENTANA MMR IHC Panel is for use on the VENTANA BenchMark ULTRA instrument. The VENTANA MMR IHC Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody and VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody. The VENTANA MMR IHC Panel is indicated in patients diagnosed with colorectal cancer (CRC) to detect mismatch repair (MMR) proteins deficiency as an aid in the identification of probable Lynch syndrome and to detect BRAF V600E protein as an aid to differentiate between sporadic CRC and probable Lynch syndrome. Results from the VENTANA MMR IHC Panel should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. The clinical performance of this device to guide treatment of MMR deficient patients has not been established. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.



#### MSH2 (G219-1129) Mouse Monoclonal Antibody

Catalog Number: 760-4265 **Ordering Code:** 05269270001 Quantity: 50 tests

**Controls:** Colon Carcinoma, Colon Mucosa

Isotypes: IgG, **Clone Name:** G219-1129 Species: Mouse Localization: Nuclear Regulatory Status:

#### INTENDED USE

MSH2 (G219-1129) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the MSH2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA** anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody

#### For use with VENTANA MMR IHC Panel

 Catalog Number:
 790-5092

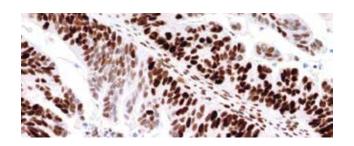
 Ordering Code:
 07862245001

 Quantity:
 50 tests

Controls: CRC tissue with an MSH6 Clinical Status of

Intact, or normal colon tissue pre-qualified with VENTANA anti-MSH6 (SP93) antibody

Isotypes:IgGClone Name:SP93Species:RabbitLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

The VENTANA MMR IHC Panel is a qualitative immunohistochemistry (IHC) test intended for use in the light microscopic assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) and BRAF V600E proteins in formalin-fixed, paraffin-embedded colorectal cancer (CRC) tissue sections. The OptiView DAB IHC Detection Kit is used with MLH1, MSH2, MSH6 and BRAF V600E, and the OptiView DAB IHC Detection Kit with OptiView Amplification Kit is used for PMS2 detection. The VENTANA MMR IHC Panel is for use on the VENTANA BenchMark ULTRA instrument. The VENTANA MMR IHC Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody and VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody. The VENTANA MMR IHC Panel is indicated in patients diagnosed with colorectal cancer (CRC) to detect mismatch repair (MMR) proteins deficiency as an aid in the identification of probable Lynch syndrome and to detect BRAF V600E protein as an aid to differentiate between sporadic CRC and probable Lynch syndrome. Results from the VENTANA MMR IHC Panel should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. The clinical performance of this device to guide treatment of MMR deficient patients has not been established. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.

# **CONFIRM anti-MSH6 (44) Mouse Monoclonal Primary Antibody**

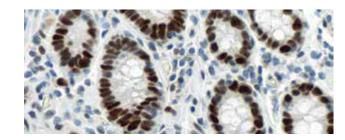
 Catalog Number:
 790-4455

 Ordering Code:
 05929911001

 Quantity:
 50 tests

Controls: Breast Carcinoma, Colon Carcinoma

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{44} \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Nuclear} \\ \textbf{Regulatory Status:} & \textbf{IVD} \\ \end{array}$ 



### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-MSH6 (44) Mouse Monoclonal Antibody is used to qualitatively identify human DNA mismatch repair (MMR) protein MSH6, expressed in the nucleus of normal proliferating cells. Deficient or low levels of MSH6 are associated with colorectal and other cancers. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA MSLN (SP74) Assay**

Catalog Number: 790-7028
Ordering Code: 08508011001
Quantity: 50 tests
Controls: Fallopian Tube
Clone Name: SP74
Species: Rabbit

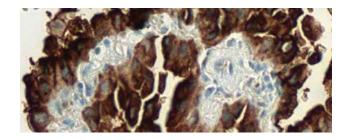
**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

## **INTENDED USE**

VENTANA MSLN (SP74) Assay is intended for the immunohistochemical assessment of the mesothelin protein in formalin-fixed, paraffin-embedded (FFPE) tissue stained with BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





# anti-MUC1 (H23) Mouse Monoclonal Primary Antibody

Catalog Number:790-4574Ordering Code:06316514001Quantity:50 tests

**Controls:** Breast, Lung, Pancreas

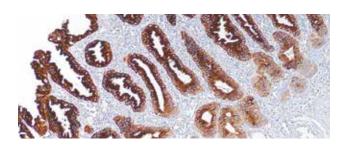
**Isotypes:** IgG **Clone Name:** H23

Species: Mouse Monoclonal
Localization: Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-MUC1 (H23) Mouse Monoclonal Primary Antibody is directed against the membrane bound, glycosylated phosphoprotein MUC1. This antibody may be used to aid in the identification of normal and neoplastic MUC1 expressing cells. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded human tissue. MUC1 is overexpressed in breast carcinoma and non-small cell lung carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **MUC2 (MRQ-18)**

 Catalog Number:
 760-4388

 Ordering Code:
 05463556001

 Quantity:
 50 tests

Controls: Colon, Colon Adenocarcinoma

 Isotypes:
 IgG<sub>1</sub>/K

 Clone Name:
 MRQ-18

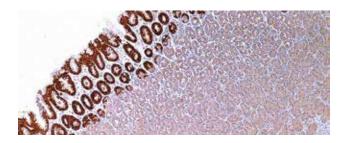
 Species:
 Mouse

 Localization:
 Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

MUC2 (MRQ-18) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the MUC2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **MUC5AC (MRQ-19)**

 Catalog Number:
 760-4389

 Ordering Code:
 05463564001

 Quantity:
 50 tests

Controls: Associated Adenocarcinomas, Stomach

Isotypes: IgG<sub>1</sub>
Clone Name: MRQ-19
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

#### **INTENDED USE**

MUC5AC (MRQ-19) MouseMonoclonal Primary Antibody is intended for laboratory use in the detection of the MUC5AC protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **MUC6 (MRQ-20)**

**Catalog Number:** 760-4390 **Ordering Code:** 05463572001 Quantity: 50 tests

**Controls:** Associated Adenocarcinomas, Stomach

Isotypes: IgG, **Clone Name:** MRQ-20 Species: Mouse Cytoplasmic Localization:

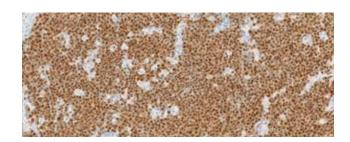
**Regulatory Status:** IVD

#### **INTENDED USE**

MUC6 (MRQ-20) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the MUC6 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



**Catalog Number:** 760-6082 **Ordering Code:** 08313482001 **Quantity:** 50 tests Controls: Tonsil Isotypes: IqG **Clone Name:** EP190 Rabbit Species: **Regulatory Status:** IVD



#### **INTENDED USE**

MUM1 (EP190) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the MUM1 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### MUM1 (MRQ-43)

**Catalog Number:** 760-4529 **Ordering Code:** 06419208001 Quantity: 50 tests **Controls:** Tonsil Isotypes: IgG, **Clone Name:** MRQ-43 Species: Rabbit

Localization: Nuclear, Cytoplasmic

**Regulatory Status:** 

## **INTENDED USE**

MUM1 (MRQ-43) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the MUM1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



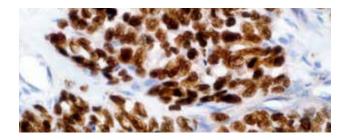
**Catalog Number:** 760-2659 **Ordering Code:** 05267692001 Quantity: 50 tests **Controls:** Bone Marrow **Clone Name:** Polyclonal Rabbit Species: Localization: Cytoplasmic

**Regulatory Status:** IVD

#### **INTENDED USE**

Anti-Myeloperoxidase Polyclonal Primary Antibody is intended for laboratory use in the detection of the myeloperoxidase protein in formalin-fixed. paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





# MyoD1 (EP212) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4900

 Ordering Code:
 07107773001

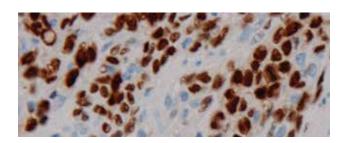
 Quantity:
 50 tests

Controls: Rhabdomyosarcoma

Isotypes:IgGClone Name:EP212Species:RabbitLocalization:NuclearRegulatory Status:IVD

#### **INTENDED USE**

MyoD1 (EP212) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the MyoD1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



## Myogenin (F5D)

 Catalog Number:
 760-2832

 Ordering Code:
 05268290001

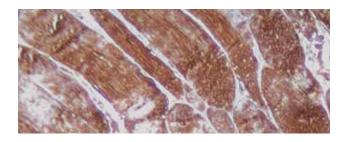
 Quantity:
 50 tests

Controls: Rhabdomyosarcoma

Isotypes:IgG1/KClone Name:F5DSpecies:MouseLocalization:NuclearRegulatory Status:IVD

#### **INTENDED USE**

Myogenin (F5D) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the myogenin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **Myoglobin (polyclonal)**

**Catalog Number:** 760-2660 **Ordering Code:** 05267706001 Quantity: 50 tests **Controls:** Skeletal Muscle **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD

#### **INTENDED USE**

Myoglobin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the Myoglobin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **Myosin, Smooth Muscle (SMMS-1)**

**Catalog Number:** 760-2704 **Ordering Code:** 05268133001 Quantity: 50 tests **Controls:** Breast, Intestine IgG₁/K Isotypes: **Clone Name:** SMMS-1 Species: Mouse

Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Localization:

Myosin, Smooth Muscle (SMMS-1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of Smooth Muscle Myosin heavy chain in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Napsin A (MRQ-60) Mouse Monoclonal **Primary Antibody**

**Catalog Number:** 760-4867 **Ordering Code:** 07047720001 Quantity: 50 tests

**Controls:** Lung Adenocarcinoma, Renal Cell Carcinoma

Isotypes: IgG₁/K **Clone Name:** MRQ-60

Species: Mouse Monoclonal Localization: Cytoplasmic

**Regulatory Status:** IVD

#### **INTENDED USE**

Napsin A (MRQ-60) Mouse Primary Antibody is intended for laboratory use in the detection of the Napsin A protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



**Catalog Number:** 760-4446 **Ordering Code:** 05973805001 Quantity: 50 tests

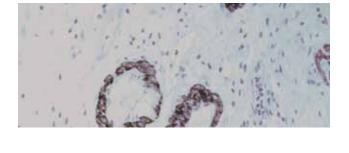
**Controls:** Lung Adenocarcinoma

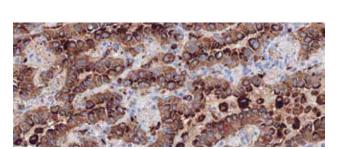
Isotypes: IgG **Clone Name:** Polyclonal Rabbit Species: Localization: Cytoplasmic

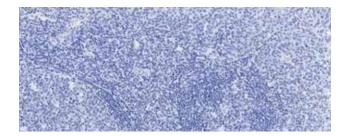
**Regulatory Status:** IVD

# **INTENDED USE**

Napsin A Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the Napsin A protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





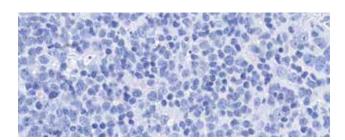


### **Negative Control (Monoclonal)**

Catalog Number: 760-2014 **Ordering Code:** 05266670001 Quantity: 250 tests **Controls:** Kidney Clone Name: MOPC21 Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Negative Control (Monoclonal) is a mouse monoclonal antibody (MOPC-211) which is not directed against a known epitope present in human tissue. The reagent is intended for use as a negative control in qualitative staining of sections of routine formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



#### **CONFIRM Negative Control Rabbit Ig**

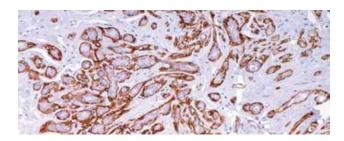
Catalog Number:760-1029Ordering Code:05266238001Quantity:250 tests

Controls: See Package Insert

Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM Negative Control Rabbit Ig is intended for laboratory use as a control for nonspecific binding of rabbit immunoglobulin in sections of formalin-fixed, paraffin-embedded tissue on VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



# **Nerve Growth Factor Receptor (NGFR) (MRQ-21)**

 Catalog Number:
 760-4391

 Ordering Code:
 05463599001

 Quantity:
 50 tests

**Controls:** Ganglia, Neurons, Malignant Melanoma Cells,

Myoepithelial Cells of Breast Ducts

 Isotypes:
 IgG1

 Clone Name:
 MRQ-21

 Species:
 Mouse

 Localization:
 Cytoplasmic

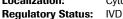
 Regulatory Status:
 IVD

#### **INTENDED USE**

NGFR (Nerve Growth Factor Receptor) (MRQ-21) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of NGFR in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## **Neurofilament (2F11)**

**Catalog Number:** 760-2661 **Ordering Code:** 05267714001 Quantity: 50 tests **Controls:** Brain IgG₁/K Isotypes: **Clone Name:** 2F11 Species: Mouse Localization: Cytoplasmic



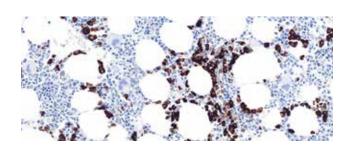
#### **INTENDED USE**

Neurofilament (2F11) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the neurofilament protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **Neutrophil Elastase (SP203) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 760-4953 **Ordering Code:** 07391455001 **Quantity:** 50 tests Controls: Bone Marrow Isotypes: IqG **Clone Name:** SP203 Species: Rabbit Localization: Cytoplasmic





#### **INTENDED USE**

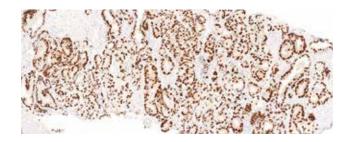
Neutrophil Elastase (SP203) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the neutrophil elastase proteinase in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 760-5086 **Ordering Code:** 07859759001 Quantity: 50 tests

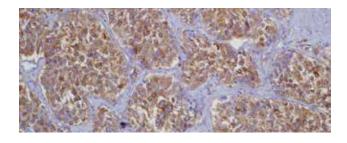
**Controls:** Prostate, Prostate Adenocarcinoma

Isotypes: IgG EP356 **Clone Name:** Species: Rabbit Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of NKX3.1 in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-NSE (MRQ-55) Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4786

 Ordering Code:
 06648568001

 Quantity:
 50 tests

Controls: Pancreas, Carcinoid Tumor

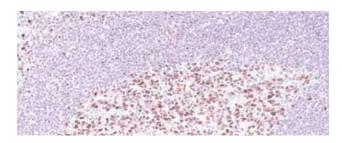
Clone Name: MRQ-55

**Species:** Mouse Monoclonal **Localization:** Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

NSE (MRQ-55) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the NSE enzyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### Oct-2 (MRQ-2)

 Catalog Number:
 760-4447

 Ordering Code:
 05973791001

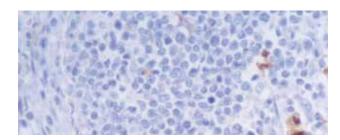
 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 $\begin{tabular}{lll} \textbf{Isotypes:} & lgG_1/K \\ \textbf{Clone Name:} & MRQ-2 \\ \textbf{Species:} & Mouse \\ \textbf{Localization:} & Nuclear \\ \textbf{Regulatory Status:} & IVD \\ \end{tabular}$ 

#### **INTENDED USE**

Oct-2 (MRQ-2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Oct-2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### Oct-4 (MRQ-10)

Catalog Number:760-4392Ordering Code:05463602001Quantity:50 tests

Controls: Dysgerminoma, Seminoma

Isotypes: IgG
Clone Name: MRQ-10
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

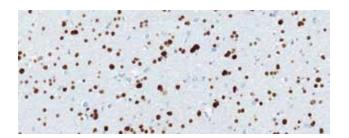
#### **INTENDED USE**

Anti-Oct-4 (MRQ-10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Oct-4 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# Olig2 (EP112) Rabbit Monoclonal Primary Antibody

Catalog Number:760-5050Ordering Code:07667973001Quantity:50 testsControls:Astrocytoma

Isotypes:IgGClone Name:EP112Species:RabbitLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

Olig2 (EP112) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Olig2 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## p21WAF1 (DCS-60.2)

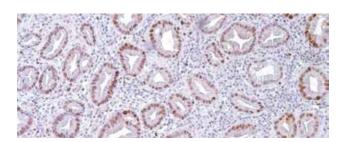
 Catalog Number:
 760-4453

 Ordering Code:
 05973961001

 Quantity:
 50 tests

Controls: Colon, Non-Small Cell Lung Carcinoma

Isotypes:IgG2aClone Name:DCS-60.2Species:ColonLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

p21WAF1 (DCS-60.2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the p21WAF1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## p27Kip1 (SX53G8)

 Catalog Number:
 760-4268

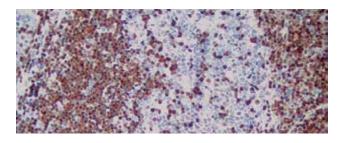
 Ordering Code:
 05269300001

 Quantity:
 50 tests

Controls: Colon, Non-Small Cell Lung Carcinoma

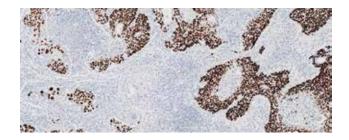
 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{Glone Name:} & & & & & & & & \\ \textbf{Sx53G8} & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \textbf{Cytoplasmic} & & & & & & \\ \end{tabular}$ 

Regulatory Status: IVD



#### **INTENDED USE**

p27Kip1 (SX53G8) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the p27Kip1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-p40 (BC28) Mouse Monoclonal Primary Antibody

Catalog Number:790-4950Ordering Code:07394420001Quantity:50 tests

Controls: Normal basal cells in prostate tissue, Lung squamous cell carcinoma

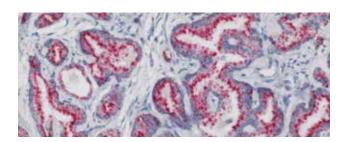
(lgG, lgA...) : lgG,

Clone Name: BC28
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

Isotypes:

#### **INTENDED USE**

Anti-p40 (BC28) Mouse Monoclonal Primary Antibody [anti-p40 (BC28)] is intended for laboratory use in the detection of the p40 protein in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

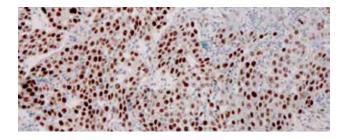


# anti-p504s (SP116) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-6011 **Ordering Code:** 08035130001 **Quantity:** 50 tests Isotypes: lgG SP116 **Clone Name:** Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Anti-p504s (SP116) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of α-methylacyl-CoA racemase (AMACR) in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### anti-p53 (Bp53-11) Primary Antibody

 Catalog Number:
 760-2542

 Ordering Code:
 05267102001

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

Isotypes:IgG2aClone Name:Bp-53-11Species:MouseLocalization:NuclearRegulatory Status:IVD

# INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) anti-p53 Primary Antibody (Bp53-11) is a mouse monoclonal antibody directed against both the mutant and wild type of the p53 nuclear phosphoprotein. Very rare normal cells express p53, but alterations in the p53 suppressor gene result in an overproduction of this protein in malignancies. This reagent may be used to aid in the identification of abnormally proliferating cells in neoplastic cell populations. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.

### **CONFIRM** anti-p53 (DO-7) Primary Antibody

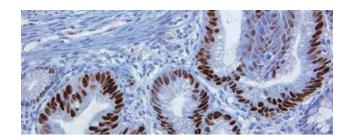
 Catalog Number:
 790-2912

 Ordering Code:
 05278074001

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

Isotypes:IgG1/KClone Name:DO-7Species:MouseLocalization:NuclearRegulatory Status:IVD

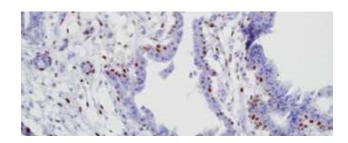


#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-p53 (DO-7) Primary Antibody is a mouse monoclonal antibody (IgG1, kappa) directed against human p53. The antibody is intended for laboratory use to qualitatively identify by light microscopy wild type and mutant p53 in sections of formalin-fixed, paraffin-embedded tissue on a Ventana automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-p57<sup>Kip2</sup> (Kp10) Mouse Monoclonal Primary Antibody

**Catalog Number:** 760-4617 **Ordering Code:** 06523897001 Quantity: 50 tests **Controls:** Placenta Isotypes: IgG<sub>2h</sub>/K **Clone Name:** Kp10 Species: Mouse Localization: Nuclear **Regulatory Status:** IVD

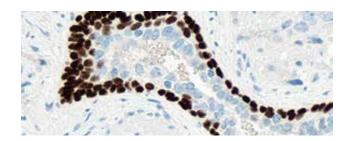


#### **INTENDED USE**

p57Kip2 (Kp10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the p57Kip2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

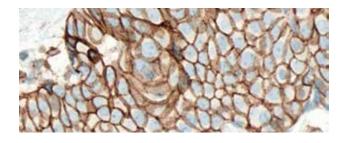
# VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody

**Catalog Number:** 790-4509 **Ordering Code:** 05867061001 Quantity: 50 tests **Controls:** Prostate, Tonsil **Isotypes:** IgG<sub>2a</sub>/K **Clone Name:** 4A4 Species: Mouse Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody (VENTANA anti-p63 (4A4)) is directed against the p63 protein. This antibody exhibits a nuclear staining pattern and may be used to aid in the differentiation of benign and malignant prostatic or breast lesions, and in the differentiation of lung squamous cell carcinoma and lung adenocarcinoma. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-4517

 Ordering Code:
 05867088001

 Quantity:
 50 tests

Controls: Normal Ducts of the Breast

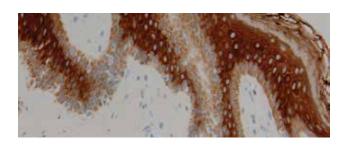
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & 98 \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$ 

**Localization:** Membraneous (ductal), Cytoplasmic (lobular)

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody is directed against human juxtamembrane protein p120 expressed as a part of the cell-cell adhesion complex in epithelial tissues. Cytoplasmic accumulation of p120 is associated with lobular breast carcinoma whereas ductal neoplasms retain membranous localization. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody

 Catalog Number:
 760-2135
 760-2595

 Ordering Code:
 05266840001
 5267145001

 Quantity:
 250 tests
 50 tests

**Controls:** Intestine, Liver IgG,

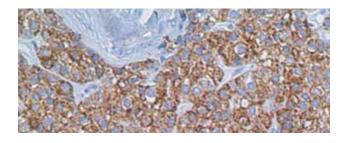
Clone Name: AE1/AE3 & PCK26

**Species:** Mouse **Localization:** Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody (Anti-Pan Keratin (AE1/AE3/PCK26) is a cocktail of antibodies directed against keratins present in simple and complex epithelial cells. This product exhibits a cytoplasmic staining pattern and may be used to aid in the identification of normal and abnormal epithelial cells, and as an aid in determining tumor lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Antibody

 Catalog Number:
 760-4532

 Ordering Code:
 06419224001

 Quantity:
 50 tests

 Controls:
 Parathyroid

 Isotypes:
 IgG<sub>2a</sub>

 Clone Name:
 MRQ-31

 Species:
 Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the parathyroid hormone in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **PAX-8 (MRQ-50)**

 Catalog Number:
 760-4618

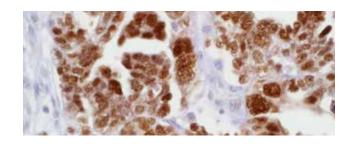
 Ordering Code:
 06523927001

 Quantity:
 50 tests

Controls: Thyroid Carcinoma, Ovarian Carcinoma

(Non-Mucinous Carcinoma)

Isotypes: IgG
Clone Name: MRQ-50
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

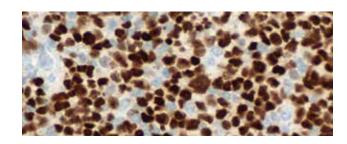


#### **INTENDED USE**

PAX-8 (MRQ-50) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the PAX-8 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody**

**Catalog Number:** 790-4420 **Ordering Code:** 05552729001 Quantity: 50 tests **Controls:** Spleen, Tonsil **Clone Name:** SP34 Species: Rabbit Nuclear Localization: **Regulatory Status:** IVD



#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody is directed against a nuclear epitope present in human B lymphocytes. This antibody may be used to aid in the identification of normal and neoplastic cells of B-lymphocytic lineage. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, shall be complemented by morphological studies and evaluation of proper controls. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## PD-1 (NAT105) Mouse Monoclonal Antibody

 Catalog Number:
 760-4895

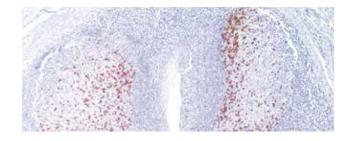
 Ordering Code:
 07099029001

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

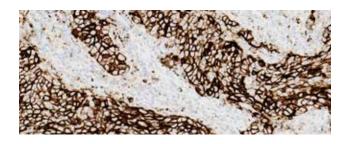
 $\begin{array}{lll} \textbf{Isotypes:} & & \textbf{IgG}_1 \\ \textbf{Clone Name:} & & \textbf{NAT105} \\ \textbf{Species:} & & \textbf{Mouse} \\ \textbf{Localization:} & & \textbf{Cytoplasmic} \\ \end{array}$ 

Regulatory Status: IVD



#### **INTENDED USE**

PD-1 (NAT105) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the PD-1 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



#### **VENTANA PD-L1 (SP142) Assay**

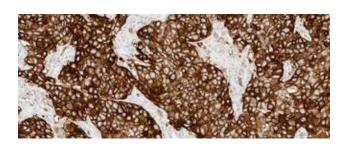
Catalog Number: 740-4859
Ordering Code: 07709374001
Quantity: 50 tests
Controls: Tonsil
Clone Name: SP142
Species: Rabbit

**Localization:** Membranous and/or Cytoplasmic Staining

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma and non-small cell lung cancer (NSCLC) tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity. PD-L1 expression in ≥ 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) in a nonrandomized study of TECENTRIQ (atezolizumab). PD-L1 expression in ≥ 50% TC or ≥ 10% IC determined by VENTANA PD-L1 (SP142) Assay in NSCLC tissue may be associated with enhanced overall survival from TECENTRIQ (atezolizumab). This product is intended for in vitro diagnostic (IVD) use.



## **VENTANA PD-L1 (SP263) Assay**

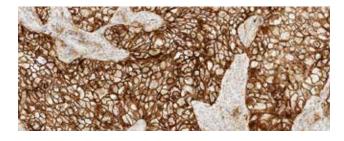
Catalog Number: 740-4907
Ordering Code: 07208162001
Quantity: 50 tests
Controls: Placenta
Clone Name: SP263
Species: Rabbit

**Localization:** Membranous and/or Cytoplasmic Staining

Regulatory Status: IVD

#### **INTENDED USE**

VENTANA PD-L1 (SP263) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma tissue stained with OptiView DAB IHC Detection Kit on a VENTANA BenchMark ULTRA instrument. PD-L1 status is determined by the percentage of tumor cells with any membrane staining above background or by the percentage of tumor-associated immune cells with staining (IC+) at any intensity above background. The percent of tumor area occupied by any tumor-associated immune cells (Immune Cells Present, ICP) is used to determine IC+, which is the percent area of ICP exhibiting PD-L1 positive immune cell staining. PD-L1 status is considered High if any of the following are met:  $\geq$  25% of tumor cells exhibit membrane staining; or, ICP > 1% and IC+  $\geq$  25%; or, ICP = 1% and IC+  $\geq$  100%. PD-L1 High status as determined by VENTANA PD-L1 (SP263) Assay was associated with increased objective response rate (ORR) in a single arm study of IMFINZI<sup>TM</sup> (durvalumab). This product is intended for in vitro diagnostic (IVD) use.



# **VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody**

Catalog Number:790-4905Ordering Code:07494190001Quantity:50 testsControls:PlacentaClone Name:SP263Species:Rabbit

**Localization:** Membranous and/or Cytoplasmic Staining

Regulatory Status: IVD

### INTENDED USE

VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the PD-L1 protein in formalin-fixed, paraffin-embedded tissue. It is intended to be stained with BenchMark IHC/ISH instruments. It is indicated as an aid in the assessment of PD-L1 expression in human tissues. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Perforin (MRQ-23)

**Catalog Number:** 760-4394 **Ordering Code:** 05463637001 Quantity: 50 tests

Lymph Node, Tonsil **Controls:** 

Isotypes: IgG<sub>1</sub> **Clone Name:** MRQ-23 Species: Mouse

Localization: Perinuclear Cytoplasmic

**Regulatory Status:** 

#### **INTENDED USE**

Perforin (MRQ-23) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the perforin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

## **PGP 9.5 Rabbit Polyclonal Antibody**

**Catalog Number:** 760-4434 **Ordering Code:** 05973953001 Quantity: 50 tests

**Controls:** Bowel Wall (Interstitial Cells of Cajal),

Nerve Tissue

**Isotypes:** IgG **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic

**Regulatory Status:** IVD

#### **INTENDED USE**

PGP 9.5 Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the PGP9.5 (UCH-L1) enzyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **Phosphohistone H3 (PHH3)**

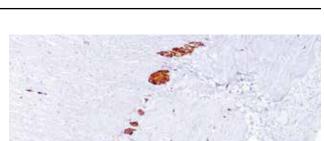
**Catalog Number:** 760-4591 **Ordering Code:** 06433405001 Quantity: 50 tests Controls: Tonsil **Clone Name:** PHH3

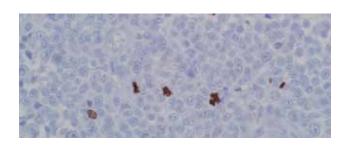
Rabbit Polyclonal Species:

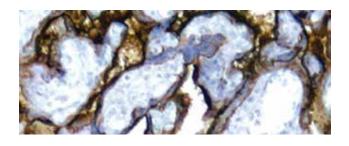
Localization: Nuclear **Regulatory Status:** IVD

## **INTENDED USE**

Phosphohistone H3 (PHH3) Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the Phosphohistone H3 (PHH3) protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.





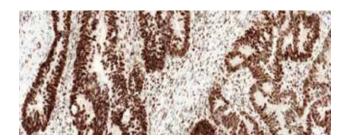


#### PLAP (NB10)

**Catalog Number:** 760-2664 **Ordering Code:** 05267757001 Quantity: 50 tests **Controls:** Placenta Isotypes: lgG **Clone Name:** NB10 Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

PLAP (NB10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the PLAP protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **VENTANA** anti-PMS2 (A16-4) Mouse Monoclonal **Primary Antibody**

#### For use with VENTANA MMR IHC Panel

 Catalog Number:
 790-5094

 Ordering Code:
 07862261001

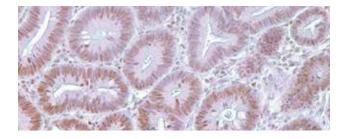
 Quantity:
 50 tests

Controls: CRC tissue with a PMS2 Clinical Status of Intact or normal colon tissue pre-qualified

with VENTANA anti-PMS2 (A16-4) antibody

# **INTENDED USE**

The VENTANA MMR IHC Panel is a qualitative immunohistochemistry (IHC) test intended for use in the light microscopic assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) and BRAF V600E proteins in formalin-fixed, paraffin-embedded colorectal cancer (CRC) tissue sections. The OptiView DAB IHC Detection Kit is used with MLH1, MSH2, MSH6 and BRAF V600E, and the OptiView DAB IHC Detection Kit with OptiView Amplification Kit is used for PMS2 detection. The VENTANA MMR IHC Panel is for use on the VENTANA BenchMark ULTRA instrument. The VENTANA MMR IHC Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody and VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody. The VENTANA MMR IHC Panel is indicated in patients diagnosed with colorectal cancer (CRC) to detect mismatch repair (MMR) proteins deficiency as an aid in the identification of probable Lynch syndrome and to detect BRAF V600E protein as an aid to differentiate between sporadic CRC and probable Lynch syndrome. Results from the VENTANA MMR IHC Panel should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. The clinical performance of this device to guide treatment of MMR deficient patients has not been established. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.



## PMS2 (EPR3947) Rabbit Monoclonal Antibody

**Catalog Number:** 760-4531 **Ordering Code:** 06419216001 Quantity: 50 tests **Controls:** Colon Isotypes: lgG **Clone Name:** EPR3947 Species: Rabbit Localization: Nuclear **Regulatory Status:** IVD

#### **INTENDED USE**

PMS2 (EPR3947) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the PMS2 enzyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Podoplanin (D2-40) Mouse Monoclonal Antibody

 Catalog Number:
 760-4395

 Ordering Code:
 05463645001

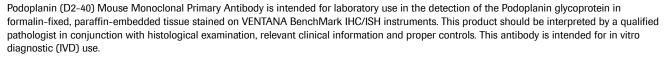
 Quantity:
 50 tests

Controls: Lymph Node, Lymphangioma

 $\begin{array}{lll} \textbf{Isotypes:} & & \text{IgG}_1 \\ \textbf{Clone Name:} & & \text{D2-40} \\ \textbf{Species:} & & \text{Mouse} \\ \textbf{Localization:} & & \text{Cytoplasmic} \\ \end{array}$ 

Regulatory Status: IVD

#### **INTENDED USE**



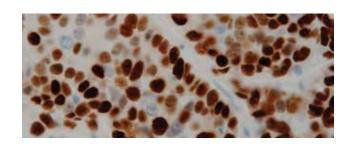
# **CONFIRM** anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-2223
 790-4296

 Ordering Code:
 05277990001
 5278392001

 Quantity:
 50 tests
 250 tests

Controls: Breast Isotypes: IgG Clone Name: 1E2 Species: Rabbit Localization: Nuclear Regulatory Status: IVD



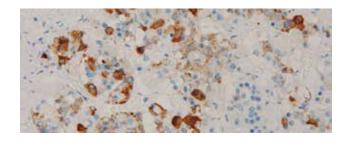
### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) is intended for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM antiPR (1E2) is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) is indicated as an aid in the management, prognosis and prediction of therapy outcome of breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. Prescription use only.

## **Prolactin (polyclonal)**

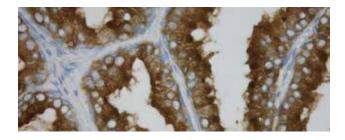
Catalog Number:760-2803Ordering Code:05268249001Quantity:50 testsControls:Normal PituitaryClone Name:PolyclonalSpecies:RabbitLocalization:Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

Prolactin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the prolactin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

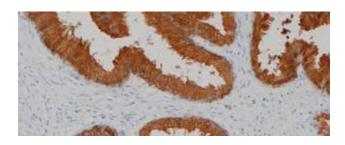


# **CONFIRM anti-Prostate Specific Antigen (PSA) Rabbit Polyclonal Primary Antibody**

Catalog Number: 760-2506 **Ordering Code:** 05266939001 Quantity: 50 tests Controls: Prostate Isotypes: lgG **Clone Name:** Polyclonal Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-Prostate Specific Antigen (PSA) Primary Antibody is a rabbit polyclonal antibody (Ig) directed against both free and bound human prostate specific antigen (PSA). This antibody is intended for use to qualitatively identify PSA by light microscopy in sections of formalin-fixed, paraffin-embedded tissue following staining on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.



#### **PSA (ER-PR8)**

 Catalog Number:
 760-4271

 Ordering Code:
 05269334001

 Quantity:
 50 tests

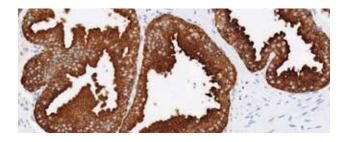
Controls: Prostate Adenocarcinoma

 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{IgG}_1/K & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Species:} & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \textbf{Cytoplasmic} & & & & & & \\ \end{tabular}$ 

Regulatory Status: IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque PSA (ER-PR8) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnosis, as an aid in the identification of prostatic adenocarcinoma within the context of an antibody panel, the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist.



#### **PSAP (PASE/4LJ)**

**Catalog Number:** 760-4272 **Ordering Code:** 05269342001 Quantity: 50 tests Controls: Prostate Isotypes: IgG<sub>1</sub> PASE/4LJ **Clone Name:** Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

PSAP (PASE/4LJ) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the PSAP protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **PSMA (EP192) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 760-6076

 Ordering Code:
 08313423001

 Quantity:
 50 tests

Controls: Prostate, Prostate Adenocarcinoma

Isotypes:IgGClone Name:EP192Species:RabbitRegulatory Status:IVD

#### **INTENDED USE**

PSMA (EP192) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the PSMA protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-5097

 Ordering Code:
 07970200001

 Quantity:
 50 tests

Controls: Pancreatic Islet Cells

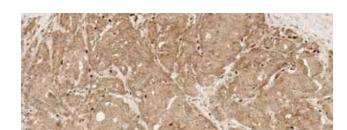
Isotypes:lgGClone Name:SP218Species:Rabbit

**Localization:** Cytoplasmic and/or Nuclear

Regulatory Status: IVD



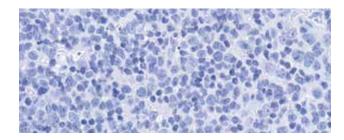
The VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative detection of the phosphatase and tensin homolog (PTEN) protein in formalin-fixed, paraffin-embedded tissue. It is intended to be stained with the VENTANA BenchMark ULTRA immunohistochemical automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.



### **Rabbit Monoclonal Negative Control Ig**

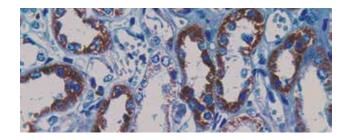
Catalog Number: 790-4795
Ordering Code: 06683380001
Quantity: 250 tests
Controls: Test Positive Tissue

Isotypes:IgGSpecies:RabbitRegulatory Status:IVD



#### **INTENDED USE**

Rabbit Monoclonal Negative Control Ig is intended for laboratory use as a control for nonspecific binding of rabbit immunoglobulin in sections of formalin-fixed, paraffin-embedded tissue when stained on VENTANA BenchMark IHC/ISH platforms (BenchMark GX, BenchMark XT and BenchMark ULTRA). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



#### **Renal Cell Carcinoma (PN-15)**

 Catalog Number:
 760-4273

 Ordering Code:
 05269369001

 Quantity:
 50 tests

Controls: Kidney, Renal Cell Carcinoma

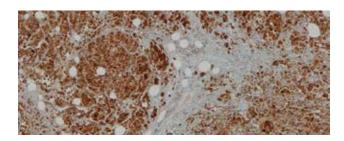
Isotypes: $lgG_1/K$ Clone Name:PN-15Species:Mouse

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Anti-Renal Cell Carcinoma (PN-15) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the GP200 glycoprotein in formalin-fixed, paraffin-embedded neoplastic tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

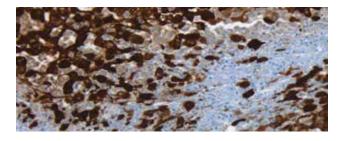


# CONFIRM anti-S100 (4C4.9) Primary Antibody

Catalog Number: 790-2914 **Ordering Code:** 05278104001 Quantity: 50 tests **Controls:** Melanoma IgG<sub>2a</sub> 4C4.9 Isotypes: **Clone Name:** Mouse Species: Localization: Cytoplasmic **Regulatory Status:** IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-S100 (4C4.9) Primary Antibody is a mouse monoclonal antibody (IgG2a) directed against S100 protein. The antibody is intended for use to qualitatively identify S100 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



# **CONFIRM anti-S100 (Polyclonal) Primary Antibody**

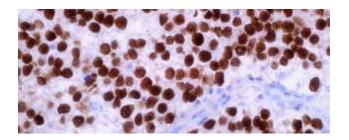
760-2523 **Catalog Number: Ordering Code:** 05267072001 Quantity: 50 tests **Controls:** Melanoma **Clone Name:** Polyclonal Rabbit Species: Localization: Cytoplasmic **Regulatory Status:** IVD

### **INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) CONFIRM anti-S100 (Polyclonal) Primary Antibody contains rabbit antiserum directed against an epitope found on S100 protein and may be used to aid in the identification of cells of normal and abnormal neuronal and neuroendocrine lineage and as an aid in the diagnosis of anaplastic tumors. The antibody is intended for qualitative staining in section of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# SALL4 (6E3) Mouse Monoclonal Primary Antibody

**Catalog Number:** 760-4864 **Ordering Code:** 07047690001 Quantity: 50 tests **Controls:** Seminoma Isotypes: IgG **Clone Name:** 6E3 Species: Mouse Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

SALL4 (6E3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the SALL4 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

#### **Smoothelin (R4A) Mouse Monoclonal Antibody**

 Catalog Number:
 760-4592

 Ordering Code:
 06433278001

 Quantity:
 50 tests

Controls: Bladder, Leiomyosarcoma

**Isotypes:** IgG<sub>1</sub> **Clone Name:** R4A

**Species:** Mouse Monoclonal **Localization:** Cytoplasmic (MP), Nuclear

Regulatory Status: IVD



Smoothelin (R4A) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Smoothelin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



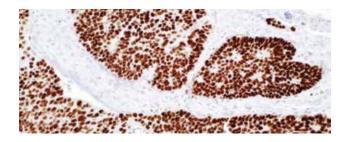
Catalog Number:760-2667Ordering Code:05267781001Quantity:50 testsControls:PancreasClone Name:PolyclonalSpecies:RabbitLocalization:Cytoplasmic

Regulatory Status: IVD



#### **INTENDED USE**

Somatostatin Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of somatostatin in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **SOX-2 (SP76)**

 Catalog Number:
 760-4621

 Ordering Code:
 06523943001

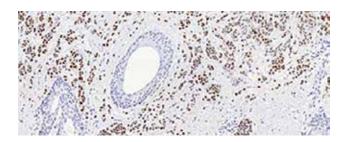
 Quantity:
 50 tests

Controls: Squamous Epithelium

Isotypes:IgGClone Name:SP76Species:RabbitLocalization:NuclearRegulatory Status:IVD

### **INTENDED USE**

SOX-2 (SP76) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-2 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### SOX-10 (SP267) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4968

 Ordering Code:
 07560389001

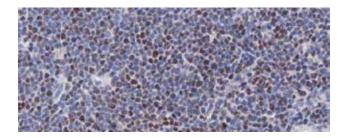
 Quantity:
 50 tests

Controls: Melanoma, Skin Melanocytes

Isotypes:IgGClone Name:SP267Species:RabbitLocalization:NuclearRegulatory Status:IVD

### **INTENDED USE**

SOX-10 (SP267) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-10 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody

Catalog Number:760-4868Ordering Code:07047738001Quantity:50 tests

Controls: Mantle Cell Lymphoma

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{MRQ-58} \end{array}$ 

Species: Mouse Monoclonal

**Localization:** Nuclear **Regulatory Status:** IVD

### **INTENDED USE**

SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-11 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Spectrin (RBC2/3D5)

**Catalog Number:** 760-4274 **Ordering Code:** 05269377001 Quantity: 50 tests **Controls:** Bone Marrow Isotypes: IgG<sub>2a</sub>/K **Clone Name:** RBC2/3D5 Species: Mouse Localization: Membranous

Regulatory Status: IVD

#### **INTENDED USE**

Spectrin (RBC2/3D5) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the spectrin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody

 Catalog Number:
 760-4595

 Ordering Code:
 06433324001

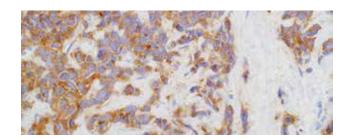
 Quantity:
 50 tests

Controls: Pancreatic Islet Cells

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{MRQ-40} \end{array}$ 

**Species:** Rabbit Monoclonal **Localization:** Cytoplasmic

Regulatory Status: IVD



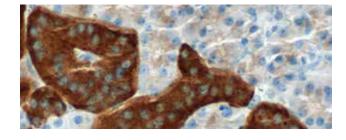
### **INTENDED USE**

Synaptophysin (MRQ-40) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Synaptophysin glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **CONFIRM** anti-Synaptophysin (SP11) Rabbit Monoclonal Primary Antibody

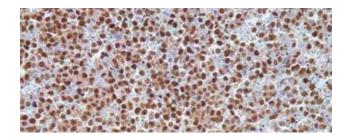
Catalog Number: 790-4407
Ordering Code: 05479304001
Quantity: 50 tests
Controls: Pancreas
Clone Name: SP11
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD



### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Synaptophysin (SP11) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of synaptophysin expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue. Positive staining results may aid in the classification of neuroendocrine tumors. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.



### T-bet (MRQ-46) Rabbit Monoclonal Antibody

 Catalog Number:
 760-4598

 Ordering Code:
 06433391001

 Quantity:
 50 tests

Controls: Hairy Cell Leukemia, Tonsil

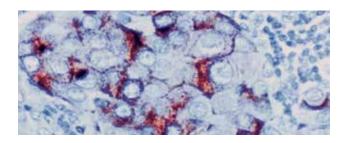
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{MRQ-46} \end{array}$ 

Species: Rabbit Monoclonal

**Localization:** Nuclear **Regulatory Status:** IVD

#### **INTENDED USE**

T-bet (MRQ-46) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the T-bet protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



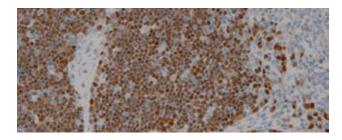
### TAG-72 (B72.3)

Catalog Number:760-2669Ordering Code:05267803001Quantity:50 testsControls:Breast CarcinomaIsotypes:IgG1/KClone Name:B72.3

Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

### **INTENDED USE**

TAG-72 (B72.3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the TAG-72 glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### TdT (polyclonal)

 Catalog Number:
 760-2670

 Ordering Code:
 05267811001

 Quantity:
 50 tests

Controls: TdT Positive Lymphomas, Thymus

Clone Name: Polyclonal
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

### **INTENDED USE**

TdT Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of TdT in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# anti-TFE3 (MRQ-37) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 760-4622

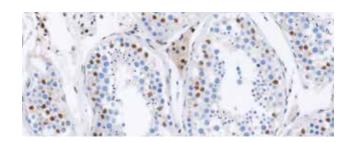
 Ordering Code:
 06523951001

 Quantity:
 50 tests

Controls: Testis (Germ Cells), XP11.2 Translocation

Renal Cell

Isotypes:IgGClone Name:MRQ-37Species:RabbitLocalization:NuclearRegulatory Status:IVD



#### **INTENDED USE**

TFE3 (MRQ-37) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the TFE3 protein in formalin-fixed, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# CONFIRM anti-Thymidine Phosphorylase (P-GF.44C) Mouse Monoclonal Primary Antibody

 Catalog Number:
 790-4454

 Ordering Code:
 05976502001

 Quantity:
 50 tests

 Isotypes:
 IgG1

 Clone Name:
 P-GF44C

 Species:
 Mouse

**Localization:** Nuclear, Cytoplasmic

Regulatory Status: IVD

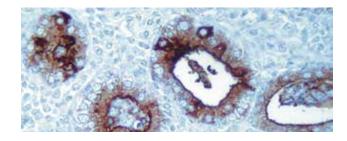
### **INTENDED USE**

CONFIRM anti-Thymidine Phosphorylase (P-GF.44C) Mouse Monoclonal Primary Antibody recognizes human thymidine phosphorylase, an angiogenic factor, expressed in varying levels by macrophages, stromal cells, glial cells and some epithelial cells. Thymidine phosphorylase shows a cytoplasmic and/or nuclear location. This antibody exhibits a nuclear and/or cytoplasmic staining pattern and may be used to aid in the detection of thymidine phosphorylase in carcinoma of the breast, esophagus, stomach, colon and rectum, pancreas, head and neck, ovaries and lung. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



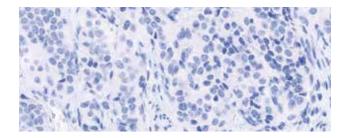
**Catalog Number:** 760-2671 **Ordering Code:** 05267820001 Quantity: 50 tests **Controls:** Thyroid Isotypes: IgG<sub>1</sub> **Clone Name:** 2H11+6E1 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



### **INTENDED USE**

Thyroglobulin (2H11+6E1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of thyroglobulin in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1) Mouse Monoclonal Primary Antibody

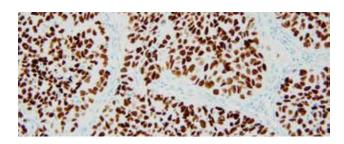
Catalog Number:790-4398Ordering Code:05479312001Quantity:50 tests

Controls: Lung, Thyroid, Lung Carcinoma

Isotypes:IgG1Clone Name:8G7G3/1Species:MouseLocalization:NuclearRegulatory Status:IVD

#### **INTENDED USE**

CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1) Mouse Monoclonal Primary Antibody (CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1)) is designed to qualitatively detect the presence of thyroid transcription factor-1 (TTF-1) expressing cells. TTF-1 positive staining results may aid in the classification of neoplasms of the lung and thyroid. The antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody

 Catalog Number:
 790-4756

 Ordering Code:
 06640613001

 Quantity:
 50 tests

**Controls:** Normal Thyroid, Lung Carcinoma, Normal Lung

Isotypes:IgGClone Name:SP141Species:RabbitLocalization:NuclearRegulatory Status:IVD

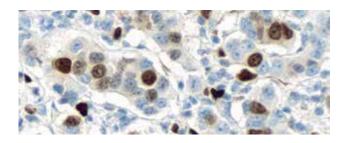
Alternate Names: Thyroid Transcription Factor - 1

### **INTENDED USE**

Anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody (anti-TTF-1 (SP141)) is directed against the thyroid transcription factor-1 (TTF-1) protein. This antibody exhibits a nuclear staining pattern and may be used to aid in the classification of neoplasms of the lung and thyroid. This antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# CONFIRM anti-Topoisomerase IIa (JS5B4) Rabbit Monoclonal Primary Antibody

**Catalog Number:** 790-4371 **Ordering Code:** 05479339001 Quantity: 50 tests **Controls:** Spleen, Tonsil **Clone Name:** JS5B4 Species: Rabbit Localization: Nuclear **Regulatory Status:** IVD



#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' CONFIRM anti-Topoisomerase IIa (JS5B4) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of topoisomerase IIa expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA BenchMark XT instrument. During the cell cycle, topoisomerase IIa is expressed in the G1, S, G2 and M phase but is absent in the G0 (quiescent) phase.¹ Assessment of the proportion of positive staining cells for topoisomerase IIa may aid in evaluation of the proliferative activity of normal and/or neoplastic tissue.²,3,4 The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

- 1. Kreipe H, Heidebrecht HJ, Hansen S, Röhlk W, Kubbres M, Wacker HH, et al. A new proliferation associated nuclear antigen detectable in paraffin-embedded tissues by monoclonal antibody Ki-S1. AM J. Pathol 1993; 142:3-9.
- 2. Rudolph P, Lappe T, Scubert C, Schmidt D, Parwaresch RM, Christophers E. Diagnostic assessment of two novel proliferation–specific antigens in benign and malignant melanocytic lesions. AM J. Pathol 1995; 147:1615-25.
- 3. Kreipe H, Alm P, Olsson H, Hauberg M, Fisher L, Parwaresch RM. Prognostic significance of a formalin resistance nuclear proliferation antigen in mammary carcinoma as determined by the monoclonal antibody Ki-S1. AM J Pathol 1993; 142:651-657.
- 4. Kellner U, Heidebrecht HJ, Rudolph P, et al. Detection of human Topoisomerase IIa in cell lines and tissue: Characterization of five novel monoclonal antibodies. J of Histochem and Cytochem 1997; 45:251-264.

# **CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody**

 Catalog Number:
 790-4430

 Ordering Code:
 05571219001

 Quantity:
 50 tests

Controls: Kidney, Non-Small Cell Lung Carcinoma,

Gastric Carcinoma

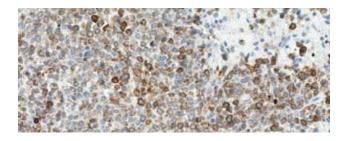
Clone Name: SP44 Species: Rabbit

**Localization:** Cytoplasmic, Membranous

Regulatory Status: IVD

### **INTENDED USE**

Ventana Medical Systems' (Ventana) CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody is directed against a membranous and/or cytoplasmic epitope present in human normal epithelial or tumor cells. This antibody may be used to aid in the identification of normal and neoplastic c-MET expressing cells. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded tissue. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This antibody is intended for in vitro diagnostic (IVD) use.



# TRAcP (9C5) Mouse Monoclonal Primary Antibody

 Catalog Number:
 760-4275

 Ordering Code:
 05269385001

 Quantity:
 50 tests

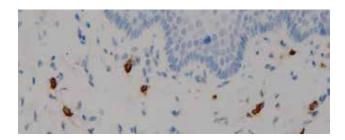
Controls: Hairy Cell Leukemia

 $\begin{tabular}{lll} \textbf{Isotypes:} & & & & & & & & & & \\ \textbf{Clone Name:} & & & & & & & & \\ \textbf{Species:} & & & & & & & & \\ \textbf{Localization:} & & & & & & & \\ \textbf{Cytoplasmic} & & & & & & \\ \hline \end{tabular}$ 

Regulatory Status: IVD

### **INTENDED USE**

TRACP (9C5) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the TRACP glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **Tryptase (G3)**

 Catalog Number:
 760-4276

 Ordering Code:
 05269393001

 Quantity:
 50 tests

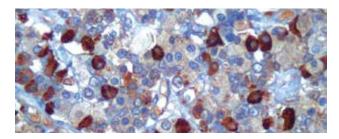
Controls: Mast Cell-Containing Tissue

 $\begin{array}{lll} \textbf{Isotypes:} & & \lg G_1 \\ \textbf{Clone Name:} & & G3 \\ \textbf{Species:} & & Mouse \\ \textbf{Localization:} & & Cytoplasmic \\ \end{array}$ 

Regulatory Status: IVD

#### **INTENDED USE**

Tryptase (G3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of tryptase in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



### **TSH** (polyclonal)

Catalog Number: 760-2709
Ordering Code: 05268184001
Quantity: 50 tests
Controls: Normal Pituitary
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic

Regulatory Status: IVD

### **INTENDED USE**

TSH Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the TSH glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

# **CONFIRM anti-Tyrosinase (T311) Mouse Monoclonal Primary Antibody**

 Catalog Number:
 790-4365

 Ordering Code:
 05479347001

 Quantity:
 50 tests

 Controls:
 Lung, Melanoma

 $\begin{tabular}{lll} \textbf{Isotypes:} & & IgG_{2a}\\ \textbf{Clone Name:} & & T311\\ \textbf{Species:} & & Mouse\\ \textbf{Localization:} & & Cytoplasmic \\ \end{tabular}$ 

Regulatory Status: IVD

### **INTENDED USE**

This antibody is intended for in vitro diagnostic use. Ventana Medical Systems' CONFIRM® anti-Tyrosinase (T311) Mouse Monoclonal Primary Antibody is designed to qualitatively detect the presence of tyrosinase expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. Positive results aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.



Catalog Number:760-4533Ordering Code:06419232001Quantity:50 testsControls:BladderIsotypes:IgG1Clone Name:SP73Species:Rabbit

**Localization:** Membranous, Cytoplasmic

Regulatory Status: IVD

#### **INTENDED USE**

Uroplakin III (SP73) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Uroplakin protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### Villin (CWWB1)

 Catalog Number:
 760-4277

 Ordering Code:
 05269407001

 Quantity:
 50 tests

Controls: Colonic Mucosa, Small Bowel Mucosa

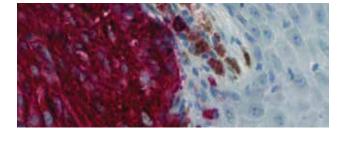
 $\begin{array}{lll} \textbf{Isotypes:} & & \textbf{IgG}_1 \\ \textbf{Clone Name:} & & \textbf{CWWB1} \\ \textbf{Species:} & & \textbf{Mouse} \\ \end{array}$ 

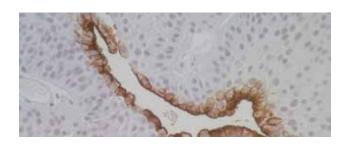
**Localization:** Cytoplasmic, Membranous

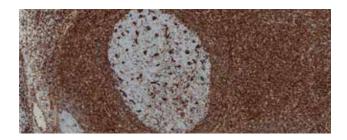
Regulatory Status: IVD

### **INTENDED USE**

Villin (CWWB1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the villin glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.







# **CONFIRM anti-Vimentin (V9) Primary Antibody**

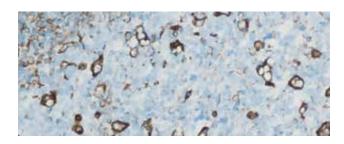
Catalog Number:790-2917Ordering Code:05278139001Quantity:50 tests

Controls: Lymph Node, Skin

Isotypes:IgG/KClone Name:V9Species:MouseLocalization:CytoplasmicRegulatory Status:IVD

#### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Vimentin (V9) Primary Antibody is a mouse monoclonal antibody (IgG1) directed against vimentin. This antibody is intended for use to qualitatively identify vimentin by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



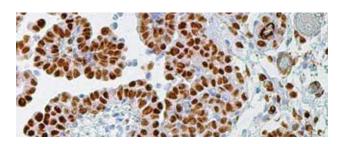
# CONFIRM anti-Vimentin (Vim 3B4) Primary Antibody

Catalog Number: 760-2512 **Ordering Code:** 05266998001 Quantity: 50 tests Controls: Intestine, Liver  $lgG_{2a}$ Isotypes: Vim 3B4 **Clone Name:** Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD

### **INTENDED USE**

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) CONFIRM anti-Vimentin (Vim 3B4) is a mouse monoclonal antibody directed against purified bovine eye lens vimentin and has been known to react specifically with human vimentin. This reagent should be used with a panel of antibodies to aid in the immunohistochemical identification of cells of normal and abnormal mesenchymal lineage as an aid in diagnosis of anaplastic tumors in formalin-fixed, paraffin-embedded tissue. CONFIRM anti-Vimentin (Vim 3B4) binds specifically with the 57kD intermediate filament protein, vimentin. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Prescription only.



### WT1 (6F-H2)

 Catalog Number:
 760-4397

 Ordering Code:
 05435706001

 Quantity:
 50 tests

**Controls:** Kidney, Testicle, Malignant Mesothelioma

### **INTENDED USE**

WT1 (6F-H2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the WT1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

### **ZAP-70 (2F3.2)**

 Catalog Number:
 760-4278

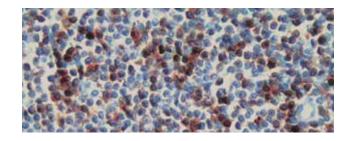
 Ordering Code:
 05269415001

 Quantity:
 50 tests

Controls: Chronic Lymphocytic Leukemia,

Lymph Node, Tonsil

Regulatory Status: IVD



### **INTENDED USE**

ZAP-70 (2F3.2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the ZAP-70 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.



# **OptiView DAB IHC Detection**

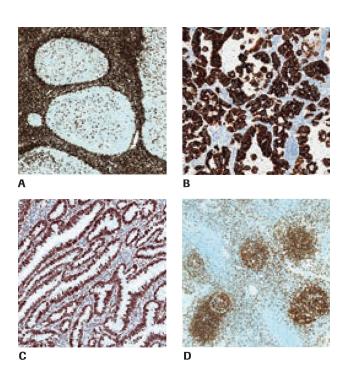
# Innovative detection for enhanced stain quality

Powered by proprietary hapten technology, the dynamic range of VENTANA OptiView DAB IHC detection delivers unparalleled sensitivity and specificity so you can detect antigens across a wide range of expression levels. Virtually eliminating background even as signal intensity increases, OptiView chemistry provides the quality, flexibility and speed you need to deliver results quickly and confidently for enhanced patient care.

- Increase sensitivity: By increasing the numbers of HRP enzymes at each primary antibody site, OptiView chemistry provides unparalleled signal intensity, empowering you to visualize even low-level markers.
- Improve specificity: Our patented synthetic, non-endogenous hapten system eliminates the potential for species-to-species interactions, which frequently cause background.
- Customize intensity: Unique chemistry and flexibility in protocol optimization enable greater control to meet your preferred staining intensity.
- Improve turnaround time: Enhanced sensitivity and software flexibility allow you to reduce turnaround time by 30 minutes or more for most assays, giving you the ability to process more slides in less time and deliver results sooner.

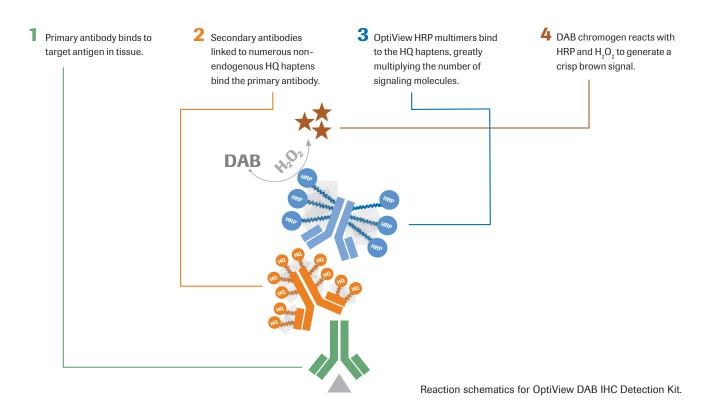
# OptiView detection chemistry: our unique formula for success

Featuring a two-step design and unique synthetic, non-endogenous hapten technology on the secondary antibody, OptiView detection provides excellent background reduction. In addition, it delivers increased sensitivity through a higher number of multimers per primary antibody. The reaction is further enhanced by a proprietary reagent that accelerates DAB color development in the presence of the HRP enzyme.



Selected antibodies stained with OptiView DAB IHC Detection Kit:

- A CONFIRM bcl-2 (124) on tonsil tissue (20x).
- B VENTANA ALK (D5F3) CDx Assay on lung tissue (10X).
- C MSH2 (G219-1129) on colon tissue (20x).
- D CONFIRM PAX5 (SP34) on tonsil tissue (10x).



### **VENTANA** ancillary products for amplification

### **Amplification Kit**

 Catalog Number:
 760-080

 Ordering Code:
 05266114001

 Quantity:
 100 tests

 Regulatory Status:
 IVD

#### **INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) Amplification Kit may be used in conjunction with VENTANA detection kits to increase the signal intensity of weak staining mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue or cytological preparations on VENTANA automated side stainers with VENTANA primary antibodies, detection kits and ancillary reagents. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This product is intended for in vitro diagnostic (IVD) use.

### **OptiView Amplification Kit**

 Catalog Number:
 760-099
 860-099

 Ordering Code:
 06396518001
 06718663001

 Quantity:
 50 tests
 250 tests

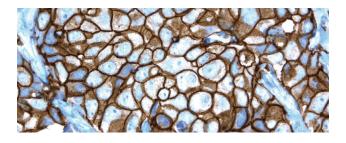
 Regulatory Status:
 IVD
 IVD

#### **INTENDED USE**

OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit (OptiView Detection Kit) to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue, or cytological preparations on VENTANA BenchMark Advanced Staining automated slide stainers with VENTANA primary antibodies and ancillary reagents, visualized by light microscopy. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This product is intended for in vitro diagnostic (IVD) use.

### **iVIEW DAB Detection Kit**

Catalog Number: 760-091
Ordering Code: 05266157001
Quantity: 250 tests
Regulatory Status: IVD

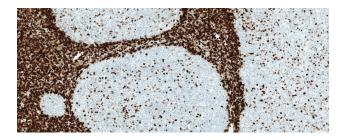


### **INTENDED USE**

Ventana Medical Systems' (Ventana) iVIEW DAB Detection Kit is an indirect biotin streptavidin system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended for laboratory use to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue on BenchMark and BenchMark XT instruments by light microscopy. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **OptiView DAB IHC Detection Kit**

Catalog Number: 760-700
Ordering Code: 06396500001
Quantity: 250 tests
Regulatory Status: IVD



### **INTENDED USE**

OptiView DAB IHC Detection Kit (OptiView) is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue that are stained on the VENTANA automated slide stainers and visualized by light microscopy. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

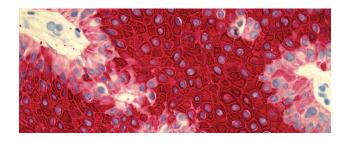
### ultraView Universal Alkaline Phosphatase Red Detection Kit

 Catalog Number:
 760-501

 Ordering Code:
 05269814001

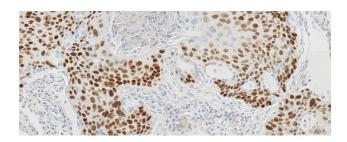
 Quantity:
 250 tests

 Regulatory Status:
 IVD



### **INTENDED USE**

The VENTANA ultraView Universal Alkaline Phosphatase Red Detection Kit (ultraView AP Red detection kit) is an indirect biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies using light microscopy. The kit is intended for laboratory use to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded tissue that are stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### ultraView Universal DAB Detection Kit

Catalog Number: 760-500
Ordering Code: 05269806001
Quantity: 250 tests
Regulatory Status: IVD

### **INTENDED USE**

Ventana Medical Systems' (Ventana) ultraView Universal DAB Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded and frozen tissue that are stained on the BenchMark, BenchMark XT and BenchMark ULTRA instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### ultraView SISH Detection Kit

Catalog Number:780-001Ordering Code:05271967001Quantity:100 testsRegulatory Status:IVD

#### **INTENDED USE**

This detection kit is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana) ultraView SISH Detection Kit is an indirect, biotin-free system for detecting rabbit primary antibodies. The kit is intended to identify targets by in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on the BenchMark Series automated slide stainers. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

### **ISH iVIEW**<sub>Blue</sub> **Plus Detection Kit**

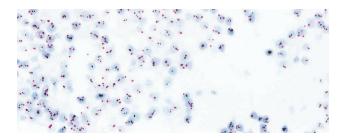
Catalog Number: 760-097
Ordering Code: 05266181001
Quantity: 100 tests
Regulatory Status: IVD

#### **INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) ISH iVIEW<sub>Blue</sub> Plus Detection Kit consists of a primary rabbit anti-DNP antibody followed by an indirect biotin streptavidin system for detecting VENTANA DNP labeled probes and antibodies. This kit is intended for staining sections of routinely fixed (neutral buffered formalin), paraffin-embedded tissue on the BenchMark Series automated slide stainers. Light microscopy is used to detect the staining intensity. Positive results aid in the classification of normal and abnormal cells and tissues and serve as an adjunct to conventional histopathology tests. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This reagent is intended for in vitro diagnostic (IVD) use.

### ultraView Red ISH DIG Detection Kit

Catalog Number: 760-505
Ordering Code: 05587778001
Quantity: 100 tests
Regulatory Status: IVD

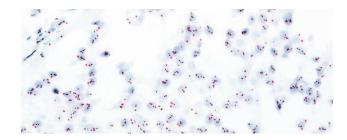


### **INTENDED USE**

Ventana Medical Systems, Inc's (Ventana) ultraView Red ISH DIG Detection Kit is an indirect, biotin-free system for detecting DIG labeled probes. The kit is intended to identify targets by chromogenic red in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on VENTANA BenchMark XT automated slide stainer or VENTANA BenchMark ULTRA automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological examination and evaluation of proper controls. Evaluation must be made by a qualified reader within the context of the patient's clinical history and other diagnostic tests. This detection kit is intended for in vitro diagnostic (IVD) use.

### ultraView SISH DNP Detection Kit

Catalog Number: 760-098
Ordering Code: 05572037001
Quantity: 100 tests
Regulatory Status: IVD



### **INTENDED USE**

Ventana Medical Systems, Inc.'s (Ventana) ultraView SISH DNP Detection Kit is an indirect, biotin-free system for detecting DNP labeled probes. The kit is intended to identify targets by silver in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on VENTANA BenchMark XT automated slide stainer or VENTANA BenchMark ULTRA automated slide stainer instruments. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological examination and evaluation of proper controls. Evaluation must be made by a qualified reader within the context of the patient's clinical history and other diagnostic tests. This detection kit is intended for in vitro diagnostic (IVD) use.

# **SPECIAL STAINING KITS**



# **Dedication**

Committed to providing automated solutions for consistent high-quality stains

# **BenchMark Special Stains staining kits**

# Improve consistency with ready-to-use reagents

The **VENTANA BenchMark Special Stains** system empowers histopathology labs with reproducible, high-quality staining capabilities through ready-to-use, quality-controlled reagents. You can count on consistent staining—run to run, slide to slide, day to day—supporting fast, accurate results. With flexible protocols, you can employ a broad range of options to achieve your desired staining results.

### Quality

 Control quality in your lab with a consistent, automated staining process that reduces the potential for variability.

### **Safety**

 Reduce risk and technicians' exposure to harmful chemicals through ready-to-use staining kits and waste-sensing alarms to protect against spills.

### Workflow

 Improve efficiency and turnaround time with automated slide deparaffinization and independent slide heating, eliminating batching and supporting Lean workflow.





VENTANA Special Stains System Selection Guide	
Special Stains for Mucin	
Alcian Blue for PAS	Light Green for PAS
Alcian Blue Staining Kit	Mucicarmine Staining Kit
Diastase Kit	PAS Staining Kit
<b>Special Stains for Connective Tissue</b>	
Elastic Staining Kit	Trichrome II Blue Staining Kit
Green for Trichrome	Trichrome III Blue Staining Kit
Jones H&E Staining Kit	Trichrome III Green Staining Kit
Jones Light Green Staining Kit	Trichrome Staining Kit
Reticulum II Staining Kit	
Special Stains for Microorganisms	·
AFB III Staining Kit	Gram Staining Kit
Alcian Yellow Staining Kit	Steiner Staining Kit
GMS II Staining Kit	Steiner II Staining Kit
Other Special Stains	
Congo Red Staining Kit	Iron Staining Kit
Giemsa Staining Kit	

For use on the VENTANA BenchMark Special Stains system.

For use on the VENTANA NexES Special Stains system. Instrument no longer available.

### BenchMark Special Stains bulk reagents and ancillary products

For additional information on these products, see page 140.

### Special Stains Wash (10x)

Catalog Number: 860-015
Ordering Code: 05279305001
Quantity: 2 L bottle

### Special Stains Wash Two Part Kit

Catalog Number: 860-040
Ordering Code: 07383568001
Quantity: 1 Kit

### BenchMark Special Stains Wash II

Ordering Code: 08309817001 Quantity: 1 Kit

### BenchMark Special Stains Deparaffinization Solution (10X)

Catalog Number: 860-036
Ordering Code: 06523102001
Quantity: 2 L bottle
Format: Concentrate

### **Special Stains Cleaning Kit**

Catalog Number: 860-016
Ordering Code: 05279313001
Quantity: 50 cleaning cycles

### **Special Stains Clean Plus**

Catalog Number: 860-037
Ordering Code: 06649327001
Quantity: 50 cleaning cycles

### **BenchMark Special Stains Liquid Coverslip**

Catalog Number: 860-034
Ordering Code: 06523072001
Quantity: 2 L bottle
Format: Ready to Use

### Special Stains Rinse (SSR) Solution

Catalog Number: 860-038
Ordering Code: 06890059001
Quantity: 2 L bottle

### **Special Staining Kits for Mucin**

### **Alcian Blue for PAS**

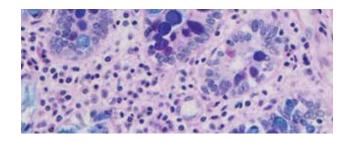
 Catalog Number:
 860-003

 Ordering Code:
 05279194001

 Quantity:
 75 tests

Controls: Colon, Salivary Gland, Small Intestine

For use on the BenchMark Special Stains and NexES Special Stains systems.



### **INTENDED USE**

Alcian Blue for PAS Staining Kit, in conjunction with the PAS Staining Kit (860-014 / 05279291001), is intended for use as a qualitative histologic stain to differentiate acid mucin from neutral polysaccharides in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Alcian Blue Staining Kit**

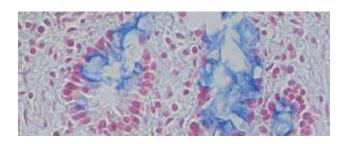
 Catalog Number:
 860-002

 Ordering Code:
 05279186001

 Quantity:
 75 tests

**Controls:** Colon, Small Intestine

For use on the BenchMark Special Stains and NexES Special Stains systems.



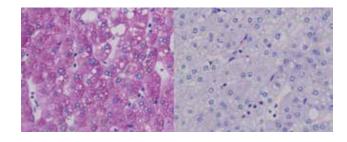
### **INTENDED USE**

Alcian Blue Staining Kit is intended for use as a qualitative histologic stain to demonstrate weakly acidic mucopolysaccharides. At pH 2.5, alcian blue stains sulfated and carboxylated acid mucopolysaccharides and sulfated and carboxylated sialomucins and glycoproteins in formalin-fixed, paraffinembedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Diastase Kit**

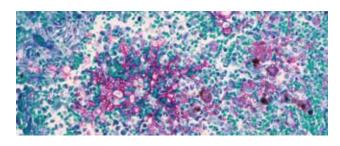
Catalog Number: 860-004
Ordering Code: 05279208001
Quantity: 75 tests
Controls: Liver

For use on the BenchMark Special Stains and NexES Special Stains systems.



### **INTENDED USE**

Diastase Kit, in conjunction with PAS Staining Kit (860-014 / 05279291001), is intended for use as a digestion reagent to aid in the determination of glycogen in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



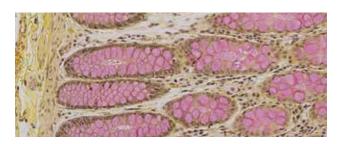
### **Light Green for PAS**

Catalog Number: 860-010
Ordering Code: 05279267001
Quantity: 75 tests
Controls: Liver

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Light Green for PAS used in conjunction with PAS Staining Kit is intended for use as a qualitative histologic stain for detection of fungus in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **Mucicarmine Staining Kit**

 Catalog Number:
 860-011

 Ordering Code:
 05279275001

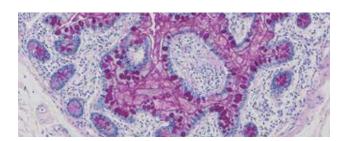
 Quantity:
 75 tests

Controls: Human Tissue with Epithelial Mucin

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Mucicarmine Staining Kit is intended for use as a qualitative histologic stain to detect acid mucopolysaccharides (mucin) in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **PAS Staining Kit**

Catalog Number:860-014Ordering Code:05279291001Quantity:75 tests

Controls: Tissue Known to be Glycogen Rich, such as

Kidney, Small Intestine, Liver, Skin, or Aorta

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

PAS Staining Kit is intended for use as a qualitative histologic stain used to demonstrate the presence of glycogen in formalin-fixed, paraffin-embedded tissue. PAS Staining Kit detects positive reticular fibers, basement membrane, fungus and neutral mucopolysaccharides. PAS Staining Kit may also be used to aid in distinguishing a PAS positive secreting adenocarcinoma from an undifferentiated PAS negative squamous cell carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

<sup>&</sup>lt;sup>1.</sup> Thompson SW. Selected Histochemical and Histopathological Methods. Springfield; CC Thomas; 1966.

<sup>&</sup>lt;sup>2</sup> Sheehan DC, Hrapchak BB. Theory and Practice of Histotechnology. 2nd edition. St. Louis, MO: C.V. Mosby Company; 1980.

### **Special Staining Kits for Connective Tissue**

### **Elastic Staining Kit**

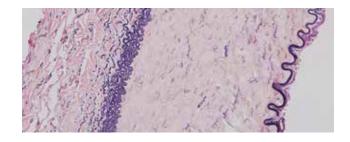
 Catalog Number:
 860-005

 Ordering Code:
 05279216001

 Quantity:
 75 tests

Controls: Kidney, Lung, Skin, Aorta, Artery

For use on the BenchMark Special Stains and NexES Special Stains systems.



### **INTENDED USE**

Elastic Staining Kit is intended for use as a qualitative histologic stain to demonstrate elastic fibers in tissue sections in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Green for Trichrome**

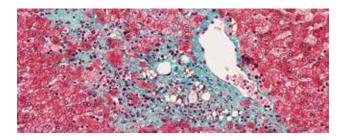
 Catalog Number:
 860-032

 Ordering Code:
 06521916001

 Quantity:
 75 tests

Controls: Colon, Kidney, Liver, Skin

For use on the BenchMark Special Stains system.



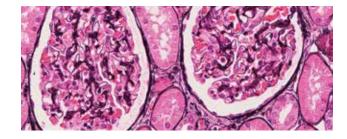
#### **INTENDED USE**

Green for Trichrome with Trichrome Staining Kit (860-031 / 06521908001) is a qualitative histologic stain used to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Jones H&E Staining Kit**

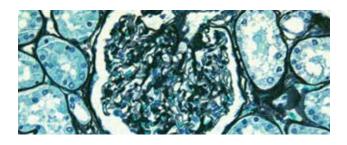
Catalog Number: 860-019
Ordering Code: 05279348001
Quantity: 40 tests
Controls: Kidney

For use on the BenchMark Special Stains and NexES Special Stains systems.



### **INTENDED USE**

Jones Staining Kit is intended for use as a qualitative histologic stain to demonstrate capillary basement membrane in formalin-fixed, paraffinembedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



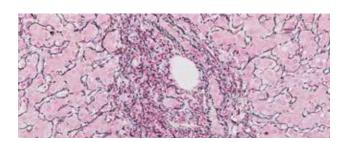
### **Jones Light Green Staining Kit**

Catalog Number: 860-020
Ordering Code: 05279356001
Quantity: 40 tests
Controls: Kidney

For use on the BenchMark Special Stains and NexES Special Stains systems.

#### **INTENDED USE**

Jones Light Green Staining Kit is intended for use as a qualitative histologic stain to demonstrate capillary basement membrane in tissue, such as kidney. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **Reticulum II Staining Kit**

 Catalog Number:
 860-024

 Ordering Code:
 05279399001

 Quantity:
 75 tests

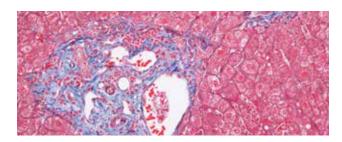
Controls: Tissue with Defined Reticular Fibers

(Liver, Spleen, Kidney, or Lymph Nodes)

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Reticulum II Staining Kit is intended for use as a qualitative histologic stain to demonstrate reticular fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **Trichrome II Blue Staining Kit**

 Catalog Number:
 860-013

 Ordering Code:
 05279283001

 Quantity:
 75 tests

Controls: Colon, Esophagus, Liver, Skin

For use on the NexES Special Stains system.

### **INTENDED USE**

Ventana Medical Systems' (Ventana) Trichrome II Staining Kit is intended as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Trichrome III Blue Staining Kit**

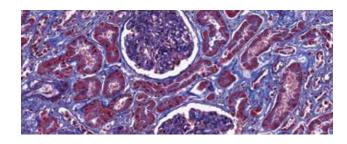
 Catalog Number:
 860-022

 Ordering Code:
 05279364001

 Quantity:
 75 tests

Controls: Colon, Esophagus, Liver, Skin

For use on the NexES Special Stains system.



### **INTENDED USE**

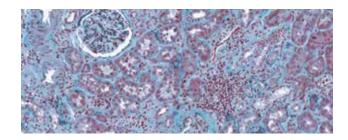
Ventana Medical Systems' (Ventana) Special Stains Trichrome III Blue Staining Kit is intended for in vitro diagnostic use (IVD) as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

### **Trichrome III Green Staining Kit**

Catalog Number:860-023Ordering Code:05279372001Quantity:75 tests

Controls: Colon, Esophagus, Liver, Skin

For use on the NexES Special Stains system.



### **INTENDED USE**

Ventana Medical Systems' (Ventana) Special Stains Trichrome III Green Staining Kit is intended for in vitro diagnostic use (IVD) as a qualitative histologic stain to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

### **Trichrome Staining Kit**

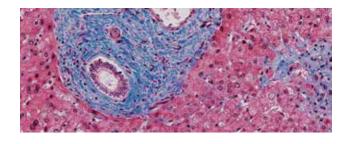
 Catalog Number:
 860-031

 Ordering Code:
 06521908001

 Quantity:
 60 tests

Controls: Colon, Kidney, Liver, Skin

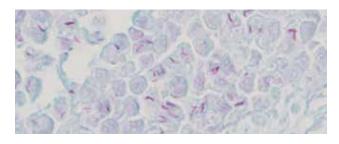
For use on the BenchMark Special Stains system.



### **INTENDED USE**

Trichrome Staining Kit is a qualitative histologic stain used to study connective tissue, muscle and collagen fibers in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Special Staining Kits for Microorganisms**



### **AFB III Staining Kit**

 Catalog Number:
 860-027

 Ordering Code:
 05279437001

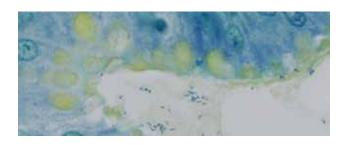
 Quantity:
 75 tests

Controls: Tissue Positive for Acid-Fast Bacteria

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

AFB III Staining Kit is intended for use as a qualitative histologic stain to selectively demonstrate Mycobacterium and other acid fast organisms or components in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **Alcian Yellow Staining Kit**

 Catalog Number:
 860-017

 Ordering Code:
 05279321001

 Quantity:
 75 tests

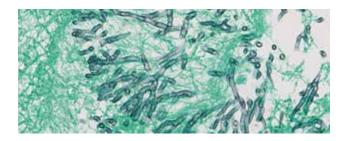
Controls: Tissue Positive for *H. pylori* 

(Stomach, Gastric Ulcer)

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Alcian Yellow Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain for *Helicobacter pylori* in formalin-fixed, paraffinembedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.



### **GMS II Staining Kit**

Catalog Number:860-028Ordering Code:05412749001Quantity:75 tests

Controls: Tissue Positive for Pathogenic Fungus

or Pneumocystis carinii

For use on the BenchMark Special Stains and NexES Special Stains systems.

### INTENDED USE

GMS II Staining Kit is intended for use as a qualitative histologic stain to demonstrate polysaccharides in the cell walls of fungi and other opportunistic organisms in formalin-fixed, paraffin-embedded tissue. This stain is primarily used to distinguish pathogenic fungi such as *Aspergillus* and *Blastomyces*<sup>1</sup> and other opportunistic organisms such as *Pneumocystis carinii* in tissue sections.<sup>2</sup> This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

- 1. Rimondi AP, Bianchini E, Barucchello G, and Panzavolta R. Addison's disease caused by adrenal blastomycosis: A case report with fine needle aspiration (FNA) cytology. Cytopathology. 1995;6:211-219.
- 2. Carson F, Hladik C. Histotechnology: A Self Instructional Text, 3rd edition. Hong Kong: American Society for Clinical Pathology Press; 2009.

### **Gram Staining Kit**

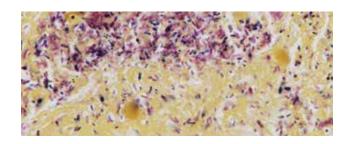
 Catalog Number:
 860-039

 Ordering Code:
 06890105001

 Quantity:
 75 tests

Controls: See Package Insert

For use on the BenchMark Special Stains system.



### **INTENDED USE**

Gram Staining Kit is intended for use as a qualitative histologic stain to demonstrate gram-negative and gram-positive bacteria in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **Steiner Staining Kit**

 Catalog Number:
 860-018

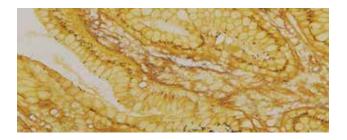
 Ordering Code:
 05279330001

 Quantity:
 40 tests

Controls: Tissue with Helicobacter pylori Organisms

and Gastric Ulcer

For use on the NexES Special Stains system.



### **INTENDED USE**

Ventana Medical Systems' (Ventana) Special Stains Steiner Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic silver stain to aide in the identification of the causative organisms of diseases such as syphilis, some gastric ulcers (*H. pylori*), Lyme disease, Legionnaire's disease, cat scratch fever and others in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

### **Steiner II Staining Kit**

 Catalog Number:
 860-030

 Ordering Code:
 06521894001

 Quantity:
 40 tests

Controls: Tissue Containing H. pylori, Spirochetes, or

L. pneumophila

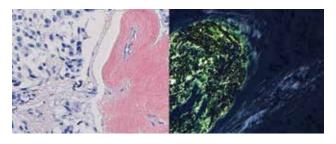
For use on the BenchMark Special Stains system.



#### **INTENDED USE**

Steiner II Staining Kit is intended for in vitro diagnostic (IVD) use. It is a qualitative histologic stain used to study specific argyrophilic microorganisms in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

### **Other Special Staining Kits**



### **Congo Red Staining Kit**

 Catalog Number:
 860-026

 Ordering Code:
 05279429001

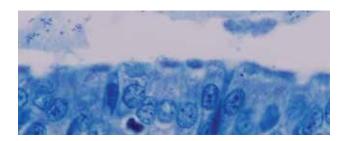
 Quantity:
 40 tests

Controls: Tissue Positive for Amyloid

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Congo Red Staining Kit is intended for use as a qualitative histologic stain to selectively demonstrate amyloid in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.



### **Giemsa Staining Kit**

Catalog Number:860-006Ordering Code:05279224001Quantity:75 tests

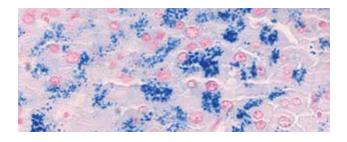
Controls: Bone Marrow, Lymph Node, Spleen

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Giemsa Staining Kit is intended for in vitro diagnostic (IVD) use as a qualitative histologic stain to differentiate leukocytes in bone marrow and other hematopoietic tissue (lymph nodes) in formalin-fixed, paraffin-embedded tissue. The stain can also be used to demonstrate some microorganisms, use has *Helicobacter pylori*. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

1. Bancroft and Stevens. Theory and Practice of Histological Techniques, 2nd edition. Edinburgh: Churchill-Livingston, 1982.



### **Iron Staining Kit**

 Catalog Number:
 860-009

 Ordering Code:
 05279259001

 Quantity:
 75 tests

Controls: Tissue with Intracellular or Extracellular Iron

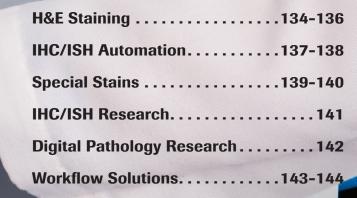
(Liver, Bone Marrow or Spleen)

For use on the BenchMark Special Stains and NexES Special Stains systems.

### **INTENDED USE**

Iron Staining Kit is intended for use as a qualitative histologic stain to detect iron pigment in bone marrow, tissue with hemochromatosis and hemosiderosis in formalin-fixed, paraffin-embedded tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.





# Leadership

Knowledge and experience underscored by the world's largest installed base of IHC/ISH automated staining instruments

# **VENTANA HE 600 system**

# Automated H&E staining

The **VENTANA HE 600 system** fully automates H&E staining, from tissue drying through coverslipping. Featuring individual slide staining and Lean design for intuitive operation, the system provides enhanced quality, workflow and safety that benefits both patients and pathology professionals.

### Quality

Count on accurate, reproducible stains:
 Consistent, high-quality stains provide confidence in patient diagnosis.

### **Workflow**

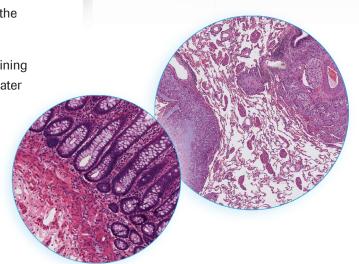
 Improve laboratory workflow: Lean workflow reduces touchpoints and wait points for improved lab efficiency and turnaround time.

### **Safety**

 Increase lab safety: Elimination of xylene and alcohol increases safety for technicians and the environment.

 Improve patient safety: Individual slide staining mitigates cross-contamination, providing greater patient safety.





### **Individual slide staining**

Fresh reagents on every slide produce consistent, high-quality H&E stains for excellent clarity and enhanced visualization of micro-anatomic detail. Discrete staining for every patient slide protects against tissue cross-contamination.

### **Protocol flexibility**

The system supports more than 400 different protocols with customization options for optimizing stain intensity to meet pathologists' preferences.

### Reagent management

All reagents are ready to use, with no mixing or dilution needed, so laboratory staff can focus on more value-added activities. The reagents are recyclable, poke yoke designed, color coded and individually numbered with radio frequency identification (RFID) technology for easy management and error prevention.

### Remote monitoring and technical assistance

The VENTANA HE 600 system is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.



# **VENTANA HE 600 system** ancillary products

### **VENTANA HE 600 Hematoxylin**

Ordering Code: 07024282001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Hematoxylin is a progressive stain used for nuclear staining. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **VENTANA HE 600 Eosin**

Ordering Code: 06544304001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. In the VENTANA HE 600 system, VENTANA HE 600 Eosin provides a counterstain for the hematoxylin-stained cellular nuclei and also allows the non-nuclear tissue components to be clearly differentiated from each other. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

(Continued next page)



### **VENTANA HE 600 system ancillary products (Continued)**

### **VENTANA HE 600 Differentiating Solution**

Ordering Code: 06544339001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Differentiating Solution is a weak acid solution that removes non-specific staining of the hematoxylin from the tissue and the glass slide surface. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **VENTANA HE 600 Bluing**

Ordering Code: 06544347001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Bluing is used in conjunction with VENTANA HE 600 Hematoxylin during tissue staining and when applied to tissue sections will change the hue of hematoxylin from purple to blue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **VENTANA HE 600 Organic Solution**

Ordering Code: 07095163001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Organic Solution is used to deparaffinize tissue prior to staining. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use

#### **VENTANA HE 600 Transfer Fluid**

Ordering Code: 06544380001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Transfer Fluid solubilizes and removes aqueous reagents from the tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

#### **VENTANA HE 600 Wash**

Ordering Code: 06544312001 Quantity: 4 L bottle

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Wash reagent is used as a rinse solution on the VENTANA HE 600 system. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### VENTANA HE 600 Cleaning Agent

Ordering Code: 08120277001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Cleaning Agent is an onboard cleaning solution designed to quickly and effectively dissolve hematoxylin precipitate within the hematoxylin fluid lines and minimize the buildup of hematoxylin precipitate within the waste reservoir of the VENTANA HE 600 System. This product is intended for in vitro diagnostic (IVD) use.

### **VENTANA HE 600 Coverslip Activator**

Ordering Code: 07534396001 Quantity: (2) 120 mL Bottles

INTENDED USE: VENTANA HE 600 solutions are intended for use as a qualitative histologic stain to demonstrate nuclear and cytoplasmic staining of fixed tissue components in paraffin-embedded tissue. VENTANA HE 600 Coverslip Activator is a Limonene solution that activates the glue layer on the coverslip allowing it to adhere to the underlying slide and tissue. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

### **VENTANA HE 600 Glass Coverslips**

Ordering Code: 06711138001 Quantity: 12 cassettes per box. Each cassette contains 170 pre-glued glass coverslips

INTENDED USE: Ventana Medical Systems' (Ventana) VENTANA HE 600 Glass Coverslips are intended for use on the VENTANA HE 600 system. The VENTANA HE 600 Glass Coverslips are applied to glass microscope slides following automated staining and dehydration processes to provide optical clarity and archivability of the stained section. This product is intended for in vitro diagnostic (IVD) use.

# BenchMark ULTRA system

# True continuous access IHC/ISH slide staining

Offering unprecedented workflow efficiency, the **VENTANA BenchMark ULTRA** system enables your lab to process samples as they arrive and easily manage urgent requests. The fully integrated staining solution delivers medical value through continuous and random processing of patient samples.

- Maximize capacity: Individual slide drawers enable single piece flow to limit wasted slide positions.
- Optimize efficiency: Single piece workflow allows for protocol flexibility and continuous access to each slide without sacrificing stain quality.
- Improve processing time: Continuous flow decreases preparation time required for slide sorting and matching of reagent.
- Quickly respond to test requests: Ultimate Reagent Access (URA) allows immediate processing of urgent and late-arriving samples.
- Increase workflow flexibility: With 30 individual slide drawers and 35 reagent positions, the instrument enables you to add or remove slides and reagents at any time.





IHC, ISH, SISH, Dual Stain and FITC slides can be processed simultaneously, improving turnaround times. The fully automated workflow enables processing of 90 slides in 8 hours, or 120 slides with an overnight run.

### Remote monitoring and technical assistance

The BenchMark ULTRA system is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.



### **BenchMark ULTRA bulk reagents**

### EZ Prep (10x)

Catalog Number: 950-102 Quantity: 2 L bottle
Ordering Code: 05279771001 Format: Concentrate

INTENDED USE: Ventana Medical Systems' (Ventana) EZ Prep Concentrate (10X) solution (EZ Prep) is used for paraffin removal from tissue samples during immunohistochemistry and in situ hybridization reactions, and to dilute 2X SSC during stringency washes during in situ hybridization reactions carried out on VENTANA automated slide stainers. This product is designed for use on BenchMark Series automated slide stainers. This reagent is intended for in vitro diagnostic (IVD) use.

### Reaction Buffer (10x)

Catalog Number: 950-300 Quantity: 2 L bottle
Ordering Code: 05353955001 Format: Concentrate

INTENDED USE: This reagent is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) Reaction Buffer Concentrate (10X) is a Tris based buffer solution (pH 7.6  $\pm$  0.2) used to rinse slides between staining steps and provide a stable aqueous environment for the immunohistochemistry (IHC) or in situ hybridization (ISH) reactions carried out on BenchMark® and BenchMark XT automated slide staining systems.

### **ULTRA Cell Conditioning (ULTRA CC1)**

Catalog Number: 950-224 Quantity: 2 L bottle
Ordering Code: 05424569001 Format: Ready to Use

INTENDED USE: ULTRA Cell Conditioning Solution (ULTRA CC1) from Ventana Medical Systems, Inc. (Ventana) is a prediluted solution used as a pretreatment step in the processing of tissue samples for immunohistochemistry (IHC) reactions carried out on the VENTANA BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

### **ULTRA Cell Conditioning (ULTRA CC2)**

Catalog Number: 950-223 Quantity: 1 L bottle
Ordering Code: 05424542001 Format: Ready to Use

INTENDED USE: ULTRA Cell Conditioning Solution (ULTRA CC2) from Ventana Medical Systems, Inc. (Ventana) is a prediluted solution used as a pretreatment step in the processing of tissue samples during immunohistochemistry (IHC) and in situ hybridization (ISH) on the VENTANA BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

### **ULTRA LCS (Predilute)**

Catalog Number: 650-210 Quantity: 2 L bottle
Ordering Code: 05424534001 Format: Ready to Use

INTENDED USE: ULTRA LCS (Predilute) from Ventana Medical Systems, Inc. (Ventana), also known as ULTRA LCS or ULTRA Liquid Coverslip (High Temperature), is a prediluted coverslip solution used as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry or in situ hybridization reactions carried out on the VENTANA BenchMark ULTRA instrument. This product is designed for use on the VENTANA BenchMark ULTRA instrument. This reagent is not to be used on the VENTANA NexES IHC, NexES Special Stains or ES Automated Slide Stainers. This reagent is intended for in vitro diagnostic (IVD) use.

### SSC (10X)

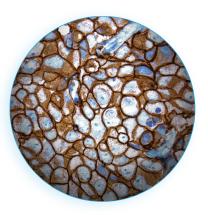
Catalog Number: 950-110 Quantity: 2 L bottle
Ordering Code: 05353947001 Format: Concentrate

INTENDED USE: This reagent is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana\*) 10X SSC, Sodium Chloride Sodium Citrate buffer solution is used for stringency washes and to rinse slides between staining steps and provide a stable aqueous environment for the in situ hybridization reactions carried out on a VENTANA automated slide stainer.

### ultraView™ Silver Wash II

Catalog Number: 780-003 Quantity: 2 L bottle
Ordering Code: 05446724001 Format: Concentrate

INTENDED USE: This reagent is intended for in vitro diagnostic use. Ventana Medical Systems' (Ventana) ultraView™ Silver Wash II solution is used to rinse slides between staining steps and provide a stable aqueous environment for the in situ hybridization chromogen reaction carried out on a VENTANA automated slide stainer when using the ultraView™ SISH Detection Kit.



THE VENTANA

# **BenchMark Special Stains system**

# Automated baking through staining

Building on the industry-leading BenchMark system technology, the **VENTANA BenchMark Special Stains** instrument brings complete baking through staining to the histology laboratory for special stains, so your lab can consistently deliver exceptional quality.

### Quality

Deliver reliable, high-quality stains:
 Ready-to-use, quality-controlled reagents provide consistent staining quality.

### **Safety**

- Improve lab safety: Reduced exposure to harmful chemicals decreases risk to technicians.
- Safeguard patients: Individual slide staining helps protect patient samples.

### Workflow

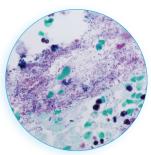
- Achieve superior workflow efficiency:
   Manual processes and temperature dependencies
   are eliminated through automated deparaffinization
   and independent slide heating.
- Expand your lab's capabilities: Reducing manual processes frees laboratory professionals for highvalue activities.
- Improve efficiencies: Automated baking through staining, random batch access, and bulk and waste fluid sensing improve turnaround time and optimize workflow.
- Expand capacity: The BenchMark Special Stains system features 20 slide positions, each with independent temperature control, and a reagent carousel with 25 positions.
- Simplify operation: The intuitive VENTANA System Software interface, used with all BenchMark systems, simplifies operation and enables connection to a BenchMark ULTRA instrument.



### Remote monitoring and technical assistance

The BenchMark Special Stains automated slide stainer is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.



### BenchMark Special Stains bulk reagents and ancillary products

#### Special Stains Wash (10x)

Catalog Number: 860-015 Quantity: 2 L bottle

Ordering Code: 05279305001

INTENDED USE: Ventana Medical Systems' (Ventana) Special Stains (10X) Wash is used in conjunction with VENTANA Special Stains reagent kits. When diluted according to instructions, Special Stains (10X) Wash is an optimized solution used for all VENTANA Special Stains reagent kits. This reagent provides a stable aqueous environment for special histological staining reactions performed on the NexES Special Stains automated slide stainer. This product is intended for in vitro diagnostic (IVD) use.

### **Special Stains Wash Two Part Kit**

Catalog Number: 860-040 Quantity: 1 Kit

Ordering Code: 07383568001

INTENDED USE: Special Stains Wash Two Part Kit is used on the VENTANA BenchMark Special Stains automated slide stainer and VENTANA NexES Special Stains automated slide stainer. When diluted according to instructions, Special Stains Wash Two Part Kit produces an optimized solution for use with the VENTANA special stains reagent kits. This solution provides a stable aqueous environment for special histological staining reactions. This product is intended for in vitro diagnostic (IVD) use.

### BenchMark Special Stains Wash II

Ordering Code: 08309817001 Quantity: 1 Kit



INTENDED USE: BenchMark Special Stains Wash II is used on the VENTANA BenchMark Special Stains automated slide stainer. When diluted according to instructions, BenchMark Special Stains Wash II produces an optimized solution for use with the VENTANA special stains reagent kits. This solution provides a stable aqueous environment for special histological staining reactions. This product is intended for in vitro diagnostic (IVD) use.

### BenchMark Special Stains Deparaffinization Solution (10X)

Catalog Number: 860-036 Quantity: 2 L bottle
Ordering Code: 06523102001 Format: Concentrate

INTENDED USE: Ventana Medical Systems, Inc.'s (Ventana) BenchMark Special Stains Deparaffinization Solution (10X) is used for paraffin removal from tissue samples during special stains reactions carried out on the VENTANA BenchMark Special Stains automated slide stainer. This reagent is intended for in vitro diagnostic (IVD) use.

### **Special Stains Cleaning Kit**

Catalog Number: 860-016 Quantity: 50 cleaning cycles

Ordering Code: 05279313001

INTENDED USE: VENTANA Special Stains Cleaning Kit is intended for use during the automated cleaning procedure on the VENTANA BenchMark Special Stains automated slide stainer and the VENTANA NexES Special Stains automated slide stainer. This kit is intended for in vitro diagnostic use.

#### **Special Stains Clean Plus**

Catalog Number: 860-037 Quantity: 50 cleaning cycles

Ordering Code: 06649327001

INTENDED USE: VENTANA Special Stains Clean Plus is used in conjunction with the VENTANA Special Stains Cleaning Kit (860-016 / 05279313001) and is intended for use during the automated cleaning procedure on the VENTANA BenchMark Special Stains automated slide stainer. This kit is intended for in vitro diagnostic (IVD) use.

### **BenchMark Special Stains Liquid Coverslip**

Catalog Number: 860-034 Quantity: 2 L bottle
Ordering Code: 06523072001 Format: Ready to Use

INTENDED USE: Ventana Medical Systems, Inc.'s (Ventana) BenchMark Special Stains Liquid Coverslip is a prediluted coverslip solution used as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the special stains reactions carried out on a VENTANA BenchMark Special Stains automated slide stainer. BenchMark Special Stains Liquid Coverslip may also be used as a deparaffinization agent in cases where microorganisms or cellular structures are not compatible with the BenchMark Special Stains Deparaffinization Solution. In these cases, BenchMark Special Stains Liquid Coverslip will be automatically applied by the BenchMark Special Stains automated slide stainer. This product is designed for use on the BenchMark Special Stains automated slide stainer. This reagent is not to be used on the VENTANA BenchMark, BenchMark GX, BenchMark XT or BenchMark ULTRA instruments or NexES Special Stains automated slide stainers. This reagent is intended for in vitro diagnostic (IVD) use.

### Special Stains Rinse (SSR) Solution

Catalog Number: 860-038 Quantity: 2 L bottle

Ordering Code: 06890059001

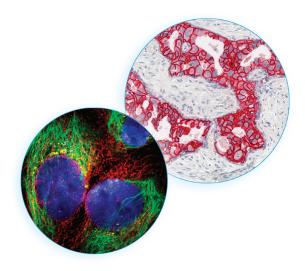
INTENDED USE: SSR Solution is used on the VENTANA BenchMark Special Stains automated slide stainer. The SSR Solution is optimized to be used in conjunction with specific VENTANA special stains protocols on the VENTANA BenchMark Special Stains automated slide stainer. This product is intended for in vitro diagnostic (IVD) use.

## **DISCOVERY ULTRA system**

## The flexibility of manual, the freedom of automation

Offering our highest level of protocol flexibility for assay development, the **VENTANA DISCOVERY ULTRA system** enables your lab to fully automate a wide variety of IHC and ISH assays with the freedom to shape the platform to your project requirements.

- Save valuable development time: Fully automated baking through staining and ready-to-use reagents minimize manual steps.
- Improve workflow efficiency: True random access enables addition and removal of reagents to support multiple assay types and users.
- Achieve clear, sensitive detection: Innovative reagents, five color options and enhanced immunofluorescence capabilities enable reproducible, high-quality IHC and ISH stains.
- Accelerate assay development: Open software, protocol flexibility and reagent choice streamline optimization of automated high-complexity assays.





DISCOVERY products are for research use only. Not for use in diagnostic procedures.

### **Throughput flexibility**

With 30 independent reaction chambers, the DISCOVERY ULTRA system enables you to run both manual and fully automated experiments simultaneously with no synchronization errors. The system provides the ability to fully automate a broad range of IHC and ISH assays, including FISH, gene and protein IHC/ISH, mRNA ISH and multiplex assays (with any combination of IHC and ISH).

For additional information, visit go.roche.com/DISCOVERYULTRA

### **VENTANA DP 200 Slide Scanner**

## Robust, reliable, high-speed scanning for research

The **VENTANA DP 200 slide scanner** provides high-quality, high-resolution images to advance pathology research. With high-speed brightfield scanning and a unique tray-based design, the scanner offers ease of use and reliability for a variety of research applications.

- Optimize workflow: High-speed scanning (<49 s at 20x), auto start upon tray load, and a user-friendly interface improve productivity and time to results.
- Improve reliability: No-touch slide processing eliminates slide-handling errors, and automatic diagnostic tests and calibrations ensure consistent image quality.
- Produce high-quality images: Auto white balance calibrations, dynamic focus, and color management ensure high-resolution imaging.





For research use only. Not for use in diagnostic procedures.

### **Research applications**

- Immediate file sharing for earlier collaboration
- Remote-site scanning
- Quantification for IHC markers
- Analysis of tissue microarrays

### Remote monitoring and technical assistance

The VENTANA DP 200 slide scanner is equipped with CareGiver automated remote monitoring technology to help maximize uptime and minimize interruptions. This service includes remote software updates, system calibration and training, and provides system information to Roche service experts to expedite troubleshooting.

For ordering information, contact your Roche representative.

### **VANTAGE Workflow Solution**

## See your lab for the first time

The **VENTANA VANTAGE** workflow solution helps protect patients from the serious risks associated with sample misidentification. Finally, labs can enjoy complete chain of custody, Lean integrated processes, and full visibility into lab operations any time, from anywhere.

- Fully track lab operations: Our comprehensive solution for histology labs—hardware, software and workflow consulting—offers a commanding view of your complex operation from a single strategic perspective.
- Improve patient safety: Implemented in over 400 labs worldwide, the VANTAGE workflow solution maintains positive sample ID with barcode scanners at each workstation and single piece flow workflow.
- Increase efficiency: The VANTAGE workflow solution is designed using Lean Six Sigma principles and includes expert workflow consulting to help you obtain immediate and ongoing workflow benefits.
- Optimize lab performance: VANTAGE business intelligence tools enable you to assess workload, monitor trends, identify problem areas, and more providing greater visibility into your lab to improve workflow.

<b>VANTAGE</b> workflow solution	Ordering Code
VANTAGE HP ProLiant DL380 Gen9 Server	07570520001
VANTAGE Scanner	07171650001
VANTAGE Printer	06543863001
VANTAGE Slide Barcode Label	05524997001
VANTAGE Overlay Dispenser	05909490001
VANTAGE Clear Overlay (3750/roll)	05525276001
VANTAGE All In One Touchscreen PC	08231869001
VANTAGE HoneyWell 3320 Compact Scanner	08356246001
VANTAGE All In One Replacement Screen Cover, 10 Pack	08231885001



### **VENTANA Connect Middleware Solution**

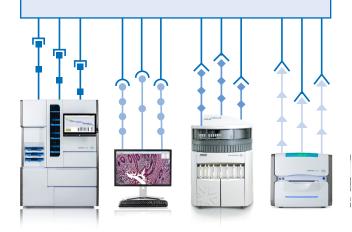
## Streamlining lab connectivity

**VENTANA Connect middleware solution** provides an efficient point of connection from Laboratory Information Systems (LIS) to VENTANA systems and software, automatically exchanging critical case information and eliminating test request re-entries that can introduce errors and slow you down.

- Optimize lab efficiency: Single, flexible interface connects multiple LIS platforms to current and future VENTANA instruments.
- Reduce errors: Important case information flows seamlessly to instruments and systems through a single, secure connection.
- Improve patient safety: VENTANA instruments and software accept LIS-originated case identifiers, increasing patient safety by using a single unique identifier at every point in the process.

# **VENTANA Connect middleware solution** at a glance

- Supports uni- and bi-directional communications from LIS
- Eliminates the need for data re-entry through use of LIS-originated case identifiers, accepted by VENTANA instruments and software
- Uses a unique identifier everywhere in the process, saving time and reducing errors
- Manages highly configurable, easy mapping of LIS data to VENTANA instruments
- Provides integration to digital pathology systems and images
- Delivers enterprise-class software for maximum scalability and reliability





## **Roche Strategic Workflow Consulting**

## Expert support to optimize workflow

Highly trained in Lean Six Sigma principles, our workflow consultants will work with you to help make your lab processes easier, faster, safer and more reliable. Working closely with your team, we'll identify and address opportunities to optimize your workflow, maximize results and lower your costs.

- Optimize workflow: Standardized processes improve performance, throughput and turnaround times.
- Improve patient safety: Improved patient sample identification helps reduce errors and decrease risk.
- Increase efficiency: Simplifying workflow and eliminating non-value-added activities reduce costs and improve productivity.
- Enhance patient care: Streamlined processes help you deliver results faster, for earlier treatment decisions.

Optimize your lab's performance from the moment you receive a sample to the time you deliver a patient's results.





# **Roche Diagnostics** *University*

# Empowering continuous learning

To help your lab achieve the greatest benefit from our products, Roche Commercial Education is committed to providing an engaging training experience with a range of resources focused on continuous learning and enhancing overall job proficiency.

Designed to prepare your lab for success, **Roche Diagnostics University** (RDU) is a one-stop online registration and learning platform supporting the right training, for the right role, at the right time.

- Experience interactive learning: Courses consist
  of an optimal mix of on-demand product and disease
  state e-Learning content, and Indianapolis-based
  classroom, hands-on experience.
- Learn from experts: Training is conducted by highly qualified histology instructors with professional certification, field or technical support expertise.
- Gain proficiency: Spanning the histology workflow process, RDU courses are designed to help you gain expertise with Roche instrumentation, including daily operation, maintenance and troubleshooting, through interactive participation.
- Easily access training documentation:
   Administrative dashboards provide easy access to training documentation, training history and program reports.





### **Getting started**

Ask your Roche representative for instructions on creating a Roche Diagnostics University account and for additional training details.

## **Roche Support Network (RSN)**

## Always on, always ready to help

At Roche, support is not an afterthought—it's our promise and our passion. Backed by a variety of highly experienced, specialized teams, the **Roche Support**Network provides a host of solutions to assist you at every stage—from procurement to ongoing onsite and offsite support.



- Get personalized support: We work with you to build a foundation for success, assessing your needs and objectives to provide customized solutions based on your lab's data and workflow, onsite observations and Lean Six Sigma techniques.
- Ease implementation: We're with you every step of the way to ensure a smooth and efficient transition to your new Roche solution, supporting you from discovery to optimization—and in all aspects after your system is installed and live.
- Optimize lab performance: To ensure your success, we partner with you and provide ongoing support that includes remote monitoring, field service and technical applications expertise, consulting and a 24/7/365 call center.

### Committed to your success throughout the implementation journey



## **CareGiver Remote Support**

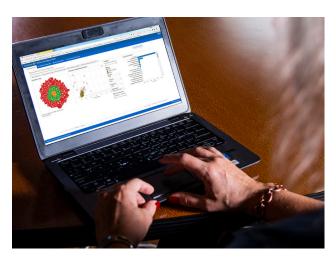
## The help you need, when you need it

Because we understand the critical nature of the work you do for patients, Roche offers **CareGiver remote support**—an innovative automated support solution for anatomic pathology labs. Through a secure internet connection, the CareGiver system provides continuous monitoring and remote service of VENTANA instruments,\* helping maximize performance to keep your lab running smoothly.

- Increase up time: Remote monitoring and support help to maintain optimum instrument performance and reduce downtime.
- Save time: System software updates are delivered automatically over a secure internet connection.
- Meet deadlines with confidence: Real-time remote monitoring helps keep your lab hardware and software operating reliably.







\*CareGiver remote support is currently available for the VENTANA
HE 600 system, VENTANA BenchMark ULTRA IHC/ISH system,
VENTANA BenchMark Special Stains platform, VENTANA Virtuoso
software, VENTANA iScan Coreo slide scanner, the VENTANA iScan
HT slide scanner, and the VENTANA DP 200 slide scanner.

### Reimbursement

## Tough questions. One easy answer.

Reimbursement for the assays and services you provide can seem confusing. The Roche Diagnostics reimbursement team can help. Our team is a reliable and credible resource you can turn to for the latest information to address reimbursement questions and issues regarding Roche Diagnostics products.

- Get the answers you need: The Roche
   Diagnostics reimbursement team can help you
   address reimbursement questions about FDA cleared or approved products marketed and sold
   in the U.S. by Roche Diagnostics Corporation
   and its affiliates.
- Save time: Our team monitors reimbursement trends and policies to keep track of the latest developments that might affect your business or have an impact on Roche Diagnostics products, so you can turn to us for answers and free up your time for more important activities.
- Count on 24/7 support: We're available by email around the clock, enabling you to contact our team for assistance at your convenience.



# Reimbursement is complex. Contacting us is easy.

If you are a healthcare professional working in a hospital, laboratory, physician office or other professional setting, you can contact our team for assistance at your convenience 24 hours a day, 7 days a week.

Please provide your name, the name of your organization and your contact information, and a brief description of your inquiry at this address:

### **Reimbursement Inquiry Email**

diagnostics.reimbursement@roche.com



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