

Roche Pathology Lab

Empowering anatomic pathology labs to deliver accurate, timely results focused on improving patient care

Product Catalog 2024

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Roche Pathology Lab

Founded by a pathologist, with a focus on innovations that change the practice of medicine

Roche Diagnostics

Innovating diagnostics, shaping healthcare, changing lives

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

Hospital

Doctor's Office

Patient Homes

Diabetes Care

Sequencing Solutions

Molecular Diagnostics

Tissue Diagnostics

Centralized Solutions

Point of Care Solutions

Roche Pathology Lab

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.

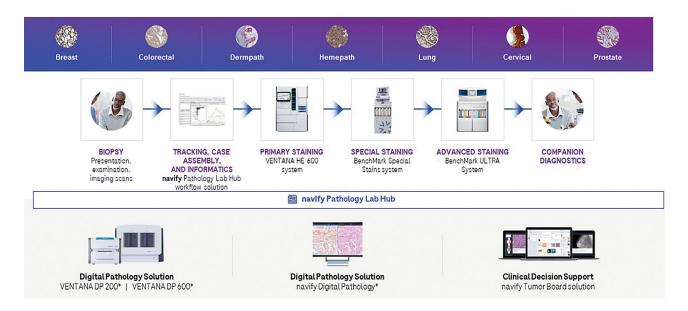
Empowering your lab from sample accessioning through case sign-out

Our broad portfolio includes VENTANA integrated staining and workflow management platforms, research use only (RUO) digital pathology solutions and a robust menu of analytical and predictive assays that help labs increase efficiency 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.



For Research Use Only. Not for use in diagnostic procedures.

Roche Pathology Lab

Partnering with healthcare professionals to improve patient's lives







INNOVATIVE PORTFOLIO of high-quality products that:

- Help healthcare professionals deliver personalized healthcare that improves patients' lives
- Comprise the industry's largest menu of unique, medical-value assays to diagnose more disease states
- Leverage extensive research and pharmaceutical collaborations

DIAGNOSTIC CONFIDENCE gained from:

- Industry-leading quality and fully automated efficiency
- Unparalleled service and support, when and where you need it
- Proactive, comprehensive education

IMPROVED PATIENT CARE resulting from:

- Precision diagnoses that drive more effective treatments
- Faster, safer tissue-based diagnosis resulting from standardized, automated assays
- Broad menu of key biomarkers to help inform personalized healthcare

Newest Additions

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.

BenchMark ULTRA PLUS

Experience the power of PLUS

Ordering Code: 09576797001

See complete product details on page 155.

The new BenchMark ULTRA PLUS system continues the evolution of the BenchMark series, which revolutionized cancer diagnostics by fully automating processes that used to be performed manually, one slide at a time.

Lab personnel will be able to manage their activities more efficiently as a result of simplified software and streamlined productivity and quality control. These enhancements can help support the quicker delivery of test results for patients who are waiting for a diagnosis.

The new system has several innovations such as new intuitive software, remote monitoring features, an integrated touch-screen for a more optimized user experience, and a more environmentally sustainable waste system and product packaging.

Learn more at go.roche.com/UltraPLUS



VENTANA DP 600 Slide Scanner RUO

Ordering Code: 09311378001

See complete product details on page 162.

The VENTANA DP 600 Slide Scanner RUO is a significant addition to the Roche Digital Pathology portfolio as it will enable pathology laboratories to perform high-volume and high-quality scanning necessary for full digitization of their pathology workflow. The VENTANA DP 600 Slide Scanner RUO allows continuous loading of up to 40 trays or 240 slides.

VENTANA slide scanners offer the peace of mind of a reliable scan, from efficient tray loading to the final high-quality whole slide image.

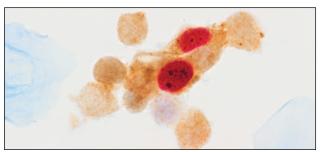
For Research Use Only. Not for use in diagnostic procedures.



Featured Assays

Introducing the latest additions to our portfolio of over 200 ready-to-use assays that empower your lab to deliver timely results with clinical confidence. See our full menu at diagnostics.roche.com

CINtec® PLUS Cytology

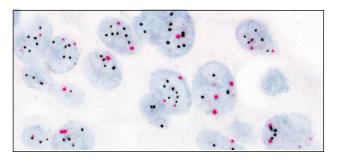


The newest member of the Roche Cervical Cancer portfolio of products, CINtec® PLUS Cytology is an objective biomarker-based triage test designed to identify the co-expression of p16 and Ki-67 within the same cell, helping to identify women with transforming HPV infections likely to lead to cancer.

Learn more at go.roche.com/cervicalsolutions

Pack Size	Ordering Code	Catalog Number
100 tests	07478496001	760-100

VENTANA HER2 Dual ISH DNA Probe Cocktail

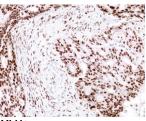


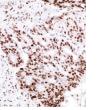
VENTANA HER2 Dual ISH Probe Cocktail assay is the next generation of the INFORM HER2 Dual ISH assay. Based on input from customers, this enhanced assay provides the same proven, fully automated brightfield technology, now optimized with oligo probes that produce faster hybridization and turnaround times, delivering high reproducibility and decreased speckling. The VENTANA HER2 Dual ISH assay is used for determining HER2 gene amplification and helps identify breast cancer patients eligible for treatment with HERCEPTIN® (trastuzumab).

Learn more at go.roche.com/H2DI

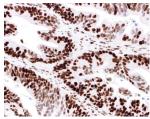
Pack Size	Ordering Code	Catalog Number
30 tests	08314365001	760-6072

VENTANA MMR RxDx Panel









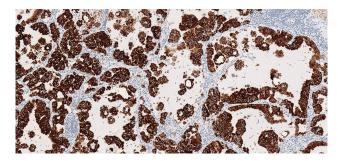
MSH₂

VENTANA MMR RxDx Panel is the latest companion diagnostic assay to the Roche portfolio. This qualitative immunohistochemistry (IHC) test is intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in solid tumors including endometrial carcinoma (EC) and is indicated as an aid in identifying patients eligible for treatment with JEMPERLI (dostarlimab-gxly) or KEYTRUDA (pembrolizumab) or endometrial carcinoma (EC) patients eligible for treatment with KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib) in accordance with approved product labeling.

Learn more at go.roche.com/MMRRxDxPanel

	Pack Size	Ordering Code	Cat. Nr.
MLH1 (M1)	50 tests	07862237001	790-5091
PMS2 (A16-4)	50 tests	07862261001	790-5094
MSH2 (G219-1129)	50 tests	07862253001	790-5093
MSH6 (G219-1129)	50 tests	07862245001	790-5092

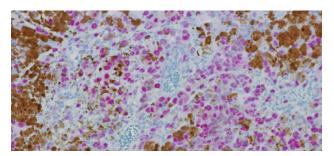
VENTANA ALK (D5F3) CDx Assay



VENTANA ALK (D5F3) CDx Assay is an IHC test for the detection of the anaplastic lymphoma kinease (ALK) protein in non-small cell lung carcinoma (NSCLC) tissue. This assay received FDA approval as an aid in identifying patients eligible for treatment with LOBRENA® (lorlatinib) in addition to its already approved indications as an aid in identifying patients eligible for XALKORI® (crizotinib), ZYKADIA® (ceritinib) and ALECENSA® (alectinib).

Pack Size	Ordering Code	Catalog Number
50 tests	06687199001	790-4796

Anti-PRAME (EPR20330) Rabbit Monoclonal Primary Antibody

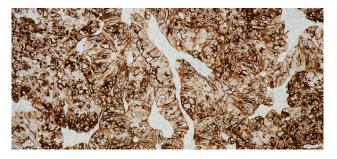


Anti-PRAME (EPR20330) Rabbit Monoclonal Primary

Antibody is intended for laboratory use in the qualitative immunohistochemical detection of PRAME by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. The detection of PRAME by IHC with anti-PRAME (EPR20330) antibody may be used as an aid to differentiate between benign and malignant melanocytic neoplasms, complementing findings from routinely used H&E and ancillary IHC panels.

Pack Size	Ordering Code	Catalog Number
50 tests	09592237001	790-7149
250 tests	09592245001	790-7150

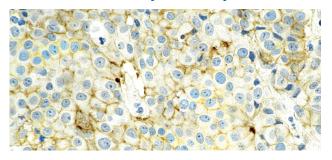
VENTANA FOLR1 (FOLR1-2.1) RxDx Assay



VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens by light microscopy.

Pack Size	Ordering Code	Catalog Number
50 tests	07727917001	740-5065

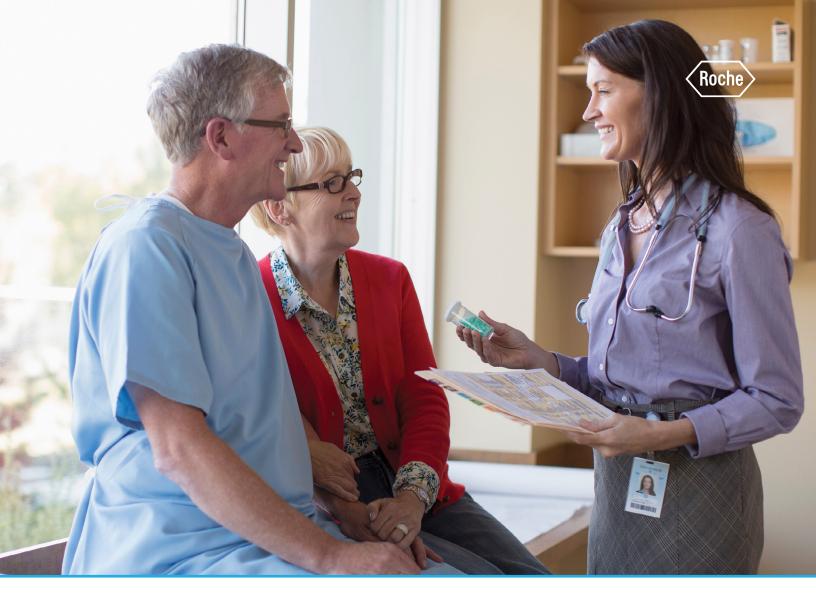
PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody



PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY anti-HER2 (4B5) antibody)

is a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded normal and neoplastic breast tissue using the *ultra*View Universal DAB Detection Kit on a BenchMark ULTRA instrument.

Pack Size	Ordering Code	Catalog Number
50 tests	05278368001	790-2991

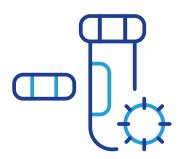


Medical Value

Pioneering solutions that drive personalized healthcare

Personalized Healthcare: Companion Diagnostics

Because your assay choice matters

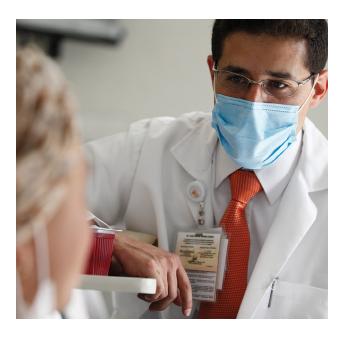


A call to personalize the practice of medicine

"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.

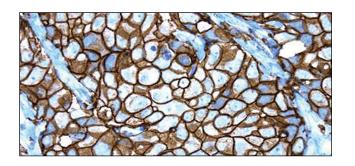
"Targeted diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers."

Severin Schwan,CEO, Roche

VENTANA Companion Diagnostics

Selective and predictive assays essential for personalized healthcare

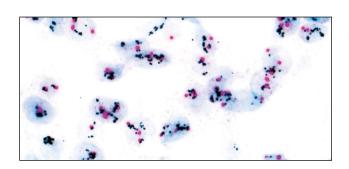
VENTANA companion diagnostics are fully automated to help improve quality and standardize testing, and can easily fit into your current workflow.



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

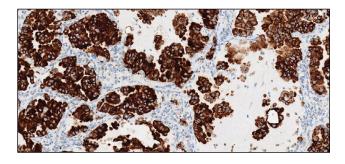
The most widely adopted HER2-IHC primary antibody, this FDA-approved assay consistently achieves high proficiency assessment scores compared to other clones.* This assay aids in the assessment for identifying breast cancer patients who are eligible for treatment with Herceptin® (IHC 3+ or IHC 2+/ISH amplified), KADCYLA® (IHC 3+ or IHC 2+/ISH amplified) or ENHERTU® (IHC 1+ or IHC 2+/ISH non-amplified).

For more information, see page 70.



VENTANA HER2 Dual ISH DNA Probe Cocktail

FDA-approved, fully automated, ready-to-use assay that allows evaluation of HER2 gene status with morphological context using brightfield microscopy. The assay helps identify breast cancer patients eligible for treatment with HERCEPTIN® (trastuzumab).

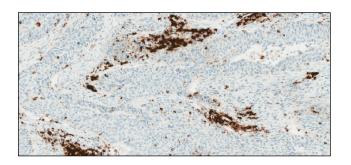


VENTANA ALK (D5F3) CDx Assay

Fully automated, easy-to-score, 4½-hour ALK IHC test that provides same-day results to aid in identifying ALK-positive non-small cell lung cancer (NSCLC) patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), ALECENSA® (alectinib) or LORBRENA® (lorlatinib).

For more information, see page 31.

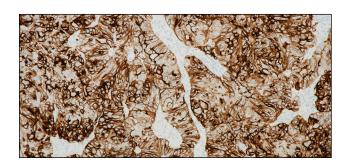
^{*}Based on data from a leading external quality assessment scheme. Retrieved from http://www.nordiqc.org/epitope.php.



VENTANA PD-L1 (SP142) Assay

FDA-approved, fully automated, ready-to-use assay for determining PD-L1 and tumor-infiltrating immune cell status. The assay helps identify non-small cell lung cancer (NSCLC) patients eligible for treatment with TECENTRIQ® (atezolizumab).

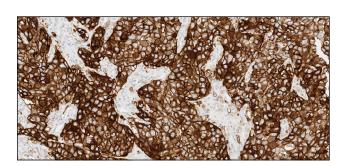
For more information, see page 90.



VENTANA FOLR1 (FOLR1-2.1) RxDx Assay

VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens by light microscopy.

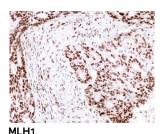
For more information, see page 64.



VENTANA PD-L1 (SP263) Assay

FDA-approved, fully automated, ready-to-use assay for determining PD-L1 status. This assay helps identify non-small cell lung cancer (NSCLC) patients eligible for treatment with TECENTRIQ® (atezolizumab)* and LIBTAYO® (cemiplimab-rwlc)**

For more information, see page 90.



MSH2



MSH6

VENTANA MMR RxDx Panel

VENTANA MMR RxDx Panel is the latest companion diagnostic assay to the Roche portfolio. This qualitative immunohistochemistry (IHC) test is intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in solid tumors including endometrial carcinoma (EC) and is indicated as an aid in identifying patients eligible for treatment with JEMPERLI (dostarlimabgxly) or KEYTRUDA (pembrolizumab), or endometrial carcinoma (EC) patients eligible for treatment with KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib) in accordance with approved product labeling.

For more information, see pages 76-78 and 92.

^{*}Based on data from a leading external quality assessment scheme. Retrieved from http://www.nordiqc.org/epitope.php.

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.*

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) Used only in clinical trials and not commercially marketed

RUOs and IUOs are not intended for clinical diagnostic use.

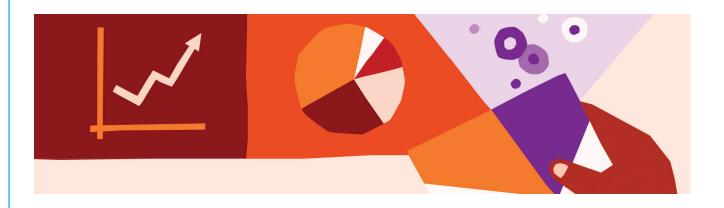
Clinical reagents include:

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

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.

https://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm123682.htm#1.



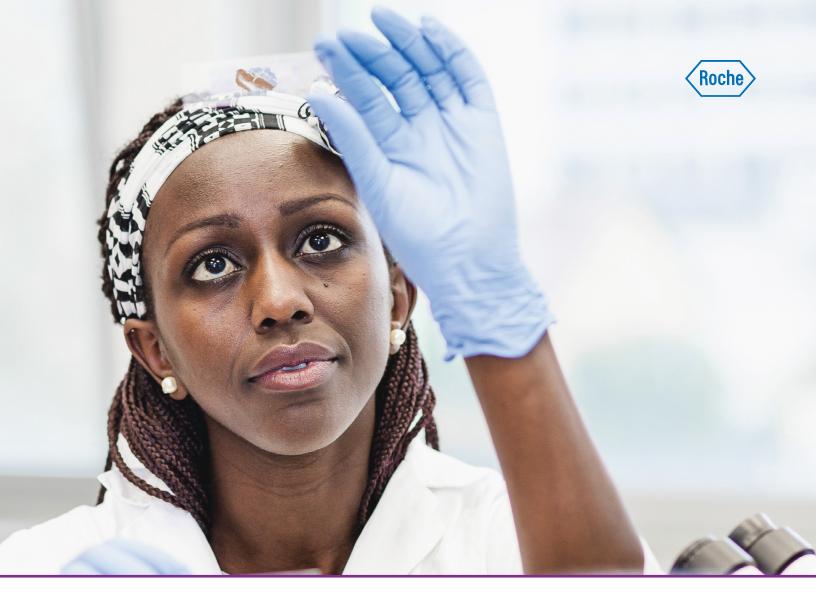
The regulatory controls for each device class include:

- 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 Il 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 Ill 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 US

		Product Classification:	RUO	Class I*	Class II	Class III
	FDA submission		No	No	Yes	PMA
_	Immunoreactivity (ToT ToB)		No	Yes	Yes	Yes
mec	Robustness		No	Yes	Yes	Yes
for	Repeatability		No	Yes	Yes	Yes
per	Pre-analytical (fixatives, etc)		No	Yes	Occasionally	Yes
dies	Stability studies		No	Yes	Yes	Yes
stu	Design validation		No	Yes	Yes	Yes
ioi	Reader precision		No	No	Yes	Yes
izat	Inter-laboratory reproducibi	lity or repeatability	No	No	Yes	Yes
cter	Proof of utility in detecting a	disease	No	No	Occasionally	Yes
Characterization studies performed	Clinical utility proving device drug outcome or potential m		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)

^{*} Registered with the FDA.



Primary Antibodies

A vast portfolio supported by the resources and global reach of a leading healthcare company

Ready-to-Use Primary Antibodies

More than 200 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.¹
- Choose from a comprehensive portfolio: We offer more than 200 ready-to-use Class I assays, including the largest menu of rabbit monoclonal IVD antibodies available.

Breast

- ER (SP1)
- PR (1E2)
- HER-2/neu (4B5)
- Ki-67 (30-9)
- p53 (DO-7)
- HER2 Dual ISH

Lung



- TTF-1 (SP141)
- Cytokeratin 5/6 (D5/16B4)
- Napsin A (MRQ-60)
- p40 (BC28)
- ALK (D5F3)
- ROS1 (SP384)
- pan-TRK (EPR17341)
- PD-L1 (SP142 & SP263)

Cervical

- CINtec® Histology
- CINtec® PLUS Cytology



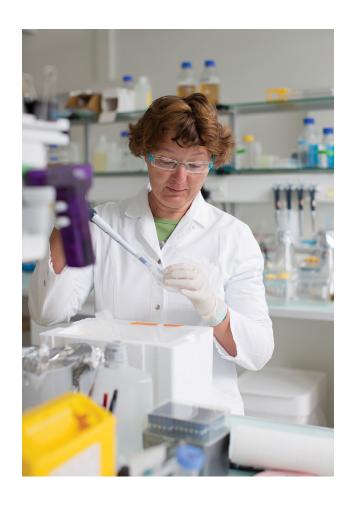
Our broad portfolio includes sensitive, specific assays for key markers. Turn the page for a complete listing of our primary antibodies and other IHC/ISH reagents by disease state. The rabbit monoclonal difference Superior sensitivity and specificity for consistent, high-quality staining²

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. https://www.nordiqc.org/downloads/assessments/58_2.pdf
- 2. 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
- VENTANA HER2 Dual ISH DNA Probe Cocktail
- Ki-67 (30-9), CONFIRM
- p53 (DO-7), CONFIRM

Actin, Smooth Muscle (1A4)

Caldesmon (E89)

Calponin-1 (EP798Y)

Cytokeratin (35BETAH11)

E-cadherin (36), VENTANA

E-cadherin (EP700Y)

Estrogen Receptor (ER) (SP1), CONFIRM, 50-test

GATA3 (L50-823)

GCDFP-15 (EP1582Y)

HER-2/neu (4B5), PATHWAY

HER-2 Dual ISH DNA Probe Cocktail, VENTANA

Ki-67 (30-9), CONFIRM

Mammaglobin (31A5)

Myosin, Smooth Muscle (SMMS-1)

Negative Control Rabbit Ig, CONFIRM

Negative Control (Monoclonal)

p53 (Bp53-11)

p53 (DO-7), CONFIRM

p57 (Kp10)

PAX-8 (EP331)

PAX-8 (MRQ-50)

Progesterone Receptor (PR) (1E2), CONFIRM, 50-test

Progesterone Receptor (PR) (1E2), CONFIRM, 250-test

Topoisomerase IIa (JS5B4), CONFIRM



Gynecological Including Cervical

Actin, Muscle Specific (HHF35)

CA-125 (OC125)

CINtec® Histology (50-test)

CINtec® Histology (250-test)

CINtec® PLUS Cytology

FOLR1 (FOLR1-2.1) RxDx Assay, VENTANA

hCG (polyclonal)

MyoD1 (EP212)

Myogenin (F5D)

Oct-4 (MRQ-10)



Typical Lung Panel Assays

- Cytokeratin 5/6 (D5/16B4)
- Napsin A (MRQ-60)
- p40 (BC28)
- Thyroid Transcription Factor-1 (SP141)
- ALK
- PD-L1

ALK (D5F3) CDx Assay, VENTANA	
Calretinin (SP65), CONFIRM	
CEA (CEA31)	
Chromogranin A (LK2H10)	
Cytokeratin (CAM 5.2)	
Cytokeratin 5 (SP27)	
Cytokeratin 5/6 (D5/16B4)	
Cytokeratin 7 (SP52), CONFIRM	
Cytokeratin 14 (SP53)	
Cytokeratin 17 (SP95)	
Cytokeratin 20 (SP33), CONFIRM	
DLL3 (SP347) Assay, VENTANA	
Ep-CAM (Epithelial Specific Antigen) (Ber-EP4)	
Mesothelial Cell HBME-1 (HBME-1)	
Total c-MET (SP44), CONFIRM	
Napsin A (MRQ-60)	
NSE (MRQ-55)	
p40 (BC28)	
Pan Keratin (AE1/AE3/PCK26), 50-test	

Pan Keratin (AE1/AE3/PCK26) 250-test
pan-TRK (EPR17341) Assay, VENTANA
PD-L1 (SP142) Assay, VENTANA
PD-L1 (SP263) Assay, VENTANA
Rabbit Monoclonal Negative Control Ig
ROS1 (SP384), VENTANA
SOX-2 (SP76)
Synaptophysin (MRQ-40)
Synaptophysin (SP11), CONFIRM
TAG-72 (B72.3)
Thyroid Transcription Factor-1 (8G7G3/1), CONFIRM
Thyroid Transcription Factor-1 (SP141)
pan-TRK (EPR17341) Assay, VENTANA
WT1 (6F-H2)

The identified typical antibodies and panels listed for disease state stratification are for informational use only and no medical value or intended use claims are being made. For that information, please refer to the specific product package insert.

IHC/ISH Reagents by Disease State (continued)



Colorectal and Gastrointestinal

Typical Colorectal Panel Assays

- MLH1 (M1), VENTANA
- MSH2 (G219-1129), VENTANA
- MSH6 (SP93), VENTANA
- PMS2 (A16-4), VENTANA
- BRAF-V600E (VE1), VENTANA

Typical Gastrointestinal Panel Assays

- CD34 (QBEnd/10), CONFIRM
- CD117 (EP10)
- CDX-2 (EPR2764Y)
- CLDN18 (43-14A), VENTANA
- Cytokeratin 7 (SP52), CONFIRM
- Cytokeratin 20 (SP33), CONFIRM
- DOG1 (SP31)
- Helicobacter pylori (SP48), VENTANA
- Smooth Muscle Actin (1A4)

Alpha-Fetoprotein (polyclonal)	
Arginase-1 (SP156)	
AREG (SP272), VENTANA	
Beta-catenin (14)	
BRAF V600E (VE1), VENTANA	
CA19-9 (121SLE)	
CD117 (EP10)	
CDX-2 (EPR2764Y)	
CLDN18 (43-14A) Assay, VENTANA	
Cytokeratin 19 (A53-B/A2.26)	
DOG1 (SP31)	
EMA (E29), CONFIRM	

Epithelial-Related Antigen (MOC-31)
EREG (SP326), VENTANA
FGFR2b (FPR2-D), VENTANA
Gastrin (polyclonal)
Glutamine Synthetase (GS-6)
GLUT1 (polyclonal)
Glypican-3 (1G12)
Glypican 3 (GC33)
Helicobacter pylori (SP48), VENTANA, 50-test
Helicobacter pylori (SP48), VENTANA, 250-test
Hepatocyte Specific Antigen (Hep Par-1) (OCH1E5)
MLH1 (M1), VENTANA
MSH2 (G219-1129), VENTANA
MSH6 (SP93), VENTANA
MUC1 (H23)
MUC2 (MRQ-18)
MUC5AC (MRQ-19)
MUC6 (MRQ-20)
P120 CATENIN (98)
PMS2 (A16-4), VENTANA
SATB2 (EP281)
TFF3 (7F1.21), VENTANA
Villin (CWWB1)



Dermatopathology

Typical Melanoma Panel Assays

- MART-1/melan A (A103), CONFIRM
- Melanosome (HMB45), CONFIRM
- Nerve Growth Factor Receptor (MRQ-21)
- \$100 (4C4.9), CONFIRM
- S100 (polyclonal), CONFIRM
- SOX-10 (SP267)
- Tyrosinase (T311), CONFIRM

A-1-Antitrypsin (polyclonal)

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

Desmin (DE-R-11), CONFIRM

Factor VIII Related Antigen (polyclonal)

Factor XIIIa (AC-1A1)

Factor XIIIa (EP3372)

MART-1/melan A (A103), CONFIRM

Melanoma Triple Cocktail (A103, HMB45, T311)

Melanosome (HMB45), CONFIRM

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

Neurofilament (2F11)

Podoplanin (D2-40)

PRAME (EPR20330), 50-test

PRAME (EPR20330), 250-test

S100 (4C4.9), CONFIRM

S100 (Polyclonal), CONFIRM

SOX-10 (SP267)

Tryptase (G3)

Tyrosinase (T311), CONFIRM

Vimentin (V9), CONFIRM



Endocrine

Calcitonin (SP17))

Calcitonin (polyclonal)

Parathyroid Hormone (PTH) (MRQ-31)

Thyroglobulin (2H11+ 6E1)

The identified typical antibodies and panels listed for disease state stratification are for informational use only and no medical value or intended use claims are being made. For that information, please refer to the specific product package insert.

IHC/ISH Reagents by Disease State (continued)



Typical Prostate Panel Assays

- Basal Cell Cocktail (34βΕ12+p63), VENTANA
- Cytokeratin 5/6 (D5/16B4)
- p504s (SP116)
- p63 (4A4), VENTANA
- PSA (polyclonal), CONFIRM
- PSAP (PASE/4LJ)

Androger	n Receptor	(SP107)	

Basal Cell Cocktail (34βE12+p63), VENTANA, 50-test

Basal Cell Cocktail (34βE12+p63), VENTANA, 250-test

C3d (polyclonal)

C4d (SP91)

C4d (polyclonal)

Carbonic Anhydrase IX (EP161)

ERG (EPR3864)

Inhibin, alpha (MRQ-63)

INI-1 (MRQ-27)

Keratin (34BE12), CONFIRM

NKX3.1 (EP356)

p504s (SP116)

p63 (4A4), VENTANA

PLAP (NB10)

PSA (polyclonal), CONFIRM

PSA (ER-PR8)

PSAP (PASE/4LJ)

PSMA (EP192)

PTEN (SP218), VENTANA

Renal Cell Carcinoma (PN-15)

SALL4 (6E3)

SF-1 (EP434)

TFE3 (MRQ-37)

Uroplakin III (SP73)



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), VENTANA
- Ki-67 (30-9), CONFIRM
- MUM1 (EP190)
- PAX5 (SP34), CONFIRM

ALK1 (ALK01), CONFIRM

bcl-2 (124), CONFIRM

bcl-2 (SP66)

bcl-6 (GI191E/A8)

BOB.1 (SP92)

CD1a (EP3622)
CD2 (MRQ-11)
CD3 (2GV6), CONFIRM
CD4 (SP35), CONFIRM
CD5 (SP19), CONFIRM
CD7 (SP94)
CD8 (SP57), CONFIRM
CD10 (SP67), VENTANA
CD15 (MMA), CONFIRM
CD16 (SP175)
CD20 (L26), CONFIRM
CD21 (2G9)
CD21 (EP3093)
CD23 (SP23), CONFIRM
CD25 (4C9)
CD30 (Ber-H2)
CD31 (JC70)
CD33 (SP266)
CD34 (QBEnd/10)
CD34 (QBEnd/10), CONFIRM
CD38 (SP149)
CD43 (L60)
CD45 (LCA) (RP2/18), CONFIRM
CD45 (LCA) (2B11 & PD7/26)
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)
CD163 (MRQ-26)
c-Myc (Y69)
Cyclin D1 (SP4-R)
Galectin-3 (9C4)
Glycophorin A (GA-R2)
Granzyme B (polyclonal)
Hemoglobin A (SP212)
IgD (Immunoglobulin D)
IgG (Immunoglobulin G)
IgG4 (MRQ-44)
IgM (Immunoglobulin M) (polyclonal)
Kappa (polyclonal), CONFIRM
Lambda (polyclonal), CONFIRM
Lysozyme (polyclonal)
MUM1 (EP190)
Myeloperoxidase (polyclonal)
Oct-2 (MRQ-2)
PAX5 (SP34), CONFIRM
PD-1 (NAT-105)
SOX-11 (MRQ-58)
TdT (polyclonal)

The identified typical antibodies and panels listed for disease state stratification are for informational use only and no medical value or intended use claims are being made. For that information, please refer to the specific product package insert.

IHC/ISH Reagents by Disease State (continued)



ACTH (polyclonal)
ATRX (polyclonal)
FSH (polyclonal)
GLIAL Fibrillary Acidic Protein (EP672Y)
Growth Hormone (polyclonal)
IDH1 R132H (MRQ-67)
LH (polyclonal)
Olig2 (EP112)
PGP 9.5 (polyclonal)
Phosphohistone H3 (PHH3)
Prolactin (polyclonal)
TSH (polyclonal)

A-1-Antitrypsin (polyclonal)

 Ordering Number:
 05267200001

 Catalog Number:
 760-2605

 Quantity:
 50 tests

Controls: Appendix, Lymph Node, Tonsil

Clone Name:PolyclonalSpecies:RabbitLocalization:Cytoplasmic

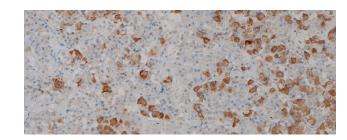
Regulatory Status: IVD

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)

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

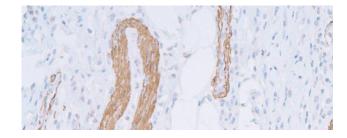


INTENDED USE

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.

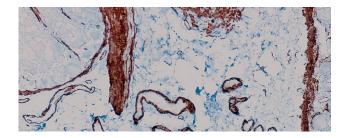
Actin, Muscle Specific (HHF35)

Ordering Number: 05267161001 Catalog Number: 760-2601 Quantity: 50 tests Controls: Skeletal Muscle IgG₁/K Isotypes: Clone Name: HHF35 Species: Mouse Localization: Cytoplasmic 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

 Ordering Number:
 05268303001

 Catalog Number:
 760-2833

 Quantity:
 50 tests

 Controls:
 Appendix, Uterus

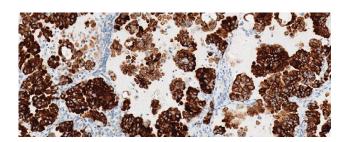
Isotypes: IgG

Clone Name: 1A4
Species: Mouse
Localization: Cytoplasmic

Regulatory 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.



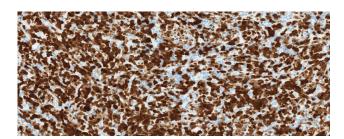
VENTANA ALK (D5F3) CDx Assay

06687199001 Ordering Number: Catalog Number: 790-4796 Quantity: 50 tests Controls: **Appendix** Isotypes: IgG D5F3 Clone Name: Species: Rabbit 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), ALECENSA® (alectinib) or LORBRENA® (lorlatinib). 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

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

Controls: Anaplastic Large Cell Lymphoma

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{3}/\textbf{K} \\ \textbf{Clone Name:} & \textbf{ALK01} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$

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.

Alpha-Fetoprotein Rabbit Polyclonal Antibody

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

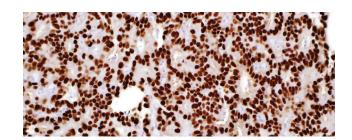


INTENDED USE

Alpha-Fetoprotein Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of Alpha-Fetoprotein 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-Androgen Receptor (SP107) Rabbit Monoclonal Primary Antibody

Ordering Number: 06523838001 Catalog Number: 760-4605 50 tests Quantity: Controls: Prostate Isotypes: IgG Clone Name: SP107 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 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-AREG (SP272) Rabbit Monoclonal Primary Antibody

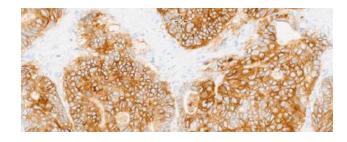
Ordering Number: 09858725001
Catalog Number: 790-7215
Quantity: 50 tests

Controls: Colorectal Adenocarcinoma

Isotypes:IgGClone Name:SP272Species:Rabbit

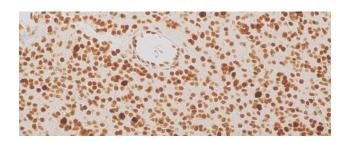
Localization: Membrane, Cytoplasm

Regulatory Status: IVD



INTENDED USE

VENTANA anti-AREG (SP272) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of amphiregulin protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.



ATRX Rabbit Polyclonal Antibody

 Ordering Number:
 09433309001

 Catalog Number:
 790-7216

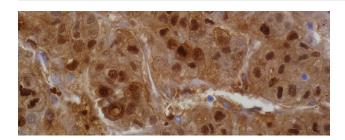
 Quantity:
 50 tests

Controls: Brain, Oligodendroglioma, Glioblastoma

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

INTENDED USE

ATRX Rabbit Polyclonal Antibody is intended for laboratory use in the detection of ATRX protein in formalin-fixed, paraffin-embedded human tissue stained in qualitative immunohistochemistry on 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

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

Controls: Hepatocellular Carcinoma, Normal Liver

Isotypes:IgGClone Name:SP156Species:Rabbit

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)

 Ordering Number:
 06364497001
 06419445001

 Catalog Number:
 790-4536
 790-1010

 Quantity:
 50 tests
 250 tests

 Controls:
 Normal Basal Cells in Prostate Tissue

Isotypes: IgG_{2a}/K

Clone Name: 34β E12 + 4A4 Species: Mouse

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

Regulatory Status: IVD

INTENDED USE

VENTANA Basal Cell Cocktail (34β E12+p63) is an antibody cocktail of anti-p63 (4A4) and anti-keratin (34β E12) mouse monoclonal antibodies. VENTANA Basal Cell Cocktail (34β E12+p63) is intended for laboratory use in the qualitative immunohistochemical detection of p63 and cytokeratin 5 in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

Ordering Number: 05986826001 Catalog Number: 790-4464 Quantity: 50 tests

Controls: Interfollicular T Cells in Tonsil,

B Cells of the Mantle Zone

Isotypes:IgG1Clone Name:124Species:MouseLocalization:Cytoplasmic

Regulatory Status: IVD



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

Ordering Number: 06446329001 Catalog Number: 790-4604 Quantity: 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 intended for laboratory use in the qualitative immunohistochemical detection of B-cell lymphoma 2 protein (bcl-2) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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)

 Ordering Number:
 05269008001

 Catalog Number:
 760-4241

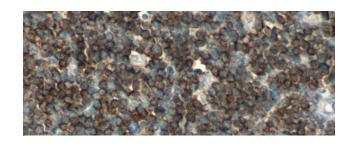
 Quantity:
 50 tests

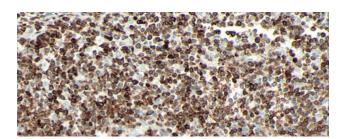
Controls: Lymph Node, Tonsil

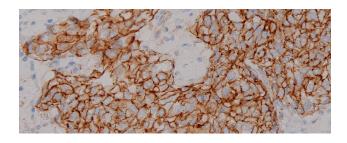
Isotypes:IgG₁Clone Name:GI191E/A8Species:MouseLocalization:NuclearRegulatory Status:IVD

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)

 Ordering Number:
 05269016001

 Catalog Number:
 760-4242

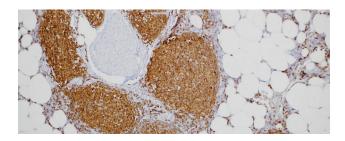
 Quantity:
 50 tests

Controls: Fibromatosis of Breast or Abdomen

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{14} \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Nuclear} \\ \textbf{Regulatory Status:} & \textbf{IVD} \\ \end{array}$

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.



BOB.1 (SP92)

 Ordering Number:
 06433308001

 Catalog Number:
 760-4593

 Quantity:
 50 tests

 Controls:
 Tonsil

 Clone Name:
 SP92

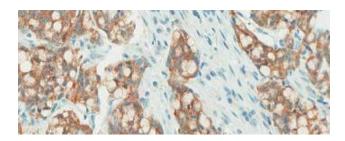
 Species:
 Rabbit

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

 Ordering Number:
 07862270001

 Catalog Number:
 790-5095

 Quantity:
 50 tests

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

VENTANA anti-BRAF V600E (VE1) antibody

 Isotypes:
 IgG_{2a}

 Clone Name:
 VE1

 Species:
 Mouse

 Localization:
 Cytoplasmic

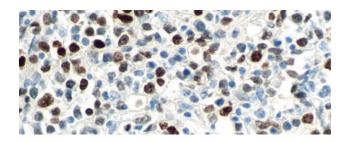
 Regulatory Status:
 IVD

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-c-MYC (Y69) Rabbit Monoclonal **Primary Antibody**

Ordering Number: 06504612001 790-4628 Catalog Number: 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 is intended for laboratory use in the qualitative immunohistochemical detection of c- MYC protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

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

Controls: Acute Rejected Kidney Transplant

Isotypes: IgG Clone Name: Polyclonal Species: Rabbit

Membranous, Cytoplasmic Localization:

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 (SP91)

06732364001 **Ordering Number:** Catalog Number: 760-4803 Quantity: 50 tests

Controls: Acute Rejected Kidney Transplant,

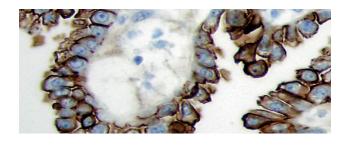
Tonsil/Lymph Node

Isotypes: IgG SP91 Clone Name: Species: Rabbit Localization: Membranous IVD

Regulatory Status:

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)

 Ordering Number:
 05267269001

 Catalog Number:
 760-2610

 Quantity:
 50 tests

Controls: Ovarian Carcinoma

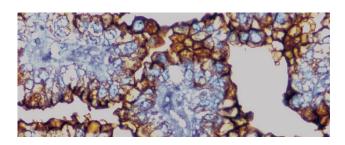
Isotypes: IgG_1/K Clone Name:OC125Species:Mouse

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)

 Ordering Number:
 05267242001

 Catalog Number:
 760-2609

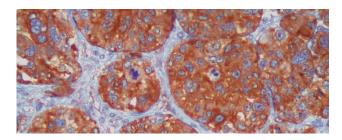
 Quantity:
 50 tests

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, 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.



Calcitonin (polyclonal)

 Ordering Number:
 05267277001

 Catalog Number:
 760-2611

 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.

anti-Calcitonin (SP17), Rabbit Monoclonal Primary Antibody

 Ordering Number:
 06586554001

 Catalog Number:
 760-4705

 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)

 Ordering Number:
 05463459001

 Catalog Number:
 760-4375

 Quantity:
 50 tests

Controls: Esophagus, Smooth Muscle from Bowel, Uterus

Isotypes:IgGClone Name:E89Species:RabbitLocalization:Cytoplasmic

Regulatory 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.

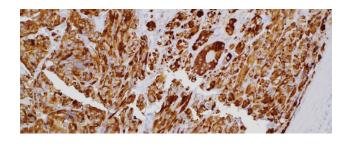
Calponin-1 (EP798Y)

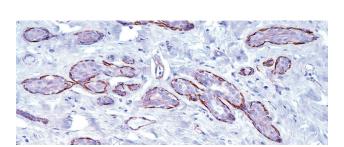
Ordering Number: 05435684001 760-4376 Catalog Number: Quantity: 50 tests Controls: **Appendix** Isotypes: IgG Clone Name: **EP798Y** Species: Rabbit Localization: Cytoplasmic

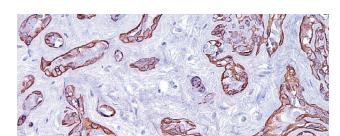
Regulatory Status: IVD

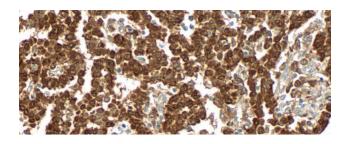
INTENDED USE

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

Ordering Number: 05992184001 Catalog Number: 790-4467 Quantity: 50 tests

Controls: Mesothelioma, Normal Appendix

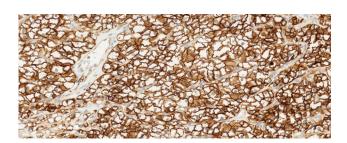
Clone Name: SP65 Species: Rabbit

Localization: Cytoplasmic, Nuclear

Regulatory Status: IVD

INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-Calretinin (SP65) Rabbit Monoclonal Primary Antibody 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

 Ordering Number:
 08313466001

 Catalog Number:
 760-6080

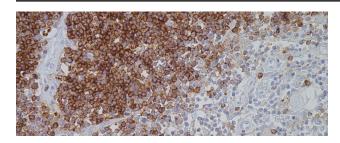
 Quantity:
 50 tests

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.



CD1a (EP3622)

Ordering Number: 06419160001 Catalog Number: 760-4525 50 tests Quantity: Controls: Thymus Isotypes: IgG, 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)

 Ordering Number:
 05463467001

 Catalog Number:
 760-4377

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Isotypes: lgG_1/K Clone Name:MRQ-11Species:Mouse

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

Ordering Number: 05278422001
Catalog Number: 790-4341
Quantity: 50 tests
Controls: Spleen, Tonsil
Clone Name: 2GV6
Species: Rabbit

Localization: Cytoplasmic, Membranous

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD3 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a 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.

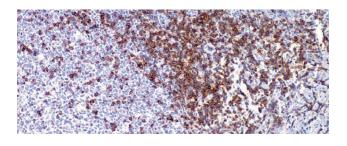


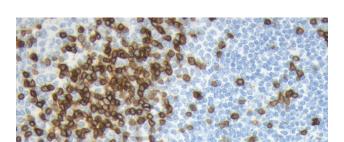
Ordering Number: 05552737001
Catalog Number: 790-4423
Quantity: 50 tests
Controls: Liver, Tonsil
Clone Name: SP35
Species: Rabbit
Localization: Membranous

Regulatory Status: IVD

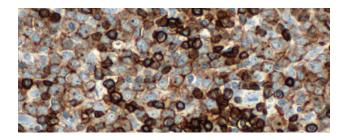
INTENDED USE

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

 Ordering Number:
 05929903001

 Catalog Number:
 790-4451

 Quantity:
 50 tests

 Controls:
 Tonsil, Lymphoma

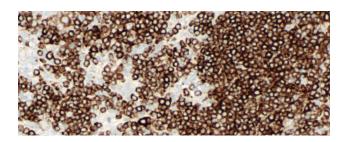
Clone Name: SP19 Species: Rabbit

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.

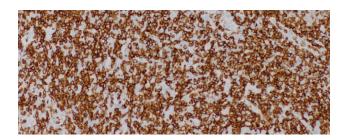


anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody

Ordering Number: 06537847001 Catalog Number: 790-4558 50 tests Quantity: Controls: Thymus, Tonsil Rabbit Ig Isotypes: Clone Name: SP94 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.



CD8 (SP239) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 09780041001

 Catalog Number:
 760-7176

 Quantity:
 50 tests

 Controls:
 Normal Tonsil

 Clone Name:
 SP239

 Species:
 Rabbit

Localization: Membrane, Cytoplasm

Regulatory Status: IVD

INTENDED USE

Anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD8 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 05857856001

 Catalog Number:
 790-4506

 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 intended for laboratory use in the qualitative immunohistochemical detection of CD10 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 05266904001

 Catalog Number:
 760-2504

 Quantity:
 50 tests

Controls: Hodgkin's Lymphoma

Isotypes:IgMClone Name:MMASpecies:Mouse

Localization: Cytoplasmic, Membranous

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD15 by light microscopy in sections of formalin-fixed, paraffin embedded tissue stained on a BenchMark IHC/ISH instrument. 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.

CD16 (SP175) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 07047681001

 Catalog Number:
 760-4863

 Quantity:
 50 tests

 Controls:
 Tonsil

 Isotypes:
 IgG

 Clone Name:
 SP175

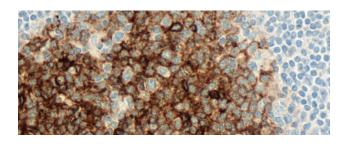
 Species:
 Rabbit

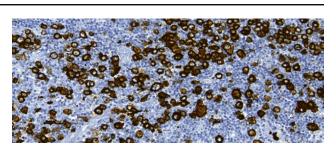
Localization: Membranous, Cytoplasmic

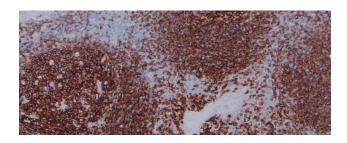
Regulatory Status: IVD

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.







CONFIRM anti-CD20 (L26) Primary Antibody

 Ordering Number:
 05267099001

 Catalog Number:
 760-2531

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 Isotypes:
 IgG_{2a}/K

 Clone Name:
 L26

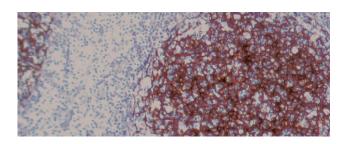
 Species:
 Mouse

 Localization:
 Membranous

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-CD20 (L26) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD20 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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 (2G9)

 Ordering Number:
 05269059001

 Catalog Number:
 760-4245

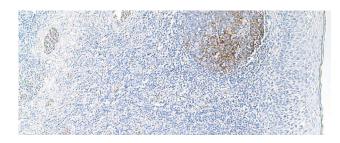
 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 $\begin{tabular}{lll} Isotypes: & IgG_{2a} \\ Clone Name: & 2G9 \\ Species: & Mouse \\ Localization: & Membranous \\ Regulatory Status: & IVD \\ \end{tabular}$

INTENDED USE

CD21 (2G9) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 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.



CD21 (EP3093)

 Ordering Number:
 05973902001

 Catalog Number:
 760-4438

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 $\begin{array}{lll} \textbf{Isotypes:} & & \textbf{IgG}_{1} \\ \textbf{Clone Name:} & & \textbf{EP3093} \\ \textbf{Species:} & & \textbf{Rabbit} \\ \end{array}$

Localization: Cytoplasmic, Membranous

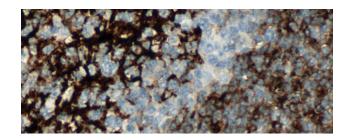
Regulatory Status: IVD

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.

CONFIRM anti-CD23 (SP23) Rabbit Monoclonal Primary Antibody

Ordering Number: 05479258001
Catalog Number: 790-4408
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)

 Ordering Number:
 05973899001

 Catalog Number:
 760-4439

 Quantity:
 50 tests

Controls: Lesions of Mastocytosis, Small Bowel

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

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

 Ordering Number:
 07007841001

 Catalog Number:
 790-4858

 Quantity:
 50 tests

Controls: Positive control tissue: Lymphoma or Tonsil

Negative control tissue: Tonsil Germinal

Center B-cells

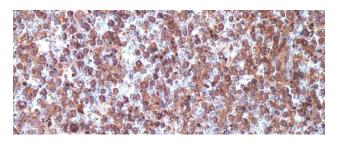
Isotypes: IgG_1/K Clone Name:Ber-H2Species:Mouse

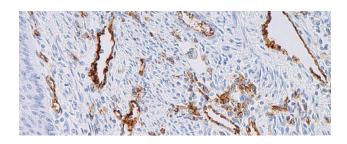
Localization: Cell Membrane, Cytoplasmic, Golgi

Regulatory Status: IVD

INTENDED USE

The anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the CD30 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.





CD31 (JC70)

 Ordering Number:
 05463475001

 Catalog Number:
 760-4378

 Quantity:
 50 tests

Controls: Appendix, Placenta, Tonsil

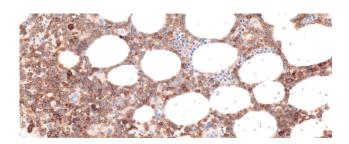
Isotypes: IgG_1/K Clone Name:JC70Species:Mouse

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, 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.



CD33 (SP266) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 07391447001

 Catalog Number:
 760-4952

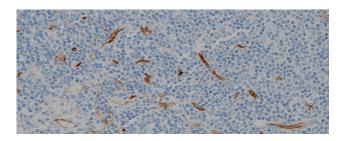
 Quantity:
 50 tests

Controls: Acute Leukemia, Placenta Syncytiotrophoblasts

Isotypes:IgGClone Name:SP266Species:RabbitLocalization:MembranousRegulatory 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

 Ordering Number:
 05278210001

 Catalog Number:
 790-2927

 Quantity:
 50 tests

Controls: Appendix, Placenta, Tonsil

 Isotypes:
 IgG₁

 Clone Name:
 QBEnd/10

 Species:
 Mouse

 Localization:
 Membranous

Regulatory Status: IVD

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

CD38 (SP149) Primary Antibody

Ordering Number: 06648550001 Catalog Number: 760-4785 Quantity: 50 tests

Controls: Bone Marrow, Lymph Node, Plasma cells,

Plasma cell myeloma

Isotypes: IgG SP149 Clone Name: Rabbit Species: Localization: Cytoplasmic

Regulatory Status:

INTENDED USE

CD38 (SP149) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD38 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-CD43 (L60) Mouse Monoclonal **Primary Antibody**

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

Controls: Lymph Node, Tonsil

Isotypes: lgG₁ L60 Clone Name: Species: Mouse Localization: Membranous IVD

Regulatory Status:

INTENDED USE

Anti-CD43 (L60) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD43 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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)

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

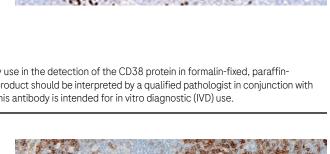
Controls: Lymph Node, Tonsil

Isotypes: IgG₄/K Clone Name: 2B11 & PD7/26 Species: Mouse Localization: Membranous

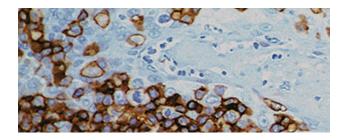
Regulatory Status: IVD

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.





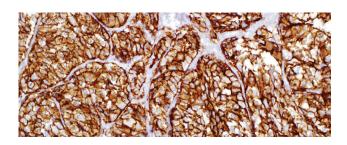


CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody

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

INTENDED 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.



CD56 (MRQ-42)

 Ordering Number:
 06433359001

 Catalog Number:
 760-4596

 Quantity:
 50 tests

Controls: Pancreatic Islet Cells, Pancreatic Endocrine

Cells, Neuroblastoma

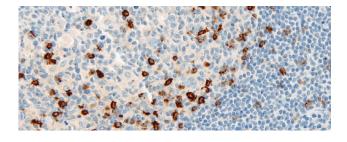
Clone Name: MRQ-42 **Species:** Rabbit

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.



CD57 (NK-1)

 Ordering Number:
 05267366001

 Catalog Number:
 760-2626

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Isotypes:IgM/KClone Name:NK-1Species:MouseLocalization:Membranous

Regulatory Status: IVD

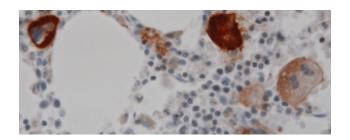
INTENDED USE

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)

05269091001 **Ordering Number:** Catalog Number: 760-4249 Quantity: 50 tests Controls: Bone Marrow Isotypes: lgG₁ Clone Name: 2f2 Species: Mouse Localization: Cytoplasmic

IVD



INTENDED USE

Regulatory Status:

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.

CONFIRM anti-CD68 (KP-1) Primary Antibody

 Ordering Number:
 05278252001

 Catalog Number:
 790-2931

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Isotypes: IgG_1/K Clone Name:KP-1Species:Mouse

Localization: Cytoplasmic, Membranous

Regulatory Status: IVD



INTENDED USE

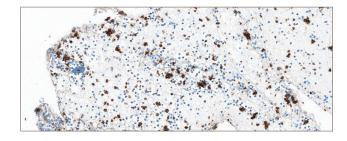
CONFIRM anti-CD68 (KP-1) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD68 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for *in vitro* diagnostic use.

CD71 (MRQ-48) Mouse Monoclonal Antibody

Ordering Number: 06433162001
Catalog Number: 760-4589
Quantity: 50 tests
Controls: Bone Marrow
Isotypes: IgG
Clone Name: MRQ-48
Species: Mouse

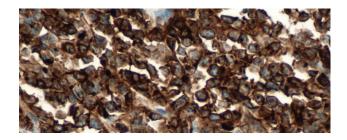
Localization: Membranous, Cytoplasmic

Regulatory Status: IVD



INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. The Cell Marque CD71 (MRQ-48) 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 as an aid in the identification of the erythroid precursors in bone marrow and in the determination of acute myeloid leukemia and myelodysplastic syndrome (MDS) within the context of an antibody panel, the patient's clinical history, and other diagnostic tests evaluated by a qualified pathologist.



CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 05640296001

 Catalog Number:
 790-4432

 Quantity:
 50 tests

Controls: Tonsil, B Cell Lymphoma

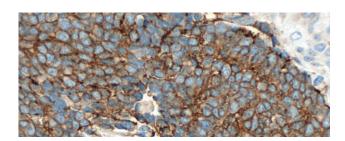
Clone Name: SP18 Species: Rabbit

Localization: Cytoplasmic, Membranous

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD79a by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 05913594001

 Catalog Number:
 790-4452

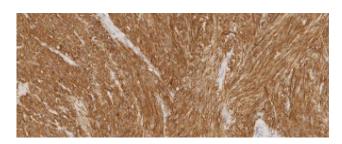
 Quantity:
 50 tests

Controls: Pancreatic Islet Cells, Sertoli Cells of the Testis

Isotypes:IgG1Clone Name:O13Species:MouseLocalization:MembranousRegulatory 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.



anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 08763909001

 Catalog Number:
 790-7061

 Quantity:
 50 tests

Controls: Normal Small Intestine or Normal Appendix

Clone Name: EP10 Species: Rabbit

Localization: Membranous and/or Cytoplasmic

Regulatory Status: IVD

INTENDED USE

Anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD117 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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)

 Ordering Number:
 05269083001

 Catalog Number:
 760-4248

 Quantity:
 50 tests

Controls: Plasmacytoma, Tonsil

Isotypes:IgGClone 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)

Ordering Number: 05973929001
Catalog Number: 760-4437
Quantity: 50 tests
Controls: Inflamed Tissue

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

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)

Ordering Number: 05463491001 **Catalog Number:** 760-4380

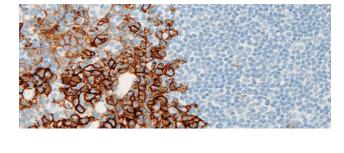
Controls: Adenocarcinoma of Colon, Normal Colon

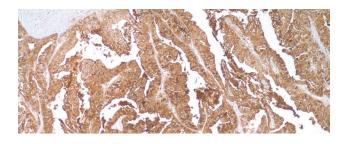
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{1}/\textbf{K} \\ \textbf{Clone Name:} & \textbf{EPR2764Y} \\ \textbf{Species:} & \textbf{Rabbit} \\ \textbf{Localization:} & \textbf{Nuclear} \\ \textbf{Regulatory Status:} & \textbf{IVD} \\ \end{array}$

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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, 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.





CEA (CEA31) Mouse Monoclonal Antibody

 Ordering Number:
 06433316001

 Catalog Number:
 760-4594

 Quantity:
 50 tests

Controls: Adenocarcinoma of Colon, Colon Mucosa

 Isotypes:
 IgG1

 Clone Name:
 CEA31

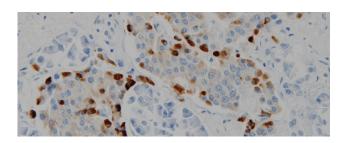
 Species:
 Mouse

 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.

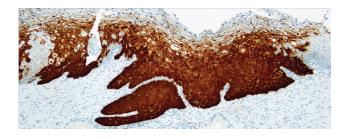


anti-Chromogranin A (LK2H10) Primary Antibody

Ordering Number: 05267056001 Catalog Number: 760-2519 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 intended for laboratory use in the qualitative immunohistochemical detection of chromogranin A by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 06680003001
 06680011001

 Catalog Number:
 705-4793
 725-4793

 Quantity:
 50 tests
 250 tests

 Controls:
 Cervical Carcinoma, CIN2, CIN3,

Normal Cervix

 $\begin{tabular}{lll} Isotypes: & IgG_{2a}\\ Clone Name: & E6H4^{TM}\\ Species: & Mouse\\ Regulatory Status: & IVD \end{tabular}$

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.

CINtec® PLUS Cytology

 Ordering Number:
 07478496001

 Catalog Number:
 760-100

 Quantity:
 100 tests

Controls: Known CINtec* PLUS Cytology positive cervical

cancer screening cytology samples collected in

ThinPrep PreservCyt®

Isotypes: p16 - $\lg G_{2a}$ Ki-67 - $\lg G$

Clone Name: p16^{INK4a} monoclonal antibody, clone E6H4

Ki-67 monoclonal antibody, clone 274-11AC3V1

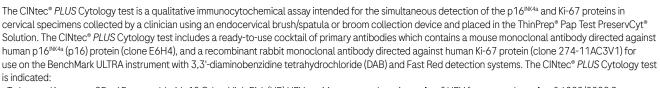
Species: p16 - Mouse Ki-67 - Rabbit

Localization: Cytoplasmic and Nuclear for p16

Nuclear for Ki-67

Regulatory Status: IVD

INTENDED USE



- To be used in women 25 65 years old with 12 Other High Risk (HR) HPV positive test results using **cobas*** HPV for use on the **cobas*** 6800/8800 Systems (**cobas*** HPV) or the **cobas*** 4800 HPV Test in primary HPV screening, to determine the need for referral to colposcopy.

 To be used in women 25 65 years old with HPV16/18 positive test results using **cobas*** HPV or the **cobas*** 4800 HPV Test in primary HPV screening where the CINtec* PLUS Cytology test results will be used in conjunction with the physician's assessment of patient screening history, other risk factors, and professional guidelines to guide patient management.
- To be used in women 30 65 years old with NILM (Negative for Intraepithelial Lesion or Malignancy) and 12 Other HR HPV positive test results using **cobas*** HPV or the **cobas*** 4800 HPV Test in adjunctive cervical cytology and HR HPV screening, to determine the need for referral to colposcopy. To be used in women 30 65 years old with NILM (Negative for Intraepithelial Lesion or Malignancy) and HPV16/18 positive test results using **cobas*** HPV or the **cobas*** 4800 HPV Test in adjunctive cervical cytology and HR HPV screening where the CINtec* *PLUS* Cytology test results will be used in conjunction with the physician's assessment of patient screening history, other risk factors, and professional guidelines to guide patient management.

 Results from the CINtec* *PLUS* Cytology test should be interpreted by a qualified pathologist.

VENTANA CLDN18 (43-14A) Assay

 Ordering Number:
 08504148001

 Catalog Number:
 790-7027

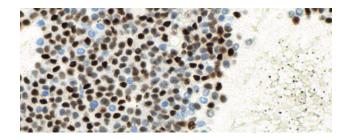
 Quantity:
 50 tests

Controls: Gastric intestinal metaplasia (positive)

Clone Name: 43-14A
Species: Mouse
Localization: Membrane
Regulatory Status: IVD

INTENDED USE

VENTANA CLDN18 (43-14A) Assay is intended for the immunohistochemical detection of the Claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues 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.



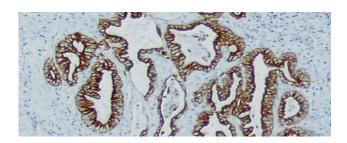
VENTANA anti-Cyclin D1 (SP4-R) Rabbit Monoclonal Primary Antibody

Ordering Number: 05862949001
Catalog Number: 790-4508
Quantity: 50 tests
Controls: 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.

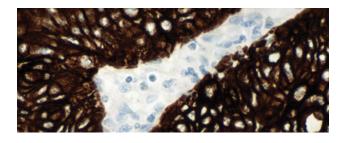


Cytokeratin (35betaH11)

Ordering Number: 05267471001 760-2637 Catalog Number: Quantity: 50 tests Controls: Prostate Isotypes: IqM/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.



anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody

Ordering Number: 06478425001
Catalog Number: 790-4555
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 is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 7 (CK7) and cytokeratin 8 (CK8) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 07292821001

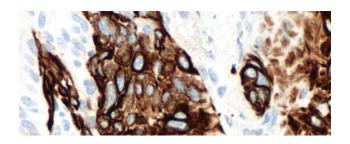
 Catalog Number:
 760-4935

 Quantity:
 50 tests

Controls: Mesothelioma, Prostate

Isotypes:IgGClone Name:SP27Species:RabbitLocalization: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.

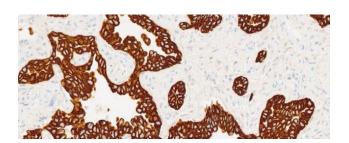
Cytokeratin (OSCAR) Mouse Monoclonal Antibody

Ordering Number: 08313440001 Catalog Number: 760-6078 Quantity: 50 tests

Controls: Colorectal Adenocarcinoma, Ductal Breast

Carcinoma, Lung Adenocarcinoma, Prostate

Clone Name: OSCAR
Species: Mouse
Localization: Cytoplasm
Regulatory Status: IVD



INTENDED USE

Cytokeratin (OSCAR) Mouse Monoclonal Antibody is intended for laboratory use in the detection of a broad spectrum of Cytokeratin proteins in formalin-fixed, paraffin-embedded human tissue stained in qualitative immunohistochemistry (IHC) on 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

 Ordering Number:
 06478441001

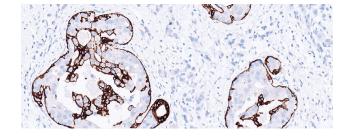
 Catalog Number:
 790-4554

 Quantity:
 50 tests

Controls: Prostate and Tonsil

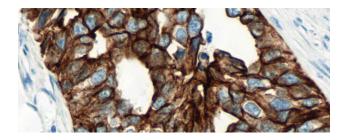
 $\begin{tabular}{lll} Isotypes: & IgG_1\\ Clone Name: & D5/16B4\\ Species: & Mouse\\ Localization: & Cytoplasmic \\ \end{tabular}$

Regulatory Status: IVD



INTENDED USE

Anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 5 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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**

05986818001 **Ordering Number:** 790-4462 Catalog Number: Quantity: 50 tests

Controls: Breast, Salivary Gland, Glandular and

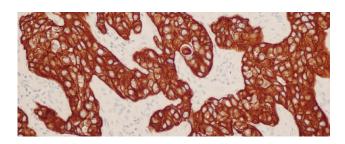
Ductal Epithelium of Lung

Clone Name: SP52 Species: Rabbit Localization: Cytoplasmic

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 7 (CK7) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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)

05269776001 Ordering Number: Catalog Number: 760-4344 50 tests Quantity:

Controls: Pancreas, Prostate, Salivary Gland

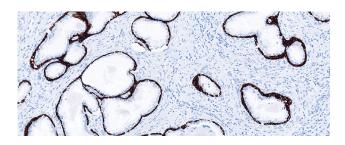
Isotypes: IgG. B22.1 & B23.1 Clone Name: Species: Mouse

Cytoplasmic **Regulatory Status:** IVD

Localization:

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 14 (SP53) Rabbit Monoclonal **Primary Antibody**

06732429001 Ordering Number: Catalog Number: 760-4805 Quantity: 50 tests

Controls: Prostate, Skin, Squamous Carcinoma

Isotypes: IgG Clone Name: SP53 Species: Rabbit Localization: Cytoplasmic IVD

Regulatory Status:

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

 Ordering Number:
 06373658001

 Catalog Number:
 790-4560

 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 is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 17 (CK17) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.



 Ordering Number:
 05269440001

 Catalog Number:
 760-4281

 Quantity:
 50 tests

Controls: Colon Carcinoma, Thyroid

Isotypes: IgG

Clone Name: A53-B/A2.26 Species: Mouse Localization: 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

 Ordering Number:
 05587760001

 Catalog Number:
 790-4431

 Quantity:
 50 tests

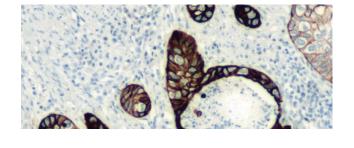
Controls: Colon Adenocarcinoma

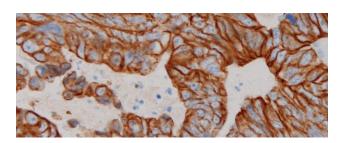
Clone Name:SP33Species:RabbitLocalization:Cytoplasmic

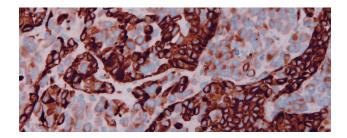
Regulatory Status: IVD

INTENDED USE

CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 20 (CK20) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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-Desmin (DE-R-11) Primary Antibody

Ordering Number: 05267005001 760-2513 Catalog Number: 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.



VENTANA DLL3 (SP347) Assay

 Ordering Number:
 08416931001

 Catalog Number:
 790-7016

 Quantity:
 50 tests

Controls: Small Cell Lung Carcinoma (positive), Normal Lung tissue (negative)

Isotypes: IgG

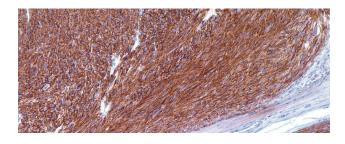
Clone Name: SP347 **Species:** Rabbit

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

 Ordering Number:
 06433189001

 Catalog Number:
 760-4590

 Quantity:
 50 tests

 Controls:
 GIST

 Isotypes:
 Rabbit Ig

 Clone Name:
 SP31

 Species:
 Rabbit

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

 Ordering Number:
 05905290001

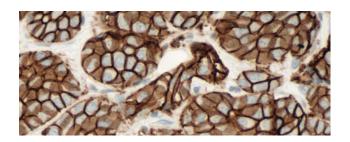
 Catalog Number:
 790-4497

 Quantity:
 50 tests

Controls: Ductal Breast Carcinoma

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

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)

 Ordering Number:
 05973872001

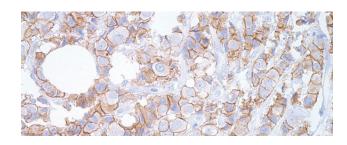
 Catalog Number:
 760-4440

 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-EMA (E29) Mouse Monoclonal Primary Antibody

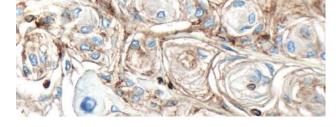
Ordering Number: 05878900001
Catalog Number: 790-4463
Quantity: 50 tests

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)

 Ordering Number:
 05435676001

 Catalog Number:
 760-4383

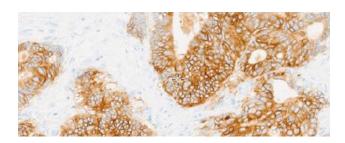
 Quantity:
 50 tests

Controls: Adenocarcinoma, Columnar Epithelium

 $\begin{tabular}{lll} Isotypes: & IgG_1/K \\ Clone Name: & Ber-EP4 \\ Species: & Mouse \\ Localization: & Cytoplasmic \\ Regulatory Status: & IVD \\ \end{tabular}$

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.



VENTANA® anti-EREG (SP326) Rabbit Monoclonal Primary Antibody

Ordering Number: 09858415001
Catalog Number: 790-7216
Quantity: 50 tests

Controls: Colorectal Carcinoma

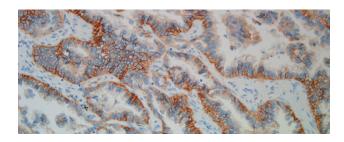
Clone Name: SP326 Species: Rabbit

Localization: Membrane, Cytoplasm

Regulatory Status: IVD

INTENDED USE

VENTANA anti-EREG (SP326) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of epiregulin protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

Ordering Number: 06374409001
Catalog Number: 790-4561
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 is intended for laboratory use in the qualitative immunohisto chemical detection of epithelial cell adhesion molecule (EpCAM) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

Ordering Number: 06478450001
Catalog Number: 790-4576
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 is intended for laboratory use in the qualitative immunohistochemical detection of both wildtype ERG, and truncated ERG resulting from ERG gene rearrangement, by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.

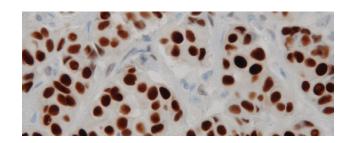
CONFIRM anti-(ER) (SP1) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 05278414001
 05278406001

 Catalog Number:
 790-4325
 790-4324

 Quantity:
 250 tests
 50 tests

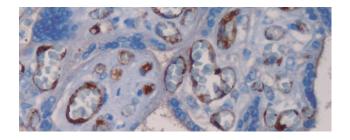
Controls: Breast
Isotypes: IgG
Clone Name: SP1
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD
INTENDED USE



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.

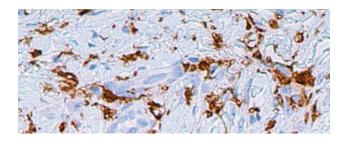
Factor VIII-R Ag. (polyclonal)

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



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)

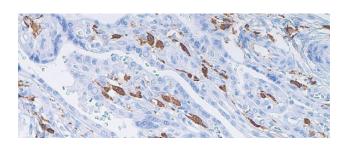
Ordering Number: 05435692001 Catalog Number: 760-4384 Quantity: 50 tests Controls: Dermatofibroma

Isotypes: lgG1 AC-1A1 Clone Name: Species: Mouse 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)

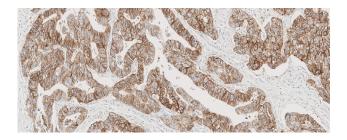
05922470001 **Ordering Number:** Catalog Number: 760-4441 Quantity: 50 tests Controls: Dermatofibroma

Isotypes: IgG EP3372 Clone Name: Species: Rabbit Localization: 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.



VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody

Ordering Number: 09829199001 790-7214 Catalog Number: Quantity: 50 tests

Controls: Non-neoplastic skin tissue

Clone Name: FPR2-D Species: Mouse Localization: Membranous **Regulatory Status:** IVD

INTENDED USE

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody is intended for laboratory use in the qualitative immunohistochemical detection of FGFR2b by light microscopy in sections of formalin-fixed, paraffin-embedded tissues stained on a BenchMark IHC/ISH instrument. 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

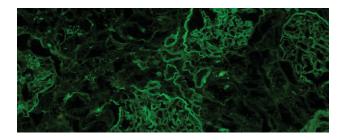
 Ordering Number:
 05268087001

 Catalog Number:
 760-2699

 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) 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

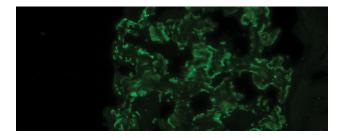
 Ordering Number:
 05267994001

 Catalog Number:
 760-2688

 Quantity:
 50 tests

Controls: Frozen, Diseased Skin or Diseased Renal Tissue

Clone Name:PolyclonalSpecies:GoatRegulatory Status:IVD



INTENDED USE

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

Medical Systems' (Ventana) 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

 Ordering Number:
 05267978001

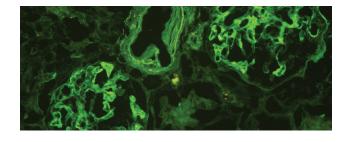
 Catalog Number:
 760-2686

 Quantity:
 50 tests

Controls: Frozen, Kidney or Skin from Lupus Cases

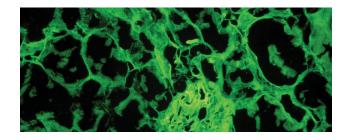
Containing C3 Deposits

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

 Ordering Number:
 05267960001

 Catalog Number:
 760-2685

 Quantity:
 50 tests

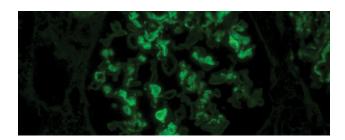
Controls: Frozen, Placenta or Tissue Containing

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

 Ordering Number:
 05267927001

 Catalog Number:
 760-2681

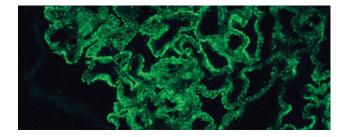
 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node

Clone Name:PolyclonalSpecies:GoatRegulatory Status:IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) 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

 Ordering Number:
 05267919001

 Catalog Number:
 760-2680

 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) 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

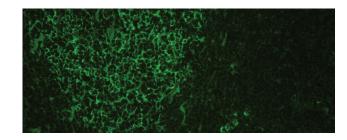
 Ordering Number:
 05267935001

 Catalog Number:
 760-2682

 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) 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

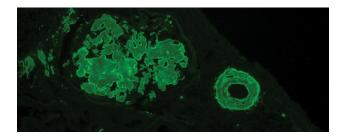
 Ordering Number:
 05267943001

 Catalog Number:
 760-2683

 Quantity:
 50 tests

Controls: Frozen, Tonsil or Lymph Node Clotted Blood

Clone Name:PolyclonalSpecies:GoatRegulatory Status:IVD



INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) 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

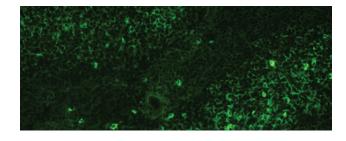
 Ordering Number:
 05267951001

 Catalog Number:
 760-2684

 Quantity:
 50 tests

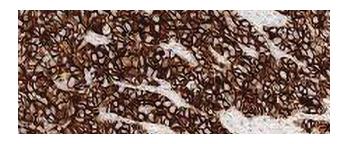
Controls: Frozen, Tonsil or Lymph Node

Clone Name:PolyclonalSpecies:BurroRegulatory Status:IVD



INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana® Medical Systems' (Ventana) 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.



VENTANA FOLR1 (FOLR1-2.1) RxDx Assay

 Ordering Number:
 07727917001

 Catalog Number:
 740-5065

 Quantity:
 50 tests

Controls: Normal fallopian tube

Clone Name: FOLR1-2 Species: Mouse

Localization: Membranous and cytoplasmic

Regulatory Status: IVD

INTENDED USE

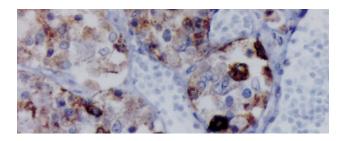
VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens by light microscopy. This assay is for use with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument. FOLR1 expression clinical cutoff is ≥75% viable tumor cells (TC) with membrane staining at moderate and/or strong intensity levels. This assay is indicated as an aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who may be eligible for treatment with ELAHERE (mirvetuximab soravtansine). Test results of the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay 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.

${\bf Table~1.~VENTANA~FOLR1~(FOLR1-2.1)~RxDx~Assay~companion~diagnostic~indication.}$

 INDICATION FOR USE
 THERAPY
 EOC

 FOLR1 Cut-off
 ELAHERE (mirvetuximab soravtansine)
 ≥ 75% TC

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls and accessories. This product is intended for in vitro diagnostic (IVD) use.



FSH (polyclonal)

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

INTENDED USE

 ${\sf FSH}\ {\sf Rabbit}\ {\sf Polyclonal}\ {\sf Primary}\ {\sf Antibody}\ {\sf is}\ {\sf intended}\ {\sf for}\ {\sf laboratory}\ {\sf use}\ {\sf in}$

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)

Ordering Number: 05269164001 Catalog Number: 760-4256 Quantity: 50 tests

Controls: Papillary or Follicular Carcinoma of Thyroid

Isotypes: 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, 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.

Gastrin (polyclonal)

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

Regulatory Status:

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**

Ordering Number: 07107749001 Catalog Number: 760-4897 Quantity: 50 tests

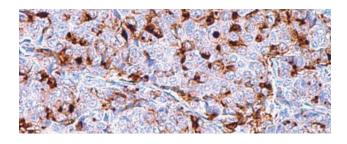
Controls: Ductal Carcinoma in situ

Isotypes: IgG L50-823 Clone Name: Species: Mouse Localization: Nuclear Regulatory 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, paraffinembedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a gualified 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

 Ordering Number:
 05463530001

 Catalog Number:
 760-4386

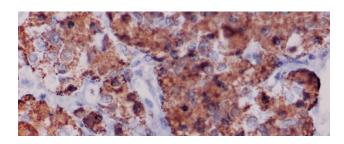
 Quantity:
 50 tests

Controls: Breast, Breast Carcinoma

Isotypes:IgGClone Name:EP1582YSpecies:RabbitLocalization:CytoplasmicRegulatory 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.

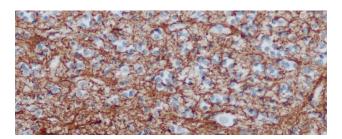


GH (polyclonal)

Ordering Number: 05268257001 Catalog Number: 760-2804 Quantity: 50 tests Controls: Normal Pituitary Clone Name: Polyclonal Species: Rabbit Localization: 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)

05269784001 Ordering Number: Catalog Number: 760-4345 Quantity: 50 tests Controls: Brain Isotypes: IgG Clone Name: EP672Y Rabbit Species: 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.

GLUT1 Rabbit Polyclonal Antibody

Ordering Number: 06419178001 Catalog Number: 760-4526 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.

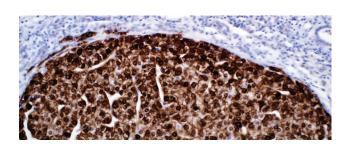
Glutamine Synthetase (GS-6) Mouse Monoclonal **Primary Antibody**

Ordering Number: 07107757001 760-4898 Catalog Number: Quantity: 50 tests

Controls: Hepatocellular Carcinoma

Isotypes: IgG Clone Name: GS-6 Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



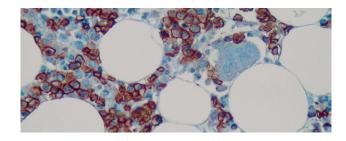
INTENDED USE

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)

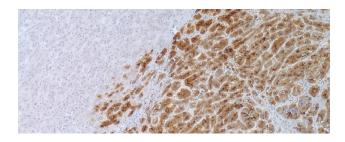
05269172001 Ordering Number: Catalog Number: 760-4257 Quantity: 50 tests Controls: Bone Marrow Isotypes: IgG_{2a}/K Clone Name: GA-R2 Species: Mouse Localization: Membranous

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)

 Ordering Number:
 05973864001

 Catalog Number:
 760-4442

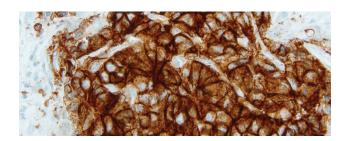
 Quantity:
 50 tests

Controls: Hepatocellular Carcinoma

Isotypes:IgG1Clone Name:1G12Species:MouseLocalization:CytoplasmicRegulatory 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

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

Controls: Placenta, Hepatocellular Carcinoma

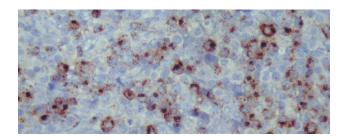
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{2a} \\ \textbf{Clone Name:} & \textbf{GC33} \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$

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)

 Ordering Number:
 05269466001

 Catalog Number:
 760-4283

 Quantity:
 50 tests

 Controls:
 Tonsil

 Clone Name:
 Polyclonal

 Species:
 Rabbit

Localization: Granular 2, Cytotoxic Thymphocytes,

Natural Killer Cells

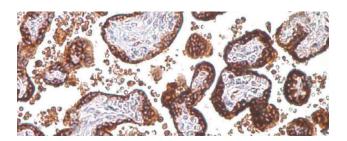
Regulatory Status: IVD

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.

hCG (polyclonal)

Ordering Number: 05267617001 Catalog Number: 760-2650 50 tests Quantity: 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

 Ordering Number:
 06425607001
 6425623001

 Catalog Number:
 790-1014
 790-1015

 Quantity:
 50 tests
 250 tests

Controls: Helicobacter pylori-Infected Stomach

Clone Name: SP48 Species: Rabbit

Localization: Whole *Helicobacter pylori* Organism

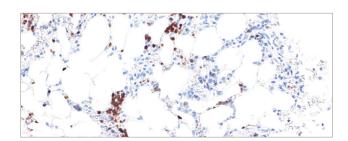
Regulatory Status: 510(k)

INTENDED USE

VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of Helicobacter pylori by light microscopy in sections of formalin-fixed, paraffin-embedded gastric biopsy tissue stained on a BenchMark IHC/ISH instrument. 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.

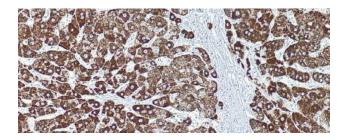


Ordering Number: 07292830001 Catalog Number: 760-4936 50 tests Quantity: Controls: Bone Marrow Isotypes: IgG Clone Name: SP212 Rabbit Species: Localization: Cytoplasmic **Regulatory Status:** IVD



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.

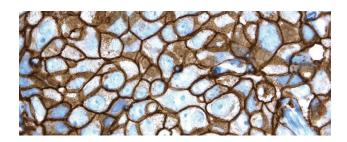


Hepatocyte Specific Antigen (Hep Par-1) (OCH1E5)

05269792001 **Ordering Number:** Catalog Number: 760-4350 Quantity: 50 tests Controls: Liver Isotypes: IgG₄/K Clone Name: OCH1E5 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

 Ordering Number:
 05278368001

 Catalog Number:
 790-2991

 Quantity:
 50 tests

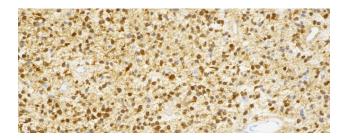
10 PATHWAY HER-2 4in1 Control Slides

Interpretation Guide
Controls: Breast Carcinoma

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

INTENDED USE

PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY anti-HER2 (4B5) antibody) is a rabbit monoclonal antibody intended for laboratory use for the semiquantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded normal and neoplastic breast tissue using the ultraView Universal DAB Detection Kit on a BenchMark ULTRA instrument. This IHC device is indicated for identifying breast cancer patients who are eligible for treatment with Herceptin® (IHC 3+ or IHC 2+/ISH amplified), KADCYLA® (IHC 3+ or IHC 2+/ISH amplified) or ENHERTU® (IHC 1+ or IHC 2+/ISH non-amplified). 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.



IDH1 R132H (MRQ-67) CM Rabbit Monoclonal Antibody

Ordering Number: 09433015001 Catalog Number: 760-7173 Quantity: 50 tests Controls: Brain Clone Name: MRQ-67 Species: Rabbit Localization: Cytoplasm **Regulatory Status:** IVD

INTENDED USE

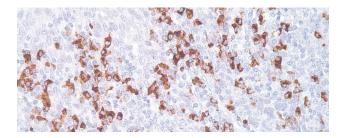
IDH1 R132H (MRQ-67) Rabbit Monoclonal Antibody is intended for laboratory use in the detection of the IDH1 R132H mutant protein in formalin-fixed, paraffin-embedded human tissue stained in qualitative immunohistochemistry on BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for *in* vitro diagnostic (IVD) use.

IgD (polyclonal)

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

Controls: Lymph Node, Tonsil

Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit
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.

IgG (polyclonal)

 Ordering Number:
 05267633001

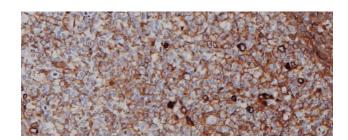
 Catalog Number:
 760-2653

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

Clone Name:PolyclonalSpecies:RabbitLocalization: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

 Ordering Number:
 06523854001

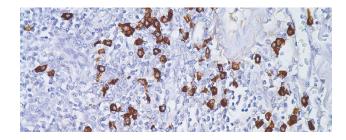
 Catalog Number:
 760-4614

 Quantity:
 50 tests

Controls: Tonsil, Plasma Cells

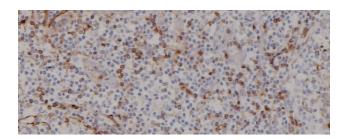
 $\begin{tabular}{lll} Isotypes: & IgG_1/K \\ Clone Name: & MRQ-44 \\ Species: & Mouse \\ Localization: & Cytoplasmic \\ \end{tabular}$

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)

 Ordering Number:
 05267641001

 Catalog Number:
 760-2654

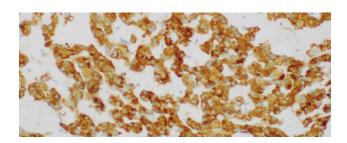
 Quantity:
 50 tests

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

 Ordering Number:
 08313474001

 Catalog Number:
 760-6081

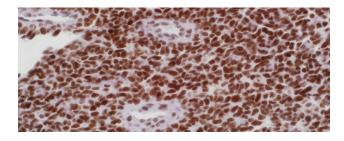
 Quantity:
 50 tests

Controls: Adrenal Cortex, Placenta, Testis

Isotypes:IgGClone Name:MRQ-63Species:RabbitRegulatory Status:IVD

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.



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

 Ordering Number:
 06523862001

 Catalog Number:
 760-4615

 Quantity:
 50 tests

Controls: Brain, Endothelial Cells, Astrocytoma

Clone Name: MRQ-27 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, 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

 Ordering Number:
 05267013001

 Catalog Number:
 760-2514

 Quantity:
 50 tests

 Controls:
 Lymph Node, To

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.



05479266001 **Ordering Number:** Catalog Number: 790-4373 Quantity: 50 tests Controls: Prostate Isotypes: IgG. Clone Name: 34βE12 Species: Mouse Localization: Cytoplasmic Regulatory Status:



CONFIRM anti-Keratin (34βE12) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 5 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody

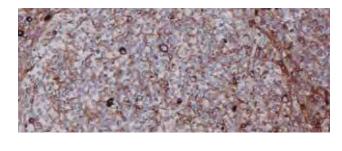
Ordering Number: 05278384001
Catalog Number: 790-4286
Quantity: 50 tests

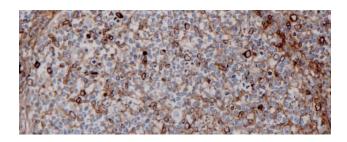
Controls: Lymph Node, Tonsil

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

INTENDED USE

CONFIRM anti-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of Ki-67 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

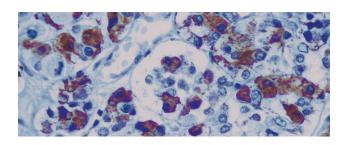
Ordering Number: 05267021001
Catalog Number: 760-2515
Quantity: 50 tests
Controls: Tonsil
Clone Name: Polyclonal
Species: Rabbit

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-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)

 Ordering Number:
 05268222001

 Catalog Number:
 760-2802

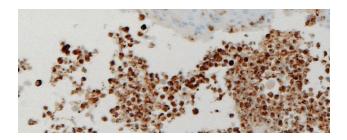
 Quantity:
 50 tests

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.



Lysozyme (polyclonal)

 Ordering Number:
 05267668001

 Catalog Number:
 760-2656

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

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

INTENDED USE

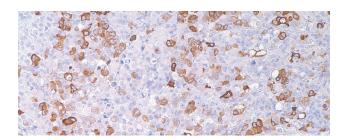
Lysozyme Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of lysozyme in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination,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

Mammaglobin (31A5)

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

Controls: Breast Carcinoma

Clone Name: 31A5 Species: Rabbit Localization: Cytoplasmic Regulatory Status: IVD



INTENDED USE

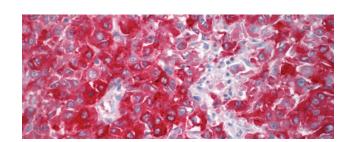
Mammaglobin (31A5) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the mammaglobin glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction 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**

Ordering Number: 05278350001 790-2990 Catalog Number: Quantity: 50 tests

Controls: Melanoma, Normal Skin

Isotypes: IgG, A103 Clone Name: Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD



INTENDED USE

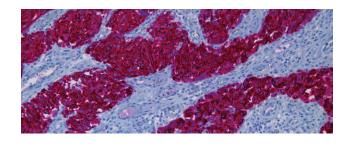
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgG,) directed against melan A. This antibody is designed to qualitatively detect the presence of melan 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 Triple Cocktail (HMB45+A103+T311) **Primary Antibody**

Ordering Number: 06527787001 Catalog Number: 790-4677 Quantity: 50 tests Controls: Melanoma HMB45+A103+T311 Clone Name:

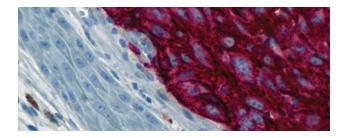
Species: N/A Localization: Cytoplasmic

Regulatory Status: IVD



INTENDED USE

Melanoma Triple Cocktail (HMB45+A103+T311) is a cocktail of anti-Melanosome (HMB45), anti-MART1/melan A (A103), and anti-Tyrosinase (T311) mouse monoclonal antibodies. Melanoma Triple Cocktail (HMB45+A103+T311) is intended for laboratory use in the qualitative immunohistochemical detection of premelanosome protein (PMEL), melan A, and tyrosinase by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

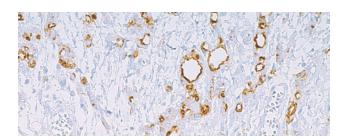
Ordering Number: 05479282001
Catalog Number: 790-4366
Quantity: 50 tests
Controls: Melanoma, Skin
Isotypes: IgG,/K

 $\begin{tabular}{lll} Isotypes: & IgG_1/K \\ Clone Name: & HMB45 \\ Species: & Mouse \\ Localization: & Cytoplasmic \\ \end{tabular}$

Regulatory Status: IVD

INTENDED USE

CONFIRM anti-Melanosome (HMB45) is a mouse monoclonal antibody intended for laboratory use in the qualitative immunohistochemical detection of premelanosome protein (PMEL) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.



Mesothelial Cell (HBME-1)

Ordering Number: 05973813001
Catalog Number: 760-4445
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.

VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody

 Ordering Number:
 07862237001

 Catalog Number:
 790-5091

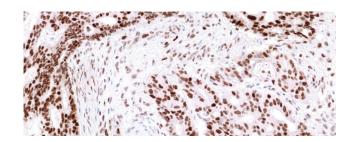
 Quantity:
 50 tests

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 PART 1

VENTANA MMR RxDx Panel

VENTANA MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy. The OptiView DAB IHC Detection Kit is used for MLH1, MSH2 and MSH6, and the OptiView DAB IHC Detection Kit with the OptiView Amplification Kit is used for PMS2 on a VENTANA BenchMark ULTRA instrument. VENTANA MMR RxDx 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, and VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody. VENTANA MMR RxDx Panel is indicated as an aid in identifying patients eligible for treatment with the therapies listed in Table 1 for the indication and MMR status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA MMR RxDx Panel Companion Diagnostic Indications

 INDICATION FOR USE
 THERAPY Status
 MMR Status

 Solid Tumors
 JEMPERLI (dostarlimab-gxly)
 deficient MMR (dMMR)

 Solid Tumors
 JEMPERLI (dostarlimab-gxly)
 deficient MMR (dMMR)

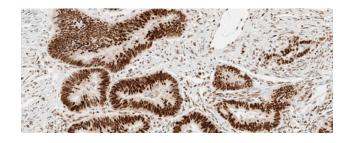
 Endometrial Carcinoma (EC)
 KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib)
 proficient MMR (pMMR)

Results of the VENTANA MMR RxDx Panel 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.

INTENDED USE PART 2

VENTANA MMR IHC Panel

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. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.



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

 Ordering Number:
 07862253001

 Catalog Number:
 790-5093

 Quantity:
 50 tests

Controls: CRC tissue with an MSH2 Clinical Status of

Intact or normal colon tissue pre-qualified with VENTANA anti-MSH2 (G219-1129) antibody

MMR Status

 Isotypes:
 IgG₁

 Clone Name:
 G219-1129

 Species:
 Mouse

 Localization:
 Nuclear

 Regulatory Status:
 IVD

INTENDED USE PART 1

VENTANA MMR RxDx Panel

VENTANA MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy. The OptiView DAB IHC Detection Kit is used for MLH1, MSH2 and MSH6, and the OptiView DAB IHC Detection Kit with the OptiView Amplification Kit is used for PMS2 on a VENTANA BenchMark ULTRA instrument. VENTANA MMR RxDx Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, and VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody. VENTANA MMR RxDx Panel is indicated as an aid in identifying patients eligible for treatment with the therapies listed in Table 1 for the indication and MMR status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA MMR RxDx Panel Companion Diagnostic Indications INDICATION FOR USE THERAPY Status

 Solid Tumors
 JEMPERLI (dostarlimab-gxly)
 deficient MMR (dMMR)

 Solid Tumors
 KEYTRUDA (pembrolizumab)
 deficient MMR (dMMR)

 Endometrial Carcinoma (EC)
 KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib)
 proficient MMR (pMMR)

Results of the VENTANA MMR RxDx Panel 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.

INTENDED USE PART 2

VENTANA MMR IHC Panel

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. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.

VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody

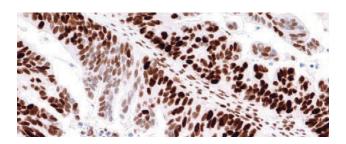
Ordering Number: 07862245001
Catalog Number: 790-5092
Quantity: 50 tests

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 PART 1

VENTANA MMR RXDX Panel

VENTANA MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy. The OptiView DAB IHC Detection Kit is used for MLH1, MSH2 and MSH6, and the OptiView DAB IHC Detection Kit with the OptiView Amplification Kit is used for PMS2 on a VENTANA BenchMark ULTRA instrument. VENTANA MMR RxDx 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, and VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody. VENTANA MMR RxDx Panel is indicated as an aid in identifying patients eligible for treatment with the therapies listed in Table 1 for the indication and MMR status in accordance with the approved therapeutic product labeling.

INTENDED USE PART 2

VENTANA MMR IHC Panel

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 MRR 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. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.

anti-MUC1 (H23) Mouse Monoclonal Primary Antibody

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

Controls: Breast, Lung, Pancreas

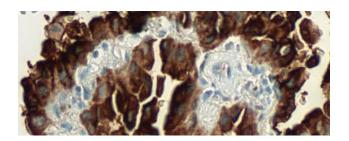
Isotypes:IgGClone Name:H23Species:Mouse

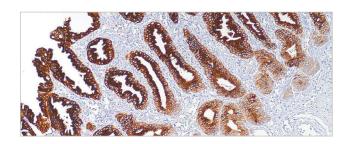
Localization: Membranous, Cytoplasmic

Regulatory Status: IVD



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)

 Ordering Number:
 05463556001

 Catalog Number:
 760-4388

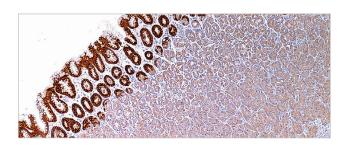
 Quantity:
 50 tests

Controls: Colon, Colon Adenocarcinoma

 $\begin{tabular}{lll} \textbf{Isotypes:} & IgG_1/K \\ \textbf{Clone Name:} & MRQ-18 \\ \textbf{Species:} & Mouse \\ \textbf{Localization:} & Cytoplasmic \\ \textbf{Regulatory Status:} & IVD \\ \end{tabular}$

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)

 Ordering Number:
 05463564001

 Catalog Number:
 760-4389

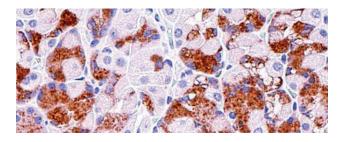
 Quantity:
 50 tests

Controls: Associated Adenocarcinomas, Stomach

Isotypes: IgG₁
Clone Name: MRQ-19
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

MUC5AC (MRQ-19) Mouse Monoclonal 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)

 Ordering Number:
 05463572001

 Catalog Number:
 760-4390

 Quantity:
 50 tests

Controls: Associated Adenocarcinomas, Stomach

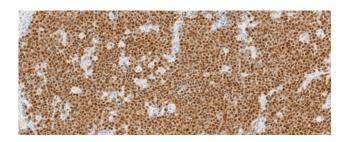
Isotypes: IgG₁
Clone Name: MRQ-20
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

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.

MUM1 (EP190) Rabbit Monoclonal Primary Antibody

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

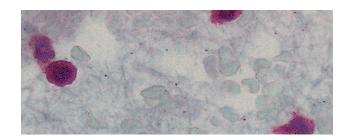


INTENDED USE

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.

Myeloperoxidase (polyclonal)

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

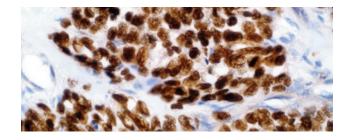
 Ordering Number:
 07107773001

 Catalog Number:
 760-4900

 Quantity:
 50 tests

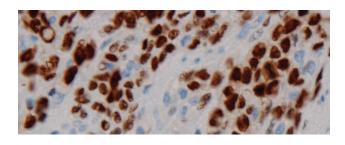
Controls: Rhabdomyosarcoma

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, 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.



Myogenin (F5D)

 Ordering Number:
 05268290001

 Catalog Number:
 760-2832

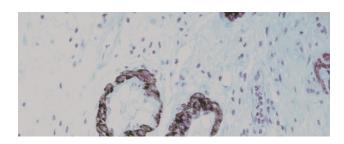
 Quantity:
 50 tests

Controls: Rhabdomyosarcoma

 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_{1}/\textbf{K} \\ \textbf{Clone Name:} & \textbf{F5D} \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Nuclear} \\ \textbf{Regulatory Status:} & \textbf{IVD} \\ \end{array}$

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.

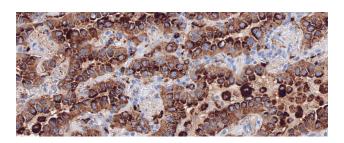


Myosin, Smooth Muscle (SMMS-1)

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

INTENDED USE

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

 Ordering Number:
 07047720001

 Catalog Number:
 760-4867

 Quantity:
 50 tests

Controls: Lung Adenocarcinoma, Renal Cell Carcinoma

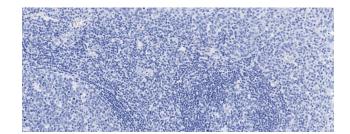
 $\begin{tabular}{lll} \textbf{Isotypes:} & IgG_1/IK \\ \textbf{Clone Name:} & MRQ-60 \\ \textbf{Species:} & Mouse \\ \textbf{Localization:} & Cytoplasmic \\ \textbf{Regulatory Status:} & IVD \\ \end{tabular}$

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, 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.

Negative Control (Monoclonal)

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



INTENDED USE

Regulatory Status:

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

IVD

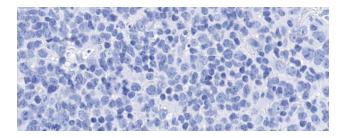
 Ordering Number:
 05266238001

 Catalog Number:
 760-1029

 Quantity:
 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)

 Ordering Number:
 05463599001

 Catalog Number:
 760-4391

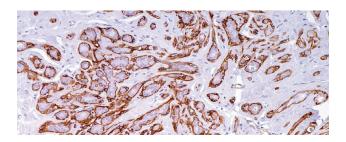
 Quantity:
 50 tests

Controls: Ganglia, Neurons, Malignant Melanoma Cells,

Myoepithelial Cells of Breast Ducts

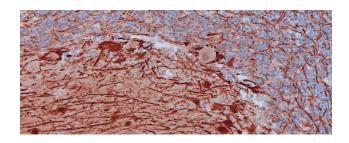
Isotypes:IgG1Clone Name:MRQ-21Species:MouseLocalization:Cytoplasmic

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.

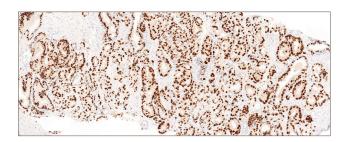


Neurofilament (2F11)

05267714001 **Ordering Number:** Catalog Number: 760-2661 Quantity: 50 tests Controls: Brain Isotypes: lgG₁/K Clone Name: 2F11 Species: Mouse Localization: Cytoplasmic **Regulatory Status:** IVD

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.



NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 07859759001

 Catalog Number:
 760-5086

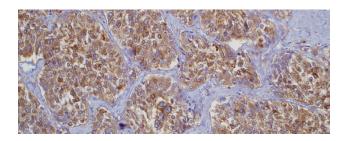
 Quantity:
 50 tests

Controls: Prostate, Prostate Adenocarcinoma

Isotypes:IgGClone Name:EP356Species:RabbitLocalization:NuclearRegulatory 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

 Ordering Number:
 06648568001

 Catalog Number:
 760-4786

 Quantity:
 50 tests

Controls: Pancreas, Carcinoid Tumor

Clone Name: MRQ-55
Species: Mouse
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)

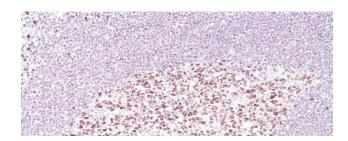
 Ordering Number:
 05973791001

 Catalog Number:
 760-4447

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

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



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)

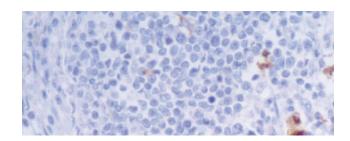
 Ordering Number:
 05463602001

 Catalog Number:
 760-4392

 Quantity:
 50 tests

Controls: Dysgerminoma, Seminoma

Isotypes:IgGClone Name:MRQ-10Species:MouseLocalization:NuclearRegulatory Status:IVD

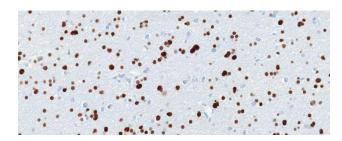


INTENDED USE

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.

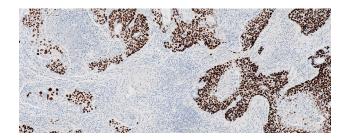
Olig2 (EP112) Rabbit Monoclonal Primary Antibody

Ordering Number: 07667973001 760-5050 Catalog Number: Quantity: 50 tests Controls: Astrocytoma Isotypes: lgG Clone Name: EP112 Species: Rabbit Localization: Nuclear Regulatory 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, 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

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

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

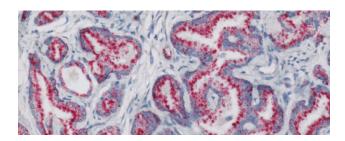
(IgG, IgA...) : IgG,

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

Isotypes:

INTENDED USE

Anti-p40 (BC28) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the p40 protein by light microscopy in formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.

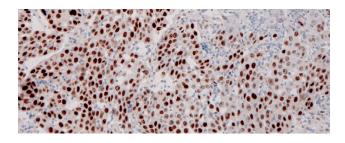


anti-p504s (SP116) Rabbit Monoclonal Primary Antibody

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

INTENDED USE

Anti-p504s (SP116) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of α-methylacyl-CoA racemase (AMACR, also known as p504s) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 05267102001

 Catalog Number:
 760-2542

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

Isotypes: IgG_{2a}
Clone Name: Bp-53-11
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE

Anti-p53 (Bp53-11) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of p53 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. 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.

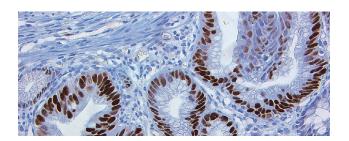
CONFIRM anti-p53 (DO-7) Primary Antibody

 Ordering Number:
 05278074001

 Catalog Number:
 790-2912

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma

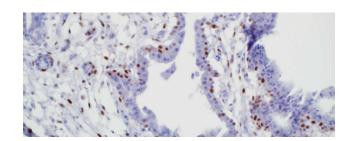


INTENDED USE

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^{Kip2} (Kp10) Mouse Monoclonal Primary Antibody

06523897001 **Ordering Number:** Catalog Number: 760-4617 Quantity: 50 tests Controls: Placenta Isotypes: IgG_{2h}/K Kp10 Clone Name: Species: Mouse Localization: Nuclear Regulatory Status: IVD



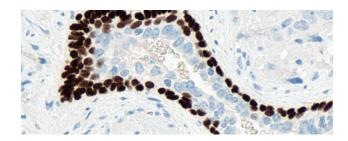
INTENDED USE

p57 ^{Kip2} (Kp10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the p57 ^{Kip2} 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-p63 (4A4) Mouse Monoclonal Primary Antibody

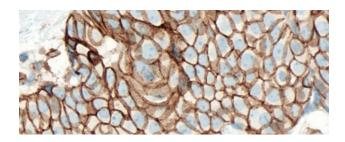
Ordering Number:05867061001Catalog Number:790-4509Quantity:50 testsControls:Prostate, TonsilIsotypes: IgG_{2a}/K Clone Name:404

Clone Name: 4A4
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD



INTENDED USE

VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the p63 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 05867088001

 Catalog Number:
 790-4517

 Quantity:
 50 tests

Controls: Normal Ducts of the Breast

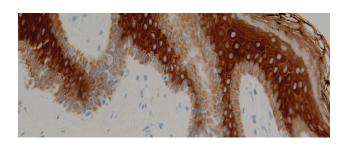
 $\begin{array}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & 98 \\ \textbf{Species:} & \textbf{Mouse} \\ \end{array}$

Localization: Membranous (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

 Ordering Number:
 05266840001
 5267145001

 Catalog Number:
 760-2135
 760-2595

 Quantity:
 250 tests
 50 tests

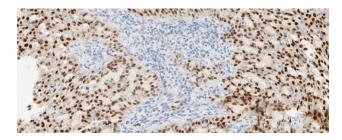
Controls: Intestine, Liver IgG_1

Clone Name: AE1/AE3 & PCK26

Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody is an antibody cocktail intended for laboratory use in the qualitative immunohistochemical detection of most acidic cytokeratins and all basic cytokeratins by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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 pan-TRK (EPR17341) Assay

Ordering Number: 08494665001
Catalog Number: 790-7026
Quantity: 50 tests

Controls: Appendix, Cerebellum

Clone Name: EPR17341 Species: Rabbit

Localization: Cytoplasmic, Membranous, Nuclear

Regulatory Status: IVD

INTENDED USE

VENTANA pan-TRK (EPR17341) Assay is intended for the immunohistochemical detection of the C-terminal region of the tropomyosin receptor kinase (TRK) proteins A, B and C, which is known to be conserved across wild-type and chimeric fusion proteins, in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues 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.

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

 Ordering Number:
 06419224001

 Catalog Number:
 760-4532

 Quantity:
 50 tests

 Controls:
 Parathyroid

 Isotypes:
 IgG_{2a}

 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)

 Ordering Number:
 06523927001

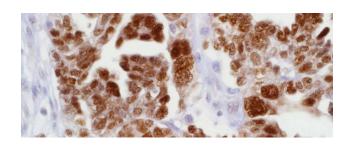
 Catalog Number:
 760-4618

 Quantity:
 50 tests

Controls: Thyroid Carcinoma, Ovarian Carcinoma (Non-

Mucinous Carcinoma)

Isotypes:IgGClone Name:MRQ-50Species:MouseLocalization:NuclearRegulatory 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.

PAX-8 (EP331) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 08313431001

 Catalog Number:
 760-6077

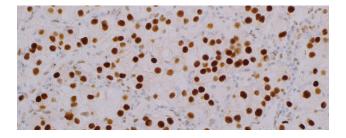
 Quantity:
 50 tests

Controls: Clear Cell Renal Cell Carcinoma,

Thyroid Carcinoma, Ovarian Carcinoma (non-

mucinous carcinoma)

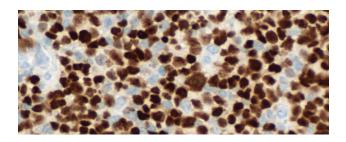
Isotypes:IgGClone Name:EP331Species:RabbitLocalization:Nuclear



Regulatory Status: IVD

INTENDED USE

PAX-8 (EP331) Rabbit 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.

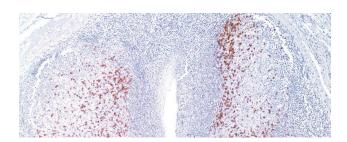


CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody

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

INTENDED USE

CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of PAX5 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

 Ordering Number:
 07099029001

 Catalog Number:
 760-4895

 Quantity:
 50 tests

Controls: Lymph Node, Tonsil

 Isotypes:
 IgG₁

 Clone Name:
 NAT105

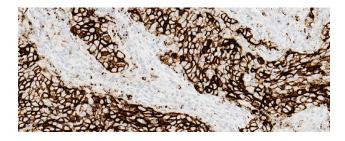
 Species:
 Mouse

 Localization:
 Cytoplasmic

 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, 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 PD-L1 (SP142) Assay

 Ordering Number:
 07709374001

 Catalog Number:
 740-4859

 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 programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor-infiltrating immune cells in the formalin-fixed, paraffin-embedded (FFPE) tissues indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a 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. VENTANA PD-L1 (SP142) Assay is indicated as an aid for identifying patients for treatment with the therapies for the respective cutoffs listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. Companion diagnostic indications for the VENTANA PD-L1 (SP142) Assay

INDICATION FOR USE THERAPY CUTOFF

Non-Small Cell Lung Cancer (NSCLC) TECENTRIQ \geq 50% TC or \geq 10% IC

Depending on therapeutic setting, PD-L1 expression in \geq 50% TC or \geq 10% IC determined by VENTANA PD-L1 (SP142) Assay in non-small cell lung cancer (NSCLC) patients may be associated with enhanced overall survival from TECENTRIQ (atezolizumab). Refer to the approved therapeutic product labeling for further information. Test results of 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 PD-L1 (SP263) Assay

Ordering Number: 07208162001
Catalog Number: 740-4907
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 immunohistochemistry assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the programmed death ligand-1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue specimens by light microscopy. The VENTANA PD-L1 (SP263) Assay is used with the OptiView DAB IHC Detection Kit for staining on the BenchMark ULTRA instrument. PD-L1 protein expression in NSCLC is determined by the percentage of tumor cells (% TC) with any membrane staining above background. VENTANA PD-L1 (SP263) Assay is indicated as an aid in identifying patients eligible for treatment with the therapy listed in Table 1 for the indication and PD-L1 status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA PD-L1 (SP263) Assay Companion Diagnostic Indication

INDICATION FOR USEPD-L1 CUTOFFTHERAPYNSCLC≥ 1% TCTECENTRIQ®
(atezolizumab)

Results of the VENTANA PD-L1 (SP263) Assay 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 PD-L1 (SP263) Rabbit Monoclonal Primary Antibody

Ordering Number: 07494190001
Catalog Number: 790-4905
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) 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.

PGP 9.5 Rabbit Polyclonal Antibody

 Ordering Number:
 05973953001

 Catalog Number:
 760-4434

 Quantity:
 50 tests

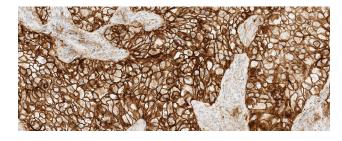
Controls: Bowel Wall (Interstitial Cells of Cajal),

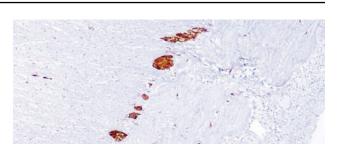
Nerve Tissue

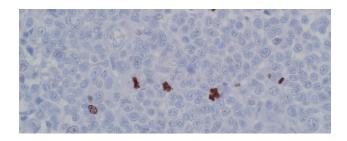
Isotypes:IgGClone Name:PolyclonalSpecies:RabbitLocalization:CytoplasmicRegulatory Status:IVD

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, 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.







Phosphohistone H3 (PHH3)

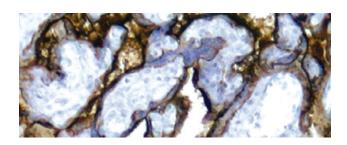
Ordering Number: 06433405001
Catalog Number: 760-4591
Quantity: 50 tests
Controls: Tonsil
Clone Name: PHH3

Species: Rabbit Polyclonal

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)

Ordering Number: 05267757001 Catalog Number: 760-2664 Quantity: 50 tests Controls: Placenta Isotypes: IgG NB10 Clone Name: 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, 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-PMS2 (A16-4) Mouse Monoclonal Primary Antibody

 Ordering Number:
 07862261001

 Catalog Number:
 790-5094

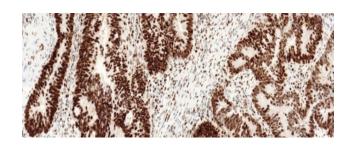
 Quantity:
 50 tests

Controls: CRC tissue with a PMS2 Clinical Status of

Intact or normal colon tissue pre-qualified with

VENTANA anti-PMS2 (A16-4) antibody

 $\begin{tabular}{lll} \textbf{Isotypes:} & \textbf{IgG}_1 \\ \textbf{Clone Name:} & \textbf{A16-4} \\ \textbf{Species:} & \textbf{Mouse} \\ \textbf{Localization:} & \textbf{Nuclear} \\ \textbf{Regulatory Status:} & \textbf{IVD} \\ \end{tabular}$



INTENDED USE PART 1 VENTANA MMR RxDx Panel

VENTANA MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy. The OptiView DAB IHC Detection Kit is used for MLH1, MSH2 and MSH6, and the OptiView DAB IHC Detection Kit with the OptiView Amplification Kit is used for PMS2 on a VENTANA BenchMark ULTRA instrument. VENTANA MMR RxDx Panel includes VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody, and VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody. VENTANA MMR RxDx Panel is indicated as an aid in identifying patients eligible for treatment with the therapies listed in Table 1 for the indication and MMR status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA MMR RxDx Panel Companion Diagnostic Indications

 INDICATION FOR USE
 THERAPY Status
 MMR Status

 Solid Tumors
 JEMPERLI (dostarlimab-gxly)
 deficient MMR (dMMR)

 Solid Tumors
 KEYTRUDA (pembrolizumab)
 deficient MMR (dMMR)

 Endometrial Carcinoma (EC)
 KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib)
 proficient MMR (pMMR)

Results of the VENTANA MMR RxDx Panel 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.

INTENDED USE PART 2

VENTANA MMR IHC Panel

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. Intended for in vitro diagnostic (IVD) use. Prescription Use Only.

Podoplanin (D2-40) Mouse Monoclonal Antibody

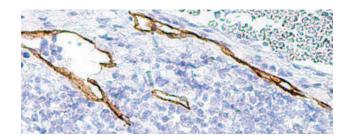
 Ordering Number:
 05463645001

 Catalog Number:
 760-4395

 Quantity:
 50 tests

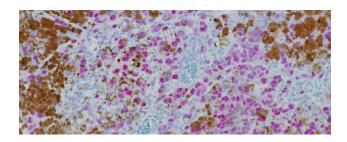
Controls: Lymph Node, Lymphangioma

Isotypes:IgG1Clone Name:D2-40Species:MouseLocalization:CytoplasmicRegulatory Status:IVD



INTENDED USE

Podoplanin (D2-40) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Podoplanin 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-PRAME (EPR20330) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 09592237001
 09592245001

 Catalog Number:
 790-7149
 790-7150

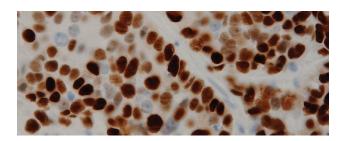
 Quantity:
 50 tests
 250 tests

Controls: Normal Testis, Positively Staining Melanomas

Isotypes:IgGClone Name:EPR20330Species:RabbitLocalization:NuclearRegulatory Status:IVD

INTENDED USE

Anti-PRAME (EPR20330) Rabbit Monoclonal Primary Antibody (anti-PRAME (EPR20330) antibody) is intended for laboratory use in the qualitative immunohistochemical detection of PRAME by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 05277990001
 5278392001

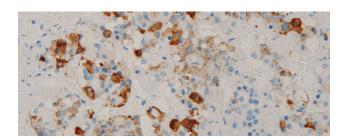
 Catalog Number:
 790-2223
 790-4296

 Quantity:
 50 tests
 250 tests

Controls:BreastIsotypes:IgGClone Name:1E2Species:RabbitLocalization:NuclearRegulatory 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 anti-PR (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)

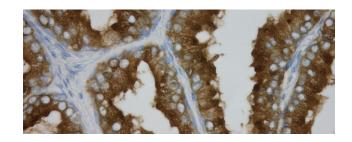
Ordering Number: 05268249001 Catalog Number: 760-2803 50 tests Quantity: Controls: Normal Pituitary Clone Name: Polyclonal Species: Rabbit Localization: Cytoplasmic **Regulatory Status:** IVD

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

05266939001 **Ordering Number:** 760-2506 Catalog Number: Quantity: 50 tests Controls: Prostate Isotypes: IgG 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.

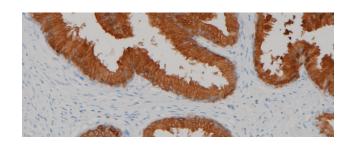
PSA (ER-PR8)

Ordering Number: 05269334001 760-4271 Catalog Number: Quantity: 50 tests

Controls: Prostate Adenocarcinoma

Isotypes: IgG₁/K ER-PR8 Clone Name: Species: Mouse Localization: Cytoplasmic

Regulatory Status: IVD



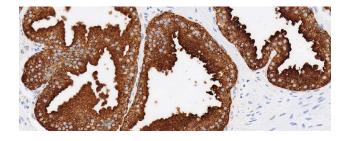
INTENDED USE

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)

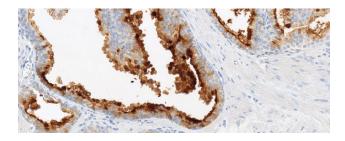
05269342001 **Ordering Number:** Catalog Number: 760-4272 Quantity: 50 tests Controls: Prostate Isotypes: IgG. Clone Name: PASE/4LJ Species: Mouse Localization: Cytoplasmic

Regulatory Status:



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

 Ordering Number:
 08313423001

 Catalog Number:
 760-6076

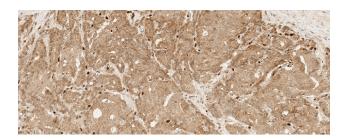
 Quantity:
 50 tests

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, 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 PTEN (SP218) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 07970200001

 Catalog Number:
 790-5097

 Quantity:
 50 tests

Controls: Pancreatic Islet Cells

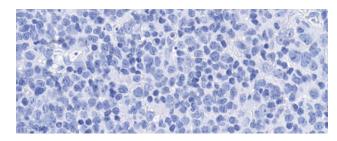
Isotypes:IgGClone Name:SP218Species:Rabbit

Localization: Cytoplasmic and/or Nuclear

Regulatory Status: IVD

INTENDED USE

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

 Ordering Number:
 06683380001

 Catalog Number:
 790-4795

 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)

 Ordering Number:
 05269369001

 Catalog Number:
 760-4273

 Quantity:
 50 tests

Controls: Kidney, Renal Cell Carcinoma

Isotypes: IgG_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.



 Ordering Number:
 08404160001

 Catalog Number:
 790-6087

 Quantity:
 50 tests

Controls: Reactive alveolar type II pneumocytes (positive)

ROS1 positive cell lines (positive)

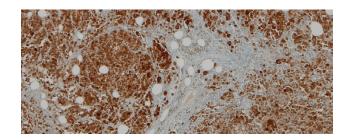
Clone Name: SP384
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative detection of ROS1 protein in formalin-fixed, paraffin-embedded tissue stained with 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.

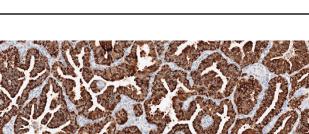
CONFIRM anti-S100 (4C4.9) Primary Antibody

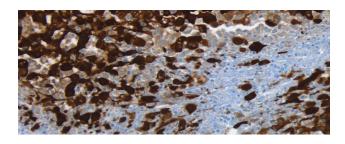
Ordering Number: 05278104001 790-2914 Catalog Number: Quantity: 50 tests Controls: Melanoma Isotypes: IgG, 4C4.9 Clone Name: Species: Mouse Localization: Cytoplasmic Regulatory Status: IVD



INTENDED USE

CONFIRM anti-S100 (4C4.9) Primary Antibody is a mouse monoclonal antibody intended for laboratory use in the qualitative immunohistochemical detection of S100 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. 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.



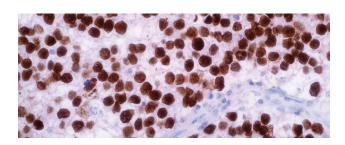


CONFIRM anti-S100 (Polyclonal) Primary Antibody

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

INTENDED USE

CONFIRM anti-S100 (Polyclonal) Primary Antibody is a rabbit polyclonal antibody intended for laboratory use in the qualitative immunohistochemical detection of S100 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. 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.

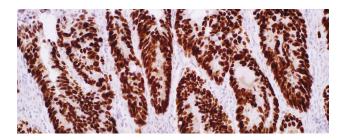


SALL4 (6E3) Mouse Monoclonal Primary Antibody

Ordering Number: 07047690001 Catalog Number: 760-4864 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.



SATB2 (EP281) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 08313415001

 Catalog Number:
 760-6075

 Quantity:
 50 tests

Controls: Colon Adenocarcinoma, Colon

Clone Name: EP281
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

INTENDED USE

SATB2 (EP281) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SATB2 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.

SF-1 (EP434) Rabbit Monoclonal Primary Antibody

 Ordering Number:
 09345892001

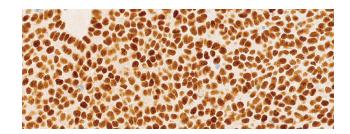
 Catalog Number:
 760-7172

 Quantity:
 50 tests

Controls: Testis, Adrenocortical carcinoma (ACC),

Granulosa cell tumor

Clone Name: EP434
Species: Rabbit
Localization: Nucelus
Regulatory Status: IVD



INTENDED USE

SF-1 (EP434) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the steroidogenic factor-1 protein in formalin-fixed, paraffin-embedded human tissue stained in qualitative immunohistochemistry on 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)

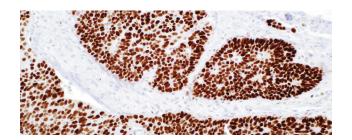
 Ordering Number:
 06523943001

 Catalog Number:
 760-4621

 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

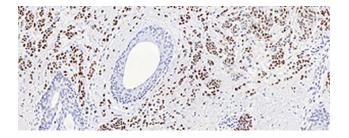
 Ordering Number:
 07560389001

 Catalog Number:
 760-4968

 Quantity:
 50 tests

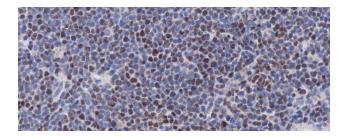
Controls: Melanoma, Skin Melanocytes

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, 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.



SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody

 Ordering Number:
 07047738001

 Catalog Number:
 760-4868

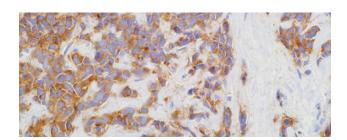
 Quantity:
 50 tests

Controls: Mantle Cell Lymphoma

Isotypes:IgG1Clone Name:MRQ-58Species:MouseLocalization:NuclearRegulatory 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, 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.



Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody

Ordering Number: 06433324001
Catalog Number: 760-4595
Quantity: 50 tests

Controls: Pancreatic Islet Cells

 Isotypes:
 IgG1

 Clone Name:
 MRQ-40

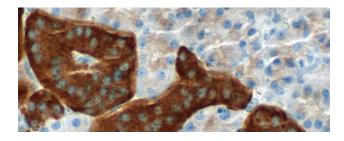
 Species:
 Rabbit

 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

Ordering Number: 05479304001
Catalog Number: 790-4407
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, paraffinembedded 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.

TAG-72 (B72.3)

 Ordering Number:
 05267803001

 Catalog Number:
 760-2669

 Quantity:
 50 tests

Controls: Breast Carcinoma

 $\begin{tabular}{lll} Isotypes: & IgG_1/K \\ Clone Name: & B72.3 \\ Species: & Mouse \\ Localization: & Cytoplasmic \\ \end{tabular}$

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)

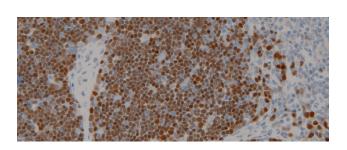
 Ordering Number:
 05267811001

 Catalog Number:
 760-2670

 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

 Ordering Number:
 06523951001

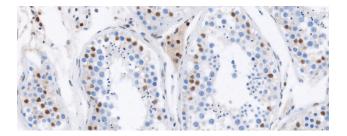
 Catalog Number:
 760-4622

 Quantity:
 50 tests

Controls: Testis (Germ Cells), XP11.2 Translocation Renal

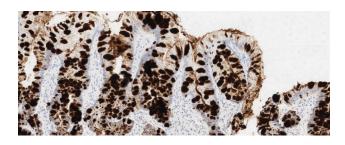
Cell

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.



VENTANA TFF3 (7F1.21) Mouse Monoclonal Primary Antibody

 Ordering Number:
 07712812001

 Catalog Number:
 790-5059

 Quantity:
 50 tests

Controls: Normal Small Intestine Cell

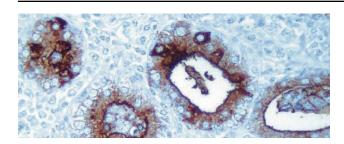
Clone Name: TF1.21 Species: Mouse

Localization: Cytoplasm, Membrane

Regulatory Status: IVD

INTENDED USE

The VENTANA TFF3 (7F1.21) Mouse Monoclonal Primary Antibody (VENTANA TFF3 (7F1.21)) is directed against a cytoplasmic epitope of the trefoil factor family 3 (TFF3) protein present in epithelial cells. This antibody may be used to aid in the identification of intestinal metaplasia (IM) of the esophagus. The antibody is intended for qualitative staining in sections of fixed, paraffin-embedded clinical samples stained with a BenchMark ULTRA automated staining instrument. The clinical interpretation of any staining, or the absence of staining, must be complemented by histological/cytological 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.

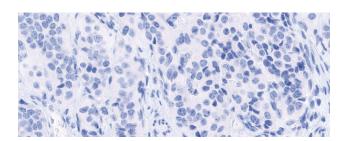


Thyroglobulin (2H11+6E1)

Ordering Number: 05267820001 Catalog Number: 760-2671 50 tests Quantity: Controls: Thyroid Isotypes: lgG₁ 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

Ordering Number: 05479312001
Catalog Number: 790-4398
Quantity: 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 is intended for laboratory use in the qualitative immunohistochemical detection of thyroid transcription factor-1 (TTF-1) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and with proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

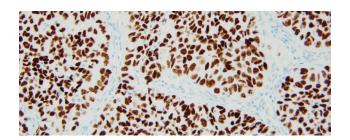
anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody

Ordering Number: 06640613001
Catalog Number: 790-4756
Quantity: 50 tests

Controls: Normal Thyroid, Lung Carcinoma, Normal Lung

Isotypes: IgG
Clone Name: SP141
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

Alternate Names: Thyroid Transcription Factor - 1

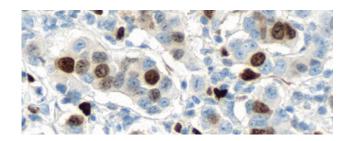


INTENDED USE

Anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of thyroid transcription factor-1 (TTF-1) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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

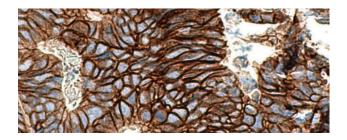
Ordering Number: 05479339001 Catalog Number: 790-4371 Quantity: 50 tests Controls: Spleen, Tonsil Clone Name: JS5B4 Species: Rabbit Localization: Nuclear Regulatory Status: IVD



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. 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. He 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 other diagnostic tests.

- 1. Kreipe H, Heidebrecht HJ, Hansen S, et al. A new proliferation-associated nuclear antigen detectable in paraffin-embedded tissues by monoclonal antibody Ki-S1. Am J Pathol. 1993;142(1):3-9.
- 2. Rudolph P, Lappe T, Schubert C, Schmidt D, Parwaresch R. Christophers E. Diagnostic assessment of two novel proliferation-specific antigens in benign and malignant melanocytic lesions. *Am J Pathol.* 1995;147(6):1615-1625.
- 3. Kreipe H, Alm P, Olson H, Hauberg M, Fischer L, Parwaresch R. Prognostic significance of a formalin-resistant nuclear proliferation antigen in mammary carcinomas as determined by the monoclonal antibody Ki-S1. *Am J Pathol.* 1993;142(2):651-657.
- 4. Kellner U, Heidebrecht HJ, Rudolph P, et al. Detection of human topoisomerase II alpha in cell lines and tissues: characterization of five novel monoclonal antibodies. *J Histochem Cytochem*. 1997;45(2):251-263.



CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody

Ordering Number: 05571219001
Catalog Number: 790-4430
Quantity: 50 tests

Controls: Kidney, Non-Small Cell Lung Carcinoma, Gastric

Carcinoma

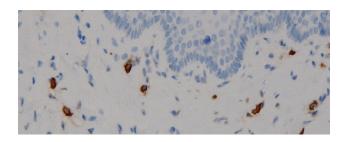
Clone Name: SP44 Species: Rabbit

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.



Tryptase (G3)

 Ordering Number:
 05269393001

 Catalog Number:
 760-4276

 Quantity:
 50 tests

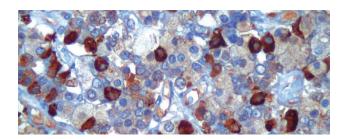
Controls: Mast Cell-Containing Tissue

Isotypes: IgG₁
Clone Name: G3
Species: Mouse
Localization: Cytoplasmic

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)

05268184001 Ordering Number: Catalog Number: 760-2709 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

Ordering Number: 05479347001
Catalog Number: 790-4365
Quantity: 50 tests
Controls: Lung, Melanoma

 $\begin{array}{lll} \text{Isotypes:} & \text{IgG}_{\text{2a}} \\ \text{Clone Name:} & \text{T311} \\ \text{Species:} & \text{Mouse} \\ \text{Localization:} & \text{Cytoplasmic} \end{array}$



INTENDED USE

CONFIRM anti-Tyrosinase (T311) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of tyrosinase by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. 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.

Uroplakin III (SP73) Rabbit Monoclonal Antibody

 Ordering Number:
 06419232001

 Catalog Number:
 760-4533

 Quantity:
 50 tests

 Controls:
 Bladder

 Isotypes:
 IgG₁

 Clone Name:
 SP73

 Species:
 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)

 Ordering Number:
 05269407001

 Catalog Number:
 760-4277

 Quantity:
 50 tests

Controls: Colonic Mucosa, Small Bowel Mucosa

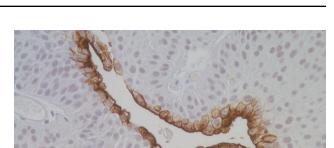
 $\begin{array}{lll} \textbf{Isotypes:} & & \text{IgG}_1 \\ \textbf{Clone Name:} & & \text{CWWB1} \\ \textbf{Species:} & & \text{Mouse} \\ \end{array}$

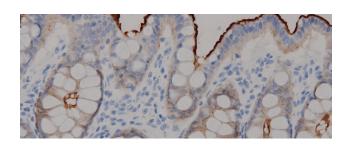
Localization: Cytoplasmic, Membranous

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, 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-Vimentin (V9) Primary Antibody

 Ordering Number:
 05278139001

 Catalog Number:
 790-2917

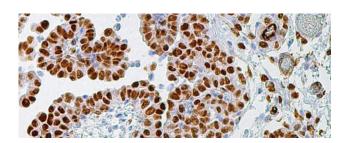
 Quantity:
 50 tests

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.



WT1 (6F-H2)

 Ordering Number:
 05435706001

 Catalog Number:
 760-4397

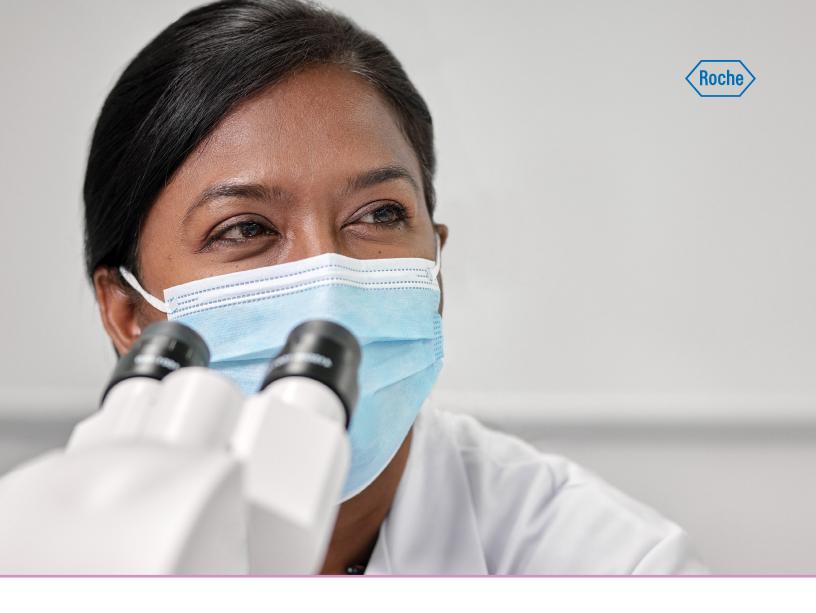
 Quantity:
 50 tests

Controls: Kidney, Testicle, Malignant Mesothelioma

 $\begin{tabular}{ll} \textbf{Isotypes:} & lgG_1/K \\ \textbf{Clone Name:} & 6F-H2 \\ \textbf{Species:} & Mouse \\ \textbf{Localization:} & Nuclear \\ \textbf{Regulatory Status:} & IVD \\ \end{tabular}$

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.



Detection Systems

Delivering solutions that empower healthcare professionals to confidently diagnose patient conditions

OptiView DAB IHC Detection

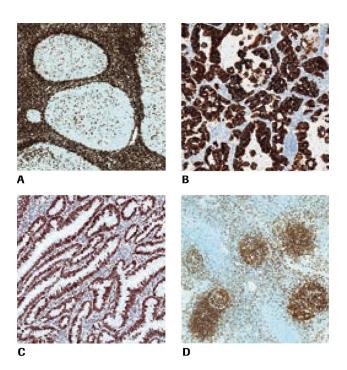
Innovative detection for enhanced stain quality

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.

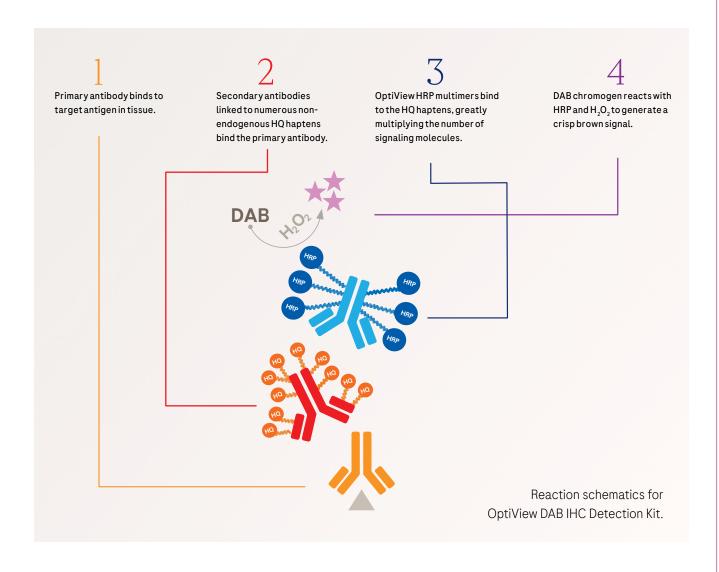
OptiView detection chemistry: our unique formula for success

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

 Ordering Code:
 05266114001

 Catalog Number:
 760-080

 Quantity:
 100 tests

 Regulatory Status:
 IVD

INTENDED USE

Ventana Medical Systems' (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 slide 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

 Ordering Code:
 06396518001
 06718663001

 Catalog Number:
 760-099
 860-099

 Quantity:
 50 tests
 250 tests

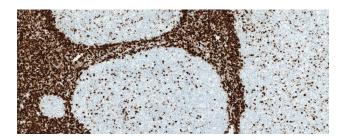
 Regulatory Status:
 IVD
 IVD

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, paraffinembedded 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.

OptiView DAB IHC Detection Kit

Ordering Code: 06396500001
Catalog Number: 760-700
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.

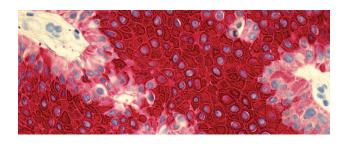
ultraView Universal Alkaline Phosphatase Red Detection Kit

 Ordering Code:
 05269814001

 Catalog Number:
 760-501

 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.

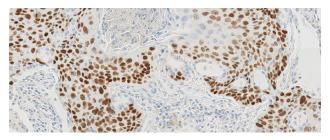
ultraView Universal DAB Detection Kit

 Ordering Code:
 05269806001

 Catalog Number:
 760-500

 Quantity:
 250 tests

 Regulatory Status:
 IVD



INTENDED USE

Ventana Medical Systems' (Ventana) *ultra* View 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.

ISH iVIEW Plus Detection Kit

 Ordering Code:
 05266181001

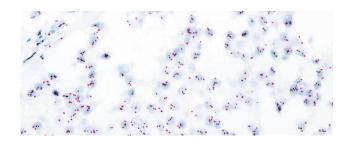
 Catalog Number:
 760-097

 Quantity:
 100 tests

 Regulatory Status:
 IVD

INTENDED USE

Ventana Medical Systems' (Ventana) ISH iVIEW 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 SISH DNP Detection Kit

 Ordering Code:
 05572037001

 Catalog Number:
 760-098

 Quantity:
 100 tests

 Regulatory Status:
 IVD

INTENDED USE

Ventana Medical Systems' (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.

VENTANA Silver ISH DNP Detection Kit

 Ordering Code:
 08318883001

 Catalog Number:
 760-516

 Quantity:
 60 tests

 Regulatory Status:
 IVD

INTENDED USE

The VENTANA Silver ISH DNP Detection Kit is an indirect system for detecting DNP labeled targets. 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 BenchMark IHC/ISH instruments. This product should be interpreted by a qualified reader in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA Red ISH DIG Detection Kit

 Ordering Code:
 08318832001

 Catalog Number:
 760-512

 Quantity:
 60 tests

 Regulatory Status:
 IVD

INTENDED USE

The VENTANA Red ISH DIG Detection Kit is an indirect system for detecting DIG-labeled targets. 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 BenchMark IHC/ISH instruments. This product should be interpreted by a qualified reader in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.



Special Staining Kits

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 Speci	cial Stains Guide
Special Stains for Mucin	
Diastase Kit	Mucicarmine Staining Kit
Light Green for PAS	PAS Staining Kit
Alcian Blue for PAS	Alcian Blue Staining Kit
Special Stains for Connective Tissue	
Special Stains Van Gieson CS	Jones Light Green Staining Kit
Green for Trichrome	Reticulum II Staining Kit
Jones H&E Staining Kit	Trichrome Staining Kit
Elastic Stain Core Kit	
Special Stains for Microorganisms	
GMS II Staining Kit	Steiner II Staining Kit
Gram Staining Kit	
Other Special Stains	
Congo Red Staining Kit	Iron Staining Kit
Giemsa Staining Kit	

For use on the VENTANA BenchMark Special Stains system.

BenchMark Special Stains bulk reagents and ancillary products

For additional information on these products, see page 161.

BenchMark Special Stains Wash II Ordering Code: 08309817001

Quantity: 1 Kit

BenchMark Special Stains Deparaffinization Solution (10X)

 Ordering Code:
 06523102001

 Catalog Number:
 860-036

 Quantity:
 2 L bottle

 Format:
 Concentrate

BenchMark Special Stains Cleaning Kit
Ordering Code: 09476580001
Catalog Number: 860-049
Format: Ready to Use

BenchMark Special Stains Liquid Coverslip

 Ordering Code:
 06523072001

 Catalog Number:
 860-034

 Quantity:
 2 L bottle

 Format:
 Ready to Use

Special Stains Rinse (SSR) Solution
Ordering Code: 06890059001
Catalog Number: 860-038
Quantity: 2 L bottle

Special Staining Kits for Mucin

Diastase Kit

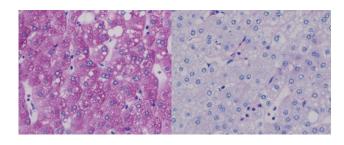
 Ordering Code:
 05279208001

 Catalog Number:
 860-004

 Quantity:
 75 tests

 Controls:
 Liver

For use on the BenchMark Special Stains.



INTENDED USE

The Diastase Kit, in conjunction with the PAS Staining Kit, is intended for laboratory use as a digestion reagent for glycogen in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

Light Green for PAS

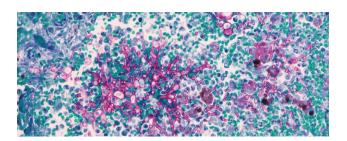
 Ordering Code:
 05279267001

 Catalog Number:
 860-010

 Quantity:
 75 tests

 Controls:
 Liver

For use on the BenchMark Special Stains.



INTENDED USE

Light Green for PAS is intended for laboratory use in staining non-target tissue components and providing contrast with target stains in sections of formalin-fixed, paraffin-embedded (FFPE) tissue on a BenchMark Special Stains instrument. This reagent is intended as a counterstain in special stains applications. This product is intended for in vitro diagnostic (IVD) use.

Mucicarmine Staining Kit

Ordering Code: 05279275001
Catalog Number: 860-011
Quantity: 75 tests

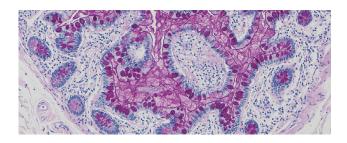
Controls: Human Tissue with Epithelial Mucin

For use on the BenchMark Special Stains.



INTENDED USE

The Mucicarmine Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate acid mucopolysaccharides (mucin) by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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

 Ordering Code:
 05279291001

 Catalog Number:
 860-014

 Quantity:
 75 tests

Controls: Tissue Known to be Glycogen Rich, such as

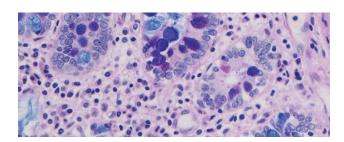
Kidney, Small Intestine, Liver, Skin, or Aorta

For use on the BenchMark Special Stains.

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.

- 1. Thompson SW. Selected Histochemical and Histopathological Methods. Springfield; CC Thomas; 1966.
- 2. Sheehan DC, Hrapchak BB. Theory and Practice of Histotechnology. 2nd edition. St. Louis, MO: C.V. Mosby Company; 1980.



Alcian Blue for PAS

 Ordering Code:
 05279194001

 Catalog Number:
 860-003

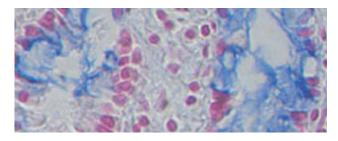
 Quantity:
 75 tests

Controls: Colon, Salivary Gland, Small Intestine

For use on the BenchMark Special Stains.

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

Ordering Code: 05279348001
Catalog Number: 860-002
Quantity: 75 tests
Controls: Kidney

INTENDED USE

The Alcian Blue Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate weakly acidic mucopolysaccharides by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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 Connective Tissue

Elastic Van Gieson, BOM # 09592229001

Special Stains Van Gieson CS

 Ordering Code:
 09185992001

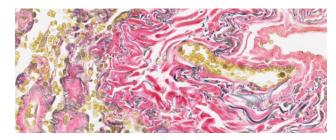
 Catalog Number:
 860-073

 Quantity:
 50 tests

Controls: Lung, Artery, Colon, Aorta, Heart

For use on the BenchMark Special Stains instrument.

Important Note: ONLY use Elastic Van Gieson material number 09592229001 when ordering Elastic staining kits. The Elastic Van Gieson #09592229001 will automatically order and ship both required kits, Special Stains Van Gieson CS & Flastic Stain Core Kit.



INTENDED USE

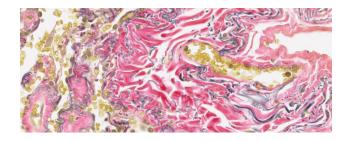
Special Stains Van Gieson CS used in conjunction with Elastic Stain Core Kit is intended for laboratory use in staining non-target tissue componenets and providing contrast with target stains in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. This reagent is intended as a counterstain in special stains applications. This product is intended for in vitro diagnostic (IVD) use.

Elastic Stain Core Kit

Ordering Code: 09185984001 Catalog Number: 860-047 Quantity: 50 tests

Controls: Lung, Artery, Colon, Aorta, Heart

For use on the BenchMark Special Stains instrument.



INTENDED USE

Elastic Stain Core Kit, used in conjunction with Special Stains Van Gieson CS is intended for laboratory use as a qualitative histologic stain to demonstrate elastic fibers by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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

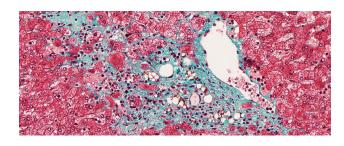
 Ordering Code:
 06521916001

 Catalog Number:
 860-032

 Quantity:
 75 tests

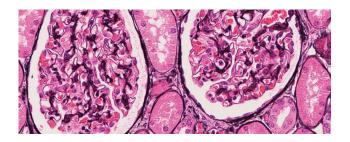
Controls: Colon, Kidney, Liver, Skin

For use on the BenchMark Special Stains system.



INTENDED USE

Green for Trichrome, in conjunction with Trichrome Staining Kit, is intended for laboratory use as a qualitative histologic stain to demonstrate collagen fibers, muscle and connective tissue by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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.



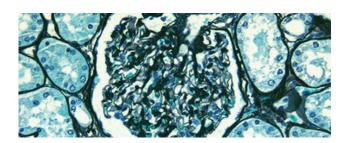
Jones H&E Staining Kit

Ordering Code: 05279348001
Catalog Number: 860-019
Quantity: 40 tests
Controls: Kidney

For use on the BenchMark Special Stains.

INTENDED USE

The Jones H&E Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate capillary basement membranes by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on the BenchMark Special Stains instrument. 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

 Ordering Code:
 05279356001

 Catalog Number:
 860-020

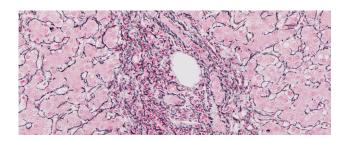
 Quantity:
 40 tests

 Controls:
 Kidney

For use on the BenchMark Special Stains.

INTENDED USE

The Jones Light Green Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate capillary basement membranes by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on the BenchMark Special Stains instrument. 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

 Ordering Code:
 05279399001

 Catalog Number:
 860-024

 Quantity:
 75 tests

Controls: Tissue with Defined Reticular Fibers

(Liver, Spleen, Kidney, or Lymph Nodes)

For use on the BenchMark Special Stains.

INTENDED USE

Reticulum II Staining Kit is intended for use as a qualitative histologic stain to demonstrate reticular fibers by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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. This product is intended for in vitro diagnostic (IVD) use.

Trichrome Staining Kit

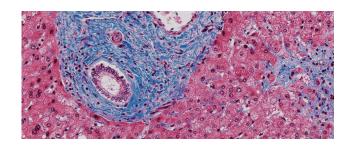
 Ordering Code:
 06521908001

 Catalog Number:
 860-031

 Quantity:
 60 tests

Controls: Colon, Kidney, Liver, Skin

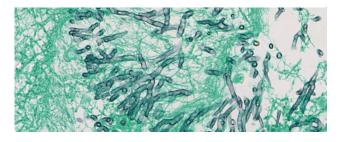
For use on the BenchMark Special Stains system.



INTENDED USE

Trichrome Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate collagen fibers, muscle and connective tissue by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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



GMS II Staining Kit

 Ordering Code:
 05412749001

 Catalog Number:
 860-028

 Quantity:
 75 tests

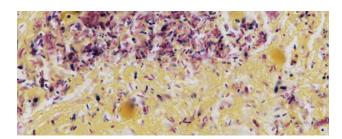
Controls: Tissue Positive for Pathogenic Fungus

or Pneumocystis carinii

For use on the BenchMark Special Stains.

INTENDED USE

GMS II Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate polysaccharides in the cell walls of fungal organisms by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on the BenchMark Special Stains instrument. 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.



Gram Staining Kit

 Ordering Code:
 06890105001

 Catalog Number:
 860-039

 Quantity:
 75 tests

Controls: See Package Insert

For use on the BenchMark Special Stains systems.

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 II Staining Kit

 Ordering Code:
 06521894001

 Catalog Number:
 860-030

 Quantity:
 40 tests

Controls: Tissue Containing H. pylori, Spirochetes, or

L. pneumophila

For use on the BenchMark Special Stains system.

INTENDED USE

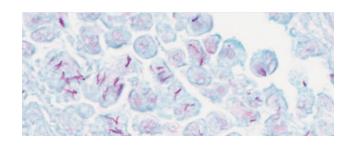
The Steiner II Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate argyrophilic microorganisms by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. This product should be interpreted 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.

BenchMark Special Stains AFB Staining Kit

Ordering Code: 08432503001 Quantity: 75 tests

Controls: Tissue Positive for Acid-Fast Bacteria

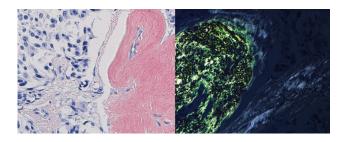
For use on the BenchMark Special Stains System.



INTENDED USE

BenchMark Special Stains AFB Staining Kit is intended to be used as a histologic stain to aid in selectively demonstrating Mycobacterium and other acid-fast organisms 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.

Other Special Staining Kits



Congo Red Staining Kit

 Ordering Code:
 05279429001

 Catalog Number:
 860-026

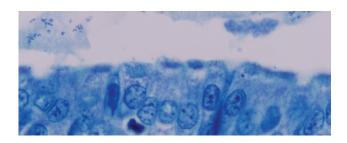
 Quantity:
 40 tests

Controls: Tissue Positive for Amyloid

For use on the BenchMark Special Stains.

INTENDED USE

Congo Red Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate amyloid in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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

 Ordering Code:
 05279224001

 Catalog Number:
 860-006

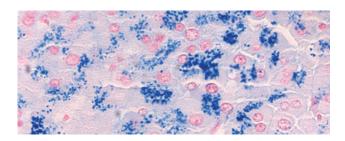
 Quantity:
 75 tests

Controls: Bone Marrow, Lymph Node, Spleen

For use on the BenchMark Special Stains.

INTENDED USE

The Giemsa Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate *Helicobacter pylori* in the stomach and differentiate hematopoietic cells by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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.



Iron Staining Kit

 Ordering Code:
 05279259001

 Catalog Number:
 860-009

 Quantity:
 75 tests

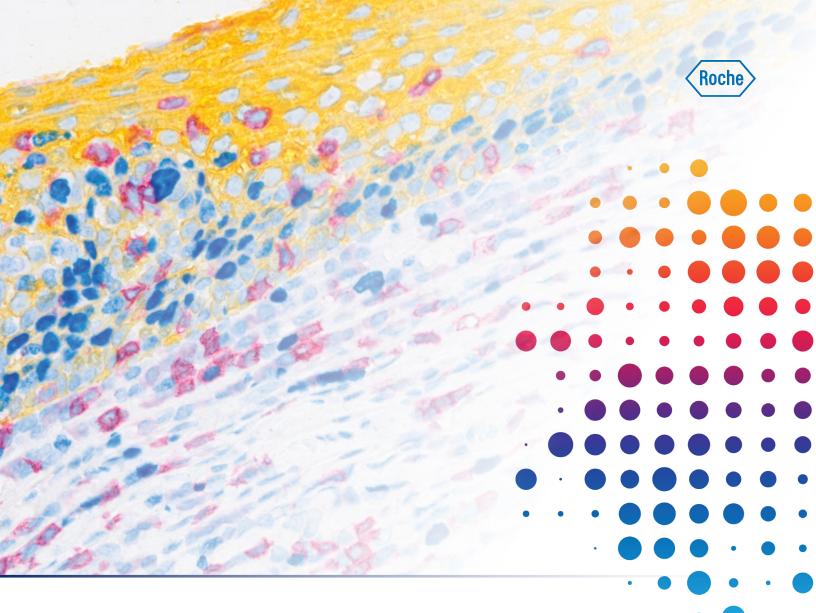
Controls: Tissue with Intracellular or Extracellular Iron

(Liver, Bone Marrow or Spleen)

For use on the BenchMark Special Stains.

INTENDED USE

The Iron Staining Kit is intended for laboratory use as a qualitative histologic stain to demonstrate iron pigment by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. 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.



DISCOVERY

Innovative IHC & ISH Research

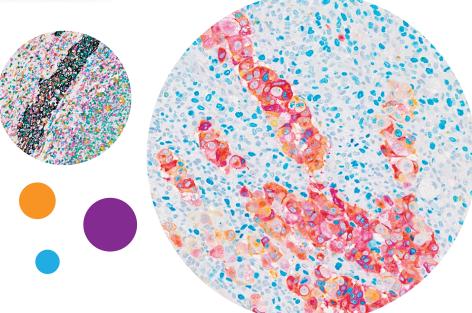
Shape the DISCOVERY ULTRA Instrument

to your research goals and push the boundaries of medical science



The DISCOVERY ULTRA enables automation of a wide range of analytic techniques such as:

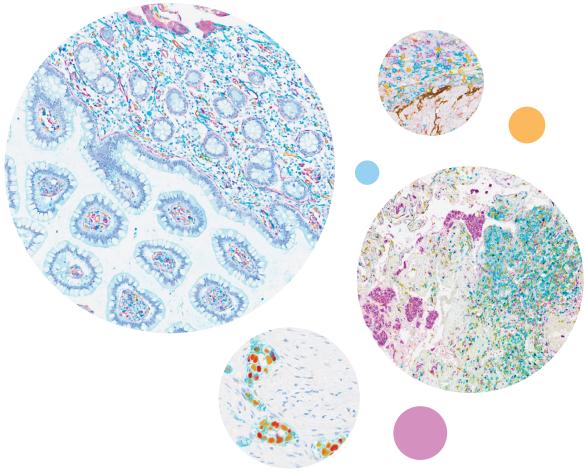
- Many options for chromogenic and fluorescent staining for both IHC and ISH
- · Leading-edge detection chemistries
- In situ hybridization for RNA, DNA, and small non-coding RNAs
- Multiplexed chromogenic and fluorescent IHC or ISH
- Same-slide multiplexed IHC & ISH in any color combination



With the DISCOVERY ULTRA research instrument for IHC/ISH, your lab will be able to:

- Push the boundaries of medical research with an instrument that allows true continuous random access.
- Expand your IHC/ISH multiplexing capabilities with highly flexible staining procedures.
- Leverage the comprehensive menu of ready-to-use reagents to create a broad range of sensitive, specific assays.
- Count on our **growing product pipeline** to support your research as it evolves.
- **Discover** every **project's full potential** with a provider experienced in **translational research**.





DISCOVERY ULTRA

Automated IHC, ISH & Multiplexing

We developed the DISCOVERY Ultra based on extensive customer feedback, market research, and Ventana's industry-leading technologies to provide comprehensive capabilities not available on any other automated staining platform.

The DISCOVERY ULTRA instrument and software is adaptable to a broad array of tissue testing capabilities. From developing novel assays on low expressing biomarkers to enabling the highest level of experimental complexity, DISCOVERY ULTRA accelerates IHC and ISH research, offering innovators significant improvements in ease of use, workflow, and system flexibility.



Automation

Process slides from baking through staining in full automation for reproducible results



Accessibility

Support multiple users, multiple projects, multiple protocols at the same time



Flexibility

Run manual applications and fully automated slides of ANY assay type simultaneously



Continuity

Add bulk fluids or empty waste while the instrument is running, so you can focus on the research, not the tasks



Quality

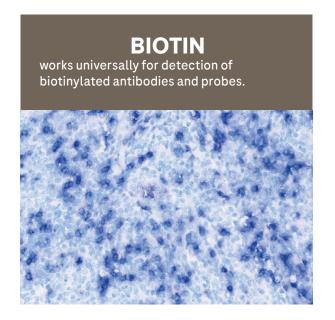
Leverage the industry's most comprehensive menu of ready-to-use research reagents for full automation to create a broad range of sensitive, specific assays

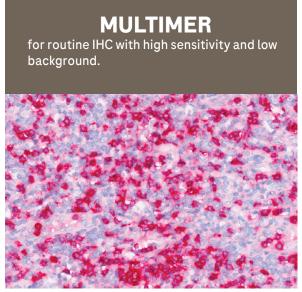
Systems and Goods

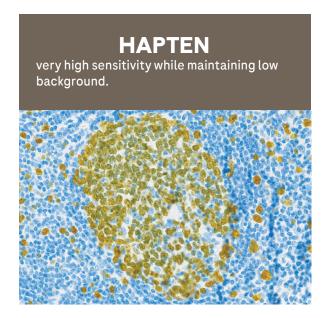
DISCOVERY ULTRA System	DISCOVERY Ultra Automated Stainer Universal Procedure Software Computer with monitor, keyboard and mouse, Windows 10, and running VENTANA System Software (VSS) for controlling the instrument
Universal Procedure Software	Flexible software system for designing staining protocols to run the DISCOVERY ULTRA. Updates to this software are installed free of charge for the life of the instrument.
Roche-provided Firewall Solution	The FortiGate is the approved and validated firewall for Roche Diagnostics. It is designed to separate and secure the Roche Laboratory Network from the main customer lab or hospital network. The FortiGate safeguards both the customer and the Roche instruments from Cyber-Security threats. The installation of a FortiGate is MANDATORY for all new instruments.
CareGiver Remote Support	CareGiver remote support is an automated remote monitoring and diagnostics solution that enables continuous monitoring and remote service of VENTANA instruments. CareGiver remote support enables users to maximize instrument performance and prevent workday service interruptions.
Ventana Connect	(Optional) NAVIFY Hub offers a middleware solution which provides universal LIS connectivity for Ventana's product portfolio within histology.
Universal Power Supply	It is strongly recommended, but not required, that the PowerVar UPS (material # 03155102002) be used in concert with all TD staining instruments
Advanced Cell Diagnostics (ACD) software module license	Enables software module for running ACD RNAscope and BASEscope probes for mRNA detection.
Installation and Implementation Process	Roche Field Application Specialist will set up instrument, and verify correct instrument operation.
Warranty and Service Contract	Each instrument includes a one-year warranty.

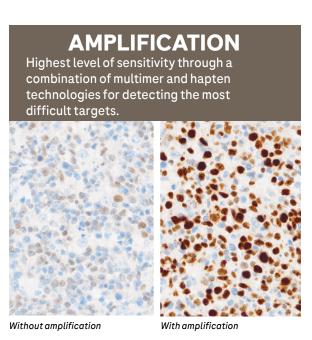
Detection

Choose from four detection technologies for the best possible performance with your specific application.









MULTIMER

High sensitivity, low background

OmniMAP

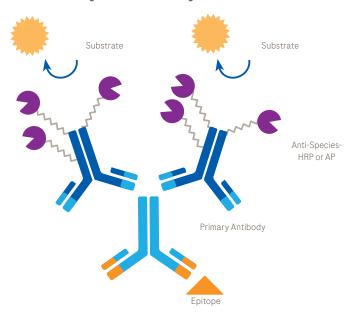
UltraMAP

HRP Mouse, Rabbit, Rat, Goat

HRP Mouse, Rabbit, Rat, Goat **AP** Mouse, Rabbit

Multimer technology produces increased signal for both chromogenic and fluorescent applications. OmniMAP is for everyday use, while UltraMAP offers greater signal and an alkaline phosphatase option when needed. Multimer technology is biotin free, thus eliminating biotin blocking steps!

Chromogenic or Fluorescent Signal



HRP Chromogens: Purple, Silver, Teal DAB, Green, Red, Yellow, Blue Fluorophores: DCC, Cy5, FAM, Red610, Rhodamine, FITC, Rhodamine 6G

Multimer detection HRP/AP kits		
Productname	Ordering code	Quantity
Multimer OmniMAP HRP		
Anti-Mouse	05269652001	125 tests
Anti-Rabbit	05269679001	125 tests
Anti-Goat	06607233001	50 tests
Anti-Rat	05891892001	125 tests

Multimer UltraMAP HRP		
Anti-Mouse	05269695001	125 tests
Anti-Rabbit	05269717001	125 tests
Anti-Goat	06607241001	50 tests
Anti-Rat	05891884001	125 tests

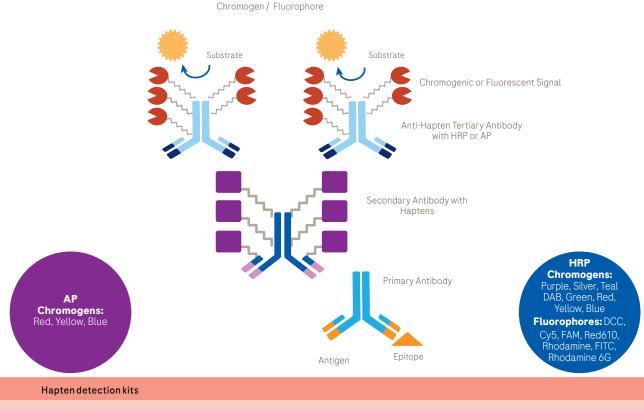
Multimer UltraMAP AP		
Anti-Mouse	05269687001	125 tests
Anti-Rabbit	05269709001	125 tests

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Chromogens: Red, Yellow, Blue

HAPTEN Increased sensitivity NP HQ AP Mouse, Rabbit HRP Mouse, Rabbit

The unique and powerful DISCOVERY hapten-linked detection systems offer the highest level of sensitivity and specificity available on the DISCOVERY research platforms. Designed with the researcher in mind, our hapten-linked detection family includes both DISCOVERY HQ-HRP and DISCOVERY NP-AP detection, so you can use any of our DISCOVERY chromogen or fluorophore kits in order to meet your staining needs. Make them your go-to detection kits for reliable, high-quality staining from your most straightforward to your most challenging projects.



Hapten detection kits		
Productname	Ordering code	Quantity
HQ-HRP Detection		
DISCOVERY Anti-Mouse HQ	07017782001	125 tests
DISCOVERY Anti-Rabbit HQ	07017812001	125 tests
DISCOVERY Anti-HQ HRP	07017936001	125 tests

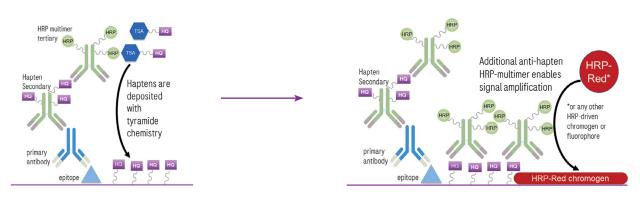
NP - Alk Phos Detection		
DISCOVERY Anti-Mouse NP	07425309001	125 tests
DISCOVERY Anti-Rabbit NP	07425317001	125 tests
DISCOVERY Anti-NP AP	07425325001	125 tests

DISCOVERY Amplification

For detection of low abundance biomarkers

DISCOVERY Amplification kits revolutionize detection technology so researchers have the edge they need for their most challenging projects. DISCOVERY Amp HQ kit delivers the sensitivity needed for low abundance protein markers. DISCOVERY Amp BF kit delivers our highest degree of intensity and is designed to pinpoint low-expressing molecular targets such as miRNA. Both kits maintain exquisite specificity while true signal is dialed up to meet your project needs.

DISCOVERY HQ/BF Amplification



Hapten deposition

Signal amplification

Amplification kits		
Productname	Ordering code	Quantity
HQAmplification		
DISCOVERY HQ Amp kit	06472320001	50 tests
DISCOVERY Amp Anti-HQ AP	06472311001	50 tests
DISCOVERY Amp Anti-HQ HRP	06442544001	50 tests
BF Amplification		
DISCOVERY BF Amp kit	07529422001	50 tests
DISCOVERY anti-BF HRP	07529449001	50 tests
DISCOVERY Amp clear	07529457001	50 tests

Chromogenic Detection

Clean, Crisp and Dialable

Along with traditional high-contrast chromogens of DAB and silver, Ventana has developed unique, high-performance chromogens based on fluorophores. These unique colors are ideal for IHC/ISH multiplexing and image analysis.

HRP driven chromogens		
Productname	Ordering code	Quantity
DISCOVERY ChromoMap DAB kit (RUO)	05266645001	125 tests
DISCOVERY Purple kit (RUO) *	07053983001	50 tests
DISCOVERY Silver kit (RUO) *	07053649001	50 tests
DISCOVERY Teal HRP kit*	08254338001	50 tests
DISCOVERY Green HRP kit*	08478295001	50 tests
DISCOVERY RED HRP kit*	09576819001	50 tests
DISCOVERY YELLOW HRP kit*	08502641001	50 tests
DISCOVERY BLUE HRP kit*	09582690001	50 tests
DISCOVERY Inhibitor *	07017944001	250 tests
DISCOVERY DAB Map kit (RUO)	05266360001	250 tests
AP-driven chromogens		
DISCOVERY ChromoMap Blue kit (RUO)	05266661001	125 tests
DISCOVERY Red kit (RUO)	07425333001	125 tests
DISCOVERY Yellow kit (RUO)	07698445001	50 tests
DISCOVERY ChromoMap Red kit (RUO)	05266653001	125 tests
DISCOVERY BlueMap kit (RUO)	05266327001	125 tests
DISCOVERY RedMap kit (RUO)	05266351001	250 tests



























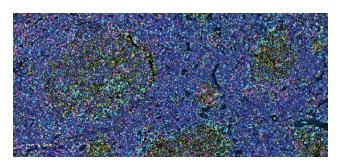




^{*} DISCOVERY Inhibitor is required to quench endogenous peroxidases when using DISCOVERY Teal, DISCOVERY Purple, DISCOVERY Silver, DISCOVERY Green HRP, DISCOVERY Red HRP, DISCOVERY Sellow HRP, and DISCOVERY Blue HRP chromogens.

Fluorescent Detection

The highly photo stable signal from DISCOVERY fluorescent detection is enabled by Tyramide Signal Amplification (TSA), and lasts for months, not mere hours—even when slides are stored at room temperature. Take the worry out of IF when you experience the staying power of DISCOVERY fluorescent detection kits.



CD20(SP32) with DISCOVERY Rhodamine 6G
CD3(SP162) with DISCOVERY DCC
CD8(SP239) with DISCOVERY Red610
CD68(SP251) with DISCOVERY Cy5
FoxP3(SP97) with DISCOVERY FAM
Stained on tonsil

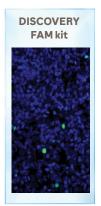
Productname	Ordering code	Ex/Em*	Quantity
DISCOVERY FITC kit (RUO)*	07259212001	Exλ-490nm Emλ-525nm	50 tests
DISCOVERY Rhodamine kit (RUO)*	07259883001	Exλ-542nm Emλ-568nm	50 tests
DISCOVERY DCC kit*	07988192001	Exλ-436nm Emλ-480nm	50 tests
DISCOVERY FAM kit*	07988150001	Exλ-490nm Emλ-520nm	50 tests
DISCOVERY Red 610 kit*	07988176001	Exλ-580nm Emλ-625nm	50 tests
DISCOVERY Rhodamine 6G kit*	07988168001	Exλ-546nm Emλ-572nm	50 tests
DISCOVERY Cy5 kit*	07551215001	xλ-643nm Emλ-680nm	50 tests
DISCOVERY Inhibitor *	07017944001		250 tests

 $[*] DISCOVERY\ Inhibitor\ is\ required\ with\ all\ DISCOVERY\ fluorescent\ detection\ kits.$











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Working Together for Spatial RNA and Protein Detection

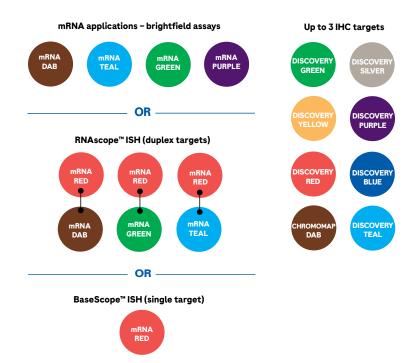
RNAscope® and BaseScope™ probes can be purchased from ACD, and used in combination with VENTANA chromogens, fluorophores, and bulk reagents for fully automated assays on the DISCOVERY ULTRA system.

Detect target RNA expression by

- ANY gene
- ANY genome
- ANY tissue/cell type with in situ hybridization

Multiple Ways to Multiplex

Don't be limited by your detection choices. Choose the optimal chromogen or fluorophore for your specific application. Roche researchers have developed a range of new chromogens and a spectrum of fluorophores specially formulated to work with ACD probes. These detection options enable you to explore mRNA expression on a wider range of tissue types. Now you can easily see expression in pigmented tissues.



Combine IHC with ISH using either chromogens or fluorophores

 $ACD's \,RNA-protein \,VS \,Co-Detection \,Kit, when used \,with \,RNA scope \,and \,BaseScope \,Assays, \,determines \,the \,relationship \,between \,mRNA \,targets \,and \,protein \,expression—on \,the \,same \,slide.$



For more information on ISH using RNAscope® and BaseScope™ probes on the DISCOVERY ULTRA, please visit our brochure.

https://go.roche.com/multiplexing-resources-acd-probes-disco-catalog

Ancillaries

antibody Diluents		
roductname	Ordering code	Quantity
antibody Dilution Buffer	05280524001	250 mL bottle
antibody Diluent with Casein	06440002001	100 mL bottle
DISCOVERY Antibody Diluent	05266319001	100 mL bottle
DISCOVERY PSS Diluent	05266815001	100 mL bottle
Blockers		
Productname	Ordering code	Quantity
DISCOVERY Antibody Block	05268869001	250 tests
DISCOVERY S-Block	05268931001	250 tests
DISCOVERY Goat Ig Block	07988214001	250 tests
DISCOVERYInhibitor	07017944001	250 tests
nzymes		
'roduct name	Ordering code	Quantity
rotease 1	05266688001	250 tests
rotease 2	05266696001	250 tests
Protease 3	05266718001	250 tests
Hybridization Buffers / ISH diluents		
Productname	Ordering code	Quantity
HybReady	05917557001	25 mL
SH Probe Diluent	06375375001	120 mL
Counterstains		
Productname	Ordering code	Quantity
Bluing Reagent	05266769001	250 tests
DISCOVERY QD DAPI	05268826001	125 tests
Hematoxylin	05266726001	250 tests
Hematoxylin II	05277965001	250 tests
Red Counterstain II	05272017001	100 tests
Application kits		

07256302001

07256299001

05268877001

50 tests

50 tests

250 tests

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DISCOVERY Universal Secondary Antibody (RUO) (biotinylated)

DISCOVERY anti-DIG AP

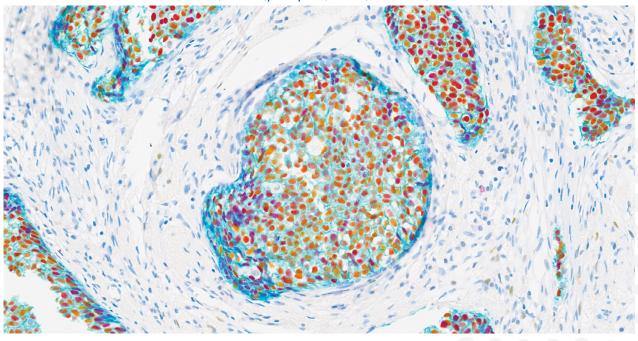
DISCOVERY anti-DIG HRP

Bulks

DISCOVERY ULTRA Bulk Solutions		
Productname	Ordering code	Quantity
DISCOVERY CC1	06414575001	2 L bottle
DISCOVERY Wash (10X) (RUO)	07311079001	2 L bottle
Reaction Buffer (10X)	05353955001	2 L bottle
Silver Wash II	05446724001	2 L bottle
SSC (10X)	05353947001	2 L bottle
ULTRA LCS (Predilute)	05424534001	2 L bottle
ULTRA Cell Conditioning (ULTRA CC2)	05424542001	1 L bottle

Productname	Ordering code	Quantity
Cell Conditioning 2 (CC2)	05279798001	1 L bottle
DISCOVERY CC1	06414575001	2 L bottle
DISCOVERY Wash (RUO)	07311079001	2 L bottle
Liquid Coverslip (High Temperature)	05264839001	2 L bottle
Reaction Buffer (10X)	05353955001	2 L bottle
Silver Wash II	05446724001	2 L bottle
SSC(10X)	05353947001	2 L bottle

Breast E-Cadherin (Teal), PR (purple) ER (Yellow)



Productname	Ordering code
	·
250 Test Antibody # 19	05270057001
250 Test Antibody # 20	05270065001
250 Test Antibody # 21	05270073001
250 Test Antibody # 22	05270081001
250 Test Antibody # 23	05270090001
250 Test Antibody # 24	05270103001
250 Test Antibody # 25	05270111001
250 Test Antibody # 26	05270120001
250 Test Antibody # 27	05270138001
250 Test Antibody # 28	05270146001
250 Test Antibody # 29	05270154001
250 Test Antibody # 30	05270162001
250 Test Antibody # 31	05270189001
250 Test Antibody # 32	05270197001
250 Test Antibody # 33	05270219001
250 Test Antibody # 34	05270227001
250 Test Antibody # 35	05270235001
250 Test Antibody # 36	05270243001
250 Test Antibody # 37	05270251001
250 Test Antibody # 38	05270260001
250 Test Antibody # 39	05270278001
250 Test Antibody # 40	05270286001
250 Test Antibody # 41	05270294001
250 Test Antibody # 42	05270308001
250 Test Antibody # 43	05270316001
250 Test Antibody # 44	05270324001
250 Test Antibody # 45	05270332001
250 Test Antibody # 46	05270359001
250 Test Antibody # 47	05270367001
250 Test Antibody # 48	05270375001
250 Test Antibody # 49	05270383001
250 Test Antibody # 50	05270391001
250 Test Antibody # 51	05270405001
250 Test Antibody # 52	05270413001
250 Test Antibody # 53	05270421001
250 Test Antibody # 54	05270430001
250 Test Antibody # 55	05270448001
250 Test Antibody # 56	05270456001

Productname	Ordering code
250 Test Antibody #58	05270472001
250 Test Antibody # 59	05270499001
250 Test Antibody # 60	05270502001
250 Test Antibody # 61	05270529001
250 Test Antibody # 62	05270537001
250 Test Antibody #63	05270545001
250 Test Antibody # 64	05270553001
250 Test Antibody # 65	05270561001
250 Test Antibody # 66	05270570001
250 Test Antibody # 67	05270588001
250 Test Antibody # 68	05270596001
250 Test Antibody # 69	05270600001
250 Test Antibody # 70	05270618001
250 Test Antibody # 71	05270626001
250 Test Antibody # 72	05270634001
250 Test Antibody # 73	05270642001
250 Test Antibody # 74	05270669001
250 Test Antibody # 75	05270677001
50 Test Antibody # 76	05270685001
50 Test Antibody # 77	05270693001
50 Test Antibody # 78	05270707001
50 Test Antibody # 79	05270715001
250 Test Antibody # 80	05270723001
50 Test Antibody #81	05270731001
50 Test Antibody #82	05270740001
50 Test Antibody # 83	05270758001
50 Test Antibody # 84	05270766001
50 Test Antibody # 85	05270774001
50 Test Antibody # 86	05270782001
50 Test Antibody # 87	05270804001
50 Test Antibody #88	05270812001
50 Test Antibody #89	05270839001
50 Test Antibody # 90	05270847001
50 Test Antibody #91	05270855001
50 Test Antibody #92	05270863001
50 Test Antibody # 93	05270871001
50 Test Antibody # 94	05270880001
50 Test Antibody # 95	05270898001

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Antibody User-Fillables - continued Product name Ordering code	
	Ordering code
50 Test Antibody # 97	05270910001
50 Test Antibody # 98	05270928001
50 Test Antibody # 99	05270936001
50 Test Antibody # 100	05270944001
50 Test Antibody # 101	05270952001
50 Test Antibody # 102	
50 Test Antibody # 103	05270987001
50 Test Antibody # 104	05270995001
50 Test Antibody # 105	05271002001
50 Test Antibody # 106	05271029001
50 Test Antibody # 107	05271037001
50 Test Antibody # 108	05271045001
50 Test Antibody # 109	05271053001
50 Test Antibody # 110	05271061001
50 Test Antibody # 111	05271070001
50 Test Antibody # 112	05271088001
50 Test Antibody # 113	05271096001
50 Test Antibody # 114	05271100001
50 Test Antibody # 115	05271118001
50 Test Antibody # 116	05271126001
50 Test Antibody # 117	05271134001
50 Test Antibody # 118	05271142001
50 Test Antibody # 119	05271169001
50 Test Antibody # 120	05271177001
50 Test Antibody # 121	05271185001
50 Test Antibody # 122	05271193001
50 Test Antibody # 123	05271207001
50 Test Antibody # 124	05271215001
50 Test Antibody # 125	05271223001
50 Test Antibody # 126	05271231001
50 Test Antibody # 127	05271240001
50 Test Antibody # 128	05271258001
50 Test Antibody # 129	05271266001
50 Test Antibody # 130	05271274001
50 Test Antibody # 131	05271282001
50 Test Antibody # 132	05271304001
50 Test Antibody # 133	05271312001
50 Test Antibody # 134	05271339001
50 Test Antibody # 135	05271347001

Antibody User-Fillables – continued	
Productname	Ordering code
250 Test Antibody # 136	05271355001
250 Test Antibody # 137	05271363001
250 Test Antibody # 138	05271371001
250 Test Antibody # 139	05271380001
250 Test Antibody # 140	05271398001
250 Test Antibody # 141	05271401001
250 Test Antibody # 142	05271410001
250 Test Antibody # 143	05271428001
250 Test Antibody # 144	05271436001
250 Test Antibody # 145	05271444001
250 Test Antibody # 146	05271452001
250 Test Antibody # 147	05271479001
250 Test Antibody # 148	05271487001
250 Test Antibody # 149	05271495001
250 Test Antibody # 150	05271509001

Probe User-Fillables	
oductname	Ordering code
50 Test Probe # 1	05279828001
50 Test Probe # 2	05279836001
50 Test Probe # 3	05279844001
50 Test Probe # 4	05279852001
50 Test Probe # 5	05279879001
50 Test Probe # 6	05279887001
50 Test Probe # 7	05279895001
50 Test Probe #8	05279909001
50 Test Probe # 9	05279917001
50 Test Probe # 10	05279925001
50 Test Probe # 11	05279933001
0 Test Probe # 12	05279941001
50 Test Probe # 13	05279950001
50 Test Probe # 14	05279968001
0 Test Probe # 15	05279976001
50 Test Probe # 16	05279984001
0 Test Probe # 17	05279992001
Test Probe # 18	05280001001
50 Test Probe # 19	05280010001
50 Test Probe # 20	05280028001

Probe User-Fillables – continued	
Productname	Ordering code
250 Test Probe # 21	05280036001
250 Test Probe # 22	05280044001
250 Test Probe # 23	05280052001
250 Test Probe # 24	05280079001
250 Test Probe # 25	05280087001
250 Test Probe # 26	08258406001
250 Test Probe # 27	08258414001
250 Test Probe # 28	08258422001
250 Test Probe # 29	08258449001
250 Test Probe # 30	08258457001
250 Test Probe # 31	08258465001
250 Test Probe # 32	08258473001
250 Test Probe # 33	08258481001
250 Test Probe # 34	08258490001
250 Test Probe # 35	08258503001
250 Test Probe # 36	08258511001
250 Test Probe # 37	08258520001
250 Test Probe # 38	08258538001
250 Test Probe # 39	08258546001
250 Test Probe # 40	08258554001

Option User-Fillables	
Productname	Ordering code
250 Test Option # 1	05271843001
250 Test Option # 2	05271851001
250 Test Option # 3	05271860001
250 Test Option # 4	05271878001
250 Test Option # 5	05271886001
250 Test Option#8	05271916001

250 Test Antibody # 19	770-019	05270057001
250 Test Antibody # 20	770-020	05270065001
250 Test Antibody # 21	770-021	05270073001
250 Test Antibody # 22	770-022	05270081001

roductname	Ordering code
	•
DISCOVERY Reagent Dispenser Card, Detection 1	05280192001
DISCOVERY Reagent Dispenser Card, Detection 2	05280206001
DISCOVERY Reagent Dispenser Card, Detection 3	05280214001
DISCOVERY Reagent Dispenser Card, Detection 4	05280222001
DISCOVERY Reagent Dispenser Card, Detection 5	05280249001
DISCOVERY Reagent Dispenser Card, Detection 6	05280257001
DISCOVERY Reagent Dispenser Card, Detection 7	05280265001
DISCOVERY Reagent Dispenser Card, Detection 8	05280273001
DISCOVERY Reagent Dispenser Card, Detection 9	05280281001
DISCOVERY Reagent Dispenser Card, Detection 10	05280290001
DISCOVERY Reagent Dispenser Card, Detection 11	05280303001
DISCOVERY Reagent Dispenser Card, Detection 12	05280311001
DISCOVERY Reagent Dispenser Card, Detection 13	05280320001
DISCOVERY Reagent Dispenser Card, Detection 14	05280338001
DISCOVERY Reagent Dispenser Card, Detection 15	05280346001
DISCOVERY Reagent Dispenser Card, Detection 16	05280354001
DISCOVERY Reagent Dispenser Card, Detection 17	05280362001
DISCOVERY Reagent Dispenser Card, Detection 18	05280389001
DISCOVERY Reagent Dispenser Card, Detection 19	05280397001
DISCOVERY Reagent Dispenser Card, Detection 20	05280419001



Systems & Software

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

Catalog Number: 07024282001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Hematoxylin is intended for use as a qualitative histologic stain to demonstrate nucleic acid staining by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on the VENTANA HE 600 system. The product should be interpreted by a qualified pathologist in conjunction with relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Eosin

Catalog Number: 06544304001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Eosin is intended for use as a qualitative histologic stain to demonstrate cytoplasmic staining by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on the VENTANA HE 600 system. The product should be interpreted by a qualified pathologist in conjunction with 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

Catalog Number: 06544339001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Differentiating Solution is intended for use on the VENTANA HE 600 system. It is used in conjunction with VENTANA HE 600 Hematoxylin and when applied to sections of formalin-fixed, paraffin-embedded (FFPE) tissue, will remove non-specific staining from the tissue and glass slide surface to improve nuclear detail. The end product (H&E stain) should be interpreted by a qualified pathologist in conjunction with relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Bluing

Catalog Number: 06544347001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Bluing is intended for use on the VENTANA HE 600 system. It is used in conjunction with VENTANA HE 600 Hematoxylin and when applied to sections of formalin-fixed, paraffin-embedded (FFPE) tissue, will change the hue of hematoxylin from purple to blue. The end product (H&E stain) should be interpreted by a qualified pathologist in conjunction with relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Organic Solution

Catalog Number: 07095163001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Organic Solution is intended for use on the VENTANA HE 600 system. It is used to deparaffinize formalin-fixed, paraffin-embedded (FFPE) tissue sections prior to staining as well as to remove aqueous reagents from slides in preparation for the coverslipping process. The end product (H&E stain) should be interpreted by a qualified pathologist in conjunction with relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Transfer Fluid

Catalog Number: 06544380001 Quantity: 2 L bottle

INTENDED USE: VENTANA HE 600 Transfer Fluid is intended for use on the VENTANA HE 600 system. It is used to solubilize and remove aqueous reagents from formalin-fixed, paraffin-embedded (FFPE) tissue slides during staining and coverslipping processes. The end product (H&E stain) should be interpreted by a qualified pathologist in conjunction with relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Wash

Catalog Number: 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

Catalog Number: 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

Catalog Number: 07534396001 Quantity: (2) 120 mL Bottles

INTENDED USE: VENTANA HE 600 Coverslip Activator is intended for use on the VENTANA HE 600 system. It is used to activate the glue layer on the VENTANA HE 600 Glass Coverslips allowing them to adhere to the underlying slide of formalin-fixed, paraffin-embedded (FFPE) tissue during the coverslipping process. The end product (stained and coverslipped slide) should be interpreted by a qualified pathologist in conjunction with relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

VENTANA HE 600 Glass Coverslips

Catalog Number: 06711138001 **Quantity:** 12 cassettes per box. Each cassette contains 170 pre-glued glass coverslips

INTENDED USE: VENTANA HE 600 Glass Coverslips are intended for use on the VENTANA HE 600 system. They are applied to the underlying microscope slide of formalin-fixed, paraffin-embedded (FFPE) tissue during the coverslipping process to provide optical clarity and archivability. The end product (stained and coverslipped slide) should be interpreted by a qualified pathologist in conjunction with relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

BenchMark ULTRA PLUS System

BenchMark ULTRA PLUS

Experience the power of PLUS

The new BenchMark ULTRA PLUS system continues the evolution of the BenchMark series, which revolutionized cancer diagnostics by fully automating processes that used to be performed manually, one slide at a time.

Lab personnel will be able to manage their activities more efficiently as a result of simplified software and streamlined productivity and quality control. These enhancements can help support the quicker delivery of test results for patients who are waiting for a diagnosis.

The new system has several innovations such as new intuitive software, remote monitoring features, an integrated touchscreen for a more optimized user experience, and a more environmentally sustainable waste system and product packaging.



The diagnostic confidence you expect from BenchMark, PLUS...

- Optimized lab workflow and user experience
- Simplified communication options
- Environmentally friendly solutions

BenchMark ULTRA PLUS System (Continued)

Optimized workflow

Improve usability while enabling time for more value added activities through:

- New light notifications communicate instrument status from across the lab
- New retractable work surface gives techs additional space to work while at the instrument
- New bulk reagent color-coded clips make bulk reagent loading easier and minimize errors
- New integrated touchscreen allows streamlined data management right in front of the instrument
- New proprietary waste management solution degrades DAB to less than 5 ppb meeting most stringent municipality requirements for nonhazardous waste

Flexible solutions

New features based on user feedback:

- New configuration is shorter than the BenchMark ULTRA
- New integrated touchscreen reduces bottlenecks by allowing many functions to be done at the instrument
- VSS 14.1 software allows for easier navigation of inventory management and ordering through a new filter as well as lot-to-lot validation on the same instrument
- VSS 14.1 software has new and expanded reporting capabilities including QA/QC

Quality is at the core

Proven BenchMark technologies deliver the right stain at the right time:

- Flexible, independent temperature control for individual slide staining optimization
- Proven staining technology of air vortex mixing with LCS create a reaction chamber allowing full slide coverage with 100ul of reagent
- New slide drawer design mitigates fluid ingress and egress resulting in continuous and highly-reliable drawer performance



200+ Ready-to-use assays

World's largest menu



30+Years of proven experience

Innovative automation



200+ Pharma and Biotech partners

Personalized healthcare



Light notification

• Visual high level instrument status

Integrated touchscreen

Conduct instrument functions without going to the host computer

Proven BenchMark ULTRA staining technology

- 30 slides and 35 reagents capacity
- Independent slide loading and slide protocol customization

Retractable work surface

• Easy reagent and slide loading

Bulk reagent loading

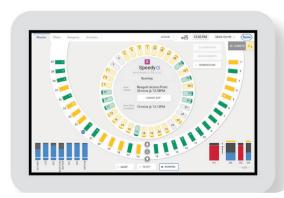
- Color coded bulk reagent clips and matching instrument location
- Refillable at any time without process interruption

Proprietary waster management solution

Fully automated DAB waste degradation and LCS segregation

Simplified communication options

- VSS 14.1 software user interface designed for intuitive usability and workflow optimization
- Seamless integration with complete menu of existing and future assays
- Track, manage & complete quality records at host PC or locally at integrated touchscreen
- View and manage registered IHC/ISH reagent inventory



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.





Throughput flexibility

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: 05279771001 Quantity: 2 L bottle
Alt. Cat. Nr.: 950-102 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 product is intended for in vitro diagnostic (IVD) use.

Reaction Buffer (10x)

Catalog Number: 05353955001 Quantity: 2 L bottle
Alt. Cat. Nr.: 950-300 Format: Concentrate

INTENDED USE: Reaction Buffer Concentrate (10X) is a Tris based buffer solution intended to be diluted for laboratory use to rinse slides between staining steps and provide a stable aqueous environment for immunohistochemistry, immunocytochemistry, and in situ hybridization applications on a BenchMark IHC/ISH instrument.

ULTRA Cell Conditioning (ULTRA CC1)

Catalog Number: 05424569001 **Quantity:** 2 L bottle **Alt. Cat. Nr.:** 950-224 **Format:** Ready to Use

INTENDED USE: ULTRA Cell Conditioning Solution (ULTRA CC1) is a pre diluted solution intended for laboratory use as a pretreatment step in the processing of formalin-fixed, paraffinembedded tissue samples, and cytological specimens for immunohistochemistry, in situ hybridization, and immunocytochemistry applications on a BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

ULTRA Cell Conditioning (ULTRA CC2)

Catalog Number: 05424542001 **Quantity:** 1 L bottle **Alt. Cat. Nr.:** 950-223 **Format:** Ready to Use

INTENDED USE: ULTRA Cell Conditioning Solution (ULTRA CC2) is a prediluted solution intended for laboratory use as a pretreatment step in the processing of formalin-fixed, paraffinembedded tissue samples during immunohistochemistry and in situ hybridization applications on the BenchMark ULTRA instrument. This product is intended for in vitro diagnostic (IVD) use.

ULTRA LCS (Predilute)

Catalog Number: 05424534001 **Quantity:** 2 L bottle **Alt. Cat. Nr.:** 650-210 **Format:** Ready to Use

INTENDED USE: ULTRA LCS (Predilute) is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry, immunocytochemistry, or in situ hybridization reactions carried out on the BenchMark ULTRA instrument. This reagent is intended for in vitro diagnostic (IVD) use

SSC (10X)

Catalog Number: 05353947001 Quantity: 2 L bottle
Alt. Cat. Nr.: 950-110 Format: Concentrate

INTENDED USE: 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 BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic (IVD) use.

*ultra*View™ Silver Wash II

Catalog Number: 05446724001 Quantity: 2 L bottle Alt. Cat. Nr.: 780-003 Format: Concentrate

INTENDED USE: *ultra*View Silver Wash II solution is intended for laboratory use to provide an appropriate aqueous environment prior to silver detection chemistry steps on a BenchMark IHC/ISH instrument. This product is intended for in vitro diagnostic (IVD) use.

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 high-value 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

BenchMark Special Stains Wash II

Catalog Number: 08309817001 Quantity: 1 Kit

INTENDED USE: The BenchMark Special Stains Wash II is intended for laboratory use to produce optimized staining results for use with the Special Stains reagents and staining kits. When diluted and prepared according to instructions, this solution provides a stable aqueous environment for qualitative histological stain in sections of formalin-fixed, paraffin- embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. This product is intended for in vitro diagnostic (IVD) use.

BenchMark Special Stains Deparaffinization Solution (10X)
Catalog Number: 06523102001 Quantity: 2 L bottle
Alt. Cat. Nr.: 860-036 Format: Concentrate

INTENDED USE: BenchMark Special Stains Deparaffinization Solution (10X) is intended for laboratory use to solubilize paraffin during the deparaffinization process for slides containing formalin-fixed, paraffin-embedded (FFPE) tissues during special stains procedures on a BenchMark Special Stains instrument. This product is intended for in vitro diagnostic (IVD) use.

BenchMark Special Stains Liquid Coverslip

Catalog Number: 06523072001 Quantity: 2 L bottle Alt. Cat. Nr.: 860-034 Format: Ready to Use

INTENDED USE: BenchMark Special Stains Liquid Coverslip is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for special stains reactions on a BenchMark Special Stains instrument. BenchMark Special Stains Liquid Coverslip is also used to solubilize paraffin during the deparaffinization process for slides containing formalin-fixed, paraffin-embedded (FFPE) tissues when using the AFB staining procedure on a BenchMark Special Stains instrument. This product is intended for in vitro diagnostic (IVD) use.

Special Stains Rinse (SSR) Solution

Catalog Number: 06890059001 Quantity: 2 L bottle

Alt. Cat. Nr.: 860-038

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.

BenchMark Special Stains Cleaning Kit

Catalog Number: 09476580001 Quantity: 1 Kit

Alt. Cat. Nr.: 860-049

INTENDED USE: BenchMark Special Stains Cleaning Kit is intended for use during the automated cleaning procedure on the BenchMark Special Stains instrument. This product is intended for in vitro diagnostic (IVD) use.

VENTANA DP 600 Slide Scanner RUO

High-quality, high-throughput scanning

Catalog Number: 09311378001

The VENTANA DP 600 Slide Scanner RUO is a significant addition to the Roche Digital Pathology portfolio as it will enable pathology laboratories to perform high-volume and high-quality scanning necessary for full digitization of their pathology workflow. The VENTANA DP 600 Slide Scanner RUO allows continuous loading of up to 40 trays or 240 slides.

VENTANA slide scanners offer the peace of mind of a reliable scan, from efficient tray loading to the final high-quality whole slide image.

For Research Use Only. Not for use in diagnostic procedures.



General characteristics

Labeling Research Use Only (RUO): United States and ex-US

countries not accepting the CE mark

Automation Auto-scanning feature enables no-click scanning

Auto-calibration for white balance

Capacity 240 slides

40 trays of 6 single slides

Slide Length: 75 - 76.53 mm specifications Width: 24.63 - 26.16 mm

Thickness: 0.9 - 1.397 mm, includes

slide sample and coverslip

Consumables Slide trays are recommended to be replaced annually

Time to view* 20x: <49 seconds for a 15mm x 15mm AOI[†]

40x: <85 seconds for a 15mm x 15mm AOI

Time to scan 20x: <36 seconds for a 15mm x 15mm AOI

40x: <73 seconds for a 15mm x 15mm AOI

Barcodes 1D

2D: DATAMATRIX, PDF417, QR code

File formats BIF, TIF, DICOM

*Time to view includes tray loading, thumbnailing and image acquisition.

[†] Area of Interest.

Optics

Optical zoom 20x, 40x

Scan resolution 20x: 0.46 µm/pixel

40x: 0.25 μm/pixel

Instrument

Footprint (WxDxH)

Slide scanner

74 cm x 74 cm x 67 cm 29.1 in x 29.1 in x 26.3 in

Computer 38 cm x 19 cm x 38 cm 14.9 in x 7.4 in x 14.9 in

F.4 F.F 70

Touchscreen monitor 54 cm x 5.5 cm x 32 cm

21.2 in x 2.1 in x 12.5 in

Weight

Slide scanner

75 kg (165.3 lbs)

Computer 8 kg (17.6 lbs)

Touchscreen monitor 3 kg (6.6 lbs)

Power requirements

Input voltage 100 - 240 V requirements

Supply frequency 50 - 60 Hz

 $\textbf{Input current} \hspace{1.5cm} 6A\,(100\,\text{V})\,\text{to}\,3A\,(240\,\text{V})$

Operating environmental conditions

Ambient temperature

11°C to 31°C

range

Vibration

17°C to 25°C

Optimal temperature range

17 0 10 20 0

Ambient humidity

10% to 80% RH, non-condensing

Ambient humidity change

<5% per hour

Operates according to specification defined by ISO 2631-2 for vibration

in buildings (1–80 Hz)

Altitude relative to sea level

-200 m to 3000 m

VENTANA DP 200 Slide Scanner RUO

Robust, reliable, high-speed scanning

Catalog Number: 8303924001

The **VENTANA DP 200 Slide Scanner RUO** leverages the latest image acquisition technology to provide laboratories with an intuitive, reliable, high-speed solution for capturing high-quality digital slide images.

- 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.

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 RUO 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.



For Research Use Only. Not for use in diagnostic procedures.



Roche uPath enterprise software and digital pathology image analysis algorithms

Offering efficient image management and analysis to enhance pathology workflow, Roche uPath enterprise software and image analysis algorithms empower pathologists to quickly, confidently and objectively assess VENTANA DP 200 slide images for faster, more accurate assessment of slides.

For Research Use Only. Not for use in diagnostic procedures. See page 7 for more information.

navify® Pathology Lab Advantage

See your lab for the first time



The **navify® Pathology Lab Advantage** 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 navify Pathology Lab Advantage
 maintains positive sample ID with barcode scanners at each
 workstation and single piece flow workflow.
- Increase efficiency: navify Pathology Lab Advantage is designed using Lean Six Sigma principles and includes expert workflow consulting to help you obtain immediate and ongoing workflow benefits.

Optimize lab performance: navify Pathology Lab
 Advantage business intelligence tools enable you to assess
 workload, monitor trends, identify problem areas, and
 more—providing greater visibility into your lab to improve
 workflow.

navify Pathology Lab Advantage

	Catalog Number
VANTAGE All-In-One Touchscreen PC	9019367001
VANTAGE Slide Barcode Label (1700/roll)	5524997001
VANTAGE Clear Overlay (3750/roll)	5525276001
VANTAGE Overlay Dispenser	5909490001
VANTAGE Handheld Barcode Scanner	7171650001
VANTAGE Compact Barcode Scanner	8356246001
VANTAGE Printer	8849323001

navify® Pathology Lab Hub

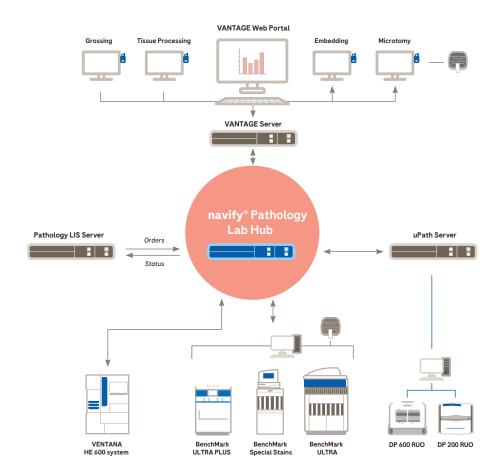
Streamlining lab connectivity

navify® Pathology Lab Hub 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 reentries 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.

navify® Pathology Lab Hub 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





Customer Experience

Fueled by the needs of patients and their healthcare professionals

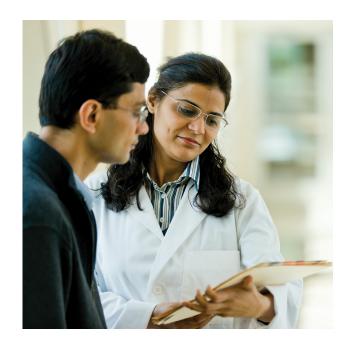
Roche Healthcare Consulting

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

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- 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.
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 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.



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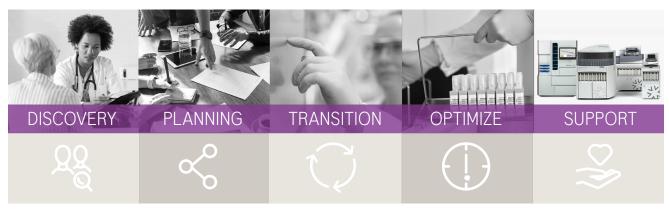
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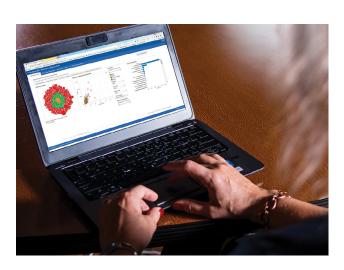
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Clinical Focus Areas

- Anatomic pathology: All solid tumors, with particular emphasis on breast, lung, colorectal, and cervical cancers.
- Personalized healthcare: Includes Companion
 Diagnostics (CDx) for cancer immunotherapy and
 biomarker-selected targeted therapeutics.





Appendices

Challenging the standard of care to improve the quality of patients' lives

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