



Roche Pathology Lab

Driving diagnostic certainty for
life-changing decisions in pathology

Product Catalog
2025



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.

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Roche Diagnostics

Innovating diagnostics, shaping healthcare, changing lives

For more than 125 years, Roche has been 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



Roche solutions span the entire spectrum of diagnostics users

Research



Academia



Pharma

Clinical Applications



Reference Lab



Hospital



Doctor's Office



Patient Homes

Sequencing Solutions

Molecular Diagnostics

Pathology Lab

Centralized Solutions

Diabetes Care

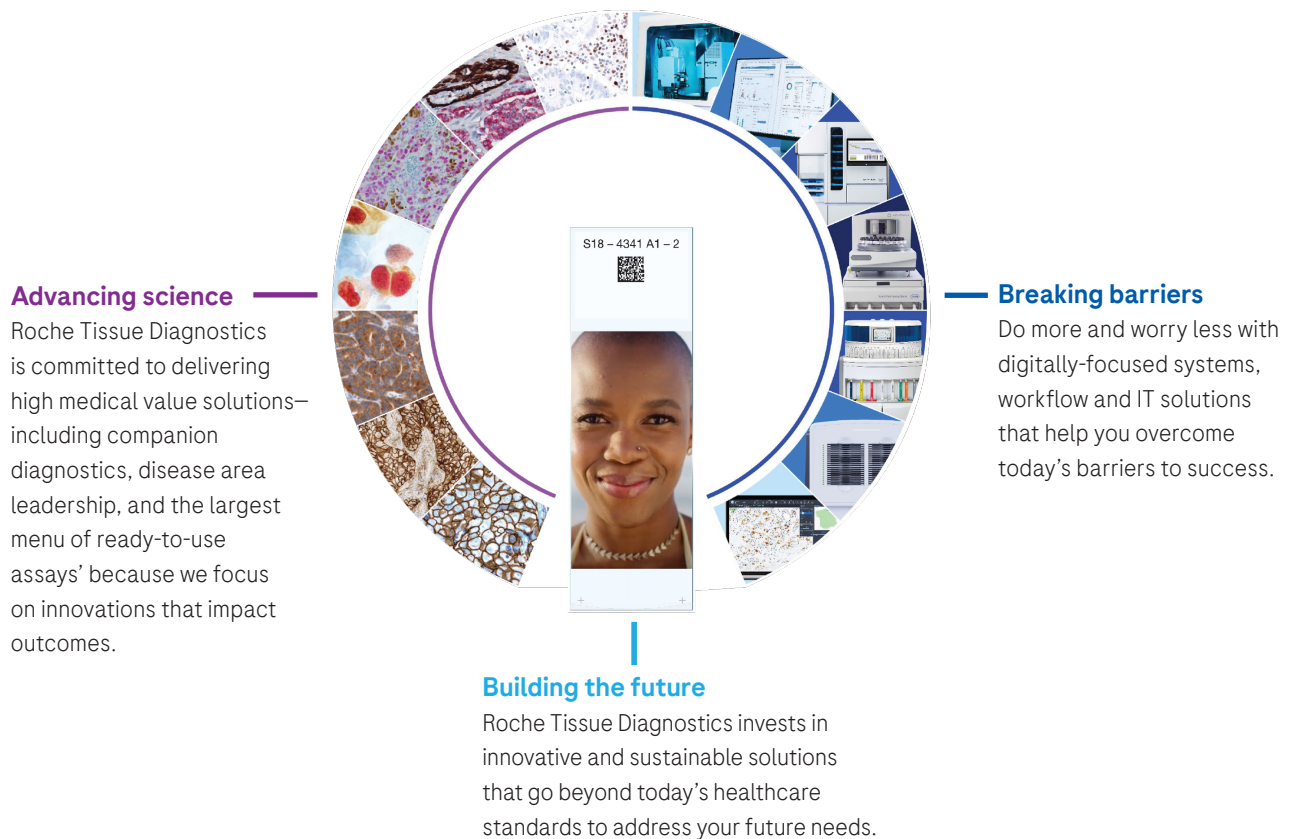
POC

Roche Pathology Lab

Driving diagnostic certainty for life-changing decisions

We are personally committed to driving diagnostic certainty for life-changing decisions in pathology.

We do this by advancing science to help improve patients' lives and by delivering innovative solutions that break down the barriers that anatomic pathology labs face every day. This empowers our customers to reach their full potential now, and build a future that holds the potential to beat cancer.



Reference:

1. Roche data on file: Data supporting HMV tissue assay menu size, number of therapies on label, and CDx portfolio size. Accessed 1 September 2024.

Roche Pathology Lab

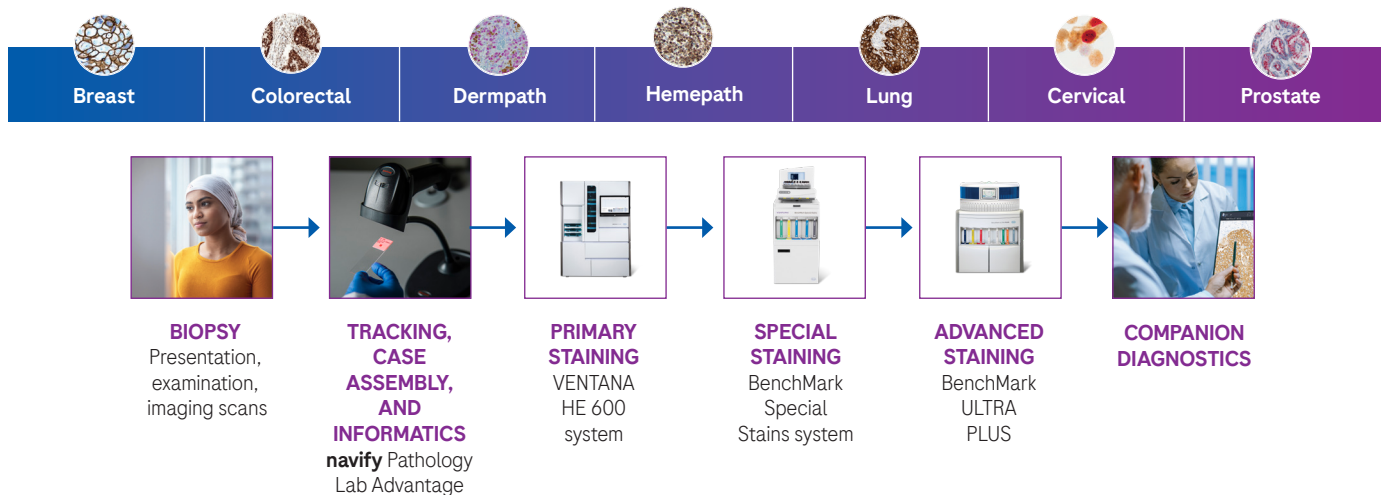
Solutions to help your lab advance patient care

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, Roche Digital Pathology Dx and research use only digital 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.



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

Improving lives through ongoing innovation

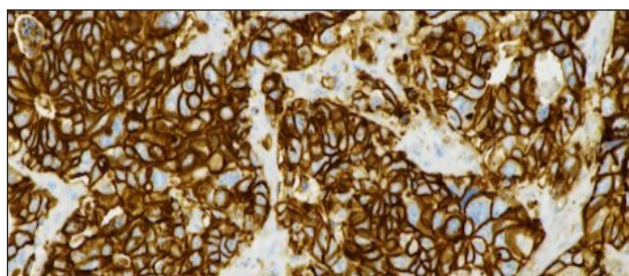
As part of Roche, we are continuously investing in diagnostic tools that address unmet medical needs and provide information to help advance patient care



Roche Digital Pathology Dx

The Roche Digital Pathology Dx is to be used as an aid to the pathologist to review and interpret digital images and was designed to drive diagnostic certainty throughout every stage of the workflow process.

More information on pages 164 and 165.

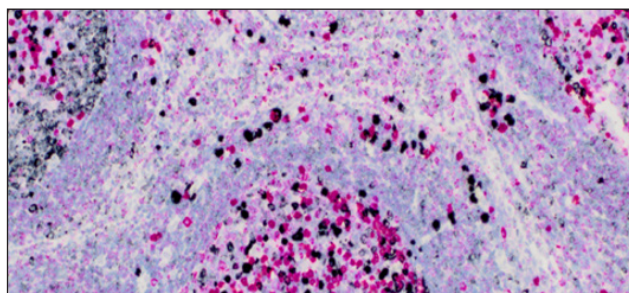


VENTANA CLDN18 (43-14A) RxDx Assay

Ordering Code: 08287066001

VENTANA CLDN18 (43-14A) RxDx assay is the first FDA-approved immunohistochemistry (IHC) companion diagnostic for determining Claudin 18 (CLDN18) protein expression. This qualitative IHC test is intended as an aid in identifying patients with gastric or GEJ adenocarcinoma who may be eligible for treatment with VYLOY (zolbetuximab) in accordance with the approved therapeutic product labeling.

More information on page 51.



VENTANA Kappa and Lambda mRNA Dual ISH Probe Cocktail

Ordering Code: 08507015001

The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail provides sensitive and dynamic detection for both kappa and lambda light chain mRNA, expanding the clinical utility to B-cells in all stages of maturation and their neoplastic counterparts. This assay is performed on a single slide of FFPE bone marrow or lymphoid tissue, conserving tissue and preserving morphological context.

More information on page 73.

VENTANA®

Roche

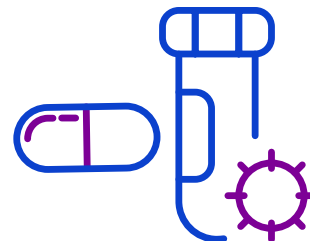


Medical Value

Our commitment to high medical value innovation means a leading-edge menu for labs and new hope for patients

Personalized Healthcare: Companion Diagnostics

Our broad portfolio offers unmatched quantity and high quality



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.

Our rigorous development discipline ensures products that deliver high quality, high reliability, and reproducible results.

- **20+ Tissue types tested**
- **15+ Assay parameters evaluated**
- **1700+ Individual patient cases reviewed**
- **170+ Hours of pathology reads performed**
- **8000+ Average work hours dedicated**

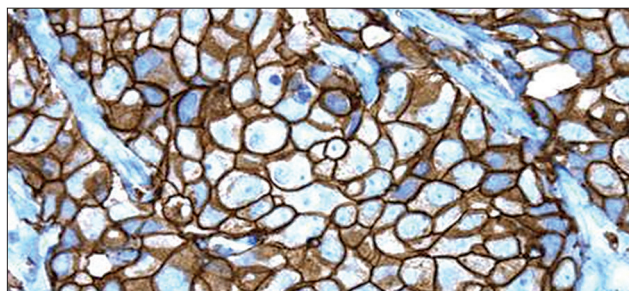
“Targeted diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers.”

— Severin Schwan,
Chairman, Roche

VENTANA Companion Diagnostics

Selective and predictive assays essential for personalized healthcare

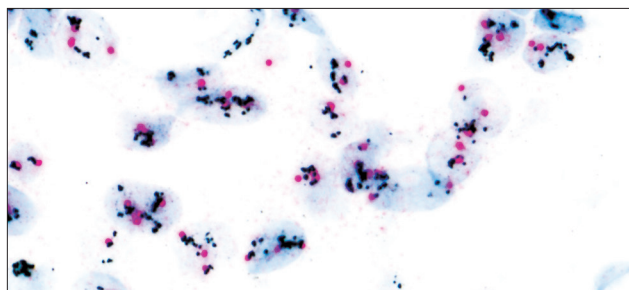
VENTANA companion diagnostics are fully automated to help improve quality and standardize testing, and can easily fit into your current workflow.



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).

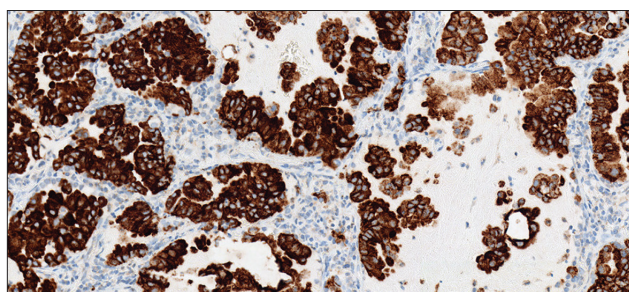
For more information, see page 69.



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).

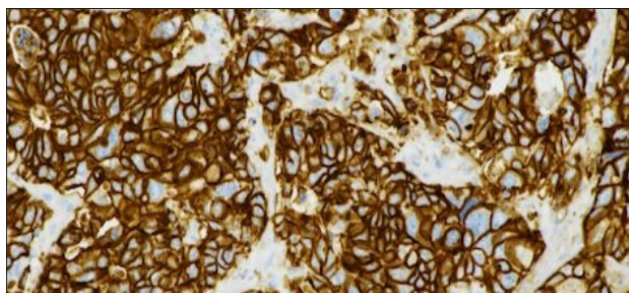
For more information, see page 70.



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 29.

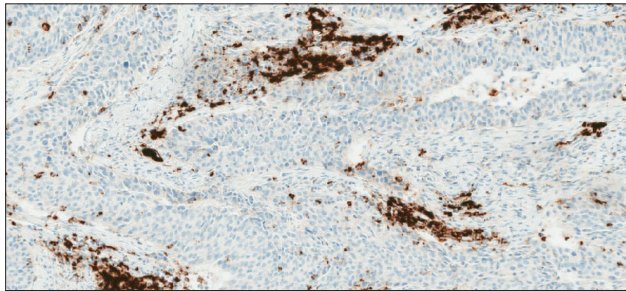


VENTANA CLDN18 (43-14A) RxDx Assay

The first FDA-approved immunohistochemistry (IHC) companion diagnostics for determining Claudin 18 (CLDN18) protein expression in patients with gastric or gastroesophageal junction (GEJ) adenocarcinoma who may be eligible for CLDN18.2-targeted treatment with Astellas' VYLOY® (zolbetuximab-clzb).

For more information, see page 51.

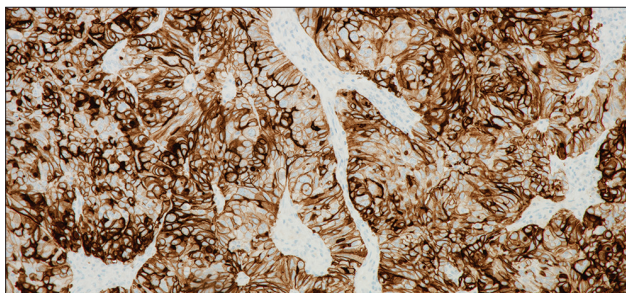
*Based on data from a leading external quality assessment scheme.
Retrieved from <http://www.nordiqc.org/epitope.php>.



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).

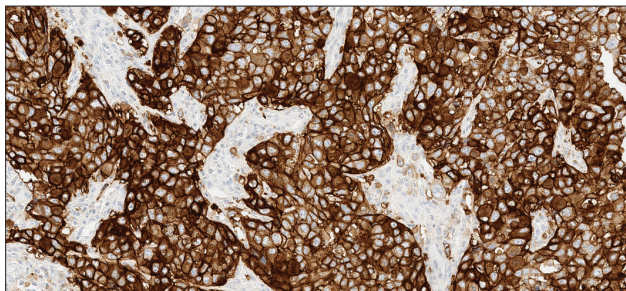
For more information, see page 91.



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.

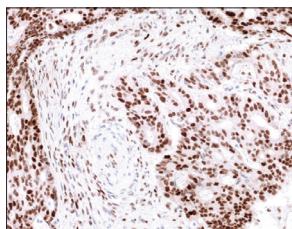
For more information, see page 63.



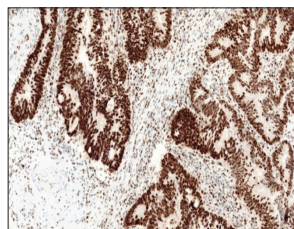
VENTANA PD-L1 (SP263) Assay

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).

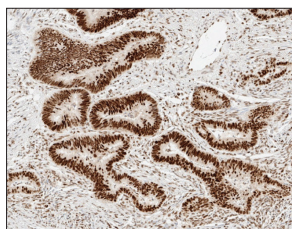
For more information, see page 92.



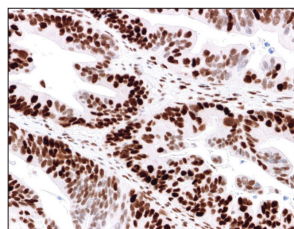
MLH1



PMS2



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 (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.

For more information, see pages 78-80 and 94.

*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.¹

FDA-regulated in vitro diagnostics are composed of 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.

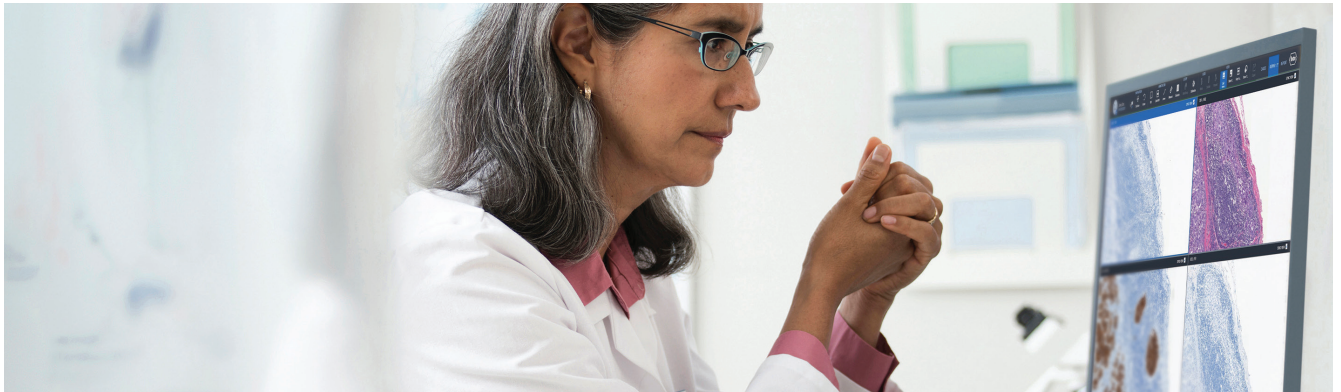
Clinical reagents include:

- 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:

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

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



The regulatory controls for each device class include:

- **RUO/IUO (Research Use Only/Investigational Use Only)**
 - RUO and IUO devices are not intended for clinical diagnostic use
- **Class I (low to moderate risk): General controls**
 - Class I devices are typically an adjuvant test, low risk and therefore subject to the least regulatory controls
- **Class II (moderate to high risk): General controls and special controls**
 - Class II products are standalone, moderate-risk assays, requiring greater regulatory controls to provide reasonable assurance of safety and effectiveness
- **Class III (high risk): General controls and Premarket Approval (PMA)**
 - Class III products are used as predictive or selective diagnostic assays, and have the highest risk. They are therefore subject to the highest level of regulatory control. These devices must be approved by the FDA prior to being promoted or sold in the US

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

*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



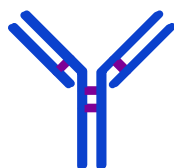
- TTF-1 (SP141)
- Cytokeratin 5/6 (D5/16B4)
- Napsin A (MRQ-60)
- p40 (BC28)
- ALK (D5F3)
- ROS1 (SP384)
- pan-TRK (EPR17341)
- PD-L1 (SP142 & SP263)

Cervical



- CINtec® Histology
- CINtec® PLUS Cytology

Our broad portfolio includes sensitive, specific assays for key markers. Go to page 20 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

The recombinant antibody difference

Securing consistent, reliable product supply and driving toward a greener, less animal reliant product menu:

- Reduced reliance on native and animal sources
- Consistent and reproducible results³
- Improve lot-to-lot consistency³
- Steady, dependable supply³
- Stronger signal intensity with less background⁴



References:

1. 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.
3. Acharya P, Quinlan A, Neumeister V. The ABCs of finding a good antibody: How to find a good antibody, validate it, and publish meaningful data. *F1000Res*. 2017 Jun 8;6:851. doi: 10.12688/f1000research.11774.1. PMID: 28713558; PMCID: PMC5499787.
4. F. Hoffmann-La Roche Ltd. D201606 CD68 (SP251c18) . [Internal report; Cited 2024 November 13]. Data on File.

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 IIα (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) Rx Dx Assay, VENTANA

hCG (polyclonal)

MyoD1 (EP212)

Myogenin (F5D)

Oct-4 (MRQ-10)



Lung

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

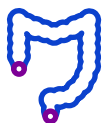
Thyroid Transcription Factor-1 (SP141)

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)

Villin (CWVB1)



Dermatopathology

Typical Melanoma Panel Assays

- MART-1/melan A (A103), CONFIRM
- Melanosome (HMB45), CONFIRM
- Nerve Growth Factor Receptor (MRQ-21)
- S100 (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)*



Genitourinary Including Prostate

Typical Prostate Panel Assays

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

Androgen 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)



Hematopathology

Typical Hematopathology Panel Assays

- bcl-2 (SP66)
- c-Myc (Y69)
- CD3 (2GV6), CONFIRM
- CD5 (SP19), CONFIRM
- CD10 (SP67), VENTANA
- CD20 (L26), CONFIRM
- CD23 (SP23), CONFIRM
- CD30 (Ber-H2)
- Cyclin D1 (SP4-R), VENTANA
- Kappa and Lambda Dual ISH mRNA Probe
- 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
Kappa and Lambda Dual ISH mRNA Probe
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)*



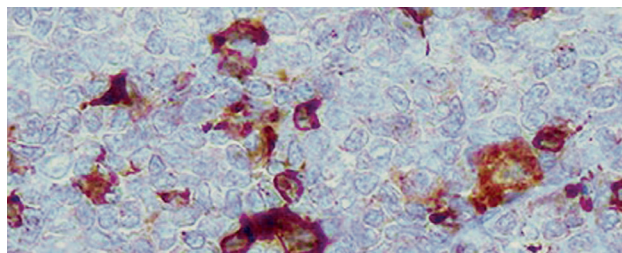
Neuropathology

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)

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.

A-1-Antitrypsin (polyclonal)

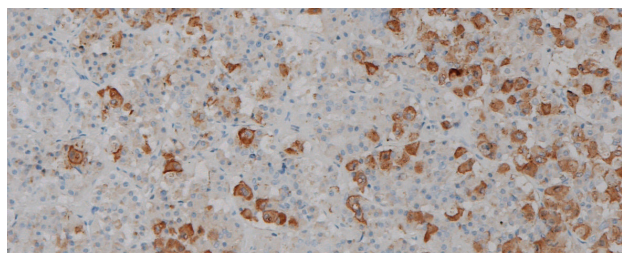
Ordering Number: 05267200001
Catalog Number: 760-2605
Quantity: 50 tests
Controls: Appendix, Lymph Node, Tonsil
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

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

ACTH (polyclonal)

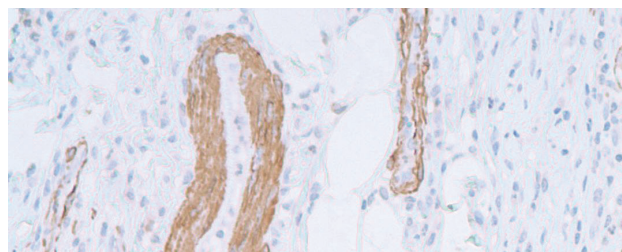
Ordering Number: 05268176001
Catalog Number: 760-2708
Quantity: 50 tests
Controls: Normal Pituitary
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

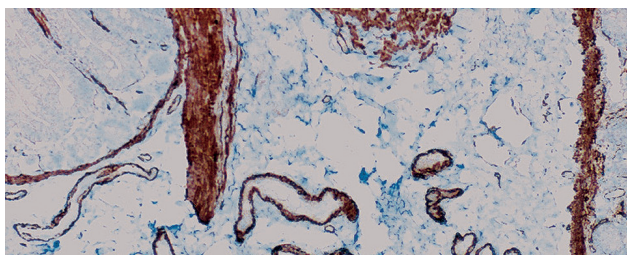
ACTH Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of the ACTH protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination,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

Actin, Muscle Specific (HHF35)

Ordering Number: 05267161001
Catalog Number: 760-2601
Quantity: 50 tests
Controls: Skeletal Muscle
Isotypes: IgG₁/K
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.

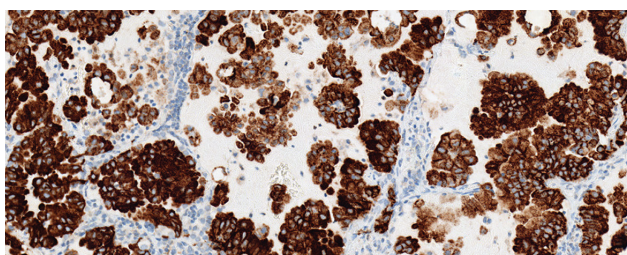


Actin, Smooth Muscle (1A4) Mouse Monoclonal Antibody

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.

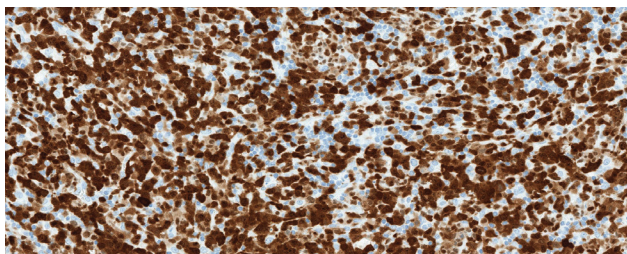


VENTANA ALK (D5F3) CDx Assay

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

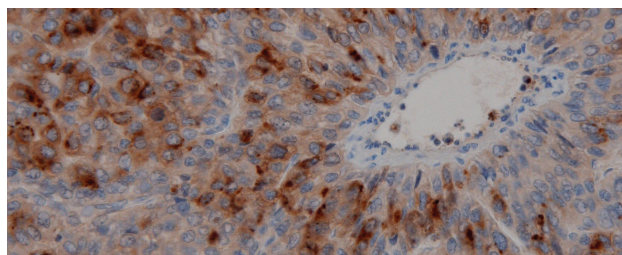
Ordering Number:	05278147001
Catalog Number:	790-2918
Quantity:	50 tests
Controls:	Anaplastic Large Cell Lymphoma
Isotypes:	IgG ₁ /K
Clone Name:	ALK01
Species:	Mouse
Localization:	Nuclear, Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

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
Regulatory Status: IVD

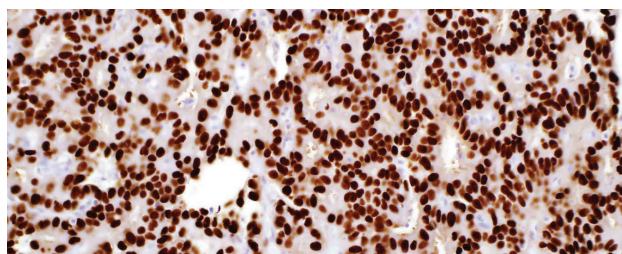


INTENDED USE

Alpha-Fetoprotein Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of Alpha-Fetoprotein in formalin-fixed, 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
Quantity: 50 tests
Controls: Prostate
Isotypes: IgG
Clone Name: SP107
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

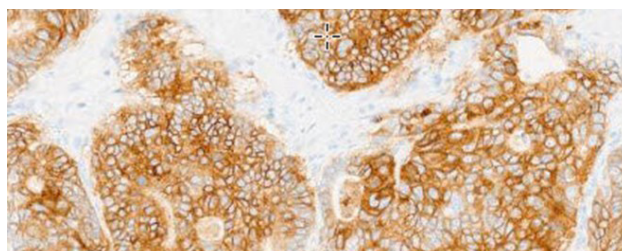


INTENDED USE

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.

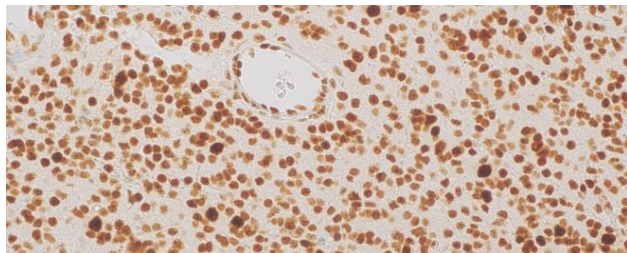
VENTANA anti-AREG (SP272) Rabbit Monoclonal Primary Antibody

Ordering Number: 09858725001
Catalog Number: 790-7215
Quantity: 50 tests
Controls: Colorectal Adenocarcinoma
Isotypes: IgG
Clone Name: SP272
Species: 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.

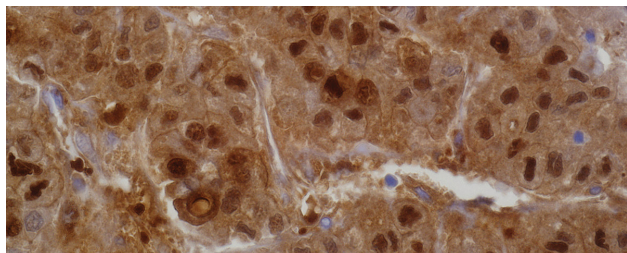


ATRX Rabbit Polyclonal Antibody

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.

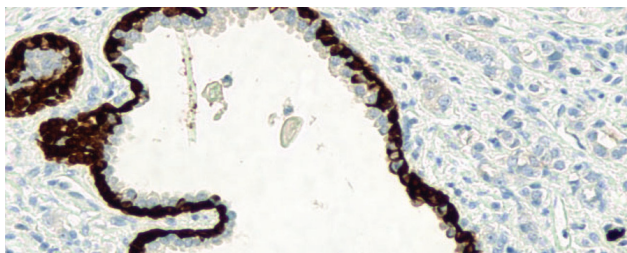


anti-Arginase-1 (SP156), Rabbit Monoclonal Primary Antibody

Ordering Number:	06732348001
Catalog Number:	760-4801
Quantity:	50 tests
Controls:	Hepatocellular Carcinoma, Normal Liver
Isotypes:	IgG
Clone Name:	SP156
Species:	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)

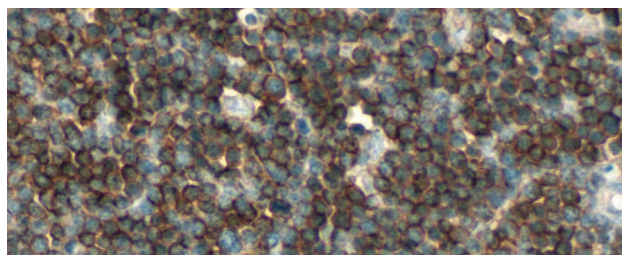
Ordering Number:	06364497001	06419445001
Catalog Number:	790-4536	790-1010
Quantity:	50 tests	250 tests
Controls:	Normal Basal Cells in Prostate Tissue	
Isotypes:	IgG _{2a} /K	
Clone Name:	34βE12 + 4A4	
Species:	Mouse	
Localization:	Cytoplasmic (34βE12), Nuclear (4A4)	
Regulatory Status:	IVD	

INTENDED USE

VENTANA Basal Cell Cocktail (34βE12+p63) is an antibody cocktail of anti-p63 (4A4) and anti-keratin (34βE12) mouse monoclonal antibodies. VENTANA Basal Cell Cocktail (34βE12+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: IgG₁
Clone Name: 124
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

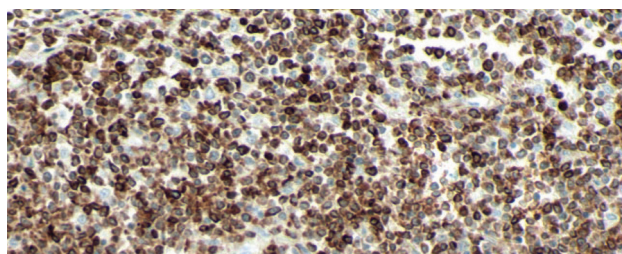


INTENDED USE

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

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

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

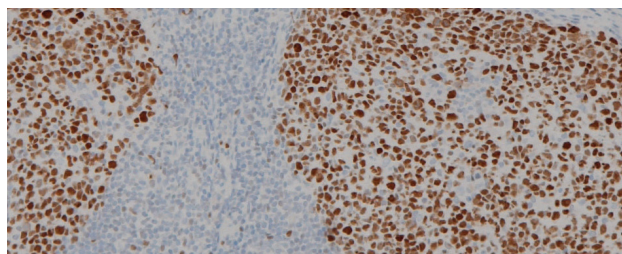


INTENDED USE

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.

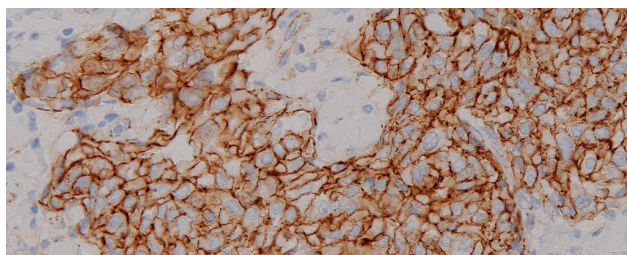
bcl-6 (GI191E/A8)

Ordering Number: 05269008001
Catalog Number: 760-4241
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁
Clone Name: GI191E/A8
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD



INTENDED USE

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

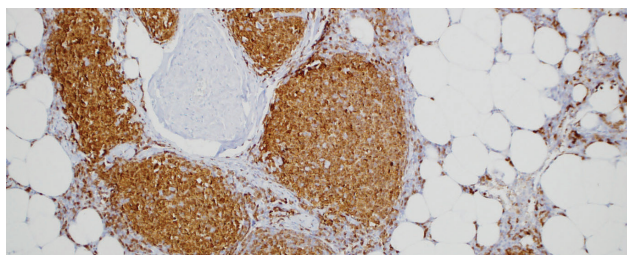


Beta-Catenin (14)

Ordering Number:	05269016001
Catalog Number:	760-4242
Quantity:	50 tests
Controls:	Fibromatosis of Breast or Abdomen
Isotypes:	IgG ₁
Clone Name:	14
Species:	Mouse
Localization:	Nuclear
Regulatory Status:	IVD

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.

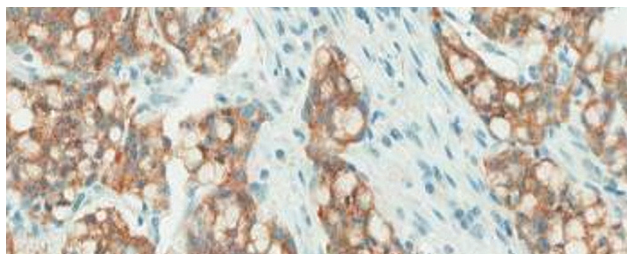


BOB.1 (SP92)

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

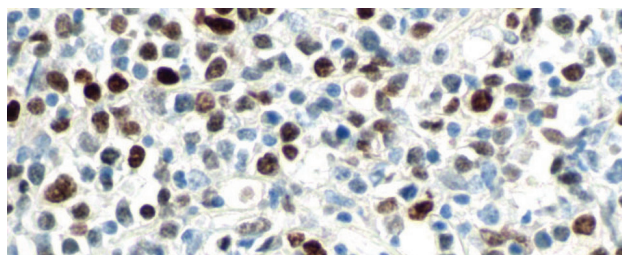
Ordering Number:	07862270001
Catalog Number:	790-5095
Quantity:	50 tests
Controls:	Pre-qualified case of CRC that is positive for the VENTANA anti-BRAF V600E (VE1) antibody
Isotypes:	IgG _{2a}
Clone Name:	VE1
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

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

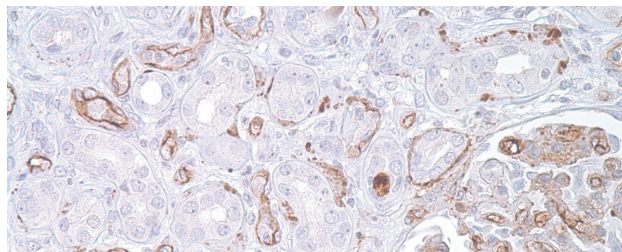


INTENDED USE

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

Ordering Number: 06419143001
Catalog Number: 760-4522
Quantity: 50 tests
Controls: Acute Rejected Kidney Transplant
Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

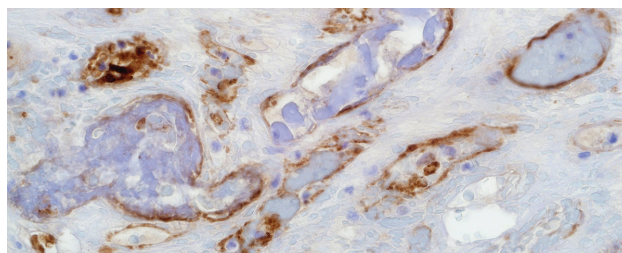


INTENDED USE

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

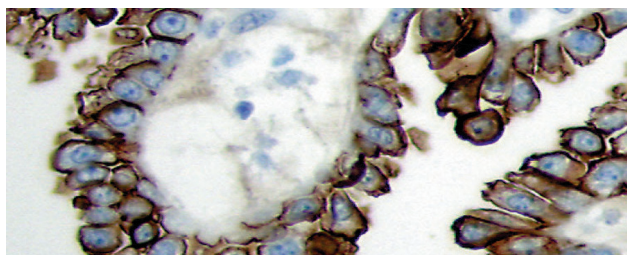
C4d (SP91)

Ordering Number: 06732364001
Catalog Number: 760-4803
Quantity: 50 tests
Controls: Acute Rejected Kidney Transplant, Tonsil/Lymph Node
Isotypes: IgG
Clone Name: SP91
Species: Rabbit
Localization: Membranous
Regulatory Status: IVD



INTENDED USE

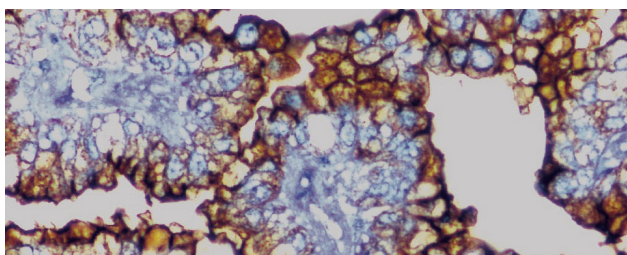
C4d (SP91) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the C4d protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological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

**CA-125 (OC125)**

Ordering Number:	05267269001
Catalog Number:	760-2610
Quantity:	50 tests
Controls:	Ovarian Carcinoma
Isotypes:	IgG ₁ /K
Clone Name:	OC125
Species:	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)**

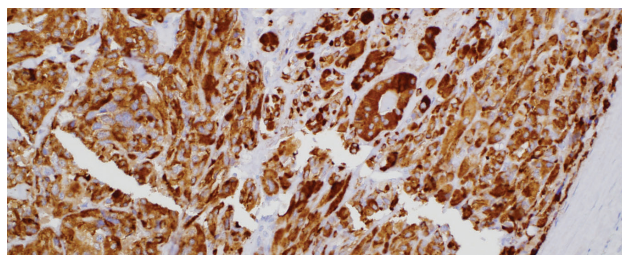
Ordering Number:	05267242001
Catalog Number:	760-2609
Quantity:	50 tests
Controls:	Colon, Salivary Gland
Isotypes:	IgM
Clone Name:	121SLE
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

anti-Calcitonin (SP17), Rabbit Monoclonal Primary Antibody

Ordering Number: 06586554001
Catalog Number: 760-4705
Quantity: 50 tests
Controls: Medullary Carcinoma of Thyroid
Isotypes: IgG
Clone Name: SP17
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

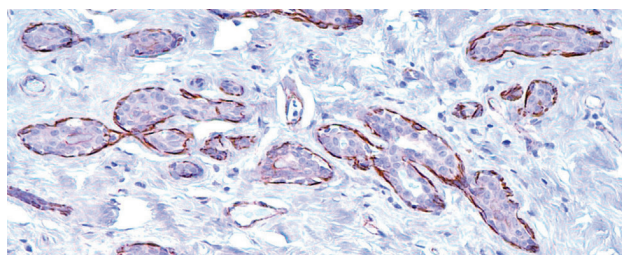


INTENDED USE

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: IgG
Clone Name: E89
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

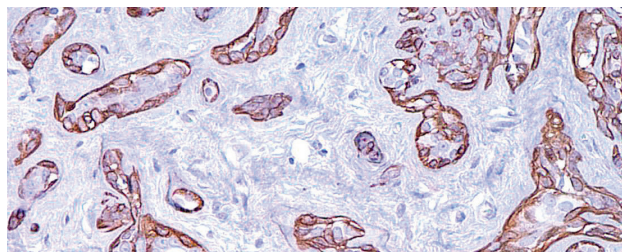


INTENDED USE

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.

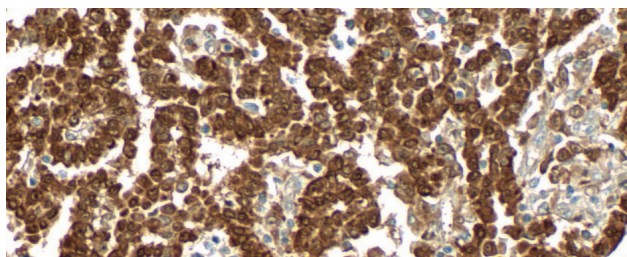
Calponin-1 (EP798Y)

Ordering Number: 05435684001
Catalog Number: 760-4376
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.

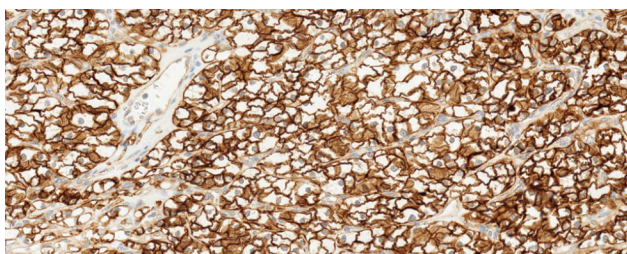


CONFIRM Calretinin (SP65) Rabbit Monoclonal Primary Antibody

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.

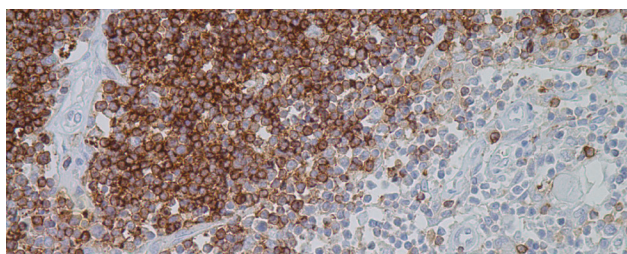


Carbonic Anhydrase IX (EP161) Rabbit Monoclonal Primary Antibody

Ordering Number:	08313466001
Catalog Number:	760-6080
Quantity:	50 tests
Controls:	Clear Cell Renal Cell Carcinoma, Gall Bladder
Isotypes:	IgG
Clone Name:	EP161
Species:	Rabbit
Regulatory 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)

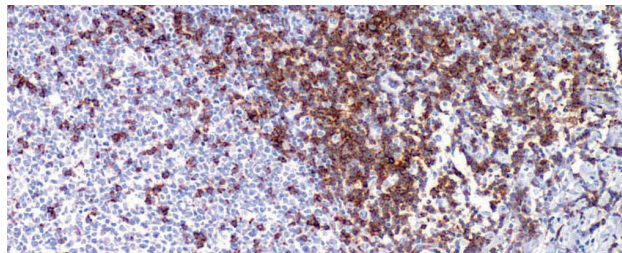
Ordering Number:	06419160001
Catalog Number:	760-4525
Quantity:	50 tests
Controls:	Thymus
Isotypes:	IgG ₁
Clone Name:	EP3622
Species:	Rabbit
Localization:	Membranous
Regulatory Status:	IVD

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)

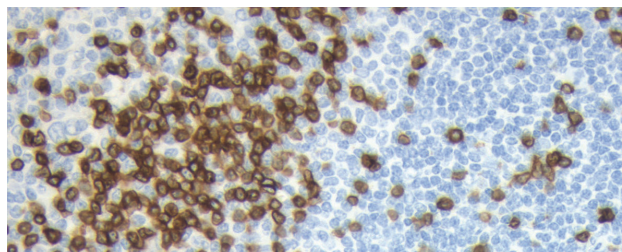
Ordering Number: 05463467001
Catalog Number: 760-4377
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁/K
Clone Name: MRQ-11
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

**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

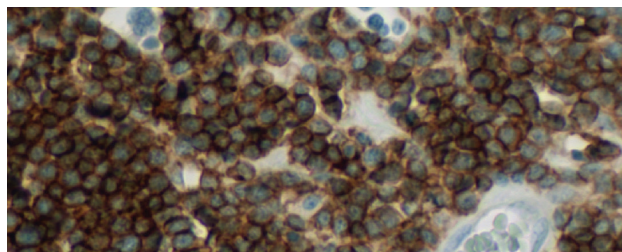
Ordering Number: 05278422001
Catalog Number: 790-4341
Quantity: 50 tests
Controls: Spleen, Tonsil
Clone Name: 2GV6
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

**INTENDED USE**

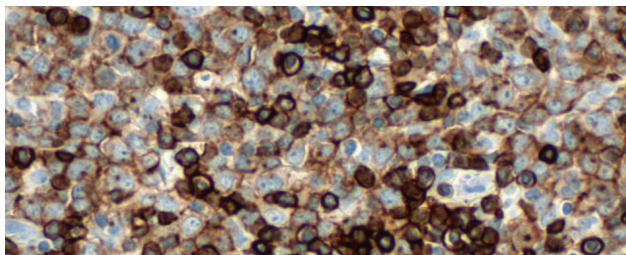
CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD3 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instruments. This product should be interpreted 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.

CONFIRM anti-CD4 (SP35) Rabbit Monoclonal Primary Antibody

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.

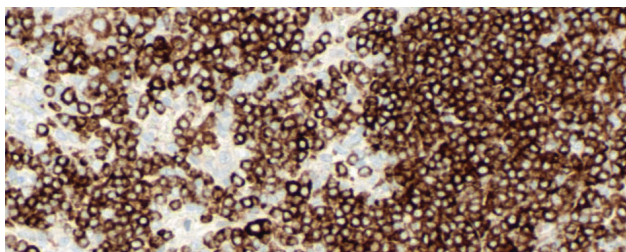


CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody

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.

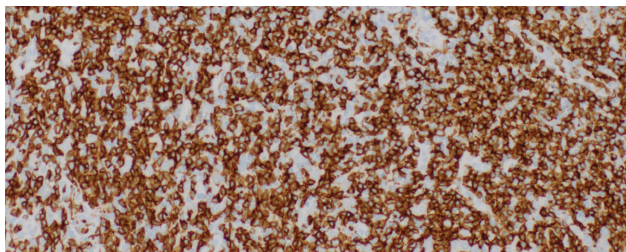


anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody

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

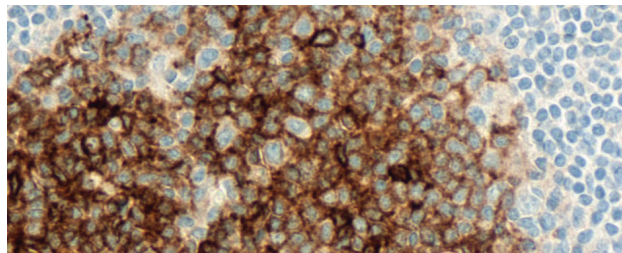
Ordering Number:	09780041001
Catalog Number:	760-7176
Quantity:	50 tests
Controls:	Normal Tonsil
Clone Name:	SP239
Species:	Rabbit
Localization:	Membrane, Cytoplasm
Regulatory Status:	IVD

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

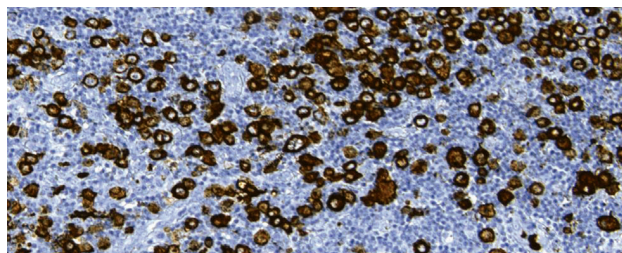
Ordering Number: 05857856001
Catalog Number: 790-4506
Quantity: 50 tests
Controls: Tonsil
Isotypes: Rabbit Ig
Clone Name: SP67
Species: Rabbit
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

**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

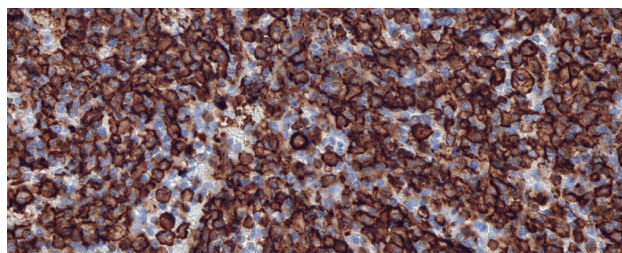
Ordering Number: 05266904001
Catalog Number: 760-2504
Quantity: 50 tests
Controls: Hodgkin's Lymphoma
Isotypes: IgM
Clone Name: MMA
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

**INTENDED USE**

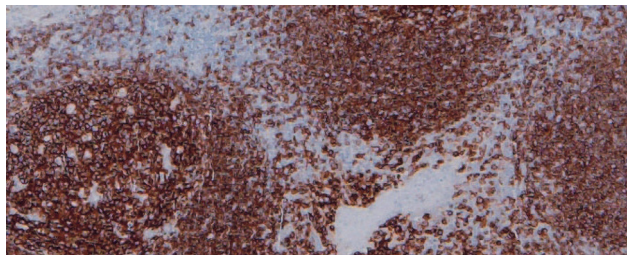
CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD15 by light microscopy in sections of formalin-fixed, paraffin embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by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

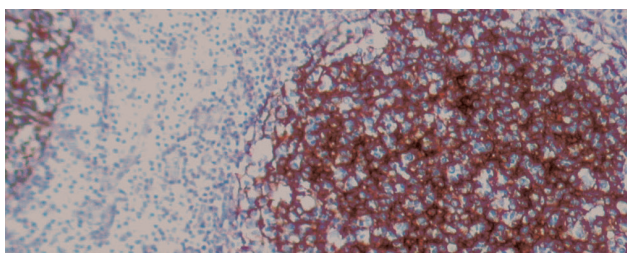


CONFIRM anti-CD20 (L26) Primary Antibody

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.

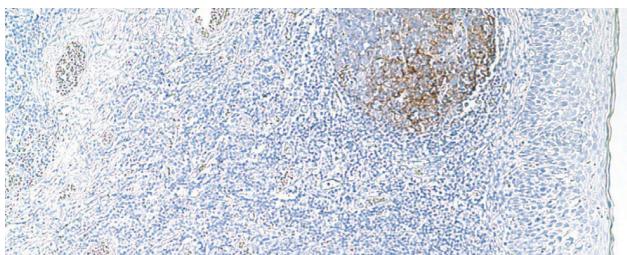


CD21 (2G9)

Ordering Number: 05269059001
Catalog Number: 760-4245
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG_{2a}
Clone Name: 2G9
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

INTENDED USE

CD21 (2G9) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 protein in formalin-fixed, 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)

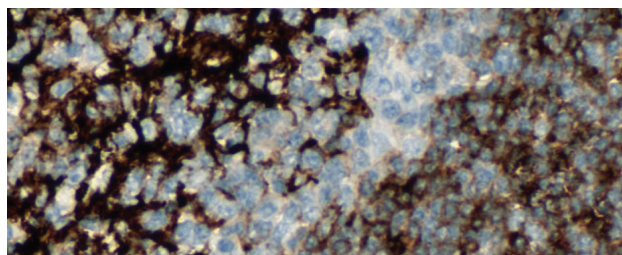
Ordering Number: 05973902001
Catalog Number: 760-4438
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁
Clone Name: EP3093
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

INTENDED USE

CD21 (EP3093) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the CD21 protein in formalin-fixed, 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-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

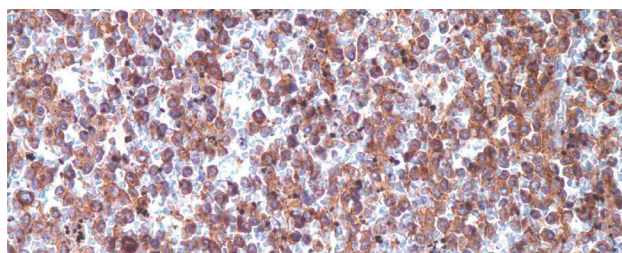


INTENDED USE

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
Isotypes: IgG_{2b}
Clone Name: 4C9
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

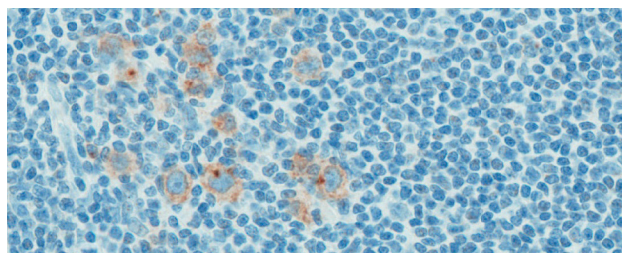


INTENDED USE

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.

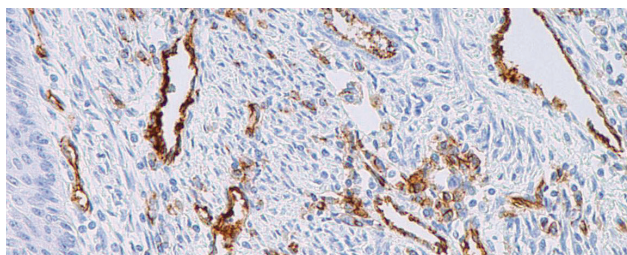
anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody

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: IgG₁/K
Clone Name: Ber-H2
Species: 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.

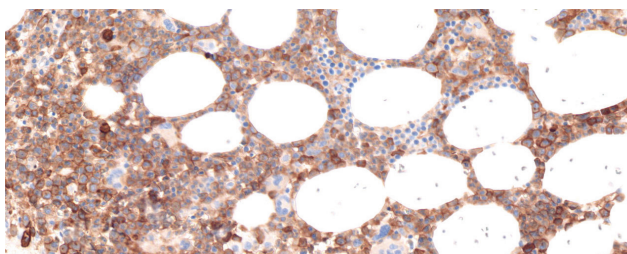


CD31 (JC70)

Ordering Number:	05463475001
Catalog Number:	760-4378
Quantity:	50 tests
Controls:	Appendix, Placenta, Tonsil
Isotypes:	IgG ₁ /K
Clone Name:	JC70
Species:	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.

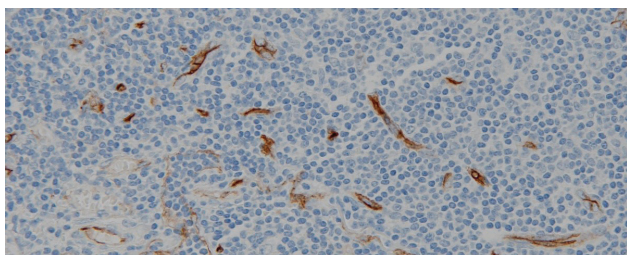


CD33 (SP266) Rabbit Monoclonal Primary Antibody

Ordering Number:	07391447001
Catalog Number:	760-4952
Quantity:	50 tests
Controls:	Acute Leukemia, Placenta Syncytiotrophoblasts
Isotypes:	IgG
Clone Name:	SP266
Species:	Rabbit
Localization:	Membranous
Regulatory Status:	IVD

INTENDED USE

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



CONFIRM anti-CD34 (QBEnd/10) Primary Antibody

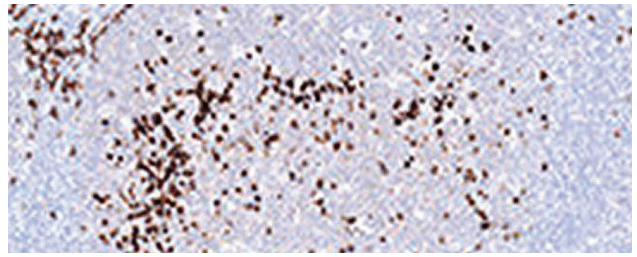
Ordering Number:	05278210001
Catalog Number:	790-2927
Quantity:	50 tests
Controls:	Appendix, Placenta, Tonsil
Isotypes:	IgG ₁
Clone Name:	QBEnd/10
Species:	Mouse
Localization:	Membranous
Regulatory Status:	IVD

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

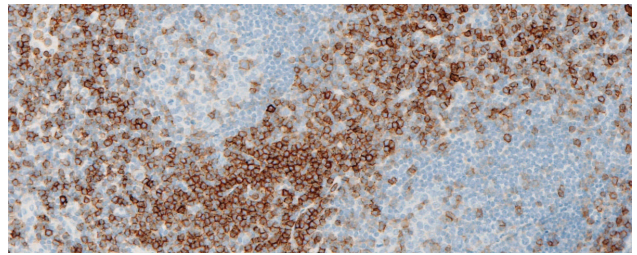
Ordering Number: 06648550001
Catalog Number: 760-4785
Quantity: 50 tests
Controls: Bone Marrow, Lymph Node, Plasma cells, Plasma cell myeloma
Isotypes: IgG
Clone Name: SP149
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

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

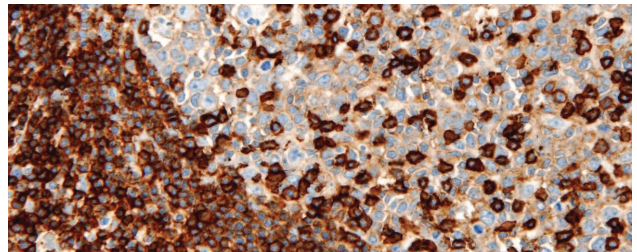
Ordering Number: 05266980001
Catalog Number: 760-2511
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁
Clone Name: L60
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

**INTENDED USE**

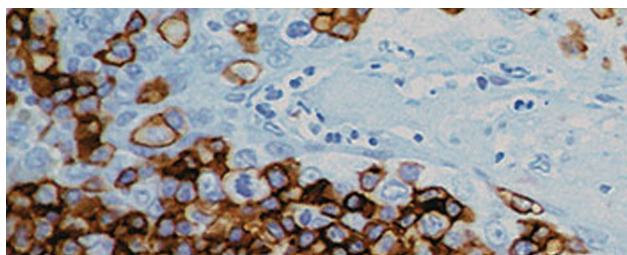
Anti-CD43 (L60) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD43 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified 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
Catalog Number: 760-4279
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁/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.

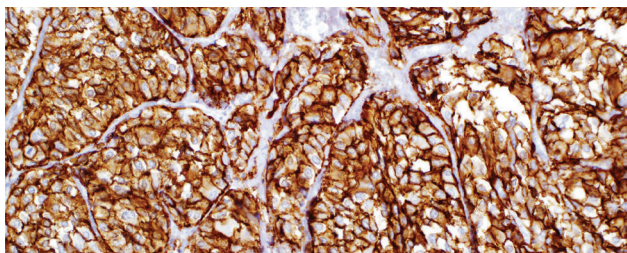


CONFIRM anti-CD45, LCA (RP2/18) Primary Antibody

Ordering Number:	05266912001
Catalog Number:	760-2505
Quantity:	50 tests
Controls:	Tonsil
Isotypes:	IgG ₁ /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.

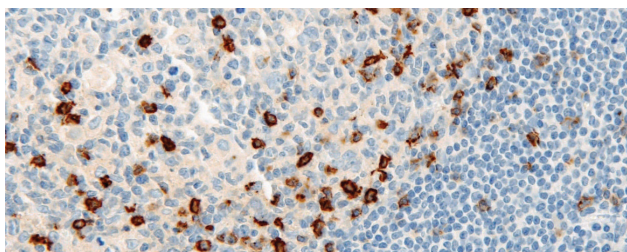


CD56 (MRQ-42)

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)

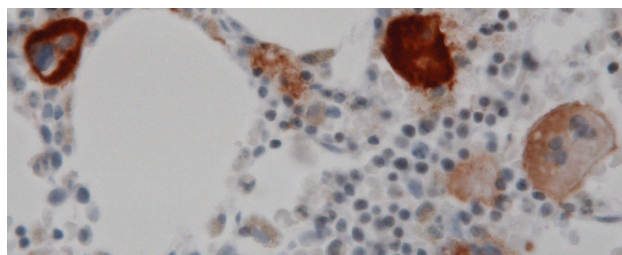
Ordering Number:	05267366001
Catalog Number:	760-2626
Quantity:	50 tests
Controls:	Lymph Node, Tonsil
Isotypes:	IgM/K
Clone Name:	NK-1
Species:	Mouse
Localization:	Membranous
Regulatory Status:	IVD

INTENDED USE

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

CD61 (2f2)

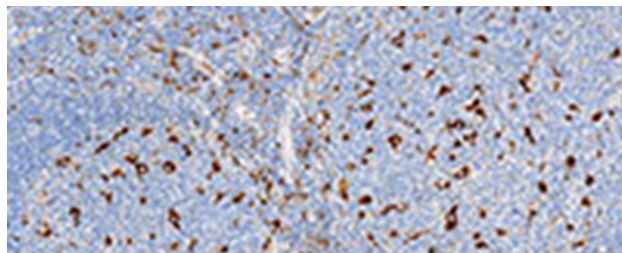
Ordering Number: 05269091001
Catalog Number: 760-4249
Quantity: 50 tests
Controls: Bone Marrow
Isotypes: IgG₁
Clone Name: 2f2
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

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

CD68 (SP251v18) Rabbit Monoclonal Antibody

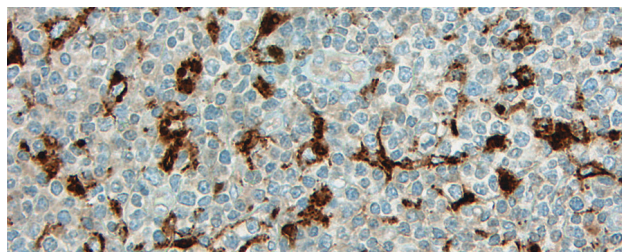
Ordering Number: 10161876001
Catalog Number: 790-7248
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁/K
Clone Name: KP-1
Species: Mouse
Localization: Cytoplasm, Membrane
Regulatory Status: IVD

**INTENDED USE**

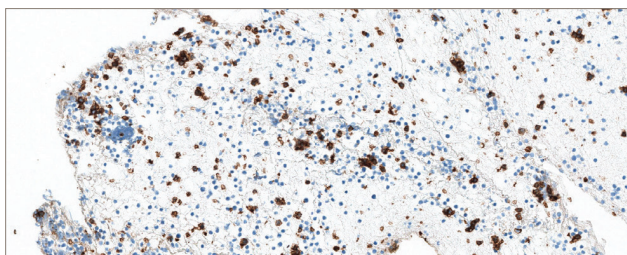
CD68 (SP251v18) Rabbit Monoclonal Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD68 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic use.

CONFIRM anti-CD68 (KP-1) Primary Antibody

Ordering Number: 05278252001
Catalog Number: 790-2931
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG₁/K
Clone Name: KP-1
Species: 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.

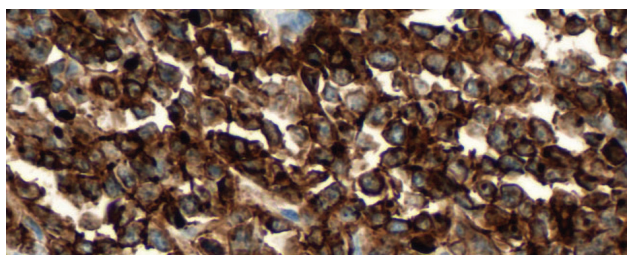


CD71 (MRQ-48) Mouse Monoclonal Antibody

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.

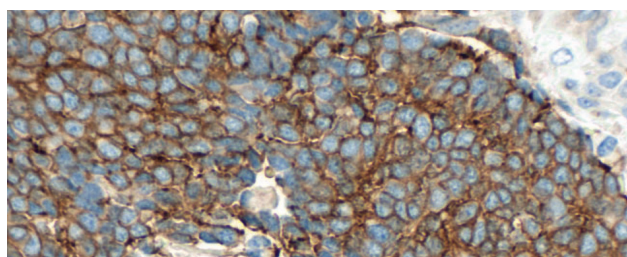


CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody

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

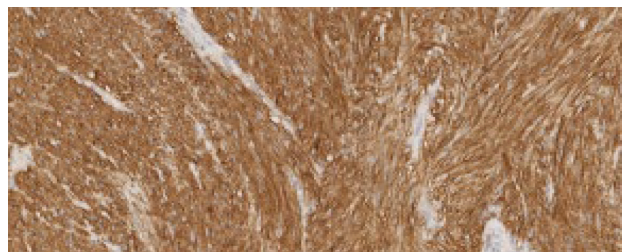
Ordering Number:	05913594001
Catalog Number:	790-4452
Quantity:	50 tests
Controls:	Pancreatic Islet Cells, Sertoli Cells of the Testis
Isotypes:	IgG ₁
Clone Name:	O13
Species:	Mouse
Localization:	Membranous
Regulatory Status:	IVD

INTENDED USE

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

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

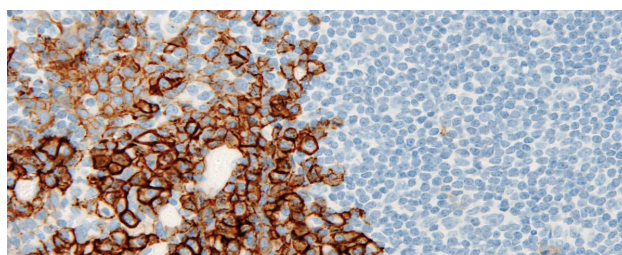


INTENDED USE

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: IgG
Clone Name: B-A38
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

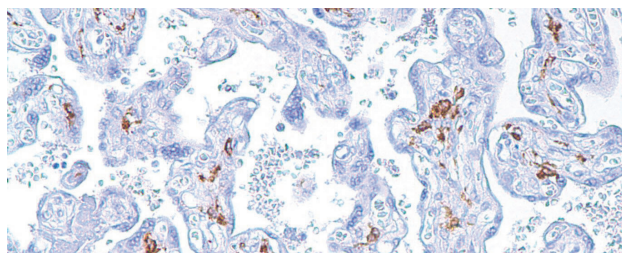


INTENDED USE

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.

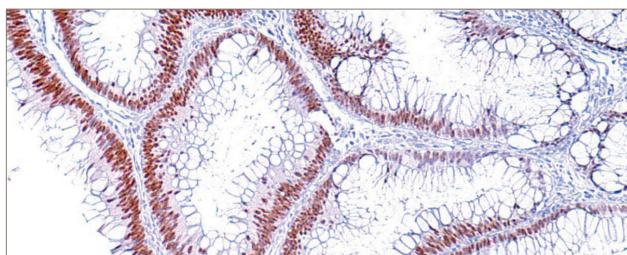
CD163 (MRQ-26)

Ordering Number: 05973929001
Catalog Number: 760-4437
Quantity: 50 tests
Controls: Inflamed Tissue
Isotypes: IgG₁
Clone Name: MRQ-26
Species: Mouse
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.

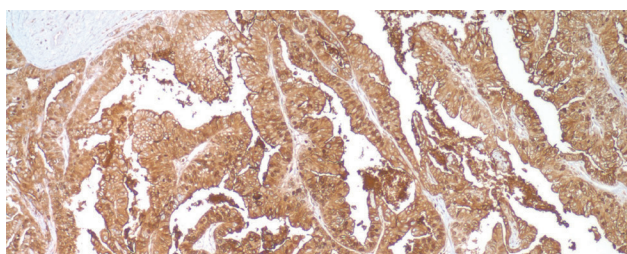


CDX-2 (EPR2764Y)

Ordering Number:	05463491001
Catalog Number:	760-4380
Controls:	Adenocarcinoma of Colon, Normal Colon
Isotypes:	IgG ₁ /K
Clone Name:	EPR2764Y
Species:	Rabbit
Localization:	Nuclear
Regulatory Status:	IVD

INTENDED USE

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

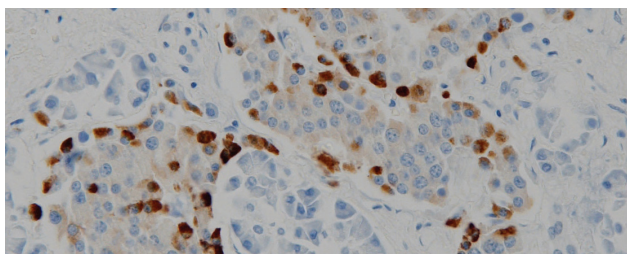


CEA (CEA31) Mouse Monoclonal Antibody

Ordering Number:	06433316001
Catalog Number:	760-4594
Quantity:	50 tests
Controls:	Adenocarcinoma of Colon, Colon Mucosa
Isotypes:	IgG ₁
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

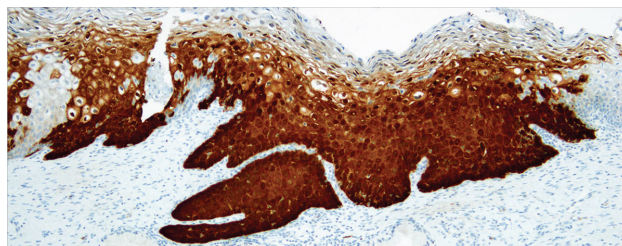
Ordering Number:	05267056001
Catalog Number:	760-2519
Quantity:	50 tests
Controls:	Pancreas
Isotypes:	IgG ₁ /K
Clone Name:	LK2H10
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

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	
Isotypes:	IgG _{2a}	
Clone Name:	E6H4™	
Species:	Mouse	
Regulatory Status:	IVD	

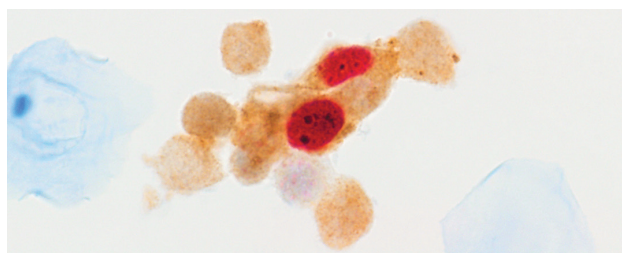


INTENDED USE

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

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 - IgG _{2a} Ki-67 - IgG
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

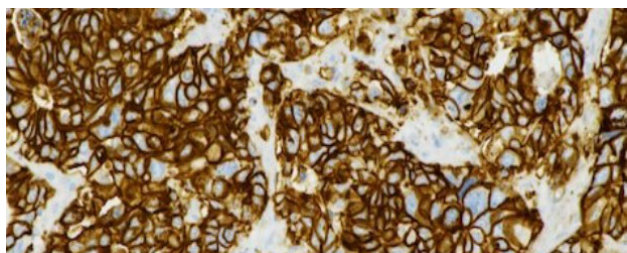


INTENDED USE

The CINtec® PLUS Cytology test is a qualitative immunocytochemical assay intended for the simultaneous detection of the p16^{INK4a} and Ki-67 proteins in cervical specimens collected by a clinician using an endocervical brush/spatula or broom collection device and placed in the ThinPrep® Pap Test PreservCyt® Solution. The CINtec® PLUS Cytology test includes a ready-to-use cocktail of primary antibodies which contains a mouse monoclonal antibody directed against human p16^{INK4a} (p16) protein (clone E6H4), and a recombinant rabbit monoclonal antibody directed against human Ki-67 protein (clone 274-11AC3V1) for use on the BenchMark ULTRA instrument with 3,3'-diaminobenzidine tetrahydrochloride (DAB) and Fast Red detection systems. The CINtec® PLUS Cytology test is indicated:

- 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.

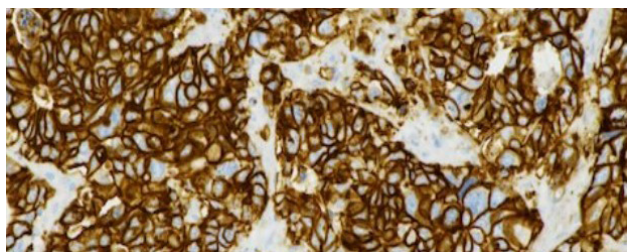


CLDN18 (43-14A) Assay

Ordering Number:	08504148001
Catalog Number:	760-700
Quantity:	50 tests
Controls:	Gastric intestinal metaplasia (positive)
Isotypes:	IgG2b
Clone Name:	43-14A
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.

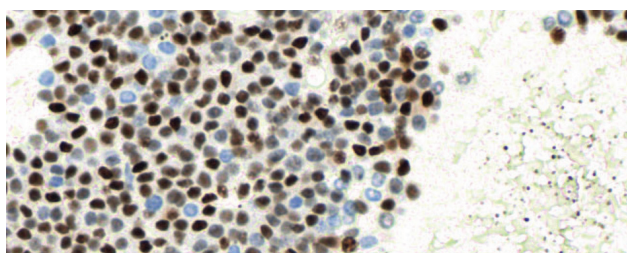


VENTANA CLDN18 (43-14A) RxDx Assay

Ordering Number:	08287066001
Catalog Number:	740-7037
Quantity:	50 tests
Controls:	Gastric intestinal metaplasia (positive)
Isotypes:	IgG2b
Clone Name:	43-14A
Species:	Mouse
Localization:	Membrane
Regulatory Status:	IVD

INTENDED USE

VENTANA CLDN18 (43-14A) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-claudin 18, clone 43-14A, intended for laboratory use in the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastroesophageal junction (GEJ) tissue specimens by light microscopy. This assay is used with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument. The assay is indicated as an aid in identifying patients with gastric or GEJ adenocarcinoma who may be eligible for treatment with VYLOY™ (zolbetuximab) in accordance with the approved therapeutic product labeling. The clinical cutoff for the therapeutic product is $\geq 75\%$ viable tumor cells (% TC) demonstrating moderate to strong membrane CLDN18 staining above background. Test results of the VENTANA CLDN18 (43-14A) 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.



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

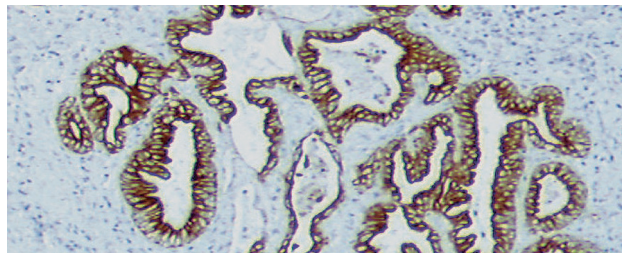
Ordering Number:	05862949001
Catalog Number:	790-4508
Quantity:	50 tests
Controls:	Normal Tonsil
Isotypes:	IgG
Clone Name:	SP4-R
Species:	Rabbit
Localization:	Nuclear
Regulatory Status:	IVD

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
Catalog Number: 760-2637
Quantity: 50 tests
Controls: Prostate
Isotypes: IgM/K
Clone Name: 35betaH11
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

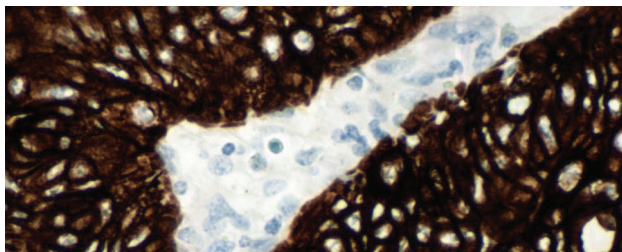


INTENDED USE

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

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: IgG
Clone Name: Cam 5.2
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

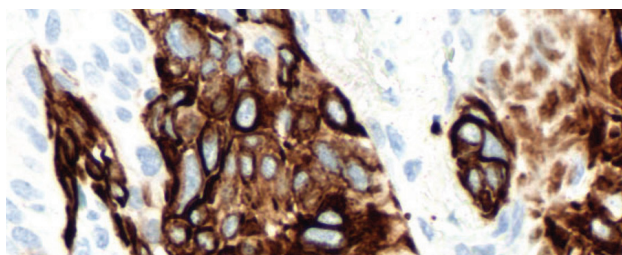


INTENDED USE

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.

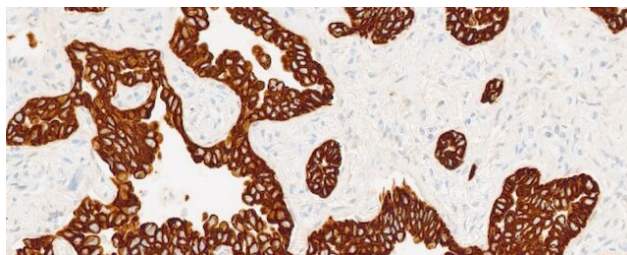
Cytokeratin 5 (SP27) Rabbit Monoclonal Primary Antibody

Ordering Number: 07292821001
Catalog Number: 760-4935
Quantity: 50 tests
Controls: Mesothelioma, Prostate
Isotypes: IgG
Clone Name: SP27
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD



INTENDED USE

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

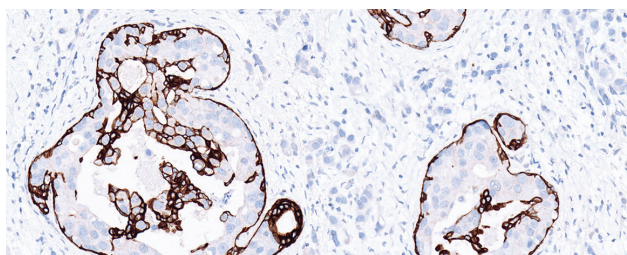


Cytokeratin (OSCAR) Mouse Monoclonal Antibody

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.

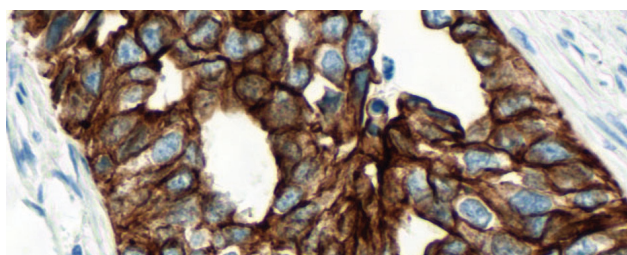


anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody

Ordering Number:	06478441001
Catalog Number:	790-4554
Quantity:	50 tests
Controls:	Prostate and Tonsil
Isotypes:	IgG ₁
Clone Name:	D5/16B4
Species:	Mouse
Localization:	Cytoplasmic
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

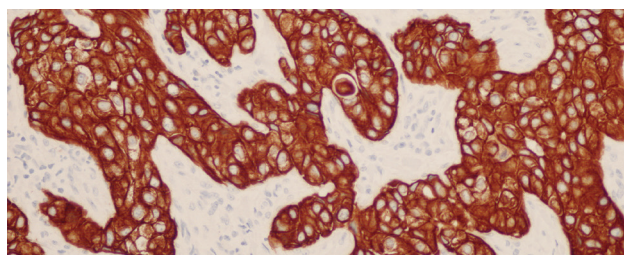
Ordering Number:	05986818001
Catalog Number:	790-4462
Quantity:	50 tests
Controls:	Breast, Salivary Gland, Glandular and Ductal Epithelium of Lung
Clone Name:	SP52
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

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)

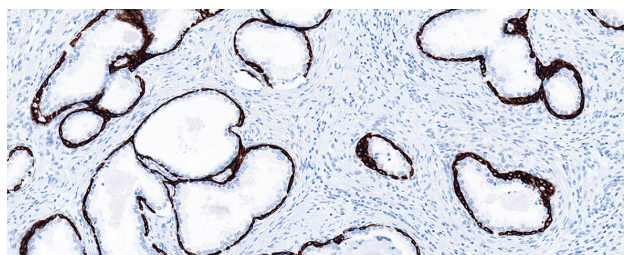
Ordering Number: 05269776001
Catalog Number: 760-4344
Quantity: 50 tests
Controls: Pancreas, Prostate, Salivary Gland
Isotypes: IgG₁
Clone Name: B22.1 & B23.1
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

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

anti-Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody

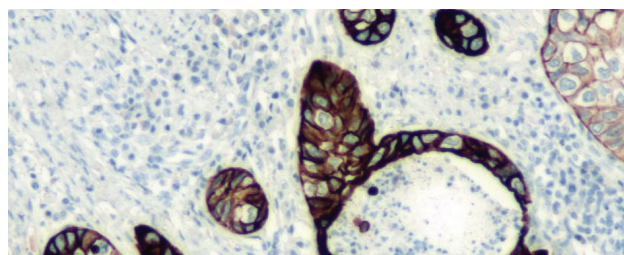
Ordering Number: 06732429001
Catalog Number: 760-4805
Quantity: 50 tests
Controls: Prostate, Skin, Squamous Carcinoma
Isotypes: IgG
Clone Name: SP53
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

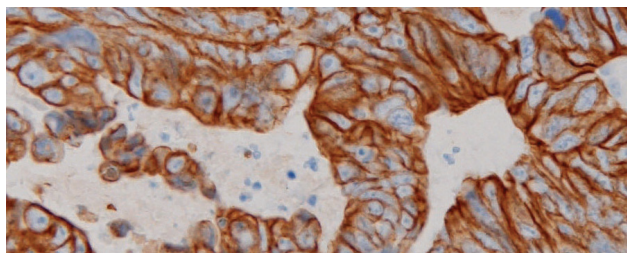
Cytokeratin 14 (SP53) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the Cytokeratin 14 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction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

anti-Cytokeratin 17 (SP95) Rabbit Monoclonal Primary Antibody

Ordering Number: 06373658001
Catalog Number: 790-4560
Quantity: 50 tests
Controls: Normal Skin, Cervical Carcinoma
Isotypes: Rabbit Ig
Clone Name: SP95
Species: 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.

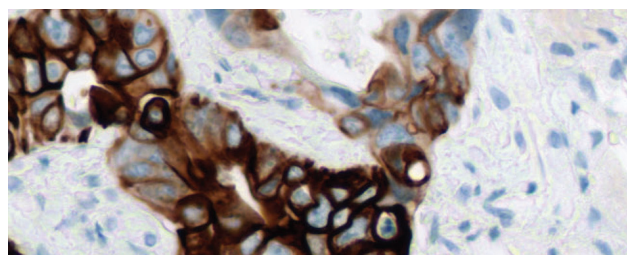


Cytokeratin 19 (A53-B/A2.26)

Ordering Number:	05269440001
Catalog Number:	760-4281
Quantity:	50 tests
Controls:	Colon Carcinoma, Thyroid
Isotypes:	IgG ₁
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.

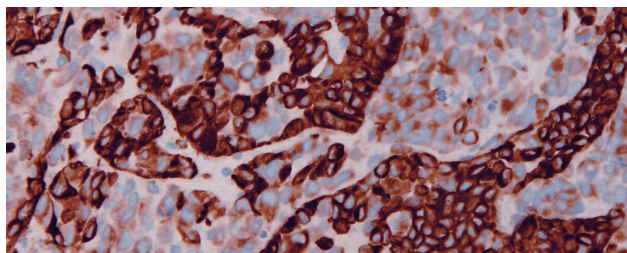


CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody

Ordering Number:	05587760001
Catalog Number:	790-4431
Quantity:	50 tests
Controls:	Colon Adenocarcinoma
Clone Name:	SP33
Species:	Rabbit
Localization:	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

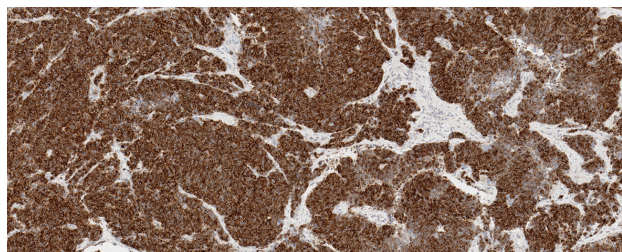
Ordering Number:	05267005001
Catalog Number:	760-2513
Quantity:	50 tests
Controls:	Intestine
Isotypes:	IgG ₁ /K
Clone Name:	DE-R-11
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

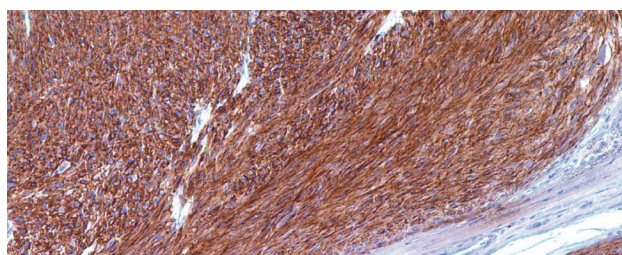
Ordering Number: 08416931001
Catalog Number: 790-7016
Quantity: 50 tests
Controls: Small Cell Lung Carcinoma (positive),
Normal Lung tissue (negative)
Isotypes: IgG
Clone Name: SP347
Species: Rabbit
Localization: Membranous and/or Cytoplasmic Staining
Regulatory Status: IVD

**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

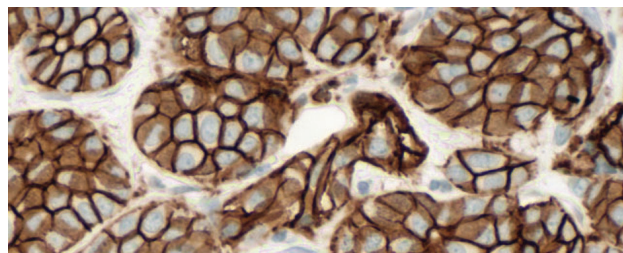
Ordering Number: 06433189001
Catalog Number: 760-4590
Quantity: 50 tests
Controls: GIST
Isotypes: Rabbit Ig
Clone Name: SP31
Species: Rabbit
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

**INTENDED USE**

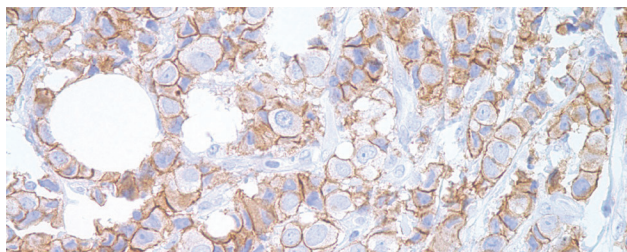
DOG1 (SP31) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the DOG1 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological 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
Isotypes: IgG_{2a}/K
Clone Name: 36
Species: Mouse
Localization: Membranous
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.

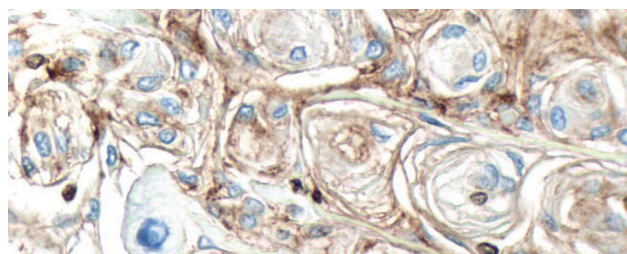


E-Cadherin (EP700Y)

Ordering Number:	05973872001
Catalog Number:	760-4440
Quantity:	50 tests
Controls:	Breast, Lung Adenocarcinoma, Pancreas
Isotypes:	IgG
Clone Name:	EP700Y
Species:	Rabbit
Localization:	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.

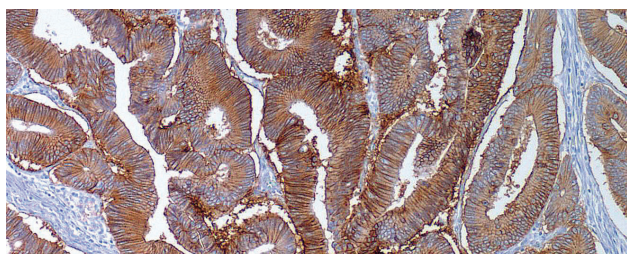


CONFIRM anti-EMA (E29) Mouse Monoclonal Primary Antibody

Ordering Number:	05878900001
Catalog Number:	790-4463
Quantity:	50 tests
Controls:	Normal Pancreas
Isotypes:	IgG _{2a}
Clone Name:	E29
Species:	Mouse
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)

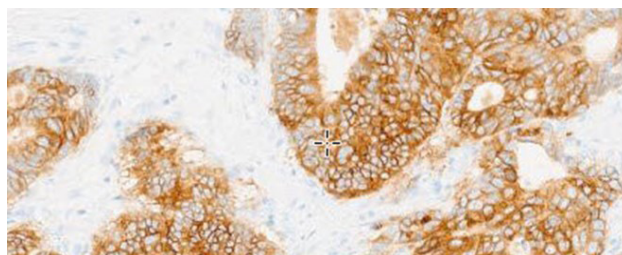
Ordering Number:	05435676001
Catalog Number:	760-4383
Quantity:	50 tests
Controls:	Adenocarcinoma, Columnar Epithelium
Isotypes:	IgG ₁ /K
Clone Name:	Ber-EP4
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

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

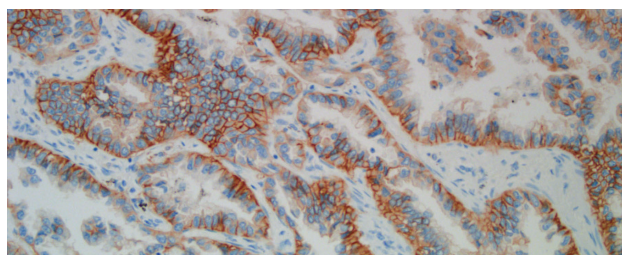


INTENDED USE

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
Isotypes: IgG₁
Clone Name: MOC-31
Species: Mouse
Localization: Membranous, Cytoplasmic
Regulatory Status: IVD

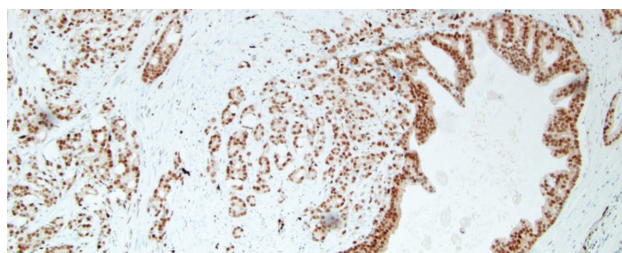


INTENDED USE

Anti-Epithelial Related Antigen (MOC-31) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical 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.

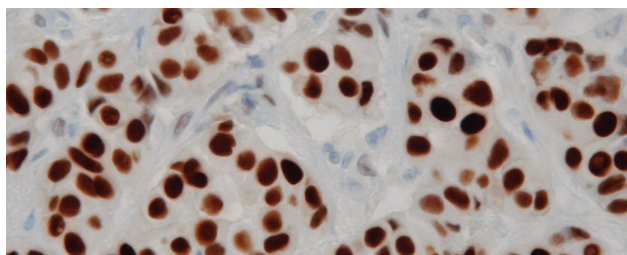
anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody

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.

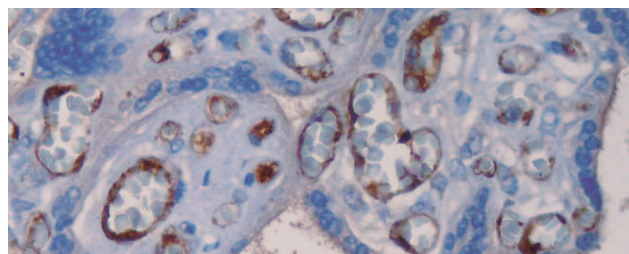


CONFIRM anti-(ER) (SP1) Rabbit Monoclonal Primary Antibody

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.

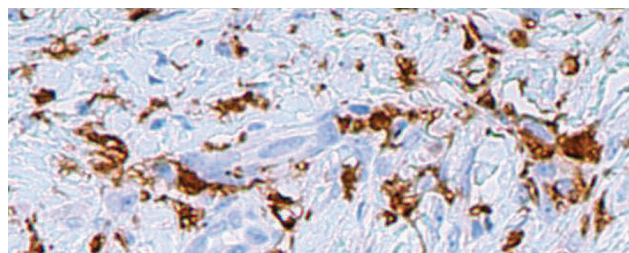


Factor VIII-R Ag. (polyclonal)

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)

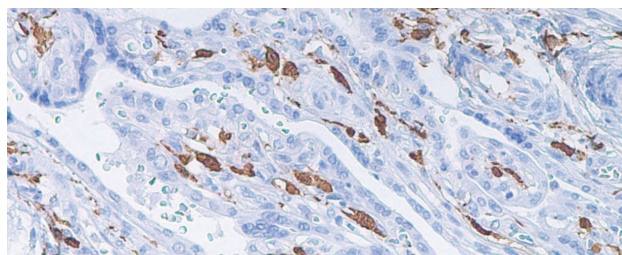
Ordering Number:	05435692001
Catalog Number:	760-4384
Quantity:	50 tests
Controls:	Dermatofibroma
Isotypes:	IgG1
Clone Name:	AC-1A1
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

Factor XIIIa (AC-1A1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of Factor XIIIa in formalin-fixed, 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 (EP3372)

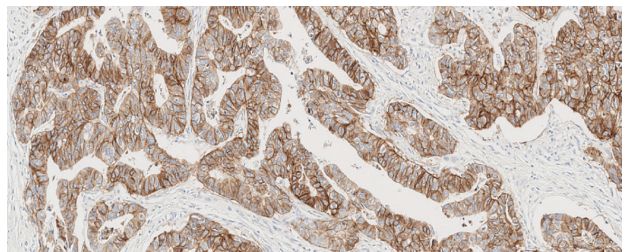
Ordering Number: 05922470001
Catalog Number: 760-4441
Quantity: 50 tests
Controls: Dermatofibroma
Isotypes: IgG
Clone Name: EP3372
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

Factor XIIIa (EP3372) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of Factor XIIIa in formalin-fixed, 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 FGFR2b (FPR2-D) Mouse Monoclonal Antibody

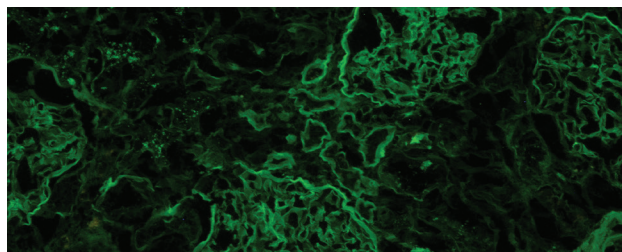
Ordering Number: 09829199001
Catalog Number: 790-7214
Quantity: 50 tests
Controls: Non-neoplastic skin tissue
Clone Name: FPR2-D
Species: Mouse
Localization: Membranous
Regulatory Status: IVD

**INTENDED USE**

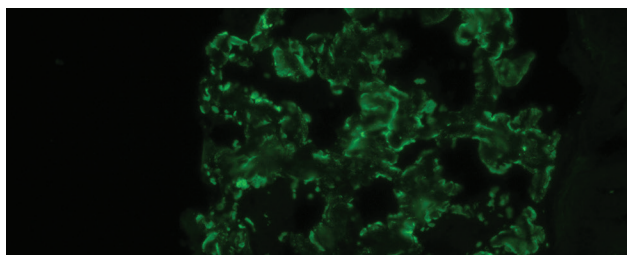
VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody is intended for laboratory use in the qualitative immunohistochemical detection of FGFR2b by light microscopy in sections of formalin-fixed, paraffin-embedded tissues stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified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

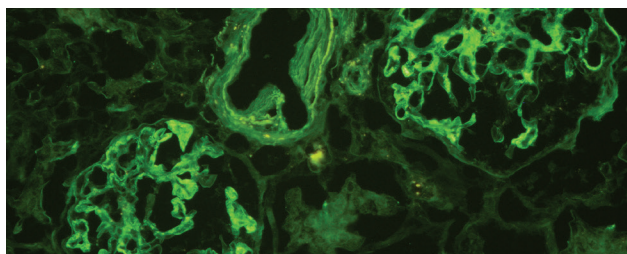


FITC anti-C1q Primary Antibody

Ordering Number:	05267994001
Catalog Number:	760-2688
Quantity:	50 tests
Controls:	Frozen, Diseased Skin or Diseased Renal Tissue
Clone Name:	Polyclonal
Species:	Goat
Regulatory 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.

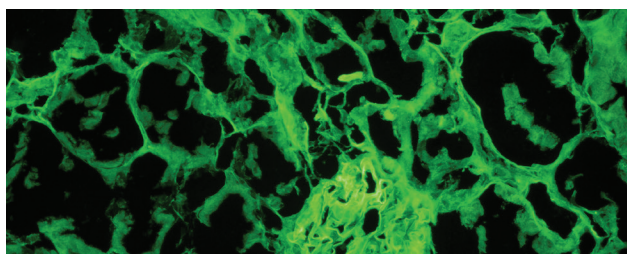


FITC anti-C3 Primary Antibody

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

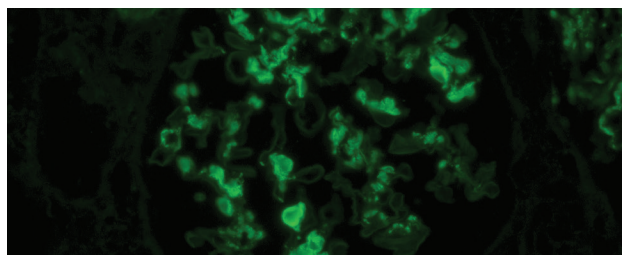
Ordering Number:	05267960001
Catalog Number:	760-2685
Quantity:	50 tests
Controls:	Frozen, Placenta or Tissue Containing Clotted Blood
Clone Name:	Polyclonal
Species:	Goat
Regulatory Status:	IVD

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: Polyclonal
Species: Goat
Regulatory Status: IVD

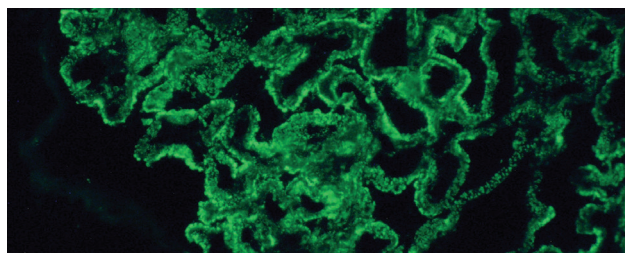


INTENDED USE

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

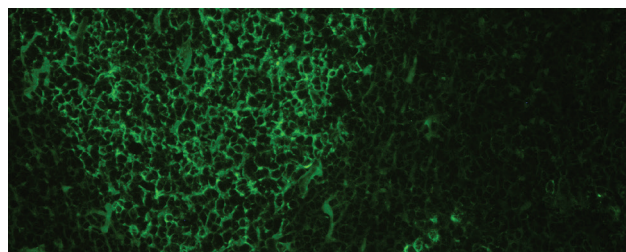


INTENDED USE

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.

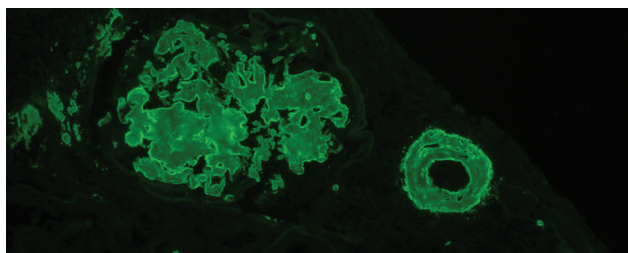
FITC anti-IgM Primary Antibody

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.

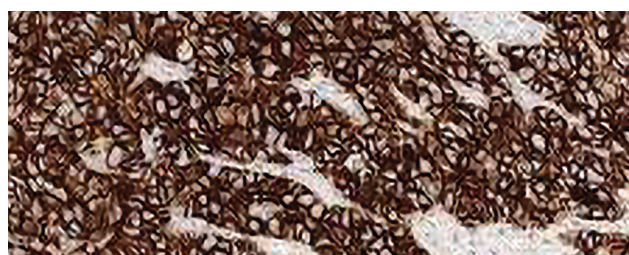


FITC anti-Kappa Primary Antibody

Ordering Number:	05267943001
Catalog Number:	760-2683
Quantity:	50 tests
Controls:	Frozen, Tonsil or Lymph Node Clotted Blood
Clone Name:	Polyclonal
Species:	Goat
Regulatory 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.



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 $\geq 75\%$ 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.

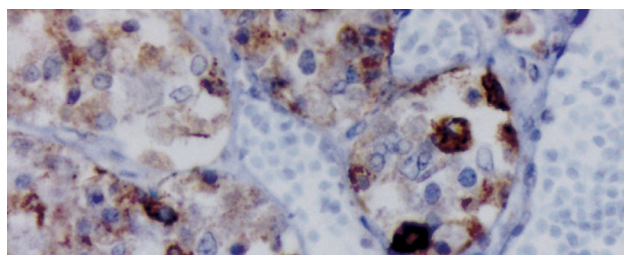
Table 1. VENTANA FOLR1 (FOLR1-2.1) RxDx Assay companion diagnostic indication.

INDICATION FOR USE	THERAPY	EOC
FOLR1 Cut-off	ELAHERE (mirvetuximab soravtansine)	$\geq 75\%$ 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)

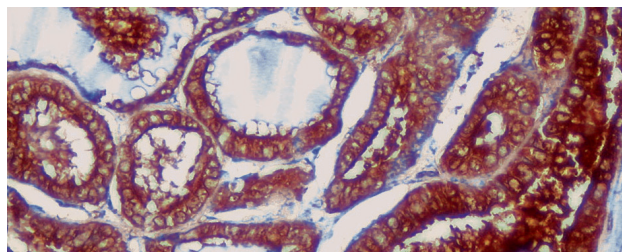
Ordering Number: 05268192001
Catalog Number: 760-2710
Quantity: 50 tests
Controls: Normal Pituitary
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

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

Galectin-3 (9C4)

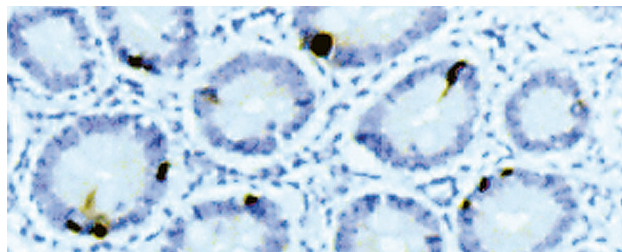
Ordering Number: 05269164001
Catalog Number: 760-4256
Quantity: 50 tests
Controls: Papillary or Follicular Carcinoma of Thyroid
Isotypes: IgG₁
Clone Name: 9C4
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

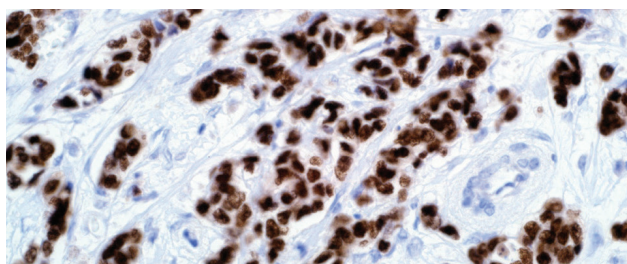
Galectin-3 (9C4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the galectin-3 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with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

Gastrin (polyclonal)

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

**INTENDED USE**

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

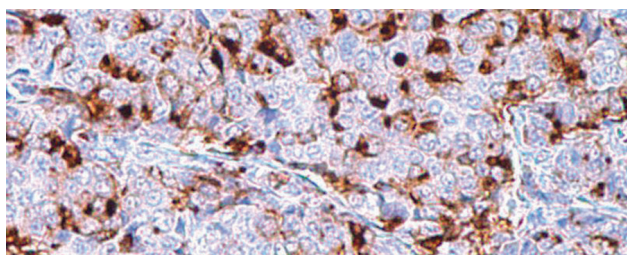


GATA3 (L50-823) Mouse Monoclonal Primary Antibody

Ordering Number:	07107749001
Catalog Number:	760-4897
Quantity:	50 tests
Controls:	Ductal Carcinoma in situ
Isotypes:	IgG
Clone Name:	L50-823
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, 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.

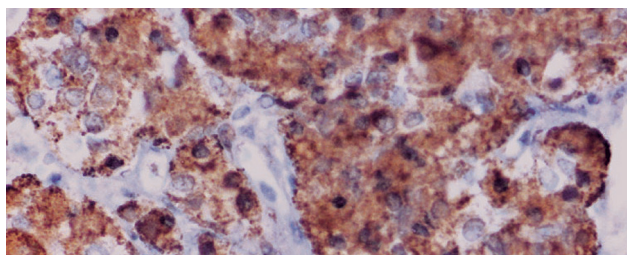


GCDPF-15 (EP1582Y) Rabbit Monoclonal Antibody

Ordering Number:	05463530001
Catalog Number:	760-4386
Quantity:	50 tests
Controls:	Breast, Breast Carcinoma
Isotypes:	IgG
Clone Name:	EP1582Y
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

GCDPF-15 (EP1582Y) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the GCDPF-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)

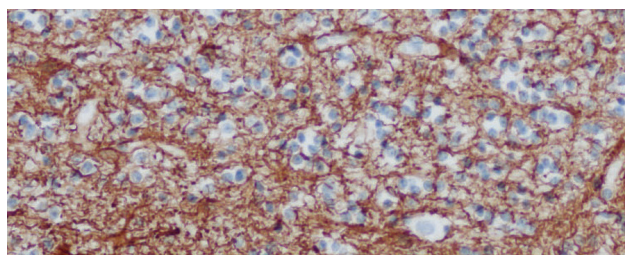
Ordering Number:	05268257001
Catalog Number:	760-2804
Quantity:	50 tests
Controls:	Normal Pituitary
Clone Name:	Polyclonal
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

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)

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

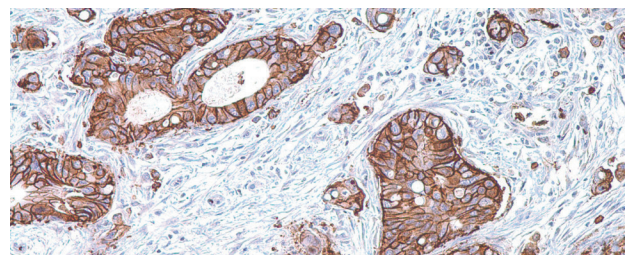


INTENDED USE

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

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

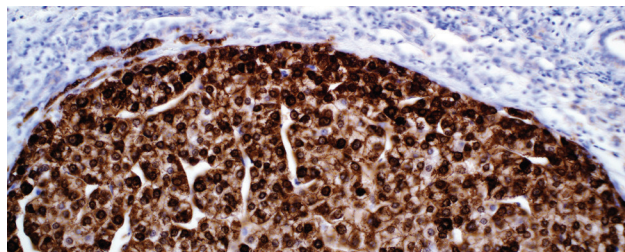


INTENDED USE

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.

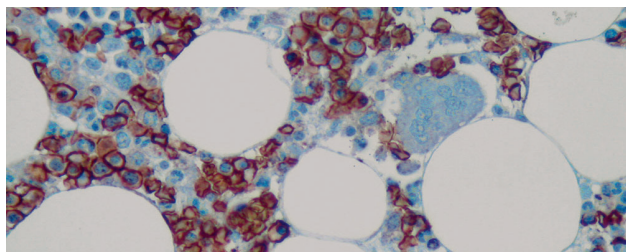
Glutamine Synthetase (GS-6) Mouse Monoclonal Primary Antibody

Ordering Number: 07107757001
Catalog Number: 760-4898
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.

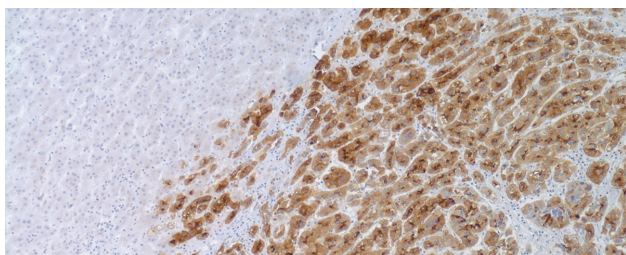


Glycophorin A (GA-R2)

Ordering Number:	05269172001
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.

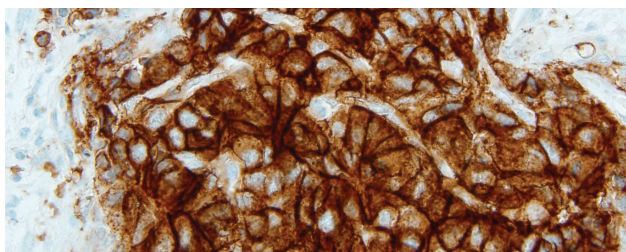


Glypican-3 (1G12)

Ordering Number:	05973864001
Catalog Number:	760-4442
Quantity:	50 tests
Controls:	Hepatocellular Carcinoma
Isotypes:	IgG ₁
Clone Name:	1G12
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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



anti-Glypican 3 (GC33) Mouse Monoclonal Primary Antibody

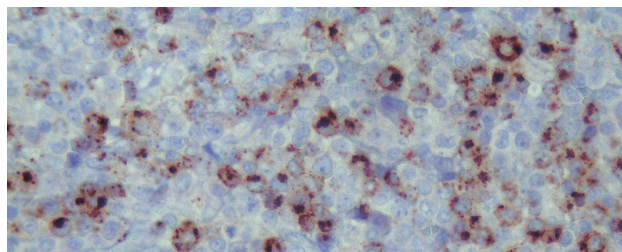
Ordering Number:	06483186001
Catalog Number:	790-4564
Quantity:	50 tests
Controls:	Placenta, Hepatocellular Carcinoma
Isotypes:	IgG _{2a}
Clone Name:	GC33
Species:	Mouse
Localization:	Granular Cytoplasmic/Membrane
Regulatory Status:	IVD

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)

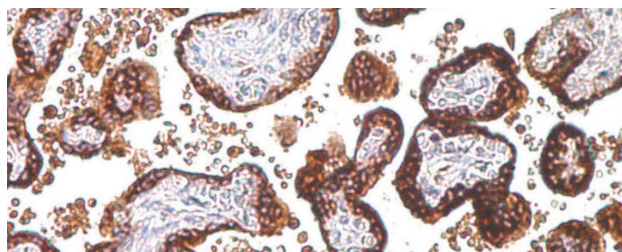
Ordering Number: 05269466001
Catalog Number: 760-4283
Quantity: 50 tests
Controls: Tonsil
Clone Name: Polyclonal
Species: Rabbit
Localization: Granular 2, Cytotoxic T Lymphocytes,
 Natural Killer Cells
Regulatory Status: IVD

**INTENDED USE**

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

hCG (polyclonal)

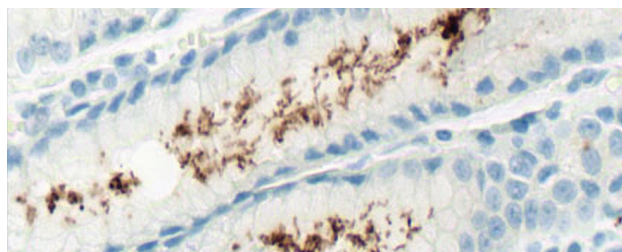
Ordering Number: 05267617001
Catalog Number: 760-2650
Quantity: 50 tests
Controls: Placenta
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

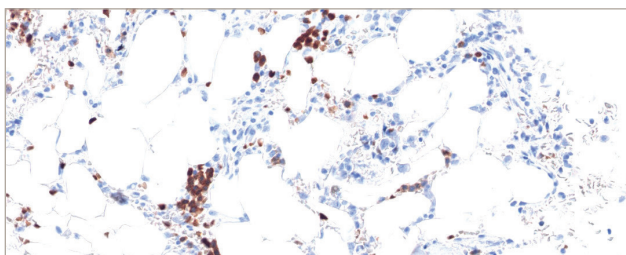
hCG Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of hCG (human chorionic gonadotropin) in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with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

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

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.

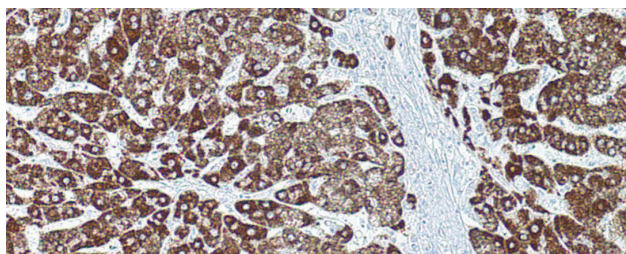


Hemoglobin A (SP212) Rabbit Monoclonal Primary Antibody

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

INTENDED USE

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

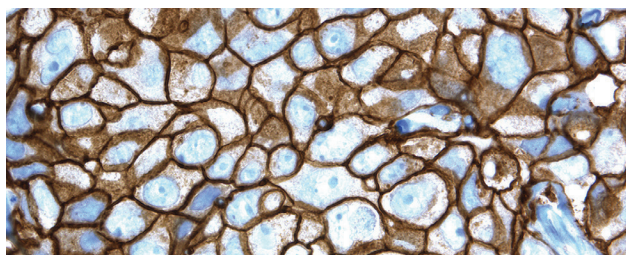


Hepatocyte Specific Antigen (Hep Par-1) (OCH1E5)

Ordering Number:	05269792001
Catalog Number:	760-4350
Quantity:	50 tests
Controls:	Liver
Isotypes:	IgG ₁ /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

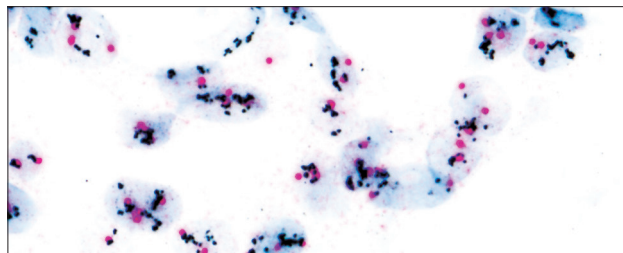
Ordering Number:	05278368001
Catalog Number:	790-2991
Quantity:	50 tests 10 PATHWAY HER-2 4in1 Control Slides Interpretation Guide
Controls:	Breast Carcinoma
Clone Name:	4B5
Species:	Rabbit
Localization:	Membranous
Regulatory Status:	IVD

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.

HER2 Dual ISH DNA Probe Cocktail

Ordering Number: 08314365001
Catalog Number: 760-6072
Quantity: 30 tests
Controls: Stromal Fibroblasts, Endothelial Cells, Lymphocytes, and Non-Neoplastic Epithelial Cells
Clone Name: HER2
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

The VENTANA HER2 Dual ISH DNA Probe Cocktail is intended to determine HER2 gene amplification status by enumeration of the ratio of the HER2 gene to Chromosome 17 by light microscopy. The HER2 and Chromosome 17 probes are detected using the VENTANA Silver ISH DNP Detection Kit and the VENTANA Red ISH DIG Detection Kit by a two-color chromogenic in situ hybridization (ISH) in formalin-fixed, paraffin-embedded human breast carcinoma tissue specimens, following staining on a BenchMark ULTRA instrument.

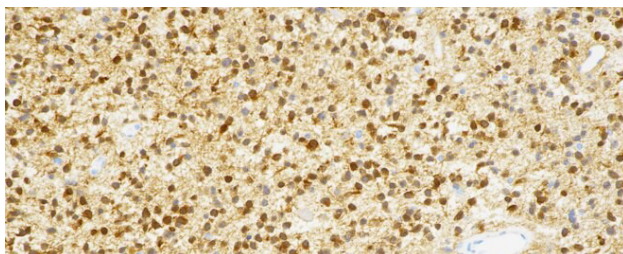
The VENTANA HER2 Dual ISH DNA Probe Cocktail is indicated as an aid in the assessment of patients for whom HERCEPTIN (trastuzumab) is being considered.

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.

IDH1 R132H (MRQ-67) CM Rabbit Monoclonal Antibody

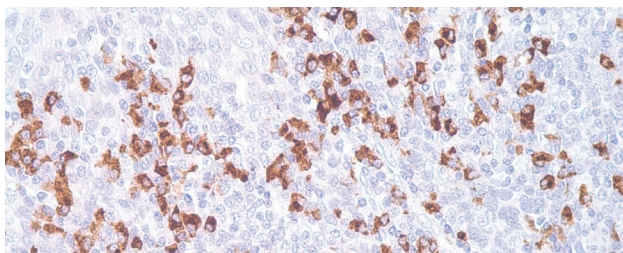
Ordering Number: 09433015001
Catalog Number: 760-7173
Quantity: 50 tests
Controls: Brain
Clone Name: MRQ-67
Species: Rabbit
Localization: Cytoplasm
Regulatory Status: IVD

**INTENDED USE**

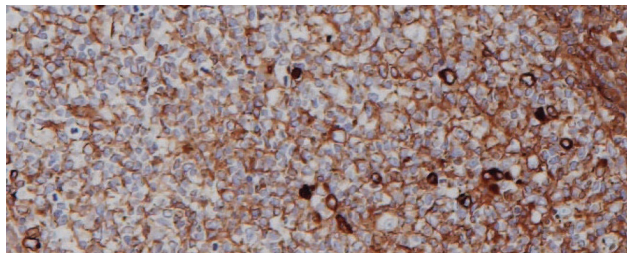
IDH1 R132H (MRQ-67) Rabbit Monoclonal Antibody is intended for laboratory use in the detection of the IDH1 R132H mutant protein in formalin-fixed, paraffin-embedded human tissue stained in qualitative immunohistochemistry on BenchMark IHC/ISH instruments. This product should be interpreted by a qualified 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.

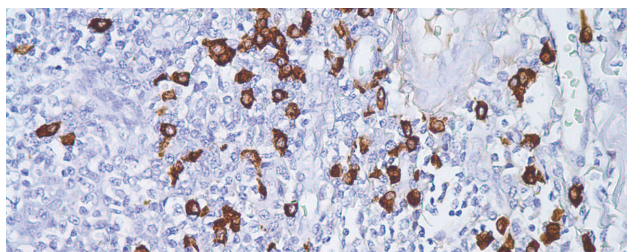


IgG (polyclonal)

Ordering Number: 05267633001
Catalog Number: 760-2653
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

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

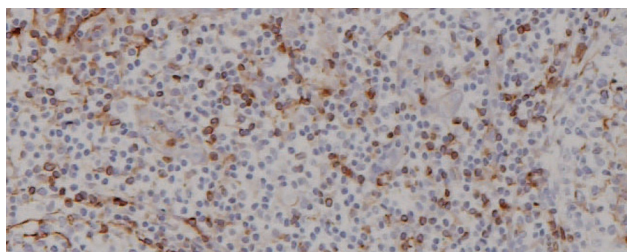


IgG4 (MRQ-44) Mouse Monoclonal Antibody

Ordering Number: 06523854001
Catalog Number: 760-4614
Quantity: 50 tests
Controls: Tonsil, Plasma Cells
Isotypes: IgG₁/k
Clone Name: MRQ-44
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

INTENDED USE

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



IgM (polyclonal)

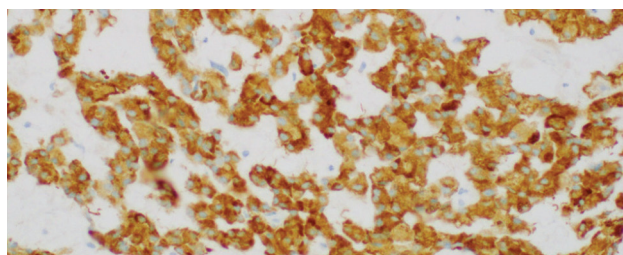
Ordering Number: 05267641001
Catalog Number: 760-2654
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

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: IgG
Clone Name: MRQ-63
Species: Rabbit
Regulatory Status: IVD

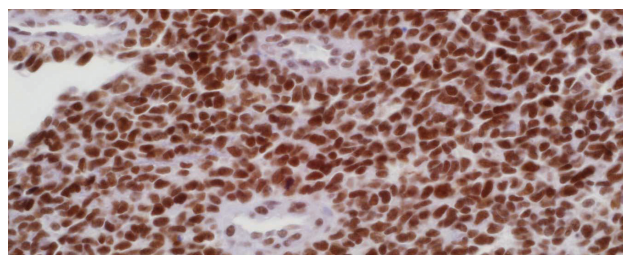


INTENDED USE

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

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

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

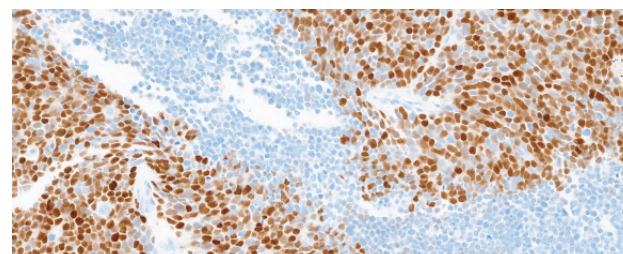


INTENDED USE

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.

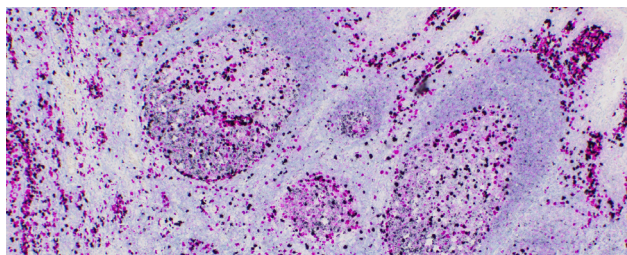
INSM1 (SP493) Rabbit Monoclonal Primary Antibody

Ordering Number: 10161949001
Catalog Number: 790-7247
Quantity: 50 tests
Controls: Pancreas
Clone Name: SP493
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD



INTENDED USE

INSM1 (SP493) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of INSM1 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.

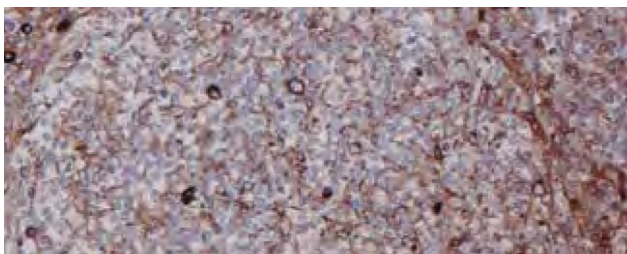


Kappa and Lambda Dual ISH mRNA Probe Cocktail

Ordering Number:	08507015001
Catalog Number:	760-6054
Quantity:	30 tests
Controls:	Tonsil
Species:	Mouse
Localization:	Cytoplasm
Regulatory Status:	IVD

INTENDED USE

The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail Assay is a qualitative assay that is used to detect the expression of kappa and lambda immunoglobulin light chains in formalin-fixed paraffin embedded (FFPE) human hematolymphoid specimens by in situ hybridization (ISH). The assay is intended as an aid in the diagnosis of mature B-cell lymphomas and plasma cell neoplasms. The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail is indicated for use when a biopsy of lymph node or bone marrow (core biopsy and clot section) indicates inconclusive results. It enables the assessment of both markers in the context of one another on a single slide as an aid in differentiating between a reactive process or B-cell lymphoma and plasma cell neoplasms. This is not a standalone test, and results should be evaluated 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.



CONFIRM anti-Kappa Rabbit Polyclonal Primary Antibody

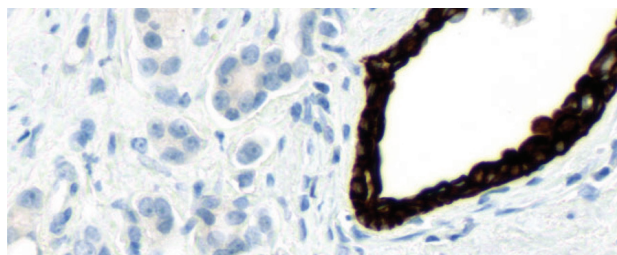
Ordering Number:	05267013001
Catalog Number:	760-2514
Quantity:	50 tests
Controls:	Lymph Node, Tonsil
Clone Name:	Polyclonal
Species:	Rabbit
Localization:	Surface Membrane, Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

CONFIRM anti-Keratin (34 β E12) Mouse Monoclonal Primary Antibody

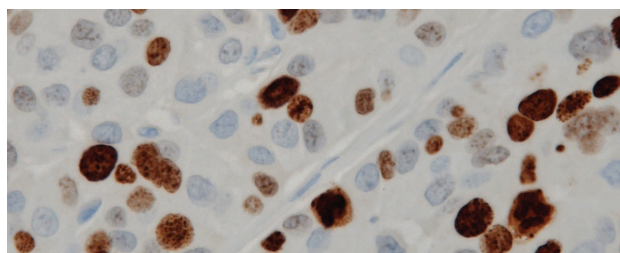
Ordering Number: 05479266001
Catalog Number: 790-4373
Quantity: 50 tests
Controls: Prostate
Isotypes: IgG₁
Clone Name: 34 β E12
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

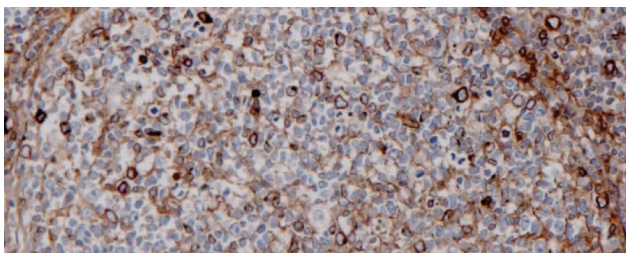
CONFIRM anti-Keratin (34 β E12) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 5 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should 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.

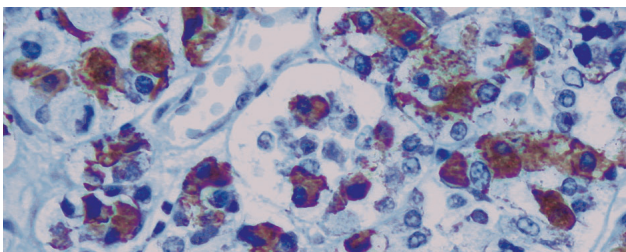


CONFIRM anti-Lambda Rabbit Polyclonal Primary Antibody

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)

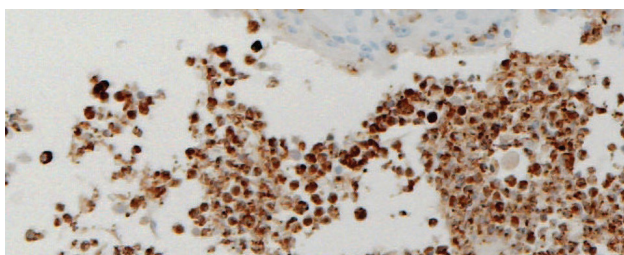
Ordering Number:	05268222001
Catalog Number:	760-2802
Quantity:	50 tests
Controls:	Lymph Node, Tonsil
Clone Name:	Polyclonal
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

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

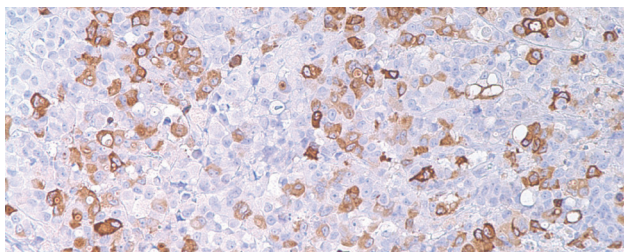


INTENDED USE

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

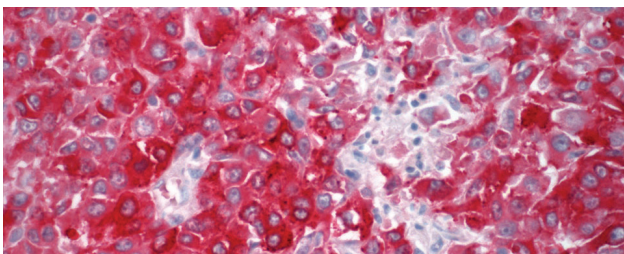


INTENDED USE

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.

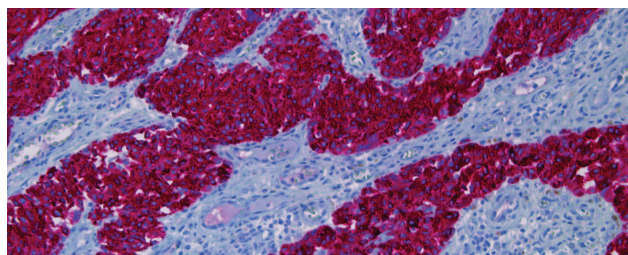
CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody

Ordering Number: 05278350001
Catalog Number: 790-2990
Quantity: 50 tests
Controls: Melanoma, Normal Skin
Isotypes: IgG₁
Clone Name: A103
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 (IgG₁) directed against melan A. This antibody is designed to qualitatively detect the presence of melan A by light microscopy in sections of formalin-fixed, paraffin-embedded tissue. Positive staining may aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

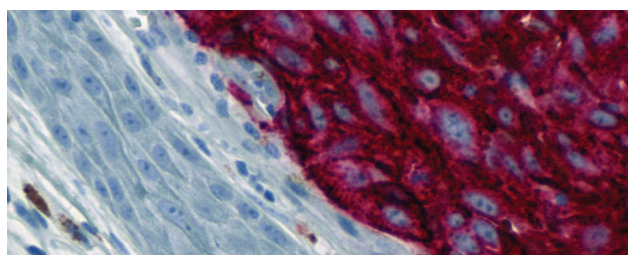


Melanoma Triple Cocktail (HMB45+A103+T311) Primary Antibody

Ordering Number:	06527787001
Catalog Number:	790-4677
Quantity:	50 tests
Controls:	Melanoma
Clone Name:	HMB45+A103+T311
Species:	N/A
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

Melanoma Triple Cocktail (HMB45+A103+T311) is 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.

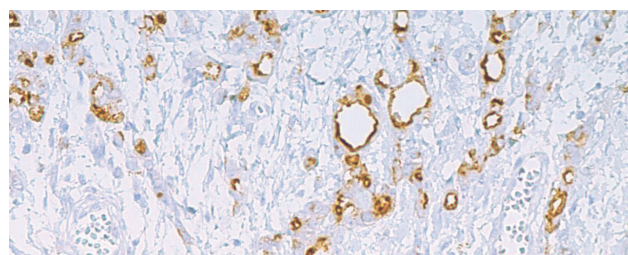


CONFIRM anti-Melanosome (HMB45) Mouse Monoclonal Primary Antibody

Ordering Number:	05479282001
Catalog Number:	790-4366
Quantity:	50 tests
Controls:	Melanoma, Skin
Isotypes:	IgG ₁ /K
Clone Name:	HMB45
Species:	Mouse
Localization:	Cytoplasmic
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)

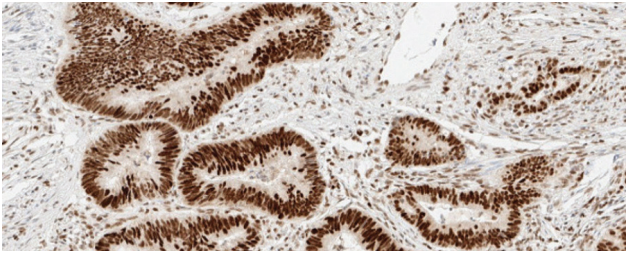
Ordering Number:	05973813001
Catalog Number:	760-4445
Quantity:	50 tests
Controls:	Mesothelioma, Thyroid Carcinoma
Isotypes:	IgM/K
Clone Name:	HBME-1
Species:	Mouse
Localization:	Cytoplasmic, Membranous
Regulatory Status:	IVD

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: IgG
Clone Name: M1
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-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

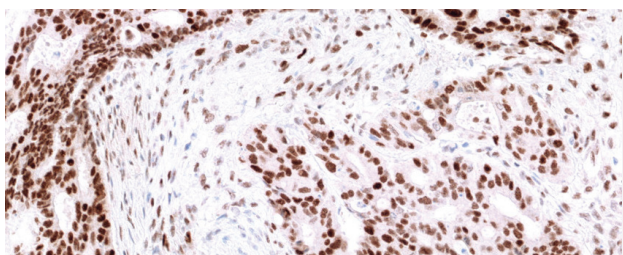
INDICATION FOR USE	THERAPY Status	MMR Status
Solid Tumors	JEMPERLI (dostarlimab-gxly)	deficient MMR (dMMR)
Solid Tumors	JEMPERLI (dostarlimab-gxly)	deficient MMR (dMMR)
Endometrial Carcinoma (EC)	KEYTRUDA (pembrolizumab) in combination with LENVIMA (lenvatinib)	proficient MMR (pMMR)

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
Isotypes:	IgG ₁
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-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	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.

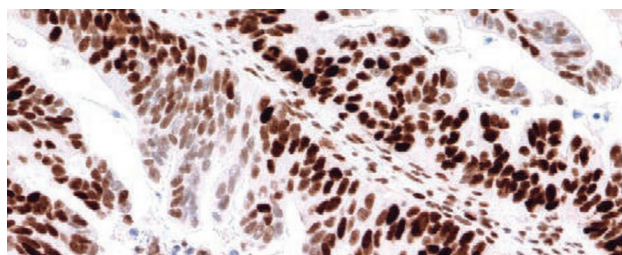
INTENDED USE PART 2

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:	IgG
Clone Name:	SP93
Species:	Rabbit
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-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.

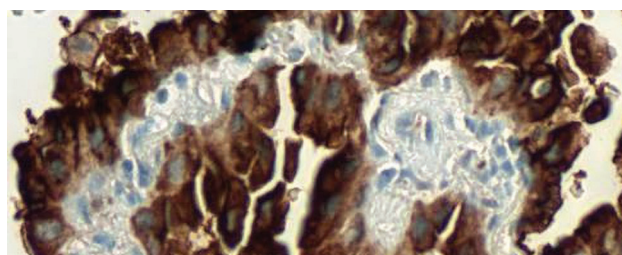
INTENDED USE PART 2

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 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.

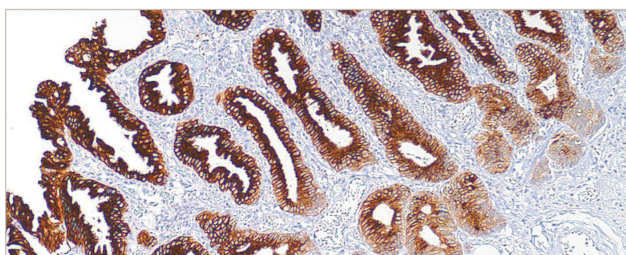
anti-MUC1 (H23) Mouse Monoclonal Primary Antibody

Ordering Number:	06316514001
Catalog Number:	790-4574
Quantity:	50 tests
Controls:	Breast, Lung, Pancreas
Isotypes:	IgG
Clone Name:	H23
Species:	Mouse
Localization:	Membranous, Cytoplasmic
Regulatory Status:	IVD



INTENDED USE

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

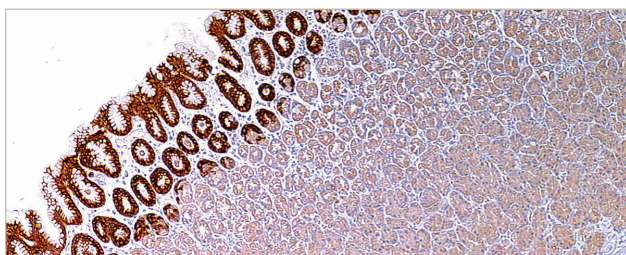


MUC2 (MRQ-18)

Ordering Number:	05463556001
Catalog Number:	760-4388
Quantity:	50 tests
Controls:	Colon, Colon Adenocarcinoma
Isotypes:	IgG ₁ /k
Clone Name:	MRQ-18
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

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

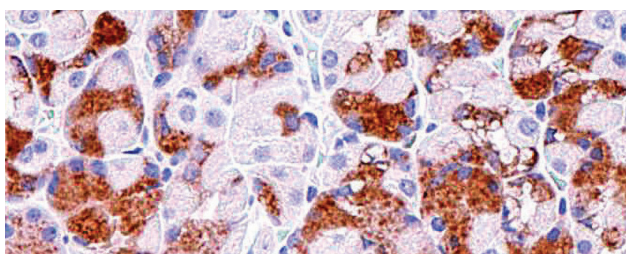


MUC5AC (MRQ-19)

Ordering Number:	05463564001
Catalog Number:	760-4389
Quantity:	50 tests
Controls:	Associated Adenocarcinomas, Stomach
Isotypes:	IgG ₁
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)

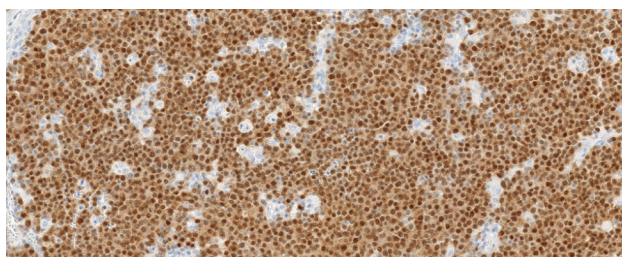
Ordering Number:	05463572001
Catalog Number:	760-4390
Quantity:	50 tests
Controls:	Associated Adenocarcinomas, Stomach
Isotypes:	IgG ₁
Clone Name:	MRQ-20
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

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

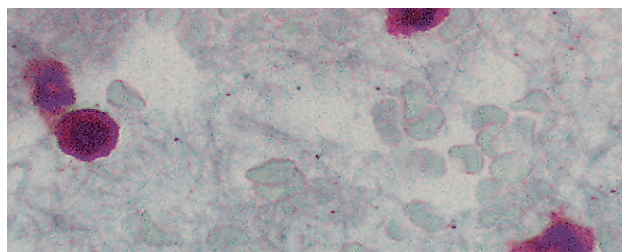
Ordering Number: 08313482001
Catalog Number: 760-6082
Quantity: 50 tests
Controls: Tonsil
Isotypes: IgG
Clone Name: EP190
Species: Rabbit
Regulatory Status: IVD

**INTENDED USE**

MUM1 (EP190) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the MUM1 protein in formalin-fixed, 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.

Myeloperoxidase (polyclonal)

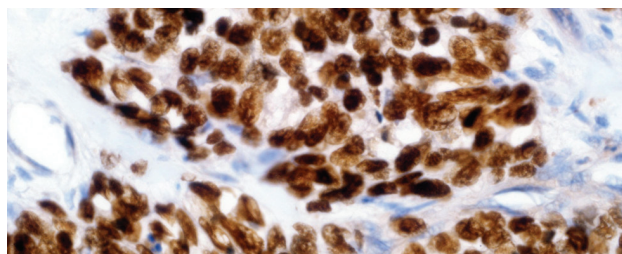
Ordering Number: 05267692001
Catalog Number: 760-2659
Quantity: 50 tests
Controls: Bone Marrow
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

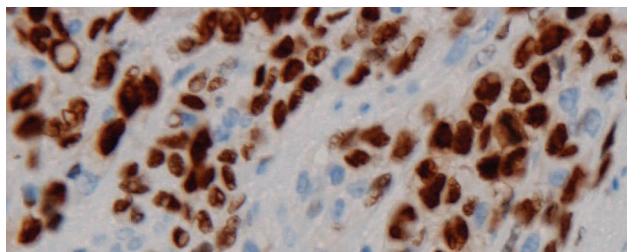
Anti-Myeloperoxidase Polyclonal Primary Antibody is intended for laboratory use in the detection of the myeloperoxidase protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with 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: IgG
Clone Name: EP212
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

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

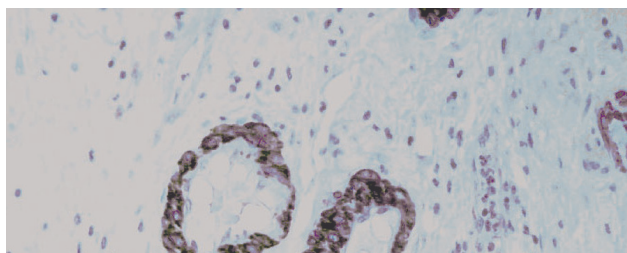


Myogenin (F5D)

Ordering Number:	05268290001
Catalog Number:	760-2832
Quantity:	50 tests
Controls:	Rhabdomyosarcoma
Isotypes:	IgG ₁ /K
Clone Name:	F5D
Species:	Mouse
Localization:	Nuclear
Regulatory Status:	IVD

INTENDED USE

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

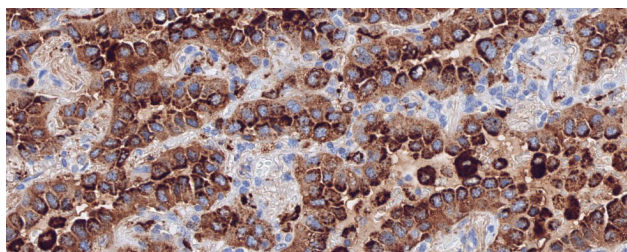


Myosin, Smooth Muscle (SMMS-1)

Ordering Number:	05268133001
Catalog Number:	760-2704
Quantity:	50 tests
Controls:	Breast, Intestine
Isotypes:	IgG ₁ /K
Clone Name:	SMMS-1
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

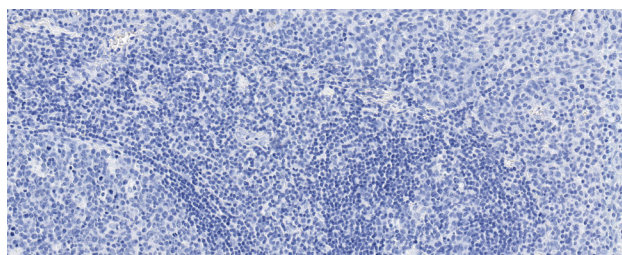
Ordering Number:	07047720001
Catalog Number:	760-4867
Quantity:	50 tests
Controls:	Lung Adenocarcinoma, Renal Cell Carcinoma
Isotypes:	IgG ₁ /K
Clone Name:	MRQ-60
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

Napsin A (MRQ-60) Mouse Primary Antibody is intended for laboratory use in the detection of the Napsin A protein in formalin-fixed, 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
Regulatory Status: IVD

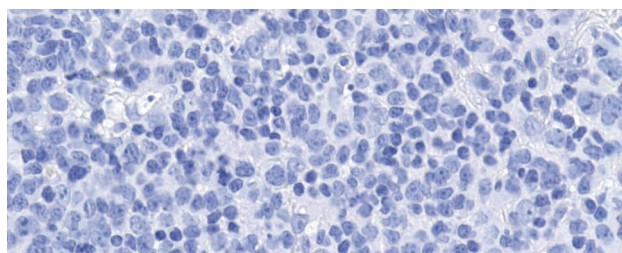


INTENDED USE

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

CONFIRM Negative Control Rabbit Ig

Ordering Number: 05266238001
Catalog Number: 760-1029
Quantity: 250 tests
Controls: See Package Insert
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD

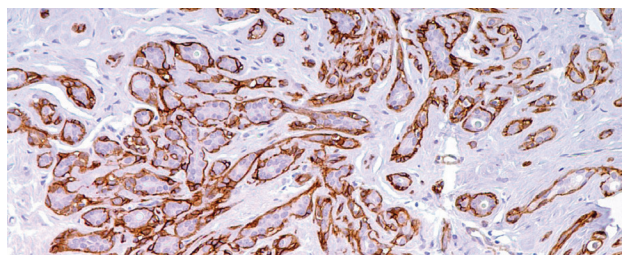


INTENDED USE

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.

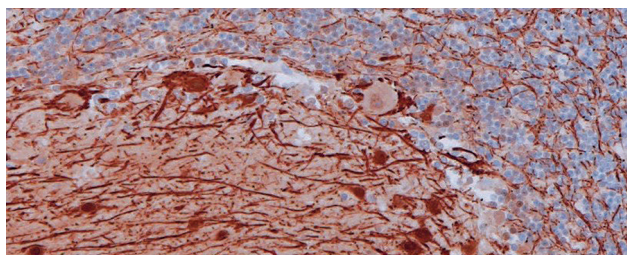
Nerve Growth Factor Receptor (NGFR) (MRQ-21)

Ordering Number: 05463599001
Catalog Number: 760-4391
Quantity: 50 tests
Controls: Ganglia, Neurons, Malignant Melanoma Cells, Myoepithelial Cells of Breast Ducts
Isotypes: IgG₁
Clone Name: MRQ-21
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD



INTENDED USE

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

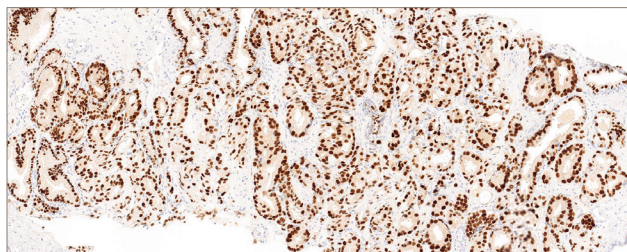


Neurofilament (2F11)

Ordering Number:	05267714001
Catalog Number:	760-2661
Quantity:	50 tests
Controls:	Brain
Isotypes:	IgG ₁ /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.

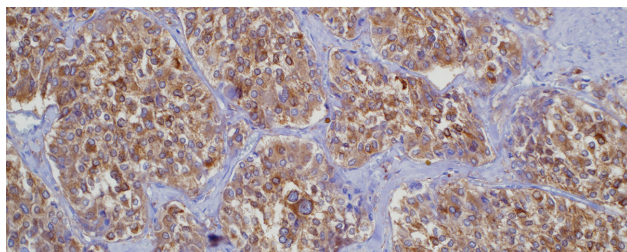


NKX3.1 (EP356) Rabbit Monoclonal Primary Antibody

Ordering Number:	07859759001
Catalog Number:	760-5086
Quantity:	50 tests
Controls:	Prostate, Prostate Adenocarcinoma
Isotypes:	IgG
Clone Name:	EP356
Species:	Rabbit
Localization:	Nuclear
Regulatory Status:	IVD

INTENDED USE

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



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

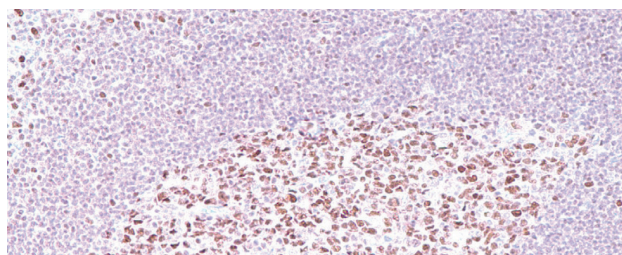
Ordering Number:	06648568001
Catalog Number:	760-4786
Quantity:	50 tests
Controls:	Pancreas, Carcinoid Tumor
Clone Name:	MRQ-55
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

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)

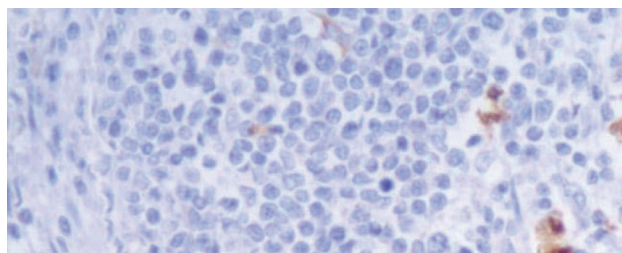
Ordering Number: 05973791001
Catalog Number: 760-4447
Quantity: 50 tests
Controls: Lymph Node, Tonsil
Isotypes: IgG, λ K
Clone Name: MRQ-2
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

**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)

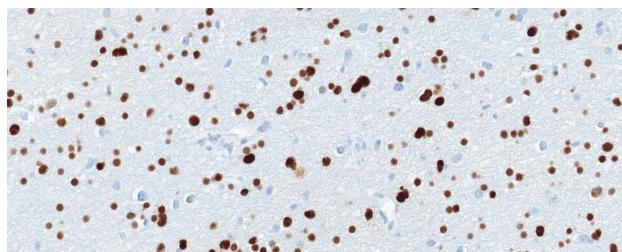
Ordering Number: 05463602001
Catalog Number: 760-4392
Quantity: 50 tests
Controls: Dysgerminoma, Seminoma
Isotypes: IgG
Clone Name: MRQ-10
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

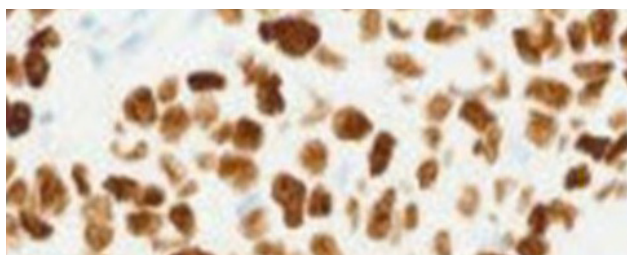
Anti-Oct-4 (MRQ-10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the Oct-4 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological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

Olig2 (EP112) Rabbit Monoclonal Primary Antibody

Ordering Number: 07667973001
Catalog Number: 760-5050
Quantity: 50 tests
Controls: Astrocytoma
Isotypes: IgG
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.

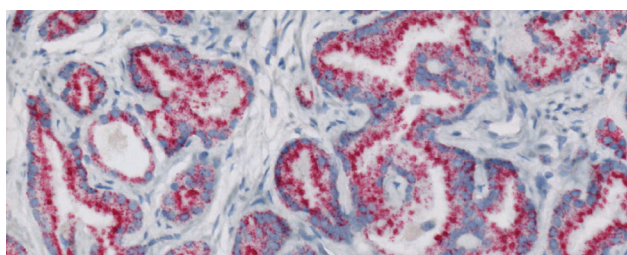


VENTANA anti-P40 (SP225) Rabbit Monoclonal Primary Antibody

Ordering Number:	9929649001
Catalog Number:	790-7219
Quantity:	50 tests
Controls:	Lung Squamous Cell Carcinoma, Prostate and Tonsil
Isotypes:	IgG
Clone Name:	SP225
Species:	Rabbit
Localization:	Nucleus
Regulatory Status:	IVD

INTENDED USE

Anti-p40 (SP225) Rabbit 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.

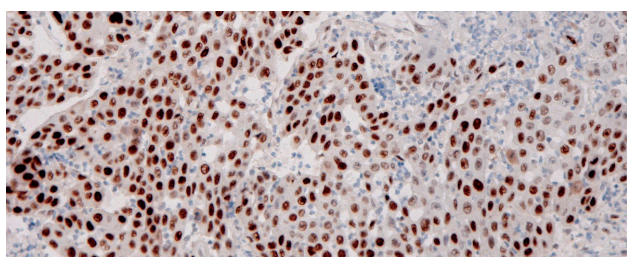


anti-p504s (SP116) Rabbit Monoclonal Primary Antibody

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

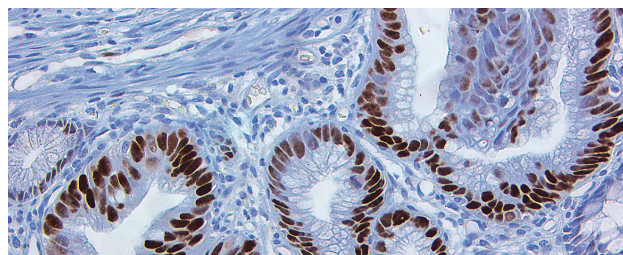
Ordering Number:	05267102001
Catalog Number:	760-2542
Quantity:	50 tests
Controls:	Colon Adenocarcinoma
Isotypes:	IgG _{2a}
Clone Name:	Bp-53-11
Species:	Mouse
Localization:	Nuclear
Regulatory Status:	IVD

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

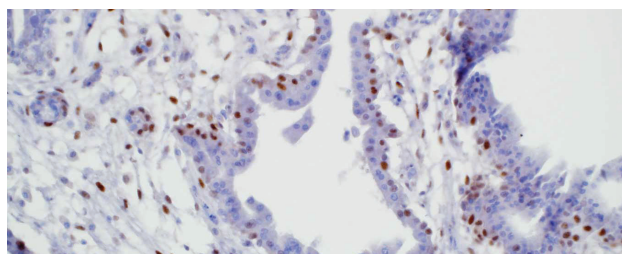
Ordering Number: 05278074001
Catalog Number: 790-2912
Quantity: 50 tests
Controls: Colon Adenocarcinoma
Isotypes: IgG₁/K
Clone Name: DO-7
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

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

anti-p57^{Kip2} (Kp10) Mouse Monoclonal Primary Antibody

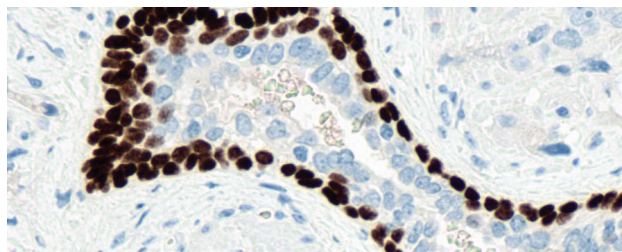
Ordering Number: 06523897001
Catalog Number: 760-4617
Quantity: 50 tests
Controls: Placenta
Isotypes: IgG_{2b}/K
Clone Name: Kp10
Species: Mouse
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

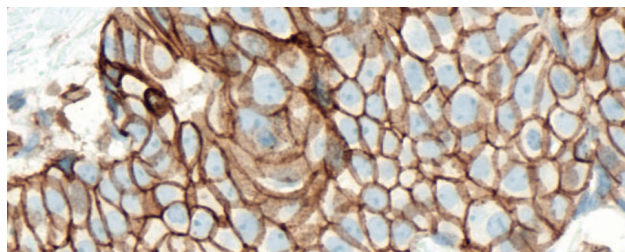
p57^{Kip2} (Kp10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the p57^{Kip2} protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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

Ordering Number: 05867061001
Catalog Number: 790-4509
Quantity: 50 tests
Controls: Prostate, Tonsil
Isotypes: IgG_{2a}/K
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.

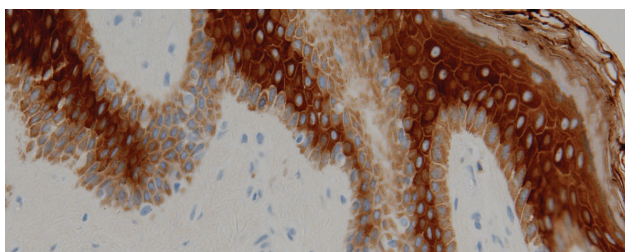


VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody

Ordering Number:	05867088001
Catalog Number:	790-4517
Quantity:	50 tests
Controls:	Normal Ducts of the Breast
Isotypes:	IgG ₁
Clone Name:	98
Species:	Mouse
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.

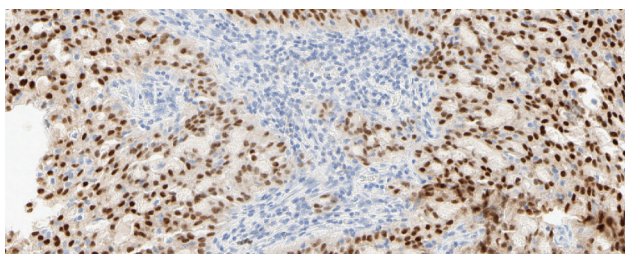


anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody

Ordering Number:	05266840001	5267145001
Catalog Number:	760-2135	760-2595
Quantity:	250 tests	50 tests
Controls:	Intestine, Liver	
Isotypes:	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

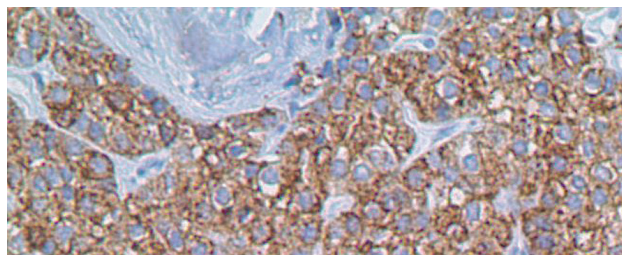
Ordering Number:	08494665001
Catalog Number:	790-7026
Quantity:	50 tests
Controls:	Appendix, Cerebellum
Clone Name:	EPR17341
Species:	Rabbit
Localization:	Cytoplasmic, Membranous, Nuclear
Regulatory Status:	IVD

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

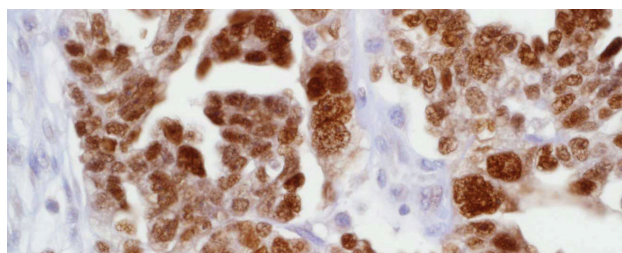


INTENDED USE

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

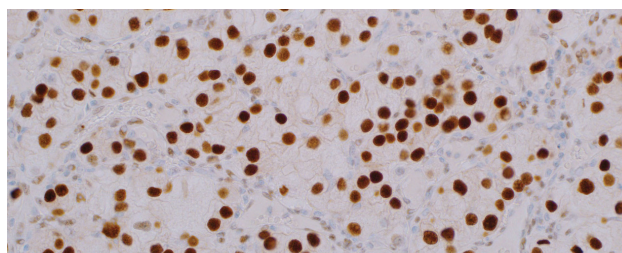


INTENDED USE

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

PAX-8 (EP331) Rabbit Monoclonal Primary Antibody

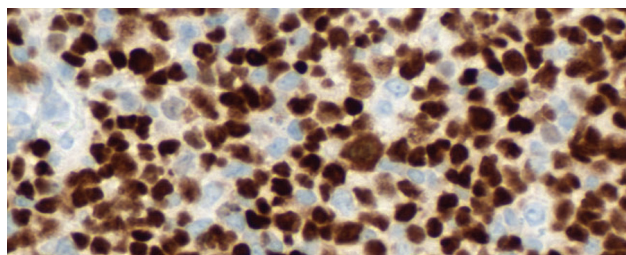
Ordering Number: 08313431001
Catalog Number: 760-6077
Quantity: 50 tests
Controls: Clear Cell Renal Cell Carcinoma, Thyroid Carcinoma, Ovarian Carcinoma (non-mucinous carcinoma)
Isotypes: IgG
Clone Name: EP331
Species: Rabbit
Localization: Nuclear



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.

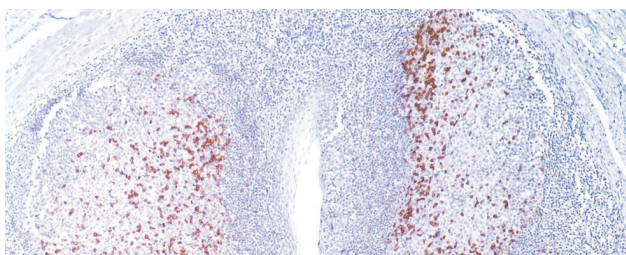


CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody

Ordering Number: 05552729001
Catalog Number: 790-4420
Quantity: 50 tests
Controls: Spleen, Tonsil
Clone Name: SP34
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.

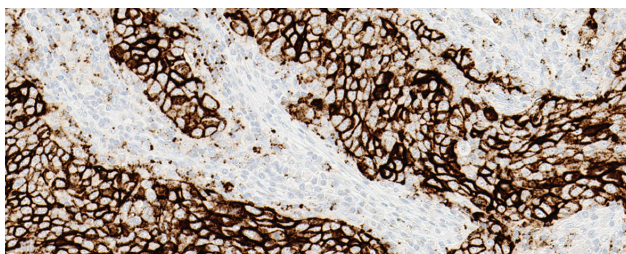


PD-1 (NAT105) Mouse Monoclonal Antibody

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.

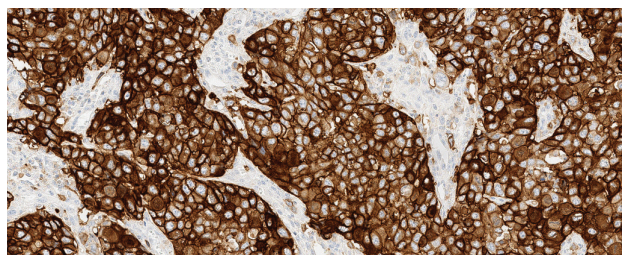
Table 1. Companion diagnostic indications for the VENTANA PD-L1 (SP142) Assay

INDICATION FOR USE	CUTOFF	THERAPY
Non-Small Cell Lung Cancer (NSCLC)	≥ 50% TC or ≥ 10% IC	TECENTRIQ

Depending on therapeutic setting, PD-L1 expression in ≥ 50% TC or ≥ 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.

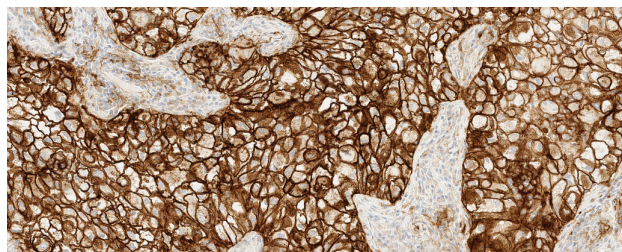
Table 1. VENTANA PD-L1 (SP263) Assay Companion Diagnostic Indication

INDICATION FOR USE	PD-L1 CUTOFF	THERAPY
NSCLC	≥ 1% TC	TECENTRIQ® (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

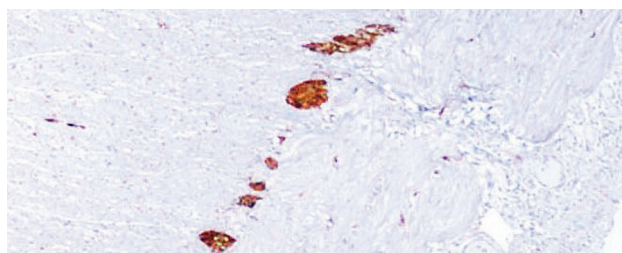


INTENDED USE

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.

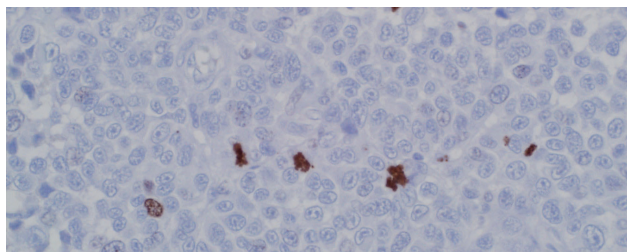
PGP 9.5 Rabbit Polyclonal Antibody

Ordering Number: 05973953001
Catalog Number: 760-4434
Quantity: 50 tests
Controls: Bowel Wall (Interstitial Cells of Cajal), Nerve Tissue
Isotypes: IgG
Clone Name: Polyclonal
Species: Rabbit
Localization: Cytoplasmic
Regulatory Status: IVD



INTENDED USE

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

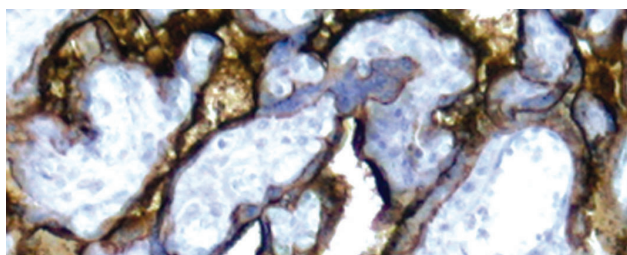


Phosphohistone H3 (PHH3)

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)

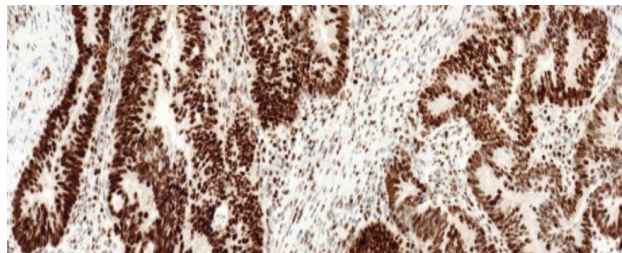
Ordering Number:	05267757001
Catalog Number:	760-2664
Quantity:	50 tests
Controls:	Placenta
Isotypes:	IgG
Clone Name:	NB10
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

PLAP (NB10) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the PLAP protein in formalin-fixed, 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
Isotypes:	IgG ₁
Clone Name:	A16-4
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-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	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.

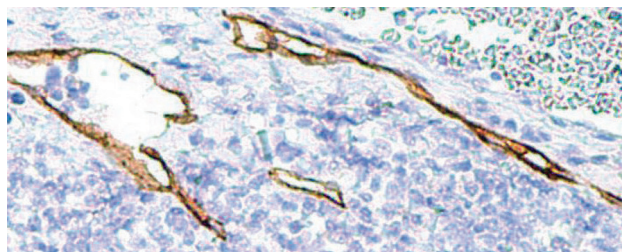
INTENDED USE PART 2

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.

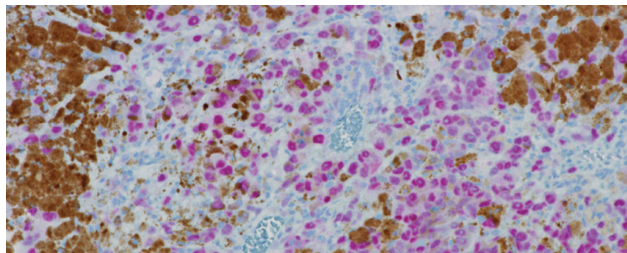
Podoplanin (D2-40) Mouse Monoclonal Antibody

Ordering Number:	05463645001
Catalog Number:	760-4395
Quantity:	50 tests
Controls:	Lymph Node, Lymphangioma
Isotypes:	IgG ₁
Clone Name:	D2-40
Species:	Mouse
Localization:	Cytoplasmic
Regulatory 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.

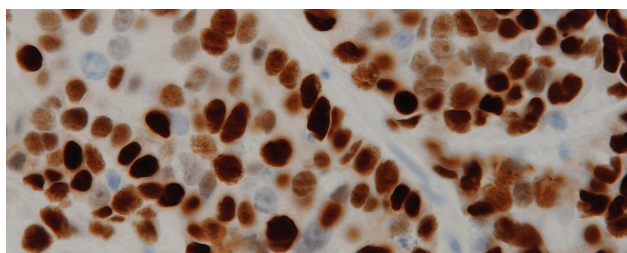


Anti-PRAME (EPR20330) Rabbit Monoclonal Primary Antibody

Ordering Number:	09592237001	09592245001
Catalog Number:	790-7149	790-7150
Quantity:	50 tests	250 tests
Controls:	Normal Testis, Positively Staining Melanomas	
Isotypes:	IgG	
Clone Name:	EPR20330	
Species:	Rabbit	
Localization:	Nuclear	
Regulatory 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.

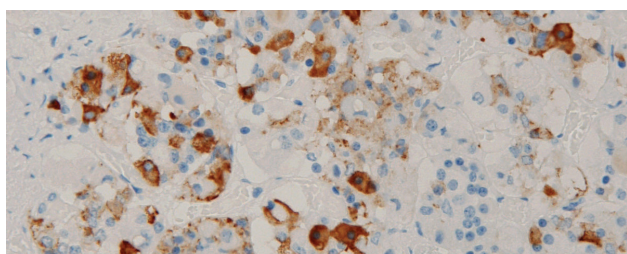


CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody

Ordering Number:	05277990001	5278392001
Catalog Number:	790-2223	790-4296
Quantity:	50 tests	250 tests
Controls:	Breast	
Isotypes:	IgG	
Clone Name:	1E2	
Species:	Rabbit	
Localization:	Nuclear	
Regulatory Status:	IVD	

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) is intended for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM 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)

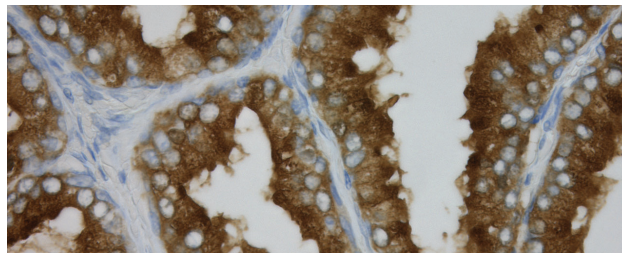
Ordering Number:	05268249001
Catalog Number:	760-2803
Quantity:	50 tests
Controls:	Normal Pituitary
Clone Name:	Polyclonal
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

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

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

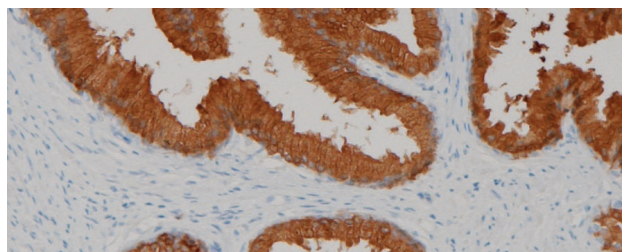


INTENDED USE

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
Catalog Number: 760-4271
Quantity: 50 tests
Controls: Prostate Adenocarcinoma
Isotypes: IgG₁/K
Clone Name: ER-PR8
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

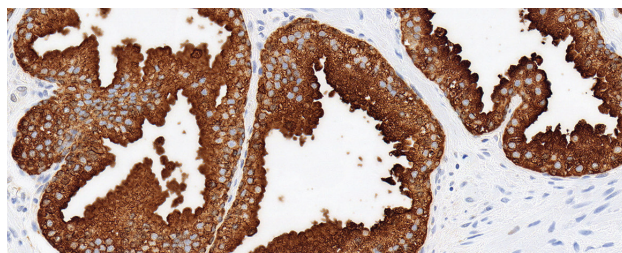


INTENDED USE

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.

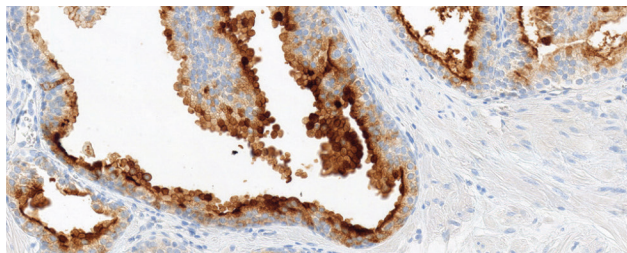
PSAP (PASE/4LJ)

Ordering Number: 05269342001
Catalog Number: 760-4272
Quantity: 50 tests
Controls: Prostate
Isotypes: IgG₁
Clone Name: PASE/4LJ
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD



INTENDED USE

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

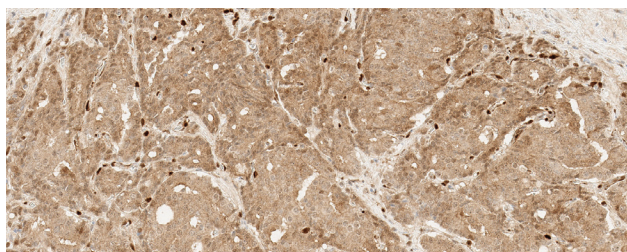


PSMA (EP192) Rabbit Monoclonal Primary Antibody

Ordering Number:	08313423001
Catalog Number:	760-6076
Quantity:	50 tests
Controls:	Prostate, Prostate Adenocarcinoma
Isotypes:	IgG
Clone Name:	EP192
Species:	Rabbit
Regulatory 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.

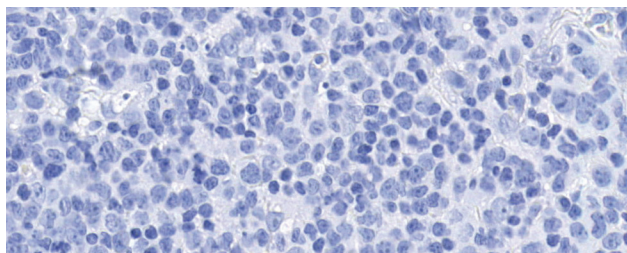


VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody

Ordering Number:	07970200001
Catalog Number:	790-5097
Quantity:	50 tests
Controls:	Pancreatic Islet Cells
Isotypes:	IgG
Clone Name:	SP218
Species:	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

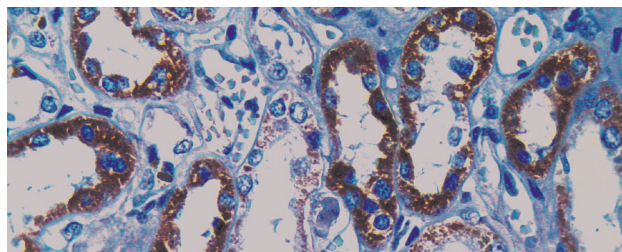
Ordering Number:	06683380001
Catalog Number:	790-4795
Quantity:	250 tests
Controls:	Test Positive Tissue
Isotypes:	IgG
Species:	Rabbit
Regulatory Status:	IVD

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: IgG₁/k
Clone Name: PN-15
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD

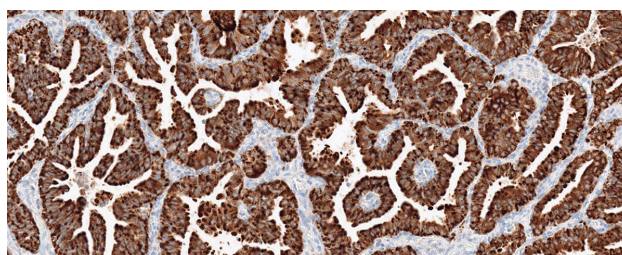


INTENDED USE

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.

VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody

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

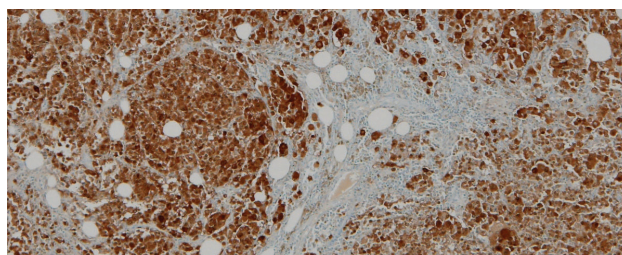


INTENDED USE

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.

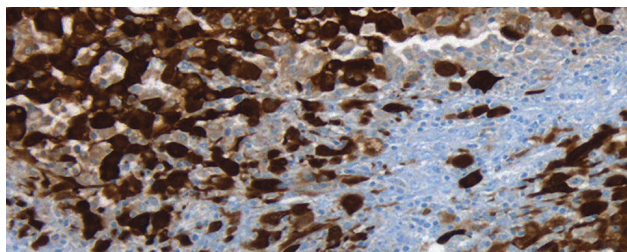
CONFIRM anti-S100 (4C4.9) Primary Antibody

Ordering Number: 05278104001
Catalog Number: 790-2914
Quantity: 50 tests
Controls: Melanoma
Isotypes: IgG_{2a}
Clone Name: 4C4.9
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.

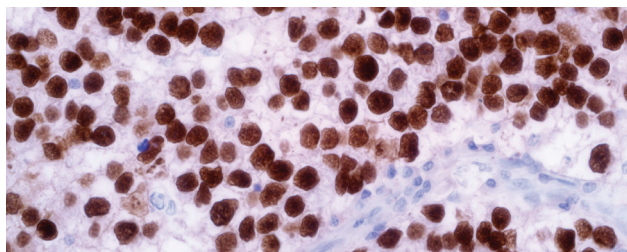


CONFIRM anti-S100 (Polyclonal) Primary Antibody

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.

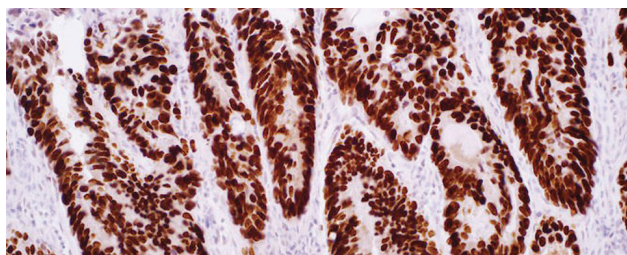


SALL4 (6E3) Mouse Monoclonal Primary Antibody

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

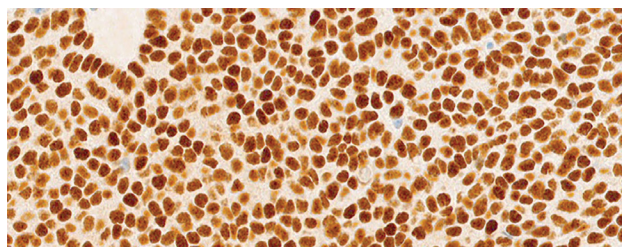
Ordering Number:	08313415001
Catalog Number:	760-6075
Quantity:	50 tests
Controls:	Colon Adenocarcinoma, Colon
Clone Name:	EP281
Species:	Rabbit
Localization:	Nuclear
Regulatory Status:	IVD

INTENDED USE

SATB2 (EP281) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SATB2 protein in formalin-fixed, 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.

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: Nucleus
Regulatory Status: IVD

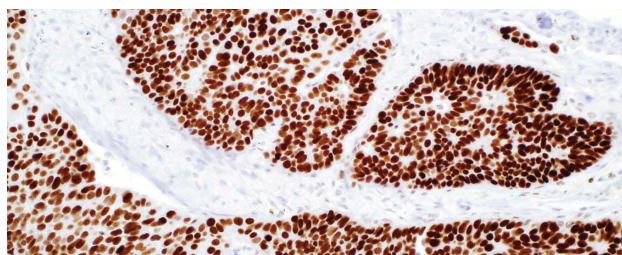


INTENDED USE

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: IgG
Clone Name: SP76
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

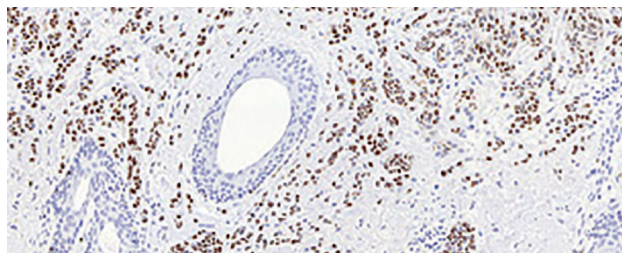


INTENDED USE

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.

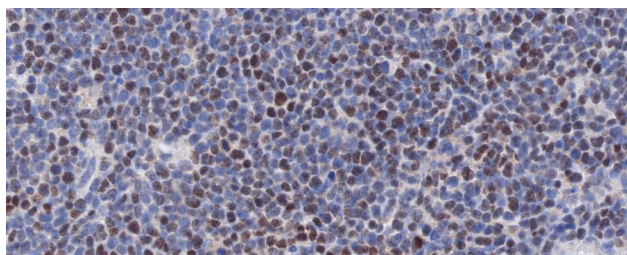
SOX-10 (SP267) Rabbit Monoclonal Primary Antibody

Ordering Number: 07560389001
Catalog Number: 760-4968
Quantity: 50 tests
Controls: Melanoma, Skin Melanocytes
Isotypes: IgG
Clone Name: SP267
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD



INTENDED USE

SOX-10 (SP267) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-10 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

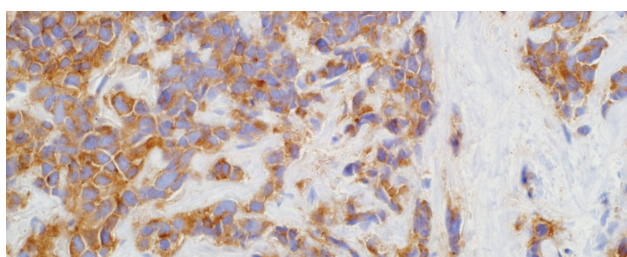


SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody

Ordering Number:	07047738001
Catalog Number:	760-4868
Quantity:	50 tests
Controls:	Mantle Cell Lymphoma
Isotypes:	IgG ₁
Clone Name:	MRQ-58
Species:	Mouse
Localization:	Nuclear
Regulatory Status:	IVD

INTENDED USE

SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the SOX-11 protein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

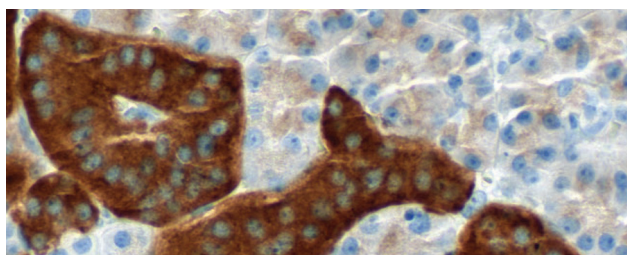


Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody

Ordering Number:	06433324001
Catalog Number:	760-4595
Quantity:	50 tests
Controls:	Pancreatic Islet Cells
Isotypes:	IgG ₁
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

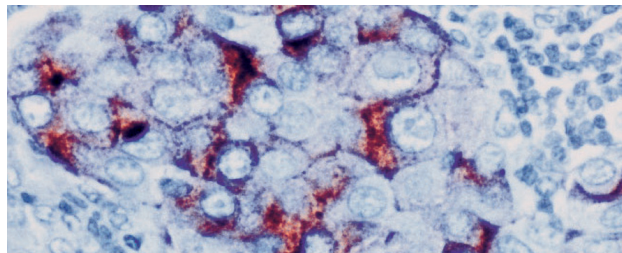
Ordering Number:	05479304001
Catalog Number:	790-4407
Quantity:	50 tests
Controls:	Pancreas
Clone Name:	SP11
Species:	Rabbit
Localization:	Cytoplasmic
Regulatory Status:	IVD

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, paraffin-embedded tissue. Positive staining results may aid in the classification of neuroendocrine tumors. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

TAG-72 (B72.3)

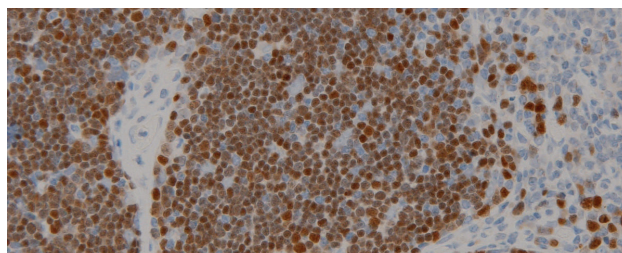
Ordering Number: 05267803001
Catalog Number: 760-2669
Quantity: 50 tests
Controls: Breast Carcinoma
Isotypes: IgG₁/K
Clone Name: B72.3
Species: Mouse
Localization: Cytoplasmic
Regulatory Status: IVD

**INTENDED USE**

TAG-72 (B72.3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the TAG-72 glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

TdT (polyclonal)

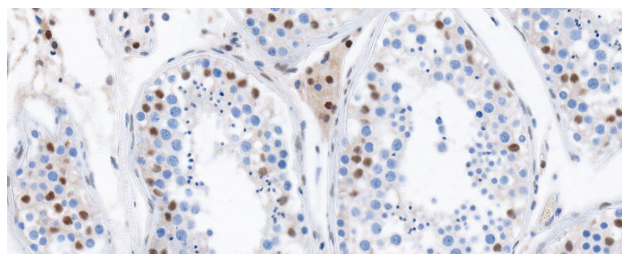
Ordering Number: 05267811001
Catalog Number: 760-2670
Quantity: 50 tests
Controls: TdT Positive Lymphomas, Thymus
Clone Name: Polyclonal
Species: Rabbit
Localization: Nuclear
Regulatory Status: IVD

**INTENDED USE**

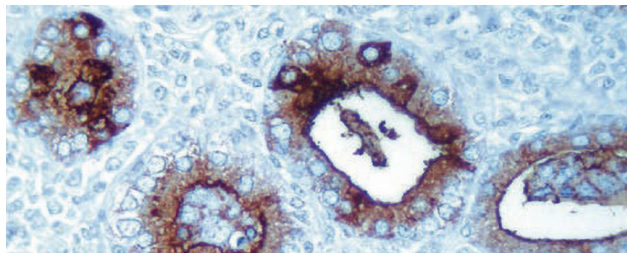
TdT Rabbit Polyclonal Primary Antibody is intended for laboratory use in the detection of TdT in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant 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: IgG
Clone Name: MRQ-37
Species: Rabbit
Localization: Nuclear
Regulatory 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, 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.

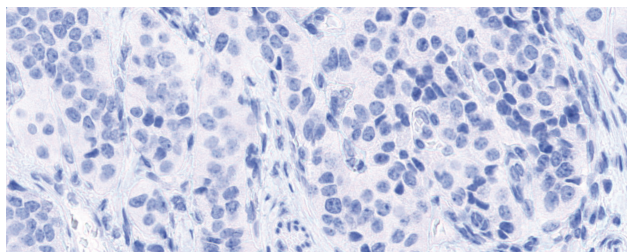


Thyroglobulin (2H11+6E1)

Ordering Number:	05267820001
Catalog Number:	760-2671
Quantity:	50 tests
Controls:	Thyroid
Isotypes:	IgG ₁
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.

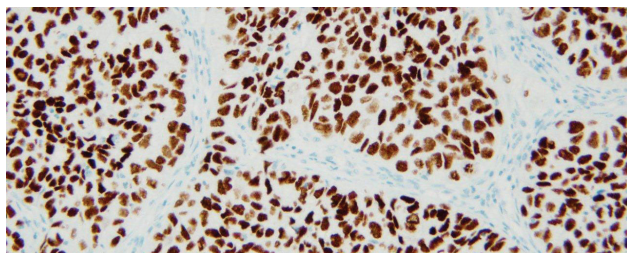


CONFIRM anti-Thyroid Transcription Factor-1 (8G7G3/1) Mouse Monoclonal Primary Antibody

Ordering Number:	05479312001
Catalog Number:	790-4398
Quantity:	50 tests
Controls:	Lung, Thyroid, Lung Carcinoma
Isotypes:	IgG ₁
Clone Name:	8G7G3/1
Species:	Mouse
Localization:	Nuclear
Regulatory 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

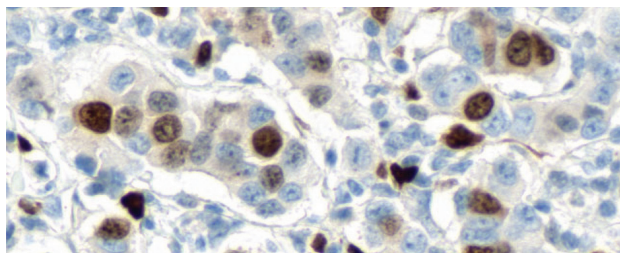
Ordering Number:	06640613001
Catalog Number:	790-4756
Quantity:	50 tests
Controls:	Normal Thyroid, Lung Carcinoma, Normal Lung
Isotypes:	IgG
Clone Name:	SP141
Species:	Rabbit
Localization:	Nuclear
Regulatory Status:	IVD
Alternate Names:	Thyroid Transcription Factor - 1

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 II α (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

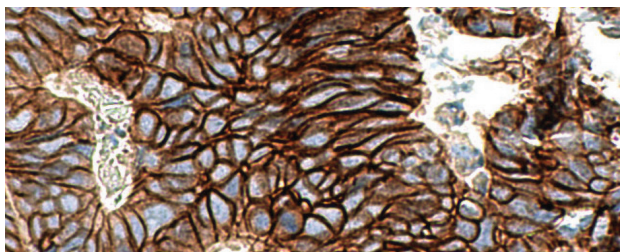
This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' CONFIRM anti-Topoisomerase II α (JS5B4) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of topoisomerase II α expressing cells via light microscopy in formalin-fixed, paraffin-embedded tissue following staining on a VENTANA BenchMark XT instrument. During the cell cycle, topoisomerase II α is expressed in the G1, S, G2 and M phase but is absent in the G0 (quiescent) phase.¹ Assessment of the proportion of positive staining cells for topoisomerase II α may aid in evaluation of the proliferative activity of normal and/or neoplastic tissue.²⁻⁴ The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history other diagnostic tests.

References:

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.

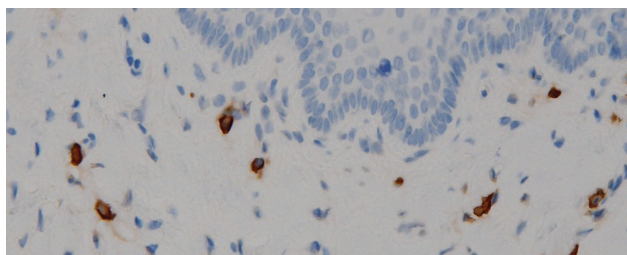
CONFIRM anti-Total c-MET (SP44) Rabbit Monoclonal Primary Antibody

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.

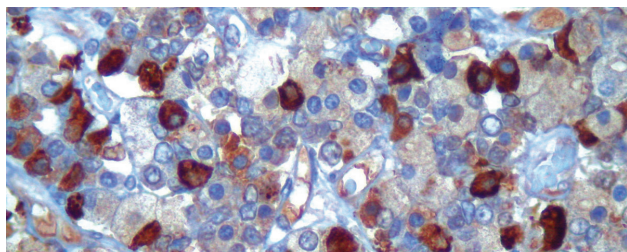


Tryptase (G3)

Ordering Number:	05269393001
Catalog Number:	760-4276
Quantity:	50 tests
Controls:	Mast Cell-Containing Tissue
Isotypes:	IgG ₁
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.

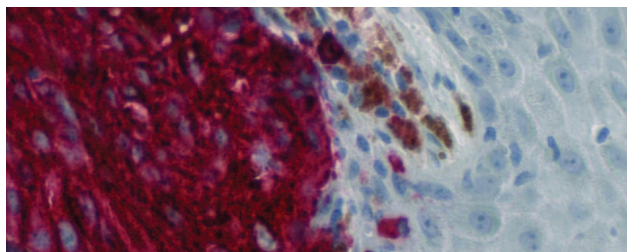


TSH (polyclonal)

Ordering Number:	05268184001
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

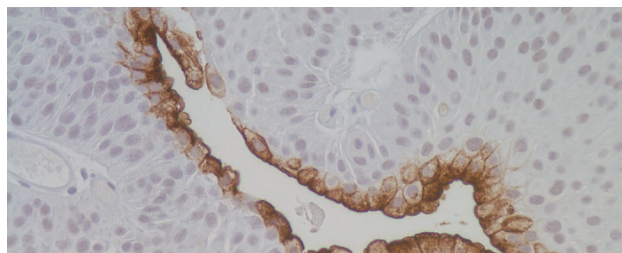
Ordering Number:	05479347001
Catalog Number:	790-4365
Quantity:	50 tests
Controls:	Lung, Melanoma
Isotypes:	IgG _{2a}
Clone Name:	T311
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

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

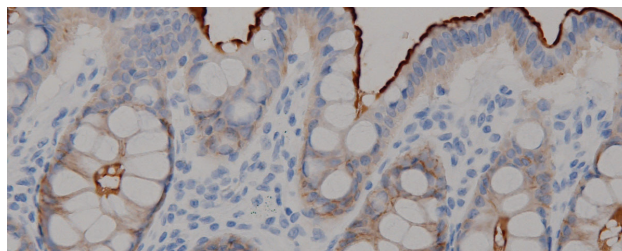


INTENDED USE

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.

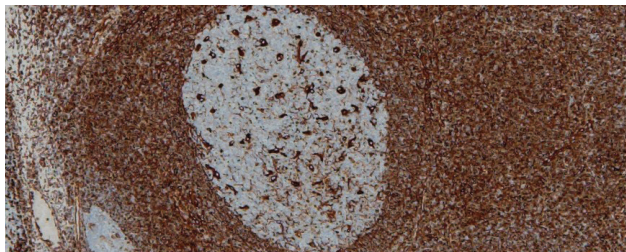
Villin (CWVB1)

Ordering Number: 05269407001
Catalog Number: 760-4277
Quantity: 50 tests
Controls: Colonic Mucosa, Small Bowel Mucosa
Isotypes: IgG₁
Clone Name: CWVB1
Species: Mouse
Localization: Cytoplasmic, Membranous
Regulatory Status: IVD



INTENDED USE

Villin (CWVB1) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the villin glycoprotein in formalin-fixed, paraffin-embedded tissue stained on VENTANA BenchMark IHC/ISH instruments. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

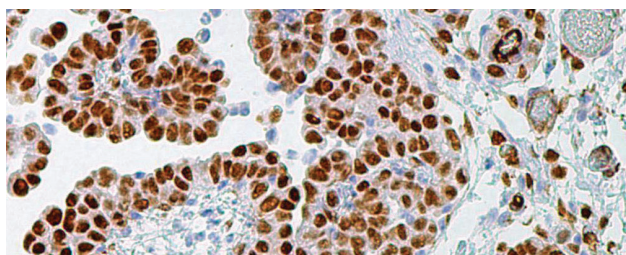


CONFIRM anti-Vimentin (V9) Primary Antibody

Ordering Number:	05278139001
Catalog Number:	790-2917
Quantity:	50 tests
Controls:	Lymph Node, Skin
Isotypes:	IgG/K
Clone Name:	V9
Species:	Mouse
Localization:	Cytoplasmic
Regulatory Status:	IVD

INTENDED USE

This antibody is intended for in vitro diagnostic (IVD) use. Ventana Medical Systems' (Ventana) CONFIRM anti-Vimentin (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
Isotypes:	IgG ₁ /K
Clone Name:	6F-H2
Species:	Mouse
Localization:	Nuclear
Regulatory Status:	IVD

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.

VENTANA®

Roche

Detection Systems

Delivering solutions that empower healthcare professionals to confidently diagnose patient conditions

OptiView DAB IHC Detection

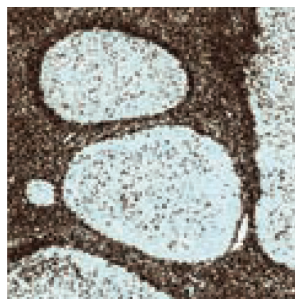
Innovative detection for enhanced stain quality

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.

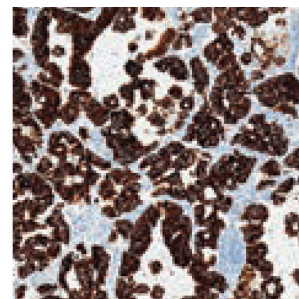
- **Increase sensitivity:** By increasing the numbers of HRP enzymes at each primary antibody site, OptiView chemistry provides unparalleled signal intensity, empowering you to visualize even low-level markers.
- **Improve specificity:** Our patented synthetic, non-endogenous hapten system eliminates 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

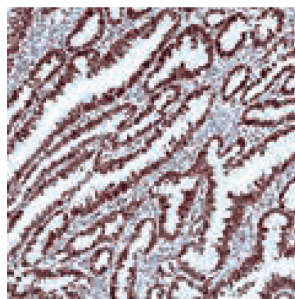
Featuring a two-step design and unique synthetic, non-endogenous hapten technology on the secondary antibody, OptiView detection provides excellent background reduction. In addition, it delivers increased sensitivity through a higher number of multimers per primary antibody. The reaction is further enhanced by a proprietary reagent that accelerates DAB color development in the presence of the HRP enzyme.



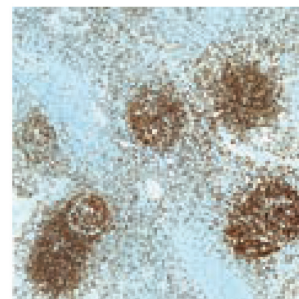
A



B



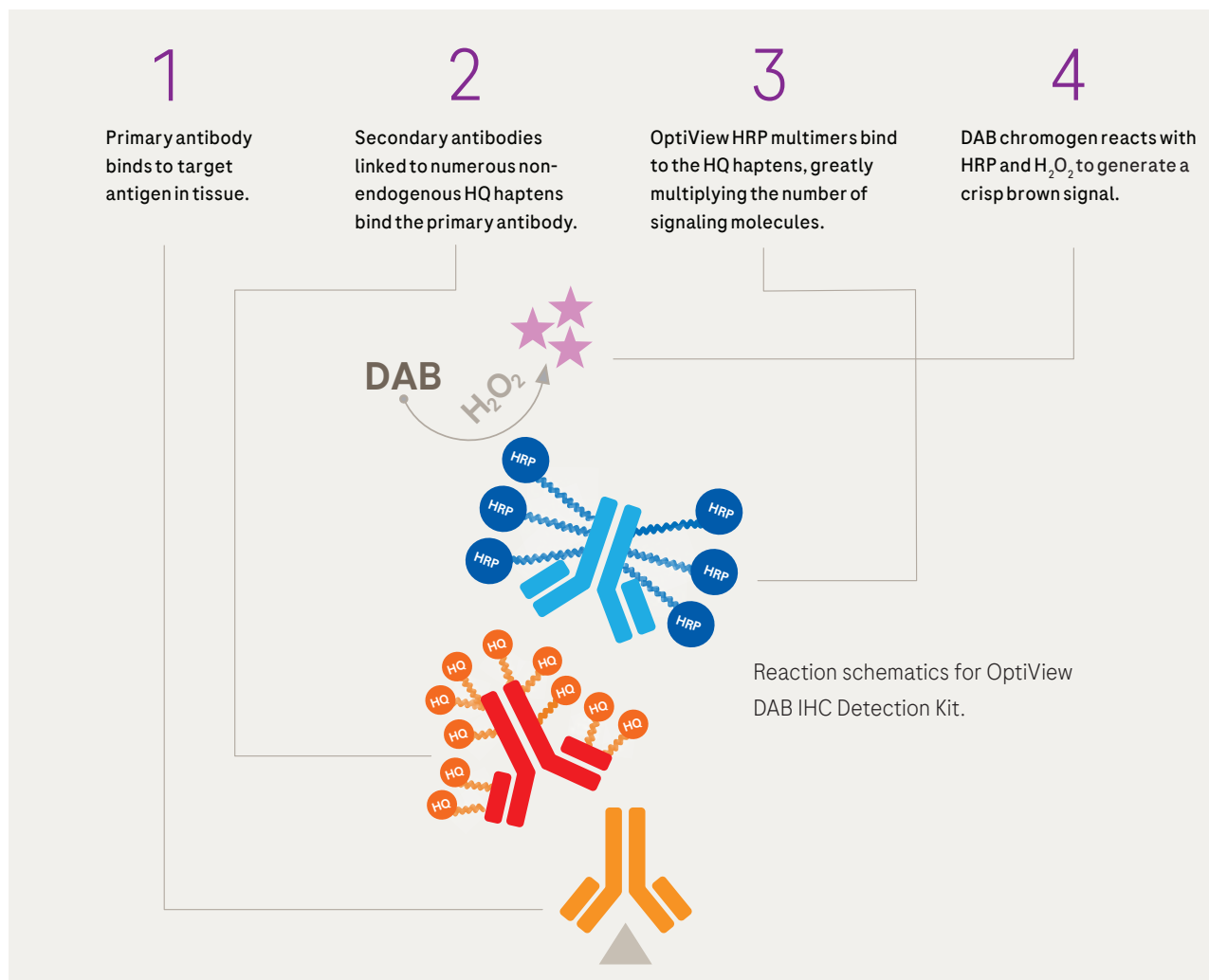
C



D

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

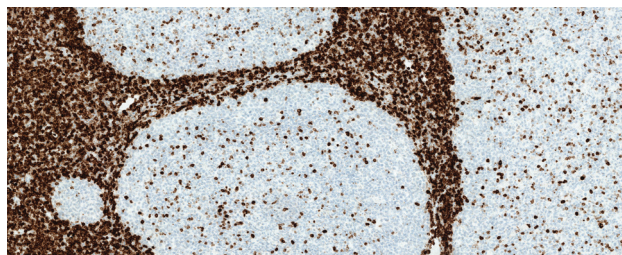
Ordering Code: 06396518001 06718663001
Catalog Number: 760-099 860-099
Quantity: 50 tests 250 tests
Regulatory Status: IVD IVD

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, paraffin-embedded tissue, frozen tissue, or cytological preparations on VENTANA BenchMark Advanced Staining automated slide stainers with VENTANA primary antibodies and ancillary reagents, visualized by light microscopy. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. This product is intended for in vitro diagnostic (IVD) use.

OptiView DAB IHC Detection Kit

Ordering Code: 06396500001
Catalog Number: 760-700
Quantity: 250 tests
Regulatory Status: IVD

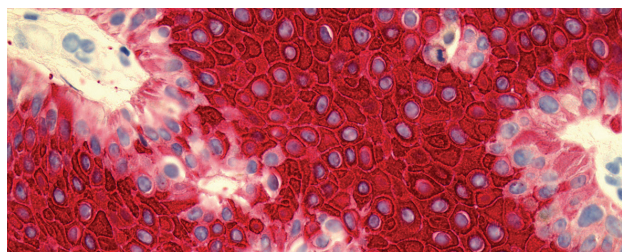


INTENDED USE

ultraView Universal DAB Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry in sections of formalin-fixed, paraffin-embedded tissue, or frozen tissue, that are stained on the 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 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

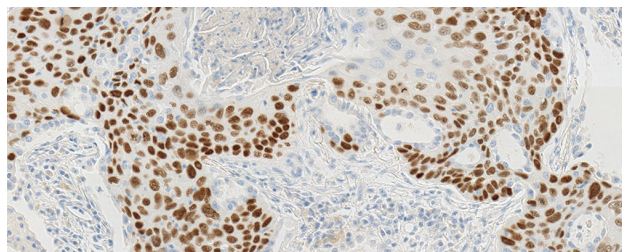


INTENDED USE

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

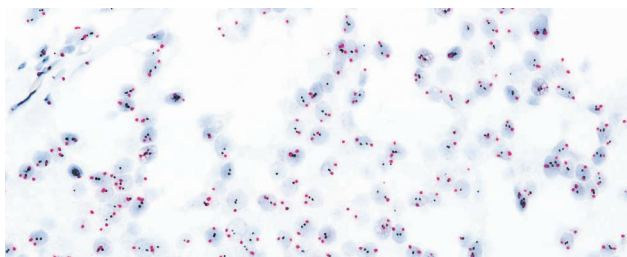
UltraView Universal DAB Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded tissue, or frozen tissue, that are stained on the BenchMark, 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 product is intended for in vitro diagnostic (IVD) use.

ISH iVIEW_{Blue} Plus Detection Kit

Ordering Code: 05266181001
Catalog Number: 760-097
Quantity: 100 tests
Regulatory Status: IVD

INTENDED USE

Ventana Medical Systems, (Ventana) ISH iVIEWBlue 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.

VENTANA®

Roche



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 Special 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

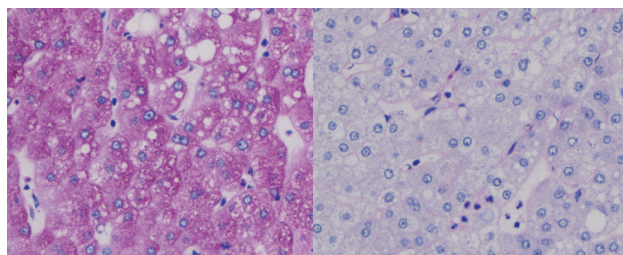
Diastase Kit

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.



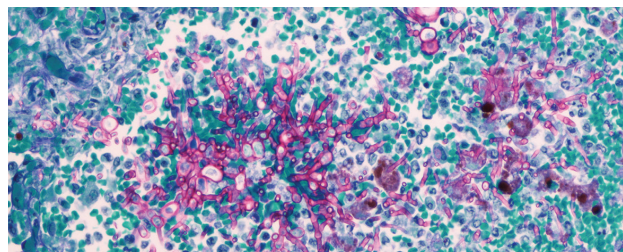
Light Green for PAS

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.



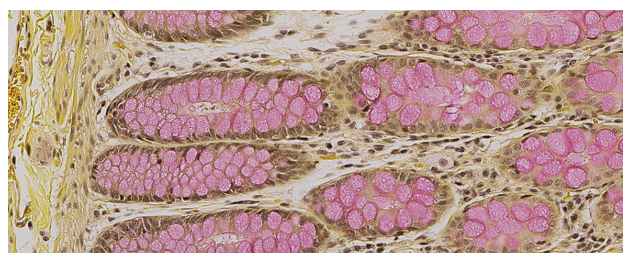
Mucicarmine Staining Kit

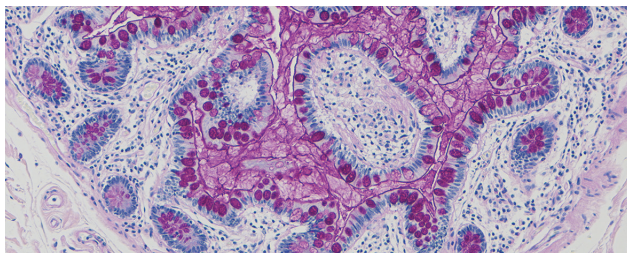
Ordering Code: 05279275001
Catalog Number: 860-011
Quantity: 75 tests
Controls: Human Tissue with Epithelial Mucin

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

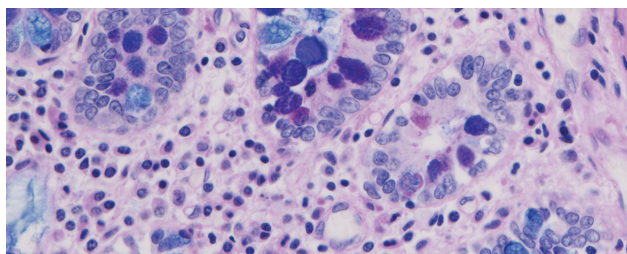
Ordering Code:	05279291001
Catalog Number:	860-014
Quantity:	75 tests
Controls:	Tissue Known to be Glycogen Rich, such as Kidney, Small Intestine, Liver, Skin, or Aorta

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.¹ PAS Staining Kit may also be used to aid in distinguishing a PAS positive secreting adenocarcinoma from an undifferentiated PAS negative squamous cell carcinoma.² 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.



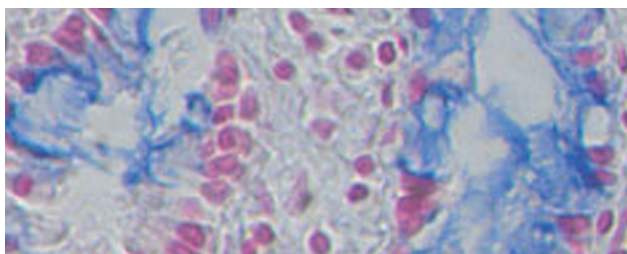
Alcian Blue for PAS

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:	05279186001
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

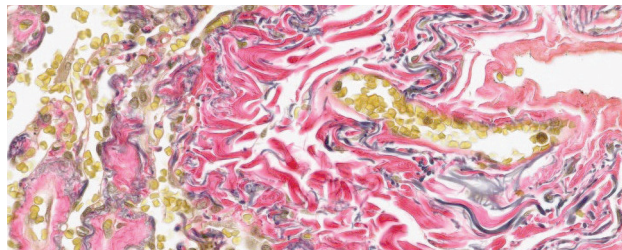
Ordering Code: 09185992001
Catalog Number: 860-073
Quantity: 50 tests
Controls: Lung, Artery, Colon, Aorta, Heart

For use on the BenchMark Special Stains instrument.

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 components 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.

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 & Elastic Stain Core Kit.



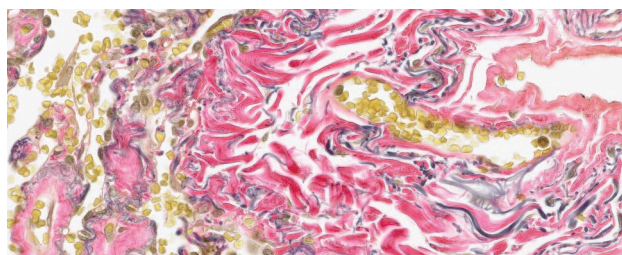
Elastic Stain Core Kit

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.



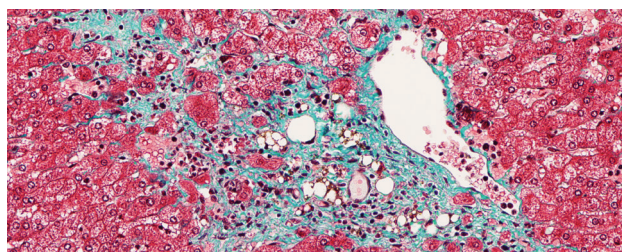
Green for Trichrome

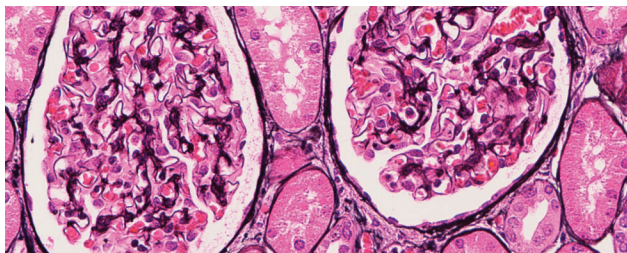
Ordering Code: 06521916001
Catalog Number: 860-032
Quantity: 75 tests
Controls: Colon, Kidney, Liver, Skin

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.





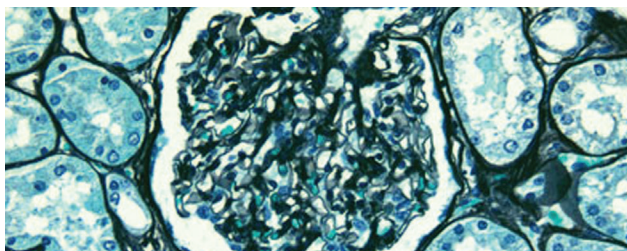
Jones H&E Staining Kit

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.



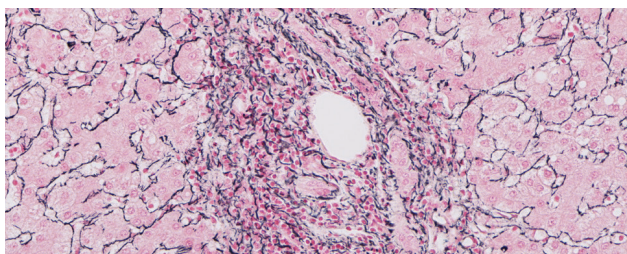
Jones Light Green Staining Kit

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.

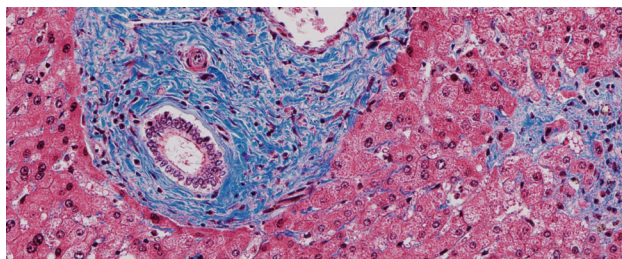
INTENDED USE

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.

Trichrome Staining Kit

Ordering Code: 06521908001
Catalog Number: 860-031
Quantity: 60 tests
Controls: Colon, Kidney, Liver, Skin

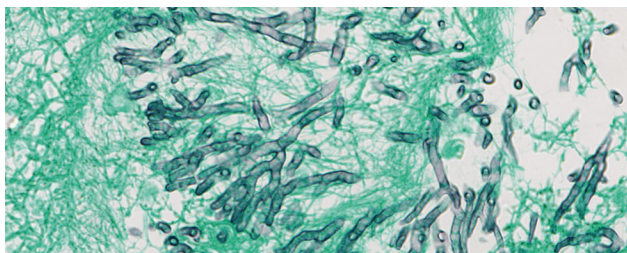
For use on the BenchMark Special Stains system.



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



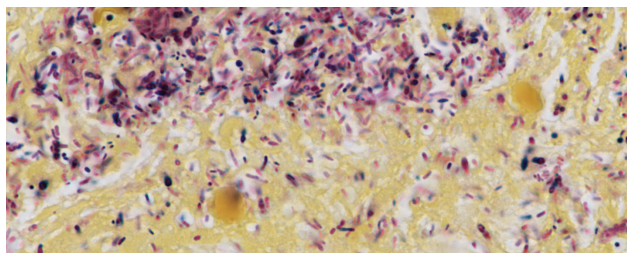
GMS II Staining Kit

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.



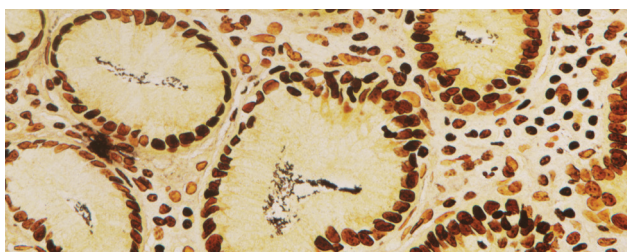
Gram Staining Kit

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.

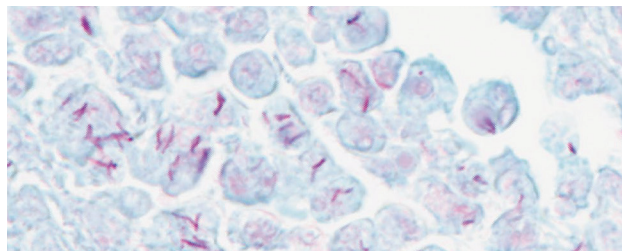
INTENDED USE

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

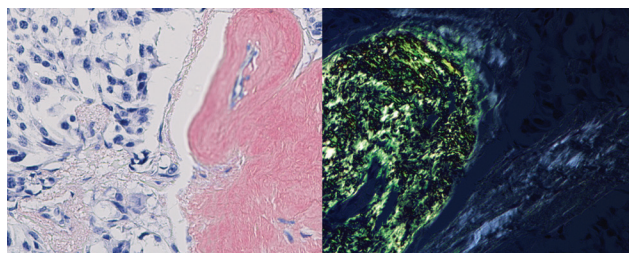
Ordering Code: 08432503001
Quantity: 75 tests
Controls: Tissue Positive for Acid-Fast Bacteria

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



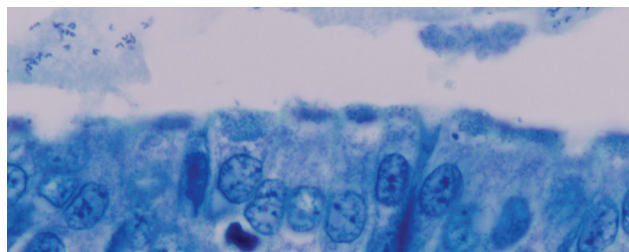
Congo Red Staining Kit

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.



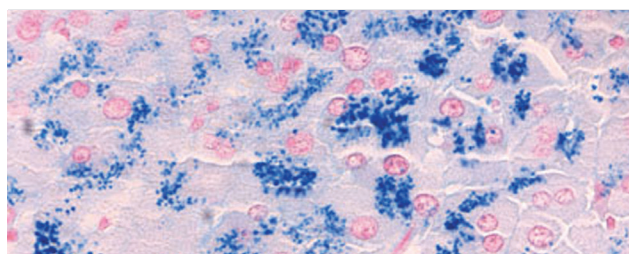
Giemsa Staining Kit

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.

VENTANA®

Roche

DISCOVERY

Innovative IHC and ISH Research

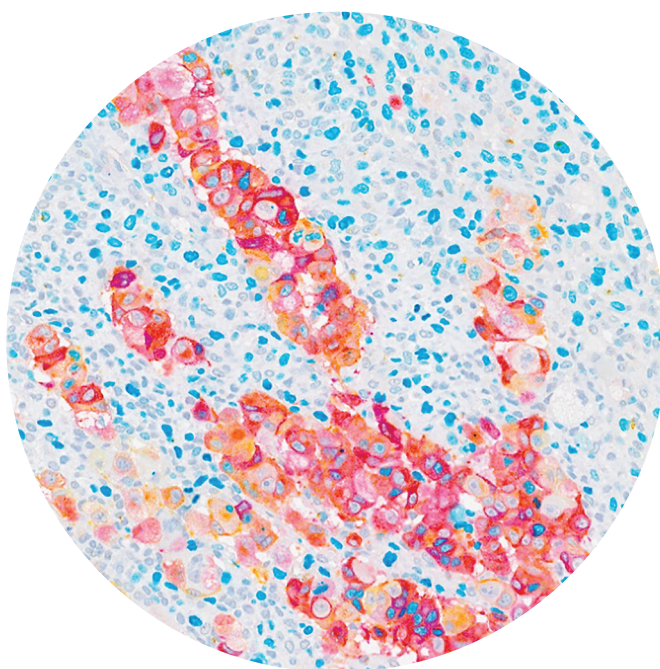
DISCOVERY ULTRA

Customize with your research goals.



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

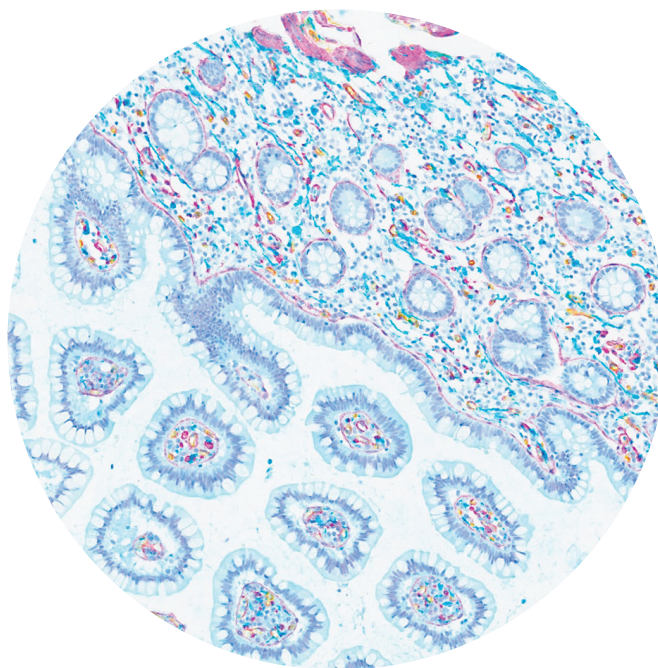
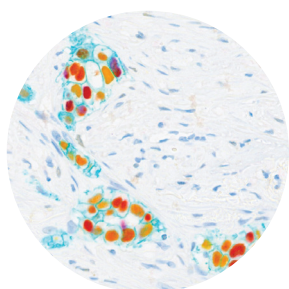
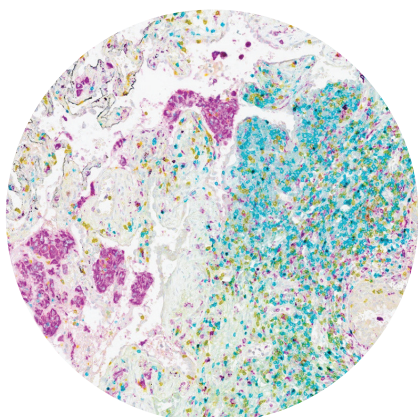
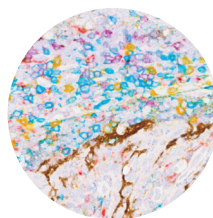
- Many options for chromogenic and fluorescent staining for both IHC and ISH
- Leading-edge detection chemistries
- In situ hybridization for RNA, DNA, and small non-coding RNAs
- Multiplexed chromogenic and fluorescent IHC or ISH
- Same-slide multiplexed IHC and ISH in any color combination



DISCOVERY products are for Research Use Only. Not for use in diagnostic procedures.

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 products are for Research Use Only. Not for use in diagnostic procedures.

DISCOVERY ULTRA

Automated IHC, ISH and 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



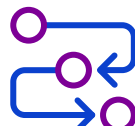
Accessibility

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	<ul style="list-style-type: none"> • 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.
navify Integrator for Services	navify Integrator for services is an automated remote monitoring and diagnostics solution that enables continuous monitoring and remote service of VENTANA instruments. navify Integrator for services enables users to maximize instrument performance and prevent workday service interruptions.
navify Pathology Lab Advantage	(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.

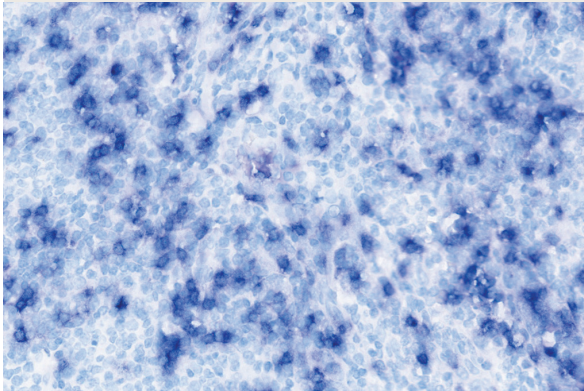
DISCOVERY products are for Research Use Only. Not for use in diagnostic procedures.

Detection

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

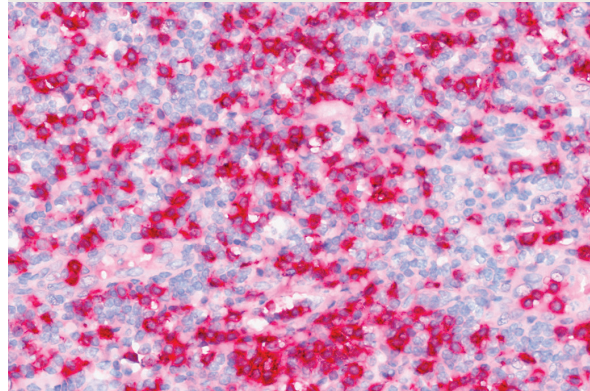
BIOTIN

Works universally for detection of biotinylated antibodies and probes.



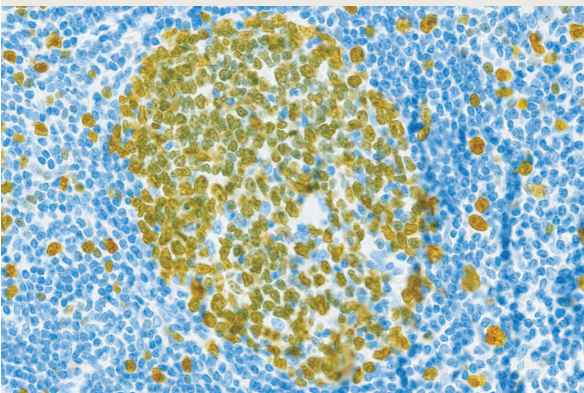
MULTIMER

For routine IHC with high sensitivity and low background.



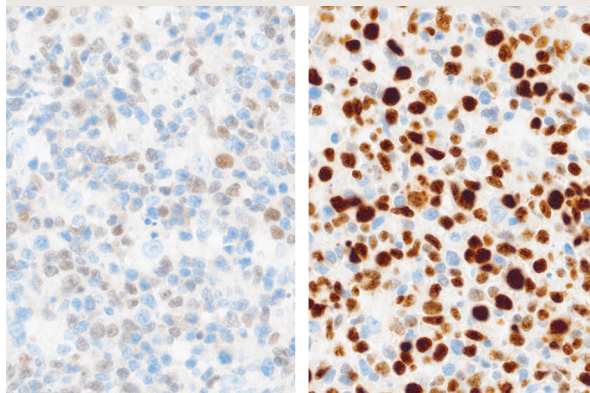
HAPTEN

Very high sensitivity while maintaining low background.



AMPLIFICATION

Highest level of sensitivity through a combination of multimer and hapten technologies for detecting the most difficult targets.



Without amplification

With amplification

MULTIMER

High sensitivity, low background

OmniMAP**HRP**

Mouse, Rabbit, Rat, Goat

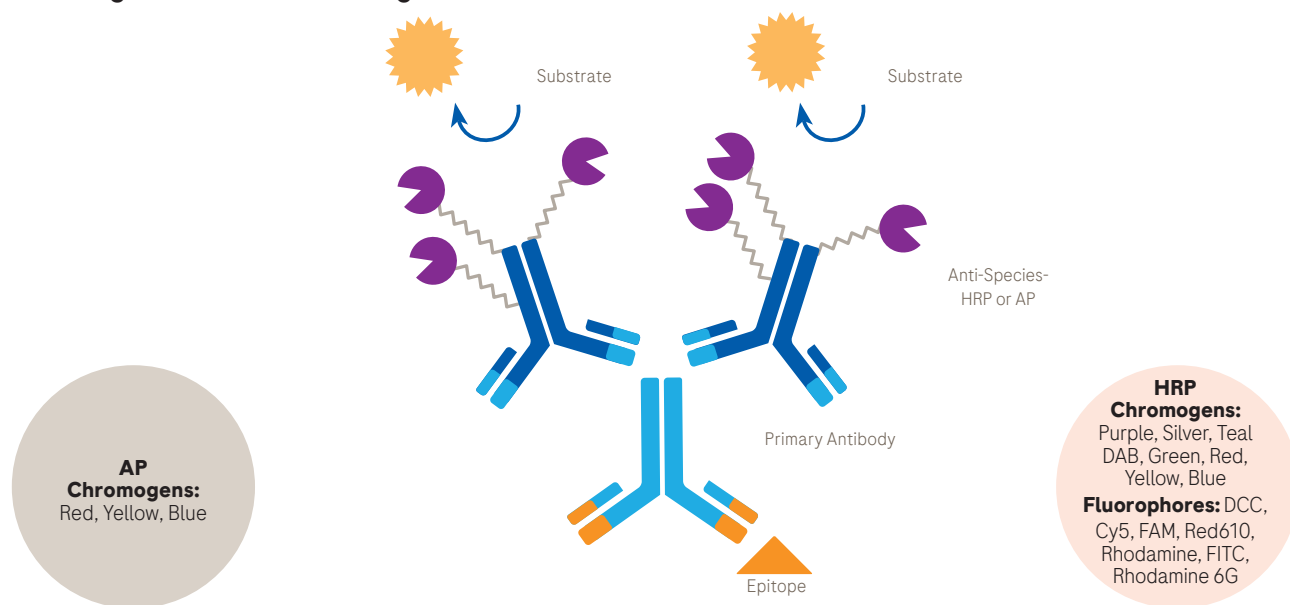
UltraMAP**HRP**

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**Multimer detection HRP/AP kits**

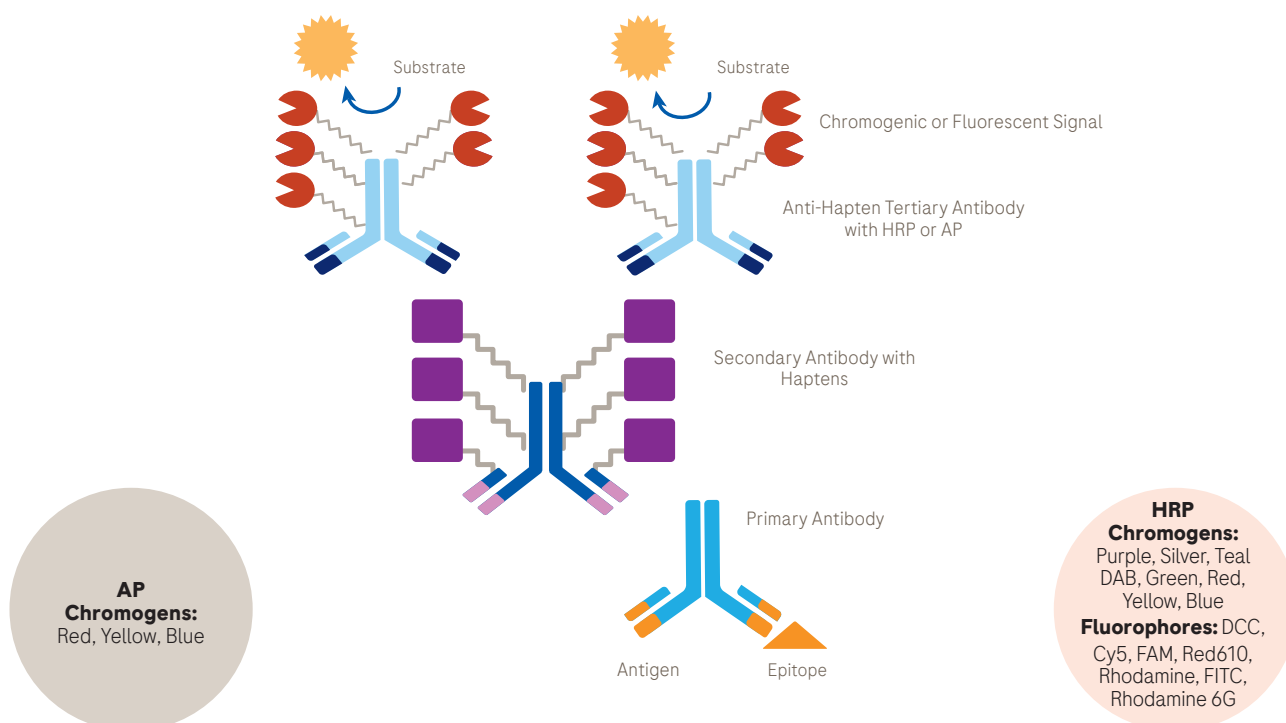
Product name	Ordering code	Quantity
Multimer OmniMAP HRP		
Anti-Mouse	05269652001	125 tests
Anti-Rabbit	05269679001	125 tests
Anti-Goat	06607233001	50 tests
Anti-Rat	05891892001	125 tests
Multimer UltraMAP HRP		
Anti-Mouse	05269695001	125 tests
Anti-Rabbit	05269717001	125 tests
Anti-Goat	06607241001	50 tests
Anti-Rat	05891884001	125 tests
Multimer UltraMAP AP		
Anti-Mouse	05269687001	125 tests
Anti-Rabbit	05269709001	125 tests

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HAPTEN Increased sensitivity	
NP	HQ
AP	HRP
Mouse, Rabbit	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.

Chromogen / Fluorophore



Hapten detection kits		
Product name	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

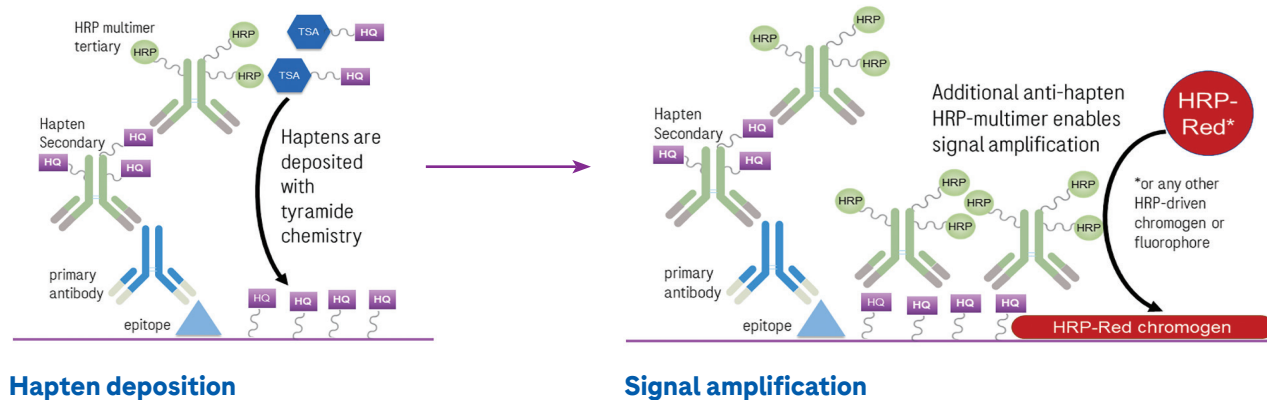
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DISCOVERY Amplification

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



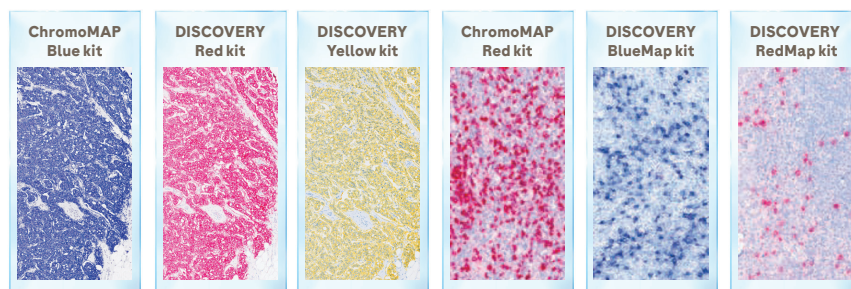
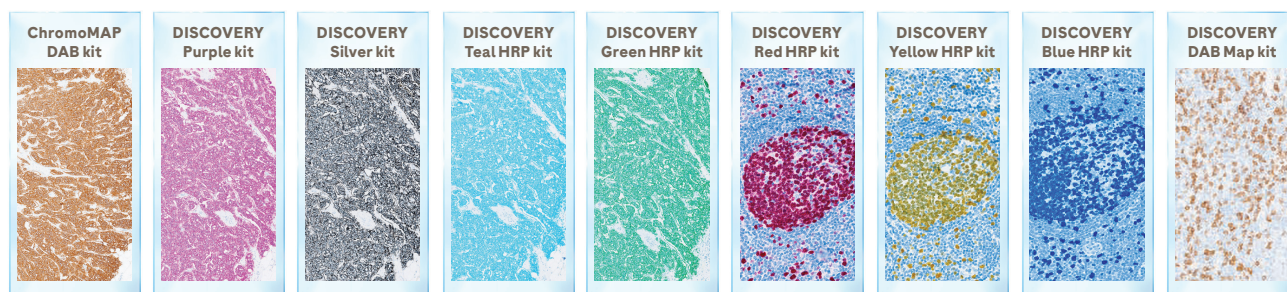
Amplification kits			
Product name		Ordering code	Quantity
HQ Amplification			
DISCOVERY HQ Amp kit		06472320001	50 tests
DISCOVERY Amp Anti-HQ AP		06472311001	50 tests
DISCOVERY Amp Anti-HQ HRP		06442544001	50 tests
BF Amplification			
DISCOVERY BF Amp kit		07529422001	50 tests
DISCOVERY anti-BF HRP		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			
Product name		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

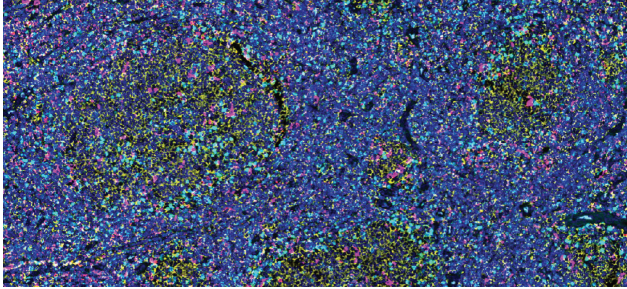


* DISCOVERY Inhibitor is required to quench endogenous peroxidases when using DISCOVERY Teal, DISCOVERY Purple, DISCOVERY Silver, DISCOVERY Green HRP, DISCOVERY Red HRP, DISCOVERY Yellow HRP, and DISCOVERY Blue HRP chromogens.

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Fluorescent Detection

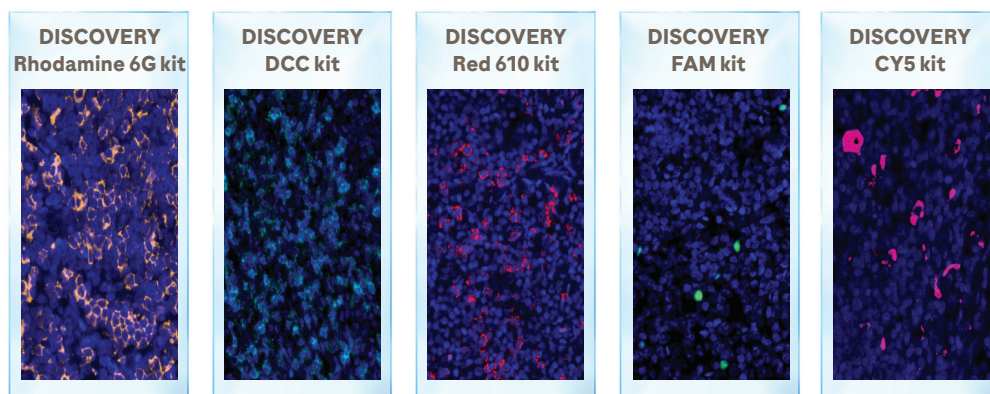
The highly photo stable signal from DISCOVERY fluorescent detection is enabled by Tyramide Signal Amplification (TSA), and lasts for months, not mere hours—even when slides are stored at room temperature. Take the worry out of IF when you experience the staying power of DISCOVERY fluorescent detection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

DISCOVERY Immunofluorescence Detection			
Product name	Ordering code	Ex / Em*	Quantity
DISCOVERY FITC kit (RUO)*	07259212001	Ex λ - 490nm Em λ - 525nm	50 tests
DISCOVERY Rhodamine kit (RUO)*	07259883001	Ex λ - 542nm Em λ - 568nm	50 tests
DISCOVERY DCC kit*	07988192001	Ex λ - 436nm Em λ - 480nm	50 tests
DISCOVERY FAM kit*	07988150001	Ex λ - 490nm Em λ - 520nm	50 tests
DISCOVERY Red 610 kit*	07988176001	Ex λ - 580nm Em λ - 625nm	50 tests
DISCOVERY Rhodamine 6G kit*	07988168001	Ex λ - 546nm Em λ - 572nm	50 tests
DISCOVERY Cy5 kit*	07551215001	x λ - 643nm Em λ - 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

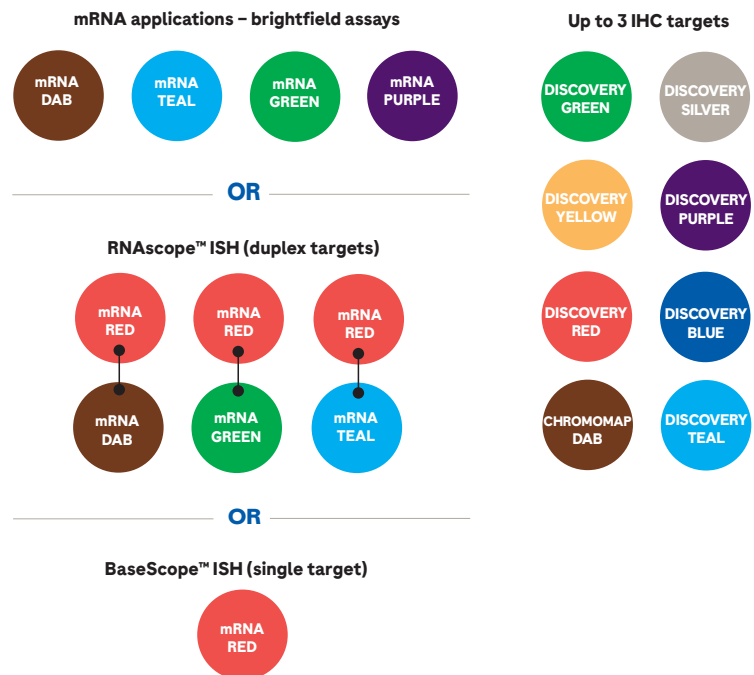
RNAscope® and BaseScope™ probes can be purchased from ACD, and used in combination with VENTANA chromogens, fluorophores, and bulk reagents for fully automated assays on the DISCOVERY ULTRA system.

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 RNAscope 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-path-lab-catalog>

Ancillaries

Antibody Diluents		
Product name	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		
Product name	Ordering code	Quantity
DISCOVERY Antibody Block	05268869001	250 tests
DISCOVERY S-Block	05268931001	250 tests
DISCOVERY Goat Ig Block	07988214001	250 tests
DISCOVERY Inhibitor	07017944001	250 tests
DISCOVERY Endogenous Biotin Blocking Kit	9965882001	250 tests

Enzymes		
Product name	Ordering code	Quantity
Protease 1	05266688001	250 tests
Protease 2	05266696001	250 tests
Protease 3	05266718001	250 tests

Hybridization Buffers / ISH diluents		
Product name	Ordering code	Quantity
HybReady	05917557001	25 mL
ISH Probe Diluent	06375375001	120 mL

Counterstains		
Product name	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		
Product name	Ordering code	Quantity
DISCOVERY anti-DIG AP	07256302001	50 tests
DISCOVERY anti-DIG HRP	07256299001	50 tests
DISCOVERY Universal Secondary Antibody (RUO) (biotinylated)	05268877001	250 tests

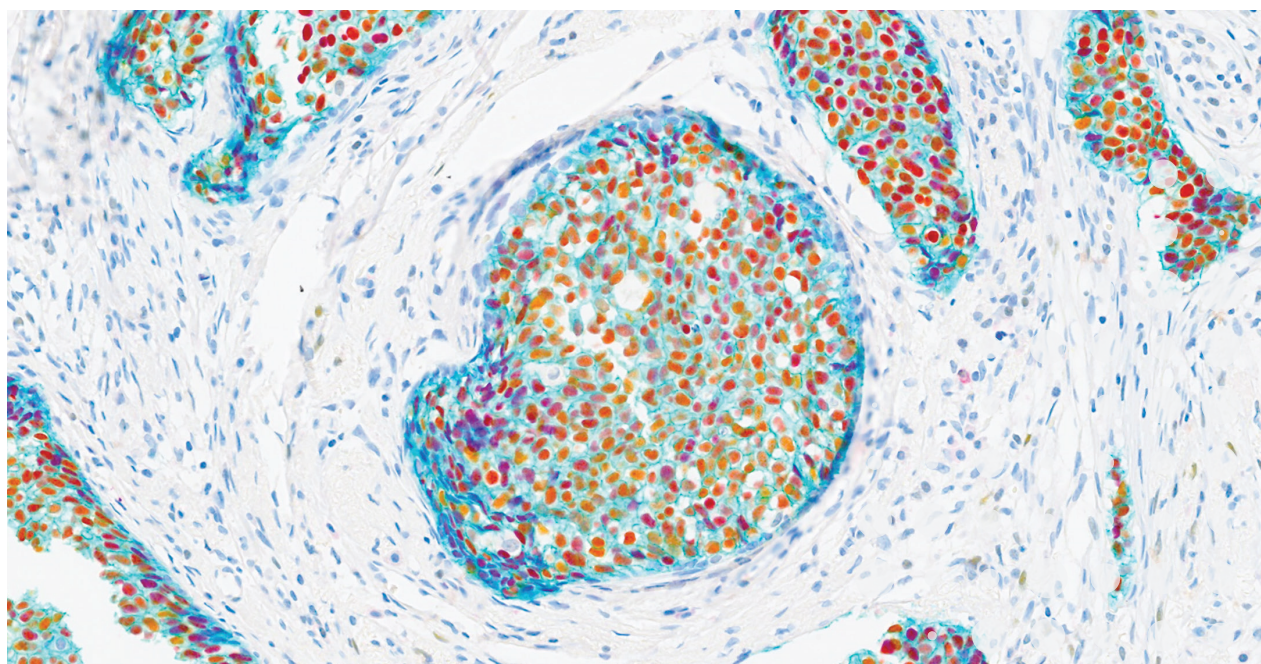
* DISCOVERY products are for Research Use Only. Not for use in diagnostic procedures.

Bulks

DISCOVERY ULTRA Bulk Solutions		
Product name	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

DISCOVERY XT Bulk Solutions		
Product name	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)



User-fillables/Prep kits



Antibody User-Fillables

Product name	Ordering code	Quantity
Light Protective Prep Kit	07475144001	250 tests
Prep Kit	05250935001	250 tests

Enzyme User-Fillables

Product name	Ordering code
Reagent Dispenser Card, Enzyme 1	05271517001
Reagent Dispenser Card, Enzyme 2	05271525001
Reagent Dispenser Card, Enzyme 3	05271533001
Reagent Dispenser Card, Enzyme 4	05271541001
Reagent Dispenser Card, Enzyme 5	05271550001

Blocker User-Fillables

Product name	Ordering code
250 Test Blocker # 1	05268885001
250 Test Blocker # 2	05268893001
250 Test Blocker # 3	05268907001
250 Test Blocker # 4	05268915001
250 Test Blocker # 5	05268923001

Pretreatment User-Fillables

Product name	Ordering code
250 Test Pretreatment # 1	05280095001
250 Test Pretreatment # 2	05280109001
250 Test Pretreatment # 3	05280117001
250 Test Pretreatment # 4	05280125001

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Fixative User-Fillables – continued

Product name	Ordering code
250 Test Pretreatment # 5	05280133001
250 Test Pretreatment # 6	05280141001
250 Test Pretreatment # 7	05280150001
250 Test Pretreatment # 8	05280168001
250 Test Pretreatment # 9	05280176001
250 Test Fixative # 1	05271614001
250 Test Fixative # 2	05271622001
250 Test Fixative # 3	05271649001
250 Test Fixative # 4	05271657001
250 Test Fixative # 5	05271665001

Counterstain User-Fillables

Product name	Ordering code
250 Test Counterstain # 1	05271720001
250 Test Counterstain # 2	05271738001
250 Test Counterstain # 3	05271746001
250 Test Counterstain # 4	05271754001
250 Test Counterstain # 5	005271762001

Antibody User-Fillables

Product name	Ordering code
250 Test Antibody # 1	05269857001
250 Test Antibody # 2	05269865001
250 Test Antibody # 3	05269873001
250 Test Antibody # 4	05269881001
250 Test Antibody # 5	05269890001
250 Test Antibody # 6	05269903001
250 Test Antibody # 7	05269911001
250 Test Antibody # 8	05269920001
250 Test Antibody # 9	05269938001
250 Test Antibody # 10	05269946001
250 Test Antibody # 11	05269954001
250 Test Antibody # 12	05269962001
250 Test Antibody # 13	05269989001
250 Test Antibody # 14	05269997001
250 Test Antibody # 15	05270006001
250 Test Antibody # 16	05270014001
250 Test Antibody # 17	05270022001
250 Test Antibody # 18	05270049001

Antibody User-Fillables – continued	
Product name	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
250 Test Antibody # 57	05270464001

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Antibody User-Fillables – continued	
Product name	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
250 Test Antibody # 76	05270685001
250 Test Antibody # 77	05270693001
250 Test Antibody # 78	05270707001
250 Test Antibody # 79	05270715001
250 Test Antibody # 80	05270723001
250 Test Antibody # 81	05270731001
250 Test Antibody # 82	05270740001
250 Test Antibody # 83	05270758001
250 Test Antibody # 84	05270766001
250 Test Antibody # 85	05270774001
250 Test Antibody # 86	05270782001
250 Test Antibody # 87	05270804001
250 Test Antibody # 88	05270812001
250 Test Antibody # 89	05270839001
250 Test Antibody # 90	05270847001
250 Test Antibody # 91	05270855001
250 Test Antibody # 92	05270863001
250 Test Antibody # 93	05270871001
250 Test Antibody # 94	05270880001
250 Test Antibody # 95	05270898001
250 Test Antibody # 96	05270901001

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Antibody User-Fillables – continued	
Product name	Ordering code
250 Test Antibody # 97	05270910001
250 Test Antibody # 98	05270928001
250 Test Antibody # 99	05270936001
250 Test Antibody # 100	05270944001
250 Test Antibody # 101	05270952001
250 Test Antibody # 102	05270979001
250 Test Antibody # 103	05270987001
250 Test Antibody # 104	05270995001
250 Test Antibody # 105	05271002001
250 Test Antibody # 106	05271029001
250 Test Antibody # 107	05271037001
250 Test Antibody # 108	05271045001
250 Test Antibody # 109	05271053001
250 Test Antibody # 110	05271061001
250 Test Antibody # 111	05271070001
250 Test Antibody # 112	05271088001
250 Test Antibody # 113	05271096001
250 Test Antibody # 114	05271100001
250 Test Antibody # 115	05271118001
250 Test Antibody # 116	05271126001
250 Test Antibody # 117	05271134001
250 Test Antibody # 118	05271142001
250 Test Antibody # 119	05271169001
250 Test Antibody # 120	05271177001
250 Test Antibody # 121	05271185001
250 Test Antibody # 122	05271193001
250 Test Antibody # 123	05271207001
250 Test Antibody # 124	05271215001
250 Test Antibody # 125	05271223001
250 Test Antibody # 126	05271231001
250 Test Antibody # 127	05271240001
250 Test Antibody # 128	05271258001
250 Test Antibody # 129	05271266001
250 Test Antibody # 130	05271274001
250 Test Antibody # 131	05271282001
250 Test Antibody # 132	05271304001
250 Test Antibody # 133	05271312001
250 Test Antibody # 134	05271339001
250 Test Antibody # 135	05271347001

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Antibody User-Fillables – continued

Product name	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

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

Probe User-Fillables – continued

Product name	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

Product name	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

Detection Dispensers	
Product name	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 and software

Knowledge and experience underscored by the world's largest installed base of IHC and 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 **navify** Integrator for services 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

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 **navify** Integrator for services 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 System *(continued)*

True continuous access IHC/ISH slide staining

BenchMark ULTRA PLUS and ULTRA bulk reagents and ancillary products

EZ Prep (10x)

Catalog Number: 05279771001

Alt. Cat. Nr.: 950-102

Quantity: 2 L bottle

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

Alt. Cat. Nr.: 950-300

Quantity: 2 L bottle

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

Alt. Cat. Nr.: 950-224

Quantity: 2 L bottle

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, paraffin-embedded 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

Alt. Cat. Nr.: 950-223

Quantity: 1 L bottle

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, paraffin-embedded 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

Alt. Cat. Nr.: 650-210

Quantity: 2 L bottle

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

Alt. Cat. Nr.: 950-110

Quantity: 2 L bottle

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.

ultraView™ Silver Wash II

Catalog Number: 05446724001

Alt. Cat. Nr.: 780-003

Quantity: 2 L bottle

Format: Concentrate

INTENDED USE: ultraView 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.

Replacement Filters

Catalog Number: 05271959001

Alt. Cat. Nr.: 772-100

Quantity: 20 filters

INTENDED USE: Inline User-Fillable Kit, Prep Kit, and Light Protective Prep Kit are used to deliver reagents and solutions on VENTANA BenchMark Series automated slide stainers (BenchMark, BenchMark GX, BenchMark XT, and BenchMark ULTRA) and may be used on DISCOVERY instrument platforms. The dispenser is intended for single use only. Ventana has not validated the cleaning of these dispensers and re-use with a second reagent. For in vitro diagnostic (IVD) use.

Amplification Kit

Catalog Number: 05266114001 **Quantity:** 100
Alt. Cat. Nr.: 760-080 **Format:** Ready to Use

INTENDED USE: Ventana Medical Systems, Inc.'s (Ventana) Amplification Kit may be used in conjunction with VENTANA detection kits to increase the signal intensity of weak staining mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue or cytological preparations on VENTANA automated 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.

Antibody Diluent

Catalog Number: 05261899001 **Quantity:** 100 mL bottle
Alt. Cat. Nr.: 251-018 **Format:** Ready to Use

INTENDED USE: Antibody Diluent is a buffered, proteinaceous solution intended for laboratory use to dilute rabbit and mouse antibodies for use on a BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic (IVD) use.

Antibody Dilution Buffer (250 mL)

Catalog Number: 05280524001 **Quantity:** 250 mL bottle
Alt. Cat. Nr.: ADB250 **Format:** Ready to Use

INTENDED USE: This solution is ready-to-use and may stabilize diluted antibodies when stored at 2°C-8°C.

Temperature Verifier Slides

Catalog Number: 05424615001 **Quantity:** 10 slides
Alt. Cat. Nr.: 600071

INTENDED USE: Temperature Verifier Slides are designed to be used with BenchMark Series automated slide stainers to check that the slide heaters are functioning properly. For in vitro diagnostic (IVD) use.

Bluing Reagent

Catalog Number: 05266769001 **Quantity:** 250 tests
Alt. Cat. Nr.: 760-2037 **Format:** Ready to Use

INTENDED USE: Bluing Reagent is an aqueous solution of buffered lithium carbonate. This reagent is intended for laboratory use to adjust the hue of hematoxylin counterstains to a blue color on a BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic use.

Cell Conditioning 2 (CC2)

Catalog Number: 05279798001 **Quantity:** 1 L bottle
Alt. Cat. Nr.: 950-123 **Format:** Ready to Use

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

Cell Conditioning 1 (CC1)

Catalog Number: 05279801001 **Quantity:** 2 L bottle
Alt. Cat. Nr.: 950-124 **Format:** Ready to Use

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

BenchMark ULTRA PLUS and ULTRA bulk reagents and ancillary products (continued)

Hematoxylin

Catalog Number: 05266726001

Alt. Cat. Nr.: 760-2021

Quantity: 250 tests

Format: Ready to Use

INTENDED USE: Hematoxylin is a modified Gill's hematoxylin intended for laboratory use in staining cellular nuclei on slides containing cells from frozen tissue, formalin-fixed, paraffin-embedded tissue, or cytologic preparations on a BenchMark IHC/ISH instrument. This reagent is intended as a counterstain to immunohistochemistry and immunocytochemistry applications. This reagent is intended for in vitro diagnostic use.

Hematoxylin II

Catalog Number: 05277965001

Alt. Cat. Nr.: 790-2208

Quantity: 250 tests

Format: Ready to Use

INTENDED USE: Hematoxylin II is a modified Mayer's hematoxylin intended for laboratory use in staining cellular nuclei on slides containing cells from frozen tissue, or formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This reagent is intended as a counterstain to immunohistochemistry, and in situ hybridization applications. This reagent is intended for in vitro diagnostic use.

OptiView Amplification Kit

Catalog Number: 06396518001

Alt. Cat. Nr.: 760-099

Quantity: 50 tests

Format: Ready to Use

INTENDED USE: OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, or frozen tissue on a BenchMark IHC/ISH instrument 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 Amplification Kit (250)

Catalog Number: 06718663001

Alt. Cat. Nr.: 860-099

Quantity: 250 tests

Format: Ready to Use

INTENDED USE: OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, or frozen tissue on a BenchMark IHC/ISH instrument 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.

Protease 1

Catalog Number: 05266688001 **Quantity:** 250 tests
Alt. Cat. Nr.: 760-2018 **Format:** Ready to Use

INTENDED USE: Protease 1 is an endopeptidase (alkaline protease) of the serine protease family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of routine formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic (IVD) use.

Protease 2

Catalog Number: 05266696001 **Quantity:** 250 tests
Alt. Cat. Nr.: 760-2019 **Format:** Ready to Use

INTENDED USE: Protease 2 is an endopeptidase (alkaline protease) of the serine protease family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of routine formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic (IVD) use.

Protease 3

Catalog Number: 05266718001 **Quantity:** 250 tests
Alt. Cat. Nr.: 760-2020 **Format:** Ready to Use

INTENDED USE: Protease 3 is an endopeptidase (alkaline protease) of the serine protease family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of formalin-fixed, paraffin-embedded tissue on BenchMark IHC/ISH instrument. This reagent is intended for in vitro diagnostic (IVD) use.

VENTANA Antibody Diluent with Casein

Catalog Number: 06440002001 **Quantity:** 100 mL bottle
Alt. Cat. Nr.: 760-219

INTENDED USE: VENTANA Antibody Diluent with Casein is a buffered, proteinaceous solution containing salt and immunoglobulins used to dilute rabbit and mouse primary antibodies for use on the BenchMark, BenchMark GX, BenchMark XT, and BenchMark ULTRA automated staining platforms. 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 **navify** Integrator for services 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.

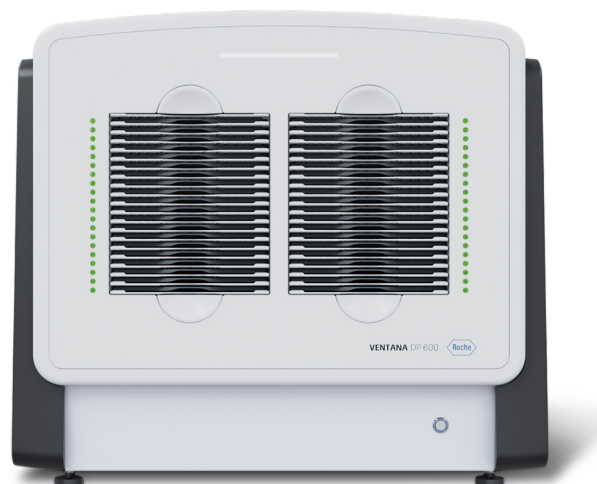
VENTANA DP 600 Slide Scanner

High-quality, high-throughput scanning

Catalog Number: 9311360001

The **VENTANA DP 600 Slide Scanner** 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 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.



General characteristics

Labeling	IVD
Automation	Auto-scanning feature enables no-click scanning Auto-calibration for white balance
Capacity	240 slides 40 trays of 6 single slides
Slide specifications	Length: 75 – 76.53 mm 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

*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
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
Input current	6A (100 V) to 3A (240 V)

Operating environmental conditions

Ambient temperature range	11°C to 31°C
Optimal temperature range	17°C to 25°C
Ambient humidity	10% to 80% RH, non-condensing
Ambient humidity change	<5% per hour
Vibration	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

Digital Pathology Dx System

Robust, reliable, high-speed scanning



The **VENTANA DP 200** and **VENTANA DP 600** slide scanners and Roche's digital pathology workflow software are available in the United States as a whole slide imaging system to aid in primary diagnosis, enabling pathologists to diagnose patients using digital images.

Streamline your workflow

- Scan slides in under one minute
- Simple user experience with no slide handling tray-based design
- No-click start, continuous processing to maximize walk-away time
- Applications including routine scanning, urgent (STAT), and slide archival scanning

Remote monitoring and technical assistance

The VENTANA DP 200 and VENTANA DP 600 slide scanners are equipped with **navify** Integrator for services 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.

Reference:

1. Roche data on file.

Why choose Roche Digital Pathology?

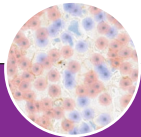
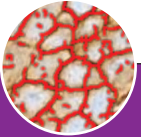
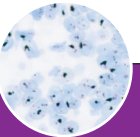
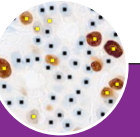
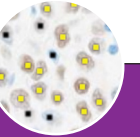
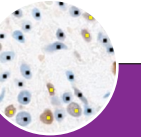
- In-house development to ensure consistency in terms of quality and compatibility
- A complete solution offering staining, scanning, viewing and analyzing slides
- Proven track record with installations and acknowledgements from key institutes across the Globe
- Ability to integrate with LIS to establish true seamless workflow
- More than 20% of Roche Tissue Diagnostics R&D is invested in digital pathology¹

Image Analysis Algorithms

Current menu

Roche **navify**® Digital Pathology enterprise software and digital pathology image analysis algorithms

Offering efficient image management and analysis to enhance pathology workflow, Roche **navify** Digital Pathology enterprise software and image analysis algorithms empower pathologists to quickly, confidently and objectively assess VENTANA DP 200 and VENTANA DP 600 slide images for faster, more accurate assessment of slides.

	 <p>uPath PDL-L1 (SP263) image analysis for non-small cell lung cancer (NSCLC) <i>Aided scoring of PD-L1 scoring in tumor cells (TC)</i></p>	 <p>uPath HER2 (4B5) image analysis for breast cancer <i>Aided scoring of HER2 expression in cell membrane</i></p>	 <p>uPath HER2 Dual ISH image analysis for breast cancer <i>Aided enumeration of HER2 gene</i></p>	 <p>uPath Ki-67 (30-9) image analysis for breast cancer <i>Aided assessment of percent of Ki-67 positivity</i></p>	 <p>uPath ER (SP1) image analysis for breast cancer <i>Aided assessment of percent of ER positivity</i></p>	 <p>uPath PR (1E2) image analysis for breast cancer <i>Aided assessment of percent of PR positivity</i></p>
Algorithm	uPath PD-L1 (SP263) image analysis, NSCLC	uPath HER2 (4B5) image analysis, Breast	uPath HER2 Dual ISH image analysis, Breast	uPath Ki-67 (30-9) image analysis, Breast	uPath ER (SP1) image analysis, Breast	uPath PR (1E2) image analysis, Breast
Assay	VENTANA PD-L1 (SP263) Assay	PATHWAY HER2 (4B5) Assay	VENTANA HER2 Dual ISH DNA Probe Cocktail	CONFIRM anti-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody	CONFIRM ER (SP1) Rabbit Monoclonal Primary Antibody	CONFIRM PR (1E2) Rabbit Monoclonal Primary Antibody
Tissue Type	NSCLC	Breast	Breast	Breast	Breast	Breast
Scoring	TC+	HER2 Score (0-3+)	HER2/Chromosome 17 Ratio	Percent Ki-67 positivity	Percent ER positivity	Percent PR positivity
Scanner	VENTANA DP slide scanners	VENTANA DP slide scanners	VENTANA DP slide scanners	VENTANA DP slide scanners	VENTANA DP slide scanners	VENTANA DP slide scanners
Software	navify Digital Pathology (uPath)	navify Digital Pathology (uPath)	navify Digital Pathology (uPath)	navify Digital Pathology (uPath)	navify Digital Pathology (uPath)	navify Digital Pathology (uPath)
Regulatory Status	RUO	RUO	RUO	RUO	RUO	RUO
Material Number	9052062001	9076182001	9076212001	8764271001	8764182001	8764255001

RUO = Research Use Only

Roche Algorithms and Open Environment are for Research Use Only (RUO). Not for use in diagnostic procedures. Roche is dedicated to clinically deploying its Digital Pathology Solutions and is actively pursuing approval/clearance for our portfolio of products.

Roche Digital Pathology Open Environment

Providing a powerful ecosystem of AI tools to pathologists

A forward-thinking vision for AI in pathology

Artificial intelligence technology shows promise in facilitating the analysis and interpretation of pathology cases, ultimately benefiting cancer patients through more precise diagnosis and potentially better targeted treatment options. Open digital pathology environments can break down barriers to allow for rapid technology advances and innovation across industry and research partners, which is critical in developing next-generation diagnostic tools.



What is the Roche Digital Pathology Open Environment?

The Roche Digital Pathology Open Environment allows third-party partners to efficiently integrate their image analysis tools within **navify**® Digital Pathology, an application

for pathologist workflow. The Open Environment allows for the secure exchange and flow of data so that pathologists can access image analysis algorithms from third parties alongside Roche's suite of artificial intelligence-based image analysis algorithms. This enables digital pathology AI developers to distribute their digital products through **navify** Digital Pathology, offering a broader set of analytical tools for pathologists.

- Access to innovative AI tools for pathologists
- Secure, rapid cloud deployment
- Fully embedded in **navify** Digital Pathology

Roche Digital Pathology Open Environment image analysis tools available via current partnerships:

Partner	Algorithm
	PathAI PD-L1 (28-8) Bundle RUO: <ul style="list-style-type: none"> • PathAI PD-L1 (28-8) HNSCC • PathAI PD-L1 (28-8) Melanoma • PathAI PD-L1 (28-8) NSCLC • PathAI PD-L1 (28-8) Urothelial Carcinoma
	Ibex Breast, RUO Ibex Prostate, RUO

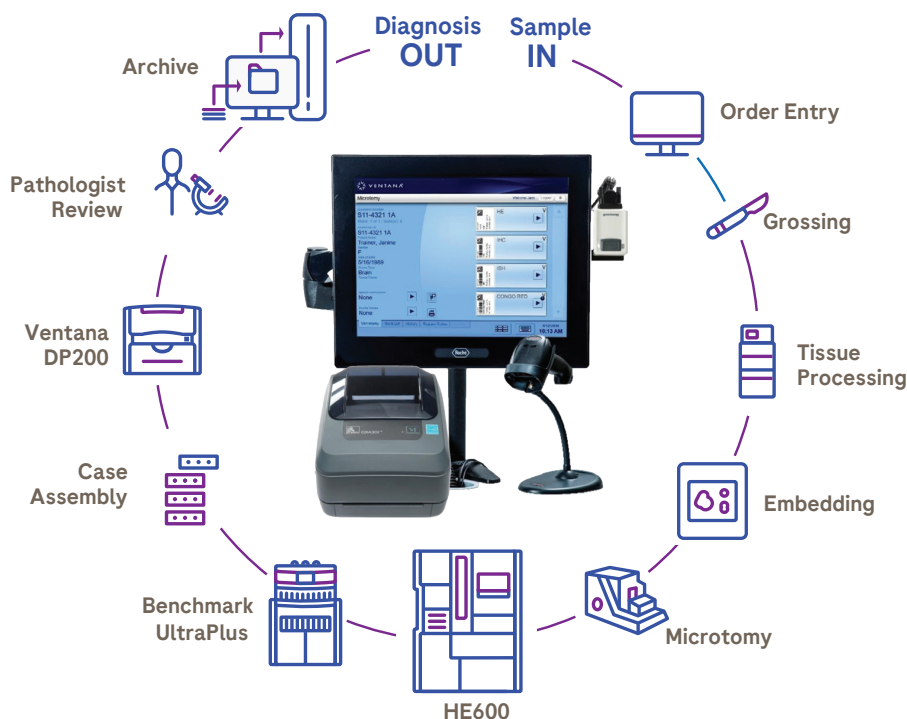


Our offerings are rapidly expanding. Check out our website for the latest menu of third-party algorithms.

Roche Algorithms and Open Environment are for Research Use Only (RUO). Not for use in diagnostic procedures. Roche is dedicated to clinically deploying its Digital Pathology Solutions and is actively pursuing approval/clearance for our portfolio of products.

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

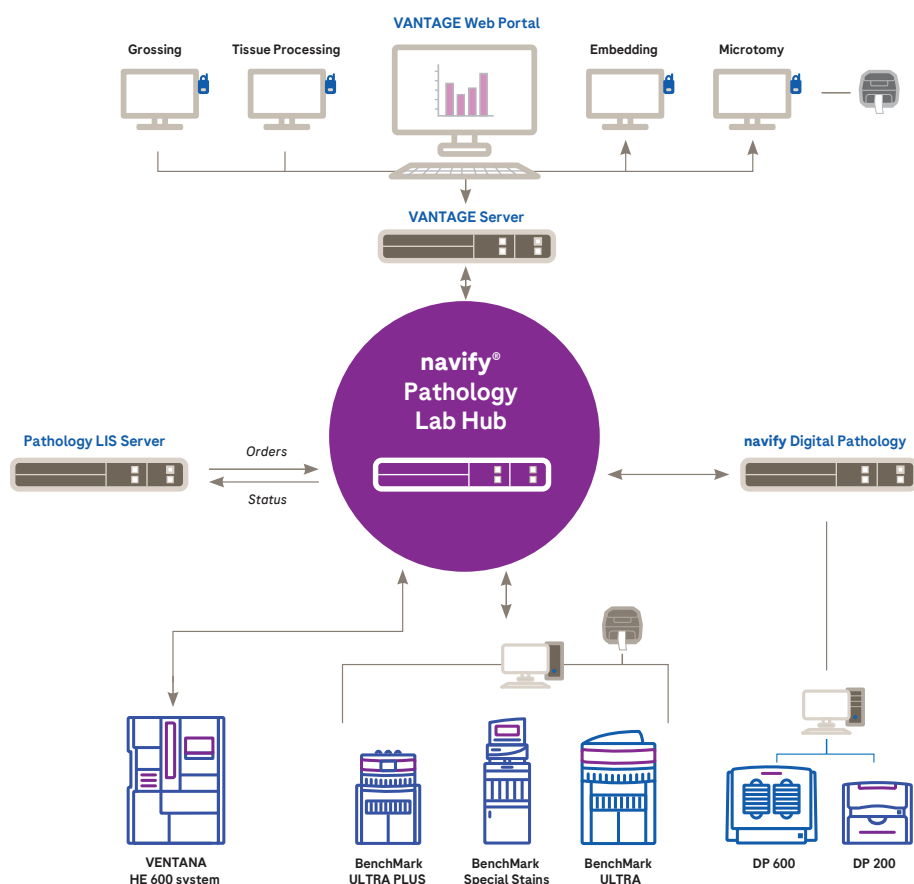
Streamlining lab connectivity

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 re-entries that can introduce errors and slow you down.

- **Optimize lab efficiency:** Single, flexible interface connects multiple LIS platforms to current and future VENTANA instruments.
- **Reduce errors:** Important case information flows seamlessly to instruments and systems through a single, secure connection.
- **Improve patient safety:** VENTANA instruments and software accept LIS-originated case identifiers, increasing patient safety by using a single unique identifier at every point in the process.

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



VENTANA®

Roche



Customer Experience

Driven to provide reliable results for
physicians and the patients under their care

Roche 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.

- **Data-driven insights:** Compile and analyze relevant data from LIS files to gain comprehensive insights into current state.
- **Workflow optimization:** Detailed review of workflow and dataflow.
- **Reducing operational complexity:** Process mapping to assess operational dimensions.
- **Performance evaluation:** Pinpoint specific opportunities based on established Key Performance Indicators (KPIs).

Optimize your lab's performance from the moment you receive a sample to the time you deliver a patient's results.



Roche Diagnostics University

Customized learning experiences to meet your business objectives

To help your lab achieve the greatest benefit from our products, Roche Commercial Education is committed to providing an engaging training experience with a range of resources focused on continuous learning and enhancing overall job proficiency.

Designed to prepare your lab for success, **Roche Diagnostics University (RDU)** is a one-stop online registration and learning platform that supports your evolving needs.

- **Experience interactive learning:** Courses consist of an optimal mix of on-demand product and disease state e-Learning content, and Indianapolis-based classroom, hands-on experience.
- **Learn from experts:** Training is conducted by highly qualified histology instructors with professional certification, field or technical support expertise.

- **Gain proficiency:** Spanning the histology workflow process, RDU courses are designed to help you gain expertise with Roche instrumentation, including daily operation, maintenance and troubleshooting, through interactive participation.

- **Easily access training documentation:**

Administrative dashboards provide easy access to training documentation, training history and program reports.

Getting started

Ask your Roche representative for instructions on creating a Roche Diagnostics University account and for additional training details.



Roche Support Network (RSN)

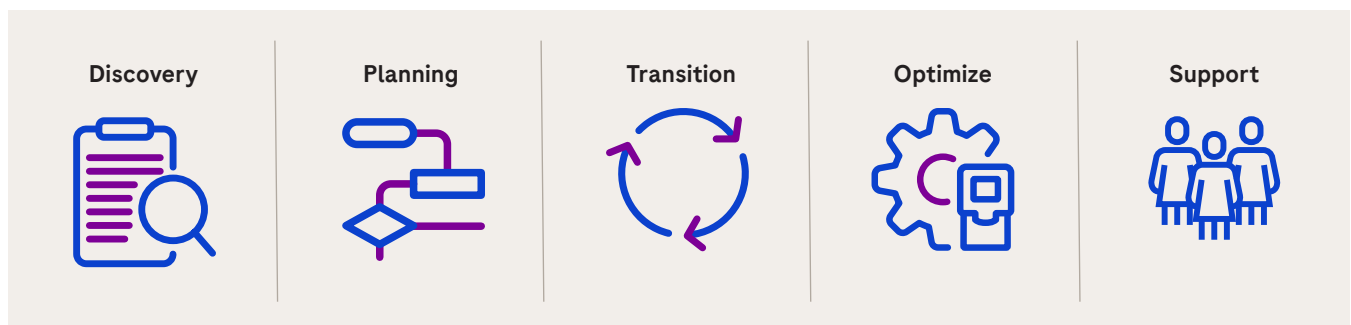
Always on, always ready to help

At Roche, support is not an afterthought—it's our promise and our passion. Backed by a variety of highly experienced, specialized teams, the **Roche Support Network** provides a host of solutions to assist you at every stage—from procurement to ongoing onsite and offsite support.



- **Get personalized support:** We work with you to build a foundation for success, assessing your needs and objectives to provide customized solutions based on your lab's data and workflow, onsite observations and Lean Six Sigma techniques.
- **Ease implementation:** We're with you every step of the way to ensure a smooth and efficient transition to your new Roche solution, supporting you from discovery to optimization—and in all aspects after your system is installed and live.
- **Optimize lab performance:** To ensure your success, we partner with you and provide ongoing support that includes remote monitoring, field service and technical applications expertise, consulting and a 24/7/365 call center.

Committed to your success throughout the implementation journey



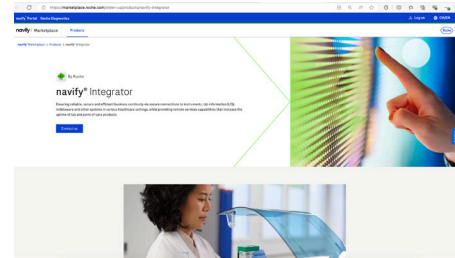
navify® Integrator for Services

The help you need, when you need it

Customers are looking for end-to-end, integrated, secure and cohesive solutions that add insights to business, save money, raise efficiency in and beyond the laboratory, and ultimately, help improve patient care.

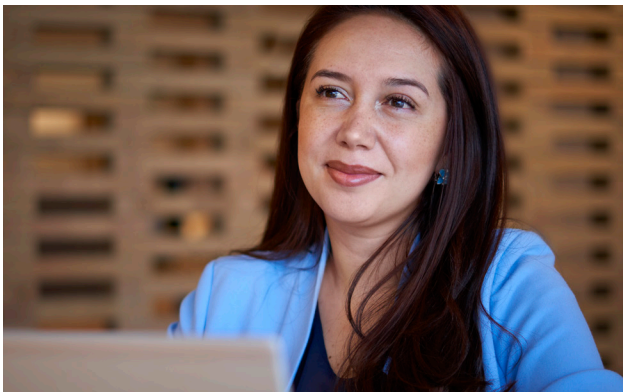
With **navify** Integrator, you can securely connect a range of data sources on a single integration point. You can also use a range of digital services designed to increase the uptime of your instruments and other lab products, as well as your operational efficiency. **navify** Integrator brings two main benefits:

- Secure, cloud-based services to optimize lab performance and minimize downtime
- Seamless platform for connecting data sources in your IT environment to support operational efficiency and clinical decision support



navify Integrator for services* is currently available for the VENTANA HE 600 system, VENTANA BenchMark ULTRA IHC/ISH system, VENTANA BenchMark ULTRA PLUS IHC/ISH system, VENTANA BenchMark Special Stains platform, VENTANA Virtuoso software, VENTANA iScan Coreo slide scanner, the VENTANA iScan HT slide scanner, the VENTANA DP 200 slide scanner, and the VENTANA DP 600 slide scanner.

*Formerly known as CareGiver Remote Support.



Reimbursement

Tough questions. One easy answer.

Reimbursement for the assays and services you provide can seem confusing. The Roche Diagnostics reimbursement team can help. Our team is a reliable and credible resource you can turn to for the latest information to address reimbursement questions and issues regarding Roche Diagnostics products.

- **Get the answers you need:** The Roche Diagnostics reimbursement team can help you address reimbursement questions about FDA-cleared or approved products marketed and sold in the U.S. by Roche Diagnostics Corporation and its affiliates.
- **Save time:** Our team monitors reimbursement trends and policies to keep track of the latest developments that might affect your business or have an impact on Roche Diagnostics products, so you can turn to us for answers and free up your time for more important activities.
- **Count on 24/7 support:** We're available by email around the clock, enabling you to contact our team for assistance at your convenience.



Reimbursement is complex.
Contacting us is easy.

If you are a healthcare professional working in a hospital, laboratory, physician office or other professional setting, you can contact our team for assistance at your convenience 24 hours a day, 7 days a week.

Please provide your name, the name of your organization and your contact information, and a brief description of your inquiry at this address:

[Reimbursement Inquiry Email](mailto:diagnostics.reimbursement@roche.com)
diagnostics.reimbursement@roche.com

Medical and Scientific Affairs

Comprehensive expertise and broad experience, available to you

Dedicated to science, research and education, the **Medical and Scientific Affairs** team offers a wealth of expertise and resources to help healthcare professionals like you improve patients' lives.

As your educational and strategic partner, we provide scientific and clinical insight that helps you better understand the medical value of Roche Diagnostics products and how they can be used to advance patient care.

- **Count on expert support:** Our experienced Tissue Diagnostics team includes U.S. board-certified pathologists and Ph.D. scientists who share a mission to improve the lives of all patients afflicted with cancer.
- **Gain insights to enhance patient care:** We provide educational and scientific support that can help you implement new standards of care and develop new clinical guidelines that result in the best possible outcomes for patients.
- **Grow your technical expertise:** Committed to helping you succeed, our team provides comprehensive training and education on cancer diagnostic tests for healthcare professionals, including pathologists, oncologists, clinicians and laboratorians.

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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