



**VENTANA**

*Innovative diagnostic instruments*

**High-value assays**

*Digital pathology & workflow*

**Companion diagnostics**

*Consultative services*

## Tissue Diagnostics

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, is one of the world's leading cancer diagnostic companies and is an innovator of tissue-based tests that enable the delivery of personalized healthcare to cancer patients.

The founder of Ventana, Thomas Grogan, M.D., Professor of Pathology, University of Arizona, fostered the concept of a single, complete report covering all aspects of a patient's case, which helps improve survivability.

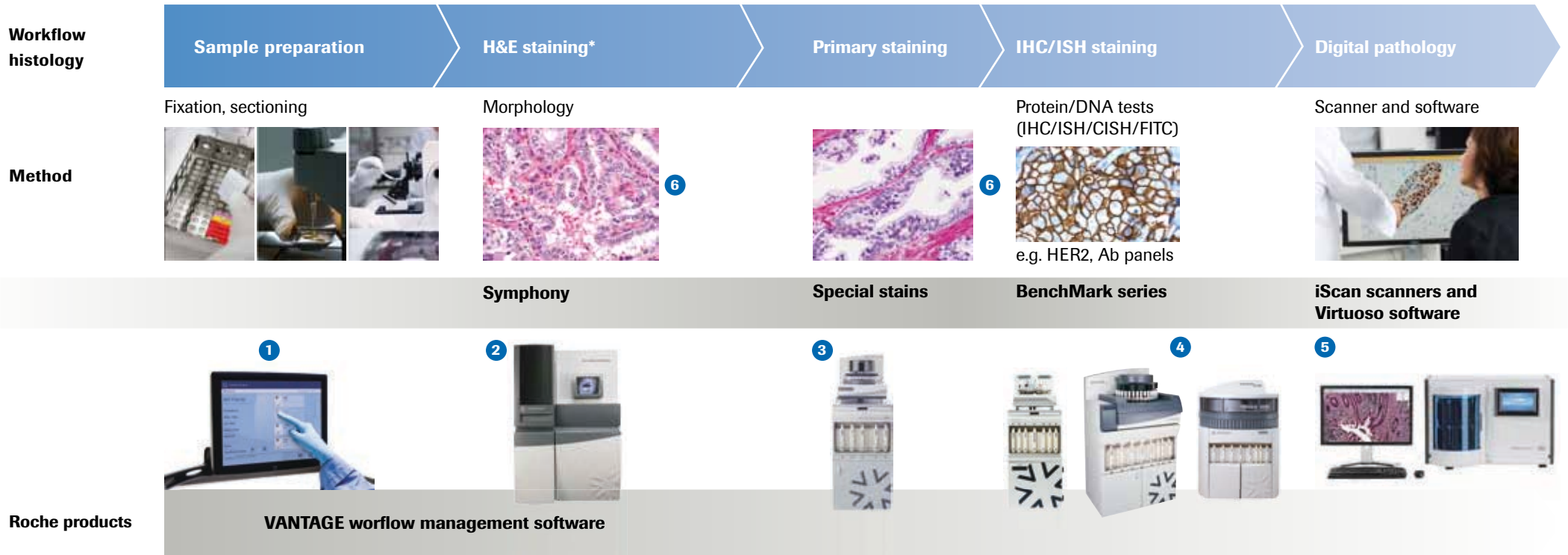
Ventana passionately pursues its mission to improve the lives of all patients afflicted with cancer, developing and delivering medical diagnostic systems and tissue-based cancer tests that are shaping the future of healthcare. VENTANA products provide healthcare professionals with a comprehensive solution for all critical steps involved in the analysis of tissue samples.

In addition, Ventana offers premier workflow solutions specially designed to improve laboratory efficiency and preserve patient safety.

Recognizing the world's rising medical needs, Ventana focuses on accelerating the discovery and development of new prognostic and predictive cancer tests that enable personalized healthcare. These tests allow pathologists to analyze patient samples at the molecular level, to help determine the best course of therapy for individual patients.

# Tissue Diagnostics

Leading future innovation



## 1 VANTAGE software

- Workflow solution from sample preparation to statistics monitoring
- Tracking of both samples and monitoring of the lab activity to ensure quality
- Fully bidirectional connectivity to LIS

## 2 SYMPHONY platform

- Fully automated H&E staining
- Capacity up to 500 slides
- Integrated coverslipper

## 3 BenchMark Special Stains instrument

- Fully automated special stains from baking to staining
- Capacity up to 20 slides per run
- Individual heater pads
- Pre-packed complete detection kits

## 4 BenchMark IHC/ISH automated staining series

- Fully automated IHC\*, ISH\*, FITC\* systems, driven by easy-to-use barcoded slides and reagents

- Systems with different capacity available to fit small to large laboratories
- Open systems for antibodies

## 5 Digital pathology

- Comprehensive digital pathology solution – from image viewing to customized reporting
- VENTANA iScan HT and VENTANA iScan Coreo scanners – combine unprecedented flexibility, throughput and reliability

- VENTANA VIRTUOSO image and workflow management software – designed for clinical laboratory use
- Industry-leading breast diagnostics deliver consistent and objective results, time after time

## 6 Reagents

- H&E, IHC\*, ISH\*, SpSt\*
- More than 250 antibodies in disease panels
- Ready-to-use and barcoded reagents

\*H&E = Hematoxylin & Eosin, ISH = In situ Hybridization,

# BenchMark Special Stains

## *Automated slide stainer*



The new VENTANA BenchMark Special Stains automated slide stainer brings complete baking through staining to the histology laboratory for special stains, so your lab can consistently deliver exceptional quality. Productivity features such as random batch access, as well as bulk and waste fluid sensing, improve turnaround time and optimize workflow.

The BenchMark Special Stains instrument is operated by the Ventana System Software with an intuitive user interface. Reduce manual processes and improve your lab capabilities by allocating your skilled laboratory professionals to higher value contributions.



### Your benefit

#### Superior special stains workflow efficiency

- Eliminating manual processes and temperature dependencies with automated deparaffinization and independent slide heating

#### Consistent quality

- Full automation and standardized protocols

#### Reduced risk

- Decreased technician risk with individual slide staining and reduced exposure to harmful chemicals

### Product features

- Workflow: Fully automated baking, deparaffinization and staining of special stains
- Slide carousel: 1–20 slides with independent temperature control for each position
- Reagent carousel: 25 reagent positions
- Slides 25 x 75 mm, 1x3" or 26x76 mm Superfrost Plus
- Bulk fluids: Up to 4 bulk fluids in 3 to 6 liter on-board containers
- Modularity: 1–8 BenchMark Special Stains and BenchMark ULTRA systems may be controlled from one PC

### VENTANA Special Stains reagents

The new BenchMark Special Stains system brings reproducible, high quality staining capabilities through ready to use and quality controlled reagents to every histopathology laboratory. In addition, the system's new features of automated deparaffinization and independent slide heating enable consistent results every day to ensure fast and accurate diagnosis.



### Special Stains menu:

- AFB III
- Alcian Blue
- Alcian Blue for PAS
- Alcian Yellow
- Congo Red
- Diastase
- Elastic
- Giemsa
- GMS II
- Iron
- Jones Light Green
- Jones Hematoxylin
- Light Green for PAS
- Mucicarmine
- PAS
- Reticulum
- Steiner II
- Trichrome
- Green for Trichrome

# Primary antibodies

Over 250 ready-to-use VENTANA antibodies



## Ready-to-use antibodies

Antibodies from Ventana, including a world-class breast panel, cover the pathology world's diagnostic requests. Ventana antibodies include IVD/CE-IVD antibodies, but also novel antibodies still in research phase.

The analysis of the staining is facilitated due to advanced antibody performance and multiple detection technologies

### Breast

Calponin-1 (EP798Y)
Cytokeratin 14 (SP53)
Cytokeratin 5/6 (D5/16B4)
E-cadherin (36)
E-cadherin (EP700Y)
CONFIRM Estrogen Receptor (ER) (SP1)
GCDFP-15 (EP1582Y)
PATHWAY HER-2/neu (4B5)
VENTANA HER-2/neu (4B5)
INFORM HER2 Dual ISH DNA Probe Cocktail
CONFIRM Ki-67 (30-9)
p120 (98)
CONFIRM p53 (DO-7)
CONFIRM Progesterone Receptor (PR) (1E2)
CONFIRM Topoisomerase IIa (JS5B4)
<b>Cervical cancer</b>
CINtec® PLUS p16/Ki-67 dual stain (Cytology) (E6H4 & 274-11 AC3)
CINtec® p16 Histology (E6H4)
<b>Colorectal</b>
Beta-catenin (14)
CEA (TF3H8-1)
CDX-2 (EPR2764Y)

COX-2 (Cyclooxygenase 2) (SP21)
Cytokeratin 19 (A53-B/A2.26)
CONFIRM Cytokeratin 7 (SP52)
CONFIRM Cytokeratin 20 (SP33)
MLH-1 (M1)
MLH1 (G168-728)
MSH2 (G219-1129)
CONFIRM MSH6 (44)
MUC1 (H23)
MUC2 (MRQ-18)
PMS2 (EPR3947)
<b>Lung</b>
CONFIRM Calretinin (SP65)
Carcinoembryonic Antigen (CEA) (TF3H8-1)
CD56 (MRQ-42)
CEA (CEA31)
Chromogranin A (LK2H10)
CONFIRM Cytokeratin 20 (SP33)
Cytokeratin 5/6 (D5/16B4)
CONFIRM Cytokeratin 7 (SP52)
CONFIRM EGFR (Epidermal Growth Factor Receptor) (5B7)
EMA (Epithelial Membrane Antigen) (E29)
Napsin A (Polyclonal)
NSE (Neuron Specific Enolase) (E27)

VENTANA p63 (4A4)
SOX-2 (SP76)
CONFIRM Synaptophysin (SP11)
CONFIRM Thyroid Transcription Factor-1 (TTF-1) (8G7G3/1)
<b>Lymphoma</b>
CONFIRM ALK1 (ALK01)
Annexin A1 (MRQ-3)
MUC1 (H23)
CONFIRM bcl-2 (124)
bcl-6 (G1191E/A8)
BOB.1 (SP92)
c-Myc (Y69)
CD1a (EP3622)
CD2 (MRQ-11)
CONFIRM CD3 (2GV6)
CONFIRM CD4 (SP35)
CONFIRM CD5 (SP19)
CD7 (SP94)
CONFIRM CD8 (SP57)
VENTANA CD10 (SP67)
CD14 (EPR3653)
CONFIRM CD15 (MMA)
CONFIRM CD20 (L26)
CD22 (SP104)
CONFIRM CD23 (SP23)
CD25 (4C9)

CONFIRM CD30 (Ber-H2)
CD31 (JC70)
CONFIRM CD34 (QBEnd/10)
CD38 (SP149)
CD43 (L60)
CD45 (LCA) (2B11 & PD7/26)
CONFIRM CD45 (LCA) (RP2/18)
CD45R (MB1)
CONFIRM CD45RO (UCHL-1)
CONFIRM CD56 (123C3)
CD56 (MRQ-42)
CD57 (NK-1)
CD61 (2f2)
CONFIRM CD68 (KP-1)
CD71 (MRQ-48)
CONFIRM CD79a (SP18)
CONFIRM CD99 (O13)
CD138 (Syndecan-1) (B-A38)
Cyclin D1 (SP4-R)
Fascin (55k-2)
FoxP1 (SP133)
Galectin-3 (9C4)
Glycophorin A (GA-R2)
Granzyme B (Polyclonal)
HGAL (MRQ-49)
IgA (Immunoglobulin A)
IgD (Immunoglobulin D)
IgG (Immunoglobulin G)
IgM (Immunoglobulin M)
CONFIRM Kappa
CONFIRM Lambda
CONFIRM LMO2 (1A9-1)
LMO2 (SP51)
Lysozyme
MUM1 (MRQ-43)
Myeloperoxidase

Oct-2 (MRQ-2)
CONFIRM PAX5 (SP34)
PD-1
Spectrin (RBC2/3D5)
T-bet (MRQ-46)
TdT
TRAcP (9C5)
ZAP-70 (2F3.2)
<b>Prostate</b>
Androgen Receptor (SP107)
VENTANA Basal Cell Cocktail (34βE12+p63)
Cytokeratin (34βE12)
Cytokeratin 20 (SP33)
Cytokeratin 5/6 (D5/16B4)
Cytokeratin 7 (SP52)
EZH2 (SP129)
VENTANA p63 (4A4)
PSA
PSA (ER-PR8)
PSAP (PASE/4LJ)
<b>PSA</b>
PSA (ER-PR8)
IIΣAII (IIAΣE/4Aθ)
α-1-Antitrypsin (AAT)
C1q, FITC
C3, FITC
C4, FITC
Carcinoembryonic Antigen (CEA) (TF3H8-1)
CD2 (MRQ-11)
CONFIRM CD3 (2GV6)
CD31 (JC70)
CONFIRM CD34 (QBEnd/10)
CD63 (NKI/C3)
CONFIRM Cytokeratin (34βE12)

CONFIRM Cytokeratin (AE1)
Cytokeratin 8 & 18 (B22.1 & B23.1)
CONFIRM Desmin (DE-R-11)
Ep-CAM (Epithelial Specific Antigen) (Ber-EP4)
Factor VIII Related Antigen
Factor XIIIa (AC-1A1)
Fibrinogen, FITC
HHV-8 (Human Herpes Virus Type 8) (13B10)
IgA (Immunoglobulin A)
IgA (Immunoglobulin A), FITC
IgG (Immunoglobulin G)
IgG (Immunoglobulin G), FITC
IgM (Immunoglobulin M)
IgM (Immunoglobulin M), FITC
Kappa, FITC
Lambda, FITC
Macrophage (HAM-56)
CONFIRM MART-1/melan A (A103)
CONFIRM Melanosome (HMB45)
Neurofilament (2F11)
CONFIRM p53 (DO-7)
p53 (Bp-53-11)
Podoplanin (D2-40)
CONFIRM S100 (4C4.9)
CONFIRM Synaptophysin (SP11)
Tryptase (G3) (T311)
CONFIRM Tyrosinase
CONFIRM Vimentin (Vim 3B4)
CONFIRM Vimentin (V9)

# IHC Detection

*Meet your needs and everything beyond*

IHC brown staining using DAB is available using three technologies:

- *i*VIEW DAB Biotin streptavidin system
- *ultra*View DAB Multimer technology
- OptiView DAB detection
- Multimer technology with a non-endogenous hapten system

IHC Red staining with *ultra*View Red is not only optimal for melanoma diseases, but many other markers based on preference. The BenchMark IHC/ISH staining platforms provide a fully automated dual stain using DAB and Red detection kits, for simultaneous visualization of two antigen types on the same glass slide. All kits are designed for use on the BenchMark IHC/ISH platforms.



VENTANA p63 stained with OptiView DAB detection.

## Your benefit

### Superior quality

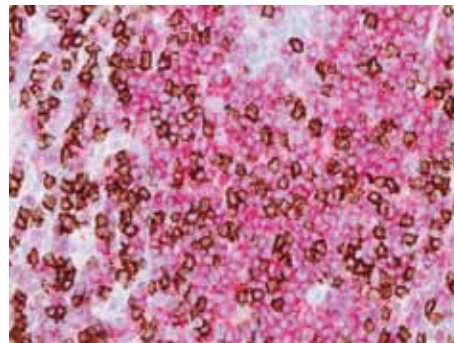
- Enhanced sensitivity of even the lowest expressing antibodies
- Improved specificity that virtually eliminates background, even as signal intensity increases

### Productivity

- Exceptional workflow efficiency
- Increased throughput
- Quicker time to results

### Flexibility

- Dialability to customize staining with the dynamic power of OptiView DAB detection



VENTANA CD4/CD8 dual staining with *ultra*View DAB and *ultra*View Red detection.

# Breast cancer diagnostics

*Empowering clinical confidence*



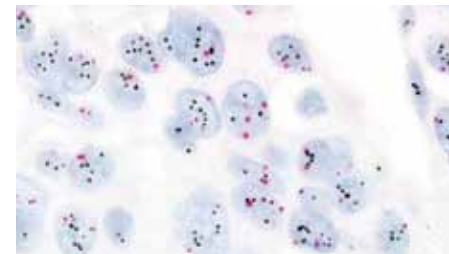
Roche delivers a comprehensive suite of validated immunohistochemistry and in situ hybridisation diagnostic solutions for breast cancer – so you can deliver the right test, with clinical confidence.

Our breast cancer predictive diagnostic offerings (HER2 IHC & ISH, ER, PR) in combination with our supporting diagnostic assays (Ki-67, p120 and E-cadherin) are fully automated on BenchMark IHC/ISH staining platforms that reduce the time to result and resources required compared to manual or semiautomated solutions.

## Your benefit

### Clinical superiority

- High accuracy and clinical confidence in short turnaround time supporting to identify patients other assays can miss



Breast carcinoma HER2 Dual ISH non-amplified; magnification: 40X.

### Analytical superiority

- Via specific and sensitive rabbit monoclonal antibodies, best-in-class probes, and powerful detection systems

### Testing efficiency

- Comprehensive breast cancer solution
- Fully automated assays on platform, with digital pathology and workflow solutions

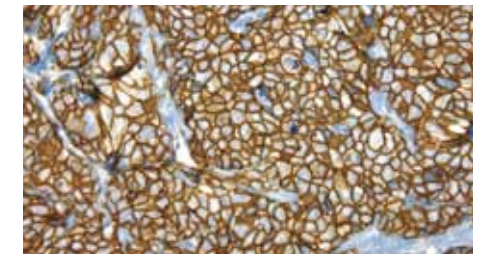
## Product features

### INFORM HER2 Dual ISH DNA Probe Cocktail assay

- Determining HER2 gene status with morphological context identifies patients that can be misclassified by FISH

### HER2 (4B5) Rabbit Monoclonal Antibody

- Rabbit monoclonal antibodies deliver superior sensitivity and specificity



Breast carcinoma HER2 (4B5) positive Score: 3+; magnification: 40X.

# Prostate cancer diagnostics

## Empowering medical value

Our powerful prostate cancer diagnostics portfolio can give you the confidence you need to improve patient care.

Empower your practice with our comprehensive menu of biomarkers that deliver increased value for men's health. Our antibodies are pre-diluted and optimized for use on the BenchMark IHC/ISH series of automated platforms for efficient, reproducible staining quality. We continue to develop novel biomarkers with promising utility – such as the anti- EZH2 (SP129) Rabbit Monoclonal Antibody and the anti-Androgen Receptor (SP107) Rabbit Monoclonal Antibody.

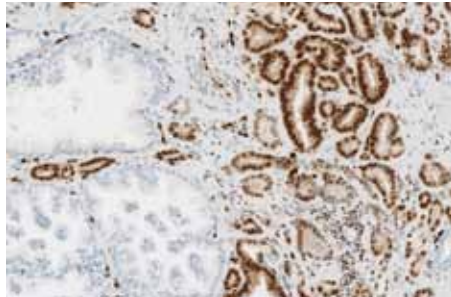
### **ERG (EPR3864) Rabbit Monoclonal Primary Antibody**

Developed for high sensitivity and specificity, the ERG (EPR3864) Rabbit Monoclonal Primary Antibody delivers:

- Specificity for prostate cancer and therefore may aid in the detection and diagnosis
- Ability to identify a molecular prostate cancer subtype
- High concordance to ERG FISH

### **VENTANA p63 (4A4) Mouse Monoclonal Primary Antibody**

The p63 (4A4) antibody empowers you to make informed, confident diagnostic decisions.



VENTANA ERG stained

- Consistently strong nuclear detail is easier to interpret
- Like high molecular weight cytokeratin 34 $\beta$ E12, p63 is specific for basal cells in the prostate gland
- VENTANA p63 (4A4) delivers the added advantage of high sensitivity for benign prostate glands

### **VENTANA Basal Cell Cocktail 34 $\beta$ E12+p63**

Our Basal Cell Cocktail combines p63 (4A4) with 34 $\beta$ E12 to aid in the differentiation of benign and malignant prostatic lesions.

- Increases the sensitivity of basal cell detection
- Decreases staining variability
- Offers more consistent basal cell immunostaining

# Haematopathology

## A comprehensive solution helping you detect and subtype

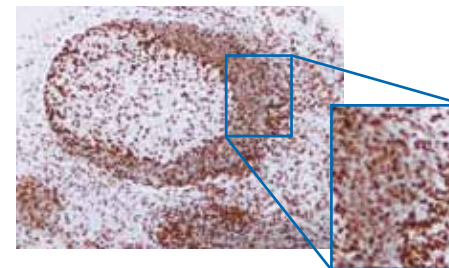


We offer you over 65 cornerstone and novel hematopathology assays (IHC antibodies and molecular probes) that aid in the detection of lymphomas and other hematopoietic diseases which provide:

- Unparalleled sensitivity and specificity with OptiView DAB IHC detection
- Innovative automation (IHC/ISH) with VENTANA BenchMark advanced staining platforms
- High-quality, pre-diluted, optimised reagents

As you pursue more precise and personalized diagnosis and treatment options for your patients, no target should be beyond your detection.

### **VENTANA CD5 with OptiView DAB IHC detection\***

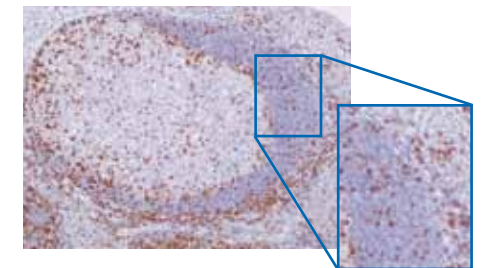


The dynamic power of the VENTANA OptiView DAB IHC Detection delivers unparalleled sensitivity and specificity so that you can:

- Even detect low level expressing antigens
- Virtually eliminate background as signal intensity increases

Mantle zones in normal tonsil are known to have very low levels of CD5 expression, as identified by techniques such as flow cytometry. This extremely low level CD5 expression has been beyond detection with previously available IHC technology.<sup>1</sup> With OptiView DAB IHC Detection, CD5 expression was detected in the mantle zone of the normal tonsil (internal study).

### **Competitor CD5 with DAB detection**



\* Increased sensitivity powered by OptiView DAB IHC detection: positive staining for low level CD5 protein expression in the mantle zone of the tonsil.

<sup>1</sup> Su, W. et al. (2000). *J Clin Pathol* 53; 395–397.

# Colorectal Cancer

## *Empowering you for diagnosis and prognosis*



Our portfolio of assays provides you with tools that empower diagnosis and prognosis of patients with colorectal cancer.


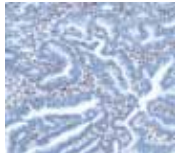
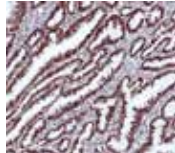
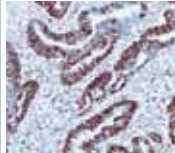


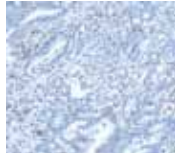
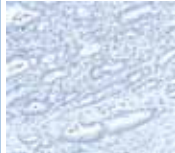
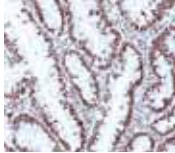
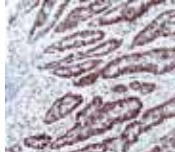


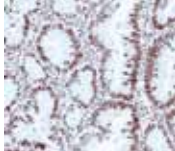

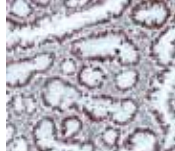

MLH1 (M1), MSH2 (G219-1129), MSH6 (44) and PMS2 (EPR947) antibodies are used as aids in the detection of the respective human DNA mismatch repair (MMR) proteins. Deficiencies in mismatch repair (MMR) proteins result in microsatellite instability.

Approximately 20% of colorectal cancers (CRC) are associated with microsatellite instability (mutations in short repetitive sequences of DNA called microsatellites).<sup>1,2</sup> These MMR proteins MLH1, MSH2, MSH6 and PMS2 are defective in 95% of MSI-related CRC.

The presence of microsatellite instability in CRC provides important prognostic and diagnostic information. The National Comprehensive Cancer Network recommends that MMR protein is tested in all patients under 50 and for those with stage II colorectal cancer.<sup>3</sup>

MMR IHC staining powered by OptiView DAB IHC detection in colorectal cancer: enabling the evaluation of mismatch repair protein status.

### MSI – mismatch repair IHC staining patterns for colorectal cancer

MMR mutations	IHC result MLH1	IHC result PMS2	IHC result MSH2	IHC result MSH6
MLH1 mutation	<b>Loss</b> 	<b>Loss</b> 	Preserved 	Preserved 
MSH2 mutation	Preserved 	Preserved 	<b>Loss</b> 	<b>Loss</b> 
MSH6 mutation	Preserved 	Preserved 	Preserved 	<b>Loss</b> 
PMS2 mutation	Preserved 	<b>Loss</b> 	Preserved 	Preserved 

Powered by OptiView DAB IHC detection system.

1 Hatch, S. et al. (2005). *Clin Cancer Res.* 15; 11(6):2180-7.

2 Sinicrope, F. (2010). *Nat Rev Clin Oncol.* 7; 174-7.

3 NCCN Guidelines. Colon Cancer. Version 3.2013.

[http://www.nccn.org/professionals/physician\\_gls/pdf/colon.pdf](http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf)

# BenchMark IHC/ISH platform

## Automated slide staining systems



Minimize diagnostic lead time, maintain consistent high quality and streamline workflow in the histology laboratory with the BenchMark IHC/ISH instruments.

The BenchMark GX, BenchMark XT and BenchMark ULTRA instruments automate all slide preparation steps of immunohistochemistry (IHC), fluorescent IHC, *in situ* hybridization (ISH) and Dual Color Silver tests. They have the flexibility you need to expand your test menu, process more slides and improve your turnaround time.

### Your benefit

#### Fully automated

- Standardized IHC, ISH and FITC staining
- Dual and triple stains

#### Flexibility

- Select from over 200 VENTANA antibodies available, or use your own antibodies
- Independent and simultaneous processing

#### Optimal quality

- Independent protocols for each slide
- Barcoded slides & reagents for case identification and traceability

#### Workflow

- Higher throughput and faster turnaround times
- Increased laboratory productivity and reduced rework

### BenchMark system features

Unique and innovative technology for best patient care by kinetically optimized reaction

- Individual Heater pads
- Liquid coverslip controls evaporation and integrity
- Full slide coverage with 100  $\mu$ L
- Air Vortex mixing

#### BenchMark GX system

- 20 slide positions
- 25 reagent positions
- Low to medium throughput
- Complete batching IHC and ISH diagnosis system

#### BenchMark XT system

- 30 slide positions
- 35 reagent positions
- Medium to high throughput
- Independently or simultaneously processing of IHC, ISH, and FITC steps

#### BenchMark ULTRA system

- 30 slide positions
- 35 reagent positions
- Flexibility to add/remove slides without impacting workflow
- Ability to add remove reagents without interrupting cases in process



- Immediately process STAT and late arriving samples
- Simultaneous IHC/ISH testing on a single platform

#### LIS or VANTAGE software connection:

- Connect multiple systems with a single computer, add a new system to existing ones
- Share reagents & protocols across instruments through Central Management software
- Download patient accession and test information from LIS to slide staining system; to mitigate data entry errors



BenchMark GX system



BenchMark XT system



BenchMark ULTRA system



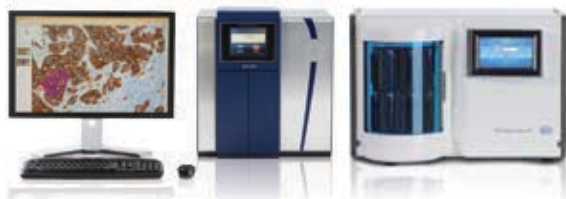
# Digital pathology

## Global consultation, image and workflow management and telepathology



VENTANA digital pathology products are revolutionizing traditional practice by automating and redefining existing standards of care. Digital pathology empowers pathologists with indispensable capabilities possible only when used in conjunction with VENTANA instrumentation, software, assays and scanning platforms. VENTANA Companion Algorithm image analysis software is also optimized from staining to reporting. VENTANA digital pathology tools enable the pathologist to accomplish routine responsibilities faster, more accurately, and at a lower cost. All of this leads to improvements in overall lab efficiency, pathologist productivity, and assists physicians to provide improved patient care.

VENTANA digital pathology products consist of high quality scanners and companion algorithm software associated to the web-based software, Virtuoso, for image and workflow management. This solution perfectly adapts to the routine workflow leading to better and ultimately better patient care.



### Your benefit

#### Flexibility with telepathology

- Collaborate anywhere, anytime
- For tumor boards, case sharing, consulting/collaboration, and education

#### Optimized case management of your patient samples

- Case management digitized
- Archive and retrieve cases instantly
- Case assembly, sorting and routing, patient report with complete information and remote digital sign-out

#### Consistent and reliable

- Image analysis with FDA 510(k) clearance and CE-IVD certification

#### Adapted to your needs

- Scanners for mid to high volume laboratories

### Product features

#### Virtuoso

- Anytime, anywhere access to slide images
- Greater efficiency and flexibility
- Enhanced workload distribution, for better resource allocation
- Assisting in improved patient care

#### Companion Algorithm image analysis software

- Comprehensive\* breast panel solution
- Consistent, objective interpretations – verified by a pathologist – for each patient
- Semi-quantitative (US) and quantitative (outside the US) scoring
- Reduced inter- and intra-observer variability in IHC stain interpretation
- FDA 510(k) clearance for PR, HER2, Ki-67, and P53 biomarkers (all five biomarkers are CE marked for IVD use)

#### iScan Coreo\* slide scanner

- Excellent image quality
- User-friendly walk-away automation
- Reliable scanning technology
- Scanning objective without manual change
- Telepathology for peer reviews and second opinions



#### VENTANA iScan HT\* slide scanner

- Continuous random access and STAT processing – with no workflow interruption
- Excellent image quality and superior scanning speed – produce 80 slides at 20X
- Excellent time to view at 20X and 40X, 360 slide capacity

\*Not FDA approved for primary diagnosis.