

## Quick Reference Guide

### *Recent Assay Additions from Roche Tissue Diagnostics*

September 2020

S18 – 4341 A1 – 2



+

+

S18 – 4341 A1 – 2



+

+

S18 – 4341 A1 – 2

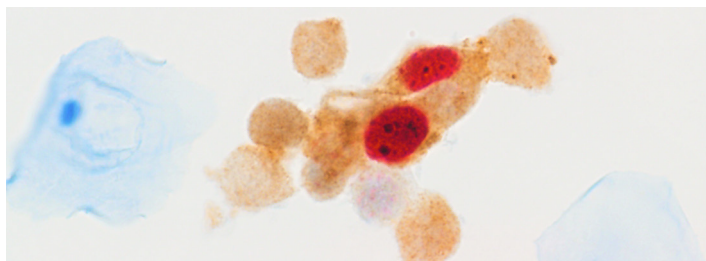


+

+

Introducing the latest additions to our portfolio of over 300 ready-to-use assays that empower your lab to deliver timely results with clinical confidence. See our full menu at [diagnostics.roche.com](https://diagnostics.roche.com)

### CINtec® PLUS Cytology

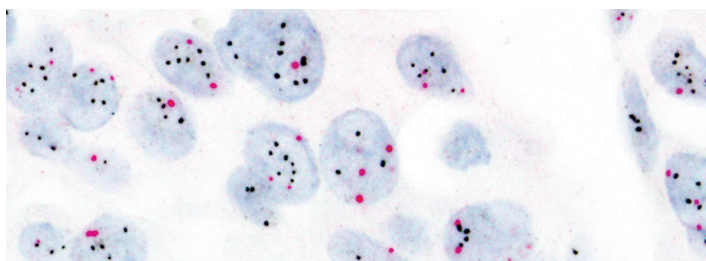


The newest member of the Roche Cervical Cancer portfolio of products, **CINtec® PLUS Cytology** is an objective biomarker-based triage test designed to identify the co-expression of p16 and Ki-67 within the same cell helping to identify women with transforming HPV infections likely to lead to cancer.

Learn more at: <https://diagnostics.roche.com/us/en/products/tests/cintec-plus.html>

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

### VENTANA HER2 DUAL ISH DNA Probe Cocktail

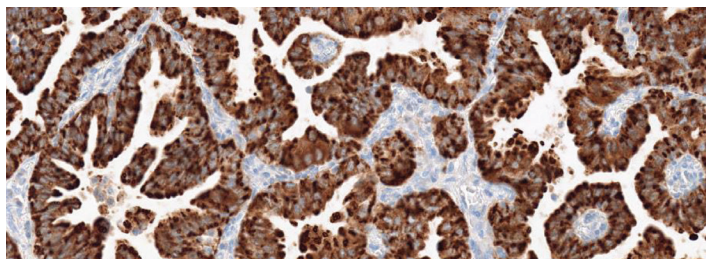


**VENTANA HER2 Dual ISH Probe Cocktail assay** is the next generation of the INFORM HER2 Dual ISH assay. Based on input from customers, this enhanced assay provides the same proven, fully-automated brightfield technology, now optimized with oligo probes that produce faster hybridization and turnaround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

Learn more at: [go.roche.com/H2DI](https://go.roche.com/H2DI)

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

### VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody



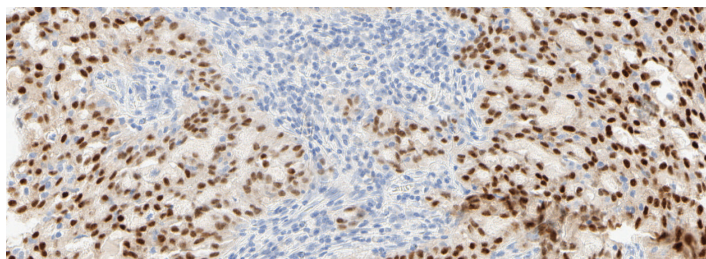
**VENTANA ROS1 (SP384)** is the first ROS1 IHC IVD product available to detect the presence of ROS1 protein expression in non-small cell lung cancer (NSCLC). Given the rarity of ROS1 rearrangements, use of an immunohistochemistry assay to detect the presence of ROS1 protein expression prior to confirmatory testing may decrease the overall cost of ROS1 testing and will satisfy current professional testing guidelines.

Learn more at: <https://diagnostics.roche.com/us/en/products/product-category/lung-cancer-diagnostics.html>

Pack Size	Ordering Code	Catalog Number
50 tests	08404160001	790-6087



### VENTANA pan-TRK (EPR17341) Assay

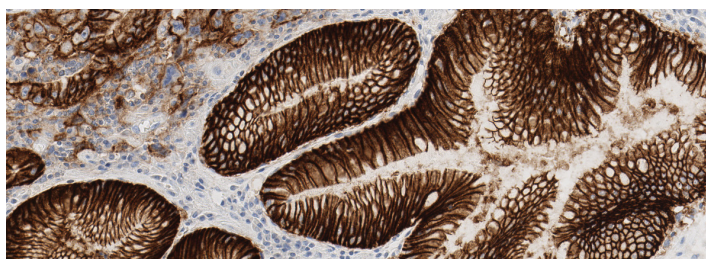


**VENTANA pan-TRK (EPR17341)** is intended for the immunohistochemical detection of the C-terminal region of the tropomyosin receptor kinase (TRK) proteins A, B, and C, which is known to be conserved across wild-type and chimeric fusion proteins. Neurotrophic tyrosine receptor kinase (NTRK) gene fusions are emerging as actionable biomarkers around a broad range of tumor types. Pan-TRK immunohistochemistry (IHC) has been shown to be a resource-efficient method to stratify patients for NTRK fusion genetic testing.

Learn more at: [go.roche.com/NTRKIHC](https://go.roche.com/NTRKIHC)

Pack Size	Ordering Code	Catalog Number
50 tests	08494665001	790-7026

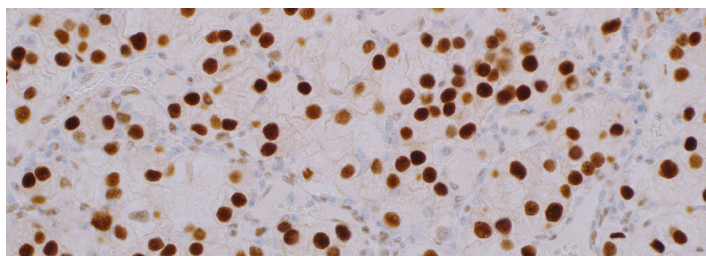
### VENTANA CLDN18 (43-14A) Assay



**VENTANA CLDN18 (43-14A) assay** is a mouse monoclonal antibody produced against CLDN18 proteins and detects both CLDN18.1 and CLDN18.2 isoforms. Isoforms of CLDN18 can be detected in differentiated epithelial cells of the normal gastric mucosa and pneumocytes in normal lung tissue, in a variety of advanced and metastatic gastrointestinal cancers, including gastric, esophageal, pancreatic, biliary duct cancers, and in non-small-cell lung cancer.

Pack Size	Ordering Code	Catalog Number
50 tests	08504148001	790-7027

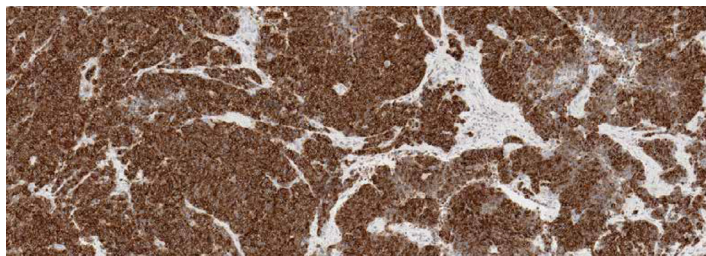
### PAX-8 (EP331) Rabbit Monoclonal Antibody



**PAX-8 (EP331)** is intended for use in the detection of the PAX-8 protein and is useful for marking several types of carcinoma included but not limited to ovarian serous carcinoma, clear cell renal cell carcinoma, and papillary thyroid carcinoma. PAX-8 (EP331) is a sensitive and specific marker for both primary and metastatic tumors.

Pack Size	Ordering Code	Catalog Number
50 tests	08313431001	760-6077

### VENTANA DLL3 (SP347) Assay

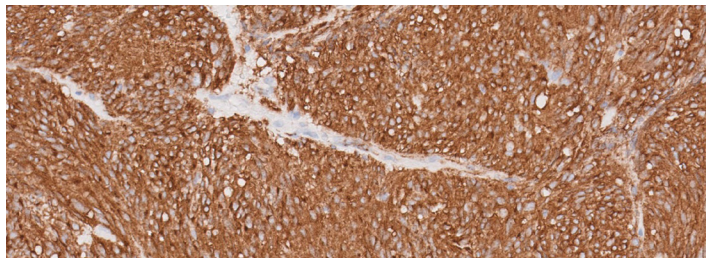


**VENTANA DLL3 (SP347)** is a rabbit monoclonal antibody for use in the detection of Delta-like protein 3 (DLL3), one of several transmembrane ligands that are involved in the regulation of the Notch pathway. Overexpression of Notch-1 has been shown to inhibit apoptosis in different cancer types, thus the inhibition of the Notch signaling pathway is a potential cancer therapeutic target.

Pack Size	Ordering Code	Catalog Number
50 tests	08416931001	790-7016



## Anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody

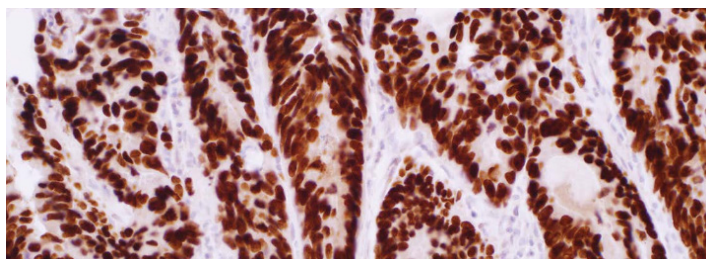


**Anti-CD117 (EP10)** is a new Class 1 IVD antibody used to evaluate the expression of CD117 protein. Along with a panel of antibodies, CD117 IHC may aid in the diagnosis of a range of diseases, including gastrointestinal stromal tumors (GIST), mast cell disorders, and germ cell neoplasms. This new reagent will replace the current Class III PATHWAY anti-c-KIT (9.7) primary antibody, allowing for broader use that will suit the current clinical application of CD117.

Learn more at: [go.roche.com/cd117](https://go.roche.com/cd117)

Pack Size	Ordering Code	Catalog Number
50 tests	08763909001	790-7061

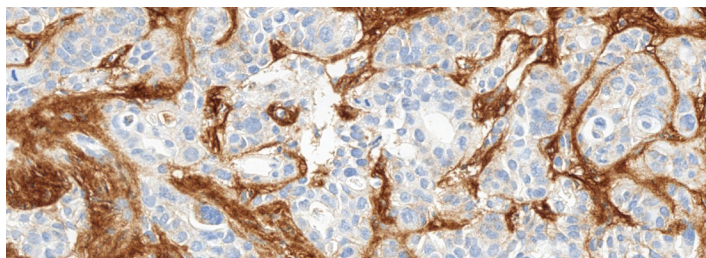
## SATB2 (EP281) Rabbit Monoclonal Primary Antibody



**SATB2 (EP281)** is an in vitro diagnostic assay with favorable sensitivity and specificity for colorectal carcinomas when utilized in the immunohistochemical panel with cytokeratin 7 and cytokeratin 20. The sensitivity and specificity of SATB2 for colorectal cancers make it a valuable antibody for differentiating carcinomas of unknown primaries.

Pack Size	Ordering Code	Catalog Number
50 tests	08313415001	760-6075

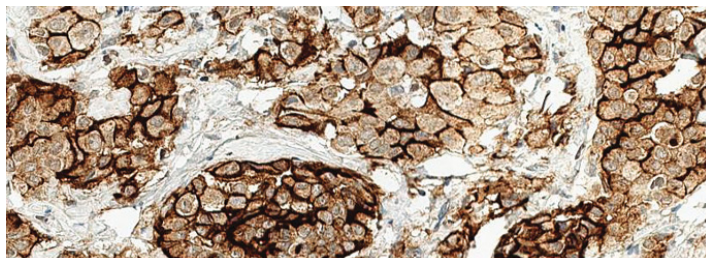
## VENTANA HA Dx Assay



**VENTANA HA Dx assay** is an affinity histochemistry (AHC) assay that is used to detect hyaluronan (HA) in tumor tissues. In a variety of solid tumors, high expression of HA within the extracellular matrix (ECM) has been identified. Abnormally high HA is associated with aggressive behavior and poor outcomes across tumor types.

Pack Size	Ordering Code	Catalog Number
50 tests	08289018001	790-6074

## VENTANA MSLN (SP74) Assay



**VENTANA MSLN (SP74)** is an immunohistochemical assay that utilizes a rabbit monoclonal primary antibody to evaluate the expression of mesothelin protein which is expressed in a variety of tumors including mesothelioma, ovarian cancer, pancreatic cancer and lung cancer. The cellular staining pattern for this assay is membranous and cytoplasmic.

Pack Size	Ordering Code	Catalog Number
50 tests	08508011001	790-7028