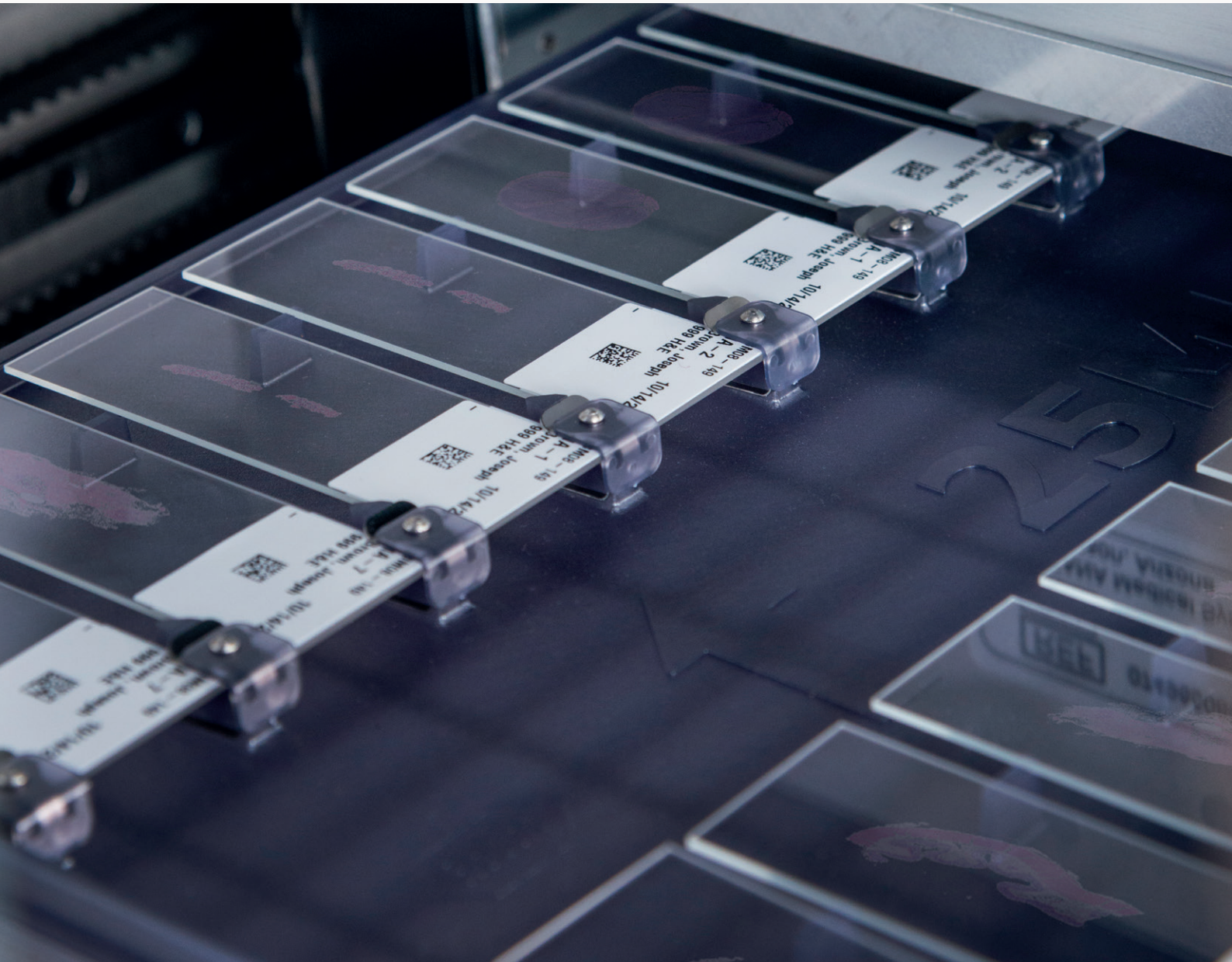
VENTANA®

Roche

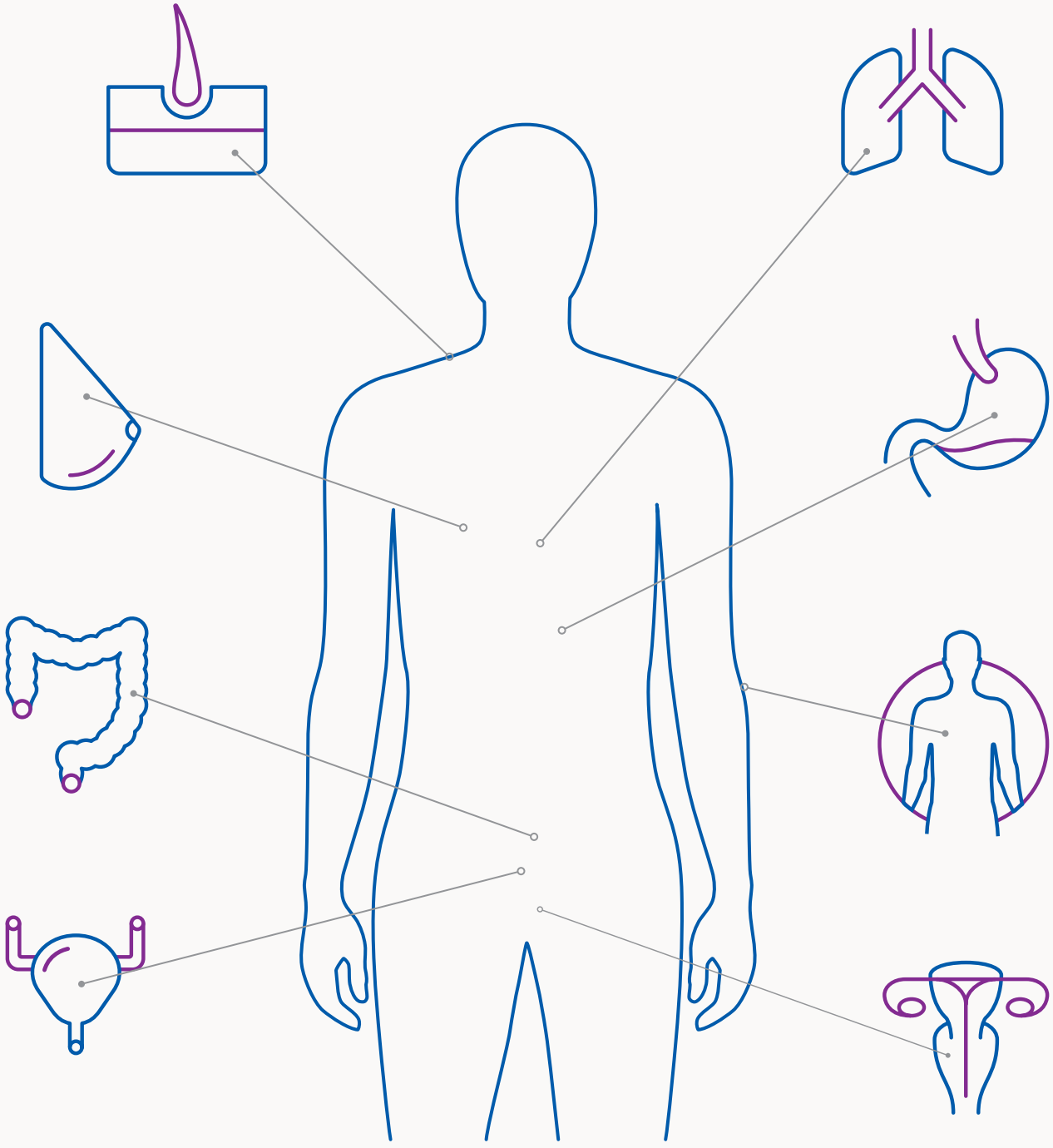
The Right Therapy, for the Right Patients, at the Right Time.

High Medical Value Assays



The Right Therapy, for the Right Patients, at the Right Time.

High Medical Value Assays

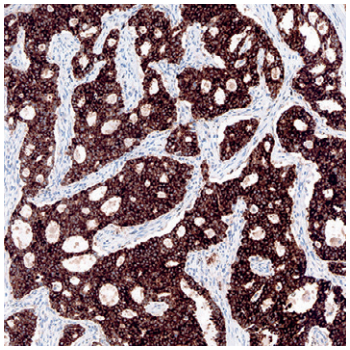


Visit us today
and explore
our portfolio:

NSCLC

ALK (D5F3) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

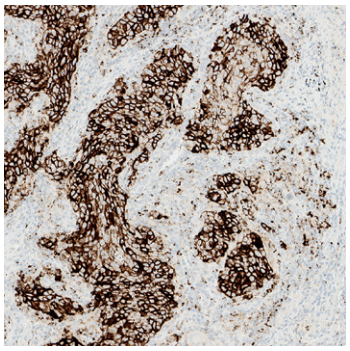


VENTANA® ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib).

Ordering Number:	Quantity:
06679072001	50 tests

PD-L1 (SP142) Assay

Ⓟ Predictive



PD-L1 expression in tumor cell (TC) membrane or in tumor-infiltrating immune cells (IC) as detected by VENTANA® PD-L1 (SP142) Assay in NSCLC is indicated as an aid for identifying patients for treatment with TECENTRIQ (atezolizumab).

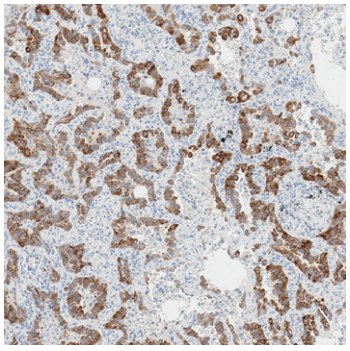
A patient's NSCLC tissue stained with the VENTANA® PD-L1 (SP142) Assay is evaluated for tumour cells (TC) and/ or tumour-infiltrating immune cells (IC) staining. TC are scored as the proportion of viable tumour cells showing PD-L1 membrane staining of any intensity. IC are scored as the proportion of tumour area that is occupied by PD-L1 staining IC of any intensity.

PD-L1 Expression Cut Off:
≥ 50% TC or ≥10% IC

Ordering Number:	Quantity:
08008540001	50 tests

ROS1 (SP384) Rabbit Monoclonal Primary Antibody

Ⓐ Analytic



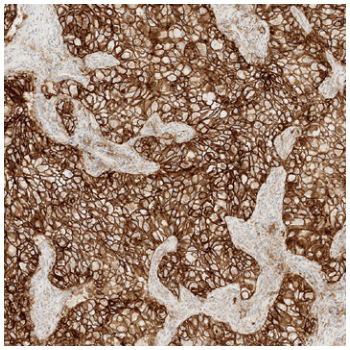
The detection of ROS1 protein by IHC with the VENTANA® ROS1 (SP384) antibody may be used to aid in the identification of non-small cell lung cancer (NSCLC) with ROS1 expression for further characterization by a molecular and/ or cytogenetic method. The staining pattern is mainly cytoplasmic and rarely membranous.

Ordering Number:	Quantity:
09365575001	50 tests

NSCLC

PD-L1 (SP263) Assay

Ⓟ **Predictive**



PD-L1 expression in non-small cell lung cancer (NSCLC) is determined by the percentage of tumor cells (% TC) with any membrane staining above background.

PD-L1 Expression Level:
≥ 1% TC
PD-L1 expression in tumor cell (TC) membrane as detected by VENTANA® PD-L1 (SP263) Assay in NSCLC is indicated as an aid in identifying patients for treatment with IMFINZI™ (durvalumab).

PD-L1 Expression Level:
≥ 50% TC, ≥ 1% TC
PD-L1 expression in tumor cell (TC) membrane as detected by VENTANA® PD-L1 (SP263) Assay in NSCLC is indicated as an aid in identifying patients for treatment with KEYTRUDA® (pembrolizumab).

PD-L1 Expression Level:
≥ 50% TC, ≥ 1% TC
PD-L1 expression in tumor cell (TC) membrane as detected by VENTANA® PD-L1 (SP263) Assay in NSCLC is indicated as an aid in identifying patients for treatment with LIBTAYO® (cemiplimab).

PD-L1 Expression Level:
≥ 50% TC
PD-L1 expression in tumor cell (TC) membrane as detected by VENTANA® PD-L1 (SP263) Assay in NSCLC is indicated as an aid in identifying patients with early stage NSCLC for adjuvant treatment with TECENTRIQ® (atezolizumab).

NON-SQUAMOUS NSCLC

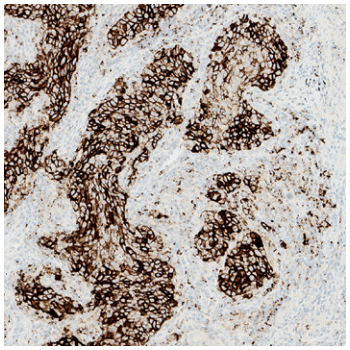
PD-L1 Expression Level:
≥ 1% TC, ≥ 5% TC, and ≥ 10% TC
PD-L1 expression in tumor cell (TC) membrane as detected by VENTANA® PD-L1 (SP263) Assay in non-squamous NSCLC may be associated with enhanced survival from OPDIVO® (nivolumab).

PD-L1 Expression Level:
≥ 50% TC
PD-L1 expression determined by tumor cell (TC) membrane as detected by VENTANA PD-L1 (SP263) Assay in non-squamous NSCLC is indicated as an aid in identifying patients for treatment with TEVIMBRA® (tislelizumab).

Ordering Number:	**Quantity:**
07419821001	50 tests

Bladder

PD-L1 (SP142) Assay	Ⓟ Predictive



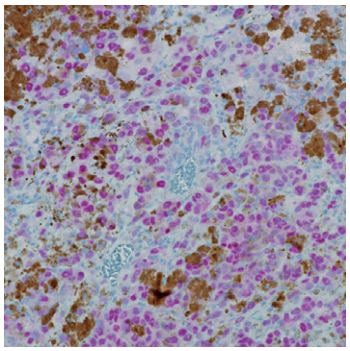
PD-L1 expression in tumor-infiltrating immune cells (IC) as detected by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma is indicated as an aid for identifying patients for treatment with TECENTRIQ (atezolizumab).

PD-L1 Expression Cut Off:
≥ 5% IC

Ordering Number:	Quantity:
08008540001	50 tests

Dermatology

PRAME (EPR20330) Rabbit Monoclonal Primary Antibody	Ⓐ Analytic



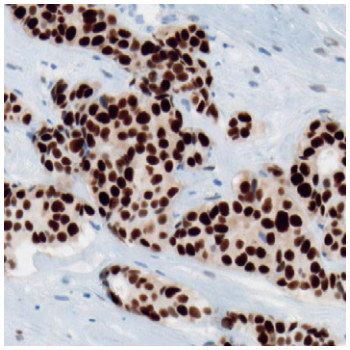
Assists with accurate diagnosis of melanoma or nevus by highlighting melanoma cells.*

Ordering Number:	Quantity:
09592237001	50 tests
09592245001	250 tests

Breast

Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

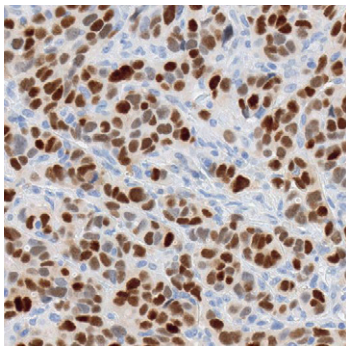


ER (SP1) is a powerful predictor of response to hormone therapy and clinical outcome of breast cancer patients.[1,2]

Ordering Number:	Quantity:
05278406001	50 tests
05278414001	250 tests

Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

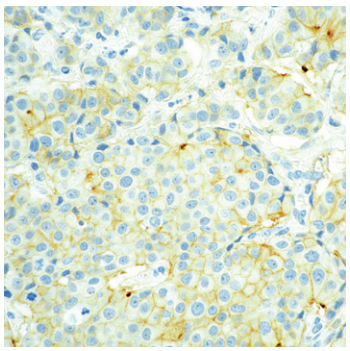


PR (1E2) status provides an independent and significant tool for predicting hormone therapy response and clinical outcome.[1,2]

Ordering Number:	Quantity:
05277990001	50 tests
05278392001	250 tests

HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx

Ⓟ Predictive

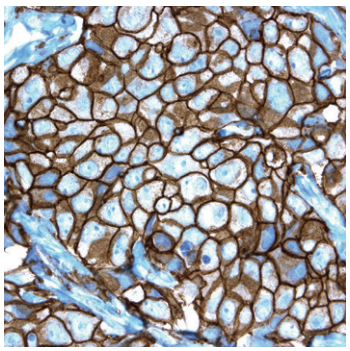


For treatment with trastuzumab (IHC 3+ or IHC 2+/ISH amplified), pertuzumab (IHC 3+ or IHC 2+/ISH amplified), trastuzumab emtansine (IHC 3+ or IHC 2+/ISH amplified), or trastuzumab deruxtecan (IHC 0 with membrane staining, IHC 1+ or IHC 2+/ISH non-amplified.)

Ordering Number:	Quantity:
09670564001	50 tests

HER2/neu (4B5) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

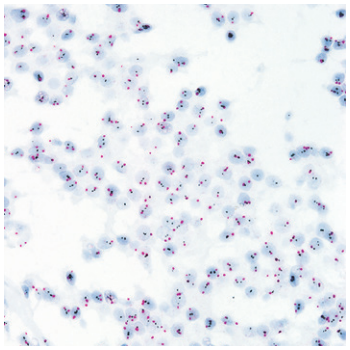


Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered

Ordering Number:	Quantity:
05999570001	50 tests

HER2 Dual ISH DNA Probe Cocktail

Ⓟ Predictive

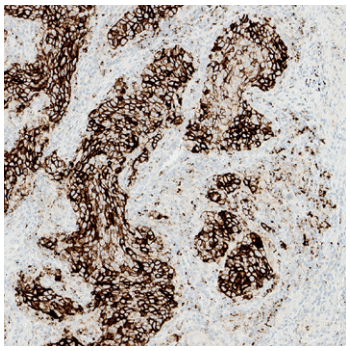


Aid in the assessment of patients for whom Herceptin (trastuzumab) is being considered.

Ordering Number:	Quantity:
08314373001	30 tests

PD-L1 (SP142) Assay

Ⓟ Predictive



PD-L1 expression in tumor-infiltrating immune cells (IC) as detected by VENTANA PD-L1 (SP142) Assay in TNBC is indicated as an aid for identifying patients for treatment with TECENTRIQ (atezolizumab).

A patient's TNBC tissue stained with the VENTANA PD-L1 (SP142) Assay is evaluated for tumour-infiltrating immune cells (IC) staining. IC are immune cells present in the intratumoral and contiguous peritumoral stroma that include lymphocytes, macrophages, dendritic cells and granulocytes. IC are scored as the proportion of tumour area that is occupied by PD-L1 staining IC of any intensity.

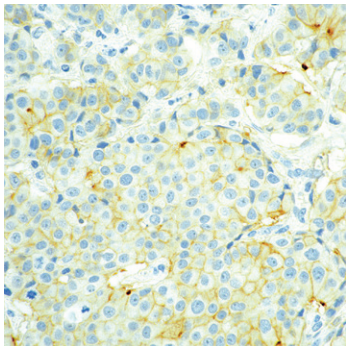
PD-L1 Expression Cut Off:
≥ 1% IC

Ordering Number:	Quantity:
08008540001	50 tests

Gastric

HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx

Ⓟ Predictive

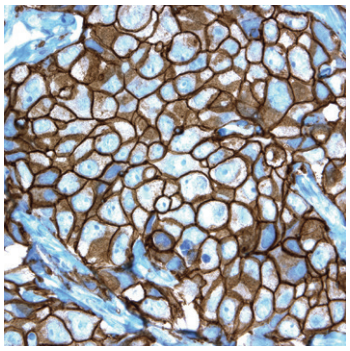


The IHC device is indicated as a companion diagnostic for identifying patients who are eligible for treatment with the following therapies in accordance with the approved therapeutic labeling: Gastric carcinoma patients for treatment with trastuzumab (IHC 3+ or IHC 2+/ISH amplified). BTC patients for treatment with zanidatamab (IHC 3+)

Ordering Number:	Quantity:
09670564001	50 tests

HER2/neu (4B5) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

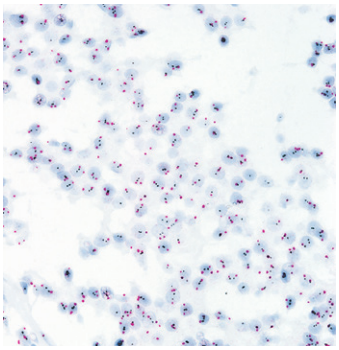


Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered.

Ordering Number:	Quantity:
05999570001	50 tests

HER2 Dual ISH DNA Probe Cocktail

Ⓟ Predictive

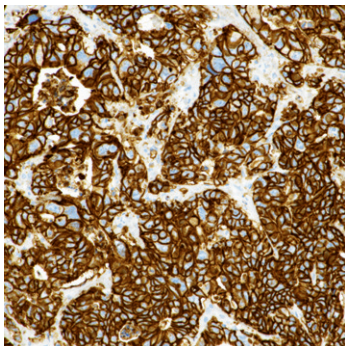


Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered.

Ordering Number:	Quantity:
08314373001	30 tests

CLDN18 (43-14A) RxDx Assay

Ⓟ Predictive

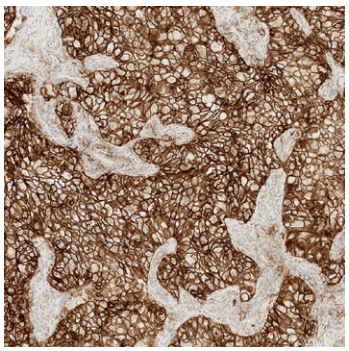


The assay is indicated as a companion diagnostic to aid in identifying patients with gastric or GEJ adenocarcinoma who may be eligible for treatment with VYLOY™ (zolbetuximab) in accordance with the approved therapeutic product labeling. The clinical cut-off for the therapeutic product is ≥ 75% viable tumor cells (%TC) demonstrating moderate to strong membrane CLDN18 staining above background.

Ordering Number:	Quantity:
08285918001	50 tests

PD-L1 (SP263) Assay

Ⓟ Predictive



PD-L1 expression in gastric or gastroesophageal junction (GEJ) adenocarcinoma is determined by Tumor Area Positivity (TAP) score, defined as the total percentage of tumor area (tumor and any desmoplastic stroma) covered by tumor cells with PD-L1 membrane staining at any intensity and tumor-associated immune cells with PD-L1 staining at any intensity as visually estimated.

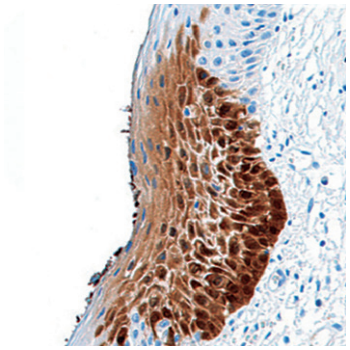
PD-L1 Expression Level:
≥ 5% TAP
PD-L1 expression determined by Tumor Area Positivity (TAP) scoring as detected by VENTANA PD-L1 (SP263) Assay in gastric or GEJ adenocarcinoma is indicated as an aid in identifying patients for treatment with TEVIMBRA® (tislelizumab).

Ordering Number:	Quantity:
07419821001	50 tests

Gynecologic

CINtec® p16 Histology

Ⓐ Analytic

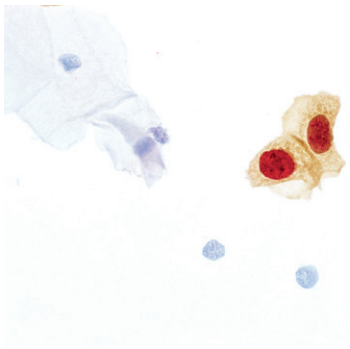


Validated p16 IHC diagnostic test for evaluation of cervical biopsies.

Ordering Number:	Quantity:
06695248001	50 tests
06695256001	250 tests

CINtec® PLUS Cytology

Ⓐ Analytic

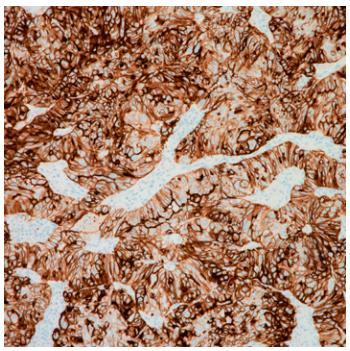


Dual-stain triage test for patients with a positive high-risk HPV (hrHPV) result. Uses dual-biomarker technology to simultaneously detect p16 and Ki-67 within a cell .

Ordering Number:	Quantity:
06889565001	100 tests

FOLR1 (FOLR1-2.1) RxDx Assay

Ⓟ Predictive



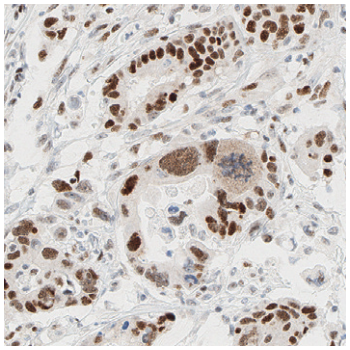
FOLR1 expression clinical cut-off is ≥ 75% viable tumor cells (TC) with membrane staining at moderate and/or strong intensity levels. The assay is indicated as a companion diagnostic to aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who may be eligible for treatment with ELAHERE (mirvetuximab soravtansine).

Ordering Number:	Quantity:
07763620001	50 tests

Colorectal

MMR IHC Panel

Ⓐ Analytic



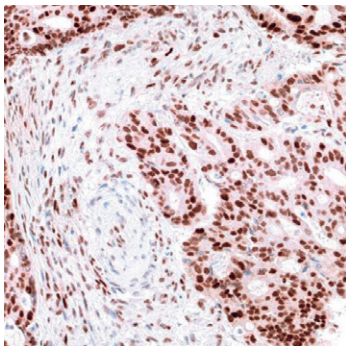
The VENTANA MMR IHC Panel is indicated in detection of mismatch repair protein deficiency as a test for the identification of individuals at risk for Lynch syndrome in patients diagnosed with colorectal cancer (CRC), and, with BRAF V600E status, as an aid to differentiate between sporadic and probable Lynch syndrome CRC in the absence of MLH1 protein expression.

MMR IHC Panel, VENTANA includes:

anti-MLH1 (M1), Mouse Monoclonal Primary Antibody
anti-PMS2 (SP487), Rabbit Monoclonal Primary Antibody
anti-MSH2 (G219-1129), Mouse Monoclonal Primary Antibody
anti-MSH6 (SP93), Mouse Monoclonal Primary Antibody
anti-BRAF V600E (VE1), Mouse Monoclonal Primary Antibody

MMR IHC Panel: anti-MLH1 (M1), Mouse Monoclonal Primary Antibody

Ⓐ Analytic

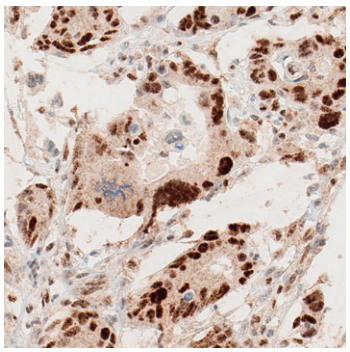


VENTANA anti-MLH1 (M1) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
09605584001	50 tests

MMR IHC Panel: anti-PMS2 (SP487), Rabbit Monoclonal Primary Antibody

Ⓐ Analytic

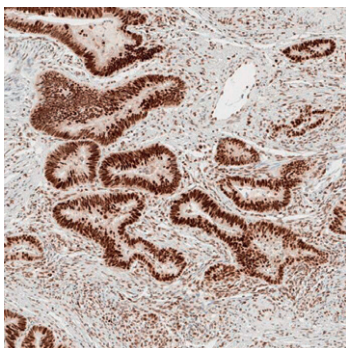


VENTANA anti-PMS2 (SP487) antibody is part of the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
09785370001	50 tests

MMR IHC Panel: anti-MSH2 (G219-1129), Mouse Monoclonal Primary Antibody

Ⓐ Analytic

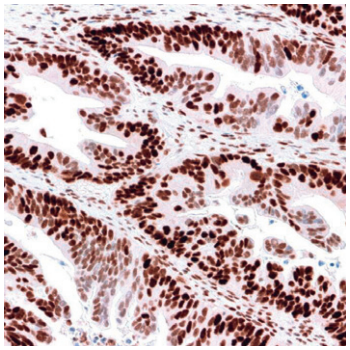


VENTANA anti-MSH2 (G219-1129) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
09607137001	50 tests

MMR IHC Panel: anti-MSH6 (SP93), Mouse Monoclonal Primary Antibody

Ⓐ Analytic

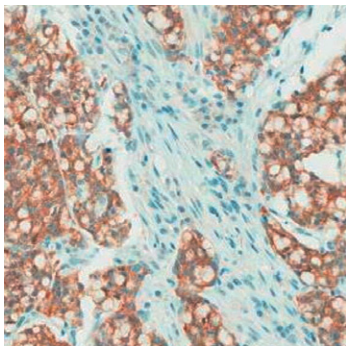


VENTANA anti-MSH6 (SP93) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
09606769001	50 tests

MMR IHC Panel: anti-BRAF V600E (VE1), Mouse Monoclonal Primary Antibody

Ⓐ Analytic



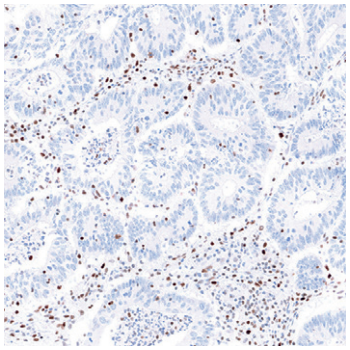
VENTANA anti-BRAF V600E (VE1) antibody is part of the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
08033706001	50 tests

Cross Indication

MMR RxDx Panel

Ⓟ Predictive



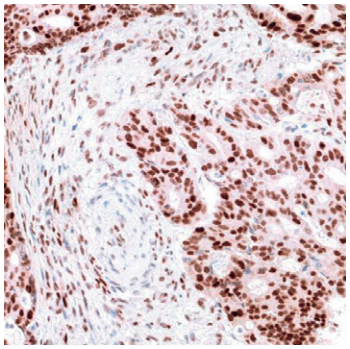
The VENTANA MMR RxDx Panel is indicated as an aid in identifying deficient MMR (dMMR) endometrial carcinoma patients eligible for treatment with JEMPERLI (dostarlimab) in accordance with the approved therapeutic product labeling.

Indications for Use	MMR Status	Therapy
Endometrial Carcinoma (EC)	dMMR	JEMPERLI (dostarlimab-gxly)
Colorectal (CRC), Endometrial, Gastric, Biliary, or Small Intestine Cancer	dMMR	KEYTRUDA (pembrolizumab)
Endometrial Carcinoma (EC)	dMMR	IMFINZI (durvalumab)
Endometrial Carcinoma (EC)	pMMR	IMFINZI (durvalumab) + LYNPARZA (olaparib)

MMR RxDx Panel, VENTANA includes:
anti-MLH1 (M1) Mouse Monoclonal Primary Antibody
anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody
anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody
anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody

MMR RxDx Panel: anti-MLH1 (M1) Mouse Monoclonal Primary Antibody

Ⓟ Predictive

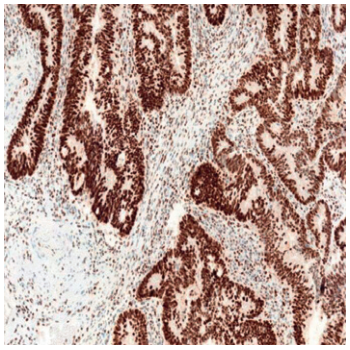


VENTANA anti-MLH1 (M1) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
08033668001	50 tests

MMR RxDx Panel: anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody

Ⓟ Predictive

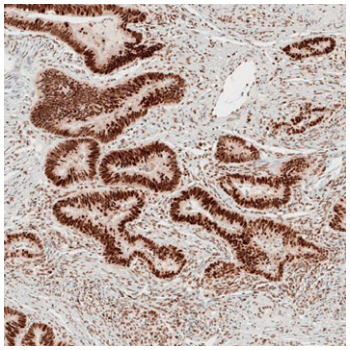


VENTANA anti-PMS2 (A16-4) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
08033692001	50 tests

MMR RxDx Panel: anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody

Ⓟ Predictive

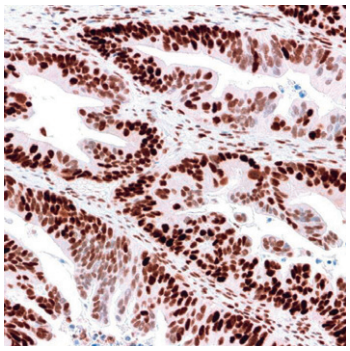


VENTANA anti-MSH2 (G219-1129) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
08033684001	50 tests

MMR RxDx Panel: anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody

Ⓟ Predictive

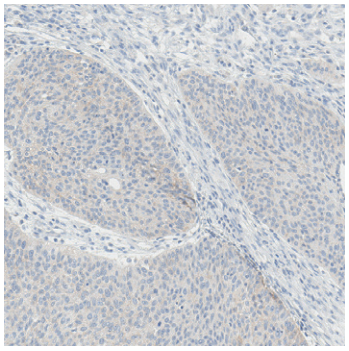


VENTANA anti-MSH6 (SP93) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:	Quantity:
08033676001	50 tests

pan-TRK (EPR17341) Assay

Ⓐ Analytic

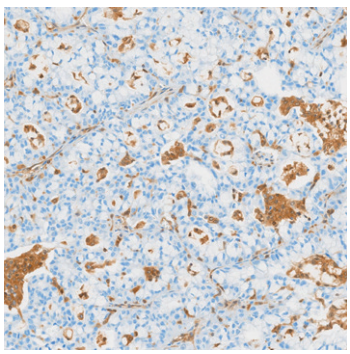


Used to identify the C-terminal region of TRK A, B and C.

Ordering Number:	Quantity:
08494665001	50 tests

MTAP (SP530) Rabbit Monoclonal Antibody

Ⓐ Analytic



VENTANA MTAP (SP530) Rabbit Monoclonal Antibody is intended for the detection of of S-methyl-5-thioadenosine phosphorylase (MTAP) loss by immunohistochemistry (IHC) and may aid in the diagnosis of malignant mesothelioma and its distinction from benign mesothelial proliferations.

Ordering Number:	Quantity:
10574518001	50 tests

References

* In conjunction with morphologic evaluation on H&E and correlation with clinical findings and/or additional ancillary tests when applicable.

1. Allison, K et al. Estrogen and Progesterone Receptor Testing in Breast Cancer. Arch Pathol Lab Med. 2019.
2. Fitzgibbons, P. et al. Template for Reporting Results of Biomarker Testing of Specimens From Patients With Carcinoma of the Breast. College of American Pathologists. 2020

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