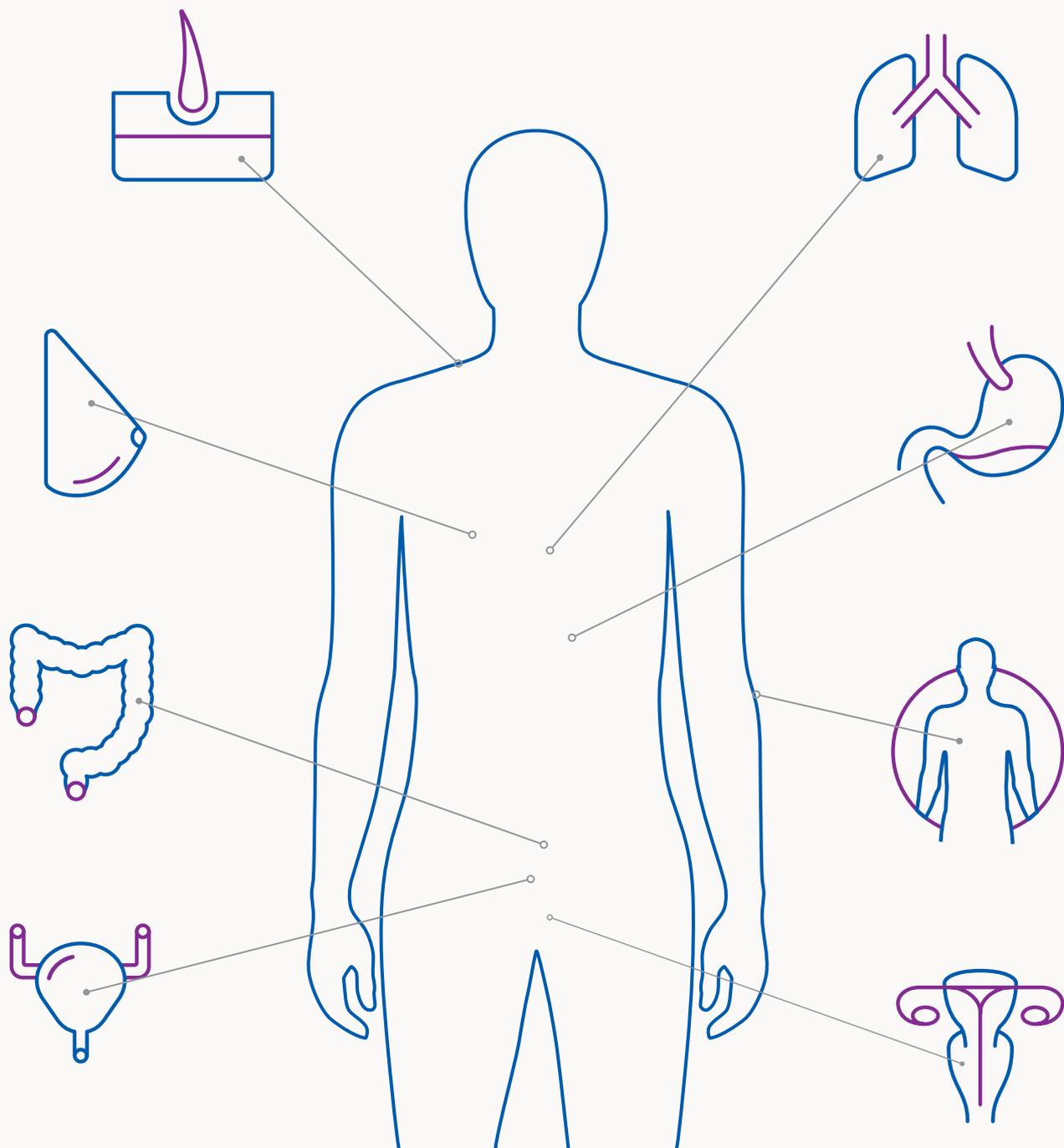


The Right Therapy, for the Right Patients, at the Right Time.

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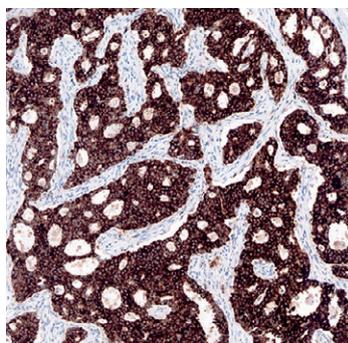
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ALK (D5F3) Rabbit Monoclonal Primary Antibody

P Predictive



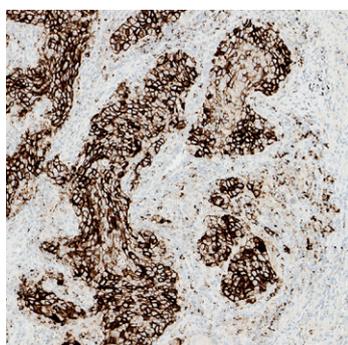
VENTANA® ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark automated staining instrument. It is indicated as an aid in identifying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

Ordering Number:
06679072001

Quantity:
50 tests

PD-L1 (SP142) Assay

P 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.

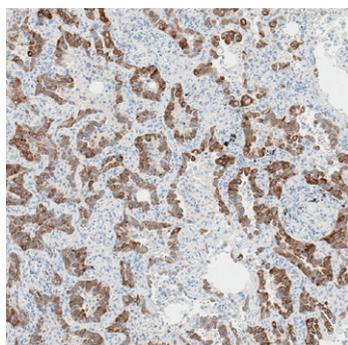
PD-L1 Expression Cut Off:
≥ 50% TC or ≥10% IC

Ordering Number:
08008540001

Quantity:
50 tests

ROS1 (SP384) Rabbit Monoclonal Primary Antibody

A Analytic

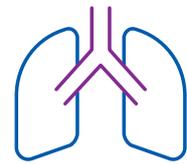


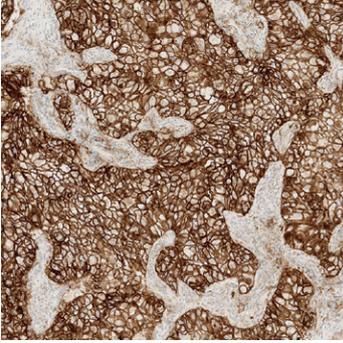
The detection of ROS1 protein by IHC with the VENTANA® ROS1 (SP384) antibody may be used to aid in the identification of non-small cell lung cancer (NSCLC) with ROS1 expression for further characterization by a molecular and/ or cytogenetic method. The staining pattern is mainly cytoplasmic and rarely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

Ordering Number:
09365575001

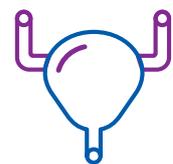
Quantity:
50 tests

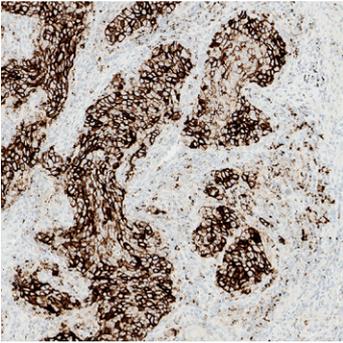
NSCLC



PD-L1 (SP263) Assay	P Predictive	
	<p>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.</p> <p>PD-L1 Expression Level: $\geq 1\%$ 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).</p> <p>PD-L1 Expression Level: $\geq 50\%$ TC, $\geq 1\%$ 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).</p> <p>PD-L1 Expression Level: $\geq 50\%$ TC, $\geq 1\%$ 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).</p> <p>PD-L1 Expression Level: $\geq 50\%$ 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).</p> <p>NON-SQUAMOUS NSCLC</p> <p>PD-L1 Expression Level: $\geq 1\%$ TC, $\geq 5\%$ TC, and $\geq 10\%$ 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).</p>	
	<p>Ordering Number: 07419821001</p>	<p>Quantity: 50 tests</p>

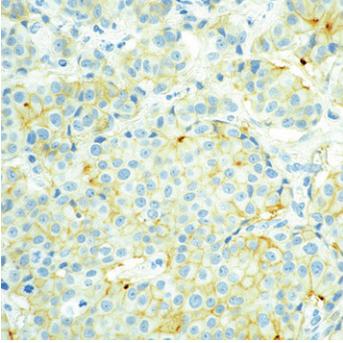
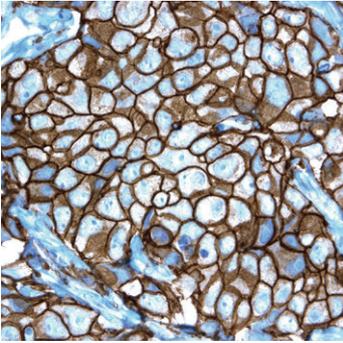
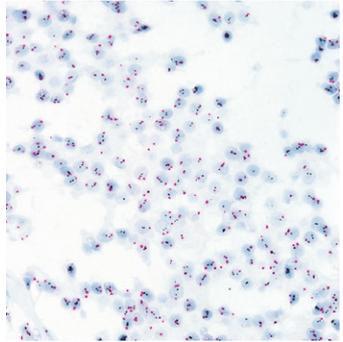
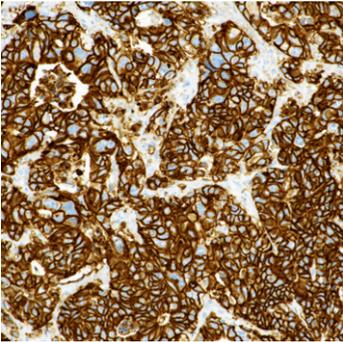
Bladder



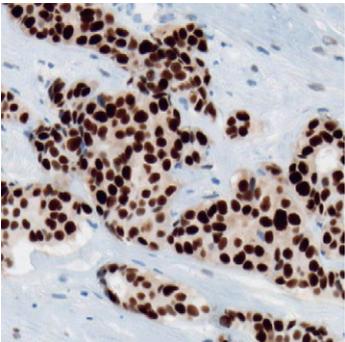
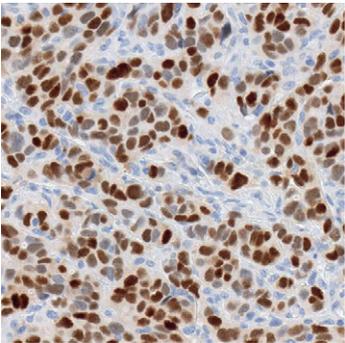
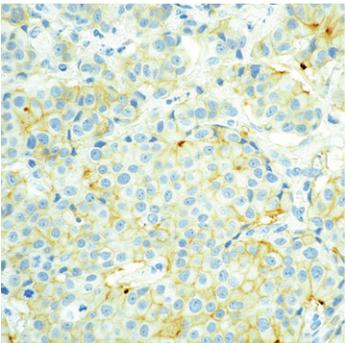
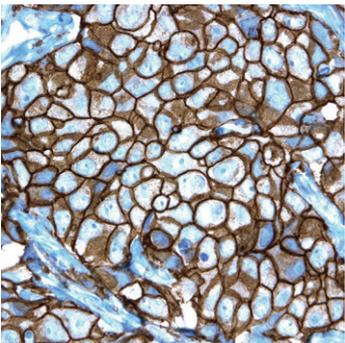
PD-L1 (SP142) assay	P Predictive	
	<p>PD-L1 expression in tumor-infiltrating immune cells (IC) as detected by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma is indicated as an aid for identifying patients for treatment with TECENTRIQ (atezolizumab).</p> <p>PD-L1 Expression Cut Off: $\geq 5\%$ IC</p>	
	<p>Ordering Number: 08008540001</p>	<p>Quantity: 50 tests</p>

Gastric

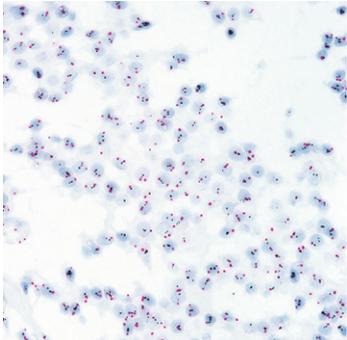


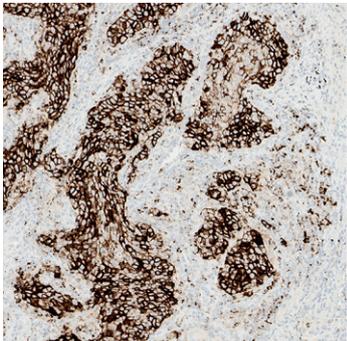
HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx		P Predictive
	<p>The IHC device is indicated as a companion diagnostic for identifying patients who are eligible for treatment with the following therapies in accordance with the approved therapeutic labeling: Gastric carcinoma patients for treatment with trastuzumab (IHC 3+ or IHC 2+/ISH amplified), BTC patients for treatment with zanidatamab (IHC 3+)</p>	
	<p>Ordering Number: 09670564001</p>	<p>Quantity: 50 tests</p>
HER2/neu (4B5) Rabbit Monoclonal Primary Antibody		P Predictive
	<p>Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered.</p>	
	<p>Ordering Number: 05999570001</p>	<p>Quantity: 50 tests</p>
HER2 Dual ISH DNA Probe Cocktail		P Predictive
	<p>Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered.</p>	
	<p>Ordering Number: 08314373001</p>	<p>Quantity: 30 tests</p>
CLDN18 (43-14A) RxDx Assay		P Predictive
	<p>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 $\geq 75\%$ viable tumor cells (%TC) demonstrating moderate to strong membrane CLDN18 staining above background.</p>	
	<p>Ordering Number: 08285918001</p>	<p>Quantity: 50 tests</p>

Breast

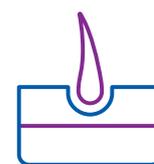
Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody		P Predictive
	ER (SP1) is a powerful predictor of response to hormone therapy and clinical outcome of breast cancer patients. ^{1,2}	
	Ordering Number: 05278406001 05278414001	Quantity: 50 tests 250 tests
Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody		P Predictive
	PR (1E2) status provides an independent and significant tool for predicting hormone therapy response and clinical outcome. ^{1,2}	
	Ordering Number: 05277990001 05278392001	Quantity: 50 tests 250 tests
HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx		P 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: 09670564001	Quantity: 50 tests
HER2/neu (4B5) Rabbit Monoclonal Primary Antibody		P Predictive
	Aid in the assessment of breast and gastric cancer patients for whom Herceptin treatment is considered	
	Ordering Number: 05999570001	Quantity: 50 tests

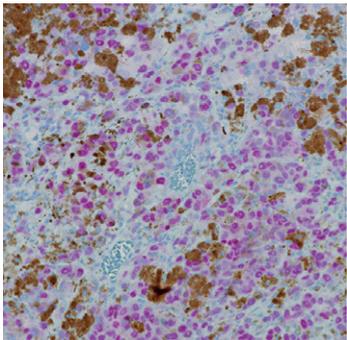


HER2 Dual ISH DNA Probe Cocktail		P Predictive
	Aid in the assessment of patients for whom Herceptin (trastuzumab) is being considered.	
	Ordering Number: 08314373001	Quantity: 30 tests

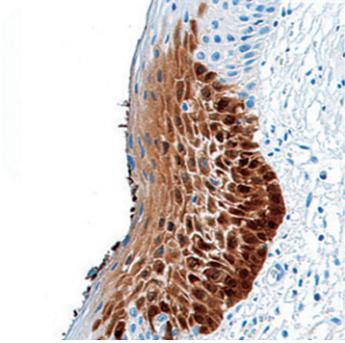
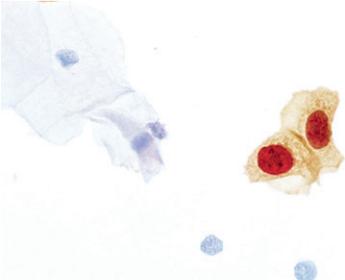
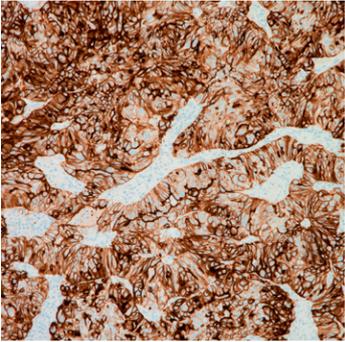
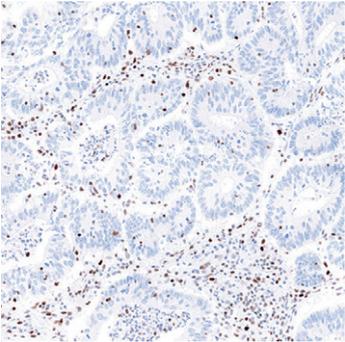
PD-L1 (SP142) Assay		P Predictive
	PD-L1 expression in tumor-infiltrating immune cells (IC) as detected by VENTANA PD-L1 (SP142) Assay in TNBC is indicated as an aid for identifying patients for treatment with TECENTRIQ (atezolizumab).	
	A patient's TNBC tissue stained with the VENTANA PD-L1 (SP142) 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: 08008540001	Quantity: 50 tests	

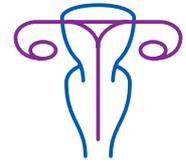
Dermatology

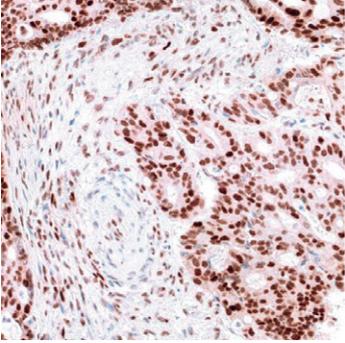
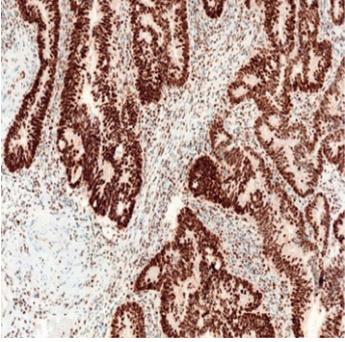
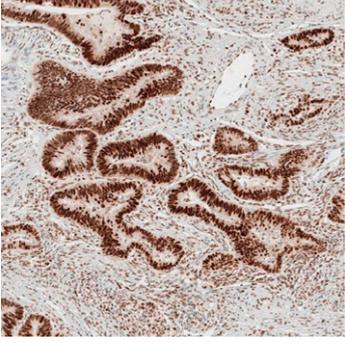
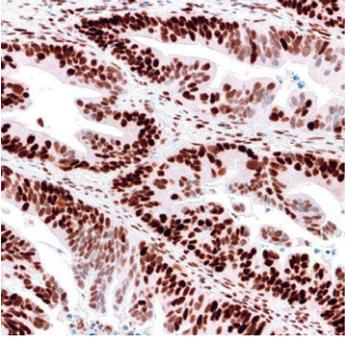


PRAME (EPR20330) Rabbit Monoclonal Primary Antibody		A Analytic
	Assists with accurate diagnosis of melanoma or nevus by highlighting melanoma cells.*	
	Ordering Number: 09592237001 09592245001	Quantity: 50 tests 250 tests

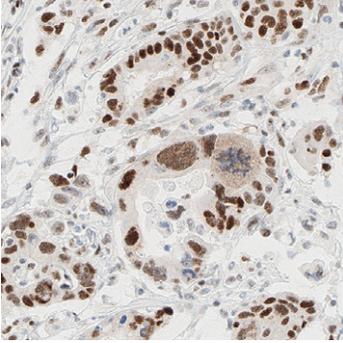
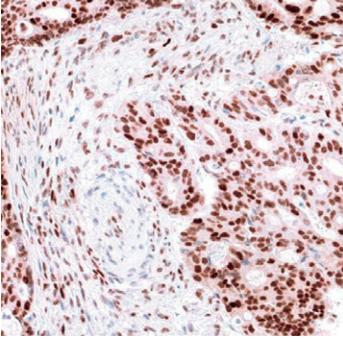
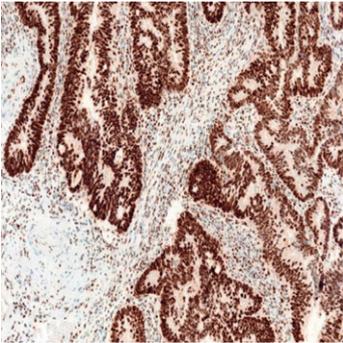
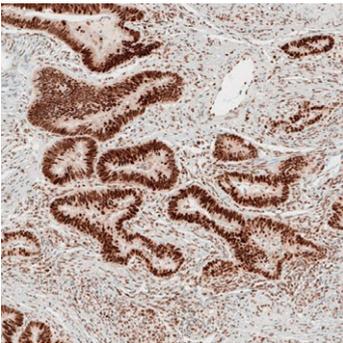
Gynecologic

CINtec® p16 Histology	A Analytic		
	<p>Validated p16 IHC diagnostic test for evaluation of cervical biopsies.</p> <table border="1" data-bbox="576 589 1426 730"> <tr> <td data-bbox="576 589 1002 730"> Ordering Number: 06695248001 06695256001 </td> <td data-bbox="1002 589 1426 730"> Quantity: 50 tests 250 tests </td> </tr> </table>	Ordering Number: 06695248001 06695256001	Quantity: 50 tests 250 tests
Ordering Number: 06695248001 06695256001	Quantity: 50 tests 250 tests		
CINtec® PLUS Cytology	A Analytic		
	<p>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 .</p> <table border="1" data-bbox="576 1086 1426 1189"> <tr> <td data-bbox="576 1086 1002 1189"> Ordering Number: 06889565001 </td> <td data-bbox="1002 1086 1426 1189"> Quantity: 100 tests </td> </tr> </table>	Ordering Number: 06889565001	Quantity: 100 tests
Ordering Number: 06889565001	Quantity: 100 tests		
FOLR1 (FOLR1-2.1) RxDx Assay	P Predictive		
	<p>FOLR1 expression clinical cut-off is $\geq 75\%$ 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).</p> <table border="1" data-bbox="576 1543 1426 1648"> <tr> <td data-bbox="576 1543 1002 1648"> Ordering Number: 07763620001 </td> <td data-bbox="1002 1543 1426 1648"> Quantity: 50 tests </td> </tr> </table>	Ordering Number: 07763620001	Quantity: 50 tests
Ordering Number: 07763620001	Quantity: 50 tests		
MMR RxDx Panel	P Predictive		
	<p>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.</p> <p>MMR RxDx Panel, VENTANA includes:</p> <ul style="list-style-type: none"> 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		P Predictive
	VENTANA anti-MLH1 (M1) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.	
	Ordering Number: 08033668001	Quantity: 50 tests
MMR RxDx Panel: anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody		P Predictive
	VENTANA anti-PMS2 (A16-4) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.	
	Ordering Number: 08033692001	Quantity: 50 tests
MMR RxDx Panel: anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody		P Predictive
	VENTANA anti-MSH2 (G219-1129) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.	
	Ordering Number: 08033684001	Quantity: 50 tests
MMR RxDx Panel: anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody		P Predictive
	VENTANA anti-MSH6 (SP93) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.	
	Ordering Number: 08033676001	Quantity: 50 tests

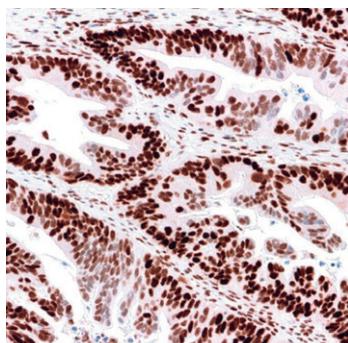
Colorectal

MMR IHC Panel		Analytic
	<p>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.</p> <p>MMR IHC 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), Mouse Monoclonal Primary Antibody anti-BRAF V600E (VE1), Mouse Monoclonal Primary Antibody</p>	
MMR IHC Panel: anti-MLH1 (M1), Mouse Monoclonal Primary Antibody		Analytic
	<p>VENTANA anti-MLH1 (M1) antibody is part of the VENTANA MMR RxTx Panel and the VENTANA MMR IHC Panel.</p>	
	Ordering Number: 08033668001	Quantity: 50 tests
MMR IHC Panel: anti-PMS2 (A16-4), Mouse Monoclonal Primary Antibody		Analytic
	<p>VENTANA anti-PMS2 (A16-4) antibody is part of the VENTANA MMR RxTx Panel and the VENTANA MMR IHC Panel.</p>	
	Ordering Number: 08033692001	Quantity: 50 tests
MMR IHC Panel: anti-MSH2 (G219-1129), Mouse Monoclonal Primary Antibody		Analytic
	<p>VENTANA anti-MSH2 (G219-1129) antibody is part of the VENTANA MMR RxTx Panel and the VENTANA MMR IHC Panel.</p>	
	Ordering Number: 08033684001	Quantity: 50 tests



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

A Analytic



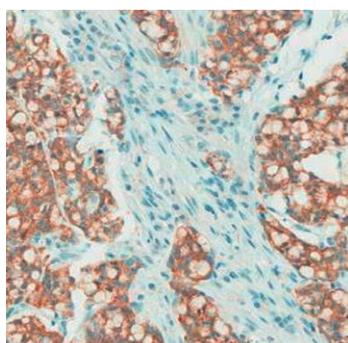
VENTANA anti-MSH6 (SP93) antibody is part of the VENTANA MMR RxDx Panel and the VENTANA MMR IHC Panel.

Ordering Number:
08033676001

Quantity:
50 tests

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

A Analytic



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

Ordering Number:
08033706001

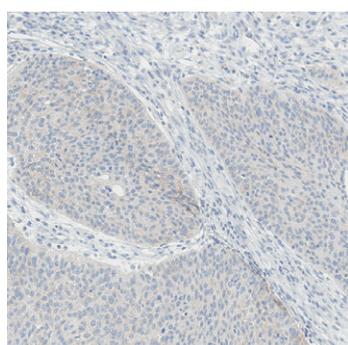
Quantity:
50 tests

Solid Tumors



pan-TRK (EPR17341) Assay

A Analytic



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

Ordering Number:
08494665001

Quantity:
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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