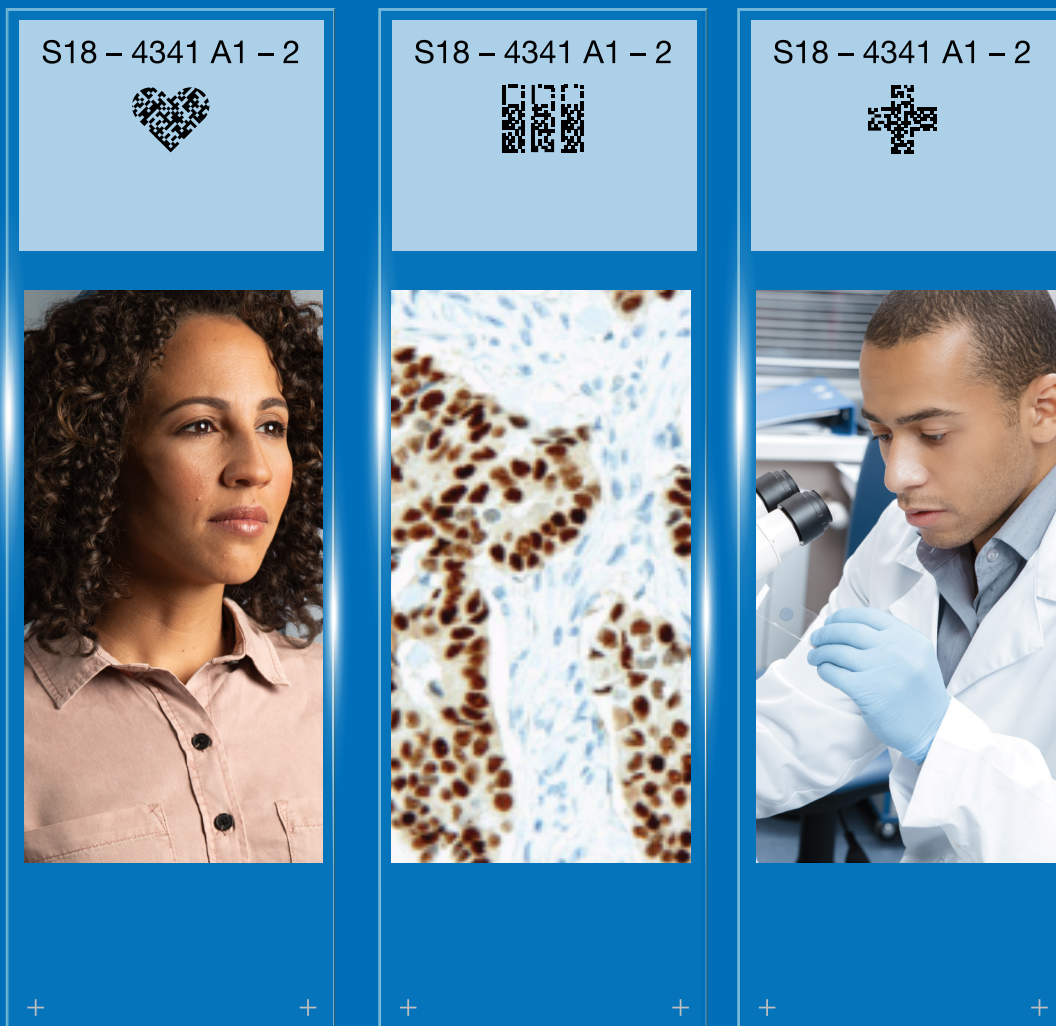


# **Breast cancer diagnostic portfolio**

*Innovating diagnostics. Delivering confidence. Improving lives.*



## Guiding the way to personalised treatment



**Roche's innovative Breast Cancer Diagnostics Portfolio** leads the way in breast oncology. Our suite of diagnostic and predictive assays plus image analysis algorithms delivers quality without compromise. Now you can consistently deliver confident answers to the patients who rely on you. The solution to precise, personalised treatment has never been clearer.



## Pushing beyond the barriers of traditional cancer treatment



*Breast cancer accounts for about 1 in 4 cancer cases in women, affecting ~2.1 million people globally on a yearly basis.<sup>1</sup>*

Early detection, innovative testing, and new therapies are helping strike a powerful blow against this disease. From 1989 to 2016, the number of breast cancer-related deaths dropped by 40%.<sup>2</sup> We celebrate the progress we have made, but we still have work to do. Breast cancer continues to claim 600,000 lives<sup>2</sup> annually worldwide.

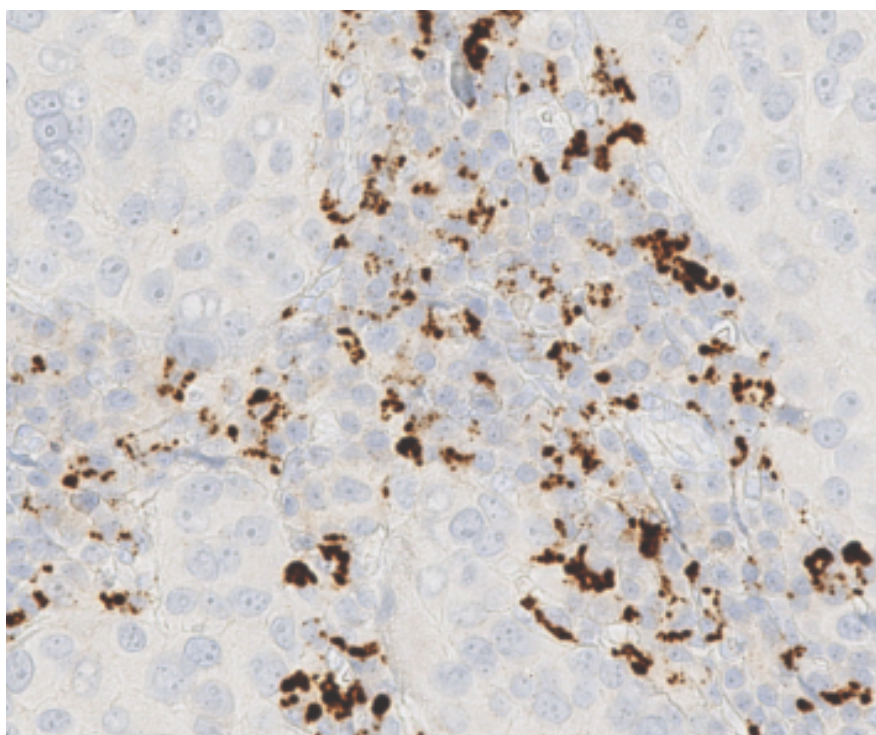
At Roche, we understand that every breast tissue sample you receive represents someone's life. Patients' questions, hopes and aspirations are in your hands. That's why we remain committed to developing solutions to guide precise, personalised treatment.

### **Research, refine, and start again – our determination is unwavering: An evolving portfolio of advanced solutions**

Our understanding of breast cancer is growing all the time, and our portfolio is evolving with it. We research, refine and begin again with unwavering determination – developing new and advanced technologies that bring clarity to the most complex disease pathways.

Today we offer a comprehensive, sensitive, and clinically actionable breast cancer diagnostic portfolio.

## Rooted in science, driven by innovation



*In 2020, IDEA Pharma rated Roche #1 for innovation, citing several exciting milestones for PD-L1 (SP142), including a groundbreaking test and treatment for Triple Negative Breast Cancer (TNBC).*

### **Roche delivers breakthrough innovations from a foundation of 120 years' experience**

Roche's enduring commitment to continuous innovation and exceptional quality has created a history of successes.<sup>1</sup> Right now, our proven foundation is enabling us to expand our transformative technologies across a broad spectrum of indications.

### **Breaking new ground – spotlight on Triple Negative Breast Cancer (TNBC)**

Until recently, no targeted therapy was available for triple-negative breast cancer (TNBC).

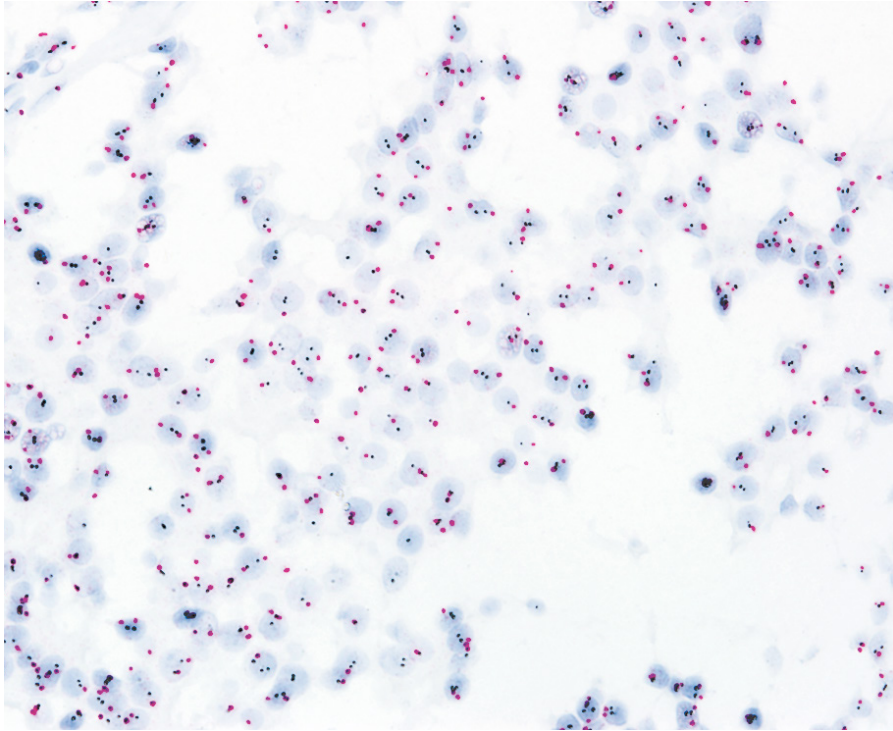
In 2019, Roche launched the VENTANA PD-L1 (SP142) Assay – the first FDA approved and CE-IVD marked assay for TNBC. This novel test allowed pathologists to identify patients who are likely to benefit from treatment with a breakthrough immunotherapy, bring new hope to thousands.

#### **Key advantages**

- Delivers the ability to confidently identify TNBC patients eligible for TECENTRIQ®
- Charts a new course for personalised treatment in breast cancer



## Reimagining HER2 testing



### **Our mission compels us to make even our best tools better**

To us, innovation means more than developing new products. We also seek opportunities to enhance technology we have on market today – because the better diagnostic tools mean greater confidence and improved patient outcomes.

*For this reason, we have reinvented our HER2 Dual ISH assay.*

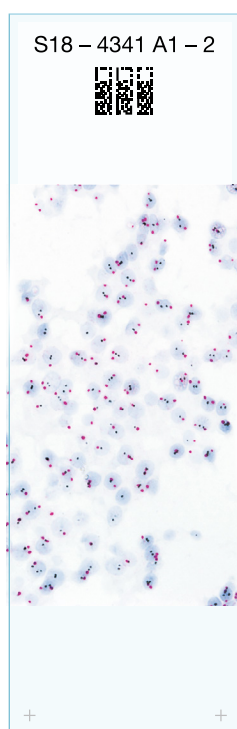
### **The VENTANA HER2 Dual ISH DNA Probe Cocktail is the clear choice to navigate breast cancer's complexity**

Building on the elements that made the original product successful – including easy reads with brightfield microscopy, interpretation within the context of tissue morphology, and archivable results – we have refined the science behind the test to make it more robust in your hands.

#### **The new VENTANA HER2 Dual ISH assay delivers:**

- Increased performance with new oligo probes, new detection kits, and high first pass rates<sup>3</sup>
- Robust and reproducible results that are highly concordant with FISH and consistent between laboratories and pathologists<sup>3</sup>
- Diagnostic confidence in our widely adopted breast cancer portfolio with proven clinical utility

## Empowering precision diagnosis – image analysis algorithm for clinical decision support



Roche is continuing to innovate in HER2 diagnostics through image analysis algorithms that minimise variables and support consistent, confident decision-making. The uPath HER2 Dual ISH image analysis algorithm (CE-IVD) for breast cancer is pathologist-trained to provide an actionable assessment of scanned slide images that are objective and reproducible.

Validated on VENTANA HER2 Dual ISH DNA Probe Cocktail, for use within Roche uPath enterprise software.

### **uPath HER2 Dual ISH image analysis, Breast Sell Sheet CE-IVD (v1.0):**

- Support for your findings with pathologist trained decision support software
- Diagnostic confidence in our widely adopted breast cancer portfolio with proven clinical utility
- Integrated convenience with seamless viewing, aligning and syncing functionality, sharing capabilities, and reporting
- Efficient and easy-to-use with quick automated scoring

### **Making even the toughest calls easier**

The emerging era of immunotherapy demands more complex assays – and so our journey to innovate breast cancer diagnostics continues.

As we pursue an end-to-end solution for cancer diagnostics, Roche is moving powerful tools that were traditionally available only for research into clinical practice. This means new capabilities and increased confidence for you, and new hope for patients around the world who are counting on us to continually reimagine breast cancer care.

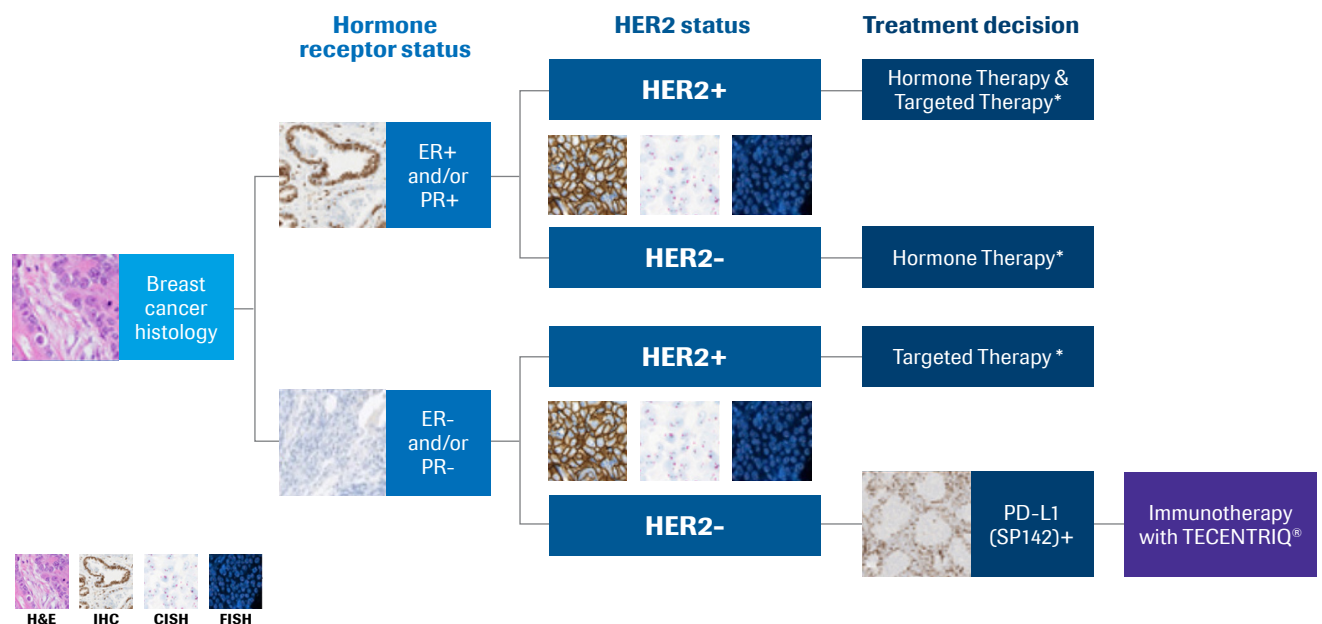


## Pathology assessments play a critical role in breast cancer management



*Breast cancer management is complex and biomarkers play an integral role in determining the status of the tumor. IHC and ISH biomarkers help facilitate decision-making for subsequent therapeutic options.<sup>5,6,7</sup>*

**Biomarker results (ER, PR, HER2, PD-L1) help predict the efficacy of hormone therapies and targeted therapies<sup>4</sup>**



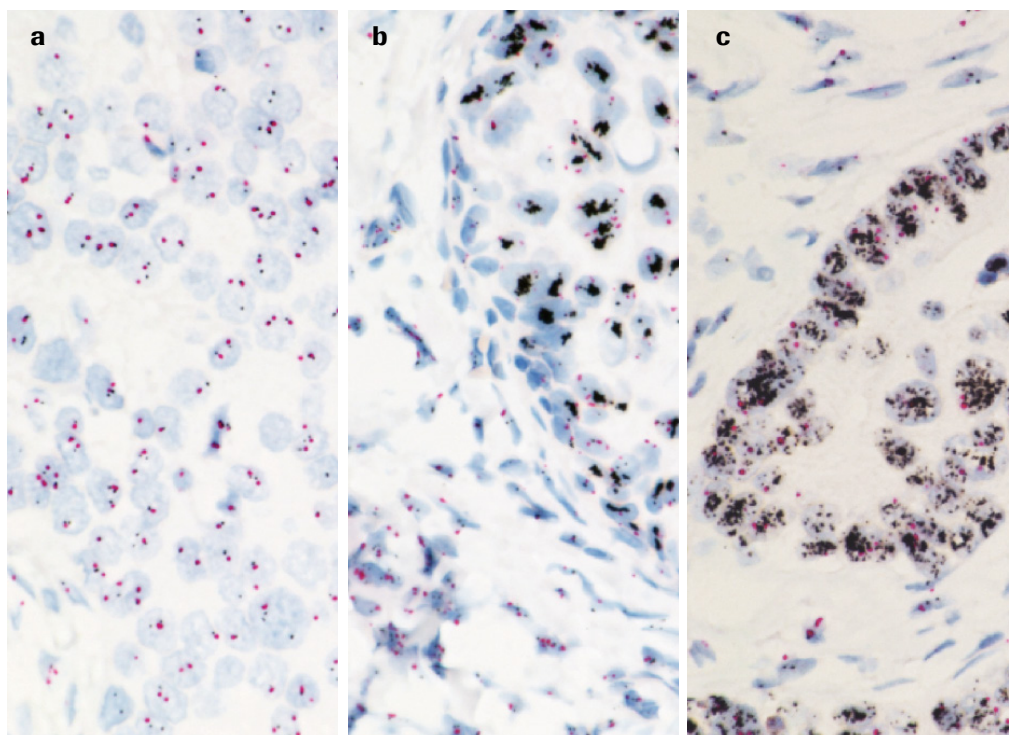
Source: Diagram is developed based on NCCN Guidelines for Patients, Invasive Breast Cancer, Version 1, 2018.<sup>4</sup>

\* Targeted Therapy can include chemotherapy with trastuzumab for HER2 positive patients: Hormone Therapy is for ER and/or PR positive patients

## Optimized with new oligo probes, the VENTANA HER2 Dual ISH assay delivers clear, confident reads

### Staining Characteristics:

Tissue stained with VENTANA HER2 Dual ISH DNA Probe Cocktail. **(a)** Breast carcinoma, 60X, Single copy HER2, non-amplified. **(b)** Breast carcinoma, 60X, HER2 clusters, amplified. **(c)** Gastric carcinoma, 60X, HER2 clusters, amplified. More information can be found in the Interpretation Guide for VENTANA HER2 Dual ISH DNA Probe Cocktail assay; Staining for Breast and Gastric Carcinoma<sup>8</sup>.



The new VENTANA HER2 Dual ISH DNA Probe Cocktail is a fully automated, ready-to-use brightfield solution for determining *HER2* gene status. VENTANA HER2 Dual ISH assay helps identify breast and gastric cancer patients eligible for treatment with HER2-targeted personalized therapies.

### Increased performance

- Oligo probes and new detection kits
- High first pass rates<sup>3</sup>

### Easily interpreted using brightfield microscopy<sup>8</sup>

- Allows for interpretation within the context of tissue morphology
- Identifies tumor heterogeneity
- Produces an archivable result

### Robust and reproducible

- Highly concordant with FISH<sup>3</sup>
- Highly reproducible between laboratories and pathologists<sup>3</sup>

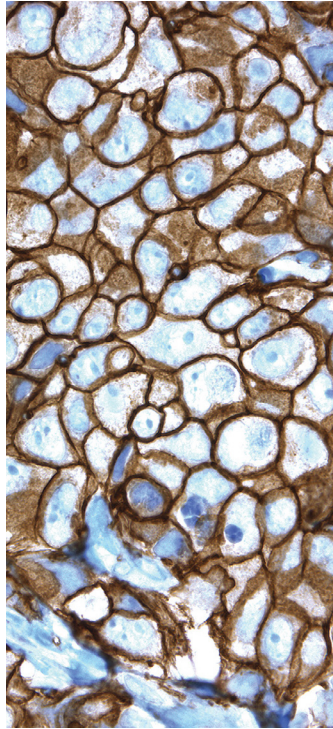
### Diagnostic confidence

- Fully automated solution with fast turnaround time
- Widely adopted breast cancer portfolio with high clinical utility



## PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody

*In a publication assessing the socioeconomic impact of inaccurate HER2 breast cancer testing, laboratory-developed in vitro diagnostics (IVD) were compared to U.S. Food and Drug Administration-approved IVD. The authors found a cost benefit in using an approved IVD test.<sup>9</sup>*

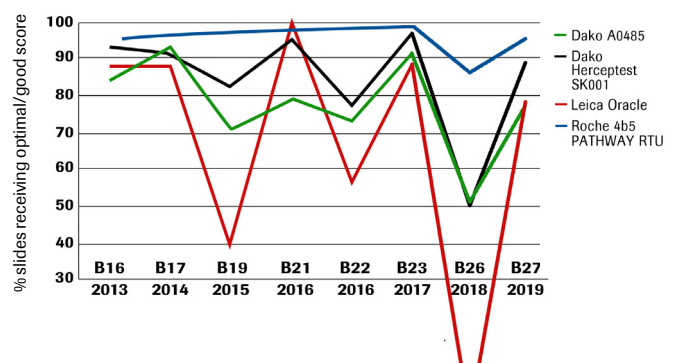


The use of pre-diluted PATHWAY HER2 (4B5), in combination with the fully automated VENTANA BenchMark IHC/ISH slide staining instrument, standardizes all IHC processes from baking through staining, and reduces the possibility of human error.<sup>10</sup> It also minimizes inherent variability resulting from individual reagent dilution and other processes found in manual and semi-automated IHC methods.

### The PATHWAY HER2 (4B5) Primary Antibody empowers you to:

- Achieve consistently high proficiency assessment scores with HER2 (4B5) antibody, compared to other clones<sup>11</sup>
- Employ the most widely adopted and reliable HER2-IHC primary antibody<sup>11</sup>
- Demonstrate high concordance with HER2 FISH<sup>12,13</sup>

### HER2 (4B5): Consistent high performance\*

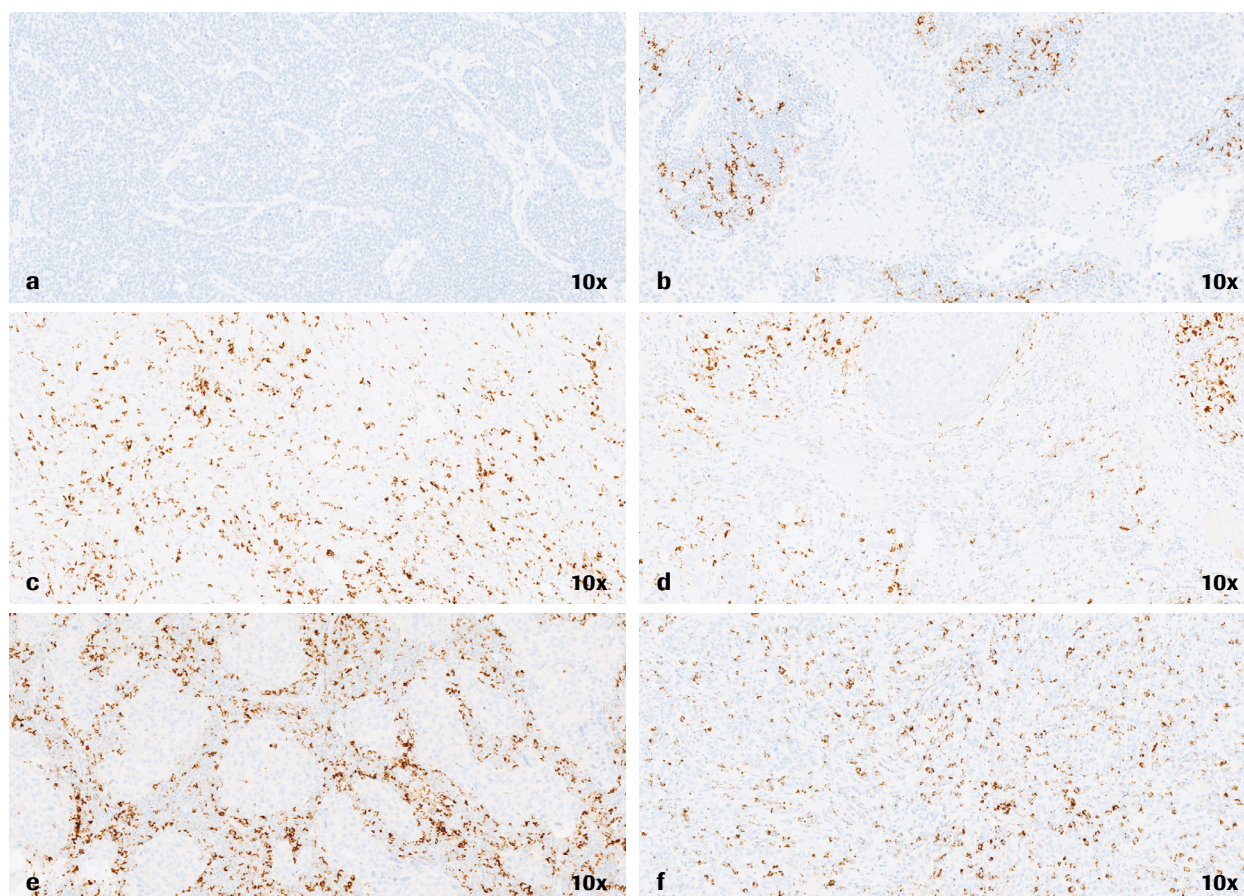


*HER2 (4B5) Antibody\* has shown the most consistent performance and superior quality when compared to other on-market HER2 clones\*\**

\* Data refers to PATHWAY and VENTANA products.

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

## VENTANA PD-L1 (SP142) Assay



**TNBC tissue stained with the VENTANA PD-L1 (SP142) Assay.** Immune cells often show dark brown punctate or linear staining. Occasionally, circumferential immune cell (IC) membrane staining is also observed, especially in cells that are morphologically consistent with macrophages and/or dendritic cells. (a) TNBC tissue with PD-L1 expression <1% in IC by the VENTANA PD-L1 (SP142) Assay; (b), (c), (d), (e), (f) TNBC tissue with PD-L1 expression of  $\geq 1\%$  IC by the VENTANA PD-L1 (SP142) Assay.

The VENTANA PD-L1 (SP142) Assay is the first FDA approved and CE-IVD marked companion diagnostic to evaluate patient PD-L1 expression using tumor-infiltrating immune cell staining and scoring within the tumor microenvironment, providing pathologists and multidisciplinary teams with relevant information needed to guide TECENTRIQ® + nab paclitaxel treatment decisions in metastatic TNBC.<sup>14,15</sup>

### **The power of immune cell staining and scoring**

Above are triple-negative breast cancer reference images using assessment of PD-L1 expression in tumor-infiltrating immune cells.



## World-class antibodies to stratify breast cancer

Product name	Catalog number	Ordering code	Quantity
CA-125 (OC125) Mouse Monoclonal Antibody	760-2610	05267269001	50 tests
Calponin-1 (EP798Y) Rabbit Monoclonal Antibody	760-4376	05435684001	50 tests
E-cadherin (36) Mouse Monoclonal Primary Antibody, VENTANA	790-4497	05905290001	50 tests
E-cadherin (EP700Y) Antibody	760-4440	05973872001	50 tests
Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody, CONFIRM	760-4324	05278406001	50 tests
Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody, CONFIRM	790-4325	05278414001	250 tests
FOXA1(2F83) Mouse Monoclonal Primary Antibody	760-4937	07292848001	50 tests
GATA3 (L50-823) Mouse Monoclonal Primary Antibody	760-4897	07107749001	50 tests
GCDFP-15 (EP1582Y) Rabbit Monoclonal Antibody	760-4386	05463530001	50 tests
GLIAL Fibrillary Acidic Protein (EP672Y) Rabbit Monoclonal Antibody	760-4345	05269784001	50 tests
Growth Hormone (polyclonal)	760-2804	05268257001	50 tests
Human Placental Lactogen (hPL) (polyclonal)	760-4443	05973830001	50 tests
HER2 Dual ISH DNA Probe Cocktail, VENTANA	800-6043	08314373001	30 tests
HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody, VENTANA	790-4493	05999570001	50 tests
HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody, PATHWAY	790-2991	05278368001	50 tests
Ki-67 (30-9) Rabbit Monoclonal Primary Antibody, CONFIRM	790-4286	05278384001	50 tests
Mammaglobin (31A5) Rabbit Monoclonal Antibody	760-4263	05269253001	50 tests
P53 (BP53-11) Primary Antibody	760-2542	05267102001	50 tests
P53 (DO-7) Primary Antibody, CONFIRM	800-2912	05278775001	50 tests
P57 (Kp10) Mouse Monoclonal Primary Antibody	760-4617	06523897001	50 tests
p63 (4A4) Mouse Monoclonal Primary Antibody, VENTANA	790-4509	05867061001	50 tests
P120 CATENIN (98) Mouse Monoclonal Primary Antibody, VENTANA	790-4517	05867088001	50 tests
PAX8 (MRQ-50) Mouse Monoclonal Primary Antibody	741-4860	08008540001	50 tests
PD-L1 (SP142) Assay, VENTANA	740-4859	07709374001	50 tests
PLAP (NB10)	760-2664	05267757001	50 tests
Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody	790-2223	05277990001	50 tests
Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody	790-4296	05278392001	250 tests
PTEN (SP218) Rabbit Monoclonal Primary Antibody	790-5097	07970200001	50 tests
Topoisomerase II $\alpha$ (JS5B4) Rabbit Monoclonal Primary Antibody	790-4371	0547933900	50 tests

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