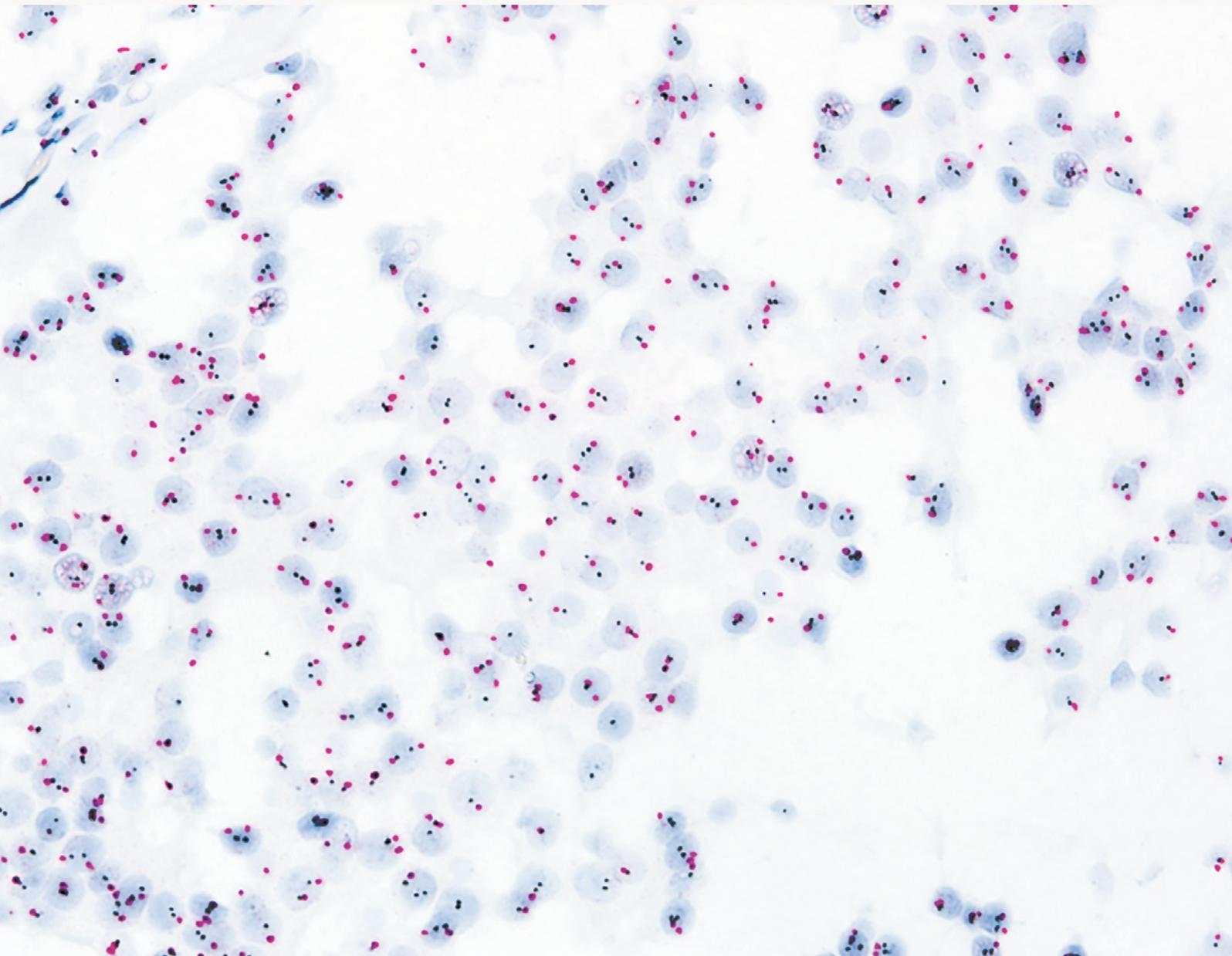
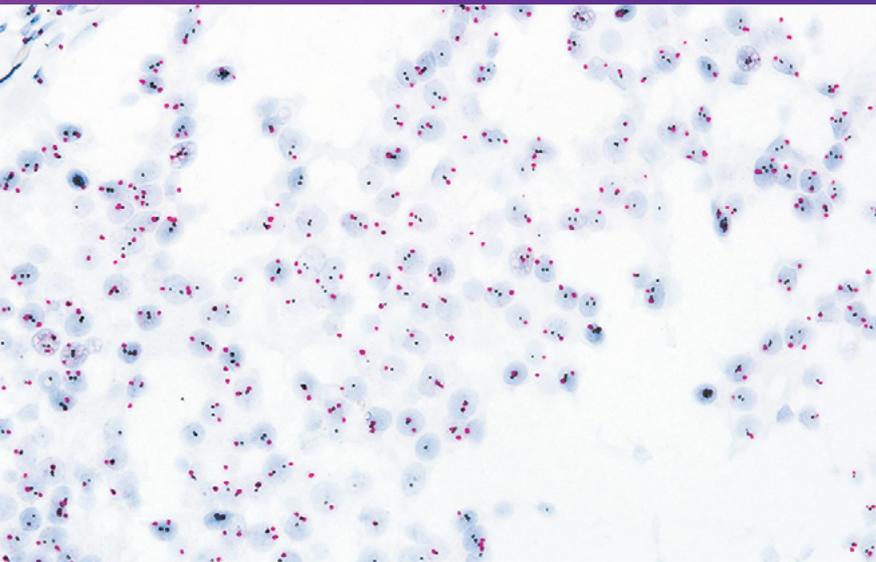


# Breast cancer diagnostic portfolio

Driving diagnostic for decisions in  
pathology



# 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 answers to the patients who rely on you. The solution to support you in making precise, personalised treatment has never been clearer.

---

## Broadening possibilities for traditional cancer treatment

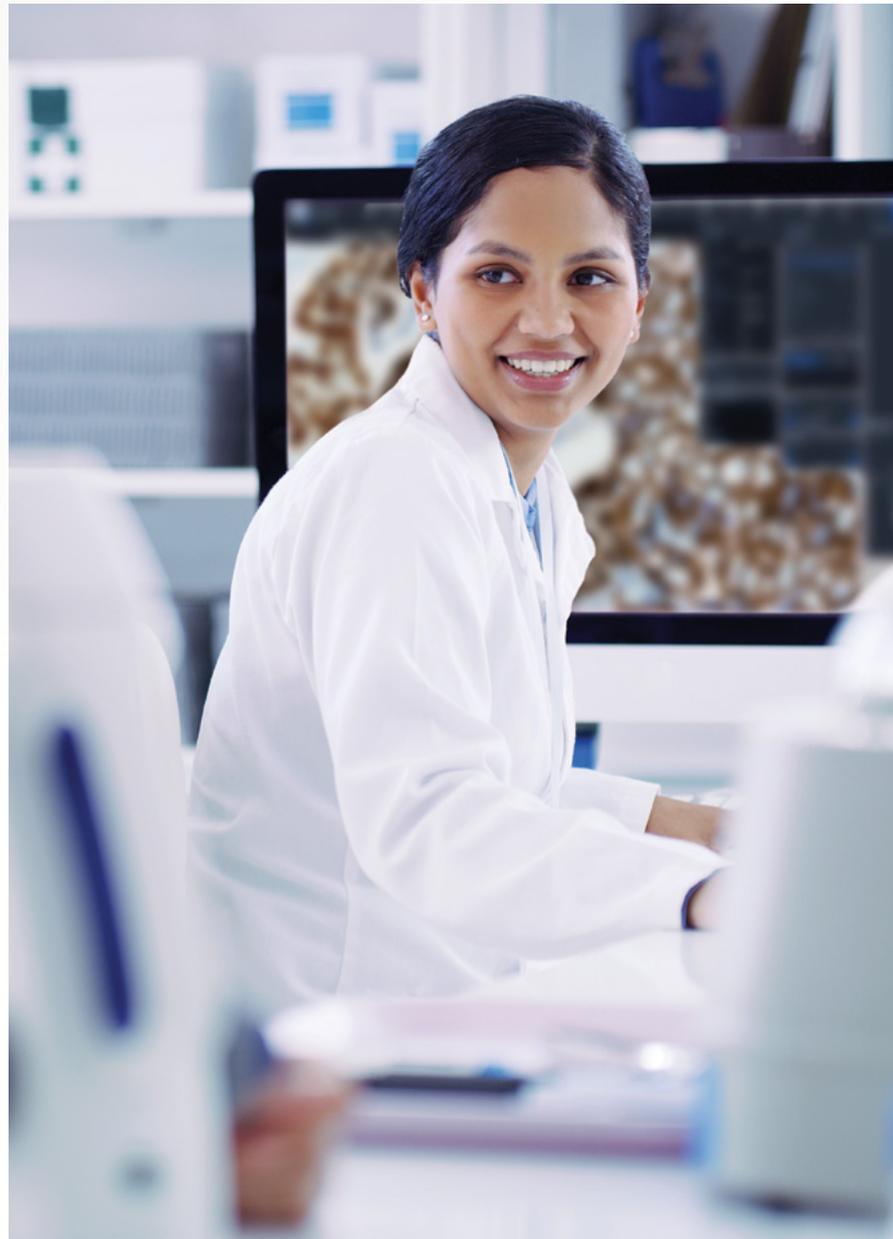
Early detection, innovative testing, and new therapies are helping strike a powerful blow against this disease. From 1989 to 2016, the number of breast cancer-related deaths dropped by 40%.<sup>2</sup> We celebrate the progress we have made, but we still have work to do. Breast cancer continues to claim 685,000 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 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 comprehensibility to the most complex disease pathways.

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



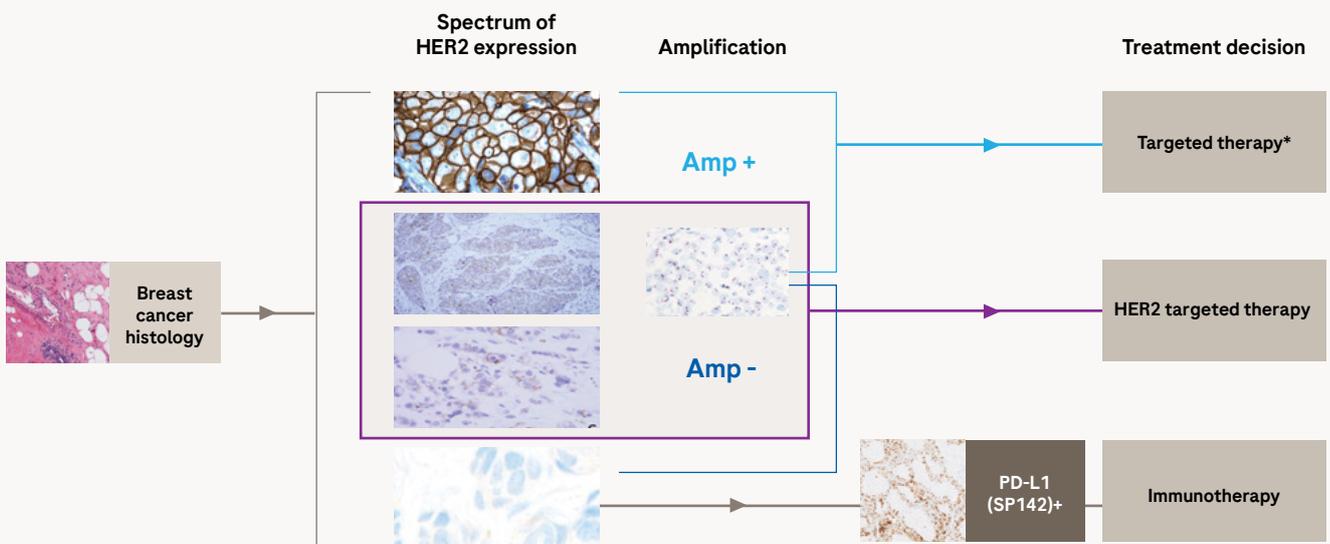
**Breast cancer accounts for about 1 in 4 cancer cases in women, affecting ~2.1 million people globally on a yearly basis.<sup>1</sup>**

# 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 tumour. IHC and ISH biomarkers help facilitate decision-making for subsequent therapeutic options.<sup>5,6,7</sup>



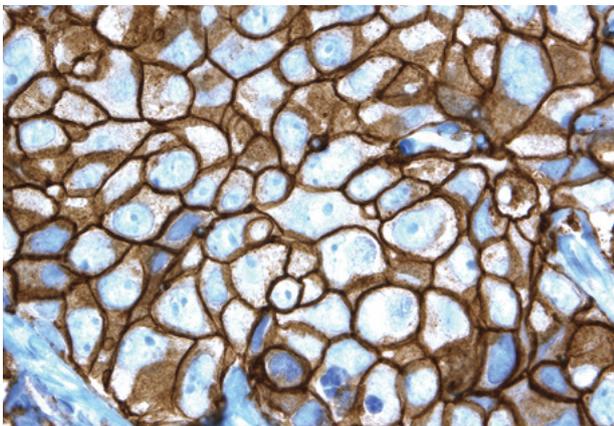
## Biomarker results (HER2, PD-L1) help predict the efficacy of targeted therapies\*



Source: Diagram is developed based on NCCN Guidelines for Patients, Invasive Breast Cancer, Version 1, 2018.4

\*Targeted therapies could include examples like, trastuzumab or pertuzumab for HER2 positive patients. Hormone therapies and several other potential breast cancer therapies are not illustrated here.

# VENTANA® anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody

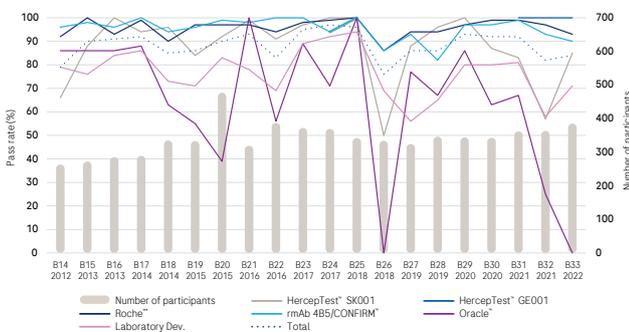


In a publication assessing the socioeconomic impact of inaccurate HER2 breast cancer testing, laboratory-developed tests (LDT) were compared to U.S. Food and Drug Administration approved in vitro diagnostics (IVD). The authors found a cost benefit in using an approved IVD test.<sup>9</sup>

The use of pre-diluted Roche HER2 (4B5), in combination with the fully automated VENTANA BenchMark IHC/ISH slide staining instrument, standardises all IHC processes from baking through staining, and reduces the possibility of human error.<sup>10</sup>

It also minimises inherent variability resulting from individual reagent dilution and other processes found in manual and semi-automated IHC methods.

**Pass rates\* of the HER2 IHC assessments in the NordiQC breast cancer module 2012-2022**



**The Roche HER2 (4B5) 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>

Roche HER2 (4B5) antibody\*\*\* has shown consistent performance and quality according to the data from NordiQC†

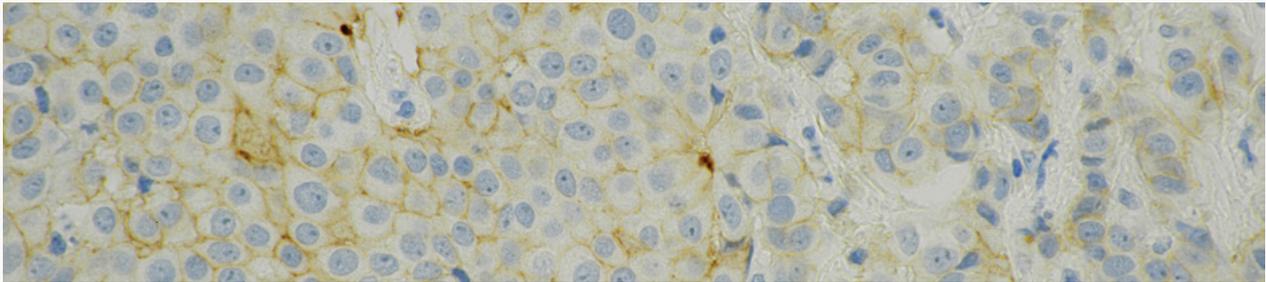
\* Pass rates using vendor recommended protocol changes

\*\* Roche HER2 (4B5) assay refers to PATHWAY® anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody and VENTANA anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody

\*\*\* 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>. Accessed on 20 February 2024.

# VENTANA® HER2 (4B5) Rabbit Monoclonal Antibody RxDx



## Alternative for lower expression

CE-marked as a companion diagnostic for HER2 targeted therapy VENTANA HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx is the **test to identify metastatic breast cancer (mBC) patients with low levels of HER2 expression** who may be eligible for targeted treatment.<sup>14</sup> Prior to the approval of HER2 targeted therapy in HER2-low mBC, this group of patients – who comprise approximately half of all patients with breast cancer – did not qualify for HER2-directed therapy.

VENTANA HER2 (4B5) Rabbit Monoclonal Antibody RxDx builds on the **same proven technology** of Roche's widely adopted HER (4B5) test,\* expanding on its clinical utility to help match even more women with highly effective personalised therapies.

- The HER2-low indication uses a lower scoring cut-off, allowing patient stratification within what was previously considered a HER2-negative population
- Indicated as an aid in the assessment of patients with HER2-low status for whom HER2 low targeted therapy is being considered as a treatment option<sup>14</sup>

# Reimagining HER2 testing



## Our mission compels us to optimize our tools

To us, innovation means more than developing new products. We also seek opportunities to enhance technology we have on market today – because the diagnostic tools are critical to help improve patient outcomes.

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

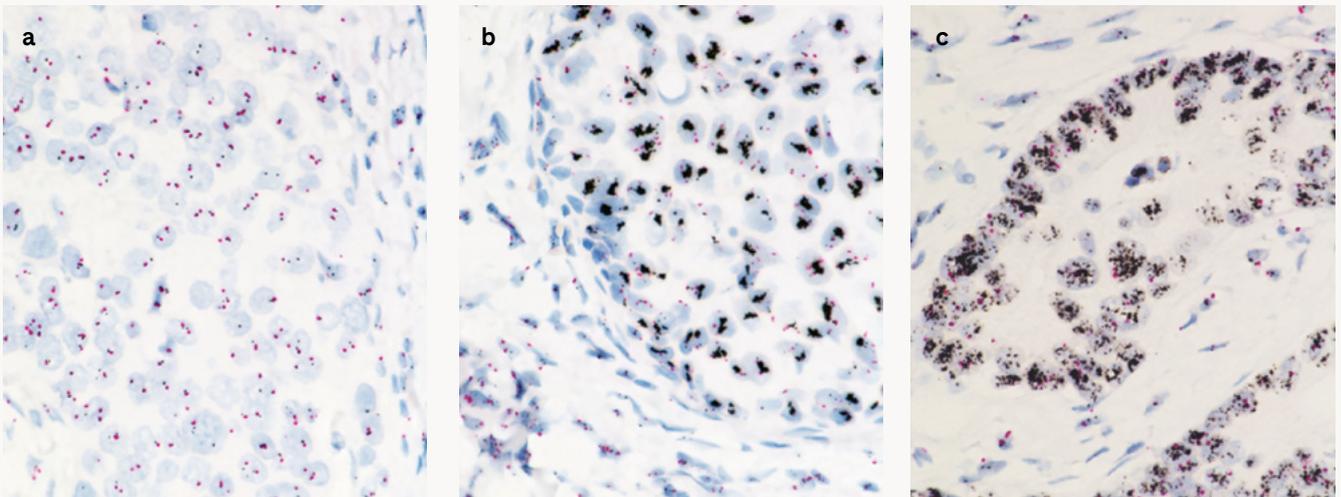
### **The VENTANA HER2 Dual ISH DNA Probe Cocktail is the choice to navigate breast cancer's complexity**

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 VENTANA HER2 Dual ISH assay delivers:**

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

# Optimised with oligo probes, the VENTANA<sup>®</sup> HER2 Dual ISH assay delivers clear 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>9</sup>

The 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 personalised 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 tumour heterogeneity
- Produces an archivable result

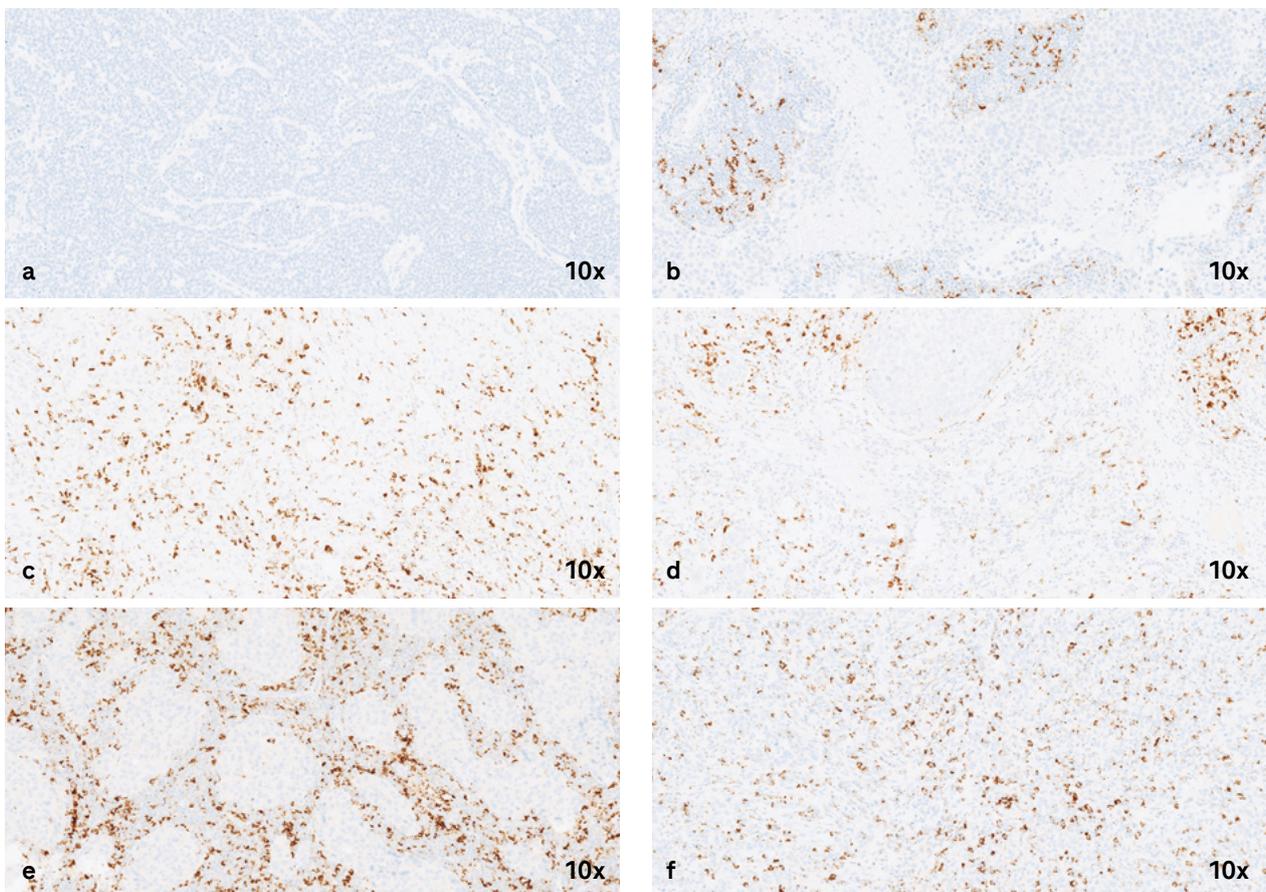
#### Robust and reproducible

- Concordant with FISH<sup>3</sup>
- Reproducible between laboratories and pathologists<sup>3</sup>

#### Diagnostic

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

# VENTANA® PD-L1 (SP142) Assay for triple-negative breast cancer (TNBC)



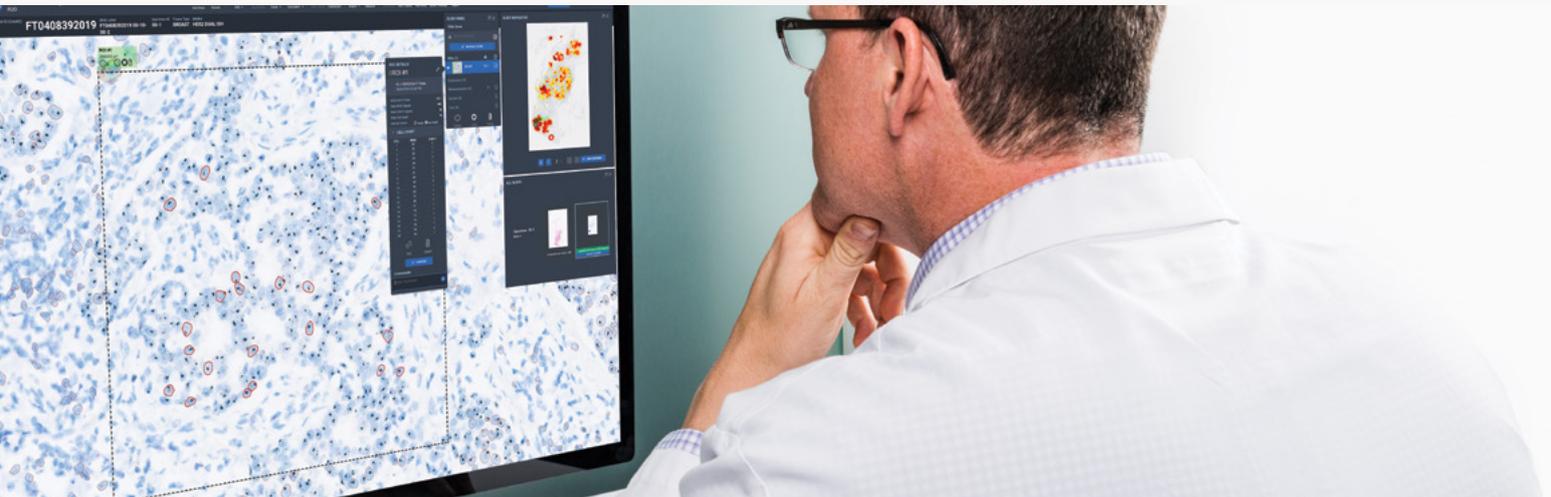
**TNBC tissue stained with the VENTANA PD-L1 (SP142) Assay.** Immune cells often show dark brown punctate or linear staining. Occasionally, circumferential immune cell (IC) membrane staining is also observed, especially in cells that are morphologically consistent with macrophages and/or dendritic cells. **(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 ≥1% IC by the VENTANA PD-L1 (SP142) Assay.

The VENTANA PD-L1 (SP142) Assay is the FDA approved and CE-IVD marked companion diagnostic to evaluate patient PD-L1 expression using tumour-infiltrating immune cell staining and scoring within the tumour microenvironment, providing pathologists and multidisciplinary teams with relevant information needed to guide treatment decisions in metastatic TNBC.<sup>15, 16</sup>

### The power of immune cell staining and scoring

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

# Empowering 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, 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**

- Support for your findings with pathologist trained decision support software
- Diagnostic 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

## Breast Cancer Care

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 for you, and new alternative for patients around the world who are counting on us to continually reimagine breast cancer care.

# Variety antibodies to stratify breast cancer

**A diagnostic solution now with expanded utility to identify patients with HER2-low status**

## Ordering information

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
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
HER2 Dual ISH DNA Probe Cocktail, VENTANA	800-6043	08314373001	30 tests
anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody, VENTANA •	790-4493	05999570001	50 tests
HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx, VENTANA •	790-7167	09670564001	50 tests
HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx, VENTANA •	744-7213	09846263001	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

- CE marked, includes additional ENHERTU/HER2-low labeling
- No CE mark, includes additional ENHERTU/HER2-low labeling
- CE marked, but no ENHERTU/HER2-low labeling

---

## References

- 1 Bray F, et al. Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA: Cancer J Clin. 2018;68:394-424.
- 2 World Health Organization. Breast cancer: Fact sheet. [Internet; cited 2022 Feb 6]. Available from: <https://www.who.int/news-room/fact-sheets/detail/breast-cancer>.
- 3 VENTANA HER2 Dual ISH DNA Probe Cocktail Package Insert. Data on File. 20 February 2024.
- 4 <https://www.nccn.org/patientresources/patientresources/guidelines-for-patients/guidelines-for-patients-details?patientGuidelineId=16>. Accessed November 29, 2023.
- 5 Parker JS, Mullins M, Cheang M, et al. Supervised risk predictor of breast cancer based on intrinsic subtypes. J Clin Oncol. 2009;27(8):1160-1167.
- 6 Purrington KS, Visscher DW, Wang C. Genes associated with histopathologic features of triple negative breast tumors predict molecular subtypes. Breast Cancer Res Treat. 2016. [Epub ahead of print] doi: 10.1007/s10549-016-3775-2.
- 7 Wolff AC, Hicks D, Hammond E. Recommendations for Human Epidermal Growth Factor Receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update. J Clin Oncol. 2013;31(31):3997-4013.
- 8 Interpretation Guide for VENTANA HER2 Dual ISH DNA Probe Cocktail assay. Staining for Breast and Gastric Carcinoma.
- 9 Vyberg M, Nielsen S, Røge R, et al. Immunohistochemical expression of HER2 in breast cancer: Socioeconomic impact of inaccurate tests. BMC Health Services Research. 2015;15:352.
- 10 VENTANA anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody Package Insert.
- 11 NordiQC Assessments. Available from: <https://www.nordiqc.org/epitope.php?id=11>. Accessed November 29, 2023.
- 12 Mayr D, et al. Comprehensive immunohistochemical analysis of Her-2/neu oncoprotein overexpression in breast cancer: Hercep Test\* (Dako) for manual testing and Her-2/neuTest 4B5 (VENTANA) for VENTANA BenchMark automatic staining system with correlation to results of BenchMark automatic staining system with correlation to results of fluorescence in situ hybridization (FISH). Virchows Arch. 2009; 454(3):241-248.
- 13 Brüggemann A, Leikaitis G, Nielsen S, et al. Testing HER2 in breast cancer: a comparative study on BRISH, FISH, and IHC. Appl Immunohistochem Mol Morphol. 2011;19(3):203-211.
- 14 VENTANA HER2 (4B5) Rabbit Monoclonal Primary Antibody RxDx Package Insert, 2023.
- 15 Schmid P, et al. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. N Engl J Med. 2018 Nov 29;379(22):2108-2121.
- 16 VENTANA PD-L1 (SP142) Assay Package Insert, Data on File. 20 February 2024.

**คำเตือน โฆษณาโดยตรงต่อผู้ประกอบวิชาชีพทางการแพทย์และ  
สาธารณสุข ที่ได้รับการยกเว้นโดยไม่ต้องขออนุญาต**

**กรุณาอ่านคำเตือนในฉลากและเอกสาร  
กำกับเครื่องมือแพทย์ก่อนใช้**

Published by:  
Roche Diagnostics (Thailand) Co., Ltd  
18-19th Floor, Rasa Tower Building  
555 Paholyothin Rd, Chatuchak, Bangkok 10900  
Thailand

MC-TH-01111  
AN 6800243  
Valid Till 25/02/2027

---

VENTANA, BENCHMARK, CONFIRM, OPTIVIEW, PATHWAY and UPATH are trademarks of Roche.  
All other trademarks are the property of their respective owners.

© 2024 Roche  
MC-13358

[diagnostics.roche.com](https://diagnostics.roche.com)

---