TISSUE DIAGNOSTICS
VENTANA HER2 DUAL ISH ASSAY

Roche

BUILT FOR YOU. **BUILT FOR HER.**

VENTANA HER2 Dual ISH DNA Probe Cocktail assay

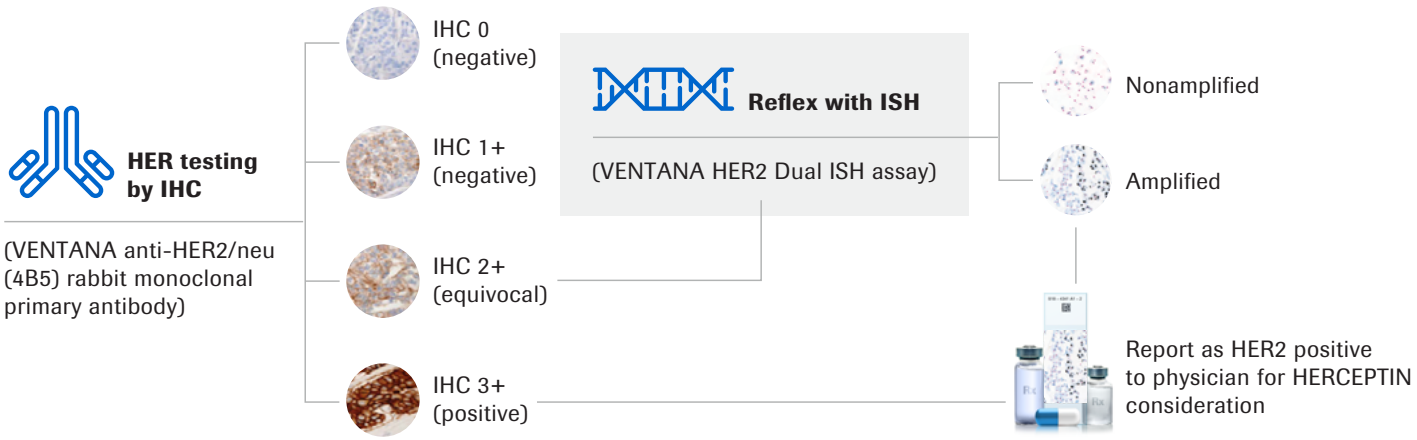
The VENTANA HER2 Dual ISH assay is a fully automated, ready-to-use brightfield solution for determining HER2 gene amplification.

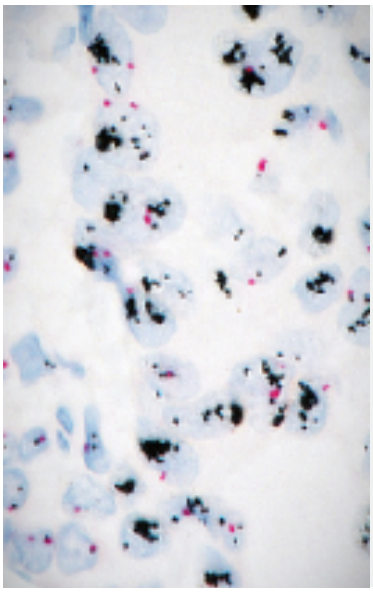
Designed with input from pathologists and lab professionals, this enhanced assay delivers robust and reproducible staining that can be performed in-house, **giving your lab the ability to deliver results fast to oncologists and their patients.**

VENTANA HER2 Dual ISH is available for use on the BenchMark ULTRA instrument and helps identify breast cancer patients eligible for treatment with HERCEPTIN® (trastuzumab).

Guideline recommendations for HER2 testing

Multiple guidelines, including NCCN and CAP/ASCO, recommend FDA-approved in situ hybridization (ISH) reflex testing for equivocal (+2) HER2 IHC staining results.





Why brightfield is better

Highly concordant with FISH and offers key benefits to the laboratory

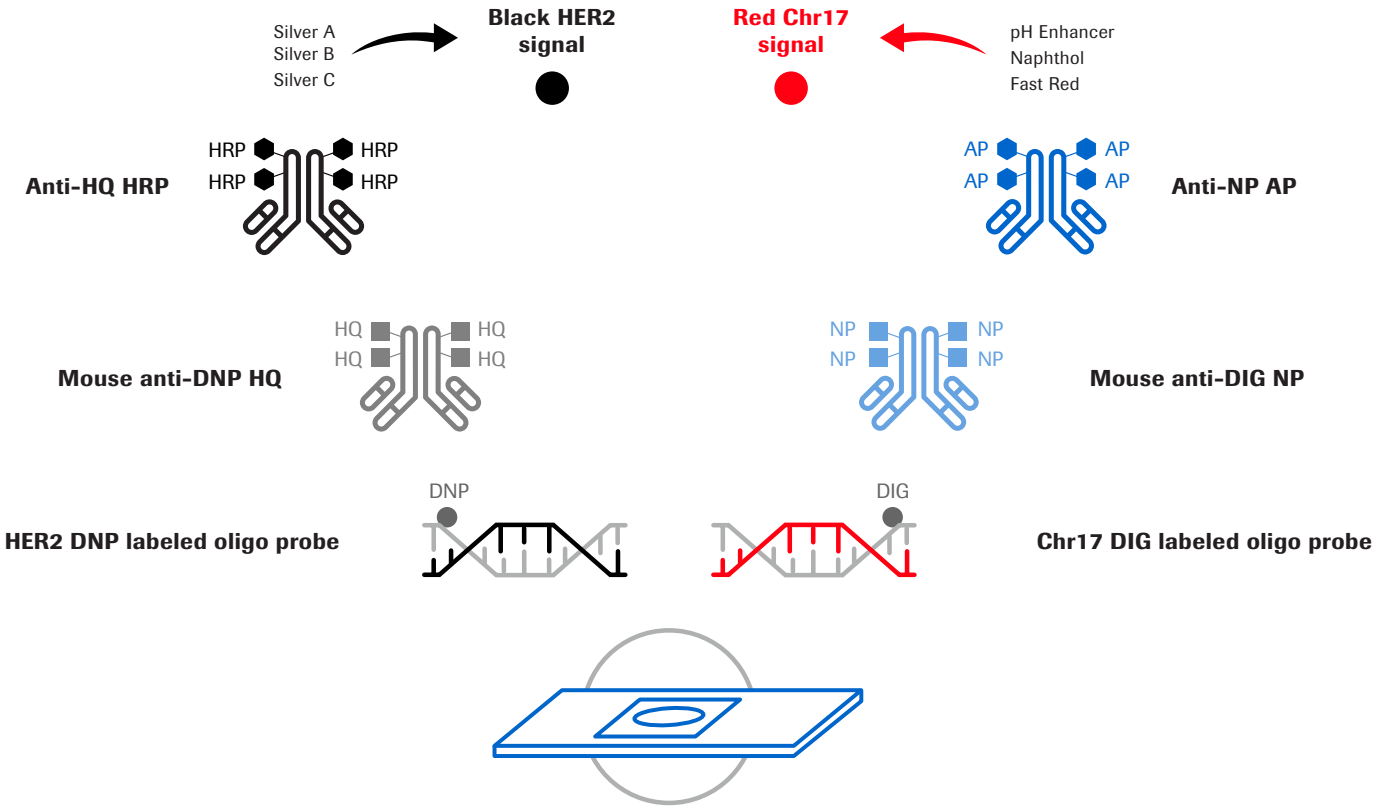
- Fits into pathologist's regular workflow at brightfield scope
- No need for fluorescent microscope/oil and darkroom
- Allows for view of entire tissue specimen, providing critical context of tissue architecture and morphology
- No interference from tissue autofluorescence or tissue marking dyes
- Produces archivable results
- Able to be read alongside other breast panel markers for easy comparison and correlation of findings
- Can be performed in-house, reducing time to diagnosis

Figure 1: Example case for primary use of IHC to determine HER2 status

Source: Diagram based on NCCN Guidelines for Invasive Breast Cancer Version 5, 2020.

High sensitivity and specificity

The VENTANA HER2 Dual ISH assay's probe design and anti-hapten detection kits produce an enhanced target retrieval system that enables recovery of more targets across a wider range of tissue preanalytical conditions.

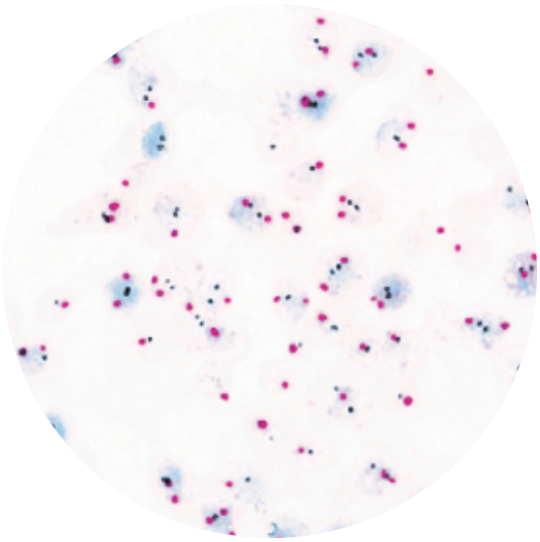


Robust, reproducible staining

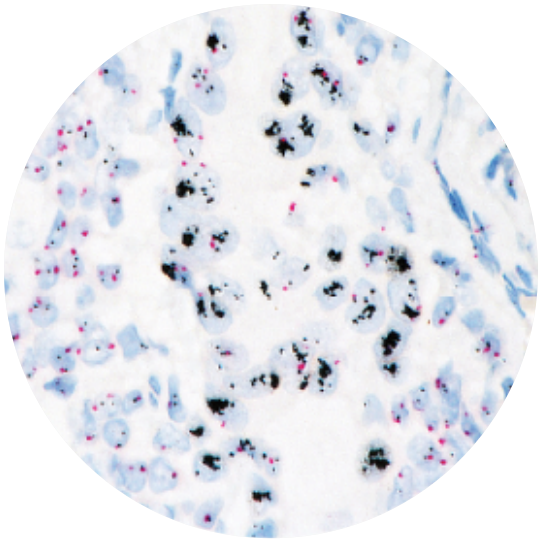
VENTANA HER2 Dual ISH assay can provide pathologists clear, confident results

- Unparalleled signal intensity without non-specific background
- 99.5% overall agreement in interlaboratory reproducibility

**Breast carcinoma, 60X,
Single copy HER2, nonamplified**



**Breast carcinoma, 60X,
HER2 clusters, amplified**



Fast turnaround

With VENTANA HER2 Dual ISH assay, every lab has the ability to run testing in-house, speeding the time to diagnosis.

VENTANA HER2 Dual ISH DNA Probe Cocktail dispenser

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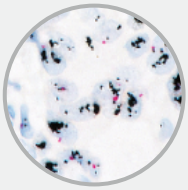
VENTANA Silver ISH **DNP** Detection Kit

VENTANA Red ISH **DIG** Detection Kit

+

BenchMark IHC/ ISH instruments



Interpretation guide

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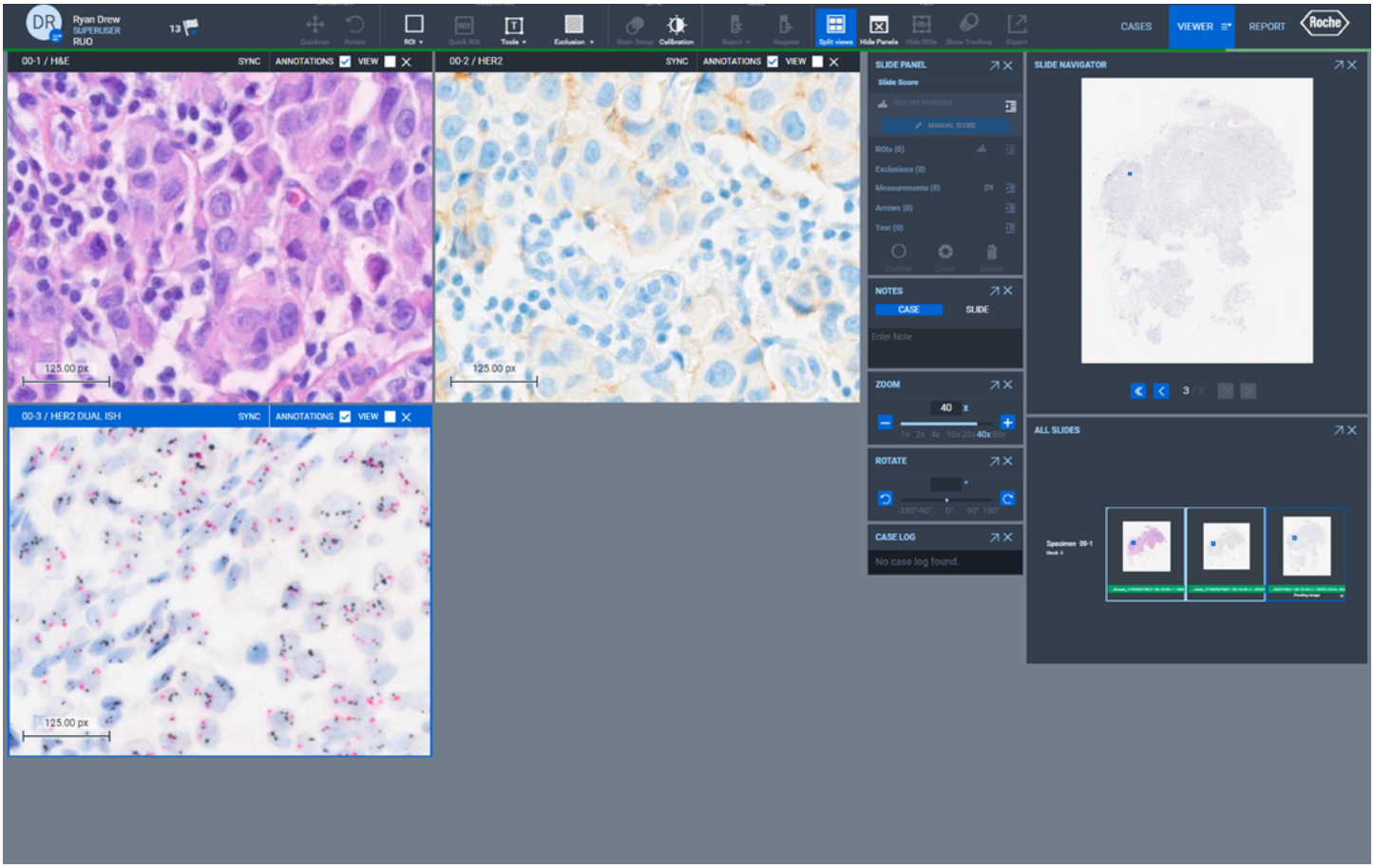
The fully automated protocol run on the BenchMark ULTRA instrument **enables same day results,* allowing patients to receive the right treatment as quickly as possible.**

*Approved protocol run time is <9 hours.

Whole slide imaging

Within a digital platform or under a microscope, the VENTANA HER2 Dual ISH assay allows for view of the entire tissue specimen.

- Identify areas of heterogeneity
- View tissue architecture and morphology in context
- Read alongside other breast markers for easy comparison and correlation of findings



New VENTANA HER2 Dual ISH assay
Built for you. Built for her.

VENTANA HER2 Dual ISH—a fully automated, ready-to-use brightfield solution that is highly concordant with FISH

Faster turnaround time

- Fully automated protocol runs in under 9 hours on the BenchMark ULTRA

High sensitivity and specificity

- Probe design and anti-hapten detection kits produce enhanced target retrieval system

Provides pathologists clear, confident reads

- Unparalleled signal intensity without non-specific background
- 99.5% overall agreement in interlaboratory reproducibility

Allows for view of entire tissue specimen

- Provides critical context of tissue architecture and morphology

Consider VENTANA HER2 Dual ISH for your laboratory.

Contact your sales representative or visit go.roche.com/H2DI for more information.

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