FOUNDATION MEDICINE®

AVAILABLE FROM FOUNDATION MEDICINE

HER2 IHC Testing

Foundation Medicine offers select types of **immunohistochemistry (IHC) testing to complement our portfolio of comprehensive genomic profiling (CGP) tests** for clinical customers. HER2 IHC can detect the presence of HER2 over-expression in tumor cells and identify patients who would benefit from a HER2-targeted therapy, helping to guide treatment decisions.

The FDA granted accelerated approval to **Enhertu® (trastuzumab deruxtecan)** as the **first antibody-drug conjugate** (ADC) with a **tumor-agnostic indication** for previously treated adults with unresectable or metastatic HER2-positive solid tumors.[1] This indication expands treatment options for cancer patients across multiple disease areas. Foundation Medicine recognizes the importance of having HER2 IHC testing and has added it to our test menu—so that you can continue to have the right information for your patients' care.

HER2 testing can be ordered for breast, gastroesophageal, and biliary tract cancer as well as for any other solid tumor. Of note, for a HER2 IHC score of 2+ in breast and gastroesophageal cancer, HER2 *in situ* (ISH) hybridization testing is reflexively performed per professional society guidelines.

The HER2 IHC test uses the **Ventana PATHWAY HER2 assay**; although not a CDx for this pan tumor indication, the Ventana PATHWAY HER2 assay can identify patients with HER2 overexpression, to better inform provider decision-making.

In **addition to HER2 IHC**, Foundation Medicine's **tests are comprehensive**.

Foundation Medicine has the **most FDA-approved pan tumor companion diagnostic (CDx) indications** on the market, so you can feel more confident that your therapy selection will be safe and effective for your advanced cancer patients[2]

With its tissue and liquid assays, Foundation Medicine **detects all guideline-recommended genes and/or biomarkers across multiple tumor types**, including NSCLC, prostate cancer, and breast cancer to aid in treatment decisions[*§‡]

HER2 over-expression can occur in many different types of solid tumors, including: breast, lung, gastric, endometrial, cervical, ovarian, bladder, and others. HER2 positivity can inform therapy selection for multiple drugs, too, beyond trastuzumab deruxtecan.[†] **Some therapies include:**

Trastuzumab:
Herceptin® (IV drug) and Herceptin Hylecta™ (injection)

Pertuzumab:
Perjeta® (IV drug) and Phesgo® (injection combined with trastuzumab)

Tucatinib, Lapatinib, Neratinib:
Tukysa®, Tykerb® and Tyverb®, and Nerlynx®
are small-molecule tyrosine kinase inhibitors (TKIs)

Ado-trastuzumab emtansine (T-DM1):
Kadcyla® is an antibody-drug conjugate (ADC)
Zanidatamab® (only has approval in biliary tract cancer)

† The Ventana PATHWAY test is not a CDx for these therapies.

Use **HER2 IHC testing** to **identify appropriate therapy options** for your advanced cancer patients.

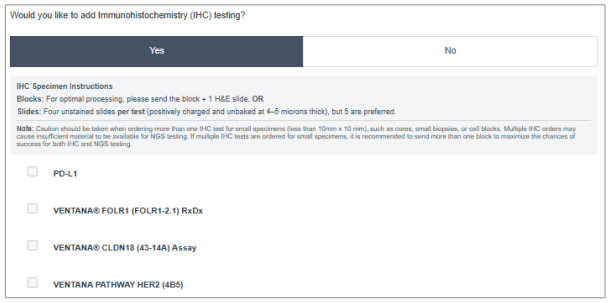
Order HER2 IHC Testing Today

HER2 and FoundationOne®CDx can be ordered together in the Foundation Medicine Online Portal, in select EMRs, or using Foundation Medicine's paper test requisition form. HER2 IHC can also be ordered with our other comprehensive genomic profiling (CGP) tests, as long as the proper tissue samples are submitted.

To order HER2 IHC with FoundationOne®CDx in the **Foundation Medicine Online Portal** or in your **EMR**, please replicate the below:

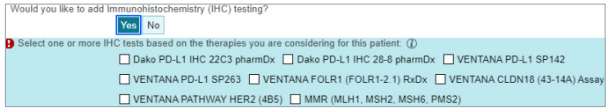
TO ORDER HER2 IHC IN THE FOUNDATION MEDICINE ONLINE PORTAL:

Select HER2 check box.



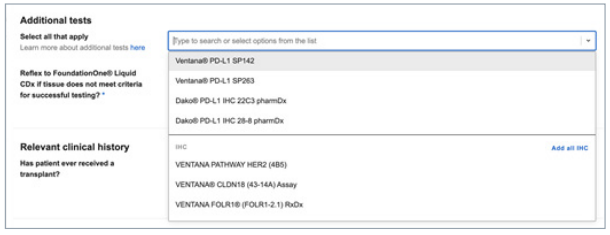
TO ORDER HER2 IHC IN EPIC EMR:

Select HER2 check box.



TO ORDER HER2 IHC IN ONCOEMR:

Select IHC checkbox.



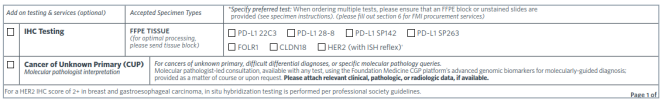
HER2 IHC CAN BE ORDERED IN OTHER EMRs IF THERE IS A FREE TEXT FIELD.

To order, add HER2 IHC into the free text field.

To order HER2 IHC with FoundationOne®CDx using **Foundation Medicine's Test Requisition Form**:

Select HER2 in IHC testing section.

IHC TESTING FOR HER2



Interested in **adding** HER2 IHC to a **prior** FoundationOne®CDx test?

Contact your Foundation Medicine Customer Experience Executive or our Client Services team at 888.988.3639 or by email at client.services@foundationmedicine.com.

SAMPLE REQUIREMENTS FOR HER2 IHC TESTING

The following is required for HER2 IHC:

- **Block + H&E; or**
- **4 USS + H&E** in addition to sample requirements for FoundationOne®CDx testing

RECEIVING YOUR HER2 IHC RESULTS

For eference lab workflow: Results will be issued based on OP ordering & reporting preferences. IHC results will be integrated into NGS tests.

Questions?

To learn more, visit: https://www.foundationmedicine.com/info/detail/ihc-testing

Contact our Client Services team at 888.988.3639 or by email at client.services@foundationmedicine.com

References

1. National Cancer Institute. https://www.cancer.gov/news-events/cancer-currents-blog/2024/fda-enhertu-her2-positive-solid-tumors. Accessed May 17, 2024.
2. https://www.fda.gov/medical-devices/in-vitro-diagnostics/companion-diagnostics. Accessed May 17, 2024.

§ Based on genomic testing guidelines in advanced breast cancer. Does not include germline or IHC testing.

* Data on File, Foundation Medicine, Inc., October 2023.

‡ Based on somatic genomic testing guidelines in advanced prostate cancer, including 19 HRR genes, MSI/MSI-H, plus 7 clinically relevant biomarkers (TMB, *MSH2, MSH6, PMS2, PTEN, RB1, TP53*).

HER2 (485) IHC is a qualitative immunohistochemical assay using rabbit monoclonal anti-HER2. VENTANA PATHWAY anti-HER-2/neu (4B5) is intended for use in the semi-quantitative detection of HER2 antigen by IHC in sections of formalin-fixed, paraffin-embedded breast carcinoma and/or biliary tract cancer tissue using the ultraView Universal DAB Detection Kit on a BenchMark ULTRA instrument. In addition, the test has been analytically validated for the performance of testing gastric or gastrosophageal (GEJ) adenocarcinoma and other solid tumors, as indicated in Table 2. This product is intended for in vitro diagnostic use. Interpretation is performed in accordance with professional society guidelines. For additional information, refer to the VENTANA PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody Package Insert, #790-2991. The kit for this test has been approved by the U.S. Food and Drug Administration. Performance characteristics were verified by Foundation Medicine, Inc., per Clinical Laboratory Improvement Amendments (CLIA '88) requirements and in accordance with the College of American Pathologists (CAP). For prescription use only.

FoundationOne®CDx is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com

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