FOUNDATION MEDICINE®

Now 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 recently 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.

The HER2 IHC test uses the Ventana PATHWAY HER2 assay; although not a CDx for this pantumor 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 Hereceptin 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)

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

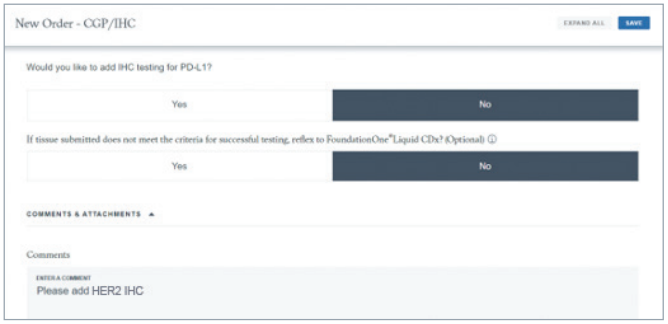
†The Ventana PATHWAY test is not a CDx for these therapies.

Order HER2 IHC Testing Today

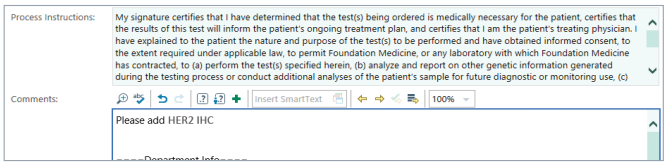
HER2 and FoundationOne®CDx can be ordered together in the Foundation Medicine Online Portal, in select EMRs, or using Foundation Medicine's paper test requisition form. HER2 IHC can also be ordered with our other comprehensive genomic profiling (CGP) tests, as long as the proper tissue samples are submitted.

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

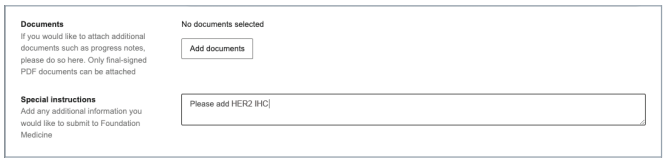
TO ORDER HER2 IHC IN THE FOUNDATION MEDICINE ONLINE PORTAL
Select "no" for PD-L1 IHC testing. Add HER2 IHC in the comments section.



TO ORDER HER2 IHC IN EPIC EMR
Add HER2 in Comments section
Note: please put the HER2 IHC comment on the very top of the comments box



TO ORDER HER2 IHC IN ONCOEMR Add HER2 IHC to the "special instructions" section



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 SECTION.

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

Write "HER2 IHC" in on the form, ideally within both the "IHC Testing for PD-L1" section and in the additional IHC testing section.

IHC TESTING FOR PD-L1

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

Once your HER2 IHC results are available, Foundation Medicine's Client Services team will issue results directly, utilizing your preferred contact method of email or fax.*

**Currently, HER2 IHC results are not available through the Foundation Medicine online portal, EMR, or included in FoundationOne®CDx test reports.*

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*).

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

Ventana Medical Systems, Inc.'s (Ventana) PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY HER2 (4B5)) is a rabbit monoclonal antibody intended for in vitro diagnostic (IVD) use for the semi-quantitative detection of HER2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue. This assay is FDA-approved and it is indicated as an aid in the assessment of breast cancer patients for whom Herceptin® (trastuzumab), Enhertu® (trastuzumab deruxtecan), or KADCYLA® (ado-trastuzumab emtansine) treatment is being considered. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

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