FOUNDATION MEDICINE®

Available From Foundation Medicine

Claudin18 IHC Testing

Foundation Medicine offers select types of immunohistochemistry (IHC) testing to complement our portfolio of comprehensive genomic profiling (CGP) tests for clinical customers.

Following the FDA-approval of Vyloy® (zolbetuximab) and the approval of the companion diagnostic (VENTANA CLDN18 (43-14A) RxDx Assay) in October 2024, Foundation Medicine now offers Claudin18 (CLND18) IHC testing. Vyloy is the first and only CLDN18.2-targeted treatment approved for patients with advanced gastric and gastroesophageal junction (GEJ) cancer whose tumors are CLDN18.2-positive.

Claudin18 IHC testing from Foundation Medicine can detect the over-expression of CLDN18.2 in tumor cells to help you identify patients with advanced gastric and GEJ cancers who may be eligible for treatment with zolbetuximab.

Sample Requirements for Claudin18 IHC testing

The following is required for Claudin18 IHC:

- **Tissue block + H&E, or**
- **4-5 USS (5 preferred) + H&E** In addition to sample requirements for Foundation Medicine testing

Receiving your Claudin18 IHC Results

Once your Claudin18 IHC results are available, Foundation Medicine's Client Services team will issue results utilizing your preferred delivery method (fax or email).

In addition to Claudin18 IHC, Foundation Medicine's tests are comprehensive for gastric and GEJ cancers.

Foundation Medicine can also help you identify patients with gastric and GEJ cancers whose tumors carry:

- ***ERBB2*** **(HER2) gene amplifications**
- ***BRAF*** **V600E mutations**
- ***HER2*** **expression by IHC**
- **PD-L1 expression by IHC**

Identification of these alterations can increase patient options for other targeted therapies.

FoundationOne CDx pan-tumor companion diagnostic indications [1]

Therapy	Biomarker(s)
Keytruda® (pembrolizumab)	MSI-High
Keytruda® (pembrolizumab)	Tumor mutational burden (TMB) ≥10 mutations per megabase
Rozlytrek® (entrectinib) Vitrakvi® (larotrectinib)	*NTRK* 1/2/3 fusions
Retevmo® (selpercatinib)	*RET* fusions

Use **Claudin18 IHC testing from Foundation Medicine** to identify appropriate therapy options for your advanced cancer patients.

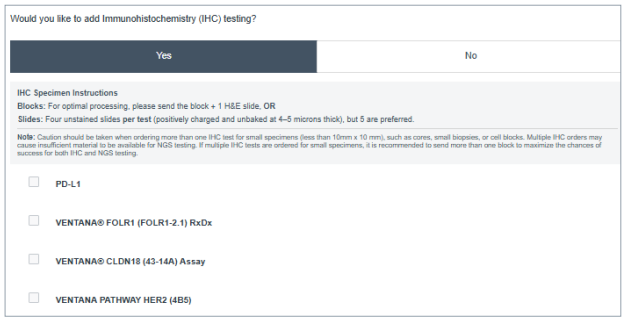
Order Claudin18 IHC Testing Today

Claudin18 IHC testing and Foundation Medicine CGP testing can be ordered together in the Foundation Medicine Online Portal, in EMRs, or using Foundation Medicine's paper test requisition form.

To order Claudin18 IHC in the **Foundation Medicine Online Portal** or in your **EMR**, please replicate the below:

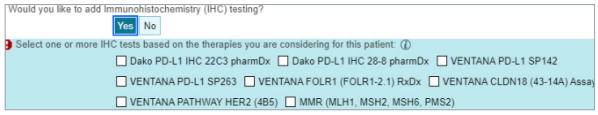
TO ORDER CLAUDIN18 IHC IN THE FOUNDATION MEDICINE ONLINE PORTAL

Select Yes to *"Would you like to add Immunohistochemistry (IHC) testing?"*. Then check the box for Claudin18.



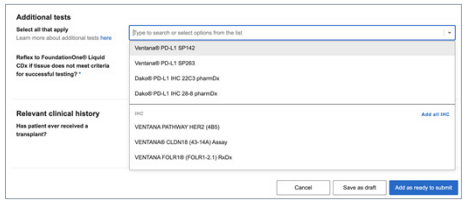
TO ORDER CLAUDIN18 IHC IN EPIC EMR

Select Yes to add IHC testing for Claudin18.
Select Claudin18.



TO ORDER CLAUDIN18 IHC IN ONCOEMR

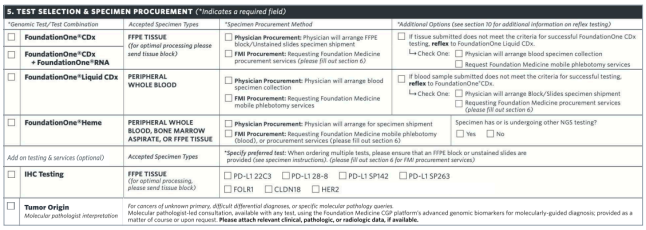
Select Claudin18 in the Additional tests section.



To order Claudin18 IHC using **Foundation Medicine's Test Requisition Form**:

Indicate the testing in Section 5:
Test Selection & Specimen Procedure

IHC TESTING FOR CLAUDIN18



ADDITIONAL CASE INFORMATION

Interested in **adding** Claudin18 IHC to a **prior** Foundation Medicine 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.

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. FoundationOne®CDx Technical Information (FDA Label).

CLDN18 IHC is a qualitative immunohistochemical assay that uses the VENTANA CLDN18 (43-14A) RDx Assay kit. The VENTANA CLDN18 (43-14A) RDx Assay, using mouse monoclonal anti-claudin 18 clone 43-14A, is intended for laboratory use in the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastrosophageal junction (GEJ tissue specimens by light microscopy. CLDN18 protein expression is determined by the percentage of viable tumor cells demonstrating moderate to strong membranous CLDN18 staining above background. This product is intended for in vitro diagnostic use. For additional information, refer to the VENTANA CLDN18 (43-14A) RDx Assay package insert, #740-7037. 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 http://www.F1CDxLabel.com

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