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.

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.

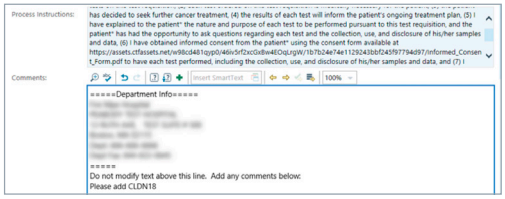
To order, please refer to the information below:

TO ORDER CLAUDIN18 IHC IN THE FOUNDATION MEDICINE ONLINE PORTAL

Type "Claudin18" or "CLDN18" in the comments section

TO ORDER CLAUDIN18 IHC IN EPIC EMR

Type "Claudin18" or "CLDN18" in the "Comments" section under "Department Info"

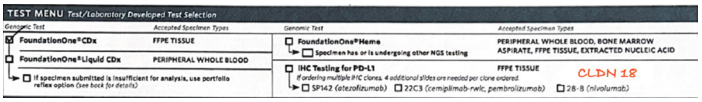


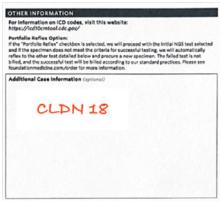
TO ORDER CLAUDIN18 IHC IN ONCOEMR

Claudin18" or "CLDN18" in the "Special Instructions

TO ORDER USING FOUNDATION MEDICINE'S TEST REQUISITION FORM

Write "Claudin18" or "CLDN18" in the "IHC Testing for PD-L1" section. Also write "Claudin18" or "CLDN18" in the "Additional Case Information" section.





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).

Ventana Medical Systems, Inc.'s (Ventana) VENTANA CLDN18 (43-14A) Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-claudin 18, clone 43-14A, intended for in *vitro* diagnostic (IVD) use for the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastroesophageal junction (GEJ) tissue specimens by light microscopy. This assay is used with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument. The assay is FDA-approved and is indicated as an aid in identifying patients with gastric or GEJ adenocarcinoma who may be eligible for treatment with VYLOY® (zolbetuximab) in accordance with the approved therapeutic product labeling. Test results of the VENTANA CLDN18 (43-14A) RxDx Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

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

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel 888.988.3639 | Fax 617.418.2290 | US-CL-2400013