

## 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 <sup>1</sup>

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.

Would you like to add Immunohistochemistry (IHC) testing?

☒ Yes ☐ No

**IHC Specimen Instructions**  
Blocks: For optimal processing, please send the block + 1 H&E slide, OR  
Slides: Four unstained slides per test (positively charged and unbaked at 4–5 microns thick), but 5 are preferred.  
Note: Caution should be taken when ordering more than one IHC test for small specimens (less than 10mm x 10 mm), such as cores, small biopsies, or cell blocks. Multiple IHC orders may cause insufficient material to be available for NGS testing. If multiple IHC tests are ordered for small specimens, it is recommended to send more than one block to maximize the chances of success for both IHC and NGS testing.

☐ PD-L1  
☐ VENTANA® FOLR1 (FOLR1-2.1) RxDx  
☐ VENTANA® CLDN18 (43-14A) Assay  
☐ VENTANA PATHWAY HER2 (4B5)

## TO ORDER CLAUDIN18 IHC IN EPIC EMR

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

Would you like to add Immunohistochemistry (IHC) testing?

☒ Yes ☐ No

Select one or more IHC tests based on the therapies you are considering for this patient: (1)

☐ Dako PD-L1 IHC 22C3 pharmDx ☐ Dako PD-L1 IHC 28-8 pharmDx ☐ VENTANA PD-L1 SP142  
☐ VENTANA PD-L1 SP263 ☐ VENTANA FOLR1 (FOLR1-2.1) RxDx ☐ VENTANA CLDN18 (43-14A) Assay  
☐ VENTANA PATHWAY HER2 (4B5) ☐ MMR (MLH1, MSH2, MSH6, PMS2)

## TO ORDER CLAUDIN18 IHC IN ONCOEMR

Select Claudin18 in the Additional tests section.

**Additional tests**  
Select all that apply  
Learn more about additional tests here

Type to search or select options from the list

Ventana® PD-L1 SP142  
Ventana® PD-L1 SP263  
Dako® PD-L1 IHC 22C3 pharmDx  
Dako® PD-L1 IHC 28-8 pharmDx

**Relevant clinical history**  
Has patient ever received a transplant?

IHC  
VENTANA PATHWAY HER2 (4B5)  
VENTANA CLDN18 (43-14A) Assay  
VENTANA FOLR1 (FOLR1-2.1) RxDx

Cancel Save as draft Add as ready to submit

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

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

## IHC TESTING FOR CLAUDIN18

Genomic Test/Ref Combination	Accepted Specimen Types	Specimen Procurement Method	Additional Options (see section 10 for additional information on reflex testing)
<input type="checkbox"/> FoundationOne®CDx	FFPE TISSUE (For optimal processing please send tissue block)	<input type="checkbox"/> Physician Procurement: Physician will arrange FFPE block/contaminated slides specimen shipment. <input type="checkbox"/> FM Procurement: Requesting Foundation Medicine procurement services (please fill out section 6)	<input type="checkbox"/> If tissue submitted does not meet the criteria for successful FoundationOne CDx testing, <b>reflex</b> to FoundationOne Liquid CDx. → Check One: <input type="checkbox"/> Physician will arrange blood specimen collection <input type="checkbox"/> Request Foundation Medicine mobile phlebotomy services
<input type="checkbox"/> FoundationOne®CDx + FoundationOne®RNA	PERIPHERAL WHOLE BLOOD	<input type="checkbox"/> Physician Procurement: Physician will arrange blood specimen collection. <input type="checkbox"/> FM Procurement: Requesting Foundation Medicine mobile phlebotomy services	<input type="checkbox"/> If blood sample submitted does not meet the criteria for successful testing, <b>reflex</b> to FoundationOne CDx. → Check One: <input type="checkbox"/> Physician will arrange Rock/Slide specimen shipment <input type="checkbox"/> Requesting Foundation Medicine procurement services (please fill out section 6)
<input type="checkbox"/> FoundationOne®Heme	PERIPHERAL WHOLE BLOOD, BONE MARROW ASPIRATE, OR FFPE TISSUE	<input type="checkbox"/> Physician Procurement: Physician will arrange for specimen shipment. <input type="checkbox"/> FM Procurement: Requesting Foundation Medicine mobile phlebotomy (blood), or procurement services (please fill out section 6)	<input type="checkbox"/> Specimen has or is undergoing other NGS testing? <input type="checkbox"/> Yes <input type="checkbox"/> No
Add on testing & services (optional)			
<input type="checkbox"/> IHC Testing	FFPE TISSUE (For optimal processing, please send tissue block)	<input type="checkbox"/> PD-L1 22C3 <input type="checkbox"/> PD-L1 28-8 <input type="checkbox"/> PD-L1 SP142 <input type="checkbox"/> PD-L1 SP263 <input type="checkbox"/> FOLR1 <input type="checkbox"/> CLDN18 <input type="checkbox"/> HER2	
<input type="checkbox"/> Tumor Origin	For cancers of unknown primary, difficult differential diagnosis, or specific molecular pathology queries. Molecular pathologist-led consultation, available with any test, using the Foundation Medicine CGP platform's advanced genomic biomarkers for molecularly-guided diagnosis, provided as a matter of course or upon request. <b>Please attach relevant clinical, pathologic, or radiologic data, if available.</b>		

## ADDITIONAL CASE INFORMATION

Add on testing & services (optional)	Accepted Specimen Types	Specimen Procurement Method
<input type="checkbox"/> IHC Testing	FFPE TISSUE (For optimal processing, please send tissue block)	<input type="checkbox"/> PD-L1 22C3 <input type="checkbox"/> PD-L1 28-8 <input type="checkbox"/> PD-L1 SP142 <input type="checkbox"/> PD-L1 SP263 <input type="checkbox"/> FOLR1 <input type="checkbox"/> CLDN18 <input type="checkbox"/> HER2

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](mailto: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](mailto: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 gastrophageal 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>

