



Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





Claudin 18 FDA (VYLOY®) for Gastric/GEJ Adenocarcinoma

Alternative Name

Claudin 18 IHC, CLDN 18, CLDN 18.2

Methodology

Immunohistochemistry (IHC)

Test Description

The VENTANA Claudin 18 (43-14A) RxDx Assay is an FDA-approved qualitative immunohistochemical assay using a mouse monoclonal anti-Claudin 18 antibody intended for use in the assessment of Claudin 18 protein in formalin-fixed, paraffin-embedded (FFPE) gastric cancer tissue on a VENTANA BenchMark ULTRA instrument. Claudin 18 is indicated as an aid in identifying patients with Gastric Adenocarcinoma including Gastroesophageal Junction (GEJ). Tumors that have Claudin 18 expression in ≥75% of tumor cells staining at 2+ and/or 3+ intensity may be eligible for treatment with VYLOY® (zolbetuximab).

Clinical Significance

Claudin 18 is expressed as two isoforms: CLDN18.1 and CLDN18.2*. While CLDN18.1 is predominantly expressed in normal and neoplastic lung tissue, CLDN18.2 is only expressed in differentiated epithelial cells of the gastric mucosa. CLDN 18.2 has been associated with various cellular functions that lead to tumor progression and metastasis, making it an attractive therapeutic target.

*The primary antibody used in the VENTANA CLDN18 (43-14A) RxDx Assay targets the conserved C-terminal region of the CLDN18 proteins, and therefore cannot distinguish CLDN18.1 from CLDN18.2

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
 - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

For evaluation, tissue submitted must have ≥50 viable tumor cells present.

Storage & Transportation

Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88360x1

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

Global: 48 hours, Tech-Only (stain only): 24 hours

References

1. VENTANA Claudin 18 (43-14A) RxDx Assay. Package insert. Roche; 2024.

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

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Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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