Test Definition: CLD18

Claudin 18 (CLDN18) (43-14A),
Semi-Quantitative Immunohistochemistry,
Manual

Overview

Useful For
Identification of tumor cells expressing claudin 18

As an aid in screening patients who may be eligible for VYLOY (zolbetuximab) treatment

Method Name
Immunohistochemistry (IHC)

NY State Available
Yes

Specimen

Specimen Type
Special

Shipping Instructions
Attach the green "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

Necessary Information
A pathology/diagnostic report and a brief history are required.

Specimen Required
This assay requires at least 50 tumor cells.

Specimen Type: Tissue
Supplies: Pathology Packaging Kit (T554)
Submit:
Formalin-fixed, paraffin-embedded tissue block
OR
3 Unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue
Additional Information:
1. One slide will be stained with hematoxylin and eosin and returned.
2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

Forms

If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

Decalcified paraffin embedded tissue	Reject
Wet/frozen tissue	Reject
Cytology smears	Reject
Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or zinc formalin	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn slides	Reject
Snowcoat slides	Reject
Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

Claudin 18 (CLDN18) is a member of the claudin protein family that regulates cell adhesion. A qualitative immunohistochemistry assessment using mouse monoclonal anti-claudin 18, clone 43-14A, serves as a biomarker in gastric and gastroesophageal junction cancer and may aid in identifying patients eligible for VYLOY (zolbetuximab) treatment.

Reference Values

An interpretive report will be provided.

Interpretation

Claudin 18.2 is a biomarker for gastric and gastroesophageal junction cancer. When positive (defined as at least moderate membranous staining in greater than or equal to 75% of viable tumor cells), it predicts response to zolbetuximab which has been approved for the treatment of gastric and gastroesophageal adenocarcinoma.

Cautions

This test has been validated for non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral buffered formalin at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 6 and 48 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen dependent. Best practice is for paraffin sections to be cut within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.
Best practices for storage of positively charged slides:
-Minimize time slides are stored after being unpackaged
-Limit exposure to high humidity and heat
-Minimize exposure to plastics

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie,

shattered in transit), they will be rejected and discarded due to safety concerns.

Clinical Reference

1. Kubota Y, Kawazoe A, Mishima S, et al. Comprehensive clinical and molecular characterization of claudin 18.2 expression in advanced gastric or gastroesophageal junction cancer. ESMO Open. 2023;8(1):100762
2. Cao W, Xing H, Li Y, et al. Claudin18.2 is a novel molecular biomarker for tumor-targeted immunotherapy. Biomark Res. 2022;10(1):38
3. Pellino A, Brignola S, Riello E, et al. Association of CLDN18 protein expression with clinicopathological features and prognosis in advanced gastric and gastroesophageal junction adenocarcinomas. J Pers Med. 2021;11(11):1095
4. Arnold A, Daum S, von Winterfeld M, et al. Prognostic impact of Claudin 18.2 in gastric and esophageal adenocarcinomas. Clin Transl Oncol. 2020;22(12):2357-2363

Performance

Method Description

Immunoperoxidase staining and detection of Claudin 18 (CLDN18) is performed in formalin-fixed, paraffin-embedded tissue sections using the VENTANA CLDN18 (43-14A) RxDx Assay. The 4-micron tissue sections are deparaffinized, subjected to heat-induced antigen retrieval and peroxidase inhibitor, incubated with a monoclonal antibody (clone 43-14A), and visualized using a proprietary kit detection system. Sections are counterstained with hematoxylin. Stained slides are examined microscopically by the consulting anatomic pathologist.(Package insert: VENTANA CLDN18 (43-14A) RxDx Assay. Ventana Medical Systems, Inc.; 1016387US Rev A, 10/11/2024)

Results are interpreted using the manufacturer-provided interpretation guide. A minimum of 50 tumor cells are required for interpretation of results.(Instruction manual: VENTANA CLDN18 (43-14A) RxDx Assay Interpretation Guide for Gastric Adenocarcinoma including Gastroesophageal Junction (GEJ). Ventana Medical Systems, Inc.; 1021576EN Rev B, 10/01/2024)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 to 7 days

Specimen Retention Time

Until reported

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88360

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CLD18	CLDN18, SemiQuant IHC, Manual	105011-1

Result ID	Test Result Name	Result LOINC® Value
620666	Interpretation	50595-8
621004	Participated in the Interpretation	No LOINC Needed
621005	Report electronically signed by	19139-5
621006	Material Received	81178-6
621007	Disclaimer	62364-5
621008	Case Number	80398-1