

Overview

Useful For

Identification of tumor cells expressing claudin 18

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

Specimen Type: Tissue

Supplies:

-Pathology Packaging Kit (T554)

Collection Instructions: Formalin-fixed, paraffin-embedded tissue block; or 3 unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information: One slide will be stained with hematoxylin and eosin and returned.

Reject Due To

Decalcified paraffin embedded tissue Wet/frozen tissue	Reject
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Cytology
smears
Nonformalin
fixed tissue
including
alcohol-formali
n-acetic acid
(AFA), 95%
ethanol,
PREFER
fixatives or
Zinc formalin
Nonparaffin
embedded
tissue
Noncharged
slides
ProbeOn slides

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Claudin 18 is a member of the claudin protein family that regulates cell adhesion. The claudin-18 isoform 2 (CLDN18.2) serves as a biomarker for gastric and gastroesophageal junction cancer.

Reference Values

An interpretive report will be provided.

Interpretation

An interpretation will be provided. This result should be interpreted in the appropriate clinical context.

Cautions

This test has been validated for nondecalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. Recommended fixation time is between 6 and 48 hours. This assay has not been validated on tissues subjected to the decalcification process or use of alternative fixatives for bone and bone marrow specimens or cell blocks.

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.

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

Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 to 7 days

Specimen Retention Time

Until reported

Performing Laboratory Location

Rochester

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It 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	In Process

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