MAYO CLINIC LABORATORIES

Test Definition: AFOLR

Folate Receptor Alpha (FOLR1), Semi-Quantitative Immunohistochemistry, Manual

Overview

Useful For
Diagnosis of epithelial ovarian cancer that may be eligible for treatment with an anti-folate receptor 1 protein antibody

Method Name
Immunohistochemistry (IHC)

NY State Available
Yes

Specimen

Specimen Type
Special

Ordering Guidance
This test may be utilized for all types of ovarian cancers.

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
Source: Ovarian tumor
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.

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

Reject Due To

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

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Folate receptor 1 protein (FOLR1), also known as folate receptor alpha (FRa), is expressed in approximately 90% of ovarian carcinomas and serves as a predictive biomarker for FOLR1-targeted therapy for epithelial ovarian cancer. FOLR1 is a member of the folate receptor family that is reported to be highly expressed in various tumors of epithelial origin but has restricted expression in normal epithelial cells. Positivity for FOLR1 is expressed on greater or equal to 75% of viable tumor cells with moderate and/or strong membrane staining, while less than 75% of viable tumor cells with moderate and/or strong membrane staining is considered negative for FOLR1.

Reference Values
An interpretive report will be provided.

Interpretation
Folate receptor 1 protein (FOLR1) is a biomarker that, when positive (at least moderate membranous staining) in greater than or equal to 75% of tumor cells, predicts response to treatment with Elahere (mirvetuximab soravtansine) and has been approved for epithelial ovarian, fallopian tube, or primary peritoneal cancer.(1)

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 hours 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. VENTANA FOLR1 (FOR-2.1) RxDx Assay. US Package Insert. Roche Diagnostics; 2022
2. Scaranti M, Cojocaru E, Banerjee S, et al. Exploiting the folate receptor alpha in oncology. Nat Rev Clin Oncol. 2020;17(6):349-359
3. Necela B, Crozier J, Andorfer C, et al. Folate receptor-alpha (FOLR1) expression and function in triple negative tumors. PLoS One. 2015;10(3):e0122209
4. Kobel M, Madore J, Ramus S, et al. Evidence for a time-dependent association between FOLR1 expression and survival from ovarian carcinoma: implications for clinical testing. An Ovarian Tumour Tissue Analysis consortium study. Br J Cancer. 2014;111:2297-2307

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

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Specimen Retention Time
Until reported

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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
AFOLR	FOLR1, SemiQuant IHC, Manual	105010-3

Result ID	Test Result Name	Result LOINC® Value
620732	Interpretation	50595-8
621015	Participated in the Interpretation	No LOINC Needed
621016	Report electronically signed by	19139-5
621017	Material Received	81178-6
621018	Disclaimer	62364-5
621019	Case Number	80398-1