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)
Submit:
Formalin-fixed, paraffin-embedded tissue block
OR
3 Unstained glass, "positively-charged" glass slides with 4-microns thick 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 an Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

Wet/frozen tissue	Reject
Decalcified paraffin embedded tissue	Reject
Cytology smears	Reject
Non-formalin 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

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 75% or more 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 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 12 hours and 72 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. 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(12):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

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