

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, positively-charged glass slides with 4-microns thick 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.

Test Definition: AFOLR

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

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
Cell Blocks	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 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(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