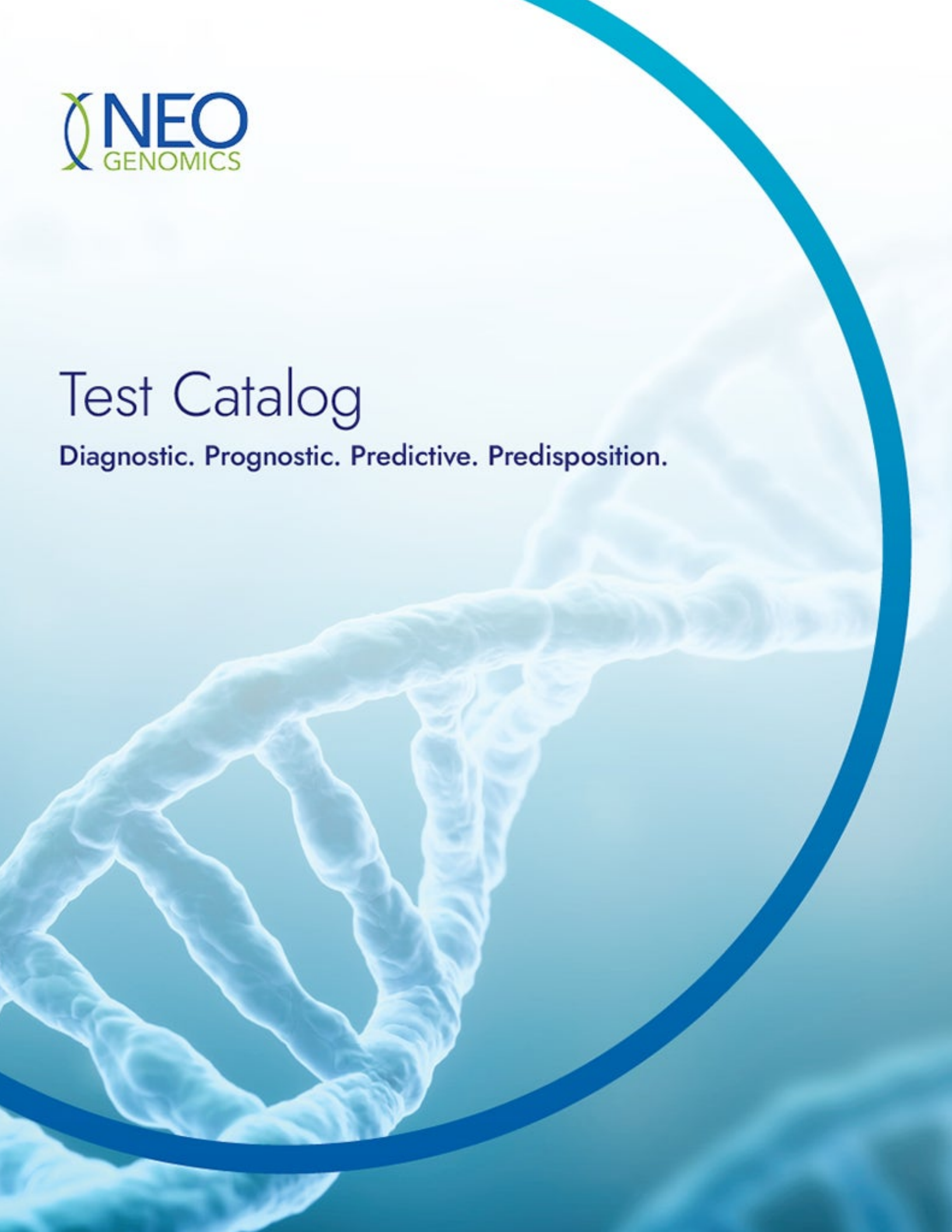
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma

Alternative Name
FOLR1 IHC CDx, Folate Receptor alpha (FR?), FOLR1 (FOLR1-2.1) RxDx Assay

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is an FDA-approved qualitative immunohistochemical assay using a mouse monoclonal anti-FOLR1 antibody intended for use in the assessment of Folate Receptor alpha (FR?) protein in formalin-fixed, paraffin-embedded (FFPE) ovarian cancer tissue on a VENTANA BenchMark ULTRA instrument. FOLR1 is indicated as an aid in identifying patients with ovarian cancer (including epithelial ovarian cancer, primary peritoneal cancer or primary fallopian tube cancer), whose tumors have FR? expression in ?75% tumor cells staining at 2+/3+ intensity, who are eligible for treatment with ELAHERE™ (mirvetuximab soravtansine-gynx).

This test is available through the ImmunoGen-sponsored FOLR1 testing program initiative called FR-ASSIST™. A separate test request form is required. Please visit the FOLR1 Ovarian Cancer Testing Program page for more information and to download the Test Request Form.

Clinical Significance
The FR? protein is expressed in 90% of ovarian cancers and has limited expression in normal tissue, making it an attractive therapeutic target. In using the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay for the evaluation of ovarian cancer patients, approximately 35% of patients are considered to have high expression of FR?—as defined by the scoring criteria mentioned above— and thus eligible for treatment with ELAHERE™.

Specimen Requirements
- Ovarian cancer (including epithelial ovarian cancer, primary peritoneal cancer and primary fallopian tube cancer) tissue is required.
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
Inquire for Testing Program details.

New York Approved
Yes

Level of Service

Global

Turnaround Time

48 hours

References

1. VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. Package insert. Roche; 2022.
2. ELAHERE. Package insert. ImmunoGen, Inc.; 2022.

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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Rev. 012823