NEO GENOMICS

866.776.5907, option 3

Histology Analysis

FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma, Sponsored Testing Program

Client 1234
Sample Client

Address
City, ST 99999
Phone: (111) 111-1111
Fax: (222) 222-2222

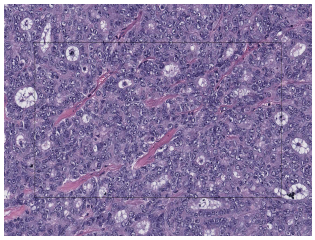
Patient Name: **Patient, Sample**
Patient DOB / Sex: **01/01/1980 / F**
Specimen Type: **Paraffin Tissue**
Body Site: **Right Ovary Tissue**
Specimen ID: **X99-99**
MRN: **9999999**

Reason for Referral: **Ovarian Carcinoma**

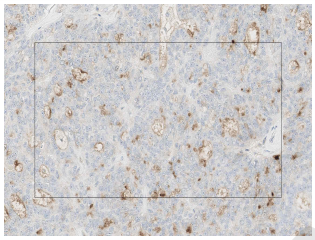
Ordering Physician(s): **Sample Doctor, MD**
Treating Physician(s): **Sample Doctor, MD**
Accession / CaseNo: **9999999 / HSG22-999999**
Collection Date: **10/24/2022**
Received Date: **10/26/2022 04:00:00 PM PDT**
Report Date: **10/28/2022 08:00:00 AM PDT**

Comments:
Results

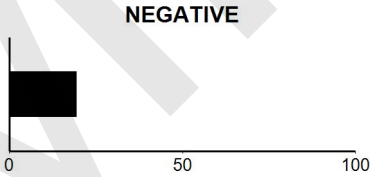
Specimen ID: **X99-99**



H&E Image for Reference only



FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma: NEGATIVE
Percentage of Cells with 2+ and/or 3+ Membrane Staining: 20%



Reference Ranges	
Positive	**>/=75%**
Negative	**<75%**

Intended Use:
Stains were scored by a pathologist using manual microscopy.
All controls were reviewed and showed appropriate positive and negative immunoreactivity.

FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma:
Ventana FOLR1 Assay is a qualitative immunohistochemical assay using mouse monoclonal FOLR1 clone FOLR1-2.1 intended for use in the assessment of the FOLR1 protein in formalin-fixed, paraffin-embedded (FFPE) for ovarian carcinoma tissues stained on Ventana BenchMark ULTRA instrument. Ventana FOLR1 is indicated as an aid in identifying ovarian carcinoma including primary peritoneal cancer and primary fallopian tube cancer patients eligible for treatment with ELAHERE™ whose tumor is positive for FOLR1 as determined by an FDA-approved test. Use of this test in an off-label manner invalidates the FDA approval for the test. The performance characteristics of this assay have not been validated for decalcified specimens. Results should be interpreted with caution given the likelihood of false negativity on decalcified specimens. See package insert for Ventana FOLR1 Assay and ELAHERE™ product label for additional information.

Methodology:

FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma:

FOLR1 staining is performed utilizing the Ventana FOLR1 FDA approved protocol using the BenchMark ULTRA instrument in combination with OptiView DAB IHC Detection Kit and ancillary reagents.

A minimum of 100 viable neoplastic cells is recommended for FOLR1 testing. FOLR1 protein expression is defined as: tumor cells showing 2+ and/or 3+ membrane staining. The specimen should be considered to be POSITIVE for FLOR1 expression if >=75 of viable tumor cells show 2+ and/or 3+ staining. The specimen is considered NEGATIVE for FLOR1 expression if <75% of viable tumor cells show 2+ and/or 3+ staining.

Cases with 2+ and/or 3+ membrane staining for FOLR1 in 65-85% of tumor cells may be reviewed by additional pathologist(s) to determine consensus scoring.

Electronic Signature

Sample Doctor, M.D., Pathologist

The Accessioning Component, Technical Component Processing and Analysis of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / CLIA #05D1021650 / Medical Director(s): Vladislav Chizhevsky, M.D.
The performance characteristics of the IHC/ISH assays have been validated on formalin-fixed paraffin embedded tissues only. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") as qualified to perform high complexity clinical laboratory testing. For the classifications of IHC antibodies, please contact the Client Services team.
Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.
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 payer being billed.