

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 FOLR1 expression if ≥75% of viable tumor cells show 2+ and/or 3+ staining. The specimen is considered NEGATIVE for FOLR1 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, 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 tissue. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") as qualified to perform high complexity clinical laboratory testing. For the classification of this laboratory, please contact the Client Service Department.
Images that may be included within this report are representative of the patient but not all testing in its entirety. We do not warrant that the images would not be used to render a diagnosis.
The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct coding is the responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

SAMPLE