FOUNDATION MEDICINE®

## Now Available From Foundation Medicine

# FOLR1 IHC Testing

In November 2022, the FDA approved the first immunohistochemistry (IHC) companion diagnostic (VENTANA FOLR1 (FOLR1-2.1) RxDx Assay) to identify patients eligible for mirvetuximab soravtansine-gynx, also approved by the FDA in November.

Now available for order from Foundation Medicine, FOLR1 IHC testing helps you identify patients with ovarian, fallopian tube, or primary peritoneal cancer, who are folate receptor alpha-positive and may be eligible for treatment with mirvetuximab soravtansine-gynx.

## Ordered in addition to FOLR1 IHC, FoundationOne®CDx delivers:

**The confidence of FDA-approved tissue comprehensive genomic profiling**

**Detection of homologous recombination deficiency (HRD) status to aid in treatment decisions**

### Plus, Foundation Medicine has the most FDA-approved companion diagnostic (CDx) indications on the market, including FoundationOne®CDx indications clinically relevant to patients with ovarian cancer.[1]

| Tumor Type | Biomarker(s) Detected | Therapy |
|---|---|---|
| Ovarian cancer | *BRCA1/2* alterations | Lynparza® (olaparib) |
| Solid tumors | *MSI-High* | Keytruda® (pembrolizumab) |
| | *TMB ≥ 10* mutations per megabase | Keytruda® (pembrolizumab) |

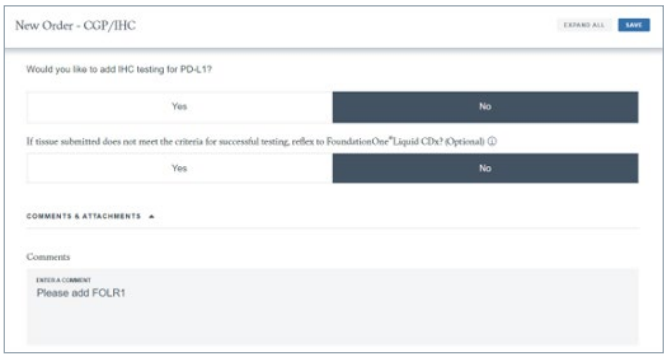
The FDA defines a companion diagnostic as ***"a medical device...which provides information that is essential for the safe and effective use of a corresponding drug..."***[2]

# Order FOLR1 IHC Testing Today

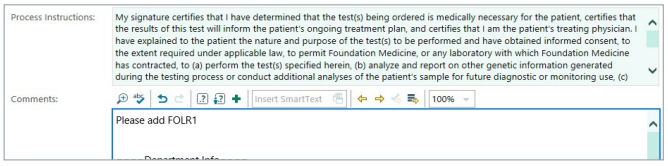
FOLR1 and FoundationOne®CDx can be ordered together in the Foundation Medicine Online Portal, in select EMRs, or using Foundation Medicine's paper test requisition form.

## To order FOLR1 IHC with FoundationOne®CDx in the Foundation Medicine Online Portal or in your EMR, please replicate the below:

**TO ORDER FOLR1 IHC IN THE FOUNDATION MEDICINE ONLINE PORTAL**
Select "no" for PD-L1 IHC testing. Add FOLR1 in the comments section.




**TO ORDER FOLR1 IHC IN EPIC EMR**
Add FOLR1 in Comments section
Note: please put the FOLR1 comment on the very top of the comments box




**TO ORDER FOLR1 IHC IN ONCOEMR** Add FOLR1 to the "special instructions" section


**FOLR1 IHC CAN BE ORDERED IN OTHER EMRS IF THERE IS A FREE TEXT FIELD. TO ORDER, ADD FOLR1 INTO THE FREE TEXT FIELD SECTION.**

## To order FOLR1 IHC with FoundationOne®CDx using Foundation Medicine's Test Requisition Form:

Write "FOLR1" in on the form, ideally within both the "IHC Testing for PD-L1" section and "Additional Case Information" field pictured below:

**IHC TESTING FOR PD-L1**


**ADDITIONAL CASE INFORMATION**


**Interested in adding FOLR1 IHC to a prior FoundationOne®CDx test?**
Contact your Foundation Medicine Customer Experience Executive or our Client Services team at 888.988.3639 or by email at client.services@foundationmedicine.com

## Sample Requirements for FOLR1 IHC testing

The following is required for FOLR1 IHC:

- **Block + H&E; or**
- **5 USS + H&E** In addition to sample requirements for FoundationOne®CDx testing.

## Receiving your FOLR1 IHC Results

Once your FOLR1 IHC results are available, Foundation Medicine's Client Services team will issue results directly, utilizing your preferred contact method of email or fax.*

**Currently, FOLR1 IHC results are not available through the Foundation Medicine Online portal, EMR or included in FoundationOne®CDx test reports.*

**Questions?**
To learn more, visit: https://www.foundationmedicine.com/info/detail/ihc-testing
Contact our Client Services team at 888.988.3639 or by email at client.services@foundationmedicine.com


**References**

1. FoundationOne®CDx Technical Information (FDA Label).
2. https://www.fda.gov/medical-devices/in-vitro-diagnostics/companion-diagnostics. Accessed April 25, 2023.


FoundationOne®CDx is a qualitative next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com

The VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is for prescription use only and is a qualitative IHC assay intended for use in the assessment of folate receptor alpha (FOLR1) in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens. This assay is FDA-approved and is indicated as an aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who may be eligible for treatment with Elahere (mirvetuximab soravtansine-gynx). Test results should be interpreted in conjunction with relevant clinical information. For the complete label please visit https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220006C.pdf

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