FOUNDATIONFOCUS™
CDx *BRCA*

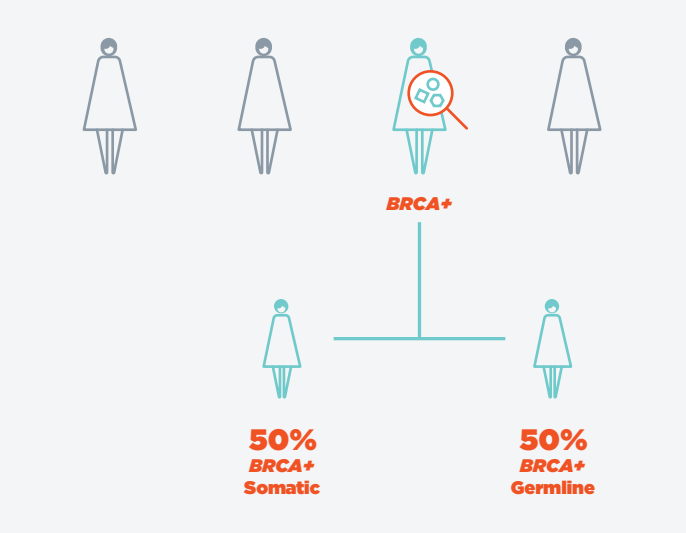
A Direct Path to Therapy in Ovarian Cancer

FoundationFocus™ CDx *BRCA* is the first FDA-approved companion diagnostic test for Rubraca® (rucaparib), a PARP inhibitor therapy for the treatment of advanced ovarian cancer.

More Patients on Therapy Sooner

1 in 4 ovarian cancer patients are *BRCA+*[1-3,5]

By testing for both germline and somatic *BRCA1/2* mutations, FoundationFocus CDx *BRCA* can help identify up to **twice as many women**[1] who may benefit from Rubraca®, a PARP inhibitor therapy as compared to germline testing alone.[1-3,5] FoundationFocus CDx *BRCA* analyzes ovarian cancer tumor tissue to detect *BRCA1/2* mutation types associated with response to PARP inhibition.[1,4]



Uncover More *BRCA* Mutations with a Single Tissue Test

FoundationFocus CDx *BRCA* is an FDA-approved tissue-based next-generation sequencing test. Alterations detected in tumor tissue may include both somatic and germline alterations.[6]

Our hybrid capture-based approach is used to achieve high, uniform depth of coverage of all coding exons, including splice sites, and select intronic regions of *BRCA1* and *BRCA2*.

When to Test

FoundationFocus CDx *BRCA* uses recent or archived tumor tissue specimens to find *BRCA* mutations that may be missed by other methods of testing.[1-4] Consider testing ovarian cancer patients...

Who have:

- No prior tissue or germline *BRCA1/2* testing or
- Prior *BRCA1/2* testing with germline *BRCA1/2* (-) results

Who would like to:

- Determine eligibility for Rubraca® therapy as a treatment option

Simplified Sample Collection and Ordering

- No need to re-biopsy; archived specimens accepted. Select the most recent specimen that meets size and tumor content criteria
- Formalin-fixed, paraffin embedded (FFPE) specimens, including cut slide specimens are acceptable[7]
- Reports available online by creating an account at *www.foundationmedicine.com* or via fax
- Typical turnaround time from receipt of specimen is < 2 weeks
- Patient financial assistance available for eligible patients - apply online at *access.foundationmedicine.com*
- Contact Client Services at 888.988.3639 for a FoundationFocus CDx *BRCA* Specimen Shipping Kit

FOUNDATION MEDICINE®

TO LEARN MORE:

Visit www.foundationmedicine.com/focus

TO ORDER:

Contact Client Services at 888.988.3639 or client.services@foundationmedicine.com

[1] Hennessy BTJ, et al. Somatic mutations in *BRCA1* and *BRCA2* could expand the number of patients that benefit from poly (ADP ribose) polymerase inhibitors in ovarian cancer. JCO. 2010;28(22):3570-6.
[2] Pennington KP, et al. Germline and somatic mutations in homologous recombination genes predict platinum response and survival in ovarian, fallopian tube, and peritoneal carcinomas. Clin Cancer Res. 2013;20(3):764-75.
[3] Arts-de Jong M, et al. Germline *BRCA1/2* mutation testing is indicated in every patient with epithelial ovarian cancer: A systematic review. Eur J Cancer. 2016;(61):137-145.
[4] Moschetta M, George A, Kaye SB, Banerjee S. *BRCA* somatic mutations and epigenetic *BRCA* modifications in serous ovarian cancer. Ann Oncol. 2016 Aug;27(8):1449-55.
[5] The ratio of germline to somatic *BRCA* alterations varies based on population studied.
[6] FoundationFocus™ CDx *BRCA* does not distinguish between germline and somatic alterations.
[7] See Specimen Instructions for full information.

Intended Use

The FoundationFocus™ CDx *BRCA* is a next generation sequencing-based *in vitro* diagnostic device for qualitative detection of *BRCA1* and *BRCA2* alterations in formalin-fixed paraffin-embedded (FFPE) ovarian tumor tissue. The FoundationFocus CDx *BRCA* assay detects sequence alterations in *BRCA1* and *BRCA2* (*BRCA1/2*) genes. Results of the test are used as an aid in identifying ovarian cancer patients for whom treatment with Rubraca® (rucaparib) is being considered. If a patient is positive for any of the deleterious alterations specified in the *BRCA1/2* classification, the patient may be eligible for treatment with Rubraca®. This assay is to be performed at Foundation Medicine, Inc., a single laboratory site located at 150 Second Street, Cambridge, MA 02141. **Contraindication** None. **Warnings and Precautions** *BRCA1/2* alterations reported include somatic (not inherited) or germline (inherited) alterations; however, the test does not distinguish between germline and somatic alterations. The test does not provide information about susceptibility. Biopsy may pose a risk to the patient when archival tissue is not available for use with the assay. The patient's physician should determine whether the patient is a candidate for biopsy. **Limitations** For *in vitro* diagnostic use. For prescription use only. For professional use only. This test must be ordered by a qualified medical professional in accordance with clinical laboratory regulations. Limited performance characteristics of the test were evaluated for insertion alterations > 4 nucleotides and deletions > 10 nucleotides. Performance of the FoundationFocus CDx *BRCA* was not established for insertions > 10 nucleotides, deletions > 12 nucleotides, alterations residing in polyC homopolymer runs, homozygous deletions or large rearrangements. Alterations in polyT homopolymer runs may not be reliably detected. Alterations detected at allele frequencies below the established limit of detection are not detected consistently. Information generated by this test is an aid in the identification of patients who are most likely to benefit from the therapeutic product. Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient's condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care in a given community. The test is intended to be performed at a single site on specific serial number-controlled instruments at Foundation Medicine, Inc. Rubraca® (rucaparib) is a product of Clovis Oncology. For additional information on the assay and detailed performance specifications, refer to the complete FoundationFocus™ CDx *BRCA* label at www.foundationmedicine.com/focus.

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