FOUNDATIONFOCUS™ CDx BRCA

Patient Name	Report Date	Tumor Type
[patientName]	[reportDate]	[tumorType]

Date of Birth	[birthdate]	**Medical Facility**	[medicalFacility]		
Sex	[gender]	**Specimen ID**	[externalSpecimenId]	**Specimen Site**	[biopsySite]
FMI Case #	[testRequest]	**Ordering Physician**	[physicianName]	**Date Collected**	[collectionDate]
Medical Record #	[medicalrecord]	**Pathologist**	[pathologist]	**Specimen Type**	[specimenType]
				Specimen Received	[recievedDate]

ABOUT THE TEST

The Foundation Medicine FoundationFocus™ CDx$_{BRCA}$ assay is a companion diagnostic to Clovis Oncology's drug Rubraca™, a poly (ADP-ribose) polymerase (PARP) inhibitor. Specimens that are found to have a deleterious *BRCA* alteration in their tumor tissue (t*BRCA+*) may be eligible for treatment with Rubraca therapy.

BRCA TEST RESULTS

Deleterious Mutations Detected	Gene	Alteration	Approved Therapies
Positive	[brcaVar][gene] :forEach]	[brcaVar][Alteration] :forEach]	Rubraca™ (Rucaparib)

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.

Electronically Signed by Jeffrey S. Ross M.D., Medical Director | CLIA Number: 22D2027531
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