Portfolio Reflex Option

We offer the option to automatically reflex between tissue and liquid sample types using our FDA-approved portfolio of FoundationOne®CDx and FoundationOne®Liquid CDx.

The Process

1. Check the Portfolio Reflex option in the Test Menu section on the Test Requisition Form.

2. Our laboratory determines if the initial specimen is insufficient for testing.

3. Foundation Medicine notifies you about the change.

4. If needed, our Client Services team works with you to collect the alternative sample type.

5. You receive test results typically within two weeks of receipt of the new sample type.

Select “Portfolio Reflex” on the test requisition form (TRF).

Foundation Medicine proceeds with initial test and if the specimen does not meet the criteria for successful testing, we will automatically reflex to the other test and procure a new specimen.

The failed test is not billed and the successful test will be billed according to our standard practices.

SEE EXAMPLE SCENARIOS ON THE BACK
FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based in vitro diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the 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 tests 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 testing with FoundationOne CDx when archival tissue is not available which may pose a risk. Patients who are tested with FoundationOne Liquid CDx and are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible.

For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and www.F1LCDxLabel.com.

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The portfolio reflex option may enable faster access to potentially actionable results for your patient.

To order a test, go to www.foundationmedicine.com/order

### Tissue to Liquid Example

1. FoundationOne CDx and “Portfolio Reflex” are selected during the ordering process.
2. The tissue submitted does not meet the criteria for successful testing.
3. Client Services team will send a blood collection kit to you to obtain peripheral whole blood for testing with FoundationOne Liquid CDx. Our mobile phlebotomy service can also be requested, if preferred.

### Liquid to Tissue Example

1. FoundationOne Liquid CDx and “Portfolio Reflex” are selected during ordering process.
2. Client Services team will notify you that the blood specimen does not meet the criteria for successful testing.
3. If the tissue specimen information is included on the TRF, we will contact the pathology lab to request the alternate tissue specimen to proceed with FoundationOne CDx testing.
4. If the tissue specimen information is not listed, we will contact you to obtain the specimen information in order to proceed with FoundationOne CDx testing.

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