FOUNDATIONONE®CDx

Specimen Instructions

FoundationOne®CDx is a next-generation sequencing based *in vitro* test intended for use by healthcare professionals for cancer patients with solid tumors. The test is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies in accordance with the approved therapeutic product labeling.

Acceptable Samples

- Formalin-fixed paraffin embedded (FFPE) specimens, including cut slide specimens are acceptable.
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6–72 hours is industry standard. DO NOT use other fixatives (Bouins, B5, AZF, Holland's).
- Do not decalcify.

Please note: Tissue blocks should be encased within a cassette before shipment (not provided).

☐ **SAMPLE SIZE**

1 When feasible, please send the block + 1 H&E slide.*

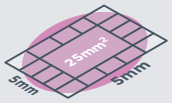
10 unstained slides (positively charged and unbaked at 4-5 microns thick) + 1 H&E slide.*

** For smaller samples, providing the original H&E will preserve material for testing.*

☐ **SURFACE AREA**

2 **MINIMUM: 25 mm²**

If sending slides, provide 10 unstained slides cut at 4-5 microns thick to achieve a tissue volume of 1 mm³.**



*** Specimens with a smaller surface area may meet volume requirements by submitting additional unstained slides (USS) or block.*

☐ **TUMOR CONTENT**

3 **OPTIMUM: 30% TN** **MINIMUM: 20% TN**

Percent tumor nuclei (%TN) = number of tumor cells divided by total number of all cells with nuclei

Note for liver specimens: higher tumor content may be required because hepatocyte nuclei have twice the DNA content of other somatic nuclei

Please note: If ordering immunohistochemistry (IHC) for PD-L1 in addition to FoundationOne CDx, an additional 4 unstained slides are required per IHC clone ordered.

Shipping Instructions

1. Place the completed Foundation Medicine Test, test requisition form, insurance information, and any other attachments into the FoundationOne CDx specimen shipping kit.
2. Place the specimen shipping kit (including samples and paperwork) into the provided clinical shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. If using shipping pack provided in this kit (recommended), recording the Kit ID # will allow you to properly track specimen. If you use a different shipping pack, consider recording that pack's tracking #.
4. Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location.

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.

FOUNDATION MEDICINE®

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