FOUNDATIONONE® CDx

Specimen Instructions

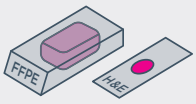
FoundationOne®CDx is an extensively validated tissue-based comprehensive genomic profiling service for all solid tumours. FoundationOne CDx analyses 324 cancer-related genes to provide potentially actionable information to help guide treatment options.[1-3]

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.

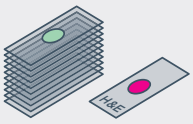
☐ **SAMPLE SIZE**

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



OR

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

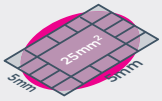


**For smaller samples, providing the original H&E will preserve material for testing.*

☐ **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.*

☐ **TUMOUR CONTENT**

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

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

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

Shipping Instructions

1. Place the samples, FoundationOne CDx requisition form, and any other attachments into the FoundationOne CDx Specimen Shipping Kit.
2. Place the specimen shipping kit (including samples and paperwork) into the shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labelled with two patient-specific identifiers. Seal the shipping pack.
3. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
4. Call to request a pick-up or drop the package at your site's designated pick-up location and ship sealed shipping pack to:

[insert local shipping information]

Intended Use

FoundationOne®CDx is a next generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including tumour mutational burden (TMB) and microsatellite instability (MSI) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with therapies in accordance with the approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumour mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms.

For full information on the intended use, assay descriptions, and for detailed performance specifications, refer to the complete FoundationOne CDx label at rochefoundationmedicine.com

References

1. FoundationOne®CDx FDA Approval, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170019a.pdf (Accessed August 2018).
2. FoundationOne®CDx FDA Approval Press Release, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587273.htm (Accessed August 2018).
3. FoundationOne®CDx Technical Specifications 2018. Available at: www.rochefoundationmedicine.com/f1cdxtech.

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