

Specimen Instructions

FoundationOne®RNA is a laboratory developed test (LDT) that is analytically validated to employ RNA sequencing across 318 cancer-related genes to capture a broad range of fusions and rearrangements. FoundationOne RNA was developed, and its performance characteristics were determined, by Foundation Medicine, Inc. FoundationOne RNA has not been cleared or approved by the United States Food and Drug Administration (FDA).

Both FoundationOne RNA and FoundationOne®CDx are run using the same tissue sample.



Acceptable Samples

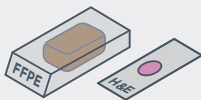
- Formalin-fixed paraffin embedded (FFPE) specimens, including cut slide specimens are acceptable.
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6-72 hours is industry standard. **DO NOT** use other fixatives (Bouins, B5, AZF, Holland's).
- Do not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

DO NOT USE strong acids (e.g. hydrochloric acid, sulfuric acid, picric acid) as these destroy nucleic acid. When decalcification is required, the use of EDTA is recommended.

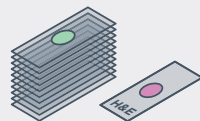
SAMPLE SIZE

- 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.*



OR

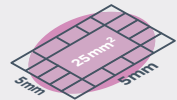


* For smaller samples, providing the original H&E will preserve material for testing.

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 RNA, an additional 4 unstained slides are required per IHC clone ordered. All cytologic and histologic specimens will be reviewed internally by a pathologist, and a determination of sample adequacy will be made. Additional or alternate material may be requested for optimal analysis.



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.

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