

Specimen Instructions

FFPE Specimens (Block or Slides)

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.

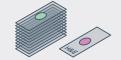
SAMPLE TYPE

1 FFPE BLOCK OR 16 UNSTAINED SLIDES (+ 1 H&E SLIDE)

Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin. DO NOT use other fixatives (AZF, B5, Bouin's, Holland's). If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness), plus 1 H&E slide.



OR



SURFACE AREA

2 OPTIMUM: 5 × 5 mm²

Tissue should have a surface area of at least 25 mm 2 (5 x 5 mm 2 , 2.5 x 10 mm 2).



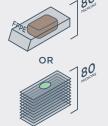
OP



SURFACE VOLUME

3 OPTIMUM: 2 mm³

Optimal sample volume can be achieved by sending optimal tissue surface area (25 mm²) at a depth of ≥80 microns. For suboptimal tissue surface area, additional depth is required.



NUCLEATED CELLULARITY

4 DNA is extracted from nucleated cells. Samples with low nucleated cellularity (e.g., those with abundant mature erythrocytes, lesional cells that contain excessive cytoplasm, or tissue with extensive associated fibrosis) may require greater tissue volume to yield sufficient DNA at extraction.



TUMOR CONTENT

5 MINIMUM: ≥20%

If the ratio of nucleated malignant to nucleated non-malignant cells is too low, sensitivity of detection of certain classes of alterations is reduced. High tumor content is preferable.



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

Note: 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. Remove the kit tracking information card and keep for your records
- 2. Label each primary specimen container (e.g. blocks, slides) with two patient-specific identifiers (e.g. name and DOB).
- 3. Put the completed Test Requisition Form into the orange box. (Alternatively, email it to Client Services or submit your order online).
- 4. If readily available, put concurrent or recent laboratory test results (e.g. pathology report) into the orange box. (These documents also may be emailed or faxed to Client Services or uploaded via our online portal.)

- 5. Place the orange box into the provided FedEx shipping packet.
- 6. Call 800.463.3339 to request a pick-up. Otherwise, drop the package at your site's designated FedEx pick-up location.

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FoundationOne*Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne Heme has not been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests (LDTs) please see their respective Technical Specifications at http://www.foundationmedicine.com.

