

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)

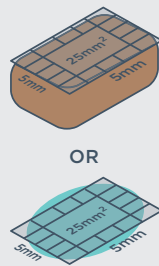
Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin. DO NOT use other fixatives (AZF, B5, Bouin's, Holland's). If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness), plus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



SURFACE AREA

2 OPTIMUM: 5 × 5 mm²

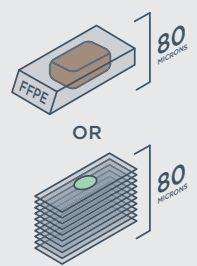
Tissue should have a surface area of at least 25 mm² (5 × 5 mm², 2.5 × 10 mm²).



SURFACE VOLUME

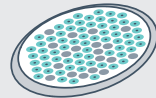
3 OPTIMUM: 2 mm³

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

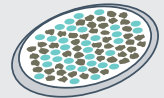
4 DNA is extracted from nucleated cells. Samples with low nucleated cellularity (e.g., those with abundant mature erythrocytes, lesional cells that contain excessive cytoplasm, or tissue with extensive associated fibrosis) may require greater tissue volume to yield sufficient DNA at extraction.



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

- Place the samples, FoundationOne®Heme requisition form, insurance information, and any other attachments into the FoundationOne Heme FFPE Specimen Shipping Kit.
- Place the specimen shipping kit (including samples and paperwork) into the provided FedEx shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
- 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 #.
- Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location and ship sealed shipping pack to:

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 Morrisville, NC 27560
 Phone: 888.988.3639