

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, brief exposure to a weak acid such as EDTA is recommended.

SAMPLE TYPE

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

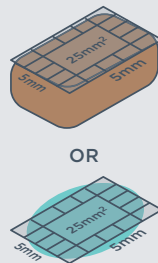
Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin. **DO NOT** use other fixatives (AZF, B5, Bouin's, Holland's). If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness),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



SURFACE AREA

2 OPTIMUM: 5 x 5 mm²

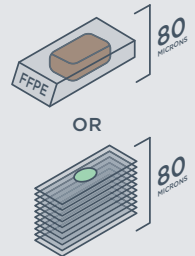
Tissue should have a surface area of at least 25 mm² (5 x 5 mm², 2.5 x 10 mm²).



SURFACE VOLUME

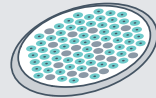
3 OPTIMUM: 2 mm³

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

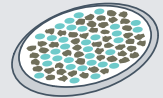
4 DNA is extracted from nucleated cells. Samples with low nucleated cellularity (e.g., those with abundant mature erythrocytes, lesional cells that contain excessive cytoplasm, or tissue with extensive associated fibrosis) may require greater tissue volume to yield sufficient DNA at extraction.



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

1. Place the samples, FoundationOne®Heme requisition form, insurance information, and any other attachments into the FoundationOneHeme FFPE Specimen Shipping Kit.
2. 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.
3. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
4. 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:

Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141
Phone: 888.988.3639

Specimen Instructions

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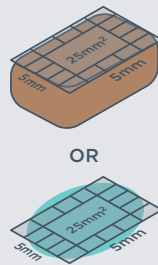
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SURFACE AREA

2 OPTIMUM: 5 x 5 mm²

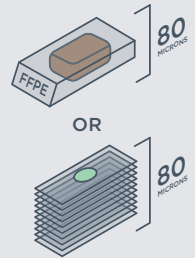
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SURFACE VOLUME

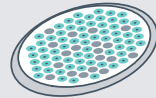
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NUCLEATED CELLULARITY

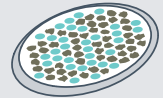
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Note: All histologic specimens will be reviewed internally by a pathologist, and a determination of sample adequacy will be made. Additional or alternate material may be requested for optimal analysis.

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Specimen Instructions

Fresh Specimens (Peripheral Whole Blood or Bone Marrow Aspirate)

Lesional tissue should constitute >20% of nucleated elements for optimal analysis.

<p>PERIPHERAL WHOLE BLOOD</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1 Fill one EDTA (lavender-top) tube with blood (for submission, not for waste). <input type="checkbox"/> 2 Collect 2.5 mL blood in one PAXgene blood RNA tube (see separate instruction sheet for additional details). <input type="checkbox"/> 3 Confirm that both the EDTA and PAXgene tubes are labeled with the specimen type (e.g., PB = peripheral blood), date of collection, and two unique patient identifiers (labels included in kit). <input type="checkbox"/> 4 Ship BOTH tubes via FedEx overnight, ambient temperature (see shipping instructions below for further details). 		<p>BONE MARROW ASPIRATE</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1 Collect 2.5 mL bone marrow aspirate in one EDTA (lavender-top) tube. <input type="checkbox"/> 2 Confirm tube is labeled with the specimen type (e.g., BMA = bone marrow aspirate), date of collection, and two unique patient identifiers (labels included in kit). <input type="checkbox"/> 3 Ship via FedEx overnight, ambient temperature (see shipping instructions below for further details). 	
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Additional Submission Requirements

1. Peripheral blood and bone marrow aspirate must be received the day after collection for optimal analysis, as sensitivity of detection may degrade with time. If procuring specimens on Friday, please FedEx priority overnight and specify Saturday delivery to ensure timely receipt.
2. Neoplastic/lesional cells must constitute at least 20% of nucleated cellular elements (tumor content will be determined based upon cytomorphologic review in conjunction with other supporting laboratory results when appropriate).
3. Specimens should NOT be frozen prior to submission.
4. Please submit concurrent or recent laboratory test results (e.g., CBC / differential, flow cytometry results, final bone marrow pathology report) if available (these documents may be faxed after specimen shipment; fax to 617.418.2290).

Extracted Nucleic Acid Submission Requirements

NUCLEIC ACID TYPE	SUBMISSION FORMAT	CONCENTRATION*	VOLUME	SHIPPING INSTRUCTIONS
DNA	Nuclease-free water	Picogreen: ≥ 3.5 ng/ μ l UV: ≥ 10 ng/ μ l	≥ 60 μ l	Domestic: ship overnight, ambient International: ship overnight, frozen on dry ice
RNA	Nuclease-free water	Ribogreen: ≥ 20 ng/ μ l	≥ 30 μ l	Domestic/International: ship overnight, frozen on dry ice

* Please specify concentration on requisition form.

See reverse for shipping instructions.

Shipping Instructions

1. Place the samples, FoundationOne®Heme requisition form, insurance information, and any other attachments into the FoundationOneHeme Specimen Collection and Shipping Kit.
2. Place the specimen kit (including samples and paperwork) into the provided FedEx shipping pack, first ensuring that primary specimen containers (e.g. tubes) are labeled with two patient-specific identifiers. Seal the shipping pack.
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Please ship priority overnight using enclosed label. (Note: Saturday delivery, when appropriate, must be specifically marked on the airbill in order to ensure proper handling.)

INTERNATIONAL ONLY: *Make three copies of the commercial invoice for FedEx courier and include with air waybill in FedEx documents pouch.*