

Specimen Instructions

Fresh Specimens (Peripheral Whole Blood or Bone Marrow Aspirate)

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

<div style="background-color: #f0f0f0; padding: 10px; border: 1px solid #ccc;"> <p style="text-align: center; background-color: #333; color: white; padding: 5px;">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). </div>		<div style="background-color: #f0f0f0; padding: 10px; border: 1px solid #ccc;"> <p style="text-align: center; background-color: #333; color: white; padding: 5px;">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). </div>	
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Additional Submission Requirements

1. Peripheral whole 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

Extracted nucleic acid (DNA & RNA) must originate from a CLIA-certified laboratory or a laboratory meeting equivalent 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 FoundationOne Heme 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.
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 and ship sealed shipping pack to:

Foundation Medicine, Inc.
7010 Kit Creek Road
Morrisville, NC 27560
Phone: 888.988.3639

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.