Fresh Specimens (Peripheral Blood Or Bone Marrow Aspirate) Preparation Instructions

Either peripheral blood or bone marrow aspirate are suitable specimens for submission. Tumor content should be >20% for optimal analysis.

**Fresh Specimen Collection & Submission Requirements**

**PERIPHERAL WHOLE BLOOD**

1. Fill one EDTA (lavender-top) tube with blood
2. Collect 2.5 mL blood in one PAXgene blood RNA tube (see separate instruction sheet; note that the PAXgene tube should always be the last tube drawn)
3. Confirm each tube is labeled with the specimen type (e.g. PB = peripheral blood), date of collection and two unique patient identifiers (labels included in kit)
4. Ship via FedEx overnight, ambient temperature (see shipping instructions below for further details)

**BONE MARROW ASPIRATES**

1. Collect 1.0 - 2.5 mL bone marrow aspirate in one EDTA (lavender-top) tube
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)
3. Ship via FedEx overnight, ambient temperature (see shipping instructions below for further details)

**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 laboratory test results (e.g. CBC/differential, flow cytometry results, final bone marrow pathology report) as soon as these become available (these documents may be faxed after specimen shipment; fax to 617.418.2290).

**Extracted Nucleic Acid Submission Requirements**

<table>
<thead>
<tr>
<th>Nucleic Acid Type</th>
<th>Submission Format</th>
<th>Concentration*</th>
<th>Volume</th>
<th>Shipping Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA</td>
<td>Nuclease free water</td>
<td>Picogreen: ≥3.5 ng/µl UV: ≥10 ng/µl</td>
<td>≥60 µl</td>
<td>Domestic: ship overnight, ambient International: ship overnight, frozen on dry ice</td>
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<tr>
<td>RNA</td>
<td>Nuclease free water</td>
<td>Ribogreen: ≥20 ng/µl</td>
<td>≥30 µl</td>
<td>Domestic/International: ship overnight, frozen on dry ice</td>
</tr>
</tbody>
</table>

* Please specify concentration on requisition form.
**FFPE Specimen (Slides Or Block Submission) Preparation Instructions**

Note: Do NOT use strong acids (e.g., hydrochloric acid, sulfuric acid, picric acid) for decalcification. EDTA is recommended when decalcification is required. Other decalcification procedures using weak acids for short periods of time may be successful but have not yet been fully validated.

### Sample Type

**FFPE Block or 16 Unstained Slides (+ 1 H&E Slide)**

Tissue should be formalin-fixed and embedded into a paraffin block. If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness) plus 1 H&E slide, ensuring that primary specimen containers are labeled with two patient-specific identifiers. Specimens of suboptimal size, cellularity, or tumor content may require additional unstained slides or an alternate tissue block.

### Surface Area

**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

**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

Nucleated cellular elements dictate DNA yield as 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

**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 and may result in a qualified report or may require an alternate specimen for analysis. High tumor content is preferable.

Note for liver specimens: Minimum tumor content is ≥40%.

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**Shipping Instructions for Fresh and FFPE Specimens**

1. Place specimen, FoundationOne®Heme Requisition form, insurance information, available reports, and accompanying documents into the FoundationOne Heme Specimen Kit.

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

2. Place the specimen kit (including samples and paperwork) into the provided FedEx shipping pack and seal the shipping pack.

3. 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 - alternate shipping label may be required).

4. Ship the sealed pack to the following address:

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

5. Drop the package at your site’s designated FedEx pick up location or call 800.463.3339 to request a pick up.