

Specimen Instructions

Fresh Specimens

(Peripheral Whole Blood or Bone Marrow Aspirate)

STEP 1

Ensure that you are utilizing the correct kit for the patient:

- Yellow kits are for FoundationOne®Heme blood or bone marrow aspirate specimens
- Accepted tumor types for FoundationOne Heme Fresh kits are leukemias and lymphomas, including myelodysplastic syndromes (MDS) and myeloproliferative neoplasms (MPN).

STEP 2

Ensure that your sample meets our specimen requirements:

Neoplastic/lesional cells must constitute at least 20% of nucleated cellular elements

(tumor content will be determined based on cytomorphologic review in conjunction with other supporting laboratory results when appropriate).




STEP 3

Understand your timeline:

All FoundationOne Heme fresh samples (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 samples on Friday, please FedEx priority overnight and specify Saturday delivery on the shipping label to ensure timely receipt.**

STEP 4

Collect the specimen. Specimens must **NEVER be frozen** prior to submission.

PERIPHERAL WHOLE BLOOD	BONE MARROW ASPIRATE
<div style="display: flex; align-items: flex-start;"> <div style="flex: 1;"> <div style="margin-bottom: 10px;"><input type="checkbox"/> 1 Fill the EDTA (lavender-top) tube with blood</div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> 2 Collect 2.5mL blood in the PAXgene Blood RNA Tube <div style="margin-left: 20px;"> a. Ensure that tube is at room temperature. b. Always ensure that the PAXgene tube is the last tube drawn in the phlebotomy procedure. </div> </div> <div style="margin-bottom: 10px;"><input type="checkbox"/> 3 Gently invert the PAXgene Blood RNA Tube 8–10 times.</div> <div><input type="checkbox"/> 4 Fill out the tube label with all requested information. (Incomplete information may delay test results.)</div> </div> <div style="flex: 0.2; text-align: center;">   </div> </div>	<div style="display: flex; align-items: flex-start;"> <div style="flex: 1;"> <div style="margin-bottom: 10px;"><input type="checkbox"/> 1 Discard the PAXgene collection tube</div> <div style="margin-bottom: 10px;"><input type="checkbox"/> 2 Collect 2.5mL bone marrow aspirate in the EDTA (lavender-top) tube</div> <div><input type="checkbox"/> 3 Fill out the tube label with all requested information. (Incomplete information may delay test results.)</div> </div> <div style="flex: 0.2; text-align: center;">  </div> </div>

STEP 5

Package and mail the specimen(s) to the Foundation Medicine laboratory. Each kit should be utilized for one patient. Do not include different patient samples in the same box.

Shipping Instructions

1. Remove the kit tracking information card and keep for your records.
2. Place each tube inside the provided absorbent Ziploc® bags.
3. Place the tube(s) back into the foam insert inside the yellow box. (If submitting bone marrow aspirate, only the lavender-top EDTA tube is required.)
4. Put the completed Test Requisition Form into the yellow box. (Alternatively, email it to Client Services or submit your order online).
5. If the patient has Medicare as his/her primary insurance, fill out an Advanced Beneficiary Notice (ABN) and put into the yellow box. (Completed ABN forms may also be sent to Foundation Medicine via fax at 866.283.5838 or emailed to myABN@foundationmedicine.com)
6. If readily available, put concurrent or recent laboratory test results (e.g. CBC/differential, flow cytometry results, final bone marrow pathology report) into the yellow box. (These documents also may be emailed or faxed to Client Services or uploaded via our online portal.)
7. Place the yellow box into the provided FedEx shipping packet.
9. Call 800.463.3339 to request a pick-up. Otherwise, drop the package at your site's designated FedEx pick-up location.
10. Ship via FedEx overnight, ambient temperature. Refer to step 3 regarding timelines for shipment.
11. Packets should be shipped to:

Foundation Medicine, Inc.

7010 Kit Creek Road

Morrisville, NC 27560

Phone: 888.988.3639

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 FoundationOne Heme, please see its Technical Specifications at foundationmedicine.com/heme.



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