

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 fresh 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

Shipping guidelines:

All FoundationOne Heme fresh peripheral blood and bone marrow aspirate samples **should be received within 3 days of collection** to prevent degradation. For optimal analysis, deliver samples the day after collection if possible. **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	
<input type="checkbox"/>	1 Fill the EDTA (lavender-top) tube with blood	<input type="checkbox"/>	1 Discard the PAXgene collection tube
<input type="checkbox"/>	2 Collect 2.5mL blood in the PAXgene Blood RNA Tube a. Ensure that tube is at room temperature. b. Always ensure that the PAXgene tube is the last tube drawn in the phlebotomy procedure.	<input type="checkbox"/>	2 Collect 2.5mL bone marrow aspirate in the EDTA (lavender-top) tube
<input type="checkbox"/>	3 Gently invert the PAXgene Blood RNA Tube 8-10 times.	<input type="checkbox"/>	3 Fill out the tube label with all requested information. (Incomplete information may delay test results.)
<input type="checkbox"/>	4 Fill out the tube label with all requested information. (Incomplete information may delay test results.)		

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 plastic resealable 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 and an Advanced Beneficiary Notice (ABN) is required, fill out an 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.)
 - NOTE: Mobile Phlebotomists do not need to collect and submit the test requisition form, ABN, or other laboratory results.
7. Place the yellow box into the provided clinical shipping packet.
8. Call 800.463.3339 to request a pick-up. Otherwise, drop the package at your site's designated FedEx pick-up location.
9. Ship via FedEx overnight, ambient temperature. Refer to step 3 regarding timelines for shipment.

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.



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)

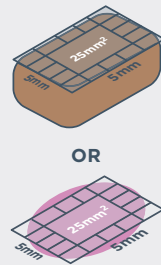
Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin. **DO NOT** use other fixatives (AZF, B5, Bouin's, Holland's). If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness),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



SURFACE AREA

2 OPTIMUM: 5 x 5 mm²

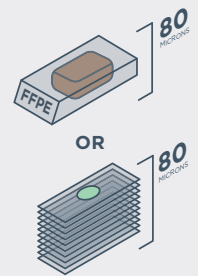
Tissue should have a surface area of at least 25 mm² (5 x 5 mm², 2.5 x 10 mm²).



SURFACE VOLUME

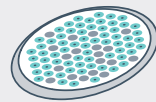
3 OPTIMUM: 2 mm³

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

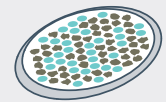
DNA is extracted from nucleated cells. Samples with low nucleated cellularity (e.g., those with abundant mature erythrocytes, lesional cells that contain excessive cytoplasm, or tissue with extensive associated fibrosis) may require greater tissue volume to yield sufficient DNA at extraction.



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. Remove the kit tracking information card and keep for your records
2. Label each primary specimen container (e.g. blocks, slides) with two patient-specific identifiers (e.g. name and date of birth).
3. Put the completed test requisition form into the orange box. (Alternatively, email it to Client Services or submit your order online).
4. If readily available, put concurrent or recent laboratory test results (e.g. pathology report) into the orange box. (These documents also may be emailed or faxed to Client Services or uploaded via our online portal.)
5. Place the orange box into the provided clinical shipping packet.
6. Call 800.463.3339 to request a pick-up. Otherwise, drop the package at your site's designated FedEx pick-up location.

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.