

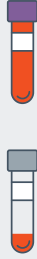
Specimen Instructions

Fresh Specimens (Peripheral Whole Blood or Bone Marrow Aspirate)

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


PERIPHERAL WHOLE BLOOD

- 1 Fill one EDTA (lavender-top) tube with blood (for submission, not for waste).
- 2 Collect 2.5 mL blood in one PAXgene blood RNA tube (see separate instruction sheet for additional details).
- 3 Confirm that both the EDTA and PAXgene tubes are labelled with the specimen type (e.g., PB = peripheral blood), date of collection, and two unique patient identifiers (labels included in kit).
- 4 Ship BOTH tubes at ambient temperature, confirming expedited / overnight shipping with courier to guarantee next day delivery (see shipping instructions below for further details).



BONE MARROW ASPIRATE

- 1 Collect 2.5 mL bone marrow aspirate in one EDTA (lavender-top) tube.
- 2 Confirm tube is labelled with the specimen type (e.g., BMA = bone marrow aspirate), date of collection, and two unique patient identifiers (labels included in kit).
- 3 Ship at ambient temperature, confirming expedited / overnight shipping with courier to guarantee next day delivery (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. Please ensure specimens are shipped from Monday through Thursday, at ambient temperature, confirming expedited / overnight shipping with courier to guarantee next day delivery. Specimens shipped on Friday can only be received before 14.00 CET on Saturday.
2. Neoplastic / lesional cells must constitute at least 20% of nucleated cellular elements (tumour 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.

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	Ship overnight, frozen on dry ice
RNA	Nuclease-free water	Ribogreen: ≥ 20 ng/ μ l	≥ 30 μ l	Ship overnight, frozen on dry ice

* Please specify concentration on requisition form.

See reverse for shipping instructions.

Shipping instructions

1. Please place the samples, FoundationOne Heme Test Requisition Form, and any other documents into the FoundationOne Heme Specimen Shipping Kit.
2. Please take out the Customs Invoice and Import Permit documents inside the FoundationOne Heme kit and place the FoundationOne Heme shipment kit that includes the sample and Test Requisition Form inside the provided shipment envelope (please seal the envelope prior shipment). Contact your Roche Foundation Medicine contact person to schedule the sample pick-up.
3. Please ensure specimens are shipped from Monday through Thursday, at ambient temperature, confirming expedited / overnight shipping with courier to guarantee next day delivery. Specimens shipped on Friday can only be received before 14.00 CET on Saturday.
4. Please print the shipment labels (Airwaybill) and hold them together with all Customs Invoice and Import Permit documents, ready outside the shipment envelope (will be provided via email after requesting the sample pick-up).
5. Please wait for the driver to pick up the sample by handing over the sealed envelope and all shipment documents for shipping to:

FMI Germany GmbH
Nonnenwald 2, Building 433
82377 Penzberg
Germany



Specimen Instructions

Sarcomas

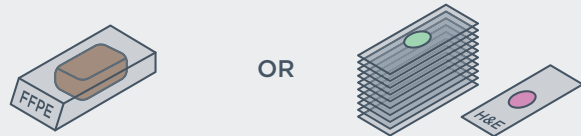
Note: Do NOT USE strong acids (e.g. hydrochloric acid, sulphuric acid, picric acid) as these destroy nucleic acid. When decalcification is required, brief exposure to a weak acid such as EDTA is recommended.

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.

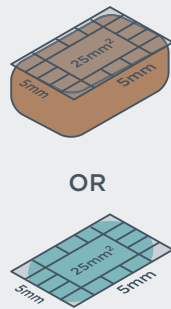
DO NOT use other fixatives (AZF, B5, Bouin's, Holland's). If sending slides, send 16 unstained slides (charged and unbaked, with tissue cut at a 5 micron thickness), plus 1 H&E slide.



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)

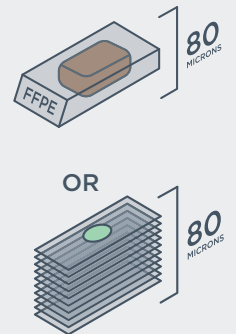


SURFACE VOLUME

3 Optimum: 2 mm³

Optimal sample volume can be achieved by sending optimal tissue surface area (25 mm²) at a depth of ≥80 microns.

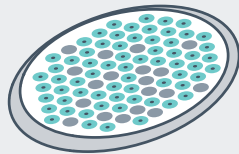
For suboptimal tissue surface area, additional depth is required.



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.



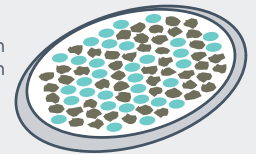
TUMOUR CONTENT

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 tumour content is preferable.

Note for liver specimens:

Higher tumour 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 Customs Invoice and Import Permit documents from the packaging.
2. Place samples, Test Requisition Form (TRF), and any other documentation into the FoundationOne Heme Specimen Shipping Kit.
3. Place the FoundationOne Heme Specimen Shipping Kit inside the provided shipment envelope. Seal the envelope.
4. Contact your Roche Foundation Medicine representative to schedule sample pick-up.
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6. When the driver arrives for pick-up, provide the driver with sealed envelope, shipment labels, Customs Invoice and Import Permits for shipping to:

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Specimen Instructions

FFPE Specimens (Block or Slides)

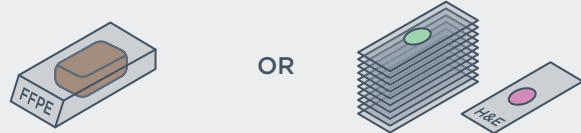
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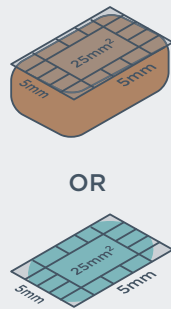
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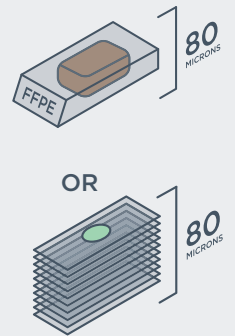
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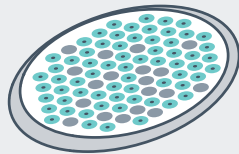
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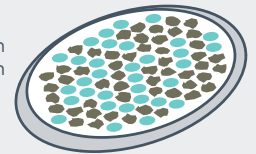
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