FOUNDATIONONE®HEME

Specimen Instructions

FFPE Specimens (Block or Slides)

FoundationOne®Heme may help you determine next steps for the care of your sarcoma and haematologic cancer patients by detecting the 4 known classes of genomic alterations.† Below are Specimen Guidelines to help ensure successful genomic profiling.†

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)**

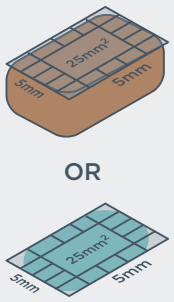
Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin.

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)

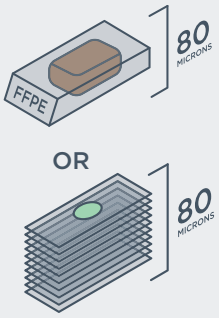


☐ **SURFACE VOLUME**

3 **Optimum: 2 mm³**

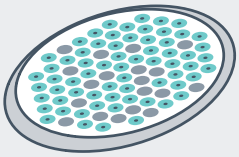
Optimal sample volume can be achieved by sending optimal tissue surface area (25 mm²) at a depth of ≥80 microns.

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.



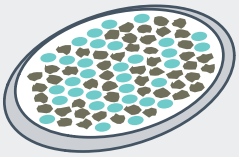
☐ **TUMOUR CONTENT**

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. Place the samples, test requisition form and any other attachments into the FoundationOne Heme FFPE Specimen Shipping Kit. Please provide the pathology report **in English**, if it is included.
2. Place the specimen shipping kit (including samples and paperwork) into the provided courier shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. Ensure commercial invoice in triplicate is initialed and included in the shipping pack.
4. Ship sealed shipping pack to:
   Accessioning, Clinical Laboratory Foundation Medicine, Inc.
   150 Second Street Cambridge, MA 02141
5. Drop the package at your site's designated FedEx pick-up location or call FedEx at 1-800-463-3339 to request a pick-up.

†He, J. et al. Integrated genomic DNA/RNA profiling of hematologic malignancies in the clinical setting. Blood 2016 Jun.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

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FOUNDATIONONE®HEME

Specimen Instructions

Fresh Specimens (Peripheral Whole Blood or Bone Marrow Aspirate)

FoundationOne®Heme may help you determine next steps for the care of your sarcoma and haematologic cancer patients by detecting the 4 known classes of genomic alterations.† Below are Specimen Guidelines to help ensure successful genomic profiling.† Lesional tissue should constitute >20% of nucleated elements for optimal analysis.

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

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 labeled 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 via FedEx overnight, ambient temperature (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 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 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

NUCLEIC ACID TYPE	SUBMISSION FORMAT	CONCENTRATION*	VOLUME	SHIPPING INSTRUCTIONS
DNA	Nuclease-free water	Picogreen: ≥ 3.5 ng/µl UV: ≥ 10 ng/µl	≥60 µl	Domestic: ship overnight, ambient International: ship overnight, frozen on dry ice
RNA	Nuclease-free water	Ribogreen: ≥ 20 ng/µl	≥30 µl	Domestic/International: ship overnight, frozen on dry ice

* Please specify concentration on requisition form.

Shipping Instructions

1. Place the samples, test requisition form and any other attachments into the FoundationOne Heme Fresh Specimen Shipping Kit. Please provide the pathology report **in English**, if it is included.
2. Place the specimen shipping kit (including samples and paperwork) into the provided courier shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. Ensure commercial invoice in triplicate is initialed and included in the shipping pack.
4. Ship sealed shipping pack to:
   Accessioning, Clinical Laboratory Foundation Medicine, Inc.
   150 Second Street Cambridge, MA 02141
5. Drop the package at your site's designated FedEx pick up location or call FedEx at 1-800-463-3339 to request a pick-up.

Please ship priority overnight using enclosed label.

1. †He, J. *et al.* Integrated genomic DNA/RNA profiling of hematologic malignancies in the clinical setting. Blood 2016 Jun.

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