

Specimen Instructions

FFPE Specimens (Block or Slides)



SAMPLE TYPE

1

FFPE BLOCK OR 16 UNSTAINED SLIDES (+ 1 H&E SLIDE)

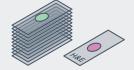
Tissue should be formalin-fixed and embedded into a paraffin block. Use standard fixation methods with 10% neutral-buffered formalin.

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.



3

OR

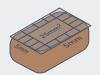


SURFACE AREA

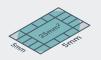
2

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)



OR

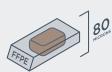


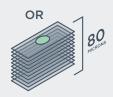
SURFACE VOLUME

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.

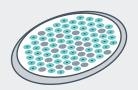




NUCLEATED CELLULARITY

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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.



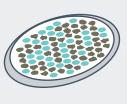
TUMOUR CONTENT

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.
- 5. Print out the shipment label (Airwaybill) provided to you via email after sample pick-up request.
- 6. When the driver arrives for pick-up, provide the driver with sealed envelope, shipment labels, Customs Invoice and Import Permits for shipping to:

FMI Germany GmbH Nonnenwald 2, Building 433 82377 Penzberg Germany



