Personalis®

Specimen Preparation for Clinical Testing FFPE

To ensure submitted specimens yield sufficient amounts of extracted DNA and RNA for sequencing and analysis, we have provided the following guidelines below for solid tumors. Decalcified bone is not accepted.

FFPE — Specimen Preparation

Guidelines for FFPE preparation:

- Fix tissue samples in 4–10% neutral buffered formalin as quickly as possible after surgical removal.
- Use a fixation time of 14–24 hours *(longer fixation times may lead to more severe DNA fragmentation, resulting in poor performance in downstream assays)*.
- Thoroughly dehydrate samples prior to embedding *(residual formalin can inhibit the proteinase K digest)*.
- FFPE sections should be as fresh as possible. Older FFPE sections may yield poorer results.
- For core biopsy, use 3–5 cores laid down so that when cut, the blade is running parallel to the long axis of the cores.

Samples can be prepared in one of the following ways:

OPTION 1

FFPE block

Curls will be prepared by Personalis and the remaining block can be shipped back to the customer upon test completion.

FFPE Block

OPTION 2

Unstained slides

Minimum 5 (10 micron thick) unstained slides must be accompanied by 1 additional unstained slide for H&E staining tumor content evaluation by Personalis. We recommend sending 8 FFPE slides because of biological variabilities (e.g., necrosis, sample quality, low tumor content). We will return all unused materials.

Minimum 5 (10 micron thick) unstained slides

1 unstained slide

Optimum tumor content required: ≥30%;
Minimum tumor content required: ≥20%

	# of Slides (10 µm thick)	Surface Area	Sample Volume
Regular tissue	≥ 5	25 mm^2/section	1 mm^3
Fatty tissue	≥ 12	25 mm^2/section	2.5 mm^3

Additional unstained slides or block may be requested if specimen surface area is < 25 mm^2/section.

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Instructions for Specimen Submission (FFPE)

1. Please email clientservices@personalis.com to request an 'FFPE sample kit' if you do not already have one.
2. FFPE samples can be shipped at room temperature.
   - Shipments must comply with all applicable local, state and federal laws governing packing, marking and labeling. Blood, fluids and other specimens containing or suspected to contain infectious substances must be shipped according to applicable government and International Air Transport Association (IATA) regulations.
3. Complete and sign all applicable fields of the test requisition form for each specimen.
4. Place the FFPE block into block container or slides into slide container. **Please make sure all samples are labeled with two unique identifiers.**
5. Place the container in the clear biohazard bag and zip closed. The back side of the bag contains a pocket for the patient's test requisition form.
6. Place the clear biohazard bag in the Personalis kit box.
7. Place the box in the provided prepaid FedEx 'Express Clinical Pak' and seal it.
8. Mail the sample at room temperature via overnight FedEx to:

Personalis Clinical Lab
1330 O'Brien Drive, Menlo Park, CA 94025
Tel: +1 (855) 373-7978

Sample Submission Checklist

Please complete this checklist to ensure efficient processing of your samples.

- ☐ Ensure sample is accompanied with a completed test requisition form.
- ☐ **U.S. customers** – please ship samples via overnight shipment using the instructions for specimen submission outlined in this document.
- ☐ **International customers** – contact Personalis for further shipping instructions.

Personalis NeXT Dx test: This laboratory developed test (LDT) will be performed in a CLIA/CAP accredited laboratory. The test was developed and its performance characteristics determined by the Personalis Clinical Laboratory. It has not been cleared or approved by the United States Food and Drug Administration (FDA). The Personalis Clinical Laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

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