Personalis®

Specimen Preparation for Clinical Use FFPE

To ensure submitted specimens yield sufficient amounts of extracted DNA and/or RNA for sequencing and analysis, we have provided the following guidelines below for solid tumors. Unacceptable specimens include hematolymphoid malignancies or decalcified bone.

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 and 1 H&E slide (if available)

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

FFPE Block + 1 H&E slide

OPTION 2

Unstained slides

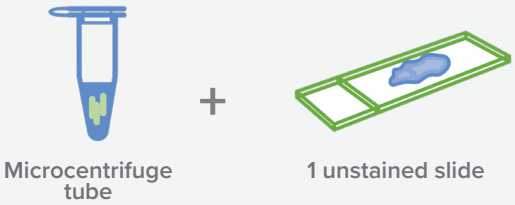
Min 5 unstained slides must be accompanied by 1 H&E slide for tumor content evaluation by Personalis.

Minimum 5 unstained slides + 1 H&E slide

OPTION 3

Unstained 5–10 micron thick curls

Place 5-10 micron thick curls into a microcentrifuge tube. Curls must also be accompanied by a slide (unstained or H&E stained) with an adjacent curl for tumor content evaluation by Personalis.



Microcentrifuge tube + 1 unstained slide

OR

Microcentrifuge tube + 1 H&E slide

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

	# of Curls	Surface Area	Sample Volume
Regular tissue	> 4	25 mm^2/section	1 mm^3
Fatty tissue	> 10	25 mm^2/section	2.5 mm^3

(continued on next page)

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Instructions for Specimen Submission (FFPE)

1. Please email clinical@personalis.com to request an 'FFPE sample kit' if you do not already have one.
2. FFPE samples can be shipped at room temperature.
   - All 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 and slides into slide container. Please make sure all samples are labeled with two unique identifiers.
   - If using microcentrifuge tubes, screw-top lids are preferred. Please use Parafilm® to cover lid for added seal precaution and clearly label tubes with water-resistant tags to ensure ink is not removed. Place individual tubes into a 50 mL conical tube filled with packing material *(such as paper towels)* to absorb the stress of shipping. Fill the void with paper to avoid physical damage during transport.
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 and other paperwork.
6. Place the clear biohazard bag in the specimen transport 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: 650-752-1300

Sample Submission Checklist

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

- ☐ Please email clinical@personalis.com to notify them of your shipment.
- ☐ Ensure sample is accompanied with a completed test requisition form and other paperwork.
- ☐ **U.S. customers** – please ship samples via overnight shipment using above guidelines.
- ☐ **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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