

Specimen Collection and Shipping Kit Instructions for Formalin-fixed, Paraffin-embedded (FFPE) Specimens

Please submit paraffin block or paraffin curls to Pathwork Diagnostics Laboratory (PDDL) using the PDDL Specimen Collection and Shipping Kit (Part No. 72948) for the Tissue of Origin Test. This kit contains the materials necessary for safely packing the specimen and shipping domestically via FedEx® overnight delivery.

SPECIMEN COLLECTION INSTRUCTIONS

WARNING

Health and Safety Precautions

Specimen and containers should be properly sealed prior to shipment.

Materials Provided by Pathwork Diagnostics Laboratory

1. Tissue of Origin Test Requisition Form (Part No. 72937 for US, Part No. 72950 for International)
2. Specimen Collection and Shipping Kit Checklist (Part No. 72947)
3. Three vials for paraffin curls
4. Clear, resealable bag
5. Foil-insulated pouch
6. Foam refrigerant
7. Outer shipping box
8. FedEx® Clinical Pak
9. FedEx® Airbill
10. FedEx® Airbill pouch

Materials Provided by Customer

1. FFPE specimen block (or curls in vials and H&E slide)
2. Pathology report for specimen

Specimen Requirements

Preferred specimen is a paraffin block of representative tissue. Alternatively, PDDL will accept a hematoxylin and eosin (H&E) slide and 3 vials, each containing curls that total 10 µm in thickness.

CONFIRM SPECIMEN MEETS THE FOLLOWING CRITERIA:

1. Tissue specimen should be obtained by routine procedures and contain at least 60% viable tumor.
2. Tissue should not sit on bench for more than 1 hour before fixation.
3. Tissue should be fixed in phosphate-buffered formalin or 4% paraformaldehyde for between 6 and 24 hours.
4. Tissue has not been decalcified.
5. Tissue is not in agar.
6. Tissue has not been previously frozen.

Specimen Rejection Criteria

PDDL will place specimens on hold and contact the customer under the following conditions:

1. Requisition Form is missing or incomplete.
2. Specimen Label is missing or incomplete.
3. Sample ID on Requisition Form does not match specimen.
4. Specimen does not meet criteria described above.
5. Specimen is damaged.
6. Paraffin block is melted.

Note: PDDL will contact the customer if a processed specimen does not yield a test result despite meeting PDDL specimen requirements.

For questions:

Call toll-free 1.877.808.0006
Outside of US: +1.650.366.1003

Email: support@pathworkdx.com
Visit our Web site: www.pathworkdx.com

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SHIPPING KIT INSTRUCTIONS

Specimen Packing

Note: Specimen should be shipped overnight to arrive Tuesday through Friday, except holidays. We do NOT recommend shipment Friday through Sunday.

Please use Specimen Collection and Shipping Kit Checklist for preparing specimen.

1. Complete one Tissue of Origin Requisition Form for each specimen according to instructions provided on the back of the Form. **NOTE:** A signature from the oncologist or ordering physician IS REQUIRED on the Requisition Form. Keep a copy of the Requisition Form for your records.
2. Ensure the specimen meets all PWDL requirements. Prepare tissue specimen for packing as follows:
 - a. Locate the Specimen Collection and Shipping Kit Checklist and obtain all materials needed for specimen packing and shipping before you begin.
 - b. Label Requisition Form, and paraffin block or vials (provided in kit) and H&E slide with Sample ID.
 - c. If sending paraffin curls, place in provided vials. **See Specimen Requirements.**
 - d. Place paraffin block or vials in the clear bag and seal it. If submitting an H&E slide, place into an appropriate slide holder.
 - e. Put all contents in foil-insulated pouch and seal it.
 - f. Place foil pouch in shipping box. Place foam refrigerant on top of foil pouch.
 - g. Place completed Requisition Form and pathology report in box.
 - h. Close box.
 - i. Place box in FedEx® Clinical Pak.

Specimen Shipping

1. Prepare package for shipping as follows:
 - a. Call FedEx® (1.800.463.3339) for same-day pickup.
 - b. Complete provided FedEx® Airbill (preprinted with shipping information).
 - c. Place completed FedEx® Airbill in FedEx® pouch.
 - d. Adhere Airbill pouch to FedEx® Clinical Pak.

Ordering Supplies

To order additional PWDL Specimen Shipping Kits, please call toll-free 1.877.808.0006 or email support@pathworkdx.com. Please allow 5 to 7 days to receive additional Shipping Kits.

Test Requisition Forms and Shipping Kit Checklists can also be downloaded and printed from our Web site at www.pathworkdx.com.

Contact Us

PWDL Customer Support will be pleased to address any questions or concerns related to the Tissue of Origin Test and shipment of specimens to our laboratory for analysis.

PWDL Customer Support

**Hours: 6 am to 5 pm (Pacific Time),
Monday through Friday**

Phone (toll-free): 1.877.808.0006
Outside of the US: +1.650.366.1003
Fax: 1.650.599.9501

Email: support@pathworkdx.com

**For additional information, visit our
Web site at www.pathworkdx.com.**