

## Specimen Collection and Shipping Kit Instructions

Please submit formalin-fixed, paraffin embedded tissue in a block or on unstained slides to Pathwork Diagnostics Laboratory (PDDL) using the PDDL Specimen Collection and Shipping Kit. 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. Test Requisition Form
2. Clear, resealable bag
3. Foil-insulated pouch
4. Cold pack
5. Outer shipping box
6. FedEx Clinical Pak
7. FedEx Airbill
8. FedEx Airbill pouch

#### Materials Provided by Customer

1. FFPE specimen block (**PREFERRED**) plus an H&E slide, if available
- OR**
2. Unstained slides (see Specimen Requirements for quantity)
  3. Pathology report for specimen

### SPECIMEN REQUIREMENTS

	Tumor area size: 1 mm <sup>2</sup> -2mm <sup>2</sup>	Tumor area size: >2mm <sup>2</sup> -5mm <sup>2</sup>	Tumor area size: >5 mm <sup>2</sup>
Tissue of Origin Test	FFPE Block or 10 USS* (5µm)	FFPE Block or 5 USS* (5µm)	FFPE Block or 3 USS* (5µm)
Mutation Test(s)	FFPE Block or 10 USS* (5µm)	FFPE Block or 5 USS* (5µm)	FFPE Block or 3 USS* (5µm)
ALK Gene Rearrangement (FISH)	Block or 4 USS (4 or 5 µm-thick) on <b>charged slides</b> (Specimen must contain at least 50 non-overlapping tumor cells)		
If sending FFPE block, one block containing 1 mm <sup>2</sup> of tumor tissue is usually sufficient for all testing (Tissue of Origin, Mutation Test(s) and ALK (FISH)). Include an H & E slide if possible.			
*Unstained Slides (USS) for Tissue of Origin or Mutation tests may be either charged or uncharged. Do NOT heat or melt paraffin.			

**Medical and scientific staff are available to answer questions about specimen suitability for testing. Please call Toll Free (877) 808-0006 between 6am and 5pm PST.**

#### Acceptable specimen types:

1. FFPE block of solid tissue
2. FFPE cell buttons from fine needle aspirates (FNA), including bone marrow aspirates
3. FFPE cell buttons from malignant effusions (except for ALK (FISH) test)
4. FFPE core needle biopsies
5. Unstained slides from any of the above

#### Unacceptable specimen types:

1. Tissue that has been decalcified (specific for Tissue of Origin testing)
2. Any unfixed tissues or fluids
3. Wet or frozen tissue, or tissue that has been previously frozen
4. Tissue pre-embedded in agar
5. Blood or urine

### SPECIMEN REJECTION CRITERIA

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

1. Test Requisition Form is missing or incomplete
2. Specimen label is missing or incomplete
3. Specimen identification does not match the Requisition Form patient identification information
4. Specimen does not meet criteria described under "Specimen Requirements"
5. Specimen is damaged
6. Paraffin block is melted

## Specimen Collection and Shipping Kit Instructions

NOTE: Specimen(s) should be shipped overnight to arrive Tuesday through Friday, except holidays. PWDL does not recommend shipment Friday through Sunday.

### SPECIMEN COLLECTION AND SHIPPING KIT CHECKLIST

Use this checklist while preparing specimen(s) for overnight shipment to Pathwork Diagnostics.

- Completed Test Requisition Form
- Copy of insurance information and face sheet
- Signature of Oncologist/Ordering Physician on Requisition Form
- Pathology report
- Paraffin block (or unstained slides) labeled with specimen ID
- Specimen sealed in foil-insulated pouch and placed in box
- Cold pack added to box
- Box closed
- Box placed in FedEx Clinical Pak
- Complete Airbill, put in pouch, and attach to FedEx Clinical Pak
- Arrange for FedEx pickup

### HOW TO ORDER SUPPLIES

To order additional PWDL Specimen Shipping Kits, please call toll free at 1.877.808.0006 or email [support@pathworkdx.com](mailto:support@pathworkdx.com). Please allow 5 – 7 days to receive additional Shipping Kits.

Test Requisition Forms and Specimen Collection and Shipping Kit Instructions can also be downloaded and printed from the Pathwork Diagnostics website at [www.pathworkdx.com](http://www.pathworkdx.com).

### HOW TO CONTACT PATHWORK DIAGNOSTICS

Call toll free 1.877.808.0006

Outside the U.S. call +1.650.366.1003

Hours of Operation: 6 AM to 5 PM (Pacific Time), Monday through Friday

### SHIPPING KIT INSTRUCTIONS

1. Complete one Test Requisition Form for each specimen according to instructions provided on the back of the Form. Keep a copy of the Form for your records.
2. Ensure the specimen meets all PWDL requirements. Prepare tissue specimen for packing as follows:
  - 2.1. Using the Specimen Collection and Shipping Kit Checklist, left, obtain all materials needed for specimen packing and shipping before you begin.
  - 2.2. Label Test Requisition Form, paraffin block or unstained slides, and H&E slide (if provided) with specimen ID.
  - 2.3. Place paraffin block in the clear bag and seal it. If sending unstained slides and/or H&E slide, place in a slide holder.
  - 2.4. Put all contents in the foil pouch and seal it.
  - 2.5. Place foil pouch in the shipping box. Place cold pack on top of foil pouch.
  - 2.6. Place completed Test Requisition Form and Pathology report in the box.
  - 2.7. Close the box, and place it in the FedEx Clinical Pak.

#### Specimen Shipping

1. Prepare package for shipping as follows:
  - 1.1. Call FedEx (1.800.463.3339) for same day pickup.
  - 1.2. Complete provided FedEx Airbill, pre-printed with shipping information.
  - 1.3. Place completed FedEx Airbill in FedEx pouch.
  - 1.4. Adhere Airbill to FedEx Clinical Pak.

Email: [support@pathworkdx.com](mailto:support@pathworkdx.com)

Visit our website: [www.pathworkdx.com](http://www.pathworkdx.com)