		<b>Biospecimen Pre-Analytical Variables (BPV) Work Instruction for Formalin-Fixed, Paraffin-Embedded (FFPE) Blue Kit Receipt and Shipping</b>	
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## 1.0 PURPOSE

This work instruction provides the specific steps necessary to pack and ship the paraffin blocks and slides in the Comprehensive Biospecimen Resource (CBR)-issued FFPE kit (Blue Kit).

The procedure section is divided into four subsections: the kit receipt at the biospecimen source site (BSS), the alert of collection, the packing instructions, and the shipping instructions.

## 2.0 ENVIRONMENTAL HEALTH AND SAFETY

- 2.1 Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association/ International Civil Aviation Organization regulations.
- 2.2 Appropriate personal protective equipment should be worn at all times, including but not limited to the following:
  - Gown or lab coat
  - Hair bonnet, mask, and shoe covers, per institutional requirements
  - Latex or Nitrile rubber gloves

## 3.0 PROCEDURE

### Kit Receipt at the BSS – FFPE

- 3.1 Contents correspond to supplies shown in Figure 1.
  - 3.1.1 Two 8-ounce Therapak freezer packs. **Please freeze at -20°C before use. Freezer packs should be placed in freezer at least 2 hours before shipment. It is recommended to put the freezer packs in the freezer upon receiving the kits.**
  - 3.1.2 One 1-gallon Ziploc bag for a 2-inch box
  - 3.1.3 An absorbent pad
  - 3.1.4 A FedEx Overnight pre-printed label for return shipment. **NOTE: Blue Kit shipments must be returned between Monday and Thursday to the CBR.**
  - 3.1.5 A Discrepancy Checklist for the Blue Kit and a 1-gallon plastic bag for paperwork
- 3.2 Upon receipt and before the kit is used, verify the contents. Do NOT use the kit if it is incomplete when verified against the **BPV Discrepancy Checklist for the Blue Kit (OP-0014-W1-F1)**. If incomplete, scan the checklist to a PDF and email it to the appropriate email address or call the appropriate phone number.
  - 3.2.1 The CBR will follow up with an action for resolution.


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Figure 1: Contents of a Blue kit

### **Alert of Collection**

#### 3.3 Timeline of alert to the CBR

3.3.1 Upon shipment of specimen. **This will occur ONLY after the Case Quality Assurance review by the BSS pathologist.**

#### 3.4 Method of alert to CBR: **EMAIL**

3.4.1 **PLEASE INCLUDE THE BPV CASE ID IN THE SUBJECT LINE OF ALL EMAILS.**

3.4.2 Indicate notice of shipment.



3.4.3 Indicate date specimen is anticipated to be shipped.

3.4.4 Indicate date specimen is anticipated to arrive at CBR.

3.4.5 Indicate tracking number used to ship specimens.

3.4.6 Use the following instructions for the email template for correspondence to CBR:

- In addition to the BPV ID number, note Source of Collection in the subject line (e.g., **Name of BSS, BPV-ID, Blue Kit**).
- Use the following template in the body of the email (Please note: **Do not state "Date of Collection or Procurement" in the body of the email or in the subject line**):  
*Hello, CBR.*  
*Please consider this email notification that one case of a BPV Blue kit is being shipped. The FedEx shipment to CBR will be shipped to you on <INSERT DATE> and is expected to arrive by <INSERT DATE>. The tracking number of the shipment to the CBR is <INSERT TRACKING NUMBER/COMPANY NAME>.*  
*Thank you,*  
*The <INSERT SITE NAME> site*


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### Packing Instructions

- 3.5 On the day on which the kit is shipped, complete the following steps:
  - 3.5.1 Ensure completion of all needed information on the appropriate case report forms.
  - 3.5.2 Place the yellow 2-inch box with all FFPE tissue cassettes collected for the case (up to 15 total) in the 1-gallon Ziploc bag.
  - 3.5.3 Place the two glass slides in the two-slide holder and place that in the Ziploc bag with the 2-inch box.
  - 3.5.4 Load the bag with the 2-inch box and slide holder in the Blue Kit.
  - 3.5.5 Remove the two freezer packs from the freezer and place them side by side in the Blue Kit on top of the 2-inch box. **Freezer packs should be completely frozen when loading into the Blue Kit.**
  - 3.5.6 Activate the data logger per the **Temperature Data Logger Usage for BSSs and Processing Centers (PBS-01.073)**.
  - 3.5.7 Load the activated data logger into the Blue Kit. Place the data logger so that it is not against the cold packs and next to the 2-inch box.
  - 3.5.8 Replace the Styrofoam lid.
  - 3.5.9 Complete the **BPV Blue Kit Manifest (OP-0014-W1-F2)**, provided in the Overpack, and place in the provided 1-gallon Ziploc bag on top of the Styrofoam lid.
  - 3.5.10 Seal the Blue Kit and apply the provided pre-printed FedEx label to the top of the box.
  - 3.5.11 Remove the yellow "PEEL OFF LABEL BEFORE SAMPLES ARE SHIPPED" label on the outside of the shipping package so that the "Exempt Human Specimens" labeling underneath is visible.

### Shipping Instructions

- 3.6 Verify all packing steps are complete and ship to the CBR via FedEx overnight to the appropriate address (using the included pre-printed FedEx return label)
- 3.7 Ensure that the pre-printed FedEx label included in the Blue Kit has been placed on top of the Blue Kit.
- 3.8 Contact FedEx to arrange a pick-up time and location.
- 3.9 **Reminder: Do NOT ship the Blue Kit on Friday. All Blue Kit shipments should occur between Monday and Thursday.**
- 3.10 Email a copy of the Chain of Custody Form (OP-0011-F1) to the appropriate recipients.

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#### 4.0 ACRONYMS

**BPV** Biospecimen Pre-Analytical Variables  
**BSS** Biospecimen Source Site  
**CBR** Comprehensive Biospecimen Resource  
**FFPE** Formalin-Fixed, Paraffin-Embedded

#### 5.0 REFERENCES

- 5.1 BPV Program Surgical Tissue Collection and Fixation, PR-0006
- 5.2 BPV Program FFPE Tissue Processing, OP-0003
- 5.3 BPV Program Paraffin Embedding of Formalin-Fixed Tissues, OP-0004
- 5.4 Chain of Custody Procedure, OP-0011
- 5.5 Temperature Data Logger Usage for BSSs and Processing Centers, PBS-01.073

#### 6.0 ATTACHMENTS

- 6.1 BPV Discrepancy Checklist for the Blue Kit, OP-0014-W1-F1
- 6.2 BPV Blue Kit Manifest, OP-0014-W1-F2
- 6.3 Chain of Custody Form, OP-0011-F1