



ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	ACTG / IMPAACT PAXgene® Blood RNA Tube Collection, Processing and Storage Policy		
SOP number:	LTC-SOP-76	Effective:	17Mar2025
Version:	v1.0	Last reviewed:	06Mar2025
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	5

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## 1. PURPOSE

The purpose of this Standard Operating Procedure is to provide a standardized method for the collection, storage, and shipping of whole blood in PAXgene® Blood RNA tubes.

## 2. BACKGROUND

The PAXgene® Blood RNA Tube contains an additive that stabilizes intracellular RNA in a closed tube for subsequent isolation and purification of intracellular RNA for use in molecular diagnostic testing.

## 3. SCOPE

Any site or laboratory staff members responsible for the collection, storage, and/or shipping of PAXgene® Blood RNA tubes for ACTG/IMPAACT studies.

## 4. DEFINITIONS

Term	Definition
ACTG	AIDS Clinical Trials Group
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials Group
LTC	ACTG/IMPAACT Laboratory Technologist Committee
SOP	Standard Operating Procedure

## 5. RESPONSIBILITIES

- 5.1. The Network Laboratory Directors (or his/her designee) have the authority to establish, review and update this procedure.
- 5.2. The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is responsible for the maintenance and control of SOP documentation.
- 5.3. The Laboratory Director is responsible for the implementation of this LTC SOP or laboratory-specific SOP and for ensuring that all appropriate personnel are trained. A laboratory SOP must:
  - 5.3.1. Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory.
  - 5.3.2. Reference the current version of the LTC SOP.
  - 5.3.3. All laboratory technicians are responsible for reading and understanding this SOP prior to performing the procedures described.
  - 5.3.4. The site's principal investigator and designees are responsible for understanding and adhering to the patient preparation and specimen collection components.
- 5.4. IATA/ICAO regulations state that any individual who handles, offers for transport, or transports dangerous goods must be formally trained and certified in Biological Substance, Category B specimen shipping. [8.2]

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## 6. EQUIPMENT AND CONSUMABLES

### 6.1. Boxes:

- 6.1.1. Example #1: Laboratory Product Sales, Inc.; Cardboard Storage Box; Product No. T233001
- 6.1.2. Example #2: Eppendorf 3P B95SQ; 4-inch box; Fisher Catalog No.50-118-0172  
Note: Any 3 or 4-inch x 5.25 inches x 5.25 inches cardboard storage box with a 49-cell divider will fit into the BRI freezer racks (8.88 inches high x 5.5 inches wide x 22.13 inches deep). The height of the box must not exceed 4.25 inches.

### 6.2. Inserts:

- 6.2.1. Example #1: Laboratory Product Sales, Inc.; 49 Cell Divider; Product Number T404901.
- 6.2.2. Example #2: Research Products International Corp; Cell Divider for Tube Storage Boxes; Fisher Catalog No.50-998-925.
- 6.2.3. Example #3: Fisherbrand™ Dividers for Fisherbrand™ Cryo/Freezer Boxes; Fisher Catalog No.03-395-460.

### 6.3. Storage Racks: Example: Laboratory Product Sales, Inc.; URO424.38. These are special order racks for storage at the repository and are not required at the processing lab.

### 6.4. Shipping Consumables

### 6.5. Category B secondary packaging that will fit 3 or 4-inch storage boxes are Saf-T-Pak STP 740/741. These will fit into the STP-320, STP-340 or other large IATA approved shippers for dry ice shipping

- 6.5.1. These will fit into the STP-320, STP-340 or other large IATA approved shippers for dry ice shipping.
- 6.5.2. Shipping multiple storage boxes will require a larger shipping container such as STP-340.

## 7. PROCEDURES

### 7.1. Specimen Collection and Processing of Blood Collected in PAXgene® Blood RNA Tubes

- 7.1.1. Ensure that the PAXgene® Blood RNA Tube is at ambient temperature (18–25°C) prior to use and properly labeled with specimen identification.
- 7.1.2. The PAXgene® Blood RNA Tube should always be the LAST tube drawn.
- 7.1.3. If the PAXgene® Blood RNA Tube is the only tube being drawn, a discard tube MUST be used to ensure the blood collection tubing volume is filled (“primed”) and the subsequent draw into the PAXgene® Blood RNA Tube is accurate (2.5mL).
- 7.1.4. Transport PAXgene® Blood RNA tubes at ambient temperature (15–25°C) to the processing laboratory; use ambient gel packs or other insulating materials when transporting specimens in extreme conditions.
- 7.1.5. Store the PAXgene® Blood RNA Tube upright at room temperature (18–25°C) in a rack for a minimum of 2 hours (maximum of 72 hours) prior to refrigerating or freezing at -20C. The blood is stable for 5 days at 2-8°C.

### 7.2. Freezing Specimens Collected in PAXgene® Blood RNA Tubes

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- 7.2.1. Transfer the PAXgene® tube to -20°C to allow tube contents to freeze homogeneously.  
*Note:* Do NOT freeze PAXgene® tubes in a Styrofoam tray, as this may cause tubes to crack.
- 7.2.2. Freeze PAXgene® tubes at -20°C for a minimum of 24hr prior to moving to -70°C / -80°C for long term storage.
- 7.2.3. Store frozen PAXgene® tubes in the appropriately sized storage boxes to avoid crowding that may damage the tubes (i.e. Laboratory Product Sales, Inc. Box #T233001 or any 3 or 4-inch-tall box, 5.25-inch square with a 49-cell divider.
- 7.2.4. Ship tubes on dry ice; do not allow PAXgene® tubes to thaw in transit.
- 7.3. Storage and Handling Recommendations
  - 7.3.1. Store unused PAXgene® tubes at 18–25°C.
  - 7.3.2. Always check the expiration date and do not use expired tubes.
  - 7.3.3. PAXgene® tubes are optimized for 2.5mL of whole blood.  
*Note:* Under-filling tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
  - 7.3.4. To reduce the risk of breakage from impact during handling and shipping, secure tubes properly in a fiberboard freezer box.
    - 7.3.4.1 Two 49-cell inserts may be stacked in storage boxes to better stabilize the tubes.
    - 7.3.4.2 Use a rubber band to secure the storage box and ensure that the properly sized secondary packaging (e.g., Tyvek bag) is used to secure the box and its contents.
    - 7.3.4.3 Do not mix different sized tubes (e.g., 2mL cryovials) in the same box as PAXgene® tubes.

## 8 REFERENCES


- 8.1 PAXgene® Blood RNA Tube IVD Product Information:  
<http://www.bdbiosciences.com/us/applications/blood-collection/cell-biomarker-preservation/paxgenereg-blood-rna-tube/p/762165>
- 8.2. *Dangerous Goods Training Guidance*. Edition 1, 01 January 2023. IATA Dangerous Goods.  
<https://www.iata.org/en/programs/cargo/dgr/>

## 9. INQUIRIES

Contact the ACTG/IMPAACT LTC Leadership at [actg.ltcleadership@fstrf.org](mailto:actg.ltcleadership@fstrf.org) for questions and comments related to these procedures.

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10. NETWORK LAB CENTER SOP APPROVAL

NAME AND TITLE	SIGNATURE	DATE OF APPROVAL
Grace Aldrovandi, MD ACTG/IMPAACT Network Laboratory Principal Investigator		17Mar2025

11. REVISION HISTORY OR RECORD RETIREMENT

VERSION #	EFFECTIVE DATE	REPLACES	DATE OF REVISION	RATIONALE FOR [REVISION/RETIREMENT]
1.0	17Mar2025			Original

12. APPENDICES – Not applicable

13. LABORATORY SOP REVIEW

LABORATORY STAFF NAME	DATE OF CONFIRMATION OF UNDERSTANDING