



**SOP 03.003, v 1.0  
SAMPLE SHIPPING & TRANSPORTATION**

**H3A Standard operating procedures  
SOP on sample shipping and transportation**

SOP Number:	03.003	Version:	1
Supersedes:		Category	Transport of biospecimens

Prepared by:	H3A Biorepository Working Group	Date Prepared:	August 2013
Signature/s:			
Date Adopted:			
Reviewed Period			

Approved by:	H3A Steering Committee Group	Date #
	Per:	Date #
	Signature	

**1.0 PURPOSE**

Biospecimens collected by H3Africa research groups will be transported to the processing/storage site (submission Site) and/or an H3Africa biorepository. When approval by the DBAC has been obtained, Biorepositories will also distribute samples to approved secondary users. Human Biospecimens are a precious resource and therefore care should be taken to preserve and maintain the integrity of these samples during the transport process.

**2.0 SCOPE**

This SOP outlines processes for shipping biospecimens within the H3Africa consortium, including but not limited to processing/storage/submission site and ultimately an H3Africa biorepository. While some of the referred documents are specific to the H3Africa consortium, the document can also serve as a reference for biological shipments in general, as needed. The SOP specifies considerations that should be followed to ensure appropriate packaging and shipping of the samples.

**3.0 LIMITATIONS**

The procedures outlined in this SOP may be subject to change depending on variations in specific laboratory procedures and they do not override national guidelines.



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**4.0 RESPONSIBILITIES**

This SOP applies to all personnel from H3Africa research groups and biorepositories who are involved in the shipping or receiving of samples.

<b>Personnel</b>	<b>Responsibility/Role</b>
Site coordinator/manager	Inform biorepository of samples to be sent. Ensure that samples are packaged correctly for shipping.
Shipper/Biobank Coordinator/Manager “when shipping to H3A biorepositories”	Initiate contact with courier to set up shipment. Coordinate sample receipt and storage

Note: It’s the responsibility of the shipper to ensure proper labeling and packaging of the consignment

**5.0 SPECIFIC NEEDS & REQUIREMENTS (Documents, forms & supplies)**

The documents and equipment listed below are required by the submission site to ensure IATA requirements are adhered to.

<b>Materials and Equipment</b>	<b>Materials and Equipment (Site Specific)</b>
MTA	
Valid Import/Export Permit (if required)	
Shipping waybill	
Temperature Loggers/monitor	
Labelled vials containing biospecimen	
Corrugated shipping carton containing Styrofoam container or Credo Shipper	
Lab tape (to secure tube in kit)	
Absorbent material	
Waterproof tape	
Sealable/Press-lock bag or Reusable ????	
Dry Ice or Ice Packs (if required)	
Shipping Category Labels (if required)	
Contact labels/markings	



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### 6.0 PROCEDURE

An established and tested shipping procedure is essential, as inadequate shipping procedures may lead to the loss of the samples and additional costs for repeat shipments.

#### 6.1 The safe and legal transport of biospecimens is based on the following mandated activities:

- a. Classification and naming of the material to be shipped
- b. Selection of packaging that will contain and protect the contents if the package is damaged
- c. Packing the shipment correctly
- d. Placing appropriate markings and labels onto the outer package
- e. Documenting relevant aspects of each package and its contents
- f. Training individuals about the requirements for appropriate packaging and shipping of biological substances and associated dangerous goods (dry ice).

#### 6.2 Ethical & Regulatory Considerations (At least one month prior to shipment)

6.2.1 [The shipper and/or recipient must contact the courier](#) to establish what supporting documentation is needed to ship the sample to the specified destination. Note: When shipping to an H3A biorepository, the [host biorepository will contact the courier](#).

- For international shipments, research any new regulations that may have been adopted or special permits that are needed for that destination.
- Determine whether “Exempt human specimen”, Category A , or Category B requirements is appropriate and attain or request the associated packaging materials. Examples of labels required for Category B and Dry Ice are included below for reference as these are most applicable to H3Africa.

6.2.2 Ensure that the Material Transfer Agreement, Import/Export Permit, project Informed Consent document, IRB/ethical approval and requisition for requested samples are attained as required and that intended storage/use is consistent with associated Informed Consent, prior to proceeding with the remaining procedures. Note: Ethical and regulatory documents noted below, which may take weeks to several months to process after initiation.

#### 6.3 Shipping Procedure



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- 6.3.1 Two weeks prior to shipment:
- a. Contact the recipient to inform them of the shipment details. Note: When shipping to an H3A biorepository a shipment notification form is required. Document/confirm telephone communication via email. Refer to H3A Shipment checklist for detailed description of requirements prior to shipping day and on the day of shipment. Please refer to the bio specimen guideline
- 6.3.2 At least one week before the shipment
- a. Verify that required supplies are available using the H3A Shipment Checklist: such as packaging, refrigerant, and MTA (Import/Export) as required. Prior arrangements can be made with certain couriers (E.g. World Courier and Marken) to provide shipping materials such as shipping box, dry ice, ice packs, sealable bags and waybill (not including ethical and regulatory documents). This arrangement must be planned in advance.
    - If temperature indicators and/or loggers will be included to monitor shipping temperature, ensure that the device is charged in advance according to the associated protocol.
    - If Credo (<http://www.pelicanbiothermal.com/products/credo>) or other shipper containing internal refrigerant is used, please ensure the shipper is charged in advance according to the associated procedures. Credo shippers eliminate the need to purchase/use refrigerant such as dry ice and ice packs due to self-contained refrigerant. They are available for controlled ambient, refrigerated and frozen shipment (-20°C and -50°C) for durations ranging up to seven days. See appendix for picture of Credo.
  - b. Prepare the H3A Shipment Manifest. The biospecimen list and quality control portions of the manifest may be either printed directly from the LIMS system or by creating the table in Microsoft Excel or Word. Ensure that all elements listed in the template are included as required. It also acceptable to complete c (below) first and create the manifest according to the order samples were pulled and arranged.
  - c. Pull the samples intended to be shipped and arrange them according to the H3A Shipment Manifest created above in the appropriate sample box, etc.
  - d. Replace the sample box/container back to storage until shipment as appropriate.
  - e. Replace any remaining samples, not being shipped, to storage.
- 6.3.3 At least one day before the shipment



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- a. Complete H3A Shipment Checklist Form, Shippers Waybill and Customs invoice (to provide contact information and to declare nature of contents to customs and regulatory agencies).
  - b. Prepare Shippers declaration as required. Dry ice is a Class 9 dangerous good, and requires completion of a shipper's declaration.
  - c. Print at least three copies of the H3A Shipment Manifest Form (one for your records, one to place inside the shipping box and one to place in the pouch attached to the outer shipping box).
  - d. Physically verify that the samples match the request and that arrangement and associated elements in the Shipment Manifest match the pulled vials. Where barcodes and scanner are available samples may be verified by scanning. If discrepancies are found correct them and ensure manifest is updated as required.
  - e. Verify that all shipping information, contacts and required documents are accurate and complete. Note: It is optimal to specify to whose attention the shipment is being delivered to. This measure should prevent the shipment from arriving and being delayed in the receiving department.
- 6.3.4 Shipment Day
- a. Retrieve samples from storage and keep frozen on dry ice, cold on gel packs or at room temperature on the bench until packaged according to the appropriate shipment temperature
  - b. Use appropriate safety procedures when handling dry ice or when retrieving samples from liquid nitrogen containers.
  - c. Document sample retrieval in database and complete shipping log or equivalent document where incoming and outgoing shipments are recorded according to established procedure. The following information should be included:
    - Waybill number for tracking package
    - Address and contact information for the Recipient / source
    - Date received or shipped
    - Courier name and contact information
    - Sample description/manifest
    - Quantity shipped
    - Researchers name
    - Study name
    - Confirmation of delivery
  - d. Package samples according to IATA shipping regulations.
    - Contact labels for both shipper and consignee are required. Please ensure that the person indicated as the consignee provides a



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- telephone number (to be included in the label) that is reachable 24 hours per day until delivery. If phone service is unreliable provide an alternative number in case the primary number is inoperable.
- Ensure shipping category labels are attached as required. Note DNA and dried blood spots are not considered dangerous goods and do not have required markings except for contact details unless shipped in a box with other biospecimen, dry ice or liquid nitrogen. (See Appendix for examples of labels/markings)
  - Triple packaging system required for Category and Category B biospecimen are referred to below (ex STP...) and pictures are also included in the appendix. Triple packaging is not required for DNA or dried blood spots; although, it is recommended if available. For more details see <https://www.saftpak.com/>. STP and similar products are also available through international vendors such as [www.fishersci.com](http://www.fishersci.com) and [www.vwr.com](http://www.vwr.com)
- e. If microtubes are being shipped, place each freezer box to be shipped into a separate sealable bag/Tyvek envelop packaging system (shown below as STP 710 & STP 711 or equivalent).
- Include a white absorbent strip, (ex. STP 152 or equivalent) in each polybag (ex. STP 711 or equivalent) containing a freezer box.
  - Try to squeeze out all access air before removing the tape and sealing the bag because if there is too much air, this pouch won't fit properly into the outer pouch (STP 710 or equivalent).
  - Place each plastic biohazard pouch containing a freezer box into a white pouch, STP 710 or equivalent (shown below underneath the clear pouch). Again, try to remove all access air before sealing the pouch.
  - In the space indicated on the white pouch, STP 710 or equivalent, please write the plate number, freezer box letter or number (Box A or Box 1...) and a detailed list of what's included in that particular freezer box. For instance 36 tubes containing ~2ml of HIV positive plasma)
- f. If vacutainers or serologic tubes are being sent, Place the blood tubes in the slots of the bubble pouch (STP 600 or equivalent, STP 109 or equivalent, or STP 110 or equivalent).
- Roll each pouch separately and place it in the Air or Sea BioJar, STP-104/ STP-104R or equivalent reusable secondary vessels, or polybag/Tyvek envelope system as described above (ex. STP 710/711 or equivalent according to number of samples).



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- g. Place temperature indicators and/or in the area where biospecimen are stored according to the corresponding protocol. Note: Please ensure the monitoring device has been properly activated prior to sealing the shipping box.
- 6.3.5 Contact (call or e-mail) consignee to provide them with Waybill number and inform them that package has been shipped. Give them an estimated delivery time so that they can anticipate arrival of the sample. Also, attach an electronic copy of the Shipment Manifest in the email unless there is an automated system of data transfer.
- 6.3.6 Both parties should Track delivery (using the online tracking capability of the courier) to monitor shipment and expedite sample if delayed by Customs or regulatory agencies.
- 6.3.7 Timing of shipping (to prevent delays in-transit):
  - a. Schedule pick-up early in the day so that the package goes out on the earliest flight available.
  - b. Schedule pick-up for early in the week (Monday or Tuesday) to prevent delays in shipment or delivery due to the weekend schedules. Early pick up schedule will vary according to country guidelines.
  - c. Do not ship just before a holiday long weekend as it usually translates into delays in transit.
  - d. Be aware of public holidays in the province or country of destination to plan for optimal shipping dates.

### 6.4 Test Shipment

In some situations, especially for extremely precious samples or when shipping to a new destination, sites may choose to send a test shipment with approximate characteristics of the actual shipment. This process may identify potential obstacles that could arise. It allows for corrective actions to be implemented, thus ensuring more successful shipment.

### 8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Canadian Tumour Repository Network: SOP on Sample Shipping and Transportation (09.001, ve2.0)

<http://www.ctrnet.ca/operating-procedures>

8.2 Declaration of Helsinki

<http://www.wma.net/en/30publications/10policies/b3/index.html>

8.3 Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010.

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

8.4 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>

8.5 International Air Transport Association (IATA)

<http://www.iata.org/Pages/default.aspx>





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8.6 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).

[http://www.isber.org/Search/search.asp?zoom\\_query=best+practices+for+repositories](http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories)

8.7 US National Biospecimen Network Blueprint

<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>

8.8 National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.

<http://bioethics.georgetown.edu/nbac/hbm.pdf>

8.9 Qualman, SJ. et al. Establishing a tumour bank: banking, informatics and ethics. Br. J. Cancer (2004). 90-1115-1119.

8.10 L.D. Gray and J.W. Snyder, (2006) Practical guidance to facilitate compliance with current international regulations that govern the packing and shipping of dangerous goods. Chapter 21 in Biological Safety, Principles and Practice, 4th edition, ed. D.O. Fleming and D.L. Hunt.

**9.0 MISCELANEOUS**

9.1 Depiction of Shipping Supplies

250mL Absorbant (STP-152 )

Polybag and Tyvek envelope (STP-710 & STP-711)



STP-600



STP-109 & 110

STP-104

STP-104R



STP-106



Labels  
UN3373 (category B)



Category B





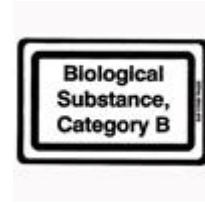
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Class 9 Hazard (Dry Ice)



Dry Ice



Credo Shipper



**10.0 REVISION HISTORY**

SOP number	Date revised	Author	Summary of Revisions

**11.0 APPENDICES**

- A. [Biospecimen Shipping & Transport Appendix A: Shipping Roadmap](#)
- B. [Biospecimen Shipping & Transport Appendix B: Shipment Notification Instructions](#)