

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

Standard Operating Procedure

SOP Number:	SHP-001.01.02
Title:	Shipment of Clinical Specimens to the NICHD Specimen Repository
Version:	6.0
Effective Date:	July 26, 2022
Approved By:	Jack Moye, NICHD
Last Review Date:	July 8, 2022
Reviewed By:	Fisher BioServices

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

Standard Operating Procedure

DOCUMENT CONTROL

Change Record:

EFFECTIVE DATE	AUTHOR(S)	VERSION	CHANGE HISTORY LOG
5/11/2011	Doreen Collins/Frances Whalen	01	
9/12/2012	Doreen Collins/Frances Whalen	02	Minor editorial changes: 1) Fisher BioServices address updated 2) 'CPS' defined 3) Reference to NIAID 'Priority Protocol Specimen List' removed
11/16/2015	Maria Wolff	03	Formatting and LN ₂ shipping instructions updated; general overhaul of procedure to make current.
10/25/2018	Laura Brockdorff	04	Added DOT compliance requirement. Updated LN ₂ filling/packing instructions for Category A dry shipper design.
3/15/2020	Jennifer Weck/Lori Merrill/Fatima Jones	5.0	<ul style="list-style-type: none"> - Definitions updated. FBS shipping address and FBS point of contact updated. References to HANC resources corrected. - Requirement for use of LDMS Shipping QA/QC barcode scanning to prepare shipment added. Scannable barcode label requirement added. Handwritten label option removed. - Full box requirement removed. Allowance for mixing different specimen types within boxes added. Prohibition against mixing different container sizes within boxes added. - CD option for shipping file removed. - Requirement for DG training/certification adjusted.

**SHIPMENT OF CLINICAL SPECIMENS TO THE
NICHD SPECIMEN REPOSITORY**

Standard Operating Procedure

EFFECTIVE DATE	AUTHOR(S)	VERSION	CHANGE HISTORY LOG
7/26/2022	Claudine Gregorio	6.0	<ul style="list-style-type: none"> - Definitions section updated. - Repository contact person changed from Ryan Patrick Babay to Laura Brockdorff (including accompanying information). - NICHDLabSpecialist email added to be copied in notifications to the Repository contact person. - Mention of fax removed from entire document. - Nonworking links replaced with current URLs. - User manual numbers for the LDMS web and Windows versions updated. - Text noting that 100% of all specimens go through QA/QC and all pass (evidenced with an LDMS-generated report) before being shipped included. - Steps in Section VIII reorganized. - Note added to clarify instructions for the filling of dry shippers. - Editorial changes made throughout document.

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

I. Purpose

To describe the requirements and procedures for shipment of clinical specimens from both domestic and international NICHD-funded sites to the NICHD Specimen Repository at Fisher BioServices.

II. Definitions

ACTG – AIDS Clinical Trials Group

ACTN – AIDS Clinical Trials Network

DBS – Dried Blood Spots

DOT – Department of Transportation

DMC – Data Management Center

HANC – HIV/AIDS Network Coordination

IATA – International Air Transport Association

LDMS – Laboratory Data Management System

LN₂ – Liquid Nitrogen

LPC – Laboratory Processing Chart

MOP – Manual of Procedures

MVE – MVE Biological Systems, manufacturer of cryoshippers

NIAID – National Institute of Allergy and Infectious Diseases

NICHD – *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

PID – Participant Identification

PBMC – Peripheral Blood Mononuclear Cell

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

III. Specimen Repository Facility – Shipping Address

Fisher BioServices - NICHD Repository

ATTN: Laura Brockdorff

625 Lofstrand Lane

Rockville, MD 20850 USA

Phone: 301-340-1620

Email: fbs.gbo@thermo.com; laura.brockdorff@thermofisher.com [CC: NICHDLabSpecialist@westat.com]

LDMS#: 243

IV. Applicability

- These procedures for specimen shipment and storage apply to specimens collected at clinical sites affiliated with the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD), National Institutes of Health (NIH).
- Clinical sites and other research networks that are affiliated with other NIH institutes, such as the National Institute of Allergy and Infectious Disease (NIAID), which are participating in IMPAACT- and other NICHD-supported clinical research studies should follow their respective repository instructions.

V. Requirements for Short-term and Long-term Specimen Storage

- Unless otherwise specified in the protocol, specimen storage is of two types: (i) short-term storage with specimen disbursement to testing laboratories at protocol-specified times and (ii) long-term archival storage.
- **Short-term storage** at the Fisher BioServices NICHD Repository applies to protocol specimens that will be batch tested more than 6 months after collection.
 - Specimens designated for "real-time" testing should be shipped directly to the testing laboratory.
 - Specimens that are not designated for "real-time" testing but will be tested within 6 months of collection should be held at the primary collection site and shipped to the testing laboratory at a time specified by the protocol.
 - Batch testing of specimens that will occur more than 6 months after collection should be shipped to the Fisher BioServices NICHD Repository when there is a full box or every 6 months unless otherwise indicated in the protocol.
- **Long-term storage** at the Fisher BioServices NICHD Repository refers to storage of specimens that are designated for future studies as defined in the protocol and the NICHD repository consent. These specimens can remain in storage for an indefinite period.

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

Standard Operating Procedure

- The specimen type (primary, additive, derivative, and sub-additive/derivative) and number of samples that are to be shipped to the Fisher BioServices NICHD Repository on a regular basis are specified in the Appendix section of each protocol and/or in the study-specific Laboratory Processing Chart (LPC).

VI. Shipping Schedules

- Shipments should be made Monday through Wednesday only. Shipments should be sent via overnight courier. No shipments should be made on or before a weekend or within 2 days of a holiday. The Fisher BioServices NICHD Repository is closed on weekends and many federal holidays and will be unable to receive the shipments. Holiday closures include: New Year's Day, Martin Luther King Day, President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the day after Thanksgiving, Christmas Day, and the day before Christmas. When unsure about holiday closures, contact Fisher BioServices NICHD Repository for confirmation.
- For domestic and international laboratories requiring charged liquid nitrogen (LN₂) dry shippers, at least 1 week prior to the site's shipping week, the Fisher BioServices NICHD Repository staff will ship charged LN₂ dry shipper from the Repository in accordance with the schedule established by the Repository staff. **NOTE:** Charged LN₂ dry shippers are available from Fisher BioServices NICHD Repository, but due to limited availability, dry shippers will be rotated between laboratories on the NICHD list.
- International sites will ship to the Repository as outlined in study-specific protocols. This may or may not involve routine shipments to the Fisher BioServices NIHCD Repository, but other guidelines for shipments do apply.
- The sites are required to use approved shipping containers to reduce improper packaging problems. All the components of the shipping containers must be used in compliance with International Air Transportation Association (IATA) regulations. No substitution of any components from other containers is allowed.
- All IATA Dangerous Goods and Department of Transportation (DOT) regulations must be followed when packing, labeling, and shipping specimens. Study and laboratory personnel involved with packaging and transporting specimens must receive adequate and appropriate training to ensure compliance to guidelines and regulations. Refer to the "[ACTG/IMPAACT Network Guidelines for Shipping and Receiving Biological Substance, Category B specimens](#)" document, [shipping demonstration video](#), and other shipping guidance on the Office of HIV/AIDS Network Coordination (HANC) website under the "Specimen Shipping" section of the ACTG/IMPAACT Laboratory Manual at <https://www.hanc.info/resources/sops-guidelines-resources/laboratory/actg-impact-laboratory-resources.html>.
- At least 24-48 hours prior to the planned shipment, the shipping site must email (laura.brockdorff@thermofisher.com AND fbgbo@thermo.com [CC: NICHDLabSpecialist@westat.com]) a notification prior to shipping using the "ACTG/IMPAACT Ambient/Refrigerated/Frozen Specimen Shipment Notice" found on the HANC website at

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

<https://www.hanc.info/content/dam/hanc/documents/laboratory/actg-impact-laboratory-manual/Ambient-Refrigerated-Frozen-Specimen-Shipment-Notice-08Apr2015-WorksheetOnly.pdf>.

VII. Storage Box and Shipping Requirements

- Where possible, to ensure maximum efficiency, laboratories should ship only full boxes to the Fisher BioServices NICHD Repository. However, partially filled boxes may be shipped if there are not enough specimens collected to fill a box within a six-month period. The Repository will repackage all specimens in new cryoboxes prior to storage.
 - For IMPAACT, storage boxes may be filled with specimens from multiple protocols.
 - Do NOT mix containers of different sizes within a box.
 - If necessary, different specimen types with the same container size and temperature requirement may be mixed within the same storage box.
 - Refer to the specimen shipping guidelines and LN₂ shipping instructions on the HANC website: <http://www.hanc.info/labs/labresources/Pages/informationActgImpactLabs.aspx>.
 - Before shipping any specimens to the Fisher BioServices NICHD Repository in LN₂, please refer to the section "Packing and Shipping LN₂ Specimens to the Fisher BioServices NICHD Repository" at the end of this SOP.

NOTE: Multiple boxes are now allowed in single shipment batches, meaning one shipping manifest and a shipment package can contain more than one freezer (specimen) box. Each specimen box is not required to have its own manifest. Manifests from multiple batches in the same shipment can be combined and sent in the same shipment package.

- 2-inch fiberboard storage boxes are to be used for shipments to the Repository. The 9x9 or the 8x8 box arrays are recommended for storage of 2.0 mL Nunc, Wheaton, or Corning tubes; the 10x10 box array should only be used for 1.8 mL Sarstedt brand tubes.
- 2-inch fiberboard boxes are also to be used for shipping Dried Blood Spots (DBS) for 1077HS study to the Repository. Refer to the 1077HS protocol Manual of Procedures (MOP) for specific storage and shipping instructions.
- 3-inch or larger fiberboard boxes may be used for shipping to the Repository if the protocol mandates larger volume storage (please refer to protocol-specific instructions). Only 3.6 mL cryovials should be used with 3-inch fiberboard boxes.
- Boxes of mixed protocol specimens designated for storage in -70°C freezers (serum, plasma, pellets, etc.) can be shipped on dry ice in the same shipping container. Please keep viable peripheral blood mononuclear cells (PBMCs) and other viable cell types that will be stored in LN₂ separate from the other samples.

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

- Boxes of cryopreserved viable PBMCs (LDMS derivative code CEL) intended for storage in LN₂ must be shipped in IATA-complaint LN₂ cryoshippers (also known as dry shippers).
- For cryopreserved PBMC, LN₂-rated fiberboard storage boxes should be used. This will allow for the direct placement of the shipment into LN₂ freezers at the Repository. These boxes should also be vented with drainage holes.

NOTE: Do not send plastic storage boxes for LN₂ or -70°C storage.

- All IATA Dangerous Goods and DOT regulations must be followed when packing, labeling, and shipping specimens. For compliance with domestic and international shipping regulations, individuals who pack and ship biological specimens should be trained and certified in Dangerous Goods Shipping.

VIII. LDMS Labeling Requirements

- A Laboratory Data Management System (LDMS) electronic shipping manifest must accompany all notifications of planned specimen shipments to the Fisher BioServices NICHD Repository. Notification of planned shipments with accompanying electronic manifests must be provided at least 24 hours in advance of shipment by email to laura.brockdorff@thermofisher.com AND fbs.gbo@thermo.com [CC: NICHDLabSpecialist@westat.com].
- Specimens must be uniformly labeled according to an LDMS-specified format with a computer-generated, **scannable barcode label** containing specific identifiers.
- All IMPAACT specimens stored after 01 October 2008 must be labeled with an LDMS-generated, scannable barcode that includes the following elements:
 - Participant Identification (PID)
 - Global Specimen ID
 - Protocol
 - Specimen Date
 - Primary/Additive/Derivative/Sub-additive
 - Specimen Time (24-hour clock)

All IMPAACT sites and laboratories must comply with the electronic LDMS inventory and labeling protocol. **NOTE:** Comments must be added to the LDMS regarding any re-labeling that has occurred. These comments are acceptable for all tube discrepancies, except

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

PIDs and Global Specimen IDs. The PID and Global Specimen IDs must match the LDMS/shipping manifest; otherwise, the testing laboratories will not accept them.

- Care should be taken that the specimen shipments comply with the labeling requirements and include the appropriate LDMS-generated documents/files, including an accurate Shipping Container Report. Fisher BioServices NICHD Repository personnel perform a quality check of 100% of the specimens received, and all sites will be notified of discrepancies.
NOTE: International shipments will be held to the same standard as the domestic shipments. Reconciliation of problem shipments will be required.
- All specimen-processing sites **must use the LDMS** as a prerequisite for shipping specimens to the Fisher BioServices NICHD Repository. Those subunits without the LDMS should either acquire the LDMS or arrange with their main clinical or laboratory site to electronically label and enter specimens into the LDMS site database before shipment to the Repository.
- Use the LDMS Shipment QA/QC function to scan specimen barcodes when preparing a container for shipment. This process checks each specimen's label against the information that LDMS will put on the shipping manifest and in the shipping file; 100% of all specimens should be QA/QCed.
 - Please refer to the *LDMS 10.0 for the Web – User Manual* (<https://www.ldms.org/resources/ldms/web/>) (Shipping>Shipment QA/QC>Performing QA/QC [<https://www.ldms.org/resources/ldms/web/#shipping/web/shipping-qa-qc.html>]) or *LDMS 13.6.1 for Windows – User Manual* (<https://www.ldms.org/resources/ldms/windows/>) (Shipping>Performing Quality Control on a Shipment [<https://www.ldms.org/resources/ldms/windows/#shipping/win/shipping-new-qa-qc.html>])).
 - **NOTE: Sites will incur costs if Fisher BioServices needs to relabel specimens, and these performance issues will be noted in annual performance evaluations.**
- Both the shipping file and storage boxes must be labeled with the batch number and laboratory or clinic site number. Multiple boxes can be put into the same shipping batch and in a single electronic shipping file. A shipping file must be emailed to the Repository with the shipment notification.
- All ACTG/IMPAACT shipments to the Repository must include:
 - LDMS-generated QA/QC Report [**NOTE:** This must show 100% pass for all specimens reviewed.]
 - LDMS-generated Shipping Manifest
 - LDMS-generated Shipping Container Report
 - LDMS Shipping Electronic file via email

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

- For specimen disbursement from the Fisher BioServices NICHD Repository to the testing site, each shipment will be accompanied by a shipping manifest and Shipping Container Report. The file will be used to import the shipped inventory into the receiving (testing) site's LDMS or other electronic inventory system, where appropriate, for either commercial or non-IMPAACT testing laboratories.

IX. Evaluation of Specimen Shipments to the Fisher BioServices NICHD Repository

- All specimen shipments to the Fisher BioServices NICHD Repository from the clinical and laboratory sites will be evaluated for compliance with proper specimen labeling, packaging, and shipping.
- The Data Management Center (DMC) will track the number and type of specimens to be sent to the Fisher BioServices NICHD Repository by each site/laboratory based on LDMS data exports from the Fisher BioServices Repository.

X. Prioritization of Specimen Shipments

- Information on the current list of approved shipments to the Fisher BioServices NICHD Repository can be found in the individual protocol LPC on the IMPAACT website.

XI. Transfer of Specimens to Testing Laboratories

- To have specimens transferred from the Fisher BioServices NICHD Repository to a testing laboratory, the protocol team **must** submit the specimen request form found on the DMC webpage. Alternatively, the team can ask the Data Manager or Laboratory Data Coordinator for the study to submit the specimen request on their behalf.
- The DMC will generate a report of specimens to be shipped by the Fisher BioServices NICHD Repository to the testing laboratory. The Fisher BioServices NICHD Repository staff will locate the specimens and ship them to the testing laboratory with an electronic shipping manifest and Shipping Container Report. At the testing laboratory, the information will be imported into the LDMS and the specimens tested. At the discretion of the protocol team, any unused specimens may be returned to the Fisher BioServices NICHD Repository for archiving, stored on site, or discarded.
- Any questions concerning these procedures can be addressed to the Westat NICHD Laboratory Specialist at NICHDLabSpecialist@westat.com.

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

PACKING AND SHIPPING LN₂ SPECIMENS TO THE FISHER BIOSERVICES NICHD REPOSITORY

These specimens are now classified as BIOLOGICAL SUBSTANCE, CATEGORY B, per the IATA Dangerous Goods Regulations.

A charged LN₂ dry shipper will be sent to your facility every 6 months to accommodate the required semi-annual shipment of viable PBMCs. The IMPAACT Primary Network Laboratory and the Fisher BioServices NICHD Repository staff will coordinate the schedule for these shipments.

Filling and Packing Instructions for LN₂ Dry Shipper

NOTE: The filling of the dry shipper may not be required if it was received fully charged and is being returned promptly to the repository. If filling is needed, begin this procedure at least 24 hours prior to the planned time of shipping.

Filling MVE LN₂ Dry Shippers:

1. Remove the dry shipper from the outer container casing.
2. Remove the metal internal canister and set to the side.
3. Fill the MVE Shipper to the bottom of the neck and allow the LN₂ to absorb.
4. Place the lid back on the dry shipper and allow it to stand for at least 24 hours (Day 1) so the absorbent material is fully saturated with LN₂. Continue to top off as necessary.
5. Twenty-four (24) hours after initial fill (Day 2), carefully refill the dry shipper with LN₂.
6. Prior to the shipment, pour out the excess LN₂. Do not pour out the LN₂ until you are ready to load the shipper with the specimen boxes/vials you plan to ship.

NOTE: When you are ready to load the specimen boxes/vials you plan to ship, there should be no liquid inside the shipper.

7. To ensure that the shipper has absorbed up to the full LN₂ capacity, it is necessary to weigh the shipper before the shipment. The acceptable range for the fully charged weight off the LN₂ shipper (with no excess LN₂ remaining) is between 47 and 53 lbs. (This does not include the outer casing, and the canister is not inserted at this point.) If the total weight of the shipper is less than 47 lbs, the LN₂ shipper may be damaged or might be insufficiently charged. It may be necessary to repeat the process or contact the shipper owner for appropriate action (i.e., repair or replace).

SHIPMENT OF CLINICAL SPECIMENS TO THE NICHD SPECIMEN REPOSITORY

Packing the MVE LN₂ Dry Shipper:

1. Generate a computer printout of the shipping manifest and Shipping Container Report to include in the shipment. Electronic copies of these files should also either be emailed to the Repository or downloaded onto a CD, which is included in the shipment.
2. Pre-cool the internal canister inside the chilled shipper before placing the specimen box(es) inside.
NOTE: Only two 2" specimen boxes can fit inside the canister. The boxes must be turned on their sides and inserted vertically, or they will not fit.
3. Place one absorbent sheet inside each 2" specimen box.
NOTE: If your samples are too high for a 2" box, you may lay them in a 2" box sideways and include enough filler to keep them secure and stable.
4. Place each box inside a plastic bag (STP-711) and seal inside a Tyvek envelope (STP-710). (This will be supplied by the Repository.) Remove all air before sealing the bag.
5. Place each specimen box vertically into the canister.
6. Place the lid on the canister and secure the screws with the provided wrench.
7. Place the lid on the shipper and secure with cable ties provided by the Repository.
8. Place the shipping manifest inside a plastic bag and secure it to the metal lid of the MVE dry shipper. If the electronic batch record is not emailed to the receiving site, a CD containing the batch record must be included in the plastic bag as well.
9. Place the MVE dry shipper inside the plastic outer container and secure the cover with cable ties.
NOTE: Shipments must be ready at least 2 hours prior to your close of business for pickup.
10. Email Fisher BioServices that the shipment has been prepared and the day you will be shipping. Contact Laura Brockdorff at laura.brockdorff@thermofisher.com and the Fisher BioServices NICHD Repository at fbs.gbo@thermo.com [CC: NICHDLabSpecialist@westat.com] to provide advance communications of the shipment.
11. Affix the appropriate shipping labels to the shipping container.
12. Complete the shipping Airbill. Ensure the total weight is recorded on the shipping Airbill.
13. Place the completed Airbill on top of the shippers.
NOTE: A Shippers Declaration of Dangerous Goods is not required.