

## NIDDK Central Repository – Resources for Research (R4R) Specimen Submission Label, Manifest, and Shipping Guidance

The following are the NIDDK Central Repository guidelines related to specimen labels (e.g., cryovial, slide) and electronic shipping manifests. The first column contains a common name for the field with the field name in the repository’s inventory database in parentheses.

		Specimen Label	Shipping Manifest
<b>Scannable specimen/ vial identifier barcode</b> (current_label)	Unique identifier assigned to a specimen/vial, typically issued in sequential order. Barcode numbers must be unique across a study (see below for scanning requirements).	Required	-
<b>Eye-readable vial identifier</b> (current_label)	Numeric representation of 1D or 2D barcode noted above	Required	Required
<b>Subject ID</b> (subject_id)	A non-HIPAA identifier for the participant from whom the specimen was collected. Unique per individual (e.g., not shared in a group such as a family trio). Sometimes referred to as the Participant ID.	Required	Required
<b>Network</b> (study_network)	A unique identifier indicating the consortia, study group, or network to which the study belongs.	Optional	Optional
<b>Study</b> (study_name)	A unique identifier indicating the study for which the specimens were collected. This may be part of the Barcode or Subject ID construct and therefore not required as a separate item on the label. Regardless, this is required as a separate column in the shipping manifest. Consortia, study groups, and networks should indicate the specific study protocol for this field.	Optional	Required
<b>Site code</b> (site_id)	A unique code for the clinical site within the study. May be included in construct of Subject ID or Participant ID. This is required as a separate column in the shipping manifest.	Optional	Required

<b>Material Type</b> (material_type)	The type of material collected (e.g., serum, plasma, whole blood, urine, DNA)	Required	Required
<b>Volume</b> (volume)	Numeric volume of specimen collected	-	Required
<b>Volume Unit</b> (volume_unit)	Relevant unit of measurement (e.g., mL, µL)	-	Required
<b>Collection Date or Collection Date and Time</b> (date_drawn)	The date that the specimen is collected/drawn	Optional	Required
<b>Visit/Timepoint</b> (visit)	The protocol visit/timepoint at which the specimen is collected:		
	- Longitudinal study (i.e., more than one specimen collected from a participant over time)	Optional	Required
	- Cross sectional study (i.e., one-time specimen collection per participant)	Optional	Recommended
<b>Comments</b> (comment)	Any additional information relevant to the specimen (e.g., hemolyzed, lysed)	-	Recommended
<b>Material Modifiers</b> (material_modifiers)	Relevant additive, preservative, stains (e.g., EDTA, H&E)	Optional	Recommended Required if > 1 type of additive, stain, etc. per material type
<b>Thaw Count</b> (thaws)	The number of times a specimen was thawed after having been frozen	-	Optional

## Additional Requirements:

### 1) Labels

- a. Label stock must be manufactured for long-term freezer storage. It is recommended that each tube has a single label and that the label does not overlap, leaving a gap available to visualize the volume. Barcodes and eye-readable information must be printed on the white portion of the label. Proper application of a cryovial label is shown below. The label must be applied with the barcode aligned vertically along the length of the tube so that the barcode is scannable. When the label is applied such that the barcode is wrapped around the vial, the barcode may not be scannable.



Labels and barcodes must be examined prior to applying them to specimens. This should include a visual check to ensure the quality of the printed information to minimize formatting issues such as the print being too small, illegible font/font cut off from the edge of the label, dark/splotchy printing, faded printing, etc. It is critical to confirm that there is sufficient “white space” surrounding the barcode to ensure its ability to be scanned. For this reason, the repository recommends test scanning labels at the time of printing.

- b. **Barcodes must be scannable at point of collection** (i.e., clinical site). If for some reason the barcode is not scannable, the specimen must be relabeled at the site and the barcode confirmed as scannable.

### 2) Shipping manifest

- a. Prior to shipping, sites are required to create an electronic manifest in either Excel or CSV to include the required and recommended fields as discussed above.
- b. In addition to the electronic manifest, sites are required to include a paper manifest to accompany specimen shipments.
- c. Every specimen included in a shipment must be included in the manifest (one line/row per specimen).
- d. On the day of the shipment, the shipping site must provide notification to the repository to include the courier and tracking information as well as an electronic copy of the manifest.

### 3) The following must be submitted to the NIDDK Repository for approval prior to implementation (or study start):

- a. Example of specimen labels
- b. Example of shipping manifest
- c. Copy of the study protocol and Manual of Operation (MOP)
- d. Brief description of DCC procedures to collect, track, and monitor specimen processes – from collection through shipping to the NIDDK Repository

Contact the NIDDK Repository with any questions at [NIDDK-CRsupport@nidk.nih.gov](mailto:NIDDK-CRsupport@nidk.nih.gov)

## Appendix 1

### Procedures for Shipping Frozen Specimens to the Repository

#### NIDDK Repository Contact Information:

Kurt Langenbach  
Precision for Medicine  
8425 Progress Drive, Suite M Frederick, MD 21701  
240-306-4100

Email: [niddk.mailbox@precisionformedicine.com](mailto:niddk.mailbox@precisionformedicine.com)

Shipments should be made Monday through Wednesday only.

Shipments should be made using the Saf-T-Pak STP 310 (or designated shipper).

1. Remove Empty Packaging Flap from front of box. A cardboard flap with the words "empty packaging" has been taped to the front of the box to cover the shipping labels when we ship the supplies to you. This flap can easily be cut from the box and removed. Once removed, all shipping labels should be present.



- a. With the Empty Packaging Flap removed, the box should contain the following labels. If any of the labels are missing, please contact Precision for Medicine for replacements.
  - i. To Label (To: Repository)
  - ii. From Label (From: your site)
  - iii. Class 9 Diamond Label
  - iv. UN3373 Biological Substance Category B Label
  - v. Dry Ice UN1845 Label with space to add weight
2. Place Dry Ice around the small inner brown box (between brown box and Styrofoam container).



3. Place Rubber band (at least ¼" thick) around Freezer Box containing specimens.
4. Place White Absorbent Strip around Freezer Box.
5. Place Freezer Box containing specimens in Clear Biohazard bag, remove as much air as possible, and seal according to instructions on the bag.



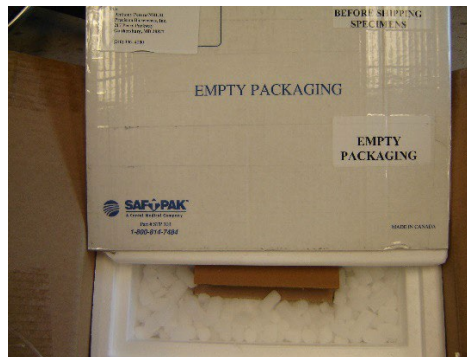
6. Place Clear Biohazard bag in White Biohazard bag, remove as much air as possible, and seal according to the instructions on the bag.



7. Place White Biohazard bag(s) in the inner brown box - the shipping container can hold three 2" freezer boxes or two 3" freezer boxes.



8. Add additional dry ice to bring total amount to the same level as the top of the brown inner box. Note that the total amount of dry ice will be ~16 lbs or 9 kgs.
9. Place the Styrofoam lid onto the container (do not tape the Styrofoam lid).
10. Place the “empty” packaging flap and the paper manifest on top of the Styrofoam, and then seal the cardboard box.



11. Place the Emergency Guideline sheet for UN2814 & UN3373 sheet along with the FedEx Airway bill in the Airway bill holder and place it on packaged box.
12. Fill in the Dry Ice Label on box with the amount of dry ice used.
13. **Prior to shipment**, send an e-mail to Precision for Medicine: [niddk.mailbox@precisionformedicine.com](mailto:niddk.mailbox@precisionformedicine.com)  
Include the following information in the e-mail:
  - Shipper’s Name
  - Shipper’s Study Name/Site ID
  - Shipper’s Address
  - Shipper’s Phone
  - Shipment Date
  - Courier
  - Tracking Number (no spaces)
  - Package Weight and Unit of Measure (e.g., 20 kg)
  - Approximate number of specimens

- Dangerous Goods Classification: Biological Substance Category B UN3373
- **An electronic copy of the shipping manifest**

14. Once the shipment is packed and ready for pick-up, call FedEx at **1.800.463.3339** and request "schedule a pickup" (Record the pickup confirmation number provided by FedEx).
15. Ensure that the package is picked up by the designated courier and that the courier has scanned the package to acknowledge pickup.
16. Once the package has been picked up, confirm the package status by visiting: <https://www.fedex.com/en-us/tracking.html> or by calling FedEx at: **1.800.463.3339**.
17. If using a Pre-printed waybill that was provided by Precision for Medicine through an emailed PDF, use each pre-printed waybill for only one (1) shipment. Discard or delete the digital copy of the waybill once it has been used for a shipment. Request additional waybills by contacting Precision for Medicine at the contact information provided above.

Please contact Precision for Medicine (at the contact information above) with any questions related to shipping.

## Appendix 2

### Procedures for Shipping Ambient Specimens to the Repository

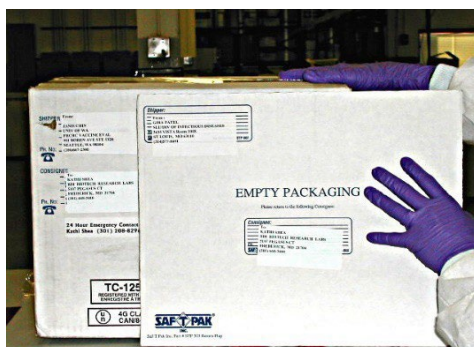
NIDDK Repository Contact Information:  
Kurt Langenbach  
Precision for Medicine  
8425 Progress Drive, Suite M Frederick, MD 21701  
240-306-4100

Email: [niddk.mailbox@precisionformedicine.com](mailto:niddk.mailbox@precisionformedicine.com)

**Shipments may be made Monday through Friday. Please provide notification on Thursday if a study visit is scheduled to ship a specimen on Friday.**

**Shipments should be made using the Saf-T-Pak STP 310.**

1. Remove Empty Packaging Flap from front of box. A cardboard flap with the words "empty packaging" has been taped to the front of the box to cover the shipping labels when we ship the supplies to you. This flap can easily be cut from the box and removed. Once removed all shipping labels should be present.



- a. With Empty Packaging Flap removed, the box should contain the following labels. If any of the labels are missing, please contact Precision for Medicine for replacements.
    - i. To Label (To: Repository)
    - ii. From Label (From: your site)
    - iii. 24 Hour Emergency Contact Label
    - iv. UN3373 Diamond Biological Substance Category B Label
2. Place specimens in Freezer Box.
  3. Place Rubber band (at least ¼" thick) around Freezer Box containing specimens.
  4. Place White Absorbent Strip around the Freezer Box.
  5. Place Freezer Box in Clear Biohazard bag and seal according to instructions on the bag.
  6. Place Clear Biohazard bag in White Biohazard bag and seal according to the instructions on the bag.
  7. Place White Biohazard bag(s) in the inner brown box (the shipping container can hold three 2" Freezer boxes or two 3" freezer boxes).
  8. Place the Styrofoam lid onto the container (do not tape the Styrofoam lid), place the "empty" Packaging flap and the paper manifest on top of the Styrofoam, and then seal the cardboard box.



9. Place the Emergency Guideline sheet for UN2814 & UN3373 sheet along with the FedEx Airway bill in the Airway bill holder and place it on packaged box.
10. **Prior to shipment**, send an e-mail to Precision for Medicine at: [niddk.mailbox@precisionformedicine.com](mailto:niddk.mailbox@precisionformedicine.com)  
Include the following information in the e-mail:
  - Shipper's Name
  - Shipper's Study/Site Number
  - Shipper's Address
  - Shipper's Phone
  - Shipment Date
  - Courier
  - Tracking Number (no spaces)
  - Package Weight and Unit of Measure (e.g., 20 kg)
  - Approximate number of specimens
  - Dangerous Goods Classification: Biological Substance Category B UN3373
  - **An electronic copy of the shipping manifest**
11. Once the shipment is packed and ready for pick-up, call FedEx at **1.800.463.3339** and request "schedule a pickup" (Record the pickup confirmation number provided by FedEx).
12. Ensure that the package is picked up by the designated courier and that the courier has scanned the package to acknowledge pickup.
13. Once the package has been picked up, confirm the package status by visiting:  
<https://www.fedex.com/en-us/tracking.html> or by calling FedEx at:  
**1.800.463.3339**.
14. If using a pre-printed airway bill that was provided by Precision for Medicine through an emailed PDF, use each airway bill for only one (1) shipment. Discard or delete the digital copy of the airway bill once it has been used for a shipment. Request additional airway bills by contacting Precision for Medicine at the contact information provided above.

Please contact Precision for Medicine (at the contact information above) with any questions related to shipping.