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

The following are NIDDK Central Repository (NIDDK-CR) guidelines related to electronic shipping manifests and values required on specimen labels. Prior to shipping, sites are required to create an electronic manifest in either Excel or CSV format that includes at minimum the required fields described below. Every specimen included in a shipment must be included on the manifest (one line/row per specimen).

In addition to the electronic manifest, sites are required to include a paper manifest to accompany specimen shipments. On the day of the shipment, the shipping site must provide notification to the repository via BSI Engage, to include the courier and tracking information, as well as an electronic copy of the manifest.

The table below describes the various information fields to include on specimen labels and in shipping manifests. The first column contains a common name for the field with the field name in the repository's inventory database in parentheses. The last two columns note if the value is required on the specimen label, shipping manifest, or both.

		Specimen Label	**Shipping Manifest**
1D or 2D Barcode of Vial Identifier (current_label)	Barcode of unique identifier assigned to a specimen/vial, typically issued in sequential order. Barcode numbers must be unique across a study.	Required	Not Applicable
Eye-readable Vial Identifier (current_label)	Alphanumeric representation of the unique identifier coded in the 1D or 2D barcode noted above.	Required	Required
Participant ID (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).	Required	Required
Network (study_network)	A unique identifier indicating the consortia, study group, or network to which the study belongs.	Optional	Optional
Study (study_name)	A unique identifier indicating the study for which the specimens were collected. Consortia, study groups, and networks should indicate the specific study protocol for this field.	Optional	Required
Site Code (site_id)	A unique code for the clinical site within the study.	Optional	Required
Material Type (material_type)	The type of material collected. Type must be selected from pre-determined list. See below (Section 3) or example manifest material type dropdown options.	Required	Required

Material Modifiers (material_modifiers)	Relevant additive, preservative, stain, collection method, etc. (e.g., EDTA, H&E, 24 hr.).	Optional	Required for specific material types
Volume (volume)	Numeric volume of specimen collected.	Optional	Required
Volume Unit (volume_unit)	Relevant unit of measurement (e.g., mL, µL).	Optional	Required
Collection Date (date_drawn)	The date that the specimen was collected/drawn.	Optional	Required
Visit (visit)	The protocol visit at which the specimen was collected: • Longitudinal study (i.e., more than one specimen collected from a participant over time). • Cross sectional study (i.e., one-time specimen collection per participant).	Optional for both study types	Required for longitudinal studies Recommended for cross sectional studies
Collection Time (timepoint) (timepoint_unit)	The time of day that the specimen was collected/drawn in 12 hour clock or 24 hour clock.	Optional	Optional
Comments (comment)	Any additional information relevant to the specimen (e.g., hemolyzed, lysed).	N/A	Recommended
Aliquot Number (sequence)	Sequential numerical value of specimen collected from the same draw.	Optional	Optional
Thaw Count (thaws)	The number of times a specimen was thawed after having been frozen.	N/A	Optional

Manifest Requirements for Biological Macromolecules Material Types (DNA, RNA, and Protein)

The requirements outlined in the table above apply to DNA, RNA, and protein specimen submissions. In addition to the table contents, several additional manifest fields are required. These fields are highlighted in green in the example manifest and are detailed below.

Required Fields

- Concentration and Concentration Unit
- Mass and Mass Unit
- Source Material Type
- Buffer

Optional Fields

- A260/280
- Extraction Method
- Quantification Method

Additional Requirements

1. Labels

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 of material in the tube. The label must be applied with the barcode aligned vertically along the length of the tube so that the barcode is scannable. If the label is applied such that the barcode is wrapped around the vial, the barcode may not be scannable. Proper application of a cryovial label is shown below.

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.

Barcodes must be scannable. If for some reason the barcode is not scannable, the specimen must be relabeled at the site and the barcode confirmed as scannable.

2. The following must be submitted to the NIDDK Repository for approval prior to initiating shipping:

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

3. Approved Material Types

Below lists the approved material types of specimens to be sent to the biorepository. The value in the material type column is how it should appear on the electronic and physical manifests. If your material type is not listed below, NIDDK-CR will provide guidance on mapping the material type. NIDDK-CR will also provide guidance on other required information and where to provide the information on the manifest.

Material Group	Material Type	Information required to be submitted with specimens
Biological Macromolecules	DNA	Specific type (e.g., cDNA) and mass, concentration, and elution buffer if known
Biological Macromolecules	RNA	Specific type (e.g., mRNA, mitochondrial RNA, RNA supernatant) and mass, concentration, and buffer if known
Biological Macromolecules	Protein	Origin of material and mass, concentration, and suspension buffer if known
Fluids	Blood	Preservative or stabilizing agent (e.g., MM tolerance test, Pax gene)
Fluids	Serum	Source and preservative
Fluids	Plasma	Source and preservative
Fluids	Urine	Source (e.g., 24 hr. urine, overnight urine) and preservative
Fluids	Stool	Preservative

Fluids	Saliva	Preservative
Fluids	Bile	Preservative and collection method
Fluids	Pancreatic	Preservative and collection method
Solids	FFPE block	Origin of material and type of staining (if any)
Solids	Tissue	Origin of material, then tissue type (e.g., biopsy, aspirate, remnant, core, explant, wedge) and type of staining (if any)
Solids	Nail clipping	
Solids	Tooth	
Solids	Dried blood spot	Origin of material
Cells	EBV transformed	Source and cell number
Cells	Fibroblast	Source and cell number
Cells	Buffy coat	Preservative
Cells	Leukocytes	Preservative
Cells	Lymphocytes	Source or type (e.g., B cells)
Cells	PBMC	Preservative
Cells	RBC	Preservative
Environmental	Water	Source
Environmental	Soil	Source
Swab	Nasal	Preservative, source, or type (e.g., cellular or solid)
Swab	Buccal	Preservative, source, or type (e.g., cellular or solid)
Swab	Urogenital	Preservative, source, or type (e.g., cellular or solid)
Swab	Perineal	Preservative, source, or type (e.g., cellular or solid)
Swab	Vaginal	Preservative, source, or type (e.g., cellular or solid)