



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 1 of 20
Approved by: ACSR Executive Committee	July 2018

1.0 PURPOSE

The purpose of this document is to establish the procedure for a safe and uniform method of shipping and receiving biospecimens for the AIDS and Cancer Specimen Resource (ACSR).

2.0 SCOPE

This standard operating procedure (SOP) describes the steps for biospecimen shipping and receiving. This SOP applies to all personnel from ACSR Regional Biospecimen Repositories (RBRs) and affiliates that are responsible for biospecimen shipping and receiving for the ACSR. The ACSR RBRs and affiliates process, bank, ship and receive biospecimens under site specific approved Human Subjects Protocols. Biospecimens, Samples, Aliquots and Derivatives are entered into the ACSR database when consent for banking and research use have been verified by the Protocol PI or ACSR designee. Each RBR and affiliate site is responsible for Human Subjects compliance as per their institutional guidelines and their local approved Human Subjects Protocol. This SOP does not cover detailed safety procedures for shipping biospecimens or handling biohazardous material and it is recommended that personnel follow institutional biosafety guidelines and training.

3.0 REFERENCE TO OTHER ACSR SOPS OR POLICIES

ACSR SOP Tech009 Biospecimen Handling

ACSR SOP Tech010 Biospecimen Labeling

4.0 DEFINITIONS

Term/Acronym	Definition
ACSR	AIDS and Cancer Specimen Resource
Aliquot	The sample has the original characteristics of the original or parent specimen but in smaller quantities (FFPE block vs unstained sections from the FFPE block)
Biospecimen	Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen.
Biospecimen Vessel	A sterile container used to transport biospecimens such as: urine cup, draw tube, conical tube or capped vessel.
Conformity	Fulfillment of a requirement, or compliance with a set standard.
Deviation	A change from what is usual or expected. Deviations can apply to any documented policy, process or procedure as well as behavior.



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 2 of 20
Approved by: ACSR Executive Committee	July 2018

Document	Information and its supporting medium; NOTE: This may be paper-based or electronic. Examples include Standard Operating Procedures and Pathology Reports.
Error	A deviation from truth, accuracy, or correctness; a mistake.
Form	A paper or electronic document on which information or results are captured; NOTE: Once completed, a form becomes a record.
PPE	Personal Protective Equipment such as gloves, lab coat, face shield.
PI	Principal Investigator
Procedure	Specified way to carry out an activity of a process. A procedure is a set of instructions that describes the stepwise actions taken to complete activities identified in processes.
Process	Set of interrelated or interacting activities that transform input into outputs.
RBR	Regional Biorepository
Record	Document stating results achieved or providing evidence of activities performed. Some examples include freezer logs, incident reports, the master equipment file, etc.
Sample	This is an aliquot, derivative or if the Parent Specimen received is stored as a whole specimen, it is referred to as a sample, as per ACSR database definition.
SOP	Standard Operating Procedure. A set of written instructions that document a routine or repetitive activity followed by an organization.
Specimen	The same as Biospecimen. Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen/ specimen.
Tissue Transport Vessels	A sterile container used to transport biospecimens such as: urine cup, draw tube, conical tube or capped vessel.
Universal Precautions	This is an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other bloodborne pathogens,

5.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel from ACSR RBRs and affiliate sites that are responsible for performing biospecimen shipping and/or receiving.

ACSR RBR Personnel	Responsibility/Role
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AIDS and Cancer
Specimen Resource

AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 3 of 20
Approved by: ACSR Executive Committee	July 2018




ACSR Staff Member	Organization of biospecimens to be shipped, packaging and shipping biospecimens. Receiving biospecimens.
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AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 4 of 20
Approved by: ACSR Executive Committee	July 2018

6.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	Materials and Equipment (Site Specific or equivalent)
Personal Protection Equipment (PPE)	Gloves, gown/scrubs, lab coat, face shield, etc. as appropriate for the environment.
Blue or black pen	
Plastic sealable bags and/ or screw cap canisters – 2 sizes	Therapak 2"x5" zip #16023, 10"x10" zip #16528 50ml conical tube BD 352070, 15ml conical tube BD 350296
Absorbent material such as paper towels or paper sponges	6"x6" absorbent sheet Therapak #10307
Packing materials such as peanuts or air pillows	Office Depot packing peanuts #1440037
Interior Styrofoam box or Interior canister	Therapak #37908 (interior Styrofoam with external box)
Exterior Cardboard box	Therapak #37908 (interior Styrofoam with external box)
Cold packs or dry ice if needed	Therapak #56400
Labels – Up arrows 	Therapak #54635
Labels – Dry Ice 	Therapak #54530
Labels – UN3373 for Biological Substance Category B or clinical biospecimens 	Therapak #54782



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 5 of 20
Approved by: ACSR Executive Committee	July 2018

7.0 PROCEDURES

7.1 SPECIAL SAFETY PRECAUTIONS

7.1.1 Comply with “Universal Precautions” when collecting and handling all biospecimens.

7.1.2 Use PPE (personal protective equipment) and complete biospecimen training in accordance with the institution’s guidelines.

7.1.3 Standard best-practice working procedures include careful manipulation of the patient biospecimens, disinfection of countertops and equipment used during testing, and disposal of biohazard waste into appropriate receptacles.

7.2 Verification of Identification Information on Storage Container

As applicable, verify the accuracy of coded patient information (in keeping with privacy and ethical policies) and ensure that it corresponds with the label or biospecimen storage container label. Ensure that all personnel are trained in the use of the ACSR database and local electronic filing system (s).

A Production of Derivative Form, Letter of Intent, Material Transfer Agreement and/or ACSR database generated biospecimen list including shipping manifest, should all be reviewed for accuracy when shipping biospecimens. Two ACSR staff should check and cross check shipping manifest with appropriate document before finalizing shipment contents.

7.3 Shipping General Considerations

7.3.1 Recommended shipping days are Monday, Tuesday and Wednesday. **Do not ship on Thursday, Fridays, Weekends, Holidays or the day before a holiday.** This is to ensure that the receiving facility has coverage. All personnel must be trained in shipping biospecimens.

7.3.2 **Call the receiving laboratory** to check their schedule, if someone will be available to receive the package and that the package is expected.

7.3.3 Organize the biospecimens to be shipped – removing them to shipped/out in the database, generating an electronic packing list (either in the database, Word or Excel). Confirmation that biospecimens are correct i.e. identifiers match should be checked by a second individual and signed off. Please see appendix for shipping manifest details. Care should be



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 6 of 20
Approved by: ACSR Executive Committee	July 2018

taken to maintain temperature integrity of frozen biospecimens at all times.

- 7.3.4** Label biospecimen vials, slides, tubes with collection date, specimen type, protocol if applicable and any other specified information. This can be assembled in the Biospecimen Reporting for Improved Study Quality (BRISK) code as per reference 8.4, if the institution is utilizing this method. At this time anonymizers can be added if needed and the key kept in the sending biorepository. This information should also be recorded in the packing list, 2 versions of the packing list (with and without linkage data) if anonymizers are used. All specimens must be labeled with ACSR identifier.
- 7.3.5** Arrange biospecimens in freezer boxes, slide boxes, tube boxes as they appear on the packing list. Include a box map of the contents and indicate on the box lid and inside the box position 1 with a reference arrow (1 →). Boxes should be labeled and secured with tape, rubber bands or aluminum foil.
- 7.3.6** Biospecimen information must accompany every shipment and be separate from the biospecimens, placing the shipping manifest in a sealed plastic bag on top of the styrofoam inner box or on top of the inner cardboard box. All shipping information and the shipping manifest should also be emailed to the recipient.
- 7.3.7** **Always ship overnight delivery or priority overnight delivery if possible.**

7.4 Packaging Category B for Shipment

- 7.4.1** Assemble packaging.
- 7.4.2** Put on gloves. You may change gloves at any time. Wear gloves at all times when handling biospecimen transport vessels or the processed biospecimen storage vessels.

7.4.3 Packaging Category B

7.4.3.1 Packing Instruction 650:

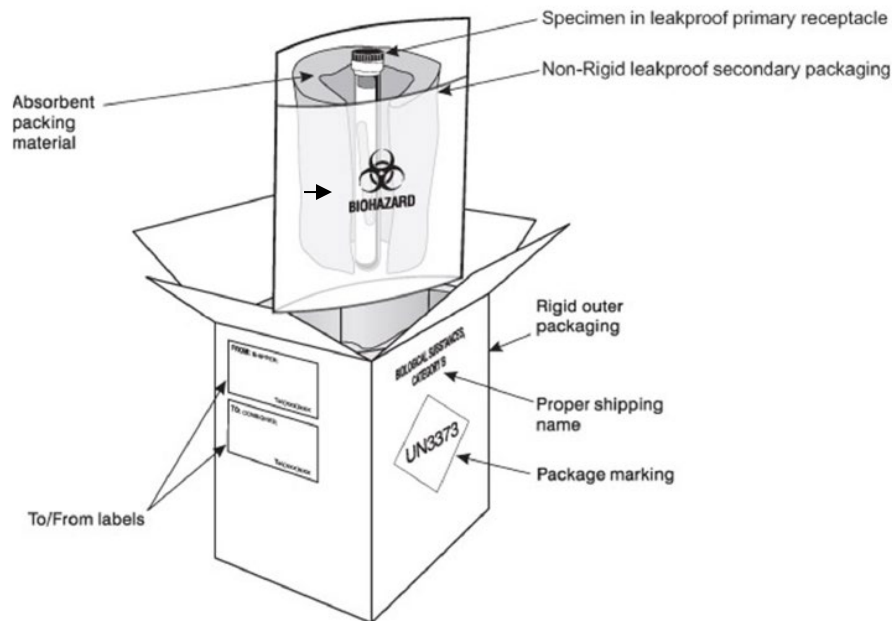
- 7.4.3.1.1** Triple packaging – sealed and leak-proof primary vessel, absorbent material and vessel placed in a leak-proof secondary packaging.

AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 7 of 20
Approved by: ACSR Executive Committee	July 2018

7.4.3.1.2 7.4.3.1.1 is placed in rigid outer packaging with appropriate padding to protect contents.

7.4.3.1.3 Diamond shaped marking, must be a minimum of 50 mm

Example of Ambient shipping



[http://www.oie.int/fileadmin/Home/eng/Conferences Events/sites/VETO2010/Session 3 3 Andrea Graf-Gruber.pdf](http://www.oie.int/fileadmin/Home/eng/Conferences%20Events/sites/VETO2010/Session%203%203%20Andrea%20Graf-Gruber.pdf)

7.4.4 Category B with **Cold Packs used April through October to maintain ambient temperature** – Interior box is required – see below

7.4.5 Category B with Dry Ice **a minimum of 7 pounds and no “dead air” space**– see below:

7.4.5.1 Packing Instructions 954:

7.4.5.1.1 Packages must be designed and constructed to permit release of Carbon Dioxide Gas



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 8 of 20
Approved by: ACSR Executive Committee	July 2018

7.4.5.1.2 When shipping with Dry Ice use the Class 9 Miscellaneous Dangerous Goods Label (see section 3.9)

7.4.5.1.3 Mark the Package – UN 1845, Dry Ice, 9

7.4.5.1.4 Net Weight of Dry Ice in Kilograms

Example of an insulated system which can be used for ice packs or dry ice.

System Components:

- Outer Box – OD 15 3/8 x 13 5/8 x 12 3/4” pre-printed with Biological Substance, Category B, UN 3373 and Exempt Human/Animal Specimen Markings
- Insulated Chest – ID 11 5/8 x 10 x 8”
- STP-111 Inner Box – OD 6 1/2 x 6 1/2 x 8”
- STP-152 250 mL Absorbent Strip (2 ea.)
- STP-609 6 x 12” Saf-T-Rap® Bubble Wrap (2 ea.)
- STP-710 Disposable 2-Part Secondary Pressure Vessel, Medium (2 ea.)
- STP-803 Class 9 Hazard Label (1 ea.)
- STP-804 Dry Ice Marking (1 ea.)



<http://www.saftpak.com/STPPack/ProductDetail.aspx?ID=298>

7.4.6 Overpacks

7.4.6.1 An Overpack can consolidate more than one package provided:

7.4.6.2 The Inner packages are correctly packed, marked, labeled and in good condition

7.4.6.3 Overpack must bear all the same marks and labels displayed on the inner packages.

7.4.6.4 The word “Overpack” must appear on the outside package.



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 9 of 20
Approved by: ACSR Executive Committee	July 2018

7.4.7 Summary

7.4.7.1 Watertight primary receptacle which has had the lid/top taped, and the primary receptacle is then wrapped in absorbent material.

7.4.7.2 Watertight non-rigid secondary container (ziplock bags or screw cap container) that holds the primary receptacle and absorbent material and can be sealed.

7.4.7.3 Outer packaging must be of sufficient strength for its capacity, weight and intended use (UN specification markings on package).

7.4.7.4 Itemized packing list/shipping manifest detailing contents and external to biospecimens. The list should be in a protective waterproof bag (ziplock bag).

7.4.7.5 Shipper contact information including phone number and same for consignee should be on the packing list.

7.4.7.6 Waybill must list UN 3373.Box labeled with upward arrows, UN 3373, refrigerate upon arrival or dry ice as needed. Shippers Declaration required for Category A only.

7.5 Receipt of Infectious Materials

7.5.1 Package should be inspected and opened on a workbench **wearing gloves and a lab coat. If there appears to be any leakage, remove to a BSL-2 hood.**

7.5.2 Open package, remove packing list and inspect contents. Evaluate shipment to determine if it has arrived in an acceptable state, in that the items have not been compromised by temperature or shipment such as: frozen still has dry ice present, paraffin blocks are not melted and slides/vials are not broken or cracked. Note any damage to contents.

7.5.3 Organize specimens and compare to packing list. Have a second person sign off on receipt of goods and date.

7.5.4 Items should be logged via log books, ACSR database and/or local information system and/or study paperwork. Assign banking/ ACSR number as required, record position on packing list and electronically as appropriate. Put items away



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 10 of 20
Approved by: ACSR Executive Committee	July 2018

7.5.5 Notify sending institution of receipt of materials via email and note any compromised biospecimens or errors on the shipping manifest.

7.5.6 If packaging has not been compromised it can be saved for future shipping needs or is returned as per directions of sender.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- 8.1** NCI Best Practices for Biospecimen Resources
<https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf>
- 8.2** Best Practices for Repositories IV. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). Feb 2018 <http://www.isber.org/?page=BPR>
- 8.3** US National Biospecimen Network Blueprint
<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>
- 8.4** Moore HM, Kelly A, Jewell SD, McShane LM, Clark DP, Greenspan R, Hainaut P, Hayes DF, Kim P, Mansfield E, Potapova O, Riegman P, Rubinstein Y, Seijo E, Somiari S, Watson P, Weier HU, Zhu C, Vaught J. Biospecimen reporting for improved study quality (BRISK). Biopreserv Biobank 2011;9:57-70.



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 12 of 20
Approved by: ACSR Executive Committee	July 2018

9.3 Examples of Category A Infectious Substances

Examples of Category A Infectious Substances

UN 2814 Infectious Substance Affecting Humans

- *Bacillus anthracis* cultures
- *Brucella abortus* cultures
- *Brucella melitensis* cultures
- *Burkholderia mallei* – *Pseudomonas mallei* – Glanders cultures
- *Burkholderia pseudomelli* – *Pseudomonas pseudomallei* cultures
- *Chlamydia psittaci* – avian strain cultures
- *Clostridium botulinum* cultures
- *Coccidioides immitis* cultures
- *Coxiella burnetii* cultures
- Crimean-Congo hemorrhagic fever virus
- Dengue virus cultures
- Eastern equine encephalitis virus cultures
- *Escherichia coli*, verotoxigenic cultures
- Ebola virus
- Flexal virus
- *Francisella tularensis* cultures
- Guanarito virus
- Hantann virus
- Hantaviruses causing hantavirus pulmonary syndromw
- Hendra virus
- Hepatitis B cultures
- Herpes B virus cultures
- Human immunodeficiency virus cultures
- Highly pathogenic avian influenza virus cultures
- Japanese Encephalitis virus cultures
- Junin virus
- Kyasanur Forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- *Mycobacterium tuberculosis* cultures
- Nipah virus
- Omsk hemorrhagic fever virus
- Poliovirus cultures
- Rabies virus
- *Rickettsia prowazekii* cultures
- *Rickettsia rickettsia* cultures
- Rift Valley fever virus
- Russian spring-summer encephalitis virus
- Sabia virus
- *Shigella dysenteriae* type 1 cultures
- Tick-borne encephalitis virus cultures
- Variola virus
- Venezuelan equine encephalitis virus
- West Nile virus cultures
- Yellow Fever virus cultures
- *Yersinia pestis* cultures

UN 2900 Infectious Substance Affecting Animals

- African horse sickness virus
- African swine fever virus
- Avian paramyxovirus Type 1 – Newcastle disease virus
- Bluetongue virus
- Classical swine fever virus
- Foot and mouth disease virus
- Lumpy skin disease virus
- *Mycoplasma mycoides* – Contagious bovine pleuropneumonia
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Goatpox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 13 of 20
Approved by: ACSR Executive Committee	July 2018

9.4 49 CFR 173.196 Infectious substances – Category A – attachment 1

§ 173.196 Category A infectious substances.

(a) *Category A infectious substances packaging.* A packaging for a Division 6.2 material that is a Category A infectious substance must meet the test standards of § 178.609 of this subchapter and must be marked in conformance with § 178.503(f) of this subchapter. A packaging for a Category A infectious substance is a triple packaging consisting of the following components:

- (1) A leakproof primary receptacle.
- (2) A leakproof secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either wrapped individually or separated to prevent contact between them.
- (3) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure not less than 100 mm (3.9 inches) at its smallest overall external dimension.
- (4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.
- (5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.
- (6) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(7) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of -40 °C to +55 °C (-40 °F to +131 °F).

(b) Additional requirements for packaging Category A infectious substances.

Category A infectious substances must be packaged according to the following requirements, depending on the physical state and other characteristics of the material.

(1) Infectious substances shipped at ambient temperatures or higher. Primary receptacles must be made of glass, metal, or plastic. Positive means of ensuring a leakproof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape, paraffin sealing tape, or manufactured locking closure. Lyophilized substances may also be transported in primary receptacles that are flame-sealed with glass ampoules or rubber-stoppered glass vials fitted with metal seals.

(2) Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice). Ice, dry ice, or other refrigerant must be placed around the secondary packaging or in an overpack with one or more complete packages marked in accordance with § 178.503 of this subchapter. Interior supports must be provided to secure the secondary packaging in the original position



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 14 of 20
Approved by: ACSR Executive Committee	July 2018

after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack must be leakproof. If dry ice is used, the outer packaging or overpack must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle

and the secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost.

(3) *Infectious substances shipped in liquid nitrogen.* The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected

against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in § 172.312(a) of this subchapter must be marked on the packaging. The packaging must be designed

to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging meeting the requirements of § 173.197.

[67 FR 53140, Aug. 14, 2002, as amended at 71

FR 32260, June 2, 2006; 74 FR 2259, Jan. 14, 2009]



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 15 of 20
Approved by: ACSR Executive Committee	July 2018

9.5 49 CFR 173.199 Diagnostic specimens/ used health care products – Category B - attachment 2

§ 173.199 Category B infectious substances.

(a) *Category B infectious substances.*

Except as provided in this paragraph (a), Category B infectious substances are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section. Category B infectious substances offered for transportation or transported under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter and to the requirements in § 175.75(b) of this subchapter concerning cargo location. Except as provided in paragraph (a)(9) of this section, a Category B infectious substance meeting the definition of a hazard class other than Division 6.2 must be offered for transportation or transported in accordance with applicable requirements of this subchapter.

(1) A Category B infectious substance must be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid outer packaging.

(2) Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging.

(3) Secondary packagings must be secured in rigid outer packagings with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

(4) The completed package must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation.

The packaging must be capable of successfully passing the drop tests in §§ 178.609(d) and (h) of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

(5) The following mark must be displayed on the outer packaging on a background of contrasting color. The width of the line must be at least 2 mm (0.08 inches) and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length. The proper shipping name “Biological substances, Category B” must be marked on the outer packaging adjacent to the diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high.



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 16 of 20
Approved by: ACSR Executive Committee	July 2018



§ 173.199 49 CFR Ch. I (10–1–11 Edition)

- (6) When packages are placed in an overpack, the package markings required by this section must be either clearly visible or reproduced on the outside of the overpack.
- (7) The name and telephone number of a person who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or has immediate access to a person who possesses such knowledge and information, must be included on a written document (such as an air waybill or bill of lading) or on the outer packaging.
- (8) For transportation by aircraft, each package, overpack, pallet, or unit load device containing a Category B infectious substance must be inspected for leakage when it is unloaded from the aircraft. If evidence of leakage is found, the cargo compartment in which

- the package, overpack, pallet, or unit load device was transported must be disinfected. Disinfection may be by any means that will make the material released ineffective at transmitting disease.
- (9) A packaging containing inner packagings of Category B infectious substances may not contain other hazardous materials except—
- (i) Refrigerants, such as dry ice or liquid nitrogen, as authorized under paragraph (d) of this section;
 - (ii) Anticoagulants used to stabilize blood or plasma; or
 - (iii) Small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging. Such preservatives are not subject to the requirements of this subchapter.
- (10) Clear instructions on filling and



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 17 of 20
Approved by: ACSR Executive Committee	July 2018

closing a packaging used to transport a Category B infectious substance must be provided by the packaging manufacturer and subsequent distributors to the consignor or person who prepares the package to enable the package to be correctly prepared for transport. A copy or electronic image of these instructions must be retained by the manufacturer and subsequent distributors for at least one year from the date of issuance, and made available for inspection by a Federal or state government representative upon request.

Packagings must be filled and closed in accordance with the information provided by the packaging manufacturer or subsequent distributor.

(b) Liquid Category B infectious substances.

Liquid Category B infectious substances must be packaged in conformance with the following provisions:

- (1) The primary receptacle must be leakproof.
- (2) Absorbent material must be placed between the primary receptacle and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles and not compromise the integrity of the cushioning material or the outer packaging.
- (3) The secondary packaging must be leakproof.
- (4) For shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure

producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(5) For shipments by aircraft, the maximum quantity contained in each primary receptacle, including any material used to stabilize or prevent degradation of the sample, may not exceed 1 L (34 ounces), and the maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples, may not exceed 4 L (1 gallon). The outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

(c) Solid Category B infectious substances.

Solid Category B infectious substances must be packaged in a triple packaging, consisting of a primary receptacle, secondary packaging, and outer packaging, conforming to the following provisions:

- (1) The primary receptacle must be siftproof.
- (2) If several fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.
- (3) The secondary packaging must be siftproof.
- (4) If residual liquid may be present in the primary receptacle during transportation, then the material must be transported in accordance with requirements in paragraph (b) of this section. A solid material that may become liquid during transportation must be transported in accordance with paragraph (b) of this section.
- (5) Except for packages containing body parts, organs, or whole bodies, for



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 18 of 20
Approved by: ACSR Executive Committee	July 2018

shipment by aircraft, the outer packaging may not contain more than 4 kg (8.8 pounds), including any material used to stabilize or prevent degradation of the samples. The outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

(d) *Refrigerated or frozen specimens (ice, dry ice, and liquid nitrogen)*. In addition to complying with the requirements in this paragraph (d), dry ice and liquid nitrogen must be offered for transportation or transported in accordance with the applicable requirements of this subchapter.

(1) Ice or dry ice must be placed outside the secondary packaging or in an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof or must have a leakproof liner. If dry ice is used, the outside packaging must permit the release of

carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle and secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft they could be subjected to if refrigeration were lost, and sufficient absorbent material must be provided to absorb all liquid, including melted ice.

(2) The package is marked "Carbon dioxide, solid" or "Dry ice" and an indication that the material being refrigerated is used for diagnostic treatment purposes (e.g., frozen medical specimens).

(e) *Training*. Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section.

[67 FR 53142, Aug. 14, 2002, as amended at 71 FR 32261, June 2, 2006; 72 FR 55693, Oct. 1, 2007]



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 19 of 20
Approved by: ACSR Executive Committee	July 2018

9.6 49 CFR 172.300 Marking and Labeling – attachment 3

Subpart D—Marking

§ 172.300 Applicability.

(a) Each person who offers a hazardous material for transportation shall mark each package, freight container, and transport vehicle containing the hazardous material in the manner required by this subpart.

(b) When assigned the function by this subpart, each carrier that transports a hazardous material shall mark each package, freight container, and transport vehicle containing the hazardous material in the manner required by this subpart.

(c) Unless otherwise provided in a specific rule, stocks of preprinted packagings marked in accordance with this subpart prior to the effective date of a final rule may be continued in use, in the manner previously authorized, until depleted or for a one-year period subsequent to the compliance date of the marking amendment, whichever is less.
[Amdt. 172–101, 45 FR 74666, Nov. 10, 1980, as amended at 76 FR 3365, Jan. 19, 2011]

§ 172.301 General marking requirements for non-bulk packaging.

(a) *Proper shipping name and identification number.* (1) Except as otherwise provided by this subchapter, each person who offers a hazardous material for transportation in a non-bulk packaging must mark the package with the proper shipping name and identification number (preceded by “UN”, “NA” or “ID,” as appropriate) for the material as shown in the § 172.101 Table.

(2) The proper shipping name for a hazardous waste (as defined in § 171.8 of this subchapter) is not required to include the word “waste” if the package bears the EPA marking prescribed by 40 CFR 262.32.

(3) *Large quantities of a single hazardous material in non-bulk packages.* A transport vehicle or freight container containing only a single hazardous material in non-bulk packages must be marked, on each side and each end as specified in the § 172.332 or § 172.336, with the identification number specified for the hazardous material in the § 172.101 Table, subject to the following provisions and limitations:

- (i) Each package is marked with the same proper shipping name and identification number;
 - (ii) The aggregate gross weight of the hazardous material is 4,000 kg (8,820 pounds) or more;
 - (iii) All of the hazardous material is loaded at one loading facility;
 - (iv) The transport vehicle or freight container contains no other material, hazardous or otherwise; and
 - (v) The identification number marking requirement of this paragraph (a)(3) does not apply to Class 1, Class 7, or to non-bulk packagings for which identification numbers are not required.
- (b) *Technical names.* In addition to the marking required by paragraph (a) of this section, each non-bulk packaging containing a hazardous material subject to the provisions of § 172.203(k) of this part, except for a Division 6.2 material, must be marked with the technical



AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Technical: Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 20 of 20
Approved by: ACSR Executive Committee	July 2018

name in parentheses in association with the proper shipping name in accordance with the requirements and exceptions specified for display of technical descriptions on shipping papers in § 172.203(k) of this part. A technical name should not be marked on the outer package of a Division 6.2 material.

(c) *Special permit packagings.* Except as provided in § 173.23 of this subchapter, the outside of each package authorized by a special permit must be plainly and durably marked "DOT-SP" followed by the special permit number assigned. Packages authorized by an exemption issued prior to October 1, 2007, may be plainly and durably marked "DOT-E" in lieu of "DOT-SP" followed by the number assigned as specified in the most recent version of that exemption.

(d) *Consignee's or consignor's name and address.* Each person who offers for transportation a hazardous material in a non-bulk package shall mark that package with the name and address of the consignor or consignee except when the package is—

(1) Transported by highway only and will not be transferred from one motor carrier to another; or

(2) Part of a carload lot, truckload lot or freight container load, and the entire contents of the rail car, truck or freight container are shipped from one consignor to one consignee.

(e) *Previously marked packagings.* A package which has been previously marked as required for the material it contains and on which the marking remains legible, need not be remarked.

(For empty packagings, see § 173.29 of

this subchapter.)

(f) *NON-ODORIZED marking on cylinders containing LPG.* No person may offer for transportation or transport a specification cylinder, except a Specification 2P or 2Q container or a Specification 39 cylinder, that contains an unodorized Liquefied petroleum gas (LPG) unless it is legibly marked NONODORIZED or NOT ODORIZED in letters not less than 6.3 mm (0.25 inc)



AIDS and Cancer
Specimen Resource

AIDS and Cancer Specimen Resource (ACSR)	Effective Date:
Technical: Standard Operating Procedure Receiving, Shipping and Packing	Version 2.0
ACSR SOP ID# Tech012	Page 21 of 20

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
Tech012	3-28-2018	PC/BGG/TY	Replace sample with biospecimen, add definitions and formatting.