Hepatitis Reference Laboratory

Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Division of Viral Hepatitis, Laboratory Branch

SOP Title: Molecular/Serology Sample Handling and Shipping instructions
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Approved by: Signature on file

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The accuracy of any Molecular or Serologic technique is dependent upon the condition of the sample that is used. Specimen handling may be particularly critical for the detection of certain microorganisms. The following procedures should be followed for any serum sample that is to be testing using molecular assays (PCR) or serologic assays (i.e. EIA).

I. SAMPLE COLLECTION

1. Blood should be collected using aseptic technique. Both serum and EDTA or citrate plasma are acceptable. Heparinized samples cannot be used.

2. Blood should not be subjected to any condition that would bring about hemolysis, such as freezing it or agitating the tube.

3. Serum/plasma should be spun at least 15 minutes at 3300 RPM and separated off of the cells as soon as possible (suggested - within 4 hours).

    - For Routine Serologic testing: storage at 3-8^{o}C is acceptable for up to one week. Storage above 15^{o}C for more than a few hours should be avoided. Long-term storage should be at -20 ^{o}C - -70 ^{o}C. Sample is aseptically poured into a sterile cryovial or transferred with a sterile transfer pipette. (Use a new pipette for each specimen and samples should be stored in a non-defrosting freezer.)

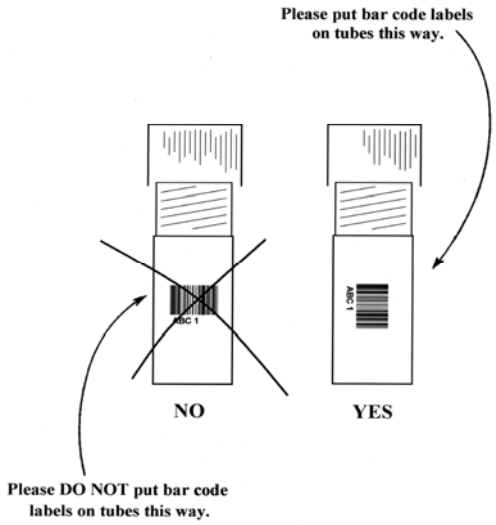
    - **Currently, due to integration of Molecular Diagnostic techniques in routine diagnostic of viral hepatitis, the following PCR grade sample handling and shipping procedure is recommended.**

        - Freeze at -70^{o}C (or -20 ^{o}C if not available) within four hours of collection. Sample is aseptically poured into a sterile cryovial or

transferred with a sterile transfer pipette. (Use a new pipette for each specimen and samples should be stored in a non-defrosting freezer.)

Note: The accuracy of any PCR technique is dependent upon the condition of the sample that is used. Specimen handling is critical for the detection/diagnosis.

4. Each cryovial should be about 3/4 full. Retain all of the serum/plasma collected, using as many vials as you need for each patient or contact. Use our pre-printed labels, whenever possible and when handwriting labels, use only permanent marker. Specimens should be submitted in Nalgene 2 mL cryovials (catalog #5000-0020) labeled with the study code and sample number. The Reference Lab will be happy to supply vials and labels. Specimens for epidemiological studies and research which are received inadequately labeled or in vials other than Nalgene #5000-0020 may be returned. If cryovials other than Nalgene 2 ml cryovials are to be used, please discuss this with the collaborating DVH epidemiologist. See below for labeling format:



5. Keep vials frozen. **DO NOT THAW**

II. PACKING SPECIMENS FOR SHIPPING – DIAGNOSTIC SPECIMENS

A diagnostic specimen is any human or animal material being transported for research, diagnosis, investigational activities, disease treatment or prevention BUT excluding life infected animals. Those known or suspected of containing Category A pathogens must be shipped as infectious substances (see below).

A. **Primary Receptacle/Packaging**

- Primary receptacle(s) must be water tight. Seal screw top containers with parafilm or something similar.
- Wrap multiple containers individually to prevent breakage.
- Primary containers cannot contain more than 1L (liquids) or 4 kg (solids). **Everything in the primary container, including transport media, is considered the diagnostic specimen.**

B. Secondary Packaging (usually a plastic or metal cylinder and a cardboard box)

- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- Secondary packaging must meet IATA packaging requirements for diagnostic specimens including 1.2 meter (3.9 feet) drop test procedure.
- Secondary packaging must be watertight (liquids) or sift proof (solids). Follow the package manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.
- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill).

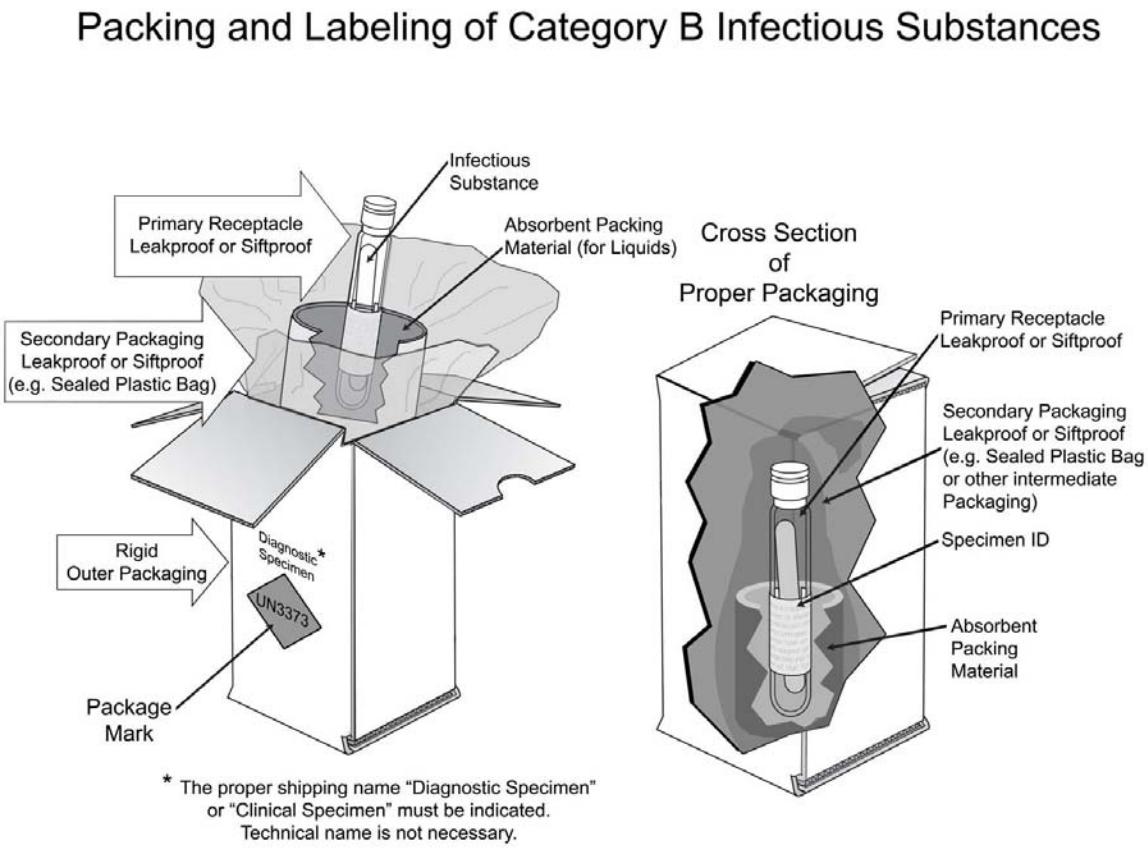
C. Outer Packaging

- An overpack is used if the secondary packaging is not large enough for all the labels, markings, and documents OR if cold packs or dry ice is used.
- The outer packaging must not contain more than 4L or 4kg.
- Both dry ice and wet ice must be placed outside of the secondary packaging.
- Dry ice: packaging must permit the release of carbon dioxide gas and not allow a buildup of pressure that could rupture the packaging.
- Wet ice: the packaging must be leak-proof.
- Each package and the air waybill must be marked with the following text (exact wording)

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. Place in a sealed plastic bag to protect from moisture.
- If overpack is used, package must be marked "Overpack". All secondary package markings must be on the overpack.
- The name, address, and telephone number of the responsible person must be on the package and the air waybill.

- You must put the words “DIAGNOSTIC SPECIMENS” or “ CLINICAL SPECIMENS” and “UN 3373” in the “Nature and Quantity of Goods” box on the air waybill.
- A Shippers Declaration for Dangerous Goods is NOT required – even if Dry ice is included

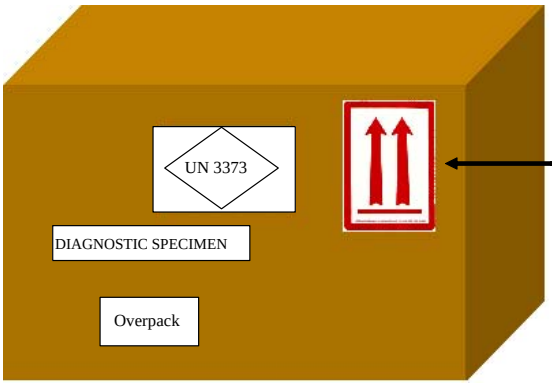
D. Packing and Labeling of Diagnostic Specimens



E. Example of outer packaging (overpack) for diagnostic specimens

Carbon dioxide, solid
(Dry ice)
UN1845
____kg.

Add this label and marking if your specimens are packed in dry ice.



Must have this label on opposite sides of the package if it contains more than 50 ml/g.

III. PACKING SPECIMENS FOR SHIPPING – INEFECTIOUS SPECIMENS

Infectious substances are substances known to contain, or reasonable expected to contain, pathogens. Pathogens are micro organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro organisms (hybrid or mutant) that are known or reasonably expected to cause infectious disease in humans or animals.

A. Primary packaging

- Primary container must be water tight. Seal screw top containers with parafilm or something similar.
- Wrap multiple containers individually to prevent breakage.
- Everything in the primary container, including transport media, is considered the infectious substance

B. Secondary packaging

- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- You must use UN specification packaging: UN Certified for Class 6.2 (Infectious Substances). Infectious substance packaging must have the required specification markings on packaging: e.g.,

  (UN) **4G/Class 6.2/99/GB/2450**

- Secondary packaging must be watertight. Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.

- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill).
- All hazardous markings and labels must be on the same side of the box, adjacent to the address label so that they can be seen at the same time.
- You must include marking, like the example below on the package:

UN2814 Infectious Substance, affecting humans

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

C. Outer packaging

- An overpack is used if the secondary packaging is not large enough for all the labels and documents OR if cold packs or dry ice is used.
- The address label should include the complete name of the person, complete name of the facility, shipping address (street address), and telephone number (no toll-free numbers) of both shipper and consignee.
- The name and telephone number of the person responsible for the shipment must be on the package as well as the Shippers Declaration for Dangerous Goods and air waybill.
- The person responsible for shipment must know the contents of the shipment and the emergency response procedures. Place the information below on the outer container:

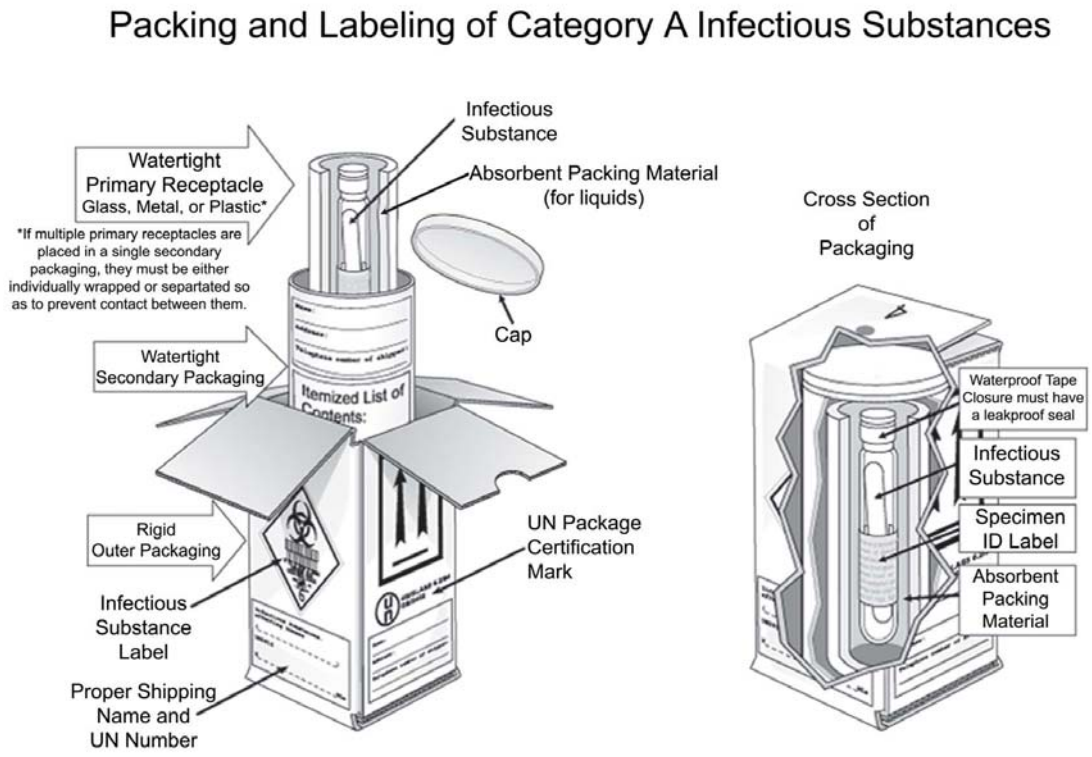
Name and telephone number of person responsible for shipment _____ Name Telephone number

- The outer packaging must not contain more than 50 g or 50 ml for passenger aircraft or 4L or 4kg for cargo.
- Both dry ice and wet ice must be placed outside the secondary packaging.
  - Dry ice: packaging must permit the release of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging.
  - Cold packs: the packaging must be leak-proof
- Include two (three for Federal Express) copies of the completed Shippers Declaration for Dangerous Goods
  - Transport Details box: if your package contains less than 50 ml/g, mark through the box containing the words “cargo aircraft only”. If your package contains more than 50 ml/g, mark through the box containing the words “passenger and cargo aircraft”.

- For animal carcasses, use Special Provision A81: the quantity limits (50 g and 4 kg) do not apply to animal body parts, whole organs, or whole bodies known to contain or suspected of containing an infectious substance. Pt "a81" in the Authorizations column of the form.
- You must include a 24-hour emergency contact telephone number.
- Nature and Quantity of Dangerous Goods box: The comma after the word substance is required; note the spelling of fibreboard; the genus/species or technical name must be in parentheses.

- **The Shippers Declaration for Dangerous Goods is a legal document – you must sign the form.**
- The person responsible for the shipment must know the contents of the shipment and the emergency response procedures.
- New certification statement: "I declare that all of the applicable air transport requirements have been met".

D. Packing and Labeling of Infectious substances



E. Example of outer packaging (overpack) for infectious substances

You *must* use UN certifed 6.2 Infectious Substance Packaging.

F. Hepatitis Reference Laboratory Address:

Office Phone number	404-639-4431
24 Hour Emergency Contact	1-800-424-9300
Fax Number	404-639-1563
Shipping Address	Hepatitis Reference Laboratory Attn: Saleem Kamili MailStop A33 Building 18, Room 3-218 Centers for Disease Control 1600 Clifton Road NE Atlanta, GA 30333
Please send the HRL Shiping Manifest spreadsheet as an attachment by e-mail to Jan Drobeniuc at the Hepatitis Reference Laboratory.	JDrobeniuc@cdc.gov

G. Sample Shippers Declaration for Dangerous Goods

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least three copies to FedEx Express)

Shipper
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
404-639-xxxx

Air Waybill No

Page 1 of 1 Pages
Shipper's Reference Number

Consignee
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333 404-639-4431 Person responsible: Dr. Saleem Kamili

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for *(delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure

Airport of Destination Atlanta, Georgia

Shipment type: *(delete non-applicable)*
NON-RADIOACTIVE | RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification: Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
CLINICAL SPECIMENS, ### x 1.0 mls (samples from patients with Viral Hepatitis)	6.2	UN3373			1 FIBREBOARD BOX		
Carbon Dioxide, solid (Dry ice)	9	UN1845	III		x 45 kg Overpack used	904	

Additional Handling Information
I declare that all of the applicable air transport requirements have been met.
Emergency Telephone Number REQUIRED 1-800-555-1234

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory
Yvonne Stifel, Her Royal Highness of Shipping
Place and Date
CDC, Atlanta, Georgia xx/xx/xxxx
Signature
(see warning above)

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT