

SPECIMEN HANDLING AND SHIPPING INFORMATION FOR HEPATITIS REFERENCE TESTING

The accuracy of any molecular or serological test is dependent upon the condition of the specimen that is used. Specimen handling may be particularly critical for the detection of certain microorganisms. The following procedures should be followed for any specimen that is to be tested using molecular (PCR) or serologic (EIA) assays.

A. SPECIMEN COLLECTION

1. Blood should be collected using aseptic technique. Both serum and EDTA or citrate plasma are acceptable. Heparinized specimens cannot be used.
2. Blood should not be subjected to any condition that would bring about hemolysis, such as freezing or agitating the tube.
3. Whole blood/plasma should be spun at least 10 minutes at 2800-3300 RPM and serum separated off of the cells as soon as possible.
4. Freeze at -70°C (or -20°C is not available) within four hours of collection. Specimen is aseptically poured into a sterile cryovial or transferred with a sterile transfer pipette (use a new pipette for each specimen). Specimens should be stored in a non-defrosting freezer.
5. Keep vials frozen. Do not thaw.

B. PACKING SPECIMENS FOR SHIPPING

A diagnostic specimen is any human or animal material being transported for research, diagnosis, investigational activities, disease treatment, or prevention, BUT excluding live infected animals.

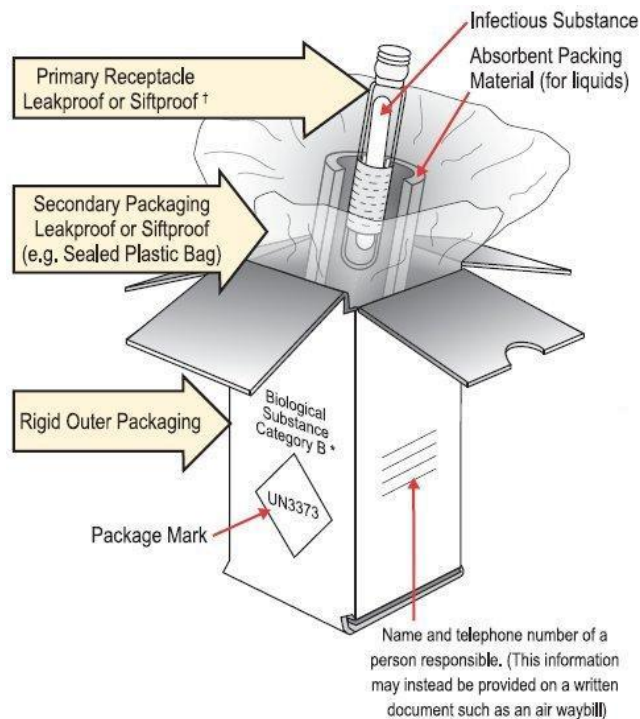
1. Primary Receptacle/Packaging
 - Primary receptacle(s) must be water tight. Seal screw top containers with parafilm or tape.
 - Wrap multiple containers individually to prevent breakage.
 - Primary containers cannot contain more than one liter (1L) of liquids or 4kg of solids.
 - Everything in the primary container, including transport media, is considered a diagnostic specimen.
2. Secondary Packaging (usually a plastic cylinder or a 95kPa bag and a cardboard box)
 - Use enough absorbent material to absorb the entire contents of all primary specimens in case of leakage or damage.
 - Secondary packaging must meet IATA packaging requirements for diagnostic specimens including the 1.2 meter (3.9 feet) drop test.
 - Secondary packaging must be watertight (liquids) or sift proof (solids). Follow the manufacturer or other authorized party's packing instructions included with the secondary packaging.
 - Package must be large enough for all markings, labels, and shipping documents (e.g., waybill).

3. 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.
- Dry ice must be placed outside of the secondary packaging.
- Packaging must permit the release of carbon dioxide gas and not allow a buildup of pressure that could rupture the package (e.g., Styrofoam).



- Each package and the waybill must be marked with the following test (exact wording): **BIOLOGICAL SUBSTANCE, CATEGORY B** and **UN3373**.
- An itemized list of contents must be enclosed between the secondary and outer packaging. Place in a zippered plastic bag to protect from moisture.
- **A copy of the CDC DASH form and copies of all lab reports must accompany each specimen.**
- If an 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 waybill.
- You must put the words “Biological Substance, Category B” and “UN3373” in the “Nature and Quantity of Goods” box on the waybill.
- A Shipper’s Declaration for Dangerous Goods is NOT required, even if dry ice is used.



(EXAMPLE)