

TITLE: Labeling, Packaging and Shipping Laboratory Specimens

Principle: Labeling, packaging and shipping are important in assuring quality patient care and maintaining result integrity by providing for and achieving optimum environmental control during transit. It is a CLIA requirement that medical testing sites maintain policies and procedures to provide adequate instructions for specimen collection, handling, preservation and transportation. The guidelines below provide a convenient reference for all laboratory staff.

Personnel: Phlebotomists, Medical Technologists, Histologists and Laboratory Secretaries

Stepwise Procedure:

Labeling:

The College of American Pathologists (CAP) Laboratory General Checklist requires that all primary specimen containers must be labeled with two identifiers at the time of collection to provide unique identification. Examples of acceptable identifiers include, but are not limited to, patient name, date of birth, hospital number, Social Security number, requisition number, accession number, and unique random number (CAP GEN.40491). The Joint Commission National Patient Safety Goals requires two ways to identify the patient (Goal 1, NPSG.01.01.01).

Blood draw tubes are ideally labeled with a patient bar code label from the laboratory information system or a patient chart label produced by the hospital registration system. If a tube or specimen container must be hand labeled it must include 2 identifiers preferably first name, last name and Date of Birth and /or medical record number. All secondary or pour off containers must be labeled with the same identifiers used on the primary tube.

Packaging:

Specimen Transport Bags

All specimens must be in leak proof primary containers (transport tubes) and must be placed in leak proof secondary containers (specimen transport bags). Couriers are prohibited from picking up specimens that are leaking or are not in secondary containers. Nursing and lab phlebotomist are responsible for packing specimens in biohazard specimen transport bags and then placing the transport bag into a larger protective bag for transport in the pneumatic tube system. Specimens that are considered irretrievable (biopsies, CSF, Joint Fluids, and Body Fluids etc.) must be hand delivered to the laboratory in biohazard transport bags. Specimens collected from outside areas and transported via courier must be package with the primary receptacle containing the specimen, a secondary packaging such as a biohazard transport bag and an outer packaging (cooler or bag) with a biohazard symbol and “exempt human specimen label.

Basic infection control procedures must also be followed, including adherence to universal precautions protocols. OSHA requires all body fluids be considered potentially infectious by those who handle them and that appropriate engineering and work practice controls be implemented while handling the specimen.

Shipping Categories

1. Category B, Biological Substances (UN3373)

UN3373: An infectious substance which does not meet the criteria for inclusion in Category A.*

2. Category A, Infectious Substances (UN2814)

UN2814: An infectious substance, which is transported in a form that when exposure to it occurs is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans.

**Some substances in Category B may be included in Category A only if they are in culture form.*

The Department of Transportation as well as air transport regulations categorize specimens as biological or infectious substances for the purposes of packaging and transport. When ground transportation is provided by a dedicated private or contracted carrier, infectious substances have reduced requirements and biological substances have a complete exception from the DOT regulations. Exempt Human Specimens are not regulated regardless of the carrier.

What Does Your Shipment Contain?

- Materials that do not contain infectious substances or are unlikely to cause disease in humans
- Inactive or neutral pathogens
- Dried blood spots
- Environmental samples
- Samples/Specimens to be used for transplant or transfusion



- Materials that contain an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans
- Substances transported for diagnostic or investigational purposes

Category B (UN3373)



BIOLOGICAL SUBSTANCE
CATEGORY B

Package as
Biological Substance
Category B (UN3373)

- Infectious substances in a form capable of permanent disability or life-threatening or fatal disease in otherwise healthy humans
- Likely to contain Category A
- Tested for Category A
- Characteristics of Category A
- Carries health risk to carrier, personnel, still unknown

Category A (UN2814)



Package as
Infectious Substance,
Category A (UN2814)

IATA regulations require recurrent training every two years, unless there are regulation changes prior to that time. DOT regulations require all training records be held as long as the employee is retained and for 90 days thereafter.

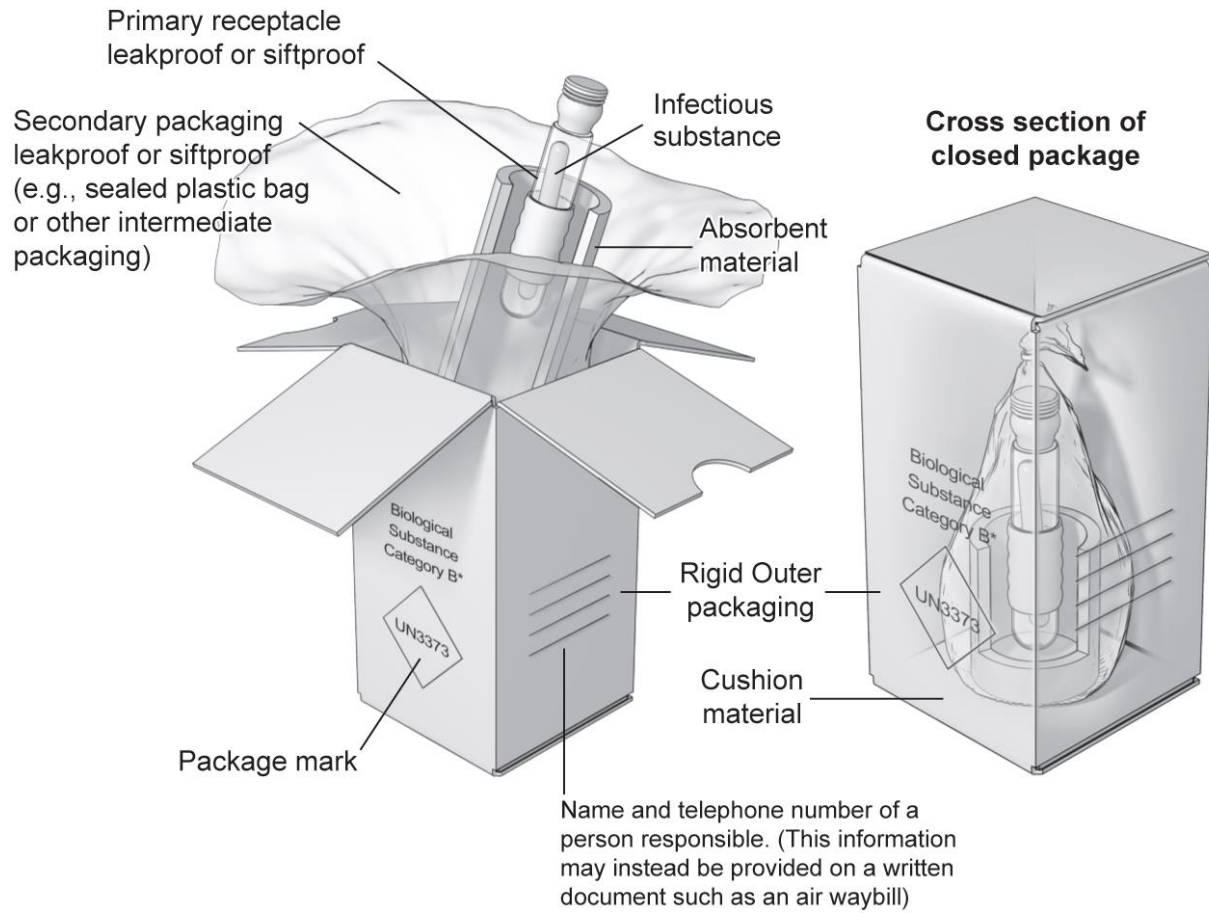
Exempt Human Specimens

These specimens comprise the largest volume of laboratory specimens being transported from one laboratory to another laboratory for testing. Although these specimens are not subject to the same regulations governing the transport of “biological substances” and Infectious Substances, we package and ship to protect against breakage, leakage or damage.

Biological Substances, Category B

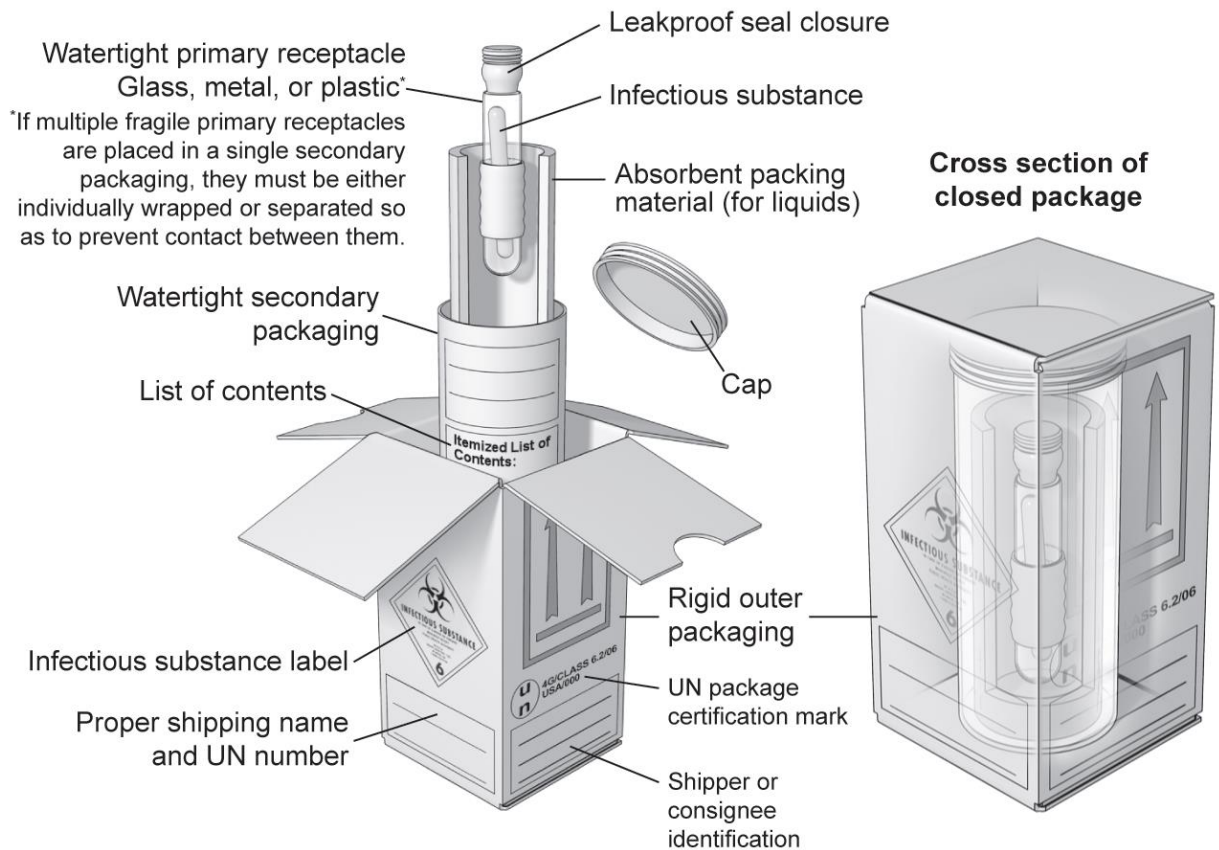
Shipping of biological substances where a relatively low probability exists that infectious substances are present must comply with the following requirements:

- A leak-proof primary container and the quantity cannot exceed 500 mL per container.
- Must have a screw top container able to be transported at -40 to 130 degrees F.
- A leak-proof secondary packaging such as a biohazard labeled plastic bag
- An absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material must be able to absorb the entire contents of the primary container.
- If multiple primary containers are placed in a single secondary package, they must be wrapped to prevent contact.
- The maximum quantity per outer packaging container must not exceed 4 Liters
- Use a shipping box with a Styrofoam core
- Each outer package must be labeled with the **diamond shaped UN3373 Biological Substances, Category B label and the “Nature and Quantity of Goods” box on the air bill must show the text “Biological Substances, Category B.”**
- If Dry Ice is used, care should be taken to allow enough space for carbon dioxide gas to escape as the dry ice evaporates.



Biological Substances, Category A

Category A Infectious Substance (UN 2814 and UN 2900): Figure 1. A Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Category A infectious substances are assigned to identification number “UN 2814” for substances that cause disease in humans or in both humans and animals, or “UN 2900” for substances that cause disease in animals only.



Training of Staff and Couriers

Our laboratory does not process / transport Category A infectious substances. Our specimens fall into the human exempt category. Staff involved in sending specimens to referral laboratories are educated on the proper packaging of Human Exempt samples. We have a dedicated courier that transports specimens from our off-site locations back to the main laboratory. They are given leak-proof labeled transport containers, and have been trained on the use of spill kits which are kept in each vehicle.