I. Purpose/Principle: This policy covers shipment protocols for Exempt Biological Materials for Bioreach Laboratories. “Exempt” materials are a broad and common categorization. Exempt materials are defined as “those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissues and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment, and prevention.” IATA/DOT/USPS uses this category for medical professionals shipping relatively benign samples, which results in less strict regulations for shipping.

# Shipping and Receiving Biological Agents

 Laboratory personnel shipping and/or receiving biological agents must comply with regulations publicized by the U.S. Department of Agriculture (USDA) to regulate importation and interstate shipment of human body fluids. U.S. Department of Transportation (DOT) regulations cover all aspects of shipping biological agents and regulated medical wastes, including packaging, labeling and other shipping requirements. All personnel who ship and/or receive human blood/body fluids, must be trained prior to engaging in such activities.

**1. Shipping Classification Definitions**

**1.1. Patient Specimens**

Specimens collected from humans at Bioreach Laboratories include blood and Urine. If the patient specimen has a minimal likelihood that pathogens are present, it may be shipped as a patient specimen.

**1.2. Infectious Substances**

Universal precautions should be adhered to for all specimens collected or received at Bioreach Laboratories

**1.3.Training**

All personnel involved in the process of shipping biological materials must receive training. Training includes instruction for properly classifying, packing and labeling a shipment. The information provided below may not include all relevant shipping criteria and is not intended to be used without first completing the official training. Medtraining.org competency documentation is used to ensure competency and document training.

**1.4. Shipping Patient Specimens (for which there is minimal likelihood that pathogens are present)**

A. Specimen packaging

1. Specimen in leak-proof primary container
	1. With sufficient absorbent material to soak up entire contents of primary container(s)
	2. Primary containers are wrapped individually
	3. Leak-proof secondary container

B. Labeling outer container

* 1. Statement: “Exempt human specimen”
		1. Miscellaneous Class 9 label if shipment contains dry ice, "UN 1845" and quantity of dry ice used in kg

C. Complete the air bill

* 1. Name and address of shipper and recipient
		1. In Section 6 (Special Handling) of the air bill, indicate that the shipment is NOT a dangerous good
		2. Check the “Dry Ice” box if applicable and indicate “UN 1845” and the quantity of dry ice in kg
		3. Shipper’s signature

 **Some examples of Exempt Patient/Human/Animal Specimens:**

* Routine testing of blood or urine tests ordered for a medical examination
* DNA tests
* Pregnancy tests
* Patient specimens for which there is minimal likelihood that pathogens are present.
* Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals
* Dried blood spots, collected by applying a drop of blood onto absorbent material.
* Fecal occult blood screening samples

According to §6.3.2.3.8 of the ICAO Technical Instructions, specimen packages marked as “Exempt human specimen” are not regulated under the Hazardous Materials Regulation (HMR). In the United States, the mark “Exempt Human/Animal Specimen” is an indication that there is no infectious substance in the package. Packages bearing these marks may be accepted by an air carrier that has made a business decision not to accept hazardous materials.

II. Policy: It is Bioreach Laboratories policy to ship only Non-Exempt human specimens via standard Air or Road Transportation/shipping. Category A or B infectious material is not collected, processed or shipped. DOT training for infectious substance shipping (Category A or B) is not required.

Packaging Instructions For Exempt Specimen

Follow and save any instructions provided with boxes and validated thermal shippers you purchase, so you always have something to reference. Triple packaging is the best practice for all classifications of biological shipments. Here are the four elements you need for your packaging:

1. Leak-proof Primary Receptacle

* This contains your sample — make sure it has a leak-proof seal, tape or parafilm screw cap.

2. Leak-proof Secondary Packaging

* This is your inner container. Ensure the primary or secondary receptacle can withstand:
	+ Pressure: not less than 95kPa.
	+ Temperature:- 40°C to 55°C

3. Cushioning and Absorbent Material

If you have a liquid substance, sufficient absorbent material must be included to absorb the entire contents of all primary receptacles. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets, and paper towels. This generally goes in between the primary and secondary packaging.

Cushioning material is also necessary — and needs to be distinct from absorbent material. Generally this is between the secondary and outer packaging.

4. Rigid Outer Packaging

The outer box must be able to meet a drop test of 1.2 meter.

The smallest external dimension must be at least 100x100mm — look to the manufacturer’s instructions for this info.

Before sealing the outer packaging, you must make an itemized list of the contents of the package and enclose the list between the secondary packaging and outer packaging.

Note: This does not include Styrofoam layer, if using wet/dry ice. Express carriers such as FedEx and UPS do not accept packages with a Styrofoam container as the outside packaging so add rigid outer packaging such as a cardboard box or validated thermal shipper.

**Disposing of or Repurposing Rigid Outer Packaging**

Before empty packaging is returned to the consignor, or sent elsewhere, it must be disinfected or sterilized to nullify any hazard and any label or mark indicating that it contained an infectious substance must be removed.

**When Shipping Blood Samples**

A biohazard symbol is required on any sample that contains human blood and other potentially infectious materials (OPIM). This label must be affixed to the primary receptacle or secondary packaging.

**Overpack**

An overpack is an extra outside packaging used when shipping multiple boxes to the same address or used to refrigerate materials being shipped in a smaller box. All markings and labels must be on the outside of the box along with the word “OVERPACK”. Since your inside package is the “triple package” you need all markings and labels on that package as well.

Labeling Instructions

Standardized labeling must be affixed to the outside. When the package dimensions are adequate, labels must be located on the same surface of the package near the Proper Shipping Name mark.

Except for the orientation arrows, mount all labels and markings on the front side of the box — all on one surface area. “Cargo Aircraft Only” labels are required when applicable.

The outer shipping container must be marked on the address side with the words “Exempt human specimen” or “Exempt animal specimen,” as appropriate.

If you are shipping a liquid, orientation arrows are required. Label must be affixed on 2 opposite sides and perpendicular to the front of the package. Orientation arrows should be red or black on a contrasting background.

**Overpack Label**

Overpack labels have a height Requirement of 12mm (~0.5 inch). Either of these styles is acceptable:

Documentation Requirements

All Shipments must include:

* Bill of Lading (if ground transport), or Airway Bill (if air transport)
* Appearance of form will vary between carriers
* 5 copies of the Commercial Invoice for international shipments
* It's best practice to save all commercial Invoices, airway bills and lists of contents in a binder for at least two years.

**Other FedEx and UPS Requirements**

* There are far fewer restrictions shipping exempt human or animal specimens than UN3373 B or Category A samples.
* Use a FedEx or UPS pouch and insert the airway bill so that it is laying flat-not folded.
* Be sure to remove the sender’s copy and save this documentation for 2 years. Affix the adhesive pouch to the top of the fiberboard box.

**Penalties and Fines**

Shipping biological substances is a tightly regulated activity. Here is a list of violations and the minimum assessments for each:

* No UN # (if required): $1,000-2,000
* No Shipping Name (if required): $1,000
* No Emergency # (if required): $2,600
* Violations related to Select Agents 42 CFR 73: $250,000/individual; $500,000 facility





