

UPDATE

FAQ: Department of Transportation Labeling Requirements

1. Who makes the determination of whether labeling should be Exempt Human Specimen or Biological Substance Category B (UN3373)?

The clinic, as shipper, is required to make the determination. There is an element of professional judgment that should be used in determining if the patient has a reasonable likelihood that pathogens are present. This may be the opinion of medical personnel or the patient's physician.

2. How should the determination regarding labeling be made?

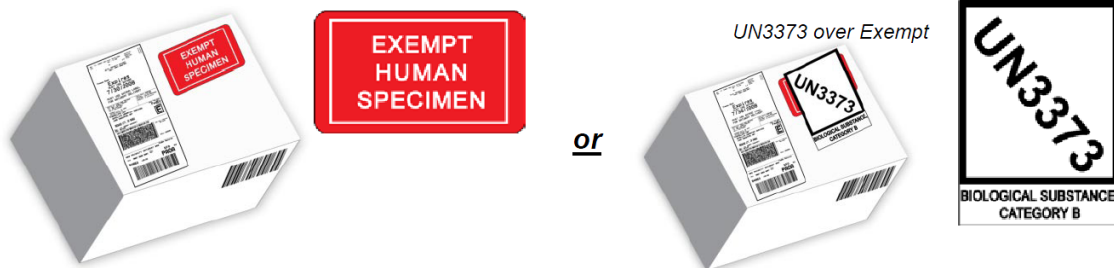
Consider the known medical history, symptoms, and individual circumstances of the patient.

3. Why can't all boxes be shipped with the UN3373 label?

The Department of Transportation (DOT) and International Civil Aviation Organization (ICAO) have significant requirements for cleaning planes and vehicles with a shipment labeled UN3373 that leaks. Should a box be marked incorrectly, and traced back to the clinic, cleanup costs and penalties can be levied against the clinic.

4. Can I use both labels on a box of mixed specimens, e.g., those from clients known to have HIV or hepatitis, and those not known to have these pathogens?

No. Only one label must be on the outside of a shipping box. If the UN3373 label is being used, it must go over the Exempt Human Specimen label.



5. If a patient is being screened but is not known to have hepatitis and/or HIV, or other pathogen(s), should I use the UN3373 label?

No. These boxes should be labeled Exempt Human Specimen.

6. If a patient is known to have hepatitis and/or HIV, or other pathogen(s), should I label the box UN3373?

Yes.

7. Should I label a box containing blood cultures UN3373?

Yes. Blood cultures are normally submitted for the purpose of ruling out pathogens. Blood cultures can be considered to have a reasonable likelihood of containing pathogens and therefore should be labeled UN3373.

8. Can water samples be shipped as Exempt Human Specimens?

Yes, unless they were known to contain a pathogen.

9. Can I mix specimens from a patient with a pathogen and those not known to contain a pathogen?

Yes, as long as you use the UN3373 label on the outside of the box.

10. What is the specific definition of Exempt Human Specimen as defined by the DOT and ICAO?

Exempt Human Specimen is defined as human specimens (blood, secretions, excretions, tissue and tissue fluids) not known to contain, or suspected to contain, a pathogen; or a specimen in which the pathogen has been neutralized or inactivated so it cannot cause a disease when exposure to it occurs. Exempt Human Specimens are excluded from hazardous materials regulation.

A specimen that originates from a patient not known or no reasonable likelihood, to contain an infectious substance (for example HIV or Hepatitis) should be transported as an Exempt Human Specimen.

Biological Substance, Category B is defined as human specimens, including excretions, secretions, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, which 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 when exposure to it occurs. Biological substances, Category B, must be identified with the label UN 3373.

11. Why do we treat all blood as potentially contaminated in the facility and not when shipping?

Several government agencies control shipping environments and have varying labeling requirements. The DOT and ICAO require that biological specimens be properly identified on the exterior of the shipping container. As the shipper, it is the clinic's responsibility to determine which identifier should apply.

The DOT and ICAO also require shippers to train personnel in the proper packing and shipping of biological substances. This required training is to be completed prior to packing and shipping specimens and must be repeated no less than every two years.