

Packaging and shipping diagnostic samples

Dee Griffin, DVM, MS

Director, Veterinary Education, Research and Outreach Program, WTAMU, College of Veterinary Medicine, Texas A&M University, College Station, TX 77843; dgriffin@tamu.edu

Abstract

This document discusses packaging and shipping veterinary diagnostic specimens (fresh tissues, fixed tissues, bacteriology specimens and cultures), US Department of Transportation packaging and shipping safety, and package labeling requirements for both standard “biological” samples and for samples shipped in dry ice. Additionally, examples of the required symbols are noted in the document examples.

Key words: diagnostic specimens, packaging, shipping

Definitions

- **Infectious substances, Category A** means an infectious substance which is transported in a form that is capable of causing permanent disability, life-threatening, or a fatal disease when exposure occurs. Practitioners may never deal with samples that fit this classification. If you think you are dealing with specimens that fit Category A, contact your state veterinarian and/or your USDA-APHIS Area Veterinarian-In-Charge before shipping the samples.
- **Biological Substances, Category B** means any human or animal material being shipped for diagnostic purposes.
 - These specimens must have both a “Biological Substance” label and a UN3373 diamond logo on the shipping container.
- **Primary or inner package** refers to a container holding the material to be shipped. For example, vial or plastic bag.
- **Secondary package** refers to a package enclosing the primary package. A secondary package may be a second plastic container, but it cannot be a plastic bag.
- **Outer package** refers to a container holding and protecting the inner and secondary packages (usually a cardboard box).
- **Hazardous Material (or Dangerous Good)**, any article or substance designated by the US DOT as being capable of posing unreasonable risk to health, safety, and property during transit.

Regulatory Agencies

- US Department of Transportation (DOT) regulates ground and air transportation of diagnostic speci-

mens, infectious substances, medical waste, and chemical and radioactive materials. (www.hazmat.com)

- Samples shipped by ground (courier, bus, postal service, etc.) follow the US DOT Code of Federal Regulations (49CFR)
- International Air Transport Assoc. (IATA), while not an agency, does write the requirements for all air transportation

Non-compliance

- Packages can be refused by the carrier
- Specimens could be damaged or destroyed
- Citations may be issued to the **sender**
- Sender subject to \$250-\$500K fine &/or <5 yr jail

Common Carriers and Package Suppliers

Carriers:

Federal Express (fedex.com) 800-463-3339
US Postal Service (usps.com) 800-275-8777
UPS – requires hazmat account

Package Suppliers:

Lab Safety Supply (labsafety.com) 800-356-0783
ULine (uline.com) 800-958-5463
Saf-T-Pak Inc. (saftpak.com) 800-814-7484

Shipping GMP (Good Management Practice)

- Place coolant packs in Ziploc® bags in case of coolant leakage or rupture
- Avoid overfilling liquid containers
- Avoid exceeding $\frac{1}{3}$ of the container capacity
- Tape Ziploc® bags and rubber stoppered tubes
- Double check for potential leakage of all containers
- Avoid breakable specimen containers ... if used, PAD
- Put paperwork in waterproof bag
- If shipment questions, contact carrier and/or lab

Exempt Animal Specimens

- For patient specimens for which there is minimal likelihood that pathogens are present, e.g. nutritional, biopsies, serology, swabs, etc.
- Shipped in a box marked with the words “**Exempt Animal Specimens**”

- Must follow standard DOT packaging requirements, 3 leak-proof layers (primary, secondary containing absorbent and a third sturdy container)
- Less than 1-liter total liquid or < 8.8 lb (4 kg) total solid with limits for primary individual containers of < ½ liter or < 1.1 lb (½ kg) solids
- Air transportation follows IATA (International Air Transport Assoc.) requirements. These are typically the same as DOT regulations for Exempt Animal Specimens.

Packaging Diagnostic Specimens (Biological Substances, Category B) (Figures 1 and 2)

- Diagnostic specimens must be triple-packed as follows:
 - Primary container, for example screw-cap tubes, taped red-top blood tubes, Whirl-paks – wrapped and tie ends twisted together. Ziploc® bags are not suitable for liquid primary containers.
 - Secondary container must be watertight and have sufficient absorbent, such as paper towels, should primary container leak or rupture. An itemized list (submission form) in a plastic bag is then placed on top of this container.
 - Outer package (third layer of the specimen shipment container) should be at least as durable as sturdy cardboard. While styrofoam is an excellent container, it should never be used as a shipping container without residing in a sturdy cardboard box. Styrofoam coolers are not acceptable as the exclusive outer container due to the potential for

rupture if dropped or impacted in a transportation accident.

- USPS limits < 1 L liquid/primary container with total of < 4 liters or < 8.8 lb (4 kg) solid per shipment. USPS requires Biohazard logo. Some carriers limit shipment to < ½ liter or < 1.1 lb (½ kg) solids.
- Shipper contact info should be on the label. Including the shipper’s phone number is always appropriate.

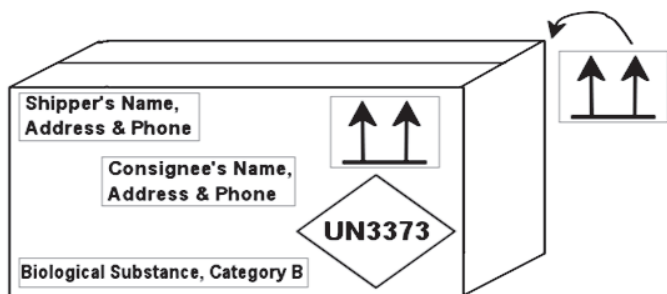
BOTTOM LINE: Diagnostic specimens must be packaged in triple packaging consisting of:

- 1) Primary container, for example screw caps, plastic bags
- 2) Secondary container must be watertight
- 3) An itemized specimen list (submission form), sealed in a plastic waterproof bag between 2nd and outer container
- 4) Outer package, usually sturdy cardboard (do not use styrofoam coolers as the outer container).

Shipping Formalin Fixed Tissues (10% formalin, with or without buffer = 3.7% formaldehyde).

Formalin-fixed tissues are not generally considered “diagnostic specimens” because they have been biologically inactivated. Thus, the possibility for these materials to pose an infectious disease risk is extremely low. Even so, these materials should be packaged in a manner that will prevent any possibility for release of liquids while in transit. This can be achieved through the following actions:

- Limit the amount of 10% formalin to **not more than 1 liter** per shipping container if sent by ground or

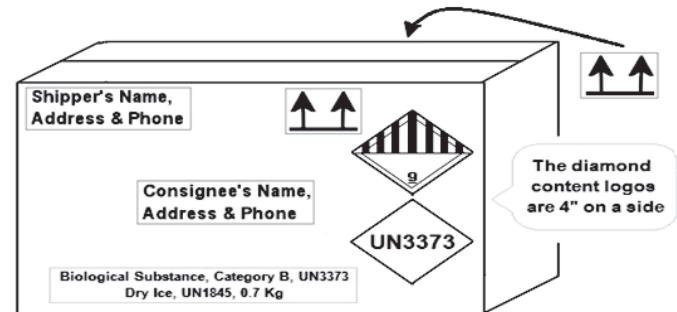


Shipping Samples by Ground Transport (See example above)

Postal service regulations require that all clinical specimens sent by US mail be shipped:

- with a minimum of First-Class postage
- with a label indicating Biological Substance, Category B, UN3373 (if samples packaged in formalin)
- packages containing diagnostic specimens must be marked with a diamond marking as shown below. When shipping liquid diagnostic specimens, orientation arrows must be applied to 2 sides of the package.

Figure 1. Packages containing formaldehyde and freezer coolant packs.



Shipping with Dry Ice (See example above)

- Only relevant markings are allowed on the outer package. All other markings must be obliterated.
- The package must be marked with the following information:
 - Proper shipping name: Carbon Dioxide, Solid or Dry Ice.
 - UN Identification number: UN1845
 - The full name and address of the shipper and consignee.
 - The net weight in kilograms, of the carbon dioxide must be marked on the outside of the package

Figure 2. Packages containing dry ice.

air transportation. Tissue samples of ~1/8 inch thick are adequate. Label container with a 4-inch diamond UN3334 content logo.

- Use non-breakable primary containers with a leak-proof seal and reinforce the seal with Parafilm or sealing tape.
- Package primary containers and enough absorbent material to absorb all liquids (in the event of a leak) in a secondary container (e.g., larger plastic container or sturdy **sealed** plastic bags, etc.).
- Use a sturdy outside container such as a heavy-duty cardboard box as the final structure holding the specimens.
- Other required labeling; include “Preserved Biological Samples” or something similar to the outer package.

Additional Notes

- If specimens are being shipped to a different state, it is best to assume some part of the trip will be by air and therefore requiring packaging to meet IATA (International Air Transport Association) shipping requirements ... eg: **1 liter of 10% formalin** per properly packaged sample container, or 30 mL per sample container if it includes formaldehyde of

> 10% concentration. Multiple 30 mL samples may be included in the secondary sealed container. All samples in primary containers must be double-bagged (secondary container) and adequate absorbent placed in the secondary container.

- All personnel involved in packaging and shipping biological samples should be trained and tested/evaluated every three years.
- Training and testing of the regulations, safety, and specimen security can be done in your workplace.
- Trainee’s name, date trained, a copy of the training materials, trainer, and testing records for verification (certification)
- Shippers (your clinic) must retain shipping records for at least 2 years.
 - Records must include items shipped and transport media (copies of Dx lab submission forms satisfy requirement)

References

1. Title 42 CFR Part 72
2. Title 49 CFR Part 173
3. International Air Transport Association (IATA) regulations