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Animal Health Diagnostic Center

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Shipping Patient Specimens to the Animal Health Diagnostic Center

U.S. Department of Transportation (DOT) and International Air Transportation Association (I.A.T.A.) regulations provide unified rules that govern the shipment of diagnostic materials from animals and humans and define the risk category assignments for these specimens to those recommended by the United Nations.

Patient specimens are defined as follows:

“Patient specimen means human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, swabs in virus isolation media, and blood culture bottles).”

Note: Cultures are not included in this definition, only inoculated transport media, if used.

Unregulated Samples

Many diagnostic patient specimens are not expected to contain infectious agents, and can be sent in a package simply labeled “Exempt Animal Specimen” using a pre-printed label or clear handwriting. No special shipping paperwork is required. Samples must still be packaged in appropriate leak-proof, triple layer packaging capable of protecting the contents. Absorbent material capable of absorbing the entire liquid contents must be included in the secondary container. When sending unregulated liquids by air transport, use containers rated to an internal pressure of 95 kPa.

Regulated samples

Materials which may or are known to contain infectious substances must be appropriately categorized and labeled. There are two categories, Category A and Category B.

Category A includes substances 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 or animals. For a list of the types of pathogens included in this category, see “Specimen Shipping List” on page 5.

Most North American veterinarians will not have a need to ship specimens included in this category. These shipments require special DOT certified triple layer packaging, labeling, and documentation. Unless you are DOT trained in routine handling of these kinds of samples, you must seek assistance before shipping anything in this category. For more information, see the

following web sites and also the links to the regulations provided later in this document:

<http://sp.ehs.cornell.edu/lab-research-safety/research-safety/hazardous-materials-shipping/Pages/Infectious.aspx>

<http://sp.ehs.cornell.edu/lab-research-safety/research-safety/hazardous-materials-shipping/Pages/Shipping-Guidance.aspx>

In general, suspicion of infection with these pathogens in animals requires reporting to your State Veterinarian or USDA Area Veterinarian in Charge (AVIC). If you are suspicious of infectious disease with any of these organisms, it is appropriate to notify either the local or state public health department or state veterinarian, and seek assistance with sample packaging and shipping. UPS and the US Post Office will not accept these packages.

Category B includes substances that may be or are known to be infectious but do not meet the criteria for inclusion in Category A. Most potentially infectious diagnostic specimens submitted for veterinary diagnostics would fall into this category, such as fecal samples, other tissues, fluids and excreta, and post-mortem tissue samples for bacteriological, parasitological or viral work-up.

These samples should be packaged in DOT rated, leak-proof, triple layer packaging. Absorbent material capable of absorbing the entire liquid contents must be included in the secondary container. If sent by air, specimens must be put in a primary or secondary container capable of withstanding aircraft cargo hold pressure changes. These containers are rated to an internal pressure of 95 kPa, and are available in a variety of sizes of rigid containers and also as rated, leak-proof pouches.

The package must be labeled “Biological Substance, Category B” and also bear a UN 3373 diamond label. These labels are available through a variety of sources including our shipping supplies service (607-253-3935); ask for UN3373, Biological Specimen, Category B labels. A printable version is included on page 6. There is a maximum size and weight limit for these packages which includes 1Liter or 4 kg (solids) maximum per primary container, and 4 Liters or 4 kg total maximum for the package. The sender and recipient’s name, address and phone number must be legibly printed on the package. This information should provide access to knowledgeable person who can provide detail regarding the contents of the package, if needed. The proper answer when asked by couriers “What is in the box?” is: **animal diagnostic specimens, Biological Substance Category B, UN3373.**

Note: The quantity limits described above do not apply to body parts, organs or whole bodies. Special provisions of the IATA and DOT regulations allows for an exception to the weight and size limits for these samples. Special Provision A82 (Title 49 CFR 172.102) or A81 (IATA) to exceed volume and weight limit: “The quantity limits do not apply to animal body parts, whole organs or whole bodies known to contain or suspected of containing an infectious substance, UN 3373, Biological Substance, Category B.”

Cultures

Prudent, professional judgment must be exercised in selecting the appropriate category for shipment of cultures and laboratory isolates, due to the high concentration of pathogens present. If exposure to a culture of a pathogen otherwise classified in Category B may result in moderate to severe disease, it is still expected that the isolate be shipped as Category A, UN2814 or UN2900, Packing Instructions 620. See information regarding Category A shipments, above.

Special permits may be required for the shipment of laboratory isolates between facilities. The regulations are described in Title 9 CFR, Chapter 1, Part 121 & 122. For more information regarding possession, use, and transfer of biological agents, select agents, and toxins, see: http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_QA.shtml

For permit applications, see: <http://www.aphis.usda.gov/permits/index.shtml> APHIS FORM 2005.

For instructions on international shipping canine and feline diagnostic specimens, which generally do not require an import permit, see:

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport?1dmy&urile=wcm%3apat h%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_import_into_us% 2Fsa_entry_requirements%2Fct_%2Bfeline_and_canine_material_1102

Dry Ice

Do not place dry ice in any sealed container from which sublimated CO₂ cannot escape, or an explosion may occur. Place dry ice outside the specimen secondary container.

We recommend using FedEx as the courier for shipments containing dry ice. Contact FedEx for their current requirements regarding dry ice shipping and follow all instructions, including how to report dry ice on the air bill. If instructed to use a Class 9 label, apply the label (sample printable label on page 7) to one of the vertical sides of the package (not the top or bottom). In addition, you need to mark the package "UN 1845 Dry Ice" and include the weight of the dry ice in kg. The maximum allowable amount of dry ice is 200 kg. Packages with 70 kg or more of dry ice must be shipped by FedEx Ground.

Shipments Containing 10% Formalin

A recent interpretive letter from the United States Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration, reference No. 06-0267, states that "Formalin containing less than 10% formaldehyde does not meet the definition for a hazardous material under the HMR (Hazardous materials Regulations; 49 CFR Parts 171-180)." 10% formalin or 10% neutral buffered formalin contains between 3.7% and 4% formaldehyde. Therefore, according to this interpretation, 10% formalin is not a regulated chemical. We no longer recommend special labeling or packaging for diagnostic specimens shipped in 10% formalin.

Links to additional materials:

- **DOT Final Rule:**
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title49/49tab_02.tpl
- DOT Hazmat Regulations:
<http://www.fmcsa.dot.gov/safety-security/hazmat/complyhmregs.htm#hm>
- International Air Transportation Association: <http://www.iata.org/dgr>
- Title 9 CFR: <http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=201109>
- Excellent shipping support materials:
<http://www.unh.edu/research/sites/www.unh.edu.research/files/docs/EHS/Chem-safety/UNH-Shipment-of-Biological-Materials-Manual.pdf>

<http://www.unh.edu/research/sites/www.unh.edu.research/files/docs/EHS/Chem-safety/HazMat%20-%20Guide-to-Shipping-with-Dry-Ice.pdf>

Note to Importers and Exporters

Packages crossing national boundaries may be required to contain additional labeling, permits or shipping contents for the purpose of clearing customs/import/export requirements. Call Lisa at 607-253-3938 for questions regarding diagnostic specimen requirements being sent to our laboratory from outside the United States. In addition, these are several links to sites with further information:

http://www.aphis.usda.gov/plant_health/index.shtml

Plant Protection and Quarantine Permits

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_import_into_us%2Fsa_a_entry_requirements%2Fct_%2Bfeline_and_canine_material_1102

Importing canine and feline diagnostic specimens not requiring permits

http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_QA.shtml

USDA biological agents and toxins importation, possession, use and transfer

<http://www.cdc.gov/od/eaipp/>

Etiologic Agent Import Permit Program

<http://www.bis.doc.gov/index.htm>

US Department of Commerce, Bureau of Industry and Security (Export permits)

<http://www.fda.gov/ora/import/>

US Food and Drug Administration Import Permits

http://www.fws.gov/le/ImpExp/Info_Importers_Exporters.htm

US Fish and Wildlife Service Import and Export permits

Special Commercial Carrier Information

UPS will not accept Infectious Substance, Category A packages. They will reject any packages requiring a Shipper's Declaration of Dangerous Goods. The US

Post Office will also not accept Category A packages.

Specimen Shipping List

Category A: Examples of Infectious Substances

(From 49 CFR Parts 171, 172, 173, and 175 Hazardous Materials: Infectious Substances; Harmonization with the United Nations Recommendations; Final Rule, 6/2/2006)

UN 2814

Infectious substances affecting humans and animals

Bacillus anthracis (cultures only)
 Brucella abortus (cultures only)
 Brucella melitensis (cultures only)
 Brucella suis (cultures only)
 Burkholderia mallei—Pseudomonas mallei—Glanders (cultures only)
 Burkholderia pseudomallei—Pseudomonas pseudomallei (cultures only)
 Chlamydia psittaci—avian strains (cultures only)
 Clostridium botulinum (cultures only).
 Coccidioides immitis (cultures only).
 Coxiella burnetii (cultures only)
 Crimean-Congo hemorrhagic fever virus.
 Dengue virus (cultures only)
 Eastern equine encephalitis virus (cultures only)
 Escherichia coli, verotoxigenic (cultures only)
 Ebola virus
 Flexal virus
 Francisella tularensis (cultures only)
 Guanarito virus
 Hantaan virus
 Hantaviruses causing hemorrhagic fever with renal syndrome
 Hendra virus
 Herpes B virus (cultures only)
 Human immunodeficiency virus (cultures only)
 Highly pathogenic avian influenza virus (cultures only)
 Japanese Encephalitis virus (cultures only)
 Junin virus
 Kyasanur forest disease virus
 Lassa virus
 Machupo virus
 Marburg virus
 Monkeypox virus

Mycobacterium tuberculosis (cultures only)
 Nipah virus
 Omsk hemorrhagic fever virus
 Poliovirus (cultures only)
 Rabies and other lyssaviruses (cultures only)
 Rickettsia prowazekii (cultures only)
 Rickettsia rickettsia (cultures only)
 Rift Valley fever virus (cultures only)
 Russian spring-summer encephalitis virus (cultures only)
 Sabia virus
 Shigella dysenteriae type I (cultures only)
 Tick-borne encephalitis virus (cultures only)
 Variola virus
 Venezuelan equine encephalitis virus (cultures only)
 Vesicular stomatitis virus (cultures only)
 West Nile virus (cultures only)
 Yellow fever virus (cultures only)
 Yersinia pestis (cultures only)

UN 2900

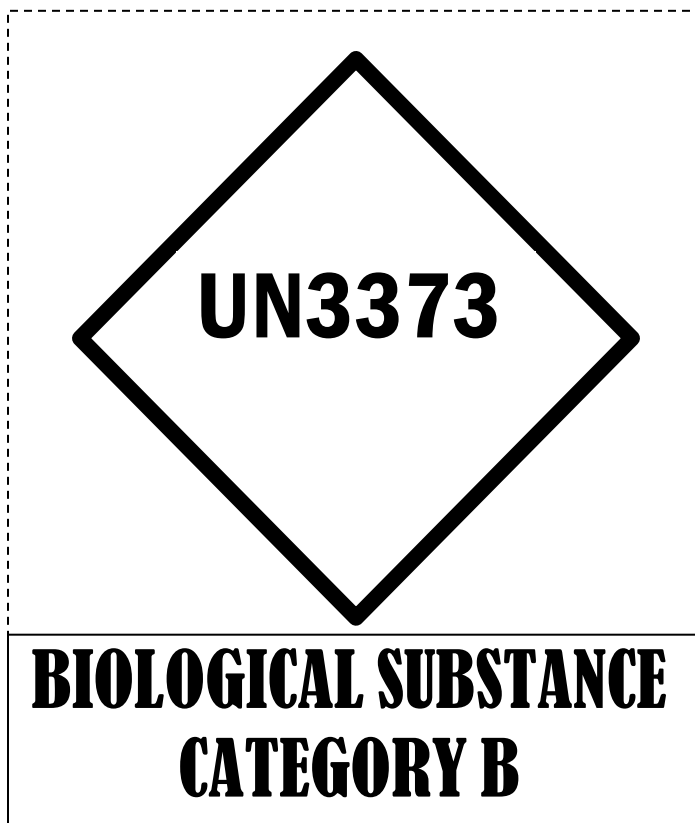
Infectious substances affecting animals only

African swine fever virus (cultures only)
 Avian paramyxovirus Type 1—Velogenic Newcastle disease virus (cultures only)
 Classical swine fever virus (cultures only)
 Foot and mouth disease virus (cultures only)
 Lumpy skin disease virus (cultures only)
 Mycoplasma mycoides—Contagious bovine pleuropneumonia (cultures only)
 Peste des petits ruminants virus (cultures only)
 Rinderpest virus (cultures only)
 Sheep-pox virus (cultures only)
 Goatpox virus (cultures only)
 Swine vesicular disease virus (cultures only)

Label 1: Biological Specimens

Category B: Shipping Label for Biological Substances

The label below should print with the proper dimension of an Infectious Substance label (minimum dimensions: 50 mm on a side, and the proper shipping name, "Biological Substance, Category B" must be in letters at least 6 mm high). Affix the label to the package by covering with clear plastic tape, so that moisture will not cause printer ink to run.



Label 2: Dry Ice Shipments

Shipping Label for Dry Ice, Class 9

The label below should print with the proper dimension of a class 9 hazardous goods label (minimum dimensions: 100mm on a side). Cut around the label and affix it to a vertical side of the package (not top or bottom), oriented as shown. Cover with clear plastic shipping tape.

