



VOLUME IX
***Packaging and
Shipping Laboratory
Specimens Guide***

PLEASE NOTE

This brochure is provided to assist you in compliance with the regulations concerning the shipping or transport of specimens by air or by ground for laboratory testing. While we believe that the procedures and practices in the brochure satisfy the requirements of DOT, IATA, and ICAO as published, your facility is responsible for assuring that appropriate packing instructions are adhered to as required by federal law and air transport association standards. We recommend that each facility make an effort to review applicable regulations and base their decisions accordingly. Each facility will also want to assign their own classifications for “Infectious Substances” and “Biological Substances.” Use of this brochure does not substitute for approved, certified training if required by regulation. We are not certified to provide this type of training.

Resources Used for This Brochure

- ▶ *Department of Transportation*
Research and Special Programs Administration
49 CFR Parts 171-185
Hazardous Materials: Revision to Standards for Infectious Substances; Final Rule Published, Federal Register, Parts 100-185, updated through October 1, 2007.
- ▶ Harmonization With the United Nations Recommendations, International Maritime Goals Code, and International Civil Aviation Organization’s Technical Instructions; Final Rule Published, Federal Register, Volume 72, No. 247, December 1, 2008.
- ▶ *IATA Dangerous Goods Regulations*
50th Edition
Effective from 1 January through 31 December 2009.
- ▶ *ICAO Technical Instructions*
2009-2010 Edition
Technical Instructions for the Safe Transport of Dangerous Goods by Air
Valid from 1 January 2009 through 31 December 2010.

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Introduction

Packaging methods and shipping guidelines are important in assuring quality patient care and maintaining result integrity by providing for and achieving optimum environmental control during transit. In addition, for the safety of others, it is imperative specimens be classified for sorting into respective shipping groups. Regulating authorities Department of Transportation (DOT), International Civil Aviation Organization (ICAO), Centers for Disease Control (CDC), World Health Organization (WHO), and International Air Transport Association (IATA) have provided in-depth regulations for appropriate classification, packaging and shipping of specimens by air and by ground. In addition, Clinical Laboratory Improvement Amendments (CLIA) require that medical test sites maintain policies and procedures to provide appropriate instructions for specimen collection, handling, preservation, and transportation.

This instructional brochure is provided to you for your convenience and reference in preparing and packaging specimens for transportation. Additional information is available to you on our web site.

General Information

Basic Packaging/Transport Instructions

Good laboratory practice and industry standards, as well as CLIA regulations, require that all laboratory specimens be handled and preserved as necessary to provide optimum specimen integrity and valid test results. Specific requirements for each test can be found in the Directory of Services or on our website.

The temperature at which specimens are held/transported is a critical component of these requirements, and different packaging will be needed for frozen, refrigerated, and room temperature requirements. Additional steps may need to be taken in seasons/locations where extremes of heat or cold could affect specimen integrity.

Basic infection control procedures must also be followed, including adherence to universal precautions protocols. Although the DOT, as well as air transport regulators, categorizes specimens as “biological” or “infectious” substances for purposes of packaging and transport, OSHA requires that all body fluids be considered potentially infectious by those who handle them and that appropriate engineering and work practice controls be implemented.

Note Regarding Ground Transport

In addition to the differentiation between Exempt Human Specimens, Biological Substances, and Infectious Substances, the vehicle/company that is providing ground transport will determine many of the packaging requirements. 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 carrier.

Dedicated private or contracted carrier is defined as a motor vehicle used exclusively to transport biological substances or biological products. While other medical/laboratory-related materials may also be transported in this vehicle, its purpose is primarily for transport of specimens.

Although these exceptions may legitimately apply, it may be advisable to package specimens for ground transport based on specimen classification (Biological Substances or Infectious Substances/Division 6.2) rather than on the mode of ground transport. In other words, all specimens would be packaged with the stricter DOT regulations that apply to commercial ground carriers. This approach could eliminate the need for multiple packaging options and would simplify training and standardize procedures for ground transport, regardless of the motor vehicle that would provide transport.

Classification of Specimens

Laboratory specimens were previously assigned to one of 4 "risk groups" based on the severity of the disease caused by the organism, the mode and relative ease of transmission, and the availability of known and effective preventative agents and treatment. These "risk groups" related more to laboratory conditions rather than transport risks. A revised classification method has been developed based on the actual risk or threat of the substance should an exposure occur while in transport.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging resulting in physical contact with humans or animals.

Infectious Substances

Infectious Substances are divided into the following categories:

Category A *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 to humans or animals. The proper shipping name for Category A specimens, UN 2814, is "Infectious Substance, Affecting Humans."*

Category B *An infectious substance which does not meet the criteria for inclusion in Category A. The proper shipping name of Category B specimens, UN 3373, is either "Biological Substances" or "Clinical Specimens."*

Note: Some substances in Category B may be included in Category A only if they are in culture form. *Cultures (laboratory stocks)* are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for biological and clinical purposes.

Exempt Human Specimens

Exempt Human Specimens are substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals and are not subject to Infectious Substance regulations.

Packaging Categories

Specimens are divided into 3 (three) packing groups for purposes of assigning packaging instructions (PI):

- ① EXEMPT HUMAN SPECIMENS (Unregulated)**
- ② BIOLOGICAL SUBSTANCES, Category B (PI 650)**
- ③ Infectious Substances, Category A (Division 6.2 or PI 602)**

EXEMPT HUMAN SPECIMENS

Packing Instructions

Exempt Human Specimens typically 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,” prudent practice would involve packaging in such a way as to provide adequate protection for the specimen containers and to prevent possible leakage or damage. It is recommended that packaging include:

- ❶ The primary receptacle containing the specimen.
- ❷ A secondary packaging such as a plastic Poly Seal Bag with adequate absorbent material.
- ❸ Outer packaging (box, carton, cooler, etc.) with biohazard symbol and “Exempt Human Specimen” label.

For specimens frozen on dry ice, refer to *Frozen Specimen Packing and Packing Instruction (PI) 904 – Dry Ice* on pages 10-11.

BIOLOGICAL SUBSTANCES, Category B

Packing Instructions

Packing Instruction (PI) 650 (Biological Substances, Category B – IATA 650)

Specimens classified as Biological Substances shall be packaged for shipping according to packing instruction 650.

Category B Classification and Notification System

For sites which are interfaced with PAML, on the PAMLnet system or using web-based products for test ordering, those samples that fall into the “Biological Substances” category will have “650” printed on the accessioning label and the Specimen Manifest.

The list of tests that PAML has identified as Biological Substances can also be found on our website at PAML.com in the Test Directory. This list is only a general guide and may not include some testing you recognize as Biological Substances, Category B.

The most current general list can be located at <http://hazmat.dot.gov>

650 General Requirements

Shippers of biological substances where a relatively low probability exists that infectious substances are present must comply with these regulations. The shipper must also ensure that shipments are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to persons or animals during shipment. If a Biological Substance, Category B is known or suspected to contain a Category A Substance, it is required to be classed as a Division 6.2 material, or Infectious Substance (and subject to the 602 packing requirements).

650 Training Requirements (See 602 Training)

Persons who ship or transport biological substances for transportation must be informed about and be able to apply the requirements for 650 transportation. The employer must provide training for employees performing shipping duties within 90 days after hired and retain documents for the duration of employment.

650 Primary Receptacle and Secondary Packaging Preparation

- ❶ **A leakproof primary receptacle.** For biological substances, the maximum quantity must not exceed 500 mL per primary receptacle. Must be in a screwtop container meeting 95kpa in the range of -40° to 130°F.
- ❷ **A leakproof secondary packaging.** A plastic leakproof bag is appropriate as this secondary packaging. A biohazard warning label should be present on this secondary packaging.
- ❸ An absorbent material must be placed between the primary receptacle and the secondary packaging. (The absorbant material must be sufficient to absorb the entire contents of all primary receptacles.)
- ❹ If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped/racked to ensure that contact between them is prevented.
- ❺ The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (13.8 psi) in the range of -40° to +55°C (-40° to +130°F).
- ❻ The maximum quantity per outer packaging for biological substances must not exceed 4 L.

650 Packaging

- ❶ An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. (The itemized list could be the manifest or individual requisitions.)
- ❷ **An outer packaging of adequate strength for its capacity, weight, and intended use** (we recommend using the PAML plastic corrugated box provided for shipping, as this packaging has undergone the testing to ensure that it is capable of successfully passing the drop test from a height of not less than 1.2m).

- ③ Each outer package must be labeled with the diamond-shaped “UN3373 **Biological Substances, Category B**” label, and the “Nature and Quantity of Goods” box of the air waybill must show the text “**BIOLOGICAL SUBSTANCES, Category B.**”
- ④ A Shippers Declaration is not required. (Specific airlines may vary with respect to this.)
- ⑤ Provided that Biological Substances are packed in accordance with these packing instructions, no other requirements of IATA or DOT apply except for:
 - A. The assignment to UN classification 3373 and
 - B. The reporting of dangerous goods accidents or incidents
 - C. Name and phone number of responsible person on air waybill or on outer package.

650 PAML and Affiliate Procedure

- ① Prepare the needed supplies for packaging:
 - ▶ Appropriate size shipping box – temperature-specific
 - ▶ Packing material to provide absorbency and cushion specimens
 - ▶ Poly Seal Bags for containing primary receptacles and requisitions
 - ▶ Absorbent material
 - ▶ Polyethylene film or shrink-wrap
 - ▶ Crush-proof secondary containers
 - ▶ Container(s) for frozen specimens, dry ice if needed
 - ▶ Appropriate airbill/waybill as needed
- ② Properly assemble the shipping box.
- ③ Verify that all specimens are appropriately contained within their shipping receptacles, properly labeled, and matched with their requisition or packing list.
- ④ Place securely capped tubes in a transport rack, placing the first tube in the first location in the lower left corner of the rack, matching it with the first requisition, and then proceed horizontally across the rack. Match either the packing list or the requisitions (in order) in a stack with the order of tubes (the top requisition with the first tube, the second requisition with the second tube, etc.), until all tubes are racked. Be certain the order of tubes correlates with the order of the requisitions or packing list. **ABSORBENT MATERIAL MUST BE PLACED IN BAG WITH RACK/TUBES.** Unless the tubes are secure within the rack, wrap the rack tightly with cellophane or “Parafilm” to prevent tubes from being dislodged during shipping. Place all requisitions/courier lists in the outside pocket of the Ziploc bag.
- ⑤ Place the rack along with the frozen ice pack (if needed) in the provided Ziplock or Poly Seal Bag.

- 6 Urine containers should have lids/closures examined for correct attachment and then should be placed in individual Ziploc bags with adequate absorbent material enclosed in the bag with the urine specimen so as to absorb the entire contents in the event of leakage.

Frozen Medical Specimen Packing

REMEMBER: Frozen specimens need to be separated from room temperature specimens by placing them in a separate insulated inner box to prevent frozen specimens from thawing and room temperature specimens from freezing.

Upon request, we will provide frozen specimen transport containers to clients who have short shipping times before arrival at the Lab. For clients with extended shipping time periods (longer than 10 hours) dry ice is preferred as it is more effective. (2.2 kg [5 lbs.] dry ice is preferred for shipping samples to assure 50+ hours of stable frozen time.)

- 1 Collect all frozen specimens and ensure that labels are securely attached. In some instances, freezing the tubes will weaken the bonding material on the label back, and it may be necessary to use cellophane tape to securely affix the label to the tube.
- 2 2. If using dry ice for shipping, place the tubes in a rack (or otherwise separated to prevent contact) in a Ziplock bag and place the bag in the insulated cardboard container with the dry ice. Place the foam in the box and push the foam down to be touching and securing the samples in the box. This will also prevent unnecessary loss of dry ice.

IATA 8.2.3 Because a shipper's declaration is **NOT** required for Medical Specimens, the "Nature and Quantity of Goods" box of the air waybill must show in sequence:

Proper shipping name *Carbon dioxide, solid*
Class or division number *Class 9*
UN or ID number *1845*
Number of packages and net quantity
of ice per package (wt. in kilograms) . . . (e.g., *1 × 2.2 kg*)

650 Packaging Wrap-Up

- 1 Fill the remaining space in the shipping box with packing material or foam insert to provide adequate cushioning during shipping and to prevent specimens from being broken or damaged.
- 2 **It is not necessary to tape the top of the cardboard boxes, and the absence of tape will give a longer life to the boxes for use.**
- 3 Place the corrugated plastic box lid down, affixing the strap through the holes and buckling it properly to ensure that all samples are secure. All boxes need to be properly labeled with the stickers that identify the contents included in the box, as well as to where it is being shipped.

- ④ If dry ice is used, care should be taken to allow enough space for carbon dioxide gas to escape as the dry ice evaporates.
- ⑤ The box should be packed to prevent any shifting of the contents during transport. This can be checked by shaking the package and checking for rattling.
- ⑥ Complete the airbill/waybill for air transport and place it on the package.

NOTIFY PAML of the shipment being sent. Call 800-541-7891 ext. 8998 (Dispatch). Tell the recipient of the call you have a package alert. Provide them with the following: Your location, tracking or waybill number, the carrier and ETA (Estimated Time of Arrival) at PAML-Spokane if available.

Packing Instruction (PI) 904 – *Dry Ice*

Solid carbon dioxide (dry ice) when offered for transport by air/ground must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a buildup of pressure that could rupture the packaging. Dry ice may be used when shipping Medical Specimens, Biological Substances, or Infectious Substances. The outer package labeling requirements remain the same for any shipment with dry ice.

The net weight of solid carbon dioxide must be marked on the outside packing on the sticker in kilograms - **not pounds** - (for example, 1 × 2.2 kg).

***When transporting by vehicle - leave window vented for CO² release.**

INFECTIOUS SUBSTANCES, Category A

Packaging Instructions

Packaging Instruction 602 (Infectious Substances-DOT Division 6.2 and IATA 602)

602 Classification and Notification System

For sites which are interfaced with PAML, PAMLnet, or using web-based products for test ordering, those samples that fall into the “Infectious Substance” category will have “**602**” printed on the accessioning label.

The list of tests that PAML has identified as potentially containing Infectious Substance can also be found on our website at PAML.com in the Test Directory. This list is only a general guide and may not include some testing you recognize as Infectious Substance.

The most current general list can be located at <http://hazmat.dot.gov>

602 Training Requirements

All individuals involved in the packing of 602 shipments must receive and have documentation of certified training in applicable regulations and also training in their facility’s procedures. It is the responsibility of the site supervisor or manager to keep records of such training on-site in the event of an inspection. Each employee involved in packing must have his/her certification renewed every two years or when/if regulations change prior to the time. (Currently PAML certifies its own employees by means of a CD purchased through Saf-T-Pak.)

** IATA regulations require recurrent training every 2 years, unless there are regulation changes prior to that time. Don’t take a chance on having your valuable shipments rejected because your markings do not meet the regulations, or risk potential penalties because your Class 6.2 training is not up to date.*

** See Employer Checklist on pg. 28 to help determine individual site needs.*

602 PAML-Provided Packaging Materials

PAML and its Affiliates will use manufactured systems that meet the testing requirements for PI 602 packaging. It is extremely important that only the containers provided by PAML be used due to the fact that other brands and styles of secondary and outer packaging may not meet regulations if combined for 602 shipments. **The secondary packaging and outer packaging must be tested as a unit to meet the stringent PI 602 criteria, and it is a violation of these regulations to use the secondary packaging from one brand with the outer packaging from another brand.**

602 Primary Receptacle and Secondary Packaging Preparation

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- 1 **A watertight primary receptacle.** For Infectious Substance specimens, the maximum quantity must not exceed 50 mL per primary receptacle. (The primary receptacle is often the culture tube or slant.) Only screw-cap primary receptacles with a leakproof seal will be accepted and must be positively secured with tape, paraffin sealing tape, or a manufactured locking closure. **Please note that petri dishes do not meet these regulation requirements for transport by air.**
- 2 **A watertight secondary packaging.** A biohazard warning label should be preset on this secondary packaging.
- 3 An absorbent material must be placed between the primary receptacle and the secondary packaging. (The absorbing material must be sufficient to absorb the entire contents of all primary receptacles.)
- 4 If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped/racked to ensure that contact between them is prevented.
- 5 The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (13.8 psi) in the range of -40° to +55°C (-40° to +130°F).
- 6 The maximum quantity per outer packaging for Infectious Substances must not exceed 50 mL for passenger aircraft or 4000 mL (4L) for cargo aircraft. This does not apply to packages transported via ground.

602 Packaging

- 1 An itemized list of contents must be enclosed between the secondary packaging and the outer packaging (corrugated plastic boxes). This packing list is required for 602 shipments and may be *in addition* to the requisitions that are sent. **Please note: this itemized list of contents requires that the shipper identify only the infectious substance and quantity. THERE IS NO REQUIREMENT TO INCLUDE A PATIENT NAME ON THE ITEMIZED LIST.**
- 2 An outer packaging of sufficient strength so as to meet design requirements. Exterior markings must comply with IATA 6.0.6 for shipments of Infectious Substances.

602 PAML and Affiliate Procedure

PAML and its affiliates will purchase and employ commercially available packaging systems that meet the above-mentioned requirements. It is important to remember that the packaging components of these systems must not be intermingled with the components of systems from other manufacturers.

It should be noted that all of the components and packing materials used for 602 shipments are quite expensive and are not to be discarded unless grossly contaminated. Recycling of components is encouraged, provided their integrity is not compromised.

Three steps must be carried out for a shipment to be properly packaged. These three steps are Packing, Labeling, and Documentation.

602 Packing

- ① Prepare the needed supplies for packaging:
 - ▶ Appropriate size 602 secondary packaging and shipping box (the shipping box is also referred to as “outer packaging”).

These two components must be part of a manufactured system, and must be used with one another.
 - ▶ Proper stickers to label the box according to the contents
 - ▶ Packing material to provide cushioning protection
 - ▶ Absorbent material
 - ▶ Container(s) for various temperatures of specimens (room temperature, refrigerated, frozen)
 - ▶ Dry ice if needed
 - ▶ Appropriate airbill/waybill as needed
 - ▶ Declaration of Dangerous Goods form(s)
- ② Verify that the outer packaging is in good repair and suitable for use. This packaging must be free of any irrelevant markings (labels, stickers, etc.) or such markings must be obliterated.
- ③ Verify that all parts of the secondary packaging are present and in good repair. For example, there may be form-fitted foam inserts that are perforated to contain a specific number of tubes. Other systems employ “bubble wrap,” which may be interchangeable. This will also include a sealable inner plastic bag and must be replaced with each use of the container. Most systems also contain a screw cap or snap lid that securely seals the secondary container. Verify that this lid contains the appropriate seal or o-ring and that it is in good condition.
- ④ At this time, verify that all specimens are appropriately contained within their shipping receptacles (tubes, containers, etc.), properly labeled, and matched with their requisitions or packing list.
- ⑤ Place securely capped tubes in a secondary packaging container. When a small number of tubes are being transported, you may use the individual transport containers designed for Infectious Substance shipping. Ensure that all samples are sealed in the inner bag and outer container.

602 Labeling

Proper labeling of the package is essential. Significant fines can be levied, even for improper labeling of the shipping container. Some of the markings or labels may be preprinted directly onto the outer packaging (shipping box). Assemble the following labels:

- ▶ A **Shipper** label clearly indicating the name and address of the shipper of the package (the shipper is the facility who is shipping the package)

- ▶ A label clearly indicating the name and address of the **Consignee** (the laboratory to which you intend the package to be shipped)
- ▶ A label indicating a **NAME** and **TELEPHONE NUMBER** of the **person responsible** for packing the shipment
- ▶ The proper UN shipping number. The UN shipping number for **Infectious Substances, Affecting Humans**, is **2814**.
- ▶ **Class 6 Infectious Substance** label.
- ▶ **Class 9 Miscellaneous Dangerous Goods** label (if shipping with dry ice). Quantity of dry ice (in kg) must appear on the label.
- ▶ **Package Orientation** label (double arrows pointing upward).

Label placement on the shipping containers is critical. The following instructions must be followed exactly. Examples of labels and marks as well as diagrams of appropriately labeled containers are on pages 20-21.

- ❶ If your shipping container is already marked with some of the required markings, make note of which labels you will need. If the markings are already on the box, simply verify that they have been applied correctly. No labels are to be placed on the top or bottom of the shipping container unless specifically noted.
- ❷ Ensure orientation labels (↑↑) are placed on two opposite sides of the container.
- ❸ Fill in the required information on the **Infectious Substance Affecting Humans** label to include the technical name(s) of the organism(s) spelled correctly (e.g., Hepatitis B Virus, Human Immunodeficiency Virus), and the shipper's information (using the same information for the declaration form for that shipment). In the area indicated on that label, write the name and phone number of the person responsible for the shipment. Affix this label to the outer shipping box where indicated or near the upper left corner of the front box face.
- ❹ Affix the **Class 6 Infectious Substance** label adjacent the label in step 3.
- ❺ When using dry ice, a **Class 9 Dangerous Good** label is also required. Place this label near the Class 6 label or use the combination **Class 6 and Class 9** label. Fill in the kg of dry ice ____**kg** (e.g., 2.2 kg which is equal to 5 lbs).
- ❻ In the area indicated on the box, affix the waybill or ship to label.

602 Frozen Specimen Packing

REMEMBER: Frozen specimens need to be separated from both refrigerated and room temperature specimens. 602 shipments must be made in such a way that only one temperature type is shipped in a specific container. Overpacks may be used for more than one temperature type, providing that the overpack is labeled with a Class 9 Miscellaneous Dangerous Goods label when dry ice is used.

- ❶ Collect all frozen specimens and ensure that labels are securely attached. In some instances, freezing the tubes will weaken the bonding material on the label back, and it may be necessary to use cellophane tape to securely affix the label to the tube.

- ② Pack the specimens into the secondary packaging provided for Infectious Substance shipping. Ensure that the inner sealable bag is sealed and all tubes are packed safely and to inspection codes. Tighten the lid on the container ensuring that the container is sealed properly. Place the secondary packaging into the insulated container and include any required packing material around the secondary packaging. Add dry ice as needed to keep the samples frozen. Record the weight of dry ice (in kg) on the Class 9 warning label.
- ③ Label as indicated above for a 602 shipment.

When a shipper’s declaration is required, the information as required by IATA 8.2.3 for solid carbon dioxide must be contained in the “Nature of Quantity of Goods” box on the waybill.

IATA 8.2.3 If a shipper’s declaration for dangerous goods is required, the “Nature and Quantity of Goods” box of the waybill must show in sequence:

Proper shipping name *Carbon dioxide, solid*
 Class or division number *Class 9*
 UN or ID number *1845*
 Packing Group *III*
 Number of packages and net quantity
 of ice per package (wt. in kilograms) . . . (e.g., *1 × 2.2 kg*)
 Packing Instruction *904*

See example on page 22.)

602 Packaging Wrap-Up

- ① Fill the remaining space in the shipping box with packing material or provided foam to provide adequate cushioning during shipping and to prevent specimens from being broken or damaged.
- ② **It is not necessary to tape the top of the cardboard boxes, and the absence of tape will give a longer life to the boxes for use.**
- ③ Place the corrugated plastic box lid down, affixing the strap through the holes and buckling it properly to ensure that all samples are secure. All boxes need to be properly labeled with the stickers that identify the contents included in the box, as well as where it is being shipped to.
- ④ If dry ice is used, care should be taken to allow enough space for carbon dioxide gas to escape as the dry ice evaporates.
- ⑤ The box should be packed to prevent any shifting of the contents during transport. This can be checked by shaking the package and checking for rattling.
- ⑥ Notify PAML of the shipment being sent. Call 800-541-7891 ext. 8998 (Dispatch) or fax the information to 509-921-7106. Tell the recipient that you have a package alert. Provide them with the following information: Your location, tracking or waybill number, the carrier and ETA at PAML-Spokane if available.

602 Repackaging / Use of Overpacks

Repackaging of specimens for shipment as Infectious Substances is not always necessary. Overpacks may be used under certain circumstances. The following rules apply:

- ❶ If PAML or an affiliate laboratory receives packaged samples from a client or an Affiliate that is accompanied by a properly executed Declaration of Dangerous Goods and appears to be packaged properly, then opening and inspecting the package is not necessary. The container may be “passed-through” or may be placed in an overpack.
- ❷ If specimens are received from a client or affiliate without a properly executed Declaration of Dangerous Goods, or if the packaging of the samples appears to be substandard, then repackaging is necessary. Pack the contents according to PI 602 or PI 650 as required.
- ❸ Overpacks must contain the statement: “**INNER PACKAGES COMPLY WITH PRESCRIBED SPECIFICATIONS.**” All markings found on the inner packages **MUST** appear on the overpack container.

602 Documentation (Shippers Declaration)

The final major step is to complete the airbill/waybill and the Declaration of Dangerous Goods (DDG) form. (A DDG is also required for ground transport of an Infectious Substance.) Once again, these steps are critical, and must be completed exactly as indicated below to assure that a shipment is not rejected. A copy of the DDG form and accompanying way/airbill (either carbon copy, photocopy or imaged copy) must be retained for two years after the shipment is accepted by the initial carrier and must include the date of acceptance by the initial carrier.

Completion of the Declaration of Dangerous Goods (DDG) form is the shipper’s responsibility. While some carriers will accept handwritten declarations, an automated solution is the most reasonable one for the precision this form demands. The example on page 22 illustrates the appearance of a properly executed DDG. Some DDGs you encounter may have several of the sections already completed or pre-printed. However, it is still the responsibility of the shipper to ensure that the DDG form is completely filled out and 100 percent correct. The shipper must fill out the components of the DDG as listed below. *A diagram is included for easy reference.*

- ❶ **Shipper:** Enter in the Name, Address, and Phone number of **your facility** along with the name of the person responsible for the shipment. Names should not be abbreviated.
- ❷ **Consignee:** Enter in the Name, Address, and Phone number of the facility **to which** you are shipping the specimens as well as the person responsible at that facility.
- ❸ **Air Waybill Number:** Enter the waybill number where indicated.
- ❹ **Transport Details:** Delete the inappropriate information by using several X’s to cross out the section. Under almost all circumstances, you will **delete** the section “**CARGO AIRCRAFT ONLY.**” This will allow either passenger or cargo aircraft to ship your samples.

- ⑤ **Airport of Departure:** Optional – Enter in the name or site code for the airport from which the shipment is leaving. For example, the code for Spokane is GEG. If this is left blank, airport personnel will fill it in.
- ⑥ **Airport of Destination:** Optional – Enter in the name or site code for the airport for which the shipment is intended. If this is left blank, airport personnel will fill it in.
- ⑦ **Shipment Type:** Delete the inappropriate information by using several X's to cross out the section. All 602 shipments from PAML and its affiliates will be non-radioactive, so the shipper must delete the **RADIOACTIVE** box.

The Nature and Quantity of Dangerous Goods

section of the Declaration of Dangerous Goods has several components:

- ⑧ **Proper Shipping Name:** The following designations must be used, depending upon the nature of the samples you are shipping:
 - A. **Infectious Substance, Affecting Humans (*enter organism name here*):** These words must be used exactly. From your facility's list of tests considered to be "Infectious," enter in the proper name of the organism, in brackets (parentheses).
 - B. **Carbon Dioxide, Solid:** When shipping with dry ice, it must be listed as a dangerous good.
- ⑨ **Class or Division:** There are two classes that apply to the shipments you will be making:
 - A. **6.2** Always used when shipping Infectious Substances.
 - B. **9** Used only when shipping with dry ice.
- ⑩ **UN or ID Number:** There are two options:
 - A. **UN 2814** Always used to identify Infectious Substance affecting humans, (liquid).
 - B. **UN 1845** Used only to identify shipments containing carbon dioxide, solid (dry ice).
- ⑪ **Packing Group:** Leave this section BLANK or enter *N/A* for the Infectious Substance line. If shipping with Dry Ice, enter "III" (Packing Group 3 in Roman numerals).
- ⑫ **Subsidiary Risk:** Leave this section BLANK or enter *N/A* for all shipments.
- ⑬ **Quantity and Type of Packing:** Enter in the following information:
 - A. For Infectious Substances, enter in the number of milliliters of sample per primary receptacle and the number of receptacles per box. For example, if you are shipping a total of 30 mL of sample, and the samples are in two primary receptacles, then you enter "30 mL × 2."
 - B. For Dry Ice, enter in the number of kg of dry ice contained in the shipment, not to exceed 2.2 kg.

- 14 **Packing Instruction:** Enter “602” for Infectious Substances. Enter “904” for shipments containing dry ice.
- 15 **Additional Handling Information:** Enter the following two pieces of information:
24-hour phone number of person responsible: 800.424.9300 (*Chemtrek*)
- 16 **Declaration Statement:** The individual preparing the DDG must enter their name and title, the place and date of preparation of the shipment, and then sign the DDG.
- 17 If there are **multiple pages** of the form that are being prepared, as in cases where a large number of samples are being shipped, enter the number of pages as indicated at the top of the form. An example of the format used would be “Page 1 of 3 pages,” “Page 2 of 3 pages,” etc.

When complete, retain one signed copy of the DDG and submit three copies with the completed shipment.

Airbill / Waybill



Complete the airbill or waybill as required by the carrier. Retain a copy for your site's records for two years.

Shipper Declaration

This is a legal document that needs to be completed

- ▶ Accurately
- ▶ Neat and Legible
- ▶ No spelling errors
- ▶ Do not use White-Out
- ▶ Make 4 copies
- ▶ Sign all changes
- ▶ Retain for TWO years *(per regulation requirements)*

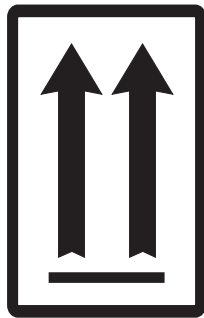
Regulated Medical Waste

- 1 Outer packaging must be rigid and securely closed to prevent leaks or punctures and marked with BIOHAZARD label.
- 2 Forbidden transport by air.

Labeling Guide

The following illustrations may aid you in identifying and placing the labels properly on the package.

** Labels must be printed*



Orientation Label

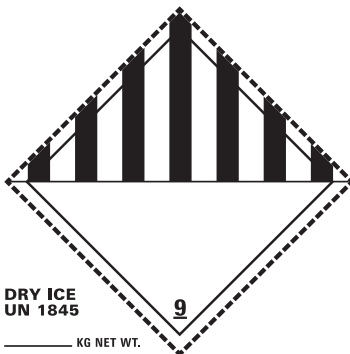
Place on two opposite sides of the shipping container.

** Required for liquids*



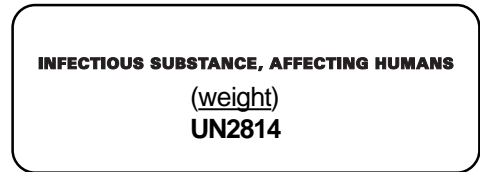
Class 6 Infectious Substance Label

Place on one of the two remaining sides of the box.



Class 9 Miscellaneous Dangerous Goods Label

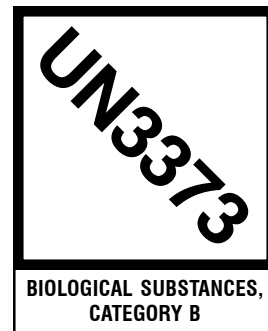
Used only when shipping with dry ice. Place label on same side of box as Class 6 label if possible. **Write in the number of kg of dry ice added.**



UN 2814 Label

Place this label at or near the top of the same side as the Class 6 label.

** Organism Name no longer required on Outer package*



UN 3373 Label

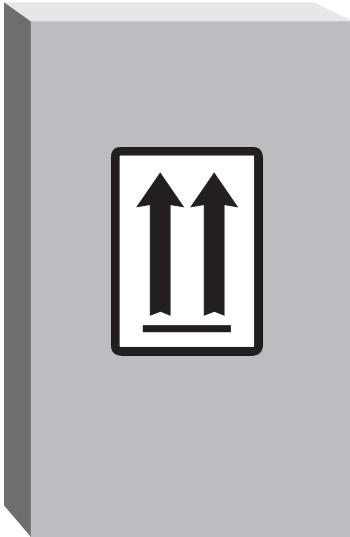
Place this label on side of box when shipping Biological Substances, Category B.



Exempt Human Specimens Label

Place this label on side of box when shipping samples that are not classified as Biological or Infectious Substance, Category A and B specimens.

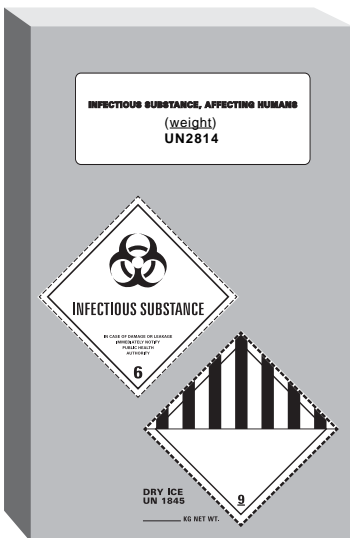
Package Labeling for Infectious Substances, Category A (602)



Orientation Label

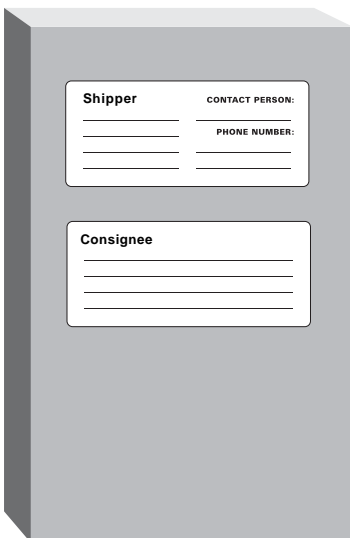
Place on two opposite sides.

REMEMBER: unless otherwise specified, do not place any labels on the top or bottom of the package. Also, affix only a Class 9 Miscellaneous Dangerous Goods label when shipping with dry ice and a Class 6 Infectious Substance label when shipping 602 Infectious Substance samples.



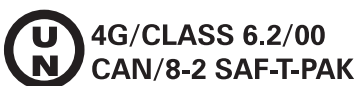
UN 2814 , Class 6 Infectious Substance, and Class 9 Miscellaneous Dangerous Goods Labels

Place on one of two remaining sides.



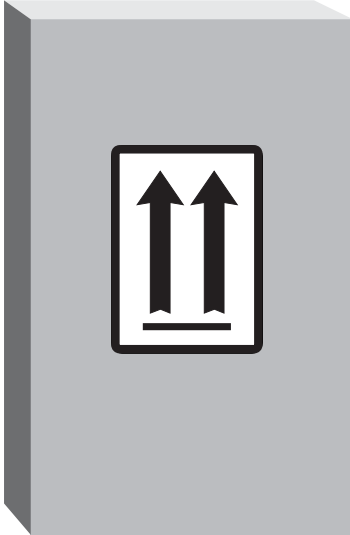
Shipper and Consignee Labels

Place on other remaining side.



This or a similar label must appear somewhere on each 602-shipping container. It is to be applied by the manufacturer. Do not use a container without this or a similar marking.

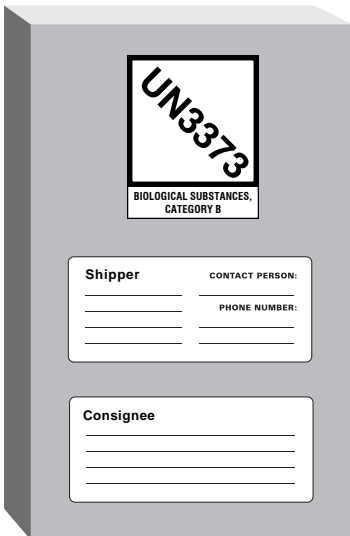
Package Labeling for Infectious Substances, Category B (650)



Orientation Label

Place on two opposite sides.

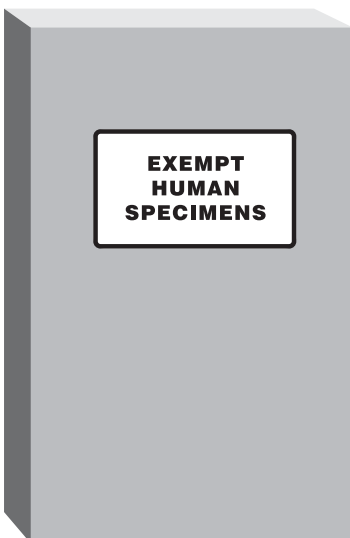
REMEMBER: unless otherwise specified, do not place any labels on the top or bottom of the package. Also, affix only a Class 9 Miscellaneous Dangerous Goods label when shipping with dry ice.



UN 3373 Biological Substances, Category B Label

Place on one of two remaining sides.

Package Labeling for Exempt Human Specimens



Exempt Human Specimens Label

Place this label on side of box when shipping samples that are not classified as Biological or Infectious Substance, Category A and B specimens.

Shipper's Declaration for Dangerous Goods Example

SHIPPER'S DECLARATION FOR DANGEROUS GOODS							
Shipper Your Laboratory 11223 Your Addresss City, State 00100 800-000-0000 or 509-000-0000 Person Responsible:				Air Waybill No. Page <u> 1 </u> of <u> 1 </u> Pages Shipper's Reference Number (optional)			
Consignee Pathology Associates Medical Labortory 110 West Cliff Ave Spokane, WA 99204 509-755-8600 Person Responsible: Annesia Oleaga				<div style="display: flex; justify-content: space-around; font-size: 2em; font-weight: bold; letter-spacing: 0.5em;"> PAML </div>			
Two completed and signed copies of this Declaration must be handed to the operator.				WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.			
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (delete non-applicable) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width: 50%; text-align: center;">XXXXXXXXXX XXXXXXXXXX</td> </tr> </table>							
PASSENGER AND CARGO AIRCRAFT	XXXXXXXXXX XXXXXXXXXX						
		Airport of Departure					
		SEA-Seattle					
Airport of Destination				Shipment type: delete non-applicable			
GEG-Spokane				NON-RADIOACTIVE RADIOACTIVE			
NATURE AND QUANTITY OF DANGEROUS GOODS (see sub-Section 8.1 of IATA Dangerous Goods Regulations)							
Dangerous Goods Identification							
UN or ID No.	Proper Shipping Name	Class or Division	Pack- ing Group	Subsi- diary Risk	Quantity and type of packing	Packing Inst.	Authorization
UN 2814	Infectious Substance, affecting humans (Virus)	6.2	N/A	N/A	X ml	602	N/A
UN 1845	Carbon Dioxide, Solid	9	III	N/A	1 X 2.5kg Packed in one fibreboard box	904	N/A
Additional handling Information							
Emergency Telephone Number 1.800.424.9300							
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packaged, marked and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and National Government Regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Your Name/Lab Assistant Place and Date Your City, State January 01, 2006 Signature (see warning above)			

Substance Being Shipped

(By Ground, USPS & Air – IATA & DOT)

Biological Substance

- Does not contain infectious substance
- Contains inactive or neutral pathogens
- Environmental samples
- Dried blood spots
- Fecal occult blood specimens
- Decontaminated medical waste
- To be used for transplant or transfusion

Patient Specimen

- Unlikely to contain pathogen(s) / not being tested for pathogen(s)
- Or Minimal likelihood of containing pathogen
- Or Unlikely to cause disease in humans or animals

Patient Specimen or Other Substance

- Likely to contain / being tested for pathogen(s)
- Has reasonable potential to cause disease in humans or animals

Exempt Substance

- Triple Pack and Label as Exempt Specimen

Exempt Human or Animal Specimen

- Triple Pack and Label as Exempt Specimen

Known or suspected **Category B**

Uncertain if **Category A or B**

Known or suspected **Category A**

Contains, likely contains, or is being tested for a **Category A** agent

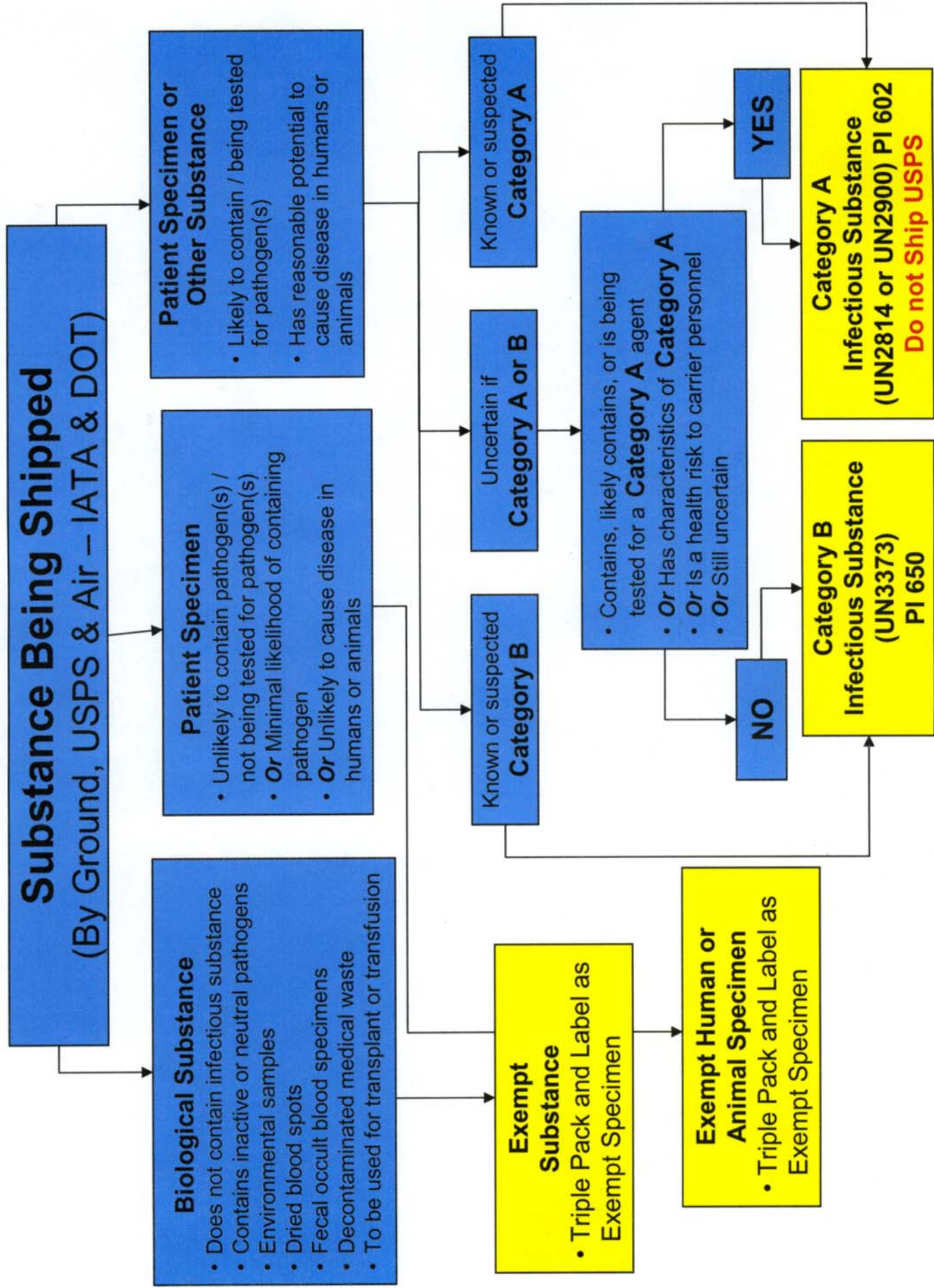
- Or Has characteristics of **Category A**
- Or Is a health risk to carrier personnel
- Or Still uncertain

NO

YES

Category B Infectious Substance (UN3373) PI 650

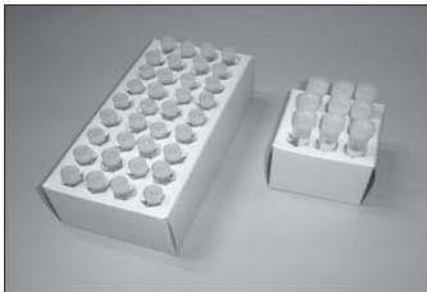
Category A Infectious Substance (UN2814 or UN2900) PI 602
Do not Ship USPS



Specimen Transport Supplies



FROM YOUR LABORATORY SERVICES PROVIDER



Each rack holds standardized transfer tubes or Vacutainers.

Part Number:

1319 9 HOLE TUBE RACK - CARDBOARD

1588 36 HOLE TUBE RACK - CARDBOARD



Each bag holds two 9 hole or one 36 hole specimen rack.



Part Number:

1610 FROZEN TEMP - BLUE SPECIMEN BAG

1611 REFRIGERATED TEMP - GRAY SPECIMEN BAG

1612 ROOM TEMPERATURE - GREEN SPECIMEN BAG



Packing list or test requisition fits in outside sleeve.

TRANSPORT RACKS

Our laboratory provides specimen tube racks and plastic bags with absorbent material sufficient to absorb up to 600 mL per bag. Two 9 hole or one 36 hole tube rack may be placed in a color-coded specimen bag. All specimens must be in leak-resistant primary containers (transport tubes), and must be placed in leak-resistant secondary containers (color-coded specimen bags).

SPECIMEN BAGS

Specimen bags are color coded to assist with keeping specimens at the correct temperature in transit. The front of the bags have a specific area for clients to enter account number, date, and number of specimens. Completion of this section is required. If specimen count is not indicated, our laboratory cannot track missing or lost specimens.

CAUTION: Be sure to tighten caps on tubes and close bags securely.

MEDICAL SPECIMEN TRANSPORT

- 1 Place specimens in the rack in the order the specimens appear on the packing list or in the same order as the test requisition.
- 2 Place the rack in the sealable portion of the correct color-coded specimen bag.
- 3 Place each urine in its own zip-lock bag, then place them together inside a color-coded specimen bag.
- 4 Completely fill in the date, client number, and specimen count on the bag, and place all the test orders into the outside sleeve.
- 5 Place specimen bag in appropriate temperature location for courier pick up.

UNACCEPTABLE CONTAINERS AND CONDITIONS

- Vacutainer tubes with stoppers that have previously been uncapped.
- Glass tubes for frozen specimens.
- Tubes from an automatic aliquoting system with a “pop-top” type of cap.
- Leaking specimens.
- Syringes with needles attached.
- 24-hour urines and 24/72-hour stools must be properly aliquoted before shipping.
- Transfer tubes secured with Parafilm (uncapped).
- Specimens received in expired transport containers or media.

If you have any questions, please call 1.800.541.7891 ext. 8864 or your client representative.

650 Biological Substances, Category B

Specimen Manifest Upgrade



27383 27383FG02252009152816									
PAML SHIPPING MANIFEST Ordering Location: PLCM Account #: 27383 Priority: All									
<small>The classification of some specimens contained within this manifest mandate that the entire shipment be packaged according to (PI) 650 (Biological Substances, Category B - IATA/650) specifications. The shipper(s) within this manifest that qualify as 650 are indicated with a 650 label. Please refer to the PAML Shipping Guide at www.paml.com for packaging instructions. Furthermore, the shipment should only be prepared by trained personnel.</small>									
Refrigerated									
Accession Number	Patient ID	Patient Name		Priority	Test Name	Tube Type	Aliquot	SENT	REC'D
H4698	EEDATC	SACTEST, FIVESIXTWO		Routine	HBEAG	SS	FG6SH	<input type="checkbox"/>	<input type="checkbox"/>
Total 1									
H4699	EEDATA	LCITEST, FIVESIXTWO		Routine	SNT	SS	FGXA	<input type="checkbox"/>	<input type="checkbox"/>
Total 1									
H4700	EEDATB	LPITEST, FIVESIXTWO		Routine	PAR/OG	SS	FGVD	<input type="checkbox"/>	<input type="checkbox"/>

Specimens require special handling, shipping and transportation regulation/requirements. The manifest will now show an indicator next to any specimen that is considered hazardous according to DOT & IATA regulations. The header of the manifest will also indicate that the shipment requires special handling, packaging and labeling.

Normally laboratory specimens are to be classified during shipment as "EXEMPT HUMAN SPECIMENS". There are a subset of orderable tests in the PAML test directory that when prepared for testing according to the PAML test menu that would classify this subset as a hazardous material and should be classified as a "UN3373" BIOLOGICAL SUBSTANCE CATEGORY B.



When one of these 650 indicators appears on the manifest next to the test:

The shipment must be packaged, prepared, labeled, and shipped according to DOT & IATA regulations as "UN3373" BIOLOGICAL SUBSTANCE CATEGORY B.



If the 650 indicators are not present on the manifest:

The shipment must be packaged, prepared, labeled, and shipped according to DOT & IATA regulations as "EXEMPT HUMAN SPECIMENS"



If you would like more information about this upgrade, please contact PAML

1-800-541-7891 Angie Croskrey at ext. 8153 or Annesia Oleaga at ext. 8864

BOX CLOSING PROCEDURES

Always make sure that the shipping container has all of the inner sections and each inner section has the polyurethane foam plug. If any of these items are missing or damaged, use another shipping container and notify PAML Supply Chain Management for a replacement.



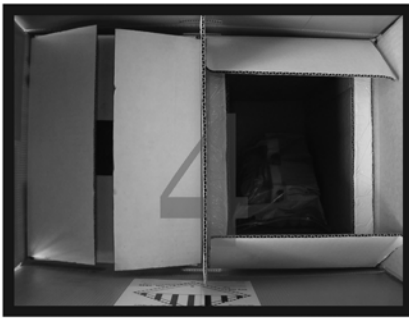
Make sure the foam plug is pushed down snug against the samples. Do not force or jam the plug down as this may break the sample tubes.



Fold closed the smaller two cardboard flaps for each insert



Fold closed the large two cardboard flaps for each insert



Ensure the inner sections (cardboard inserts) are secured in the larger plastic box



Fold closed the smaller outside plastic box flaps



Fold closed the larger outside plastic box flaps that does not have the PAML logo on it

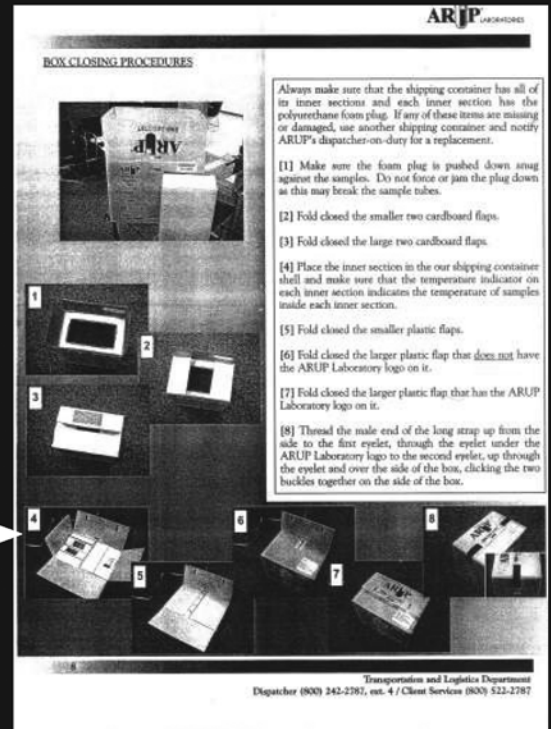


Fold closed the larger outside plastic box flaps that has the PAML logo on it



Thread the male end of the black long strap up for the side to the eyelet on the top of the box, through the eyelet under the PAML logo, clicking the two buckles together on the top of the box.

This PAML procedure is referenced from the direct manufactures box closing procedure Project No. H20708-23.



Employer Checklist For Shipping Infectious Materials Training

- A written shipping protocol
- A written training program in place
 - ▶ Information on how to classify all specimens or samples
 - ▶ Information on how to identify any special arrangements
 - ▶ Information on how to pack specimens properly
 - ▶ Information on how to label and mark packages
 - ▶ Information on how to prepare document for each type of shipment
 - ▶ Testing of all employees that handle shipping specimens
- Provide all appropriate materials for shipping any type of specimen
- Provide and document training for employees performing shipping duties
 - ▶ Hazmat
 - ▶ Safety
 - ▶ Security
 - ▶ Chain of Custody
- Assures training is compliant
 - ▶ Provide security for all Category A specimens in your lab
- Training records should include
 - ▶ Employee name
 - ▶ Most recent date of training
 - ▶ Training materials ~ copies of handouts, description of class or location
 - ▶ Name and address of trainer
- Certification of each employee
- Shipping Competency checklist

Provided for the clients of

PATHOLOGY ASSOCIATES MEDICAL LABORATORIES
PACLAB NETWORK LABORATORIES
TRI-CITIES LABORATORY
TREASURE VALLEY LABORATORY
ALPHA MEDICAL LABORATORY
MOUNTAINSTAR CLINICAL LABORATORIES

*For more information, please contact
your local representative.*