Packaging & Shipping Laboratory Specimens Guide

Volume 14

PAML is not certified to provide regulatory training. This guide is to be used in addition to training and certification by a regulated agency.
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.

PAML recommends that each facility make an effort to review applicable regulations and base their decisions accordingly.

Use of this brochure is not a substitute for approved, certified training if required by regulation. PAML is not certified to provide this type of training.

**Facility Checklist**

- 1. Facility Staff is Trained and Certified to Package and Ship Specimens
- 3. Dangerous Goods Shipping Documents on hand
- 4. Specimen Supplies — Poly Seal Bag, Specimen Racks, Manifest or Requisitions
- 5. Packaging Supplies — Box, Labels, Air Waybill (if transported by air)
- 6. Courier Contact Information
- 7. Destination Information

**STOP**

- Please stop here if you have not met the criteria above.
- Call PAML Logistics for more information at 509-755-8996.
Introduction to Specimen Shipping

Packing 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.

PAML recognizes the importance of specimen integrity. This publication has been created to standardize the methods and procedures in which all specimens are packaged and transported to their final destination. The temperature at which specimens are held and or transported is a critical component of these requirements and different packaging will be needed for frozen, refrigerated and ambient temperatures. 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. OSHA requires all body fluids be considered potentially infectious by those who handle them and that appropriate engineering and work practice controls be implemented while handling the specimen.

While the specimen(s) is in transport, it may be classified as Exempt Human Specimens, Biological Substance (Category B), or Infectious Substance (Category A).

Every Hazmat employee must complete Security Awareness Training. This may be found under the Specimen Transport link by clicking on HazMat Digipak7, or by clicking HERE.

Ground Transportation
1. Exempt Human Specimens are not regulated by ground transportation.
2. Category A and B specimens are regulated by the DOT.
3. Dedicated private or contracted courier is defined as a motor vehicle used exclusively to transport biological substances or biological products.
4. While other medical or laboratory related materials may also be transported in this vehicle, its purpose is primarily for transport of specimens.

Air Transportation
1. Charter, Commercial and Cargo Aircraft are used for transportation of specimens to PAML.
2. IATA regulations must be followed for all of the listed air transport options.
3. Regulations include procedures for Dry Ice, Category A versus Category B specimens, Markings and Labeling of shipments, as well as any documentation guidelines.

IATA regulations require recurrent training every 2 years, unless there are regulation changes prior to that time. DOT regulations require all training records be held as long as the employee is retained and for 90 days thereafter.
Classification of Specimens

(Proper Shipping Categories are in **BOLD** type)

1. **Exempt Human Specimens**

   NOT REGULATED; Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in a packaging which will prevent any leakage and is marked with the words "Exempt Human Specimen."

2. **Category B, Biological Substances (650)**

   UN3373; An infectious substance which does not meet the criteria for inclusion in Category A.

3. **Category A, Infectious Substances (620)**

   UN2814; 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 in otherwise healthy humans.

   * **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.

   * If there is doubt whether or not a substance meets the criteria it must be included in Category A.

   * IATA; 57th Edition, Chapter 3 – Classification

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**Training**

§172.701d—"A hazmat employer shall ensure that each of its hazmat employees is tested by appropriate means on the training subjects covered in §172.704.

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**Frequently Asked Questions**

1. **Does hospital send out staff need training if there is a courier packing the box?**

   YES — §172.700 of the 49CFR states that Hazmat employers must train their staff, if the staff is classifying, and/or preparing specimens for transportation. The hospital, clinic and doctor's office are considered the shipper of the package.

2. **Does the person placing specimens into a PAML box for shipment need to be trained and certified?**

   YES — Any persons handling specimens for transport must be trained and certified to handle medical specimens.

3. **What Category of specimens require Dangerous Goods Training?**

   ALL — Staff must be trained if providing specimens (dangerous goods) for transportation. Many organizations offer training and certification for specimen handling. Please contact PAML Logistics for assistance with training and certification needs.

4. **Where can lab staff/couriers receive training for Dangerous Goods Handling?**

   Employers must provide training for their employees. PAML Transportation may provide direction on organizations offering this training and certification.
What Does Your Shipment Contain?

- Materials that do not contain infectious substance or are unlikely to cause disease in humans
- Inactive or neutral pathogens
- Dried Blood Spots
- Environmental Samples
- Samples/Specimens to be used for transplant or transfusion

- Materials that 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
- Substances transported for diagnostic or investigational purposes

- Infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans
- Likely to contain Category A
- Tested for Category A
- Characteristics of Category A
- Carries health risk to carrier, personnel, still unknown

Category B (650)

Category A (620)

EXEMPT HUMAN SPECIMENS

UN3373

BIOLOGICAL SUBSTANCE, CATEGORY B

THOSE SHIPPING VIA SOUTHWEST AIRLINES:

Southwest Airlines does not allow the Class 9: Miscellaneous Hazmat label to be displayed on packages containing dry ice.

The "WN-659 Dry Ice" label may be used to meet these marking requirements.

Each shipment of specimens may only be identified with one of the above classifications.

Any frozen shipment containing carbon dioxide, solid (dry ice) must bear the Class 9, Misc. label. This is required for air and ground transport.
Packaging is preparing a specimen for shipment from one location to another. Packing a specimen is the act of placing the packaged specimen in the outer container it will travel in while in transport.

**SHIPPER PACKAGING RESPONSIBILITIES:**

1. Primary receptacle containing the specimen(s).
2. Secondary packaging such as a plastic Poly Seal Bag with adequate absorbent material(s).
3. Place all paperwork in pouch of secondary receptacle.

**COURIER PACKING RESPONSIBILITIES:**

1. Outer packaging (corrugated box, fiberboard box, cooler, etc.) with biohazard symbol and/or appropriate labels.
2. Packing sample in appropriate temperature for specimen transport.

**Exempt Human Specimens**

These specimens are not regulated via ground, however prudence on behalf of the shipper client and the transporter should necessitate packing the specimens in such a way as to provide adequate protection from possible leakage or damage.
Packing Instructions for Room-Temperature & Refrigerated

Room Temperature specimens should be packed in a separate chamber.
Keep specimens as level as possible when layering with ice packs.
Foam inserts are to be placed level for improved stability.
Packing Instructions for Frozen Specimens

- The maximum allowable amount of dry ice in a shipment is 2.2kg, or 5 pounds.

- **USE NO LESS THAN 2.2kg OF DRY ICE PER BOX.**

- Dry ice must completely surround the specimens before sealing the package.

- If there is not enough room for the full 2.2 kg of dry ice, use an additional box for the overflow of specimens. This will require additional 2.2 kgs of dry ice.

- The shipment must be shipped with a dry ice sticker (Class 9).

- Shipping via FedEx requires the Priority Alert air waybill, provided by the PAML Transportation Team.

- The Priority Alert air waybill also requires that the Priority Alert label be placed on the box provided by the PAML Transportation Team.

- If shipping over a long holiday, please contact the Transportation Team for instructions for shipping frozen specimens.
Category B, Biological Substances (650)

PAML has indicated which tests are Category B within the test directory. The PAML identification is only a general guide and may not include all tests recognized as Category B. Shippers must ensure that each specimen is properly prepared for transportation.

If a Category B specimen is known or suspected to contain a Category A substance, it is required to be classified as a Category A Specimen and transported as such.

Category B shipment must be packaged as follows:

- Leak proof primary receptacle. Category B primary receptacles must not exceed 1 L.
- Leak proof secondary receptacle. A plastic leak proof bag is appropriate as secondary packaging. A biohazard warning label should be present on secondary packaging.
- Absorbent material must be placed in between the primary and secondary receptacles. This must be sufficient to absorb the entire contents of all primary receptacles in the secondary packaging.
- If there are multiple specimens in a secondary packaging, they must be wrapped/racked to ensure that contact between specimens is prevented.
- Primary or secondary receptacles must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95kpa (13.8psi) in the range of –40° to 130°F (–40° to 55°C).
- The maximum quantity per outer packaging for Category B specimens must not exceed 4 L.
Category A (620) – Infectious Substance Affecting Humans

Most current general list is located HERE. All individuals involved in the packing of Category A shipments must receive and have documentation of certified training in applicable regulations and also training in their facility’s procedures.

Packaging for this category of specimen is provided via the PAML Supply department, part 1789K. It is mandatory that only PAML approved packaging be used for this part as PAML uses and recognizes the regulations of the UN approved packaging.

The kit provided by PAML contains the stabilizing foam, bag, secondary receptacle (canister), Shipping Papers x 4, Outer receptacle, and all appropriate markings and labeling required by DOT and IATA.

**IMPORTANT!**

Primary Receptacles for Category A Specimens: only receptacles with a leak proof seal will be accepted and must be positively secured with tape, paraffin sealing tape, or a manufactured locking closure.

**PETRI DISHES DO NOT MEET THESE REGULATION REQUIREMENTS FOR TRANSPORTATION.**

An itemized list of contents must be enclosed between canister and the fiberboard box provided by PAML Supply Department. This packing list is required for Category A shipments and is in addition to the requisition or manifests that are sent.

Directions on this Category A kit will be provided in the kit.

- Category A specimens CANNOT be transported in the same primary, secondary, or tertiary receptacle as any other category of specimen.
- PAML does not permit shipping of Category A Substances on commercial air carriers.
Category A (620) – Infectious Substance Affecting Humans (continued)

**Labeling**
Proper labeling of Category A specimens 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 shipping container (ie. Infectious Substance Affecting Humans).

**Shipper Marking**
Indicating the name and address of the shipper (the shipper is the facility sending the package).

**Consignee Marking**
Indicating the name and the address of the intended receiver of the package.

**Responsible Party Marking**
Indicating the name and phone number of a person "responsible for the shipment" on the outside of package.

**Class 6 Infectious Substance Label**
Indicating shipment contains Category A Infectious Substance Affecting Humans.

**UN Specific Label**
Indicating the UN2814 substance and total weight of the specimens inside the package.

**Class 9 Miscellaneous Dangerous Label**
Only for shipments containing dry ice. The quantity must be included on this label as (___kg). (no more than 2.2kg of dry ice is allowed per shipping container.)

**Package Orientation Markings**
Double up arrows pointing upwards must be on opposing sides of the box not containing labels.

**Final Packaging**
Place the pre-packed tape strip across the box only in one direction. If dry ice is used, care should be taken to allow enough space for carbon dioxide gas to escape as dry ice dissipates.

**NOTIFY PAML of Category A shipments.**

1. E-mail Paml Dispatch at SD@paml.com
2. Indicate that you have a Category A shipment and provide them with the following information: Your location, tracking or waybill number, the carrier and ETA to Spokane.
3. Overpacks must contain the statement: "INNER PACKAGES COMPLY WITH PRESCRIBED SPECIFICATIONS." All markings found on the inner packages must appear on the overpack container.
PURPOSE  The purpose of this policy is to clarify PAML’s position related to appropriate methods of shipping Petri Dishes, including restrictions based on hazard class and mode of transportation.

SCOPE  PAML employees will follow the regulations for specimens which may be shipped from a PAML site. PAML will also work with clients and partners to assist them in complying with these regulations when shipping their testing to a PAML site. Shipping regulations depend on the transport service used and include those regulations set forth by the United States Department of Transportation (DOT) and the International Air Transport Association (IATA) and any other appropriate regulatory agencies.

POLICY  Rules for Shipping Petri Dishes

1. Category A (620) specimens can never be shipped in a Petri Dish, either via Ground or Air, as they do not meet the minimum requirements of Federal Regulations. This is based on 49 CFR (Code of Federal Regulations) Part 173.196 “Category A infectious substances.”

The packaging requirements for shipping Category A are as follows:

   (1) A leakproof primary receptacle.
   (2) A leakproof secondary packaging.
   (3) A rigid outer packaging of adequate strength for its capacity and intended use.
   (4) Absorbent included for liquid infectious substances.

   Note: The only acceptable container for Category A culture is a slant. The preferred packaging for all Category A shipments is the Exakt-Pak Canister kit, which can be ordered as PAML part number 1789K. The kit includes a complete Exakt-Pak Canister kit, 4 sheets of redbar paper and a pre-printed FedEx Airbill.

   THIS KIT MAY NOT BE ALTERED FOR SHIPPING.

2. Category B (650) & Exempt Human specimens can be shipped in a Petri Dish, only via Ground, but not via Air (only a slant can be the primary container for air shipments of cultures).

When shipping Category B or Exempt Human via ground in a Petri Dish the specimen must also be:

   (1) Taped or wired together and placed in a ziplock/leakproof plastic baggie (as per PHMSA (US DOT - Pipeline and Hazardous Materials Safety Administration) Interpretations #08-0158 and #08-0276). Once placed in the baggie, the baggie becomes the primary receptacle.

   (2) Absorbent material added to the baggie.

   (3) Primary packaging in baggie placed into a screw top secondary container PAML part number 1257.

   (4) All contents then placed in a rigid outer container for shipment.
Instructions for completing the Shippers Declaration

1. **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.

2. **Consignee**
   Enter in the Name, Address of the facility to which you are shipping the specimens as well as the person responsible at that facility.

3. **Air Waybill Number**
   Enter the waybill number where indicated.

4. **Transport Details**
   Delete the inappropriate information by using several X’s to cross out the section. Under almost all circumstances, you will cross out the section “CARGO AIRCRAFT ONLY.” This will allow either passenger or cargo aircraft to ship your samples.

5. **Airport of Departure**
   Enter in the City and State for the airport from which the shipment is leaving.

6. **Airport of Destination**
   Enter in the City and State for the airport for which the shipment is intended.

7. **Shipment Type**
   Delete the inappropriate information by using several X’s to cross out the section. All 620 shipments from PAML and its affiliates will be non-radioactive, so the shipper must cross out 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** (Suspected Category A infectious substance):
      These words must be used exactly. Note: We no longer are required to enter the exact name of the suspected organism if we’re not sure.
      As per IATA exemption A140 the term “Suspected Category A infectious substance” can be entered.
      If the suspicious substance is known, then it can be entered as “Suspected” with the name of the substance and the A140 is then removed.

   B. **Carbon Dioxide, Solid:** When shipping with dry ice, it must be listed as a dangerous good.
      When not shipping with dry ice, delete this line off of the form.

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. If no dry ice is being shipped, delete this line.
**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), if dry ice is being shipped.

**Packing Group**

Leave this section BLANK for the Infectious Substance line, as well as the dry ice line (if dry ice is being shipped).

**Subsidiary Risk**

Leave this section BLANK for all shipments.

**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 (not to exceed 50 ml for commercial). For example, if you are shipping a total of 10 ml of sample, and the samples are in two primary receptacles, then you enter "20 ml".
B. When shipping with Dry Ice, enter in the number of kg of dry ice contained in the shipment, not to exceed 2.2 kg. (5 lbs).

**Packing Instruction**

Enter “620” for Infectious Substances. Enter “954” for shipments containing dry ice.

**Proper Shipping Name**

When shipping Category A and the Proper Shipping Name is known, enter the proper name in the parenthesis under “Infectious Substance affecting humans” in the Proper Shipping Name column.

If the Proper Shipping Name is unknown, enter “Suspected Category A infectious substance” in the parenthesis; also enter “A140” in the Authorization column for the IATA exemption, which allows the “Suspected Category A infectious substance” statement.

**Shipping Multiple Line Items**

When shipping multiple line items, under all items in the Quantity and Type of Packaging column enter “All packed in one fibreboard box” under all items.

If there is only one item, then remove the word “All” so that it states: “Packed in one fibreboard box.”

**Additional Handling Information**

The following information should be on the form:

24-hour phone number of person responsible: CHEMTREC (800)424-9300 (PAML Account)

**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.

**Multiple Pages of the Form**

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 Form and submit three copies with the completed shipment.
**SHIPPER’S DECLARATION FOR DANGEROUS GOODS**

### Shipper
- Name of Shipper: Location
- Street Address
- City, State, Zip Code
- Phone Number
- Person Responsible

### Air Waybill No.
- Enter Number Here

### Page 1 of 1 Pages
- Shipper’s Reference Number (optional)

### Consignee
- Pathology Associates Medical Labs
- 110 W. Cliff Drive
- Spokane, WA 99204
- Phone Number: (509)755-8864
- Person Responsible: JoAnn Farnsworth

Four 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
- Airport of Departure: Enter City and State
- Shipment type: (delete non-applicable)

### NATURE AND QUANTITY OF DANGEROUS GOODS

#### Dangerous Goods Identification
- **UN or ID No.:** 2814
- **Proper Shipping Name:** Infectious Substance, affecting humans (Suspected Category A infectious substance)
- **Class or Division (subsidary risk):** 6.2
- **Packing Group:** 9
- **Quantity and Type of Packing:** Enter number ml

#### Additional Handling Information
- 2.2 kgs
- All packed in one fibreboard box

**Emergency contact 24-hr number:** CHEMTREC (800)424-9300 (PAML Acct.)

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

<table>
<thead>
<tr>
<th>your Name</th>
<th>Your Title</th>
<th>Your City, State, Month, Day, 20XX</th>
<th>Signature (See warning above)</th>
</tr>
</thead>
</table>

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Regulating authorities have provided in-depth regulations for appropriate classification, packaging and shipping for specimens by air and by ground. In addition to shipping, medical test sites are required to maintain policies and procedures to provide appropriate instructions for specimen collection, handling, preservation, and transportation.

**These authorities are:**

- Department of Transportation (DOT)
  www.dot.gov

- International Civil Aviation Organization (ICAO)
  www.icao.int

- Centers for Disease Control (CDC)
  www.cdc.gov

- World Health Organization (WHO)
  www.who.int

- International Air Transportation Association (IATA)
  www.iata.org

- Clinical Laboratory Improvement Amendments (CLIA)
  www.cdc.gov/clia/

**Resources used for this brochure:**

- Department of Transportation: Research & Special Programs Administration: 49 CFR Parts 100-185
- IATA Dangerous Goods Regulations
- ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air