Packaging & Shipping Laboratory Specimens Guide

Volume XI

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

☐ Facility Staff is Trained and Certified to Package and Ship Specimens
☐ Hazmat / Dangerous Goods Certifications on file
☐ Dangerous Goods Shipping Documents
☐ Specimen Supplies—Poly Seal Bag, Specimen Racks, Manifest or Requisitions
☐ Packaging Supplies—Box, Labels, Air Waybill (if transported by air)
☐ Courier Contact Information
☐ Destination Information

• Please stop here if you have not met these criteria.
• Call PAML Logistics for more information.

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 does not substitute for approved, certified training if required by regulation. PAML is not certified to provide this type of training.
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).

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 carrier 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/Labeling of shipments, and any documentation guidelines.
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 are which 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 propagate 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.3.6.2.2.1
   * IATA; 51st Edition, Chapter 3– Classification

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.

FAQ’s

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/packaging 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

- 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

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.
Biological Substances, Category B
Specimen Manifest Upgrade

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.

Specimens are often classified as “EXEMPT HUMAN SPECIMENS”. However, there is a subset of orderable tests in the PAML test directory that, when prepared for testing according to the PAML test menu, would qualify as a hazardous material and should be classified as a “UN3373” BIOLOGICAL SUBSTANCES, CATEGORY B.

When one of these Category B 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 Category B 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 the PAML Logistics Department at: (800)541-7891 Ext. 9996
Packaging / Packing & Labeling Instructions

Packaging is preparing a specimen for shipment from one location to another. Packing a specimen is the act of placing the specimen in the outer container it will travel in while in transport.

1. 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.

   Follow Packaging instructions below.

Exempt Human: No Dry Ice

Exempt Human: With Dry Ice

Packaging ALL SPECIMENS
• Primary receptacle containing the specimen.
• Secondary packaging such as a plastic Poly Seal Bag with adequate absorbent material.
• Outer packaging (corrugated box, fibreboard box, cooler, etc.) with biohazard symbol & appropriate labels.
• Packaging sample in appropriate temperature for specimen transport.
2. **Category B, Biological Substances (650)**

PAML has indicated which tests are Category B within the test directory. Tests categorized as B, will have a marking along the left side of the directory stating the Packing Instruction of 650. 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 packed as follows:**

- Leak proof primary receptacle. Category B primary receptacles must not exceed 500ml.
- The specimen must be contained in a screw top container meeting 95kpa in the range of –40° to 130°F.
- 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 and 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 B: No Dry Ice**

**Category B: With Dry Ice**
3. **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 screw-cap 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 fibreboard box provided by PAML Supply. 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.*

Category A and Category B cannot be in the same box.  
PAML does not permit shipping of Category A Substances on commercial air carriers.
3. **Category A (620) - Infectious Substance Affecting Humans**

**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.

**Shipper Marking**
Indicating the name and address of the shipper of the package (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 the 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 take to allow enough space for carbon dioxide gas to escape as dry ice dissipates.

**NOTIFY PAML of Category A shipments.**

1. Call **800-541-7891 x8996** (Flight/Ground Coordinators) of shipment en-route to PAML.

2. Tell the recipient 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.
Transport in Petri Dishes

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 into 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 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.

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).

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.
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), if dry ice is being shipped.

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

12. Subsidiary Risk
    Leave this section BLANK 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 (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.).

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

15. 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.

16. 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.”

17. Additional Handling Information
    The following information should be on the form:
    24-hour phone number of person responsible: CHEMTREC (800)424-9300 (PAML Account)

18. 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.

19. 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

1. Shipper
   Name of Shipper Location
   Street Address
   City, State Zip Code
   Phone Number:
   Person Responsible: Enter

2. Consignee
   Pathology Associates Medical Laboratories
   110 W. Cliff Drive
   Spokane, WA 99204
   Phone Number: (509)755-8125
   Person Responsible: Mike Fowler

3. Air Waybill No. Enter Number Here

4. Airport of Departure
   Enter City & State

5. Airport of Destination:
   Enter City & State

6. NON-RADIOACTIVE RADIOACTIVE

7. Danger Goods Identification
   UN or ID No. Proper Shipping Name Class or Division (subsidiary risk) Packing Group Quantity and Type of Packing: Packing Inst.
   UN 2814 Infectious Substance, affecting humans (Suspected Category A infectious substance) 6.2 13a 620 A140
   UN 1845 Dry Ice 9 13b 954
   All packed in one fibreboard box

8. Additional Handling Information
   Shipment is made under the provisions of ICAO

17. 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/placed, 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.

Name/Title of Signatory
Your Name / Your Title

Place and Date
Your City, State Month Day, 2011

Signature (See warning above)
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)
- International Civil Aviation Organization (ICAO)
- Centers for Disease Control (CDC)
- World Health Organization (WHO)
- International Air Transportation Association (IATA)
- Clinical Laboratory Improvement Amendments (CLIA)

**Resources used for this brochure:**

Department of Transportation: Research & Special Programs Administration: 49 CFR Parts 100-185

Harmonization With the United Nations Recommendations, International Maritime Goals Code, and International Civil Aviation Organization’s Technical Instructions

IATA Dangerous Goods Regulations

ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air