

SPECIMEN LABELING, STORAGE & HANDLING

Purpose of this document

The purpose of this document is to provide guidelines for storage and handling of clinical specimens during a respiratory disease outbreak when the pathogen is unknown.

Note: Consult your local or state health department about the potential respiratory outbreak as soon as possible. All specimen submissions to CDC require approval by the individual state health department and CDC before shipment.

Specimen containers

Use sterile specimen containers. Container caps should be closed securely and sealed with Parafilm® to avoid leakage. Vials should have external caps with internal O-ring seals.

Specimen labeling

Label all specimen containers with the following:

- Patient name
- Patient ID number
- Specimen type(s)
- Date collected.

Identifying information can be provided by writing directly onto the vials in indelible ink. If labels are used, they should be secured to insure retention during freezing.

Specimen storage

To increase the sensitivity of diagnostic testing all specimens should be stored frozen (optimally at -70oC) and shipped on dry ice with the exception of fixed tissues and specimens collected in a glass tube (whole blood, whole blood EDTA, whole blood Heparin, serum separating tubes, CPT tubes, etc). If freezing is not possible, specimens that will be evaluated within 1 to 2 days after collection may be stored refrigerated at 4oC and shipped on refrigerant gel packs. Fixed tissues should be stored and shipped in a separate box at room temperature. Specimens collected in a glass tube should be refrigerated at 4oC and shipped on refrigerant gel packs.

Accompanying documentation

Each package should contain a line list with the following information for each included specimen: patient name, ID number, date collected, specimen type, clinical contact name and phone number, and submitter contact name, affiliation, phone number and e-mail address. An electronic version of the line listing should also be provided. If an autopsy was performed, a preliminary autopsy report should be provided with the tissues.

In addition, relevant clinical information (e.g., date of onset of illness, results of other diagnostic

or clinical testing) is required. If multiple specimens are submitted, indicate any specimens for which testing should be prioritized. If a specimen is being sent to CDC, please contact CDC for approval prior to shipping a specimen (see Shipping section) and include a completed [CDC Specimen Submission Form](#) (CDC 50.34). The accompanying specimen information should include the name, telephone, and e-mail of a contact person, as well as any relevant clinical information.

Packing Infectious Substances for Transport: Definitions

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

Culture: An infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen as defined above.

Infectious substances: are substances known to contain, or reasonably expected to contain, pathogens. Pathogens are microorganisms (including bacteria, viruses, rickettsia, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals.

Category A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses a higher degree of risk than Category B. Category A infectious substances rarely cause outbreaks of respiratory infections (e.g., *Yersinia pestis*, anthrax, tularemia). See current list of [Category A and B agents](#).

Those materials known or suspected of containing Category A pathogens must be shipped as infectious substances (UN 2814 or UN 2900) unless otherwise indicated on the Category A List.

Suspected Category A: The technical name for an unknown substance suspected of containing Category A infectious substances using UN2814 or UN2900.

Category B: An infectious substance that does not meet the criteria of a Category A infectious substance; an infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes.

Category B infectious substances are packed and transported as Biological substance, Category B and assigned to UN 3373.

Packing and Labeling Infectious Substances for Transport

Packing Biological Substances, Category A for Transport

The U.S. Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations, 49 CFR Parts 171 - 180, require all persons who offer or transport infectious substances, including patient specimens to comply with applicable regulations.

U.S. Department of Transportation (DOT) regulations require initial and recurrent training of all employees who perform work functions covered by the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Any employee whose work directly affects hazardous materials transportation safety is required to have training.

You as the shipper – not the transport company – are responsible for the shipment until the package reaches the consignee.

Primary packaging

- Primary container must be water tight. Seal screw top containers securely with parafilm, adhesive tape or something similar.
- Wrap multiple containers individually to prevent breakage.
- Everything in the primary container, including transport media, is considered the infectious substance.

Secondary packaging

- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- You must use UN specification packaging: UN Certified for Class 6.2 (Infectious Substances). Infectious substance packaging must have the required specification markings on packaging:



- Secondary packaging must be watertight. Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.
- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill and shipper's declaration for dangerous goods).
- All hazardous markings and labels must be on the same side of the box, adjacent to the address label so that they can be seen at the same time.

- You must include marking, like the example to the right, on the package:
- No technical name on the outer package.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

Infectious Substance, affecting humans UN2814 X 20 mls

Outer packaging

- An overpack is used if the secondary packaging is not large enough for all the labels and documents OR if cold packs or dry ice is used.
- The address label should include the complete name of person, complete name of facility, shipping address (street address, city, state and zip code) and telephone number (no toll-free numbers) of both shipper and consignee.
- The name and telephone number of the person responsible for the shipment must be on the package as well as the [Shipper’s Declaration for Dangerous Goods](#) and air waybill.
- The person responsible for shipment must know the contents of the shipment and the emergency response procedures. Place the information below on the outer container:

Name and telephone number of person responsible for shipment	
_____	_____
Name	Telephone number

- The outer packaging must not contain more than 50 g or 50 ml for passenger aircraft and 4 L or 4 kg for cargo aircraft only.
- Both dry ice and cold packs or wet ice must be placed outside the secondary packaging.
 - o Dry ice: packaging must permit the release of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging.
 - o Cold packs, wet ice: the packaging must be leak-proof.
- Include two (three for Federal Express) copies of the completed [Shipper's Declaration for Dangerous Goods](#). You must use the original form with red and white striped borders—copies are not acceptable.
 - o Transport Details box: if your package contains less than 50 ml/g, mark through the box containing the words “cargo aircraft only.” If your package contains more than 50ml/g, mark through the box containing the words “passenger and cargo aircraft.”
 - o You must include a 24-hour emergency contact telephone number.

o Nature and Quantity of Dangerous Goods box: The comma after the word substance is required; note the spelling of fibreboard; the genus/species or technical name must be in parentheses. For unidentified infectious substances, use “suspected Category A” for the technical name. Also, use this for the technical name on the itemized list of contents.

- **The Shipper’s Declaration for Dangerous Goods is a legal document—you must sign the form.**
- The person responsible for the shipment must know the contents of the shipment and the emergency response procedures.
- Certification statement: “I declare that all of the applicable air transport requirements have been met.”

Packing Biological Substances, Category B for Transport

The U.S. Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations, 49 CFR Parts 171 - 180, require all persons who offer or transport infectious substances, including patient specimens to comply with applicable regulations.

You as the shipper – not the transport company – are responsible for the shipment until the package reaches the consignee.

Primary packaging

- Primary container must be water tight. Seal screw top containers with adhesive tape, parafilm, or something similar.
- Wrap multiple containers individually to prevent breakage.
- Primary containers cannot contain more than 1 L (liquids) or 4 kg (solids). Everything in the primary container, including transport media, is considered the patient specimen.

Secondary packaging

- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- Secondary packaging must meet the US DOT and IATA packaging requirements for Category B Infectious substances: including 1.2 meter (3.9 feet) drop test procedure.
- For liquid shipments by aircraft, 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.
- Secondary packaging must be watertight (liquids) or siftproof (solids). Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.
- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill).

Outer packaging

- An overpack is used if the secondary packaging is not large enough for all the markings, labels, and documents OR if cold packs or dry ice is used.
- The outer packaging must not contain more than 4 L or 4 kg.
- Both dry ice and wet ice must be placed outside the secondary packaging.
- Dry ice: packaging must permit the release of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging.
- Wet ice: the packaging must be leak-proof.
- Each package and the air waybill must be marked with “Biological substance, Category B” (exact wording) and each package must be marked with the square-on-end UN3373 marking.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. Place in a sealed plastic bag to protect from moisture.
- If overpack used, package must be marked “Overpack”. All secondary package markings must be on the overpack.
- You must put the words “UN 3373” and the text “BIOLOGICAL SUBSTANCE, CATEGORY B” in the “Nature and Quantity of Goods” box on the air waybill.
- The name and telephone number of the person responsible for the shipment must be on the package or the air waybill. The person responsible for shipment must know the contents of the shipment and the emergency response procedures.
- [A Shipper's Declaration for Dangerous Goods is NOT required.](#)

General information

Testing may be conducted by clinical laboratories, reference laboratories or city, county or state public health laboratories. Only state health departments and other Federal agencies may submit specimens for reference testing to CDC. **All specimen submissions to CDC require first approval by the individual state health department and CDC prior to shipment.**

Private citizens, health practitioners and hospitals must contact their local (city or county) health department about how and when to submit specimens. If the local health department is unable to make a determination, they will forward the specimen to their state health department.

[State and Local Health Departments](#)

[State list of the Association of State and Territorial Public Health Officials](#)

Special arrangements will be made for specimens collected for studies/projects by collaborators of CDC investigators. Contact the Principle Investigator for specific instructions.

Because CDC is not a hospital or clinical facility, testing of specimens for diagnostic purposes will not be conducted without prior notification. Local physicians or clinics seeking laboratory testing assistance should first contact their county or state health department. If you are a health professional or government official on you

require immediate assistance, contact the CDC Emergency Operations Center at 770-488-7100.

If testing by CDC has been approved, ship all packages via overnight delivery (FedEx 1-800-463-3339) to:

Centers for Disease Control and Prevention
ATT: STAT Lab/Outbreak Name
1600 Clifton Road, NE
Atlanta, GA 30329-4027