



Pointers on Shipping: Clinical Samples, Biological Substance Category B and Environmental Test Samples



At FedEx Express, we understand the importance of ensuring the safe shipping of clinical samples such as human or animal materials, including excreta, secretions, blood (including FDA-approved pharmaceuticals that are blood products), tissue and tissue fluids, as well as environmental test samples of soil and water. Our objective is to deliver these special shipments safely to their destinations in the same good condition as we receive them from you.

This brochure provides essential pointers to help you meet FedEx Express requirements on the proper packaging of these materials. In addition, all shipments must comply with all applicable local, state and federal laws governing packing, marking and labeling. Blood, urine, fluids and other specimens containing or suspected of containing infectious substances must be shipped according to applicable government and International Air Transport Association (IATA) regulations. For more information, call 1.800.GoFedEx 1.800.463.3339 and press "81" to reach the Dangerous Goods/Hazardous Materials Hotline.

The illustrations depict sample packaging that is acceptable for shipping clinical samples such as human or animal materials, including excreta, secretions, blood (including FDA-approved pharmaceuticals that are blood products), tissue and tissue fluids, as well as environmental test samples of soil and water. All of the packaging illustrated here are acceptable and may be used in any combination as long as the four basic requirements for acceptable packaging are met.

NOTE: Specific requirements for Diagnostic Specimens are highlighted and underlined below.*

GENERAL ACCEPTABLE PACKAGING

Proper packaging of clinical samples and environmental test samples includes four basic requirements:

1. Watertight Primary Receptacles
2. Watertight Secondary Receptacles
3. Absorbent Material
4. Sturdy Outer Packaging

NOTE: Internal filler or cushioning is recommended to protect fragile contents and limit movement.

For Diagnostic Specimens containing liquids, absorbent material is required between the primary and secondary receptacles. For both liquids and solids, cushioning material is required.

1. Watertight Primary Receptacles

All primary receptacles must have positive closures (such as screw-on, snap-on or push-on lids) that must be taped.

For Diagnostic Specimens, primary receptacles may be glass, metal or plastic. Positive means of ensuring a leak-proof seal, skirted stopper or metal crimp seal must be provided. Reinforce screw caps with adhesive tape.

For liquid specimens, the primary receptacle(s) must be leak-proof and must not contain more than 1 L.

The primary or secondary receptacle(s) must be able to withstand, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40 C to 55 C (-40 F to 130 F).

For solid specimens, the primary receptacle(s) must be siftproof and not contain more than 500 g.



Plastic Canister



Glass/Plastic Jar



Glass/Plastic Vial

2. Watertight Secondary Receptacles

To prevent contact between multiple fragile primary receptacles, individually wrap or separate each and place inside a leak-proof secondary receptacle.

For Diagnostic Specimens, enclose an itemized list of contents between the secondary packaging and the outer packaging. For solids, the secondary packaging must be siftproof. These illustrations below are not intended to represent secondary containers for Diagnostic Specimens. Secondary containers for Diagnostic Specimens must be certified by the manufacturer prior to use.



Sealed Styrofoam® Container
(1-inch-thick minimum)



Sealed
Plastic Bag



Plastic
Canister



Screw-Cap
Can

*Dangerous-goods regulations can be reviewed in the IATA Packing Instruction 650.

3. Absorbent Material

Place absorbent material between the primary and secondary receptacle, making sure that multiple primary receptacles are individually wrapped to prevent contact. Use enough absorbent material to absorb the entire contents of all primary receptacles.



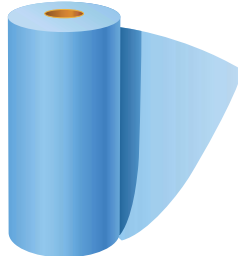
Cellulose Wadding



Cotton Balls



Super-Absorbent Packet



Paper Towels

4. Sturdy Outer Packaging

Sturdy outer packaging must be rigid, consisting of corrugated fiberboard, wood, metal or rigid plastic and be appropriately sized for content.

For liquids, the outer packaging must not contain more than 4 L.

For solids, the outer packaging must not contain more than 4 kg.

When using an airbill pouch on outer packaging, the minimum package size that FedEx Express will accept is 7" x 4" x 2". For outer packaging smaller than these dimensions, use a plastic FedEx® Clinical Pak as an overwrap. As long as the final package meets the four basic packaging requirements, you may insert your package into the FedEx Clinical Pak to comply with the minimum acceptable size. (See "FedEx Clinical Pak" on the following page.)

For Diagnostic Specimens, the minimum outer-container size in the smallest overall external dimension is 4 inches.

Each completed package must be capable of withstanding a 4-foot (1.2-meter) drop test outlined in IATA 6.6.1. The outer package must be rigid.



Corrugated Fiberboard



Wood



Rigid Cooler



Rigid Plastic Container

MARKINGS: Patient specimens for which there is minimal likelihood that pathogens are present are marked by the shipper "Exempt human specimen" or "Exempt animal specimen" as appropriate to comply with current IATA regulations. Each UN3373 shipment must show the text: "BIOLOGICAL SUBSTANCE CATEGORY B," "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS" at least 6 mm high, marked on the outer package adjacent to the following diamond-shaped mark.



The UN mark must be in the form of a square set at an angle of 45 degrees with each side having a length of at least 50 mm (2 inches). The width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high.

The name, address and telephone number of a responsible person must be marked on the package OR provided on the airbill.

Finally, if more than one properly prepared Diagnostic Specimen shipment is placed into another outer package, this constitutes an overpack. The word "OVERPACK" must be marked on the outer package and all other required package markings must be reproduced on the outside of the overpack.

Specific requirements:

Please consult the current ICAO/IATA regulations handbook for specific requirements for the following:

- Diagnostic Specimens shipped refrigerated or frozen.
- Diagnostic Specimens shipped in liquid nitrogen.

AIRBILL ENTRIES

If a paper airbill is used, the following text must be included: "Biological Substance Category B," "Diagnostic Specimens" or "Clinical Specimens" and "UN 3373." If not marked on the outer package, the name, address and telephone number of a responsible person must be marked on the airbill.

UNACCEPTABLE OUTER PACKAGING

Styrofoam® boxes, plastic bags and paper envelopes are UNACCEPTABLE outer packaging.



Styrofoam Boxes



Plastic Bags



Paper Envelopes

In addition, FedEx Express will not accept Diagnostic Specimens or environmental test samples packaged in the FedEx® Envelope, FedEx® Tube, FedEx® Pak or any FedEx box.



FedEx Packaging

FedEx® CLINICAL PAK

FedEx provides a plastic FedEx Clinical Pak for clinical samples, Diagnostic Specimens and environmental test samples with outer packaging sizes under 7" x 4" x 2". The small clinical pak (inventory No. 150948) measures 14" x 9" and is suitable for shipping single and smaller-sized test specimens. The large clinical pak (inventory No. 135629) measures 19" x 14" and is more appropriate for multiple and larger specimen shipments. Any individual specimen packages placed in the FedEx Clinical Pak must meet the four basic packaging requirements (watertight primary receptacle, watertight secondary receptacle, absorbent material and sturdy outer packaging).

Shipments marked or labeled 6.2 (infectious materials) and/or containing dry ice cannot be shipped inside the FedEx Clinical Pak. For more information on shipping infectious substances, call 1.800.GoFedEx 1.800.463.3339 and press "81" to reach the Dangerous Goods/Hazardous Materials Hotline.



*Large Clinical Pak
(Front View)*



*Small Clinical Pak
(Back View)*

Clinical Samples That Are Dried and Noninfectious:

Dried samples such as dried blood, tissue, saliva, hair.

While noninfectious samples of dried blood are not dangerous goods and are not required to meet dangerous-goods regulations, they do require special packaging that meets FedEx Express guidelines. Dried-blood samples on absorbent pads or cards for diagnostic testing must be enclosed in watertight plastic bags and shipped in a sturdy outer container or commercial envelope. Samples on glass or plastic slides must be adequately cushioned and may be shipped inside a sturdy outer container or flexible-envelope packaging. Use of the FedEx Clinical Pak is optional.

Environmental Test Samples

Packaging of environmental test samples such as soil and water must meet the four basic packaging requirements for blood, urine or other clinical samples. Adequate internal filler or cushioning must be provided to protect contents. Temperature-control requirements of environmental test samples are the shipper's responsibility. For information on temperature-control methods, read Packaging Pointers: Perishable Shipments at **fedex.com**.

FedEx Package Testing and Design Services

FedEx offers package testing, evaluation and design services that may help you avoid damage problems and eliminate unnecessary packaging costs. The FedEx Packaging Design and Development department encourages all shippers of clinical samples or environmental test samples to submit packaging samples for test or evaluation. To obtain a Package Services Application, go to **fedex.com** or call 1.800.633.7019.

FedEx Information Resources

For information regarding noninfectious, infectious or dangerous-goods shipments, call 1.800.GoFedEx 1.800.463.3339 and press "81" to reach the Dangerous Goods/Hazardous Materials Hotline.

Don't Forget ...

- Infectious substances or probable infectious substances require additional specifications and must be shipped according to applicable government and IATA requirements.
- Shipments marked or labeled 6.2 (infectious materials) and/or containing dry ice cannot be shipped inside the FedEx® Clinical Pak.
- Consult the Occupational Safety and Health Administration (OSHA) regulations to determine if your commodity requires the biohazard label.
- FedEx Express will not accept clinical samples, Diagnostic Specimens or environmental test samples packaged in the FedEx® Envelope, FedEx® Tube, FedEx® Pak or any FedEx box.
- Don't place clinical samples, Diagnostic Specimens (UN3373) or environmental test samples in a FedEx Express® Drop Box. Please call FedEx for pickup, or you can drop off the shipment at any staffed FedEx location or FedEx Authorized ShipCenter®. FedEx Kinko's Office and Print Centers may accept FedEx Clinical Pak shipments provided they do not contain UN3373. For further assistance call 1.800.GoFedEx 1.800.463.3339.
- Mark and weigh packages correctly.
- Have packages ready when you call for pickup.



NOTICE

FedEx Express will refuse to accept packages not meeting FedEx Express, government or IATA requirements.

This brochure is in no way intended to replace requirements mandated by 49CFR and IATA. This is for informational purposes only.

This packaging brochure is provided free to FedEx Express customers to reduce the possibility of loss or damage during transit. It is NOT intended to be a comprehensive guide for packaging items we accept for transit. We make no warranties, expressed or implied, regarding this information. Proper packaging is the sole responsibility of the shipper. For more information and comprehensive guidelines, contact the FedEx Dangerous Goods/Hazardous Materials Hotline at 1.800.GoFedEx 1.800.463.3339, and press "81." Refer to the current FedEx Service Guide for terms, conditions and limitations applicable to FedEx® delivery services.

