Clinical Samples, Biological Substance Category B (UN 3373) 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, secreta, 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, secreta, 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.

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 Biological Substance Category B (UN 3373), 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 sifproof and must not exceed the outer packaging weight limit.

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 Biological Substance Category B (UN 3373), enclose an itemized list of contents between the secondary packaging and the outer packaging. For liquids, the secondary packaging must be leakproof; for solids, the secondary packaging must be sifproof. These illustrations below are not intended to represent secondary containers for Biological Substance Category B (UN 3373). Secondary containers for Biological Substance Category B (UN 3373) must be certified by the manufacturer prior to use.

NOTE: Specific requirements for Biological Substance Category B (UN 3373) 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 Biological Substance Category B (UN 3373) for both liquids and solids, cushioning material is required.

*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.

For Biological Substance Category B (UN 3373) containing liquids, absorbent material is required between the primary and secondary receptacles.

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.

However, each UN 3373 shipment must show the text: “BIOLOGICAL SUBSTANCE CATEGORY B,” 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 and telephone number of a responsible person must be marked on the package OR provided on the airbill.

The name and address of the shipper and the consignee must be marked on the package. When the shipper or consignee is also the “person responsible,” the name and address need only be marked once in order to satisfy the name and address provisions.

Finally, if more than one properly prepared Biological Substance Category B (UN 3373) 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 for specific requirements for the following:

a. Biological Substance Category B (UN 3373) shipped refrigerated or frozen.

b. Biological Substance Category B (UN 3373) shipped in liquid nitrogen.

AIRBILL ENTRIES
If a paper airbill is used, the following text must be included: “Biological Substance Category B” 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.

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 Biological Substance Category B (UN 3373), 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.
FedEx provides a plastic FedEx Clinical Pak for clinical samples, Biological Substance Category B (UN 3373) and environmental test samples with outer packaging sizes under 7” x 4” x 2”. The small clinical pak (inventory No. 150948) measures 12 1/4” x 9 1/2” and is suitable for shipping single and smaller-sized test specimens. The large clinical pak (inventory No. 135629) measures 16” x 12 7/8” 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).

In addition, FedEx Express will not accept Biological Substance Category B (UN 3373) or environmental test samples packaged in the FedEx® Envelope, FedEx® Tube, FedEx® Pak or any FedEx box.

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.

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, Biological Substance Category B (UN 3373) or environmental test samples packaged in the FedEx Envelope, FedEx Tube, FedEx Pak or any FedEx box.

- Don't place clinical samples, Biological Substance Category B (UN 3373) 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 Biological Substance Category B (UN 3373). For further assistance call 1.800.GoFedEx 1.800.463.3339.

- Mark and weigh packages correctly.

- Have packages ready when you call for pickup.

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**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 customers to help 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” or e-mail pkglab@mail.fedex.com for the FedEx Packaging Design and Development department. Refer to the current FedEx Service Guide for terms, conditions and limitations applicable to FedEx® delivery services.

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