

Infectious Material-Meriter Laboratories

Most non-infectious medical specimens sent to an esoteric laboratory such as Meriter Laboratories (ML) are flown on passenger aircraft or are carried by common air carrier such as FedEx. The International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) have established stringent rules to protect passengers and package handlers from exposure to these potentially infectious substances. These regulations are enforced by the Federal Aviation Administration (FAA) or other similar enforcement agencies around the world who can levy significant fines against shippers and carriers who violate the regulations. You should be aware that your test send-out area is considered the “shipper” when they send specimens to a reference laboratory. Therefore, your send-out area must understand and follow regulations for shipping infectious substances. It is the responsibility of the “shipper” to ensure correct identification, classification, packaging, labeling, marking, and documentation for all shipments of infectious substances. In addition, the “shipper” is responsible for ensuring that all persons involved in the transport of infectious substances receive the required initial and recurrent training. Information on these requirements can be found in the following websites:

- <http://www.iata.org/whatwedo/cargo/pages/index.aspx>
- <https://www.fmcsa.dot.gov/regulations/hazardous-materials/how-comply-federal-hazardous-materials-regulations>

We will focus on the regulations for shipping infectious substances by air. If you use a ground service as UPS, you must follow U.S. Department of Transportation (DOT) regulations. If you use the U.S. Postal Service, you must follow Post Office regulations. In either case, contact the Dangerous Goods Departments of the carrier you plan to use for details.

IATA and ICAO have established 2 categories of specimens, Diagnostic Specimens and Infectious Substances.^{1,2} Both specimen types require specific packaging and handling procedures designed to protect anyone who comes in contact with the package. The shipper (your send-out staff) must decide in which category specimens belong.

With the implementation of Universal Precautions, all blood and body fluids are considered potentially infectious. To clarify the situation for air transport, the regulators redefined “Infectious Substances.” “Infectious Substances are substances known to contain, or reasonably expected to contain, pathogens.”⁴ These specimens must be packaged as infectious substances, following IATA Packing Instruction 602.⁵

On the other hand, specimens sent for diagnostic or investigational purposes are considered diagnostic specimens. Similarly, most clinical laboratory tests (eg, sodium, thyroid-stimulating hormone) are considered diagnostic specimens. These specimens must be packaged as diagnostic specimens, following IATA Packing Instruction 650.³

Note: Cultures of pathogens must be considered infectious.

Shipping Cultures of Microorganisms

Aerobic and Anaerobic Bacteria, Mycobacteria, Fungi, and Yeast

Use either of the following methods for isolating the organism for transportation (agar plates are NOT acceptable):

Method A. Transfer organism to appropriate agar slant, broth, or anaerobic transport vial. Incubate agar slant or broth for 18-24 hours or until actively growing.

Method B. Cut out a piece of the agar on which there is a colony of the organism to be tested. Place the agar in a screw-capped, sterile (serum) vial and cap the vial tightly.

Note: Organism must be in pure culture, actively growing. Agar plates are NOT acceptable. Mixed cultures will not be processed.

Send culture to the testing laboratory inside an ML mailer.

Prepack the culture specimens for shipping using large ML infectious mailers (or an ML small infectious mailer). You may also use commercial packaging. Follow instructions carefully.

General Infectious Blood and Serum

Under Universal Precautions, all specimens should be considered potentially infectious; however, not all specimens should be sent as infectious substances. Your send-out staff must decide which specimens must be shipped as infectious substances.

If the name of the test you are sending to ML includes 1 of the pathogens listed in “Exceptionally Dangerous Infectious Agents,” it should presumptively be considered infectious. Of course, medical knowledge can override generalities. Some specimens may not be capable of transmitting disease. The judgement of your medical director should prevail in our opinion.

Regulators require that the name of an infectious substance (eg, culture's name) must be on the airbill and on the outside of the box. This poses a problem when a specimen is being sent for identification; its "name" is unknown. We suggest it is better to send the specimen as infectious and provide a potential name for the infectious agent.

Shipping Infectious Specimens by Commercial Courier

Once specimens are prepacked, they must be boxed for shipment. If you are using a commercial infectious mailer, follow their instructions carefully. If you are using an ML mailer, someone must place the prepacked specimens into an ML shipping box for shipment. ML couriers have been trained to follow our standard procedures for shipping infectious substances. If your send-out area must ship the specimens themselves, be warned that the process requires the shipper to follow the "Letter of the Law." We suggest that you contact ML for a copy of our "Courier Procedure for Shipping Infectious Substances to ML." Preprinted documentation for shipping ML packages can also be obtained as needed.

Once the labels are attached and documentation is completed, tender the box with a common carrier. If any part of the labeling or documentation is incorrect, the box will be returned on the next working day. BE SURE to complete every label and document correctly.

Packages Damaged While in Transit to ML

If a package leaks in transit, the carrier will first contact ML for instructions and then will notify:

Centers for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road Northeast
Atlanta, GA 30333
(telephone: [404] 633-5313)

The carrier shall also notify the sender whose name appears on the infectious label and airbill. Carriers will insist on seeing the information in both places.

Exceptionally Dangerous Infectious Agents

Some microorganisms are so dangerous that the CDC has required them to be sent by registered mail or equivalent system. If they are not received within 5 days, the CDC must be notified. The Code of Federal Regulations (PART 72) governs the shipment of infectious substances, it also contains special provisions from the CDC that apply here.

- S 72.3(f) Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery.
- Coccidioides immitis*
 - Ebola virus*
 - Francisella (Pasteurella) tularensis*
 - Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses*
 - Herpesvirus simiae (B virus)
 - Histoplasma capsulatum*
 - Lassa virus*
 - Marburg virus*
 - Pseudomonas mallei*
 - Pseudomonas pseudomallei*
 - Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses*
 - Variola major, Variola minor, and Whitepox viruses*
 - Yersinia (Pasteurella) pestis*

* ML cannot process the (*) organisms. In general, specimens containing these organisms must be sent to your local State Health Department or Ministry who may refer the specimen to the CDC or another laboratory.

S 72.4 Notice of Delivery; Failure to Receive.

When notice of delivery of materials known to contain or is reasonably believed to contain etiologic agents listed in S 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify:

Centers for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road Northeast
Atlanta, GA 30333
(telephone: [404] 633-5313)

Other Infectious Substances

All actively growing cultures and stocks in slants, broths, and plates must be packaged and shipped as “Infectious.” All “Risk Group 4” pathogens such as those listed above under “Exceptionally Dangerous Infectious Agents” must also be packaged and shipped as “Infectious” according to IATA Packaging Instruction 602.

References

1. “Section 3 – Classification,” Dangerous Goods Regulations, 44th Edition, International Air Transport Association, Montreal-Geneva, 2003, pp 106-107
2. “Technical Instructions for the Safe Transport of Dangerous Goods by Air,” International Civil Aviation Organization, Montreal, Quebec, Canada, 2002, pp 2-6-5 and 2-6-6
3. “Packing Instruction 650,” Dangerous Goods Regulations, 40th Edition, International Air Transport Association, Montreal-Geneva, 2003, pp 451-452
4. “Infectious Substances, Section 3.6.2.1.1,” Dangerous Goods Regulations, 40th Edition, International Air Transport Association, Montreal-Geneva, 2003, p 106
5. “Packing Instruction 602,” Dangerous Goods Regulations, 40th Edition, International Air Transport Association, Montreal-Geneva, 2003, pp 418-419