Isolate Submittal Policy: Clinical Isolates That Cannot Be Ruled-Out As Select Agents

POLICY

In the event a Sentinel Laboratory is unable to "rule-out"* an isolate as a Select Agent**, it must be "referred-in" to the Maryland Department of Health (MDH) Laboratories Administration. Isolates that cannot be ruled-out as Select Agents require special consideration, and it is imperative that these procedures are followed to ensure the protection and integrity of the isolate and the safety of the personnel handling it. Consultation with the MDH Laboratories Administration (and MDH Physician-On-Call) is required.

PROCEDURE

If an isolate cannot be ruled-out as a Select Agent, contact the Laboratories Administration at the following numbers before submission:

MDH Laboratories Administration
Office of Laboratory Emergency Preparedness and Response

Monday – Friday 8:00 a.m. - 4:30 p.m. (Dial in order)	**AFTER HOURS** (Dial in order)
443-681-3787 - Office phone	**410-925-3121 - Cell Phone**
410-925-3121 - Cell Phone	**410-408-7521 - Pager**
443-681-3789 - Office phone	
410-408-7521 - Pager	

DO NOT submit isolates that cannot be ruled-out as a Select Agent without first contacting the MDH Laboratories Administration for consultation (numbers listed above).

It is important that the Sentinel Laboratory contact the MDH Laboratories Administration **EACH** and **EVERY** time there is an isolate that cannot be ruled-out as a Select Agent. Consultation received is for the isolate in question only. It does **NOT** apply to future or previous isolates.

SHIPPING GUIDELINES

Refer to the attached document (**Basic Triple Packaging**) for packaging and shipping guidelines. If necessary, the MDH Laboratories Administration will arrange for an emergency courier, but will only do so after consultation with the patient's physician and MDH Physician-On-Call. A completed **INFECTIOUS AGENTS: CULTURE/DETECTION** Request Form (**DHMH 4676**) must accompany each isolate.

This document (effective 12/06/2017) supersedes all previous documents regarding the transport and shipping of specimens that cannot be ruled-out as Select Agents.

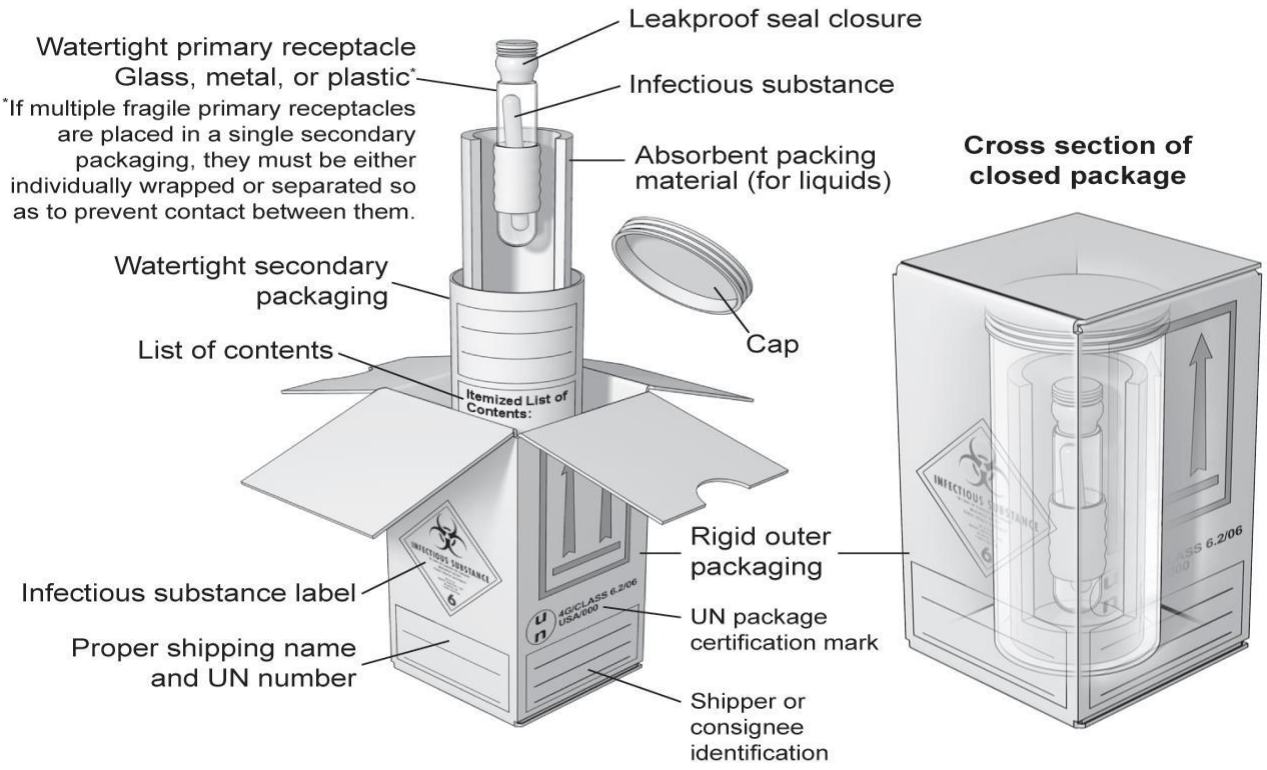
REFERENCES

*Refer to the Laboratories Administration website for the Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases for rule-out protocols: http://www.asm.org/index.php/guidelines/sentinel-guidelines

** A "Select Agent" is defined as any of the biological agents or toxins listed in 42 CFR 73.3 and 73.4. You can visit the CDC website on select agents http://www.selectagents.gov/ for further information and a current and comprehensive list of select agents at: http://www.selectagents.gov/SelectAgentsandToxinsList.html.

BASIC TRIPLE PACKAGING

Basic triple packaging systems include a primary receptacle such as a tube with adhesive tape around the screw cap or a plate with parafilm around the edges. The primary (1°) receptacle, along with required absorbent and cushioning material, is placed inside a secondary (2°) container. The 2° container for diagnostic specimens should be a sealed biohazard or Ziploc bag. The 2° container is then securely placed within an outer shipping container (tertiary (3°) container), generally a corrugated cardboard box with cushioning material inside to surround the 2° container. This outermost container bears the name, address, and telephone number of shipper, name of person responsible with 24/7 telephone number, and **the complete name**, shipping address, and telephone number of the recipient, plus all the required markings. Include an itemized list of contents in a sealed plastic bag, placed between the 3° and 2° containers.



BASIC TRIPLE PACKAGING:

1) A watertight primary receptacle.

2) A watertight secondary receptacle.

3) An outer packaging of adequate strength for its capacity, mass and intended use.

Note: For a liquid specimen, absorbent material must be placed between the primary and secondary containers and be capable of absorbing the entire contents of the primary receptacle(s).

Certified packaging systems are designed to withstand specific pressure changes and drop tests. Packaging systems that meet the packing instruction standards are currently available from vendors specializing in products certified to meet the IATA, USPS, and other carriers' requirements. Packaging systems using fiberboard or aluminum canisters, zip-lock bags, or other uncertified components may not be in compliance.

IT IS THE RESPONSIBILITY OF THE SHIPPER TO COMPLY WITH ALL LAWS AND REGULATIONS REGARDING THE SHIPPING OF INFECTIOUS SUBSTANCES.