

## 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 Laboratories Administration Central Facility. 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 Laboratories Administration and DHMH 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:

<b>DHMH, Laboratories Administration</b>	
<b>Office of Laboratory Emergency Preparedness and Response</b>	
<b>Monday – Friday 8:00 a.m. - 4:30 p.m.</b> (Dial in order)	<b>AFTER HOURS</b> (Dial in order)
<b>443-681-3787 - Office phone</b>	<b>410-925-3121 - Cell Phone</b>
<b>410-925-3121 - Cell Phone</b>	<b>410-408-7521 - Pager</b>
<b>443-681-3789 - Office phone</b>	
<b>410-408-7521 - Pager</b>	

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

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

### SHIPPING GUIDELINES

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

**This document (effective 04/15/2016) 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>.