

## Highly Hazardous and Suspect Biothreat Organisms

### Use

For the evaluation of clinical isolates and specimens to rule-out and, when possible, to confirm the identification of highly hazardous organisms that pose a threat to the safety and health of the public. This process is a critical component of public health preparedness and response to ensure potential threats are identified and addressed promptly and effectively.

### Clinical Significance

Isolates that cannot be ruled out as possible biothreat agents must be submitted to the OSDH PHL for further testing. Background information, fact sheets, statistics and educational resources for specific infections are available through the [Centers of Disease Control and Prevention \(CDC\)](#) and [OSDH Infectious Disease Services](#) websites.

### Methodology

Isolates are examined for purity, subcultured as appropriate, and analyzed using traditional microbiological and biochemical methods, as well as molecular (PCR) techniques, as indicated. Some or all testing may be performed at laboratories other than the OSDH PHL.

### Specimen Type

- Isolate (e.g., *Bacillus anthracis*, *Brucella* spp., *Burkholderia mallei/pseudomallei*, *Francisella tularensis*, *Yersinia pestis*):
  - Pure, viable isolate grown on media that supports the growth of the bacterial isolate submitted
- Clinical Specimen (e.g., *Clostridium botulinum*, Marburg, Ebola, Smallpox):
  - *Clostridium botulinum*: Refer to Botulism test description on the [Laboratory Testing – Highly Hazardous Organisms](#) web page.
  - Marburg virus: Two tubes of EDTA whole blood (plastic tubes), each containing a minimum of 4 mL of blood.
  - Ebola virus: Two tubes of EDTA whole blood (plastic tubes), each containing a minimum of 4 mL of blood (see CDC [Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States](#))
  - Smallpox:
    - Swab (Dacron or polyester) of lesion; dry, sterile – do not use viral transport media
    - Crusts from vesicles or pustules without transport media in sterile tube
    - Other specimens – see [Smallpox Specimen Collection](#) at CDC website.

### Minimum Volume/Size

- Isolate:
  - 1 media plate (preferred) or slant with visible growth. Tape plate shut and ensure the plate or slant is properly labeled.
- Clinical Specimen: (*type depends on suspect agent*)
  - Swabs: 1 (minimum) to 4 (preferred)
  - EDTA blood: 2 tubes
  - Lesion crusts: 1 or 4

### Collection Instructions

Primary specimens should be collected according to the submitting institution's standard procedure.

Sentinel laboratories are expected to follow American Society for Microbiology (ASM) rule-out protocols, including:

- [LRN Sentinel Level Clinical Laboratory Protocols \(asm.org\)](#)
- [CDC Specimen Storage and Shipping Guidance](#)

Submitters must notify the OSDH PHL BioThreat Team prior to specimen submission at (405) 406-3511.

- Isolate:
  - Specimen source and suspected organism information is required.
  - Must be accompanied by [Microbiology Supplemental Form](#).
- Clinical Specimen:
  - Physician consultation with an OSDH [Infectious Disease Prevention and Response \(IDPR\)](#) epidemiologist (available 24/7 at (405) 426-8710) is required prior to submission of specimens from patients with suspected botulism, Marburg, Ebola, or Smallpox infection to verify the patient meets clinical case criteria.

### Common Causes for Rejection

- No growth
- Mixed cultures
- Non-viable organisms
- Incorrect transport temperature
- Mismatch between patient identifiers on specimen label and test requisition form.

### Shipping and Storage

- Store and ship isolates at ambient temperatures (18-30°C) for delivery within 2 days of subculture.
- Store and ship blood refrigerated (2-8°C); do not freeze.
- Store and ship dry swabs and crusts of lesions frozen (preferred; -20°C or lower) or refrigerated (2-8°C).
- Place each specimen in an individually sealed bag.
- Submitters are responsible for packaging and shipping specimens according to regulatory requirements.
- Laboratory does not supply collection kits or shipping materials.

### Turn-around Time

Results are typically reported within 21 working days from receipt

### Reference Range

- Isolate:
  - Complete identification of clinically significant isolates
- Clinical Specimen:
  - Not Detected

### Reportable Results

- Isolate:
  - Bacterial isolate, identification/confirmation; genus/species identified
  - Isolate could not be identified to species level
  - Non-viable specimen
- Clinical Specimen:
  - BioThreat agent detected, identification/confirmation; genus/species identified
  - BioThreat agent not detected

**Note:** *Specimens exhibiting insufficient amplification of human DNA in molecular (PCR) assays indicate inadequate specimen collection and will be reported as inconclusive.*

**Interpretation**

A negative result indicates the absence of detectable target material in the specimen tested and does not exclude infection or disease. For a positive result, the organism identified reflects characterization of the submitted specimen to the genus and species level and does not, by itself, establish causation of disease. Results should be interpreted in the context of the patient's clinical presentation and other laboratory findings.

**Limitations/Interferences**

- Results may be affected by improper specimen collection or transport, inhibitory substances, or technical factors
- Cotton swabs and swabs in media designed for bacterial preservation or transport may inhibit PCR and should not be used

**CPT Codes**

CPT codes will vary depending on the organism identified and methods used.

**Notes**

These tests are intended as an aid for infection control of microorganisms in healthcare settings. These tests are not intended to guide or monitor treatment.