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TECHNICAL BULLETIN

DATE: January 27, 2025
TOPIC: Nevada State Public Health Laboratory Guidance for Tuberculosis and Bacillus Testing
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TO: Hospitals and Clinical Laboratories

Background

The purpose of this technical bulletin is to provide guidance on two Nevada State Public Health Laboratory (NSPHL) specimen/isolate submission updates: 1) *Mycobacterium tuberculosis* (MTB) rapid test utilizing the Cepheid GeneXpert MTB/RIF (rifampin resistance) assay for sputum and non-sputum samples; and 2) sentinel laboratory criteria for submission of isolates suspected of *Bacillus anthracis* and *Bacillus cereus* biovar *anthracis*.

CepheiD genexpert MTB/RIF asssay for rapid detection of Mycobacterium tuberculosis

The performance of the Xpert MTB/RIF assay was evaluated and FDA-approved using induced or expectorated sputum samples. Testing of non-sputum, clinical specimens has not been evaluated and may affect the test performance. Due to recent changes in FDA oversight of laboratory-developed tests, modifications have been made regarding what the NSPHL is authorized to develop and offer for off-label testing. For non-sputum and non-sputum concentrate specimens, the NSPHL will no longer offer MTB rapid testing using the Xpert MTB/RIF assay. However, Xpert MTB/RIF testing of sputum specimens remains a key rapid diagnostic test performed by the NSPHL.

The Centers for Disease Control and Prevention recommends the clinical best practice of collecting a sputum specimen from all adults with suspected pulmonary TB, regardless of bronchoscopy specimen.[†] A post-bronchoscopy sputum specimen is more ideal for acid fast bacillus smear, culture, and rapid Xpert or PCR analysis. Additionally, commercial reference laboratories are validated and available to perform direct-PCR testing for the detection of the MTB on clinical non-sputum specimens.

Sentinel clinical laboratory guidelines for sample submission of isolates suspected of bacillus anthracis and bacillus cereus biovar anthracis

Before submitting isolates suspected of *Bacillus anthracis* or *Bacillus cereus* biovar *anthracis* to the NSPHL for Laboratory Response Network for Biological Threats (LRN-B) testing, sentinel laboratories must combine morphological differentiation with the performance of several conventional tests.

These tests and the results that require further LRN-B testing are:

1. Gram Stain: Demonstrates spore-forming, large gram-positive bacilli.
2. Catalase Test: Positive result.
3. Hemolysis: Observation of no beta hemolysis after 24 hours of incubation.
   Note: Beta hemolysis rules out both B. anthracis and B. cereus biovar anthracis.

The NSPHL has changed the LRN-B final reports to indicate findings for both B. *anthracis* and B. *cereus* biovar *anthracis*.

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†Lewinsohn, D., Leonard, M., LoBue, P., et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. Clin Infect Dis 2017; 64: e1-e33.

Questions

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email StateLab@unr.edu or call (775) 682-6240 for other questions regarding tuberculosis and Bacillus testing.

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