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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Technical Bulletin

Date: **February 16, 2023**
Topic: **Tuberculosis GeneXpert MTB/Rif® Assay Detection of Rifampin Resistance: Immediate Specimen Submission to the Nevada State Public Health Laboratory**
Contact: **Susan McElhany, DMD, Division of Public and Behavioral Health, Tuberculosis (TB) Program**
To: **Health Care Providers, Health Care Facilities, Health Care Administration, Laboratories, Infection Prevention and Control Department, Local Health Authorities**

Background:

The best practice to evaluate a suspected case of tuberculosis (TB) is to order rapid molecular tests, nucleic acid amplification (NAA), or polymerase chain reaction (PCR-type), for the causative agent, *Mycobacterium tuberculosis* (MTB).[1] The Nevada Division of Public and Behavioral Health's (DPBH) recommendations for NAA test best practices and application to infection control can be found in the April 2022 Technical Bulletin *Rapid NAA Tests for MTB Detection: The Standard of Care*, and the companion slide presentation, *Effective Use of NAATs for Rapid MTB Detection*, available on the Nevada DPBH Tuberculosis website's Publications page.

The NAA test, the Cepheid Xpert MTB/Rif® assay, provides preliminary molecular detection of MTB rifampin (Rif) resistance. Rif resistance is suggestive of additional TB medication resistance, or multi-drug and extreme-drug resistance.[2] In addition to the use of the NAA rapid molecular test, culture-based resistance testing remains imperative to ensure that correct anti-TB therapy is initiated as rapidly as possible. Subsequent DNA sequencing of the suspected Rif-resistant specimen can both confirm and further inform treatment.

Purpose:

This technical bulletin provides instructions on submission requirements for specimens whereby the Cepheid Xpert MTB/Rif® assay has generated the result "***MTB detected with Rifampin resistance detected"***. To contain and eliminate multi-drug resistant TB, the Centers for Disease Control and Prevention (CDC) requires that public health TB programs confirm Rif resistance by submitting the MTB isolates suspected of Rif resistance to the CDC's Molecular Detection of Drug Resistance Laboratory for DNA sequencing. To this end, the Nevada State Public Health Laboratory (NSPHL) performs confirmation of such specimens via subsequent culture, identification and culture-based drug-susceptibility testing. The NSPHL also submits the isolate to the CDC. The following information instructs health care facilities and laboratories on the appropriate notification and submission of the specimen when the Cepheid Xpert MTB/Rif® result is **MTB detected with Rifampin resistance is detected**.

Submission of Specimen with a Cepheid Xpert MTB/Rif® assay *Rifampin Resistance Detected* Result

When MTB is detected and the result for Rif resistance is *detected*, the health care facility must notify the local health authority per Nevada Administrative Code 441A for the reporting of communicable diseases. Moreover, the health care facility's laboratory should immediately send the specimen that yielded the result to the NSPHL.

For additional information and/or clarification on specimen submission, contact the NSPHL TB Laboratory directly at (775) 682-6218.

Items to be included for NSPHL MTB/Rif detected specimen submission:

- The original **specimen** that resulted **MTB detected and Rif resistance detected**, along with the details of specimen collection and processing, such as raw sputum or concentrated sputum sediment.
- The accompanying **Cepheid Xpert MTB/Rif® Instrument Analysis report** containing the *cycle threshold or Ct values.*
- The direct **acid-fast bacillus (AFB) smear result** for the specimen.

References:

1. Association of Public Health Laboratories. Laboratory considerations for use of Cepheid Xpert MTB/RIF Assay. 2013. Available at: http://www.aphl.org/AboutAPHL/publications/Documents/ID_2013Nov_Cepheid-Xpert-Fact-Sheet.pdf
2. Dagnra AY, Mlaga KD, Adjoh K, Kadanga E, Disse K, Adekambi T. Prevalence of multidrug-resistant tuberculosis cases among HIV-positive and HIV-negative patients eligible for retreatment regimen in Togo using GeneXpert MTB/RIF. New Microbes New Infect. 2015 Sep 10;8:24-27. doi: 10.1016/j.nmni.2015.09.001. PMID: 28626586; PMCID: PMC5460073.

Resources:

Nevada Administrative Codes related to TB Testing, NAC 441A.370-380:
https://www.leg.state.nv.us/NAC/NAC-441A.html#NAC441A
Centers for Disease Control and Prevention TB website: https://www.cdc.gov/tb/default.htm
Nevada Division of Public and Behavioral Health: http://dpbh.nv.gov/

Questions:

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email Susan McElhany, DMD, DPBH TB Program, at smcelhany@health.nv.gov for other questions regarding NAAT use in tuberculosis.

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