



GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

GUAM PUBLIC HEALTH LABORATORY GUIDELINES
SPECIMEN REQUIREMENTS FOR MTB-RIF ASSAY
IN SPUTUM SAMPLES

<p>Methodology:</p>	<p>Cepheid GeneXpert Dx System MTB-Rif Assay</p> <p>Qualitative in vitro diagnostic test for rapid detection of <i>Mycobacterium tuberculosis</i> (MTB) and the resistance of MTB to Rifampicin.</p>
<p>Performed at Guam Public Health Lab:</p> <p>Criteria for testing:</p>	<p>Xpert MTB-Rif Real-Time RT-PCR Assay is an FDA approved assay:</p> <ul style="list-style-type: none"> • For the detection of the gene sequences of <i>Mycobacterium tuberculosis</i> and rpoB gene mutations associated with Rifampicin resistance. • Intended as an aid in the diagnosis of active PTB and enables physicians to make critical patient management decisions regarding therapy during the same medical encounter. • Following the diagnostic workup guidelines and algorithms recommended by the Centers for Disease Control and Prevention (CDC). <p>Testing of clinical sputum specimens with the Xpert MTB-Rif Real-Time RT-PCR Assay should not be performed unless the patient meets clinical signs and symptoms compatible with pulmonary tuberculosis infection (PTB) and/or specimens meet proper induction and expectoration of fresh sputum.</p> <p>Testing of clinical sputum specimens with the Xpert MTB-Rif Real-Time RT-PCR Assay will not be performed for follow-up examinations. Only sputum specimens collected for the Diagnostic Examination will be accepted for testing.</p> <p>Required Fresh Sputum Specimen Volume:</p> <ul style="list-style-type: none"> • Minimum Volume for One (1) Test only = 1 ml • Minimum Volume for One (1) Test and Re-test = 2 ml <p>Note: Guam Public Health Laboratory (GPHL) testing for MTB-Rif Assay is performed daily from 8:00AM–12:00PM except on Government of Guam Holidays. Specimens received after 12:00PM will be processed and tested the next business day.</p>

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<p>For private clinics and providers:</p>	<p>Specimen Submission Guidelines</p> <ol style="list-style-type: none"> 1. Submit minimum of 1ml fresh sputum specimen collected in sterile 50 ml conical tube. Submit each conical tube with one (1) Cepheid Xpert MTB-Rif cartridge. 2. Fill out required form(s) <u>COMPLETELY</u>: Patient Information, Physician Information, General Treatment Information, and Specimen Collection Details. Complete one (1) form for each specimen submitted. Send forms with the specimen. 3. Refrigerate sputum specimen and MTB-Rif cartridge at 4°C or maintain on ice for no longer than 24 hours. If transport will exceed 24 hours, specimens and cartridges can be stored for seven (7) days at 4°C. 4. Send sputum specimens and MTB-Rif cartridges to GPHL business days Mondays-Fridays 8AM-4:30PM. Specimens received after 12PM will be processed and tested the next business day. <p>Limitations of Procedure</p> <ol style="list-style-type: none"> 1. Patients on lidocaine, mucin, ethambutol, guaifenesin, phenylephrine or tea tree oil may produce false negative results. 2. Presence of <i>Mycobacterium scrofulaceum</i> in the specimen may produce false positive results. 3. Healthcare professionals should interpret assay results in conjunction with the patient’s medical history, clinical signs and symptoms, and the results of other diagnostic tests.
<p>Specimen Required:</p>	<p>The laboratory requires a fresh sputum sample that is induced and expectorated by patients suspected of having pulmonary tuberculosis infection (PTB).</p>
<p>Specimen Collection:</p>	<ul style="list-style-type: none"> • Provide patients/clients with Sputum Collection Instructions (Appendix A) • Ensure patients/clients follow recommendations for fresh sputum specimen collection when they wake up in the morning.
<p>Specimen Transport, Storage and Stability</p>	<p>Store and transport sputum specimens and MTB-Rif cartridges on ice at 4°C. Stable for seven (7) days at 4°C. For USAPI Laboratories, follow the PIHOA Shipping Mechanism Guidelines.</p>
<p>Specimen Submission</p>	<ul style="list-style-type: none"> • Ensure that when transporting human sputum specimens and MTB-Rif cartridges, all applicable regulations for transport of potentially infectious biological specimens are met. • Transport/ship human sputum samples and MTB-Rif cartridges on ice.

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<p>(Cont.) Specimen Submission</p>	<ul style="list-style-type: none"> • When applicable, follow instructions for Class B – Biological Substance of the U.S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA) for packing and shipping. • Call the GPHL (671) 300-9083 to inform staff of the specimen delivery. <p>NOTE: It is the responsibility of the submitter to track the arrival of the specimens and the cartridges along with the MTB-Rif request form at GPHL to ensure that these specimens and cartridges are received by the laboratory staff.</p>
<p>Rejection Criteria</p>	<ul style="list-style-type: none"> • Specimen is not induced and expectorated fresh sputum; • Specimen with obvious food particles and other solid particles; • Specimen quantity is insufficient to perform the test (less than 1 ml volume); • Specimen is not collected in a proper container or special handling instruction is not followed; • Specimen received in a container that is leaking; • Specimen and MTB-Rif cartridge are not received at 4°C or packed in ice pack; • Specimen received without MTB-Rif cartridge; • Specimen received without laboratory request/submission form; • Unlabeled specimens; • Illegible/ incomplete information and labeling/documentation.
<p>Submission Form</p>	<p>Specimen Laboratory Request/Submission Form</p> <ul style="list-style-type: none"> • Each specimen submitted must have a completed Guam Public Health Laboratory Request/Submission Form for TB Smear Microscopy and Xpert MTB/RIF (Appendix B), with the patient name, patient medical record number, physician name, date/time of collection, date sent to GPHL, test(s) requested and other pertinent information. • Submission forms that are not consistent with the specimen submitted will be rejected and requesting facility will be asked to re-submit. • Submission forms must not be in direct contact with the specimen(s). • Fill out required form(s) <u>COMPLETELY</u>. <p>>Incomplete forms will be rejected.</p>
<p>Result Notification:</p>	<p>Laboratory reports will be forwarded by GPHL, to the submitting facility and the BCDC Administrator via Facsimile.</p> <p>Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted.</p>
<p>Contact:</p>	<p>Lea Nisay, Microbiologist II, GPHL (671) 300-9083 (671) 300-9098 FAX lea.nisay@dphss.guam.gov</p>

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Reference:

1. Cepheid GeneXpert Dx System Real Time RT-PCR Assay Operator Manual, 300-7607. Rev. C, Installed May 2011.
2. MTB/RIF Assay: Xpert MTB-RIF ENGLISH Package Insert 301-1404 Rev. B February 2015.
3. Guam Public Health Laboratory Cepheid Xpert, Mycobacteriology Procedure Manual, Revised July 2014.