Newfoundland & Labrador

PROVINCIAL PUBLIC HEALTH LABORATORY NETWORK

Dr. LA Miller Centre, 100 Forest Road, St. John's, NL A1A 3Z9 (709) 777-6583 www.publichealthlab.ca

FROM: NEWFOUNDLAND PROVINICAL PUBLIC HEALTH and MICROBIOLOGY LABORATORY

TO: All Physicians, Nurse Practitioners, Pharmacists and Healthcare staff across the Province

RE: NEW METHOD FOR RAPID MOLECULAR DETECTION OF *MTB/MYCOBACTERIA SPP*. DNA

Dear Colleagues,

This is to inform you that on November 18, 2019, PHML will be introducing a new and more sensitive **multiplexed Real-time PCR assay for detection of *Mycobacterium tuberculosis/Mycobacteria spp.* DNA in primary non-fixed clinical specimens.**

Key aspects of the assay and workflow changes are highlighted below:

A. **Higher sensitivity for MTB complex detection** than prior method due to the use of a multi-copy target IS6110 gene (Limit of Detection (LOD) ~5 CFU/ml).

B. An additional target for **pan detection of *Mycobacteria spp*.** is included in the multiplexed assay (LOD ~ 100 CFU/ml).

C. All non-fixed clinical specimens from patients submitted to PHML for MTB/*Mycobacteria* testing will be rapidly screened by the multiplexed PCR assay (including specimens that are microscopically acid-fast smear staining negative). Screening multiple respiratory specimens is expected to increase the sensitivity of rapid molecular diagnosis of respiratory tuberculosis.

D. Every effort will be made to complete the testing within **~48 hours** after receipt of specimens.

Notes:

a. There are no changes to specimen submission or test ordering. **This supplemental assay is to be used in conjunction with culture which remains the gold standard for *MTB complex/Mycobacteria spp.* detection (with highest sensitivity for detection)**. Antibiotic susceptibility will continue to be performed on clinical isolates when applicable.

b. A positive result by the molecular assay does not differentiate between live and dead organisms. For this reason, molecular detection should NOT be used on specimens collected from patients who have received antimicrobials for more than 7 days or have received such therapy in the last 12 months prior to collection**. The use of this assay is NOT recommended for monitoring treatment responses.**

We anticipate the introduction of this assay to facilitate rapid initial diagnosis promoting more rapid and efficient infection control and therapeutic interventions leading to better patient outcomes.

Further information can be found at http://publichealthlab.ca. Please direct your questions/concerns to the Office of the Director, PHML at 709-777-7233.

Eastern Health Western Health Central Health Labrador-Grenfell Health