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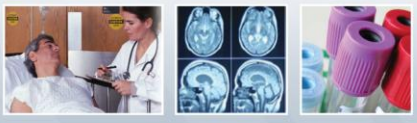
Physician Alert



Clinical Practice Change: Clinical Microbiology

Date: December 23, 2013

To: All physicians who submit sputum samples to Westman Laboratory

From: Dr. Michelle Alfa, Medical Director and Shirley Hoban, Technical Director, Clinical Microbiology, DSM

Re: **Rapid PCR Testing for *Mycobacterium tuberculosis* in Sputum Specimens**

Take Home Message:
Effective January 2, 2014
ALL sputum specimens sent to Westman Microbiology laboratory requesting AFB culture on patients NOT previously known to have TB will automatically get PCR testing for *M. tuberculosis*.

NEW TEST: TB PCR
Recently, the Clinical Microbiology Discipline, Diagnostic Services of Manitoba has validated a PCR test that can reliably determine if *M. tuberculosis* is present in sputum specimens. An onsite evaluation showed that the overall sensitivity and specificity for unconcentrated sputum samples was 87.5% and 100%, respectively. For AFB smear positive sputum the sensitivity and specificity were both 100%. For AFB smear negative sputum samples, the sensitivity and specificity were 66.7% and 100%, respectively. These results are similar to those from larger studies[1]. As part of our DSM Provincial TB program initiative, direct TB PCR test will automatically be performed on **one sputum** from any new patient whose sputum sample is submitted to WL.

In 2012, approximately 30% of all new TB patients were AFB smear positive and on average it took 10.3 days for *M. tuberculosis* to grow (range of 4 to 21 days). For new TB patients who were AFB smear negative, it took an average of 21.9 days for the culture to grow (range: 8 to 38 days). The TB PCR test will allow practitioners to know more quickly if the patient has respiratory TB. This TB PCR test is ***in addition to AFB smear and culture*** as we still need to grow the *M. tuberculosis* strain in order to do susceptibility testing and MIRU typing.

This TB PCR test is to be used for diagnosis of new patients and is not to be used to follow treatment response in patients on TB therapy.

Test Availability: This testing will be performed for one sputum sample for each new patient within 24 hours of receipt seven days a week.

Airborne Precautions:
Because the overall sensitivity is 87.5% and for smear negative sputum is 66.7%, we recommend that Airborne Precautions be maintained for any new, admitted patient in whom there is a strong clinical suspicion of TB but who tests negative by the TB PCR test. Decisions regarding the need for Airborne Precautions for any patient should always be made in consultation with Infection Prevention and Control.

Reporting of TB PCR results
The following comments will be used to report the results of the TB PCR test:

1. **Positive result:**
   "Positive for: Mycobacterium tuberculosis complex DNA by Real-time PCR"

   "Test performed using a commercial Health Canada- cleared assay. In-house validation demonstrated a sensitivity of 87.50% and specificity of 100%. Always correlate TB PCR results with the patient's clinical picture. Consult Infection Prevention and Control for airborne precautions for admitted patients."

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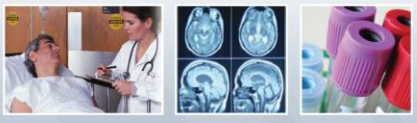

2. **Negative result:**
   "Negative for: Mycobacterium tuberculosis complex DNA by Real-time PCR"

   "Test performed using a commercial Health Canada -cleared assay. In-house validation demonstrated a sensitivity of 87.5% and specificity of 100%. Always correlate TB PCR results with the patient's clinical picture. Consult Infection Prevention and Control for airborne precautions for admitted patients. The TB PCR tests may be negative in 12.5% of patients with TB, please refer to AFB culture results."

3. **Invalid result:**
   "Invalid: Real-time PCR for Mycobacterium tuberculosis complex DNA not reported due to presence of PCR inhibitors in sample. Refer to AFB culture results."

If you have any questions or require further information, please contact Dr. Michelle Alfa or Shirley Hoban at 237-2484.

References:

1. Lawn S.D. et al Advances in tuberculosis diagnostics: the Xpert MTB/RIF assay and future prospects for a pointe-of-care test. Lancet Infect. Dis 2013;13:349-61.

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