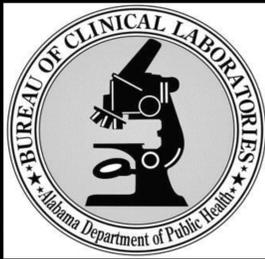




Testing Algorithms for *Mycobacterium tuberculosis complex* using Real Time-Polymerase Chain Reaction:



When to implement the PCR?

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Introduction

Traditionally, *Mycobacterium tuberculosis complex* (MTB-complex) is identified by conventional staining and culturing methods. However, molecular procedures are currently being used more often as is the case at the Bureau of Clinical Laboratories (BCL) where the Cepheid GeneXpert® MTB/RIF assay is utilized. The previous algorithm for new acid fast bacilli (AFB) smear positive patients specimens received at the BCL included running them on the GeneXpert® only. The Xpert® MTB/RIF assay, performed on the GeneXpert® Instrument Systems, is a qualitative, nested real-time polymerase chain reaction (PCR) *in vitro* diagnostic test for the detection of MTB-complex DNA in raw sputum or concentrated sputum sediment. In specimens where MTB-complex is detected, the Xpert MTB/RIF assay also detects the rifampin-resistance associated mutations of the *rpoB* gene. To increase the number of TB cases rapidly identified in Alabama, a new algorithm was developed using this assay.

Revised GeneXpert MTB/RIF Assay

A revised process for the GeneXpert MTB/RIF assay was used to test 551 respiratory specimens between January, 2015 and October, 2016 at the BCL. Prior to this modification, the standard algorithm for use of the GeneXpert assay was based on a respiratory specimen that was smear positive for AFB on a new patient. The revised algorithm is based on an AFB smear negative result along with a physician's request to test for TB based on clinical presentation of the patient.

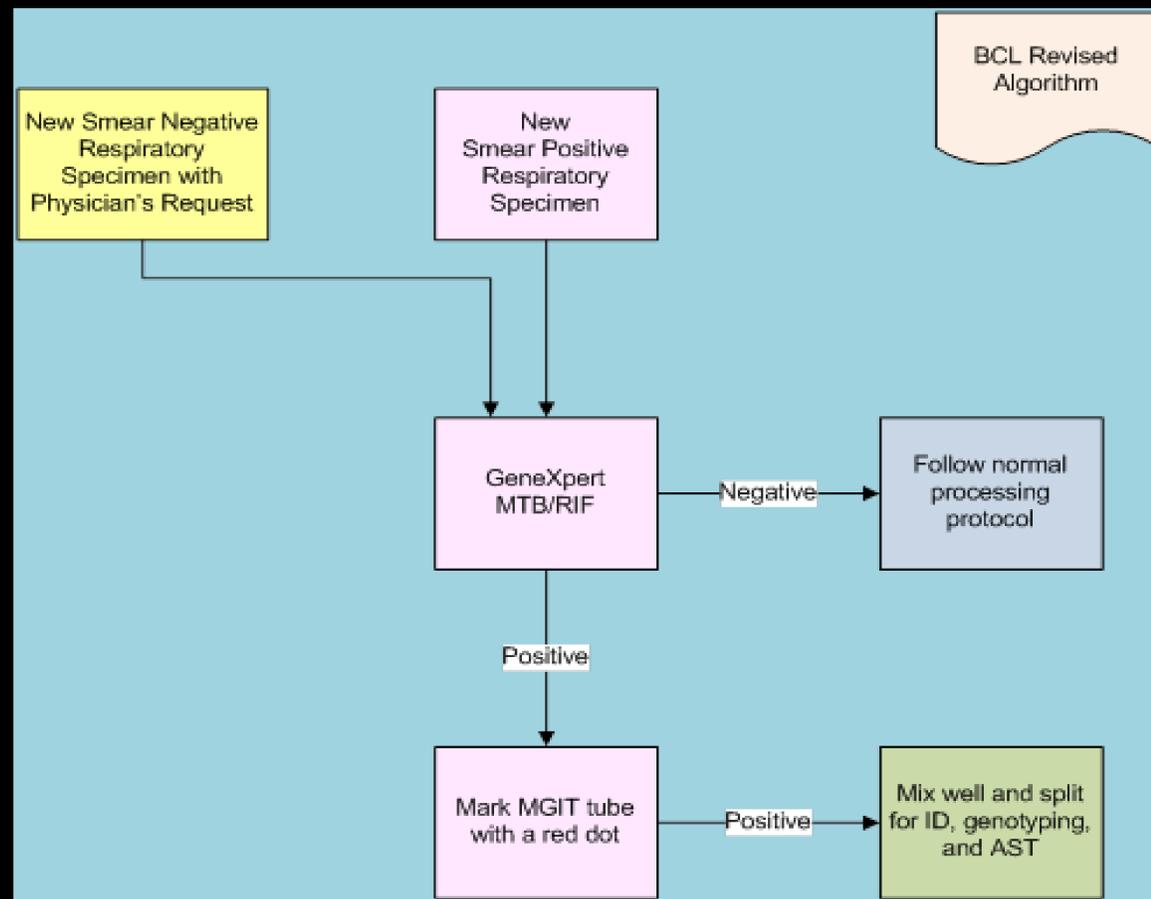
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BCL Revised Algorithm (in Yellow)



Benefits for Revised Algorithm

- The revised algorithm decreases the turnaround time for the susceptibility testing.
 - All positive new patients identified by GeneXpert receive an Avery® red dot taped to the MGIT tube. When the tube becomes positive in the Bactec 960, it is well mixed and split.
 - One portion is for identification and genotyping, and the other portion is for the Automatic Susceptibility Test (AST) using the Bactec 960.
- The special requests from the physicians have the added benefit of decreasing turnaround time for the susceptibility of these smear negative cultures.
 - Smear negative and GeneXpert positive cultures formerly were outliers and not detected until the culture growth was observed.

Results & Conclusion

Of the 551 specimens tested, 108 were positive by GeneXpert yielding a positivity rate of nearly 20%. The use of the revised algorithm where the negative AFB smear result was received with the physician's request for testing based on clinical presentation yielded an additional 10 positives.

These 10 positive tests would not have been recognized using the original algorithm until final culture results were determined several weeks later. Utilizing the negative AFB smear result with the physicians' requests boosted the rate of positive GeneXpert samples.

Cepheid GeneXpert



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