Implementation of GeneXpert MTB/RIF Testing in Non-Sputum Sources

Tennessee Experience
Outline of Presentation

• Why did we take on this project?
• How did we plan for this project?
• Difficulties obtaining specimens
• Results
• What impact has this problem had?
• CLIA approval
WHY DID WE TAKE ON THIS PROJECT?
Reasons for Project Initiation

- Lab was receiving requests from the Tennessee TB Elimination Program to perform GeneXpert testing on non-sputum sources for rapid detection
- Next logical step…why not try?
Sites of Disease of TB Cases, Tennessee 2009-2016

- Pulmonary: 68.7%
- Extra Pulmonary: 19.4%
- Both: 11.9%
HOW DID WE PLAN FOR THIS PROJECT?
Specimen Collection

• Specimens eligible for testing were received from July 2014 – September 2015

• Specimen sources included:
  • Bronchial washing
  • Lymph nodes (tissue)
  • Urine
  • Stool
  • Blood
  • CSF
  • Bone Marrow
  • Endotracheal aspirate
  • Throat aspirate
  • Bladder tissue
Specimen Processing

- Specimens underwent decontamination (if necessary)
- AFB smear and cultures were set up
  - If AFB smear positive—GX set up
  - If AFB smear negative but culture positive—GX set up
- No results were actually reported to providers
Testing Workflow

- **Decontamination (if necessary)**
- **Set up AFB smear and culture**
  - **Smear-positive**: Set up GeneXpert
  - **Smear-negative**: **Culture-negative**: No additional testing
  - **Culture-positive**: **Culture-negative**:
DIFFICULTIES OBTAINING SPECIMENS
Difficulties Obtaining Specimens

• Most non-sputum specimens are not collected at public health departments
• Area hospitals that perform AFB testing were not exactly willing to submit specimens knowing that a result would not be provided
Difficulties Obtaining Specimens

Tennessee TB Elimination Program’s role

• Assisted with outreach to area hospitals
  – Most hospitals that perform AFB testing do not hold specimens beyond 24 hrs.
  – Specimens are sent to out of state reference laboratories
RESULTS
Number of Specimens Received

- A total of 25 specimens were tested between July 2014 and September 2015
  - 14 months time period
Non-Sputum Sources (N=25)

- CSF: 24.0%
- Aspirate: 12.0%
- Tissue: 8.0%
- Bone Marrow: 8.0%
- Urine: 8.0%
- Stool: 8.0%
- Blood: 8.0%
- Bronch wash: 4.0%
- Pleural fluid: 4.0%
GX Results from Validation

% of Total Results

Specimen Source

CSF
Urine
Bronch wash
Aspirate
Tissue
Stool
Blood
Bone marrow
Pleural fluid

- Other
- Smear+/Culture-/GX-
- Smear+/Culture+/GX+
- Smear-/Culture-/GX-
WHAT IMPACT HAS THIS PROJECT HAD?
Public Health Impact

- In 2016, the Tennessee Department of Health, Division of Laboratory Services ran GeneXpert tests on eight (8) non-sputum samples
  - 5 (62.5%) were AFB smear-negative
    - 2 (40.0%) were GX-positive
    - 3 (60.0%) were GX-negative
  - 2 (25.0%) were AFB smear-positive
    - 2 (100%) were GX-positive
  - 1 (12.5%) did not have a smear done
    - GX was negative
Reporting

Comments:
This test has been approved by U.S. Food and Drug Administration for analysis of sputum specimens. Performance characteristics from specimen types other than sputum have been determined by TDH Laboratories Services.
Source: Fine needle aspirate

MTB DNA Results: Detected. This is a preliminary NAAT result; refer to culture result for final determination.
rpoB mutation Results: Not Detected. This is a preliminary result denoting the lack of detection of the gene mutation associated with Rifampin resistance; refer to DST result for final determination.
CLIA APPROVAL
Approval Process

November 6, 2015: Validation testing signed by lab director

December 6, 2015: CLIA Inspection
Only had two questions:
1. Why did we test such a low number?
2. Why did the process take so long?
The CLIA Inspection

Only had one answer:

That is all we could get, from January - June 2016 we had not received a single smear or culture positive non-sputum specimen
Implementation of GX testing on non-sputum sources allows for a rapid result regarding the presence of M. tuberculosis complex in a specimen thus allowing for timely intervention to treat TB and prevent the spread to others.
Acknowledgements

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