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# 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?



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# Reasons for Project Initiation

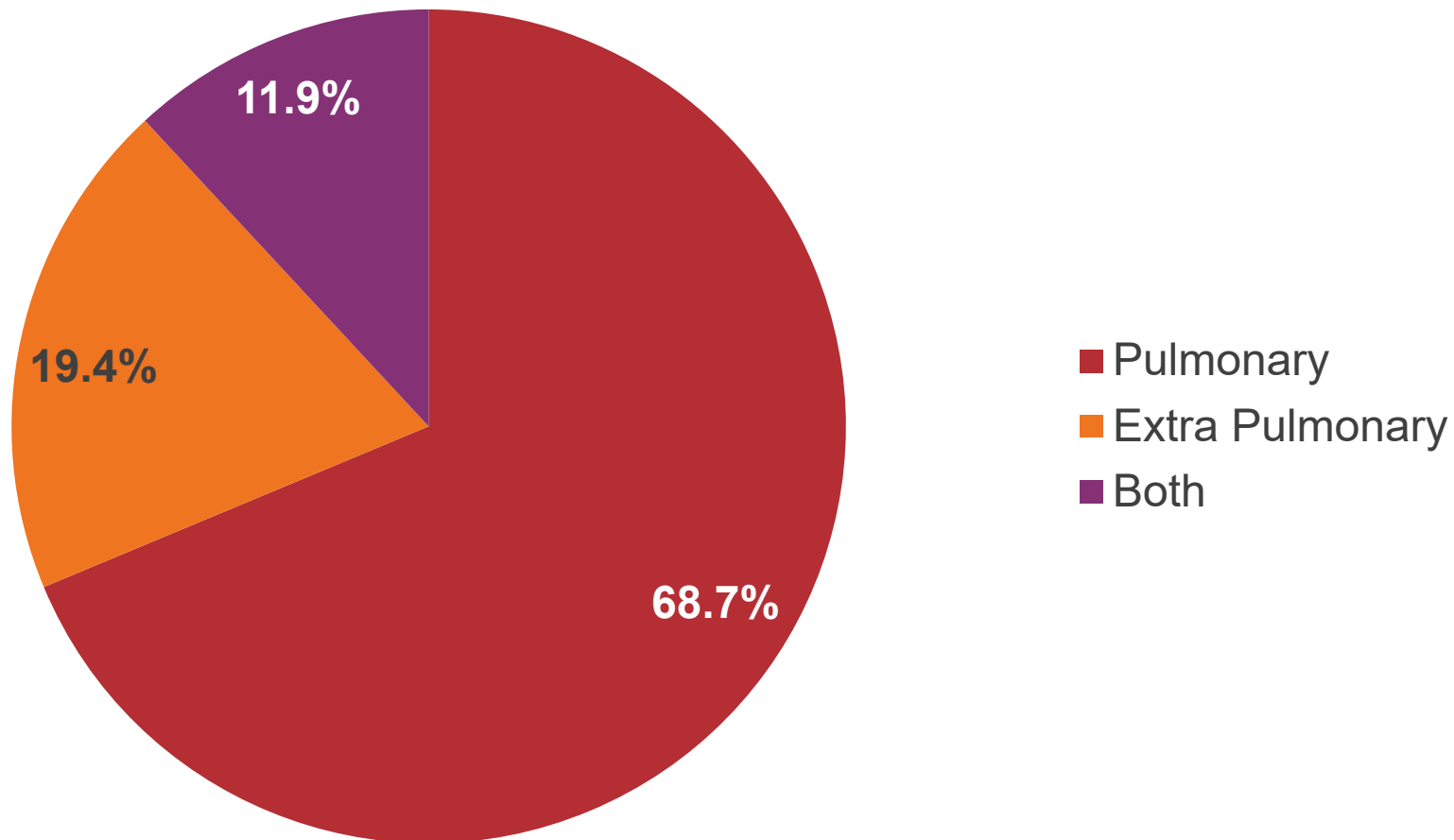
- Lab was receiving requests from the Tennessee TB Elimination Program to perform GeneXpert testing on non-sputum sources for rapid detection
- Next logical step...why not try?



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## Sites of Disease of TB Cases, Tennessee 2009-2016



# HOW DID WE PLAN FOR THIS PROJECT?



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# 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



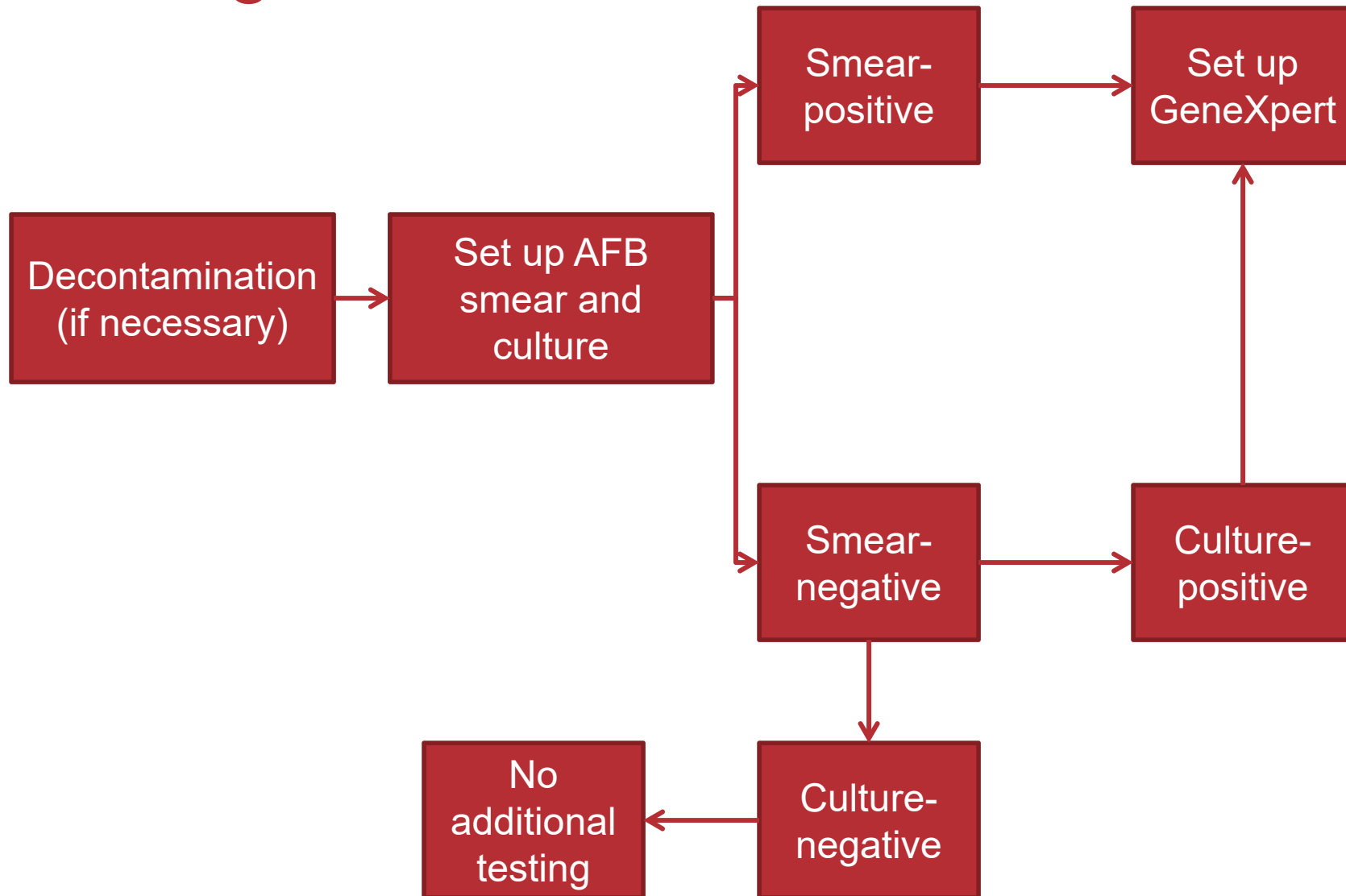
# Specimen Processing

- 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



# DIFFICULTIES OBTAINING SPECIMENS



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# 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



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# RESULTS



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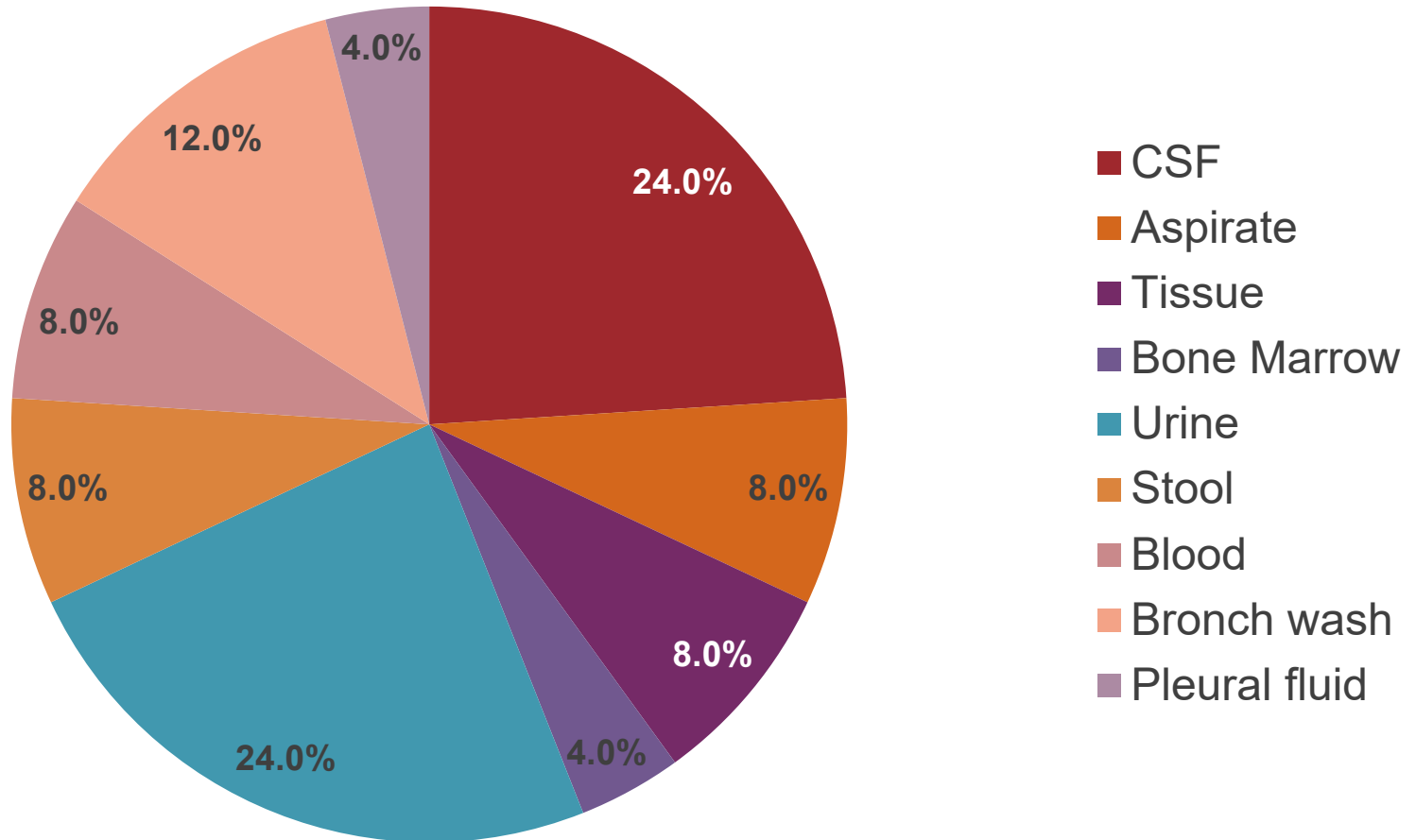
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# Number of Specimens Received

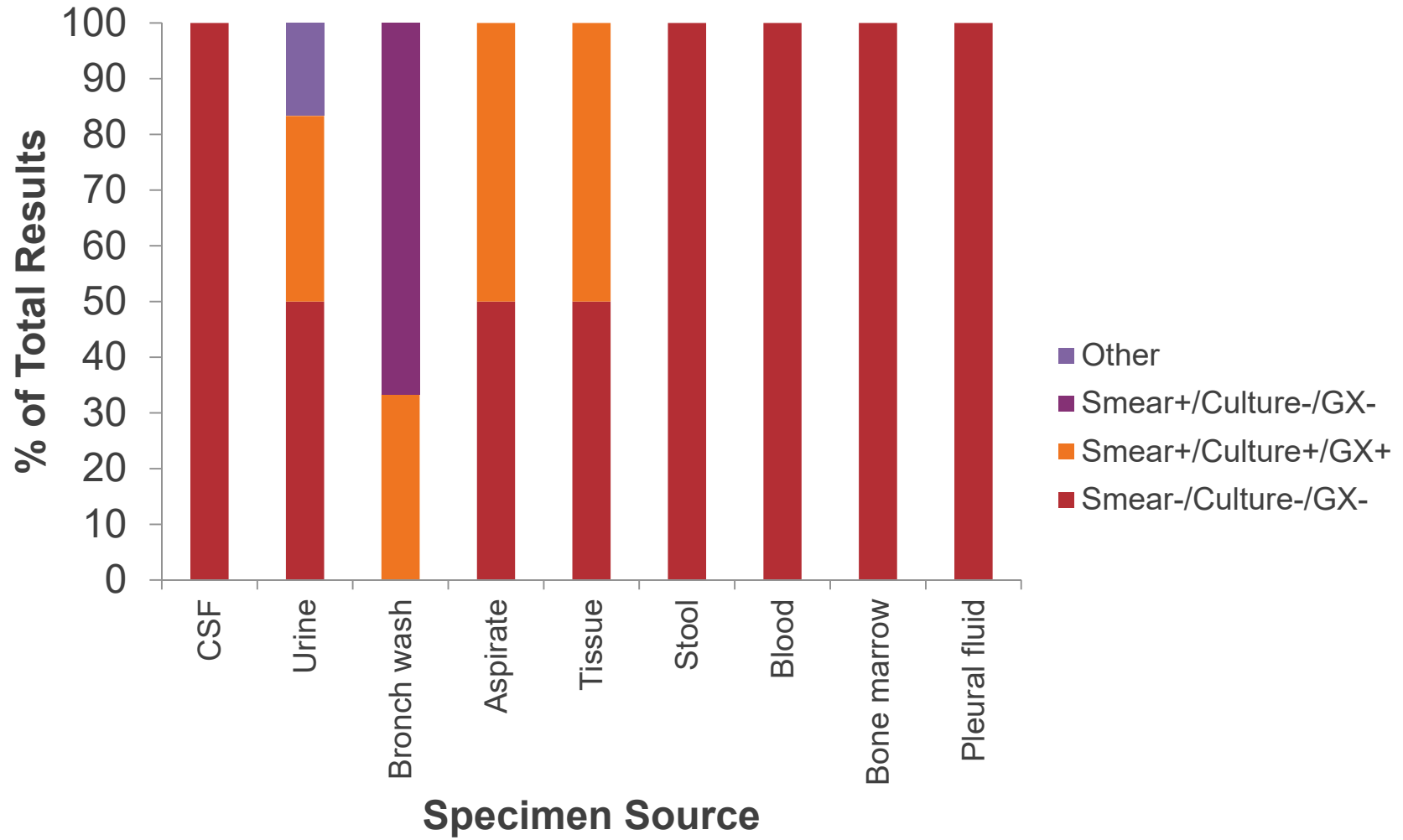
- A total of 25 specimens were tested between July 2014 and September 2015
  - 14 months time period



## Non-Sputum Sources (N=25)



## GX Results from Validation





# WHAT IMPACT HAS THIS PROJECT HAD?



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# 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.



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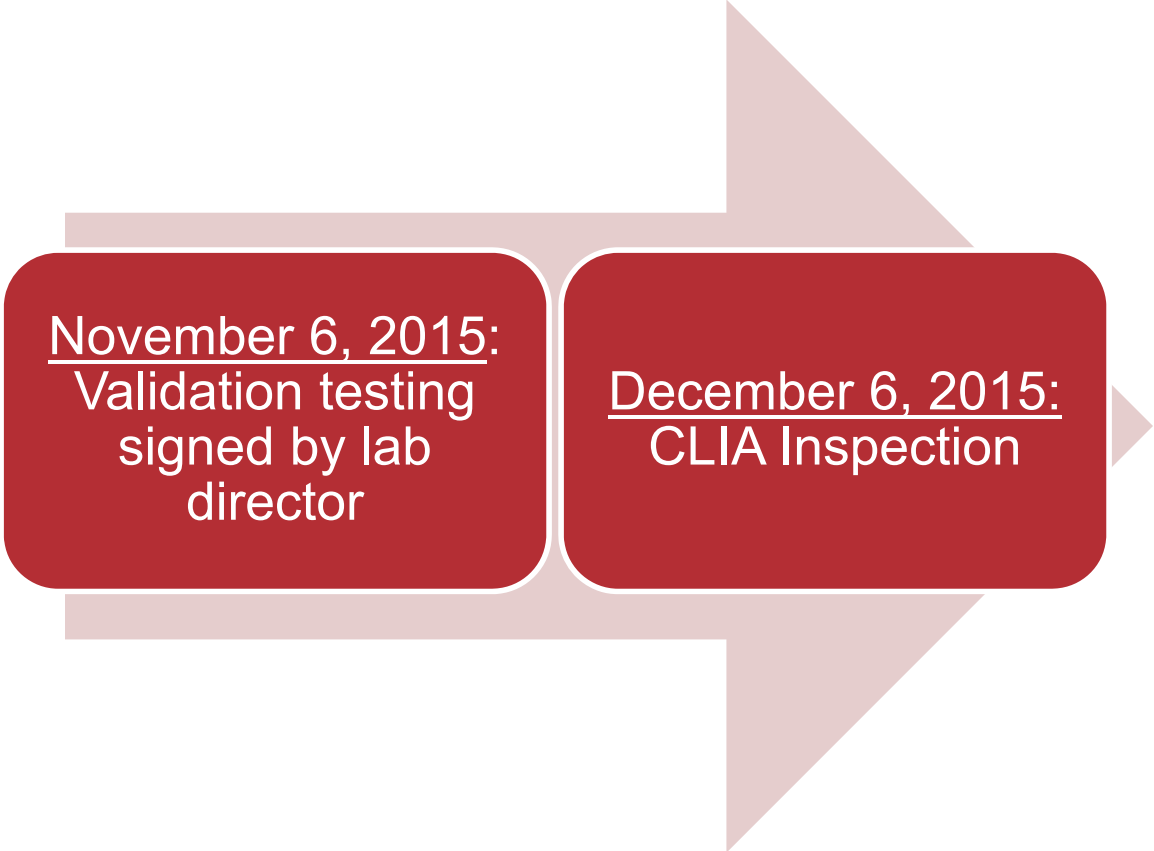
# CLIA APPROVAL



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# Approval Process



November 6, 2015:  
Validation testing  
signed by lab  
director

December 6, 2015:  
CLIA Inspection

# The 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

- Tennessee Department of Health, Division of Laboratory Services Staff
- Tennessee TB Elimination Program



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