



Diagnostic Accuracy of Single versus Multiple Gene Xpert for discontinuation of Airborne Infection Isolation in Suspected Pulmonary Tuberculosis Patients at a US Safety-Net Hospital

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EXCEPTIONAL CARE. WITHOUT EXCEPTION.

INTRODUCTION

- Patients suspected to have pulmonary tuberculosis (PTB) undergo serial sputum analysis under airborne infection isolation (AII).
- The US FDA approved the Cepheid GeneXpert-MTB-Rif® to support removing patients from AII.
- The FDA requires that “either one or two” separate sputum specimens be examined.
- To clarify this statement, the National Tuberculosis Controllers’ Association and the Association of Public Health Laboratories published guidelines that recommend that two sputum specimens be used and recommend that each institution examine their own data to determine if one specimen is sufficient. (1)
- Most patients in low prevalence settings do not have PTB yet are tested several times; an optimal testing strategy will reduce unnecessary isolation and related expenses.

OBJECTIVES

- To determine the diagnostic accuracy of a single versus two sputum samples for Xpert MTB/RIF in discharging suspected PTB patients from AII.

METHODS

Setting: Inpatient services, Boston Medical Center

Subjects: Retrospective review of patients admitted between September 2016 to January 2018 was undertaken.

METHODS

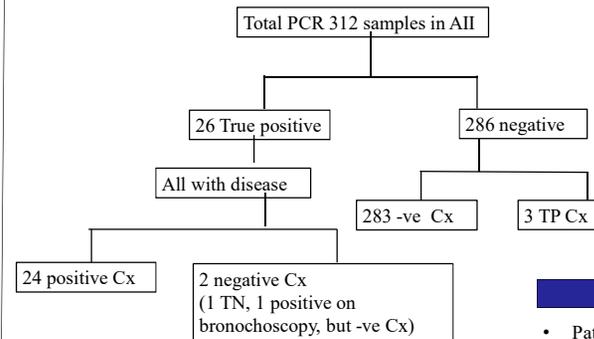
Statistical analysis:

- Sensitivity, specificity, positive and negative predictive values, for MTB gene Xpert in comparison to *Mycobacterial* culture as the gold standard.
- The sensitivity and specificity obtained were very close to 100%. Consequently, we did not use the usual methods for the calculation of the 95% confidence intervals for these.
- Due to these issues, and particularly because the numbers were small, we computed the exact confidence intervals for the sensitivities and specificities based on binomial probabilities using an online computer program. (2)

RESULTS

- 171 patients were reviewed, 17.5% of whom were HIV+, mostly of non-US origins (64%)
- 312 samples for Xpert MTB/RIF, of which 26 were Xpert-positive were obtained.
- These 26 samples came from 15 patients, 14 of whom were diagnosed using the first sample tested with Xpert MTB/RIF.
- Sensitivity and specificity of the first sample tested with Xpert MTB/RIF was more than those for the first two samples considered together or for all tested samples.
- Of these 15 positive cases, 13 were confirmed on sputum culture; 10 were positive from the first, one from the second, and two from the third sputum samples cultured.

FIGURES



Flowchart: Samples collected (TP: True Positive, Cx: Culture, -ve: negative)

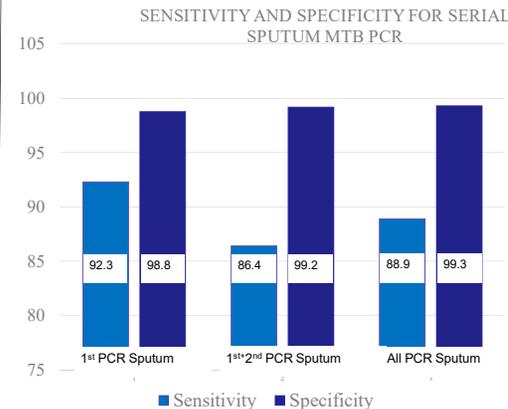


Table: Positive and Negative predictive values for serial PCR samples

Test details	PPV	NPV
1 st Sample PCR	85.7%	99.4%
1 st + 2 nd Sample PCR	90.5%	98.8%
All Samples PCR	92.3%	98.9%

CONCLUSIONS

- Patients suspected to have PTB at our facility can be rapidly and accurately discharged from AII after testing a single sputum sample for MTB/RIF Xpert.
- This may significantly reduce rates of overutilization of healthcare resources, and may be cost-effective

REFERENCES/CONTACT

1. Genexpert. Consensus statement on the use of Cepheid Xpert MTB/RIF® assay in making decisions to discontinue airborne infection isolation in healthcare settings. 2016. Available from http://www.tbcontrollers.org/docs/resources/NTCA_APHL_GeneXpert_Consensus_Statement_Final.pdf
2. Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*. 1934;26:404-413 <http://statpages.info/confint.html>

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