



Rapid, Comprehensive TB Diagnosis and Resistance Profiling with Deeplex® Myc-TB: A Clinically Actionable NGS Approach



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BACKGROUND

- Timely diagnosis of *Mycobacterium tuberculosis* complex (MTBC) and its drug resistance profile is essential for initiating effective therapy, especially in the context of rising multidrug-resistant TB (MDR-TB) and the availability of new drugs and drug regimens.
- The GenoScreen Deeplex® Myc-TB assay is a rapid, WHO pre-qualified, targeted next-generation sequencing (tNGS) solution that provides:
 - High-resolution detection of MTBC
 - Prediction of drug resistance (detection of mutations associated with resistance to 15 anti-TB drugs)
 - Phylogenetic lineage
- The Florida State Public Health Laboratory clinically validated and implemented the Deeplex assay in January 2024. In August 2025, Clear Labs , Inc. launched the Clear Dx™ Deeplex® Myc-TB assay in collaboration with GenoScreen which automates the workflow. A comparison of the manual versus automated methods was performed.

IMPLEMENTATION CONSIDERATIONS

- Technical expertise required for manual vs automated run
- Number of samples per run – batch testing for optimal cost saving (13 samples per run)
- Data analysis and reporting (LIMS configuration, mutations of unknown significance)
- Value for adding test – incidence of TB and DR-TB in your jurisdiction
- Validating/reporting NTM identification
- Instrumentation required for manual vs automated run and preventive maintenance costs

Cost and TAT Components	Manual Deeplex® Myc-TB Workflow		Automated Clear Dx™ Deeplex® Myc-TB Workflow	
	Cost	Time (Hours)	Cost	Time (Hours)
Specimen Extraction	\$8.44	4 hrs	\$8.44	4 hrs
Deeplex® Myc-TB Reagent Kits (multiplex PCR)	\$71.80	3 hrs	\$220 (Combined cost)	24 hrs (Combined time)
Library prep and sequencing Kits for MiSeq® or iSeq® 100	\$95.83	28 hrs		
Data Analysis & Reporting (in hours)	NA	2 hrs	NA	2 hrs
Total	\$176.07	37 hrs (10 hrs hands on tech time)	\$228.44	28 hrs (4 hrs hands on tech time)
Batch Size per Run	13 samples		13 samples	
Cost per Sample (including hands on tech time)	\$207		\$240	

RESULTS

Clinical Validation of the GenoScreen Deeplex® Myc-TB Assay

Performance Metrics – Deeplex Result (compared to RT-PCR and AFB Smear)	Primary Clinical Specimens	Pure Culture Isolates
No. of specimens tested	80	50
No. of specimens with a Deeplex result	46 (57.5%)	47 (94%)
Sensitivity - compared to RT-PCR positivity - Compared to AFB smear positivity	53 (66%) (CT <30 on PCR, 41/48, 85%) 44 (55%) (AFB smear positive, 37/44, 84%)	NA
Specificity (for MTB)	3/3 (100%)	4/4 (100%)

Performance Metrics – Drug Resistance (compared to phenotypic MIC method)	Data points compared
No. of data points	560
True positive (resistance identified)	17
True negative	539
False positive	2
False negative	2
Sensitivity	89.5
Specificity	99.6
Positive Predictive Value	89.5
Negative Predictive Value	99.6

Performance Comparison Between Manual and Automated Deeplex® Myc-TB Workflows

Performance Metrics	Manual Deeplex® Myc-TB Workflow	Automated Clear Dx™ Deeplex® Myc-TB Workflow
Successful run on positive specimens/ RT-PCR Ct <30	20/20	17/20
Successful run on specimens/ RT-PCR Ct ≥30	2/4	0/4
Successful run on MTBC isolates/no. tested	6/6	6/6
Concordance with ID and DR mutations	100%	100%
No. of specimens with TB drug resistance identified	4/4	4/4

CONCLUSION

- Deeplex Myc-TB provides rapid and accurate detection of ID and drug resistance for MTBC. tNGS is faster, cheaper and can be performed directly on the primary clinical sample (when compared to WGS) with good performance for samples with lower RT-PCR Ct and AFB Smear positivity
 - Sensitivity and specificity is 89.5% and 99.6%, respectively (in detecting mutations vs MIC) .
 - There is 100% concordance between the manual method and automated method.
 - Performance of the assay drops with low mycobacterial load e.g., smear neg/higher RT-PCR Ct and with non-respiratory specimen type e.g., BAL.
- Cost analysis and TAT:
 - 6 hours of hands-on time is saved by laboratorians with the automated method.
 - The increased cost per sample is offset by technical hands-on time and expertise to perform testing.
- Deeplex manual or automated methods can be easily adopted into routine workflow with no bioinformatics expertise required.

METHODS

