NAME	**: Dr. PUNEETI**		
AGE/ GENDER	: 36 YRS/FEMALE	**PATIENT ID**	: 1572269
COLLECTED BY	:	**REG. NO./LAB NO.**	**: 012408060049**
REFERRED BY	: C. LAL HOSPITAL (AMBALA CANTT)	**REGISTRATION DATE**	: 06/Aug/2024 12:35 PM
BARCODE NO.	: 01514597	**COLLECTION DATE**	: 06/Aug/2024 12:36PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB	**REPORTING DATE**	: 06/Aug/2024 05:45PM
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval

MOLECULAR PATHOLOGY

GENE XPERT FOR MYCOBACTERIUM TUBERCULOSIS (MTB)

TYPE OF SAMPLE — SPUTUM

by RT-PCR (REAL TIME-POLYMERASE CHAIN REACTION)

MYCOBACTERIUM TUBERCULOSIS COMPLEX — NEGATIVE (-ve)

by RT-PCR (REAL TIME-POLYMERASE CHAIN REACTION)

INTERPRETATION:

RESULT	REMARKS
Mycobacterium Tuberculosis Complex (MTB): **DETECTED (High/Medium/Low/Very low** Rifampicin Resistance: **DETECTED**	MTB target is present within sample: Considered positive for use in clinical decision A Mutation in the rpoB gene target sequence has been detected implicating resistance to rifampicin
Mycobacterium Tuberculosis Complex (MTB): **DETECTED (High/Medium/Low/Very low** Rifampicin Resistance: **INTERMEDIATE**	MTB target is present within sample: Considered positive for use in clinical decision Rifampicin Resistance could not be determined due to invalid melt peaks. Intermediate result of Rifampicin resistance should be subjected to culture bases drug sensitivity testing
Mycobacterium Tuberculosis Complex (MTB): **DETECTED (High/Medium/Low/Very low** Rifampicin Resistance: **NOT DETECTED**	MTB target is present within sample: Considered positive for use in clinical decision No mutation in the rpoB gene target has been detected
Mycobacterium Tuberculosis Complex (MTB): **NOT DETECTED**	MTB target is not detected present within sample: Considered negative for use in clinical decision
Mycobacterium Tuberculosis Complex (MTB): **DETECTED TRACE**	Low levels of MTB are detected but Rifampicin resistance could not be determined due to insufficient signal detection because of too low concentration of bacilli. This occurs due to the increased sensitivity of TB detection using multi copy targets IS6110 and IS1081 as opposed to Rifampicin resistance detection using the single copy rpoB gene. Trace positive Result of MTB is true positive and is sufficient treatment in those with known or suspected HIV

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Test Name	Value	Unit	Biological Reference interval
	inspection, children and for extra pulmonary samples		

NOTE:

1. This is a rapid semi quantitative DNA based real time PCR & melt peak detection which detects the nucleic acid of Mycobacterium tuberculosis complex DNA signifying that infection is likely with any of the following species namely M. tuberculosis, M. africanum, M. bovis, M. canettii, M. microti, M. caprae or M. pinnipedii forming the Mycobacterium tuberculosis complex and Rifampicin susceptibility qualitatively.
2. Primers in the Xpert MTB/RIF Ultra Assay amplify a portion of the rpoB gene containing the 81 base pair "core" region and portions of the multi-copy IS1081 and IS6110 insertion elements target sequences. The melt analysis with four rpoB probes is able to differentiate between the conserved wild-type sequence and mutations in the core region that are associated with Rifampicin resistance.
3. Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown MDR-MTB or Rifampicin resistant strains resulting in a false Rifampicin-sensitive result.
4. This assay does not provide confirmation of Rifampicin susceptibility since mechanisms of Rifampicin Resistance other than those detected by this device may exist that may be associated with a lack of clinical response to treatment.
5. Limit of detection is approximately 11.8 CFU/ mL with sensitivity of smear positive / culture positive cases 99.5%, smear negative culture positive cases 73.3%; and specificity of 95.5%.
6. It does not distinguish between species of Mycobacteria tuberculosis complex nor detects atypical Mycobacteria.
7. This assay should not be used for monitoring the efficacy of anti-tubercular treatment.
8. Negative result does not rule out the presence of Mycobacterium tuberculosis complex or active disease because the organism may be present at levels below the limit of detection of this assay.

COMMENTS

The World Health Organization (WHO) has recommended the use of this assay in all settings for semi-quantitative detection of Mycobacterium tuberculosis complex and Rifampicin susceptibility. The recommendation on the Ultra cartridge is based on a recent WHO Expert Group evaluation of data from a study coordinated by FIND, in collaboration with the Tuberculosis Clinical Diagnostics Research Consortium (CDRC). The increased sensitivity of the Ultra assay is almost exclusively due to its low TB detection limit. The improved sensitivity of the Ultra assay is specially seen in children and individuals with HIV infection. This method ensures a better performance of the assay for detecting Rifampicin resistance without compromising

*** End Of Report ***

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