

Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:27PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval
-----------	-------	------	-------------------------------

HAEMATOLOGY

COMPLETE BLOOD COUNT (CBC)

RED BLOOD CELLS (RBCS) COUNT AND INDICES

HAEMOGLOBIN (HB) <i>by CALORIMETRIC</i>	11.1 ^L	gm/dL	12.0 - 16.0
RED BLOOD CELL (RBC) COUNT <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	4.69	Millions/cmm	3.50 - 5.00
PACKED CELL VOLUME (PCV) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	35.5 ^L	%	37.0 - 50.0
MEAN CORPUSCULAR VOLUME (MCV) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	75.7 ^L	fL	80.0 - 100.0
MEAN CORPUSCULAR HAEMOGLOBIN (MCH) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	23.6 ^L	pg	27.0 - 34.0
MEAN CORPUSCULAR HEMOGLOBIN CONC. (MCHC) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	31.2 ^L	g/dL	32.0 - 36.0
RED CELL DISTRIBUTION WIDTH (RDW-CV) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	19.4 ^H	%	11.00 - 16.00
RED CELL DISTRIBUTION WIDTH (RDW-SD) <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	55.3	fL	35.0 - 56.0
MENTZERS INDEX <i>by CALCULATED</i>	16.14	RATIO	BETA THALASSEMIA TRAIT: < 13.0 IRON DEFICIENCY ANEMIA: >13.0
GREEN & KING INDEX <i>by CALCULATED</i>	31.22	RATIO	BETA THALASSEMIA TRAIT:<= 65.0 IRON DEFICIENCY ANEMIA: > 65.0

WHITE BLOOD CELLS (WBCS)

TOTAL LEUCOCYTE COUNT (TLC) <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	9670	/cmm	4000 - 11000
NUCLEATED RED BLOOD CELLS (nRBCS) <i>by AUTOMATED 6 PART HEMATOLOGY ANALYZER</i>	NIL		0.00 - 20.00
NUCLEATED RED BLOOD CELLS (nRBCS) % <i>by CALCULATED BY AUTOMATED HEMATOLOGY ANALYZER</i>	NIL	%	< 10 %




 DR. VINAY CHOPRA

CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


 DR. YUGAM CHOPRA

CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:27PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval
<u>DIFFERENTIAL LEUCOCYTE COUNT (DLC)</u>			
NEUTROPHILS <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	73 ^H	%	50 - 70
LYMPHOCYTES <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	18 ^L	%	20 - 40
EOSINOPHILS <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	3	%	1 - 6
MONOCYTES <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	6	%	2 - 12
BASOPHILS <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	0	%	0 - 1
<u>ABSOLUTE LEUKOCYTES (WBC) COUNT</u>			
ABSOLUTE NEUTROPHIL COUNT <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	7059	/cmm	2000 - 7500
ABSOLUTE LYMPHOCYTE COUNT <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	1741	/cmm	800 - 4900
ABSOLUTE EOSINOPHIL COUNT <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	290	/cmm	40 - 440
ABSOLUTE MONOCYTE COUNT <i>by FLOW CYTOMETRY BY SF CUBE & MICROSCOPY</i>	580	/cmm	80 - 880
<u>PLATELETS AND OTHER PLATELET PREDICTIVE MARKERS.</u>			
PLATELET COUNT (PLT) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	311000	/cmm	150000 - 450000
PLATELET CRIT (PCT) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	0.32	%	0.10 - 0.36
MEAN PLATELET VOLUME (MPV) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	10	fL	6.50 - 12.0
PLATELET LARGE CELL COUNT (P-LCC) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	87000	/cmm	30000 - 90000
PLATELET LARGE CELL RATIO (P-LCR) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	28.1	%	11.0 - 45.0
PLATELET DISTRIBUTION WIDTH (PDW) <i>by HYDRO DYNAMIC FOCUSING, ELECTRICAL IMPEDENCE</i>	15.7	%	15.0 - 17.0
NOTE: TEST CONDUCTED ON EDTA WHOLE BLOOD			





DR. VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)



DR. YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:48PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval
-----------	-------	------	-------------------------------

CLINICAL CHEMISTRY/BIOCHEMISTRY

LIVER FUNCTION TEST (COMPLETE)

BILIRUBIN TOTAL: SERUM <i>by DIAZOTIZATION, SPECTROPHOTOMETRY</i>	0.53	mg/dL	INFANT: 0.20 - 8.00 ADULT: 0.00 - 1.20
BILIRUBIN DIRECT (CONJUGATED): SERUM <i>by DIAZO MODIFIED, SPECTROPHOTOMETRY</i>	0.15	mg/dL	0.00 - 0.40
BILIRUBIN INDIRECT (UNCONJUGATED): SERUM <i>by CALCULATED, SPECTROPHOTOMETRY</i>	0.38	mg/dL	0.10 - 1.00
SGOT/AST: SERUM <i>by IFCC, WITHOUT PYRIDOXAL PHOSPHATE</i>	48.3^H	U/L	7.00 - 45.00
SGPT/ALT: SERUM <i>by IFCC, WITHOUT PYRIDOXAL PHOSPHATE</i>	19.86	U/L	0.00 - 49.00
AST/ALT RATIO: SERUM <i>by CALCULATED, SPECTROPHOTOMETRY</i>	2.43	RATIO	0.00 - 46.00
ALKALINE PHOSPHATASE: SERUM <i>by PARA NITROPHENYL PHOSPHATASE BY AMINO METHYL PROPANOL</i>	88.69	U/L	40.0 - 130.0
GAMMA GLUTAMYL TRANSFERASE (GGT): SERUM <i>by SZASZ, SPECTROPHOTOMETRY</i>	27.81	U/L	0.00 - 55.0
TOTAL PROTEINS: SERUM <i>by BIURET, SPECTROPHOTOMETRY</i>	7.33	gm/dL	6.20 - 8.00
ALBUMIN: SERUM <i>by BROMOCRESOL GREEN</i>	3.84	gm/dL	3.50 - 5.50
GLOBULIN: SERUM <i>by CALCULATED, SPECTROPHOTOMETRY</i>	3.49	gm/dL	2.30 - 3.50
A : G RATIO: SERUM <i>by CALCULATED, SPECTROPHOTOMETRY</i>	1.1	RATIO	1.00 - 2.00

INTERPRETATION

NOTE:- To be correlated in individuals having SGOT and SGPT values higher than Normal Reference Range.

USE:- Differential diagnosis of diseases of hepatobiliary system and pancreas.

INCREASED:

DRUG HEPATOTOXICITY	> 2
ALCOHOLIC HEPATITIS	> 2 (Highly Suggestive)
CIRRHOSIS	1.4 - 2.0
INTRAHEPATIC CHOLESTATIS	> 1.5




 DR.VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


 DR.YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:48PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval
HEPATOCELLULAR CARCINOMA & CHRONIC HEPATITIS	> 1.3 (Slightly Increased)		
DECREASED:			
1. Acute Hepatitis due to virus, drugs, toxins (with AST increased 3 to 10 times upper limit of normal)			
2. Extra Hepatic cholestatis: 0.8 (normal or slightly decreased).			
PROGNOSTIC SIGNIFICANCE:			
NORMAL	< 0.65		
GOOD PROGNOSTIC SIGN	0.3 - 0.6		
POOR PROGNOSTIC SIGN	1.2 - 1.6		




DR.VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


DR.YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:48PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		


Test Name	Value	Unit	Biological Reference interval
-----------	-------	------	-------------------------------

CREATININE

CREATININE: SERUM	0.83	mg/dL	0.40 - 1.20
by ENZYMATIC, SPECTROPHOTOMETRY			




 DR.VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


 DR.YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 12:48PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

Test Name	Value	Unit	Biological Reference interval
-----------	-------	------	-------------------------------

IMMUNOPATHOLOGY/SEROLOGY C-REACTIVE PROTEIN (CRP)

C-REACTIVE PROTEIN (CRP) QUANTITATIVE: **25.22^H** mg/L 0.0 - 6.0
 SERUM
 by NEPHLOMETRY

INTERPRETATION:

1. C-reactive protein (CRP) is one of the most sensitive acute-phase reactants for inflammation.
2. CRP levels can increase dramatically (100-fold or more) after severe trauma, bacterial infection, inflammation, surgery, or neoplastic proliferation.
3. CRP levels (Quantitative) has been used to assess activity of inflammatory disease, to detect infections after surgery, to detect transplant rejection, and to monitor these inflammatory processes.
4. As compared to ESR, CRP shows an earlier rise in inflammatory disorders which begins in 4-6 hrs, the intensity of the rise being higher than ESR and the recovery being earlier than ESR. Unlike ESR, CRP levels are not influenced by hematologic conditions like Anemia, Polycythemia etc.,
5. Elevated values are consistent with an acute inflammatory process.

- NOTE:**
1. Elevated C-reactive protein (CRP) values are nonspecific and should not be interpreted without a complete clinical history.
 2. Oral contraceptives may increase CRP levels.




DR. VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


DR. YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 01:44PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

MICROBIOLOGY

ACID FAST BACILLI (AFB)/ZEIHL-NEESEN (Z-N) STAIN EXAMINATION

TEST NAME:

ACID FAST BACILLI (AFB)/ZEIHL-NEESEN (Z-N) STAIN EXAMINATION

CLINICAL HISTORY (IF ANY):

NATURE OF SPECIMEN:

SPUTUM

MICROSCOPIC EXAMINATION :

Smear show a few epithelial cells & many inflammatory cells in a mucoid background .

ZEIHL NEESEN (Z.N) STAIN FOR ACID FAST BACILLI:

No acid fast bacilli seen in Z.N stanned smear .

IMPRESSION:

Negative for AFB (Acid fast bacilli) .



[Signature]

DR.VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)

[Signature]

DR.YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS , MD (PATHOLOGY)





Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 05/Feb/2025 01:44PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		




DR. VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


DR. YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 07/Feb/2025 01:50PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
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
 by RT-PCR (REAL TIME-POLYMERASE CHAIN REACTION)
 MYCOBACTERIUM TUBERCULOSIS COMPLEX
 by RT-PCR (REAL TIME-POLYMERASE CHAIN REACTION)

SPUTUM
 NEGATIVE (-ve)

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




 DR.VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)


 DR.YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)



Dr. Vinay Chopra
 MD (Pathology & Microbiology)
 Chairman & Consultant Pathologist

Dr. Yugam Chopra
 MD (Pathology)
 CEO & Consultant Pathologist

NAME	: Mrs. REETA MALHOTRA	PATIENT ID	: 1746250
AGE/ GENDER	: 65 YRS/FEMALE	REG. NO./LAB NO.	: 012502050037
COLLECTED BY	: SURJESH	REGISTRATION DATE	: 05/Feb/2025 11:49 AM
REFERRED BY	:	COLLECTION DATE	: 05/Feb/2025 12:02PM
BARCODE NO.	: 01525004	REPORTING DATE	: 07/Feb/2025 01:50PM
CLIENT CODE.	: KOS DIAGNOSTIC LAB		
CLIENT ADDRESS	: 6349/1, NICHOLSON ROAD, AMBALA CANTT		

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 ***



Dr. Vinay Chopra

DR. VINAY CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY & MICROBIOLOGY)

Dr. Yugam Chopra

DR. YUGAM CHOPRA
 CONSULTANT PATHOLOGIST
 MBBS, MD (PATHOLOGY)

