



Laboratory: **Advance Pathology Lab**

Discipline: Bio-Chemistry, Clinical Pathology, Serology and Immunochemistry and Hematology

Certificate Number: MLS- 009

Issue Date: 16-07-2024

Expiry Date: 15-07-2027

Annexure: Scope

The clinical laboratories under the scope of AERSSC accreditation (ISO 15189:2022) are:

1 . Biochemistry:

S.N.	Product(S)/material test	Specific tests Performed	Test Method/Standard against which tests are performed	Range of Testing/ Limits of Detection
1	Serum	Glucose	Hexokinase	5-800mg/dl
2	Serum	Albumin	BCG Colorimetric Method	03-12.0g/dl
3	Serum	Alkaline Phosphatase(ALP)	IFCC-amp	5-1080U/L
4	Serum	Aspartate Aminotransferase(SG OT)	Modified IFCC kinetic	4-390U/L
5	Serum	Alanine Aminotransferase(SG PT)	Modified IFCC kinetic	4.4-360U/L
6	Serum	Amylase	2-chloro-p- nitrophenyl- α -D-maltoside	5-365 U/L
7	Serum	Bilirubin Total	Walter and Gerard	0-39.0mg/dl
8	Serum	Bilirubin Direct	Walter and Gerard	0-23mg/dl
9	Serum	Total Calcium	ISE- Direct	0-22 mg/dl



10	Serum	Creatinine	Enzymatic(creatinase and sarcosine oxidase)	0.042-64.5 mg/dl
11	Serum	Cholesterol Total	cholesterol oxidase (CHOD) and peroxidase(POD)	1.8-650 mg/dl
12	Serum	Cholesterol-HDL	(PEGME)	0.90-193mg/dl
13	Serum	Cholesterol -LDL	Direct Method PVS & PEG	2.60-263mg/dl
14	Serum	Magnesium	Xylidyle Blue Method	0.1-4.16 mg/dl
15	Serum	Phosphorus	UVPhosphomolybdate Method	0.9-12.3mg/dl
16	Serum	Sodium	ISE-direct	30-200 mmol/L
17	Serum	Total Protein	Biuret Colorimetric Method	0.37-15 g/dl
18	Serum	Triglyceride	GPO-PAP-enzymatic method.	8.8-1106 mg/dl
19	Serum	Uric Acid	Uricase	0.39-25.0mg/dl
20	Serum	Urea	Urease GLDH	4-300 mg/dl
21	Whole blood	HBA1C	HPLC	3-18%
22	serum	Potassium	ISE-direct	Upto 0.5-15 mmol/L
23	serum	Lipase	Enzymatic colorimetric	8.2-300U/L
24	serum	Lactate Dehydrogenase(LDH)	Uv-kinetic method-DGKHC	Upto 2000u/l
25	serum	Iron	Ferrozine	8.66-890 ug/dl
26	serum	UIBC	Ferrozine	12.2-830ug/dL



Calculated Parameter				
SN	Parameter	Profile	Formula used	References Range
1	globulin	Liver function test	Total protein-albumin	2.3 - 3.5
2	Albumin/Globulin ratio	Liver function test	Albumin/globulin	Active
3	Indirect-bilirubin	Liver function test	Total bilirubin- Direct bilirubin	0.2 - 1.0
4	VLDL-cholesterol	Lipid profile	Triglycerides/5	<40
5	Cholesterol / HDL Ratio	Lipid profile	Total cholesterol/HDL	3.3 - 4.4
6	LDLc / HDLc Ratio	Lipid Profile	LDL cholesterol/HDL cholesterol	<3.1
7	Total iron binding capacity	Iron profile	Iron+ UIBC	250 - 400 μ g/dl

2. Serology

S.N	Product(S)/material test	Specific tests Performed	Test Method/Standard against which tests are performed	Range of Testing/ Limits of Detection
1	Serum/Plasma	Hepatitis C Virus (anti HCV)	Immunochromatography	Negative/Positive
2	Serum/Plasma	Hepatitis B surface antigen (HBsAg)	Immunochromatography	Negative/Positive
3	Serum/Plasma	Human Immuno Virus (HIV)	Immunochromatography	Negative/Positive
4	Serum/Plasma	Treponema Pallidum Hemagglutination	Immunochromatography	Negative/Positive



		Assay and (TPHA) and VDRL)		
5	Serum/Plasma	Tuberculosis TB Antibody Rapid Test	Immunochromatography	Negative/Positive
6	Serum/Plasma	Typhoid IgG IgM Rapid Test	Immunochromatography	Negative/Positive
7	Serum/Plasma	Dengue IGG/IgM Ns1 Rapid	Immunochromatography	Negative/Positive
8	Serum/Plasma	Hepatitis virus A (HAV IgG/rapid)	Immunochromatography	Negative/Positive
9	Serum/Plasma	Hepatitis virus A (HAV IgM, Rapid)	Immunochromatography	Negative/Positive
10	Serum/Plasma	Hepatitis virus E(HEV IgM, Rapid)	Immunochromatography	Negative/Positive
11	Serum/Plasma	Hepatitis virus E (HEV IgG, Rapid)	Immunochromatography	Negative/Positive
12	Serum/plasma	C-Reactive Protien (CRP)	Nephelometry	0-300mg/dl
13	Serum/plasma	Rheumatoid arthritis(RA Factor)	Nephelometry	0-100IU/ml
14	Serum/plasma	Anti Streptolysin-O (ASO)	Nephelometry	0- 1000 IU/ml
15	Serum/plasma	Complement 3	Nephelometry	0- 400mg/dl
16	Serum/plasma	Complement 4	Nephelometry	0-80 mg/dL

3.Hematology

S.N.	Products(s)/Material Of Testing	Specific tests performed	*Test method/Standard against which tests are performed	Range of Testing/ limits of detection
1	Whole blood EDTA	White blood cells	Flow Cytometry	(Whole blood mode, Low WBC mode) 0.00 to 440.00 $\times 10^3/\mu\text{L}$



2	Whole blood EDTA	Red blood cells	Electrical Impedance	0.00 to $8.60 \times 10^6/\mu\text{L}$
3	Whole blood EDTA	Hemoglobin - total	Cyanide -Free SLS method	0 to 260 g/L
4	Whole blood EDTA	Hematocrit	Numeric integration	0.0 to 75.0%
5	Whole blood EDTA	Platelets	Electrical Impedance	3000-1400000/cumm
6	Whole blood EDTA	Mean corpuscular volume	Electrical Impedance	0-150fl
7	Whole blood EDTA	Mean corpuscular Hemoglobin	Calculated	calculation
8	Whole blood EDTA	Mean corpuscular Hemoglobin concentration	Calculated	calculation
9	Whole blood EDTA	Red cells distribution width-cv%	Calculated	calculation
10	Whole blood EDTA	Neutrophils Differential count	Fluorescence Flow Cytometry	0-100%
			Manual	0-100%
11	Whole blood EDTA	Lymphocytes Differential count	Fluorescence Flow Cytometry	0-100%
			Manual	0-100%
12	Whole blood EDTA	Eosinophils Differential count	Fluorescence Flow Cytometry	0-100%
			Manual	0-100%
13	Whole blood EDTA	Monocytes Differential count	Fluorescence Flow Cytometry	0-100%



			Manual	0-100%
14	Whole blood EDTA	Basophils Differential count	Fluorescence Flow Cytometry	0-100%
			Manual	0-100%
15	Whole blood EDTA	Erythrocytes sedimentation rate(ESR)	Wintrobe method	High limit: 100 mm/hr
16	Whole blood EDTA	Peripheral blood smears	Peripheral smear examination	Manual staining(Lesihman Stain) and Microscopy
17	Citrated plasma	Prothrombin time	Turbo-densitometric, opto-mechanical	0-70 sec
18	Citrated plasma	Activated partial thromboplastin time	Turbo-densitometric, opto-mechanical	0-120 sec

4. Clinical Pathology: Urine Routine Analysis

S.N	Product(S)/material test	Specific tests Performed	Test Method/Standard against which tests are performed	Range of Testing/ Limits of Detection
1	Urine	Color	Naked eye examination	Light yellw, Yellowish,Reddish ETC
2	Urine	Appearance	Manual	Clear, S turbid Turbid
3	Urine	Ph	Bromthymol blue	6.0-9.0
4	Urine	Specific gravity	Bromthymol blue indicator	1.000-1.030
5	Urine	Sugar	Dipstick and manual(benedicts)	Trace +,++,+++,++++
6	Urine	Albumin	Tetrabromophenol blue	Trace +,++,+++,++++



7	Urine	Blood	TMB	Trace +,+,+,+++
8	Urine	Ketone	Sodium nitroprusside buffer	Trace +,+,+,++++,++++
9	Urine	Urobilinogen	p-diethylaminobenzaldehyde	Trace +,+,+,++++,++++
10	Urine	Pus cells/WBCs	Microscopy and wet mount	See for wbc
11	Urine	Epithelial cells	Microscopy and wet mount	See for types of epithelial cells
12	Urine	RBC	Microscopy and wet mount	Types of RBCS , normal and abnormal
13	Urine	Crystal	Microscopy and wet mount	Present/absent and types
14	Urine	Casts	Microscopy and wet mount	Present/absent and types
15	Urine	Bacteria	Microscopy and wet mount	Present/absent
16	Urine	Urine Pregnancy Test	Immunochromatography	Negative/Positive

4.Clinical Pathology: Stool Routine Examination

S.N	Product(s)/Material test	Specific tests performed	Test Method/Standard against which tests are performed	Range of Testing/Limits of Detection
1	Stool	Color	Naked eye examination	Yellowish,brownish, greenish etc
2	Stool	Consistency	Visual	Solid, semi solid
3	Stool	Blood	Visual	Present /absent
4	Stool	Pus cells	Microscopy	0-2,1-3,2-4 (grading)
5	Stool	RBCs	Microscopy	0-2,1-3,2-4 (grading)
6	Stool	Protozoa	Microscopy	Seen/not seen



7	Stool	Helminth	Microscopy	Seen/not seen
8	Stool	Undigested food particles	Microscopy	Seen/not seen
9	Stool	Fat droplets	Microscopy	Seen/not seen
10	Stool	Mucus	Microscopy	Seen/not seen
11	Stool	Reducing substances	Benedict's test	Negative/positive
12	Stool	Cyst	Microscopy	Seen/not seen
13	Stool	Occult blood	Immunochemistry	Positive/negative
14	Stool	Ova and parasite	Microscopy	Seen/not seen
15	Stool	Bacteria	Microscopy	Seen/not seen

4. Clinical Pathology: Semen Analysis

S.N	Product(S)/material test	Specific tests Performed	Test Method/Standard against which tests are performed	Range of Testing/ Limits of Detection
1	Semen	Epithelial cells	Microscopy(pap Stain)	0-2,1-3,2-4 (grading)
2	Semen	Pus cells	Microscopy	0-2,1-3,2-4 (grading)
3	Semen	Sperm motility (immotile/motile/progressive/non progressive/slow progressive)	Microscopy	Percentage calculation
4	Semen	Total sperm count	Microscopy	millions/cumm
5	Semen	Viscosity	Microscopy	Normal/increased
6	Semen	Color	Visual	Depending on semen



7	Semen	RBCs	Microscopy	0-2,1-3,2-4 (grading)
8	Semen	Volume	Visual	ml
9	Semen	Appearance	Naked eye examination	Pearly white, reddish etc
10	Semen	Liquefaction time	Naked eye examination	In minutes
11	Semen	Ph	Ph meter	6-9
12	Semen	Total num of sperm/ejaculate	Microscopy and calculation	Calculated
13	Semen	Total motile progressive	Microscopy and calculation	calculated
14	Semen	Morphology(normal abnormal, head defects, globular defects, macro had, tail defects, short tail, bi tail, others)	Microscopy(pap Stain)	Percentage calculation

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5. Immunochemistry

S.N.	Product(s) /material	Specific test performed	Test Method/Standard against which tests are performed	Range of testing/limits of detection
1	Serum	Thyroid Stimulating Hormone	CLIA	0-150mIU/ ml
2	Serum	Free T3	CLIA	0.2-20 pg/ ml
3	Serum	Free T4	CLIA	0.1-12.0 ng/dL
4	Serum	Vitamin D	CLIA	3-150 ng/mL
5	Serum	Vitamin B12	CLIA	12.5-2000 pg/ ml
6	Serum	Cortisol	CLIA	2.5-600 ng/mL
7	Serum	Anti Nuclear Antibody	CLIA	1.0-400 au/ ml
8	Serum	Prolactin	CLIA	5-500 ng/ ml
9	Serum	Prostate specific Antigen	CLIA	0.02-400 ng/ ml
10	Serum	Ferritin	CLIA	0.2-3000 ng/ ml