



Kathmandu Path Lab Pvt. Ltd

Kathmandu, Nepal

**Discipline: CLINICAL BIO-CHEMISTRY, HEMATOLOGY, SEROLOGY,
HISTOPATHOLOGY & CYTOPATHOLOGY**

Certificate Number: MLS-002/04

Issue Date: 09-06-2024

Expiry Date: 08-06-2027

Scope of Accreditation

The clinical laboratories under the scope of AERSSC accreditation

(ISO 15189:2022) are:

Clinical Biochemistry, Hormones and tumor markers

S. N	Materials examined/tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV %
1	Serum	Albumin	Bromocresol green(BCG)	0.3-6.0 g/dL	3.0
2	Serum	ALP	IFCC Modified	5.0 - 800.0 U/L	11.8
3	Serum	ALT	IFCC method without Pyridoxalphosphate -Kinetic	4.0 - 1000.0 U/L	8.3
4	Serum	AST	IFCC method without Pyridoxalphosphate -Kinetic	4- 800.0 U/L	6.2
5	Serum	Bilirubin Direct	Malloy-Evelyn Modified-Endpoint	0.05-15.0mg/dL	8.1
6	Serum	Bilirubin Total	Malloy-Evelyn Modified-Endpoint	0.09-35.0 mg/dL	7.1
7	Serum	Cholesterol - Total	Enzymatic /PAP-End point (CHOD-POD)	3.85-769.23 mg/dL	8.3
8	Serum	Creatinine	Sarcosine Oxidase	0.11-79.3 mg/dL	4.7

9	Plasma	Glucose	GOD-POD	5.0 - 450.0 mg/dL	2.8
10	Serum	HDL Cholesterol	Accelerator Selective detergent	1.93 - 232.0 mg/dL	11.4
11	Serum	Iron	Ferrozine -End point	5.0-1117.0µg/dL	6.6
12	Serum	Total Protein	Biuret End point	0.20-12.0 g/dL	5.7
13	Serum	Triglyceride	GPO-POD End point	8.0-1106.0 mg/dL	4.8
14	Serum	Urea	Urease/GLDH-Kinetic-UV	2.0-240.0 mg/dL	8.0
15	Serum	Uric Acid	Uricase	0.35-25.0 mg/dL	7.2
16	Serum	Sodium	ISE	70.0-200.0mmol/L	0.4
17	Serum	Potassium	ISE	1.0-20.0mmol/L	1.0
18	Whole Blood (EDTA)	HbA1C	HPLC	3.9%-18.8%	1.8
19	Serum	AFP	CLIA	0.04-2000.0 ng/ml	10.0
20	Serum	ANTI-TPO	CLIA	0.04-1000.0 IU/ml	5.3
21	Serum	BETA hCG	CLIA	1.20-15000.0 mIU/ml	10.2
22	Serum	CA 125	CLIA	1.0-1000.0 U/ml	13.5
23	Serum	CA 15.3	CLIA	0.5-800.0 U/ml	9.6
24	Serum	CA19.9	CLIA	2.0-1200.0 U/ml	11.0
25	Serum	CEA	CLIA	0.5-1500.0 ng/ml	10.7
26	Serum	Estradiol	CLIA	10-1000.0 pg/ml	10.1
27	Serum	Ferritin	CLIA	1.0-2000.0 ng/ml	10.3
28	Serum	Free T3	CLIA	1.5-20.0 pg/ml	13.2
29	Serum	Free T4	CLIA	0.4-5.0 ng/dl	10.9
30	Serum	FSH	CLIA	1.02 -111.0 mIU/ml	10.5
31	Serum	LH	CLIA	0.03 -250 mIU/ml	11.1

32	Serum	Prolactin	CLIA	0.6- 200.0 ng/ml	12.0
33	Serum	PSA-Total	CLIA	0.004 -100.0 ng/ml	14.2
34	Serum	Testosterone- Total	CLIA	12.98-1009.0 ng/dL	10.0
35	Serum	Thyroid Stimulating Hormone (TSH)	CLIA	0.01-100.0 μ IU/ml	9.6
36	Serum	Vitamin B12	CLIA	83-2000.0 pg/ml	13.2
37	Serum	Vitamin D3 (25- HYDROXY)	CLIA	2.2-155.9 ng/ml	15.0

CLIA: Chemiluminescent immunoassay

Hematology

S. N	Materials examined/tested	Specific tests/examination	Specification, standard (method) or technique	Range of testing/ Limit of detection	CV
1	Whole blood	Total Leucocyte Count	Flowcytometry	0.03-418.70 (10 ³ /μL)	3.33
2	Whole blood	Differential Leucocyte Count	Flowcytometry	NA	NA
3	Whole blood	Hemoglobin	Non cyanide(SLS) HGB Method	0.01-21.75 g/dl	1.2
4	Whole blood	RBC	Hydrodynamic focusing DC detection method	0.0001-8.61 (10 ⁶ /μL)	1.0
5	Whole blood	Platelets	Hydrodynamic focusing DC detection method	1.0 - 971.0 (10 ³ /μL)	9.8
6	Whole blood	Hematocrit Value	Calculation(RBC Pulse Height Detection)	NA	NA
7	Whole blood	Mean Corpuscular Volume	Calculation	NA	NA
8	Whole blood	Mean Corpuscular Hemoglobin	Calculation	NA	NA
9	Whole blood	Mean Corpuscular Hemoglobin Concentration	Calculation	NA	NA

NA: Not Applicable

Serology/Immunology

S.N	Materials examined/tested	Specific tests/ examination performed	Specification, standard(method) or technique used	Range of testing/ Limit of detection	CV
1	Serum	Anti-Nuclear Antibody(ANA)	ELISA	0.08	1.56
2	Serum	Anti-Double Stranded DNA (ANTI-Ds DNA)	ELISA	2.6 IU/ml	2.76
3	Serum	Hepatitis B Surface Antigen(HBsAg)	ELISA	NA	11.38
4	Serum	Hepatitis B Envelope Antigen (HBeAg)	ELISA	NA	1.58
5	Serum	Hepatitis B Envelope Antibody (ANTI- HBe)	ELISA	NA	1.21
6	Serum	Hepatitis A Virus Antibody (ANTI-HAV IgM)	ELISA	NA	2.75
7	Serum	Hepatitis E Virus Antibody (ANTI-HEV IgM)	ELISA	Ratio=0.0	4.69
8	Serum	Hepatitis C Virus Antibody (ANTI- HCV IgM)	ELISA	NA	4.16
9	Serum	HIV I&II Antibody IgM	ELISA	NA	4.17
10	Serum	Toxoplasma Antibody (IgG/IgM)	ELISA	IgG-0.3 IU/ml	IgG-1.09
11	Serum	Rubella Virus Antibody (IgG/IgM)	ELISA	IgG-0.3 IU/ml IgM-Ratio-0.04	IgG-1.85 IgM-1.72
12	Serum	Cytomegalovirus (CMV-IgG/IgM)	ELISA	IgG-0.4 RU/ml IgM-Ratio-0.05	IgG-1.86 IgM-1.01

S.N	Materials examined/tested	Specific tests/ examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV
13	Serum	Herpes Simplex Virus-1 antibody, Hsv- 1 (IgG/IgM)	ELISA	IgG-0.8 RU/ml IgM-Ratio-0.04	IgG-1.76 IgM-1.32
14	Serum	Herpes Simplex Virus-2 Antibody, Hsv- 2(IgG/IgM)	ELISA	IgG-0.8 RU/ml IgM-Ratio-0.04	IgG-1.76 IgM-1.32

ELISA: Enzyme Linked Immunosorbent Assay

NA: Not Applicable

Histopathology/Cytopathology

HISTOPATHOLOGY

S. N	Materials examined/tested	Specific tests/ examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV
A	Biopsy				
1	Small, Medium & Large tissues	Grossing , Decalcification, Processing, Paraffin, embedding, Microtomy, H& E Staining (Conventional)	Light Microscopy with Interpretation	Descriptive	NA
2	Slides for second opinion	Stained / Unstained slides	Light Microscopy with Interpretation	Descriptive	NA
3	Paraffin Blocks for second Opinion	Microtomy H & E Staining (Convention)	Light Microscopy, Interpretation	Descriptive	NA
B	Histo-chemistry (All special stains performed to be listed)				
4	Tissue / Paraffin block / Unstained slide	PAS stain	Light Microscopy with Interpretation	Descriptive	NA
5	Tissue / Paraffin block / Unstained slide	ZN stain for AFB	Light Microscopy with Interpretation	Descriptive	NA
6	Tissue / Paraffin block / Unstained slide	Giemsa stain	Light Microscopy with Interpretation	Descriptive	NA

NA: Not Applicable

CYTOPATHOLOGY

S. N	Materials examined/tested	Specific tests/ examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV
A	Cytopathology: Non-Gynaec				
1	Palpable or non palpable lesion involving any organ	FNA, smear preparation, Giemsa staining with or without PAP / H & E	Light Microscopy with Interpretation	Descriptive	NA
2	Unstained smears	Giemsa staining with or without PAP / H & E	Light Microscopy with Interpretation	Descriptive	NA
B	Cytopathology: Gynaec				
3	Cervical and vaginal smears (Conventional / Liquid based, to be mentioned)	PAP stain	Light Microscopy with Interpretation	Descriptive	NA

NA: Not Applicable

