



Samyak Diagnostic Laboratory Pvt. Ltd

Jawalakhel, Lalitpur, Nepal

Discipline: **BIO-CHEMISTRY, IMMUNOASSAY, HEMATOLOGY,  
CLINICAL PATHOLOGY, SEROLOGY, MOLECULAR  
BIOLOGY and CYTOPATHOLOGY**

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### Scope of Accreditation

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

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
<b>1:Biochemistry</b>					
1.	Serum	Albumin	Bromocresol Green	0.30 – 9.4 g/dL	4.1
2.	Serum	Alanine aminotransferase	NADH without P5P	2.0 - 4113 U/L	3.8
3.	Serum	Amylase	CNPG3 Substrate	11.0-4200 U/L	3.4
4.	Serum	Aspartate aminotransferase	NADH without P5P	2.2 42.2 U/L	2.3
5.	Serum	Alkaline Phosphatase	P-NPP	5 - 2200 U/L	2.3
6.	Serum	Calcium	Arsenazo III	0.5 -24.0 mg/dL	4.1
7.	Serum	HDL-Cholesterol	Accelerator Selective Detergent	2.5 - 180 mg/dL	3.4
8.	Serum	Lactate dehydrogenase	Lactate to Pyruvate	5.0-4732 U/L	2.8
9.	Serum	Cholesterol	Oxidase/Enzymatic End point	5 -748 mg/dL	4.8
10.	Serum	Creatine Kinase	NAC activated	5-4267 U/L	4.0
11.	Serum	Creatinine	Kinetic Alkaline picrate	0.09 -37.34 mg/dL	3.1

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12.	Serum	Gamma glutamyl transferase	L- gama -glutamyl-3 - carbox-4 nitroanilide substrate	5-7782 U/L	5.9
13.	Serum	Glucose	Hexokinase	2.5 - 800 mg/dL	5.0
14.	Serum	Iron	Ferene	0.9 – 179.0 µmol/L	3.6
15.	Serum	Magnesium	Enzymatic	0.60 - 9.50 mg/dL	4.1
16.	Serum	Phosphorus	Phosphomolybdate	0.25 - 25.3 mg/dL	4.6
17.	Serum	Total protein	Biuret reaction endpoint	0.5 – 18.4 g/dL	6.1
18.	Serum	Triglyceride	Glycerol phosphate Oxidase	5 - 1420 mg/dL	4.3
19.	Serum	Urea	Urease kinetic	3.0-128 mg/dL	4.8
20.	Serum	Total Bilirubin	Diazonium Salt	0.1 -25 mg/dL	6.3
21.	Serum	Direct Bilirubin	Diazo Reaction	0.1-15 mg/dL	3.6
22.	Serum	Lipase	Quinone Dye	1.6-1200 U/L	6.0
23.	Serum	Uric acid	Uricase	0.1 -33.1 mg/dL	3.7
24.	Serum	Sodium	ISE	40-220 mmol/L	1.5
25.	Serum	Potassium	ISE	1-30 mmol/L	1.9
26.	Serum	Ceruloplasmin	Immunonephlometry	0.1-2.5 g/L	2.5
27.	Serum	Procalcitonin	Immunoassay	0.1-50 ng/mL	NA
28.	Serum	NT-ProBNP	Immunoassay	100-3500 pg/mL	NA
29.	Serum	Hs-CRP	Immunoassay	0.5-200 mg/L	NA
30.	Serum	Total Iron Binding Capacity	Colorimetric method	40-683 µg/dL	5.02
31.	Serum/Whole Blood	Troponin I	Membrane based Immunoassay	NA	NA
32.	Urine	Microalbumin	Immunonephlometry	10-220 mg/dL	4.9
33.	Whole Blood	Hba1c	HPLC	3.8-18.5 %	3.3
34.	Whole blood	Lead	Electrochemical	3.3-65 µg/dL	NA
<b>2. Immunoassay</b>					
1.	Serum	Free T3	Competitive immunoassay	1.0 30.0 pg/mL	7.3
2.	Serum	Free T4	Competitive immunoassay	0.4-6.0 ng/dL	9.5
3.	Serum	Thyroid stimulating hormone	Sandwich immunoassay	0.0025 -100 µIU/mL	10.2

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
4.	Serum	Follicle- stimulating hormone	Sandwich immunoassay	0.3-20 mIU/mL	7.9
5.	Serum	Luteinizing Hormone	Sandwich immunoassay	0.07-200 mIU/mL	7.5
6.	Serum	Prolactin	Sandwich immunoassay	0.3-200 ng/mL	7.7
7.	Serum	Progesterone	Competitive immunoassay	0.21-60 ng/mL	6.0
8.	Serum	Estradiol	Competitive immunoassay	118.-3000 IU/mL	5.8
9.	Serum	Total Beta HCG	Two site sandwich immunoassays	2- 1000 mIU/mL	10.7
10.	Serum	Testosterone Total	Competitive immunoassay	10-1500 ng/dL	6.3
11.	Serum	Alpha fetoprotein	Two site sandwich immunoassay	1.3-1000 ng/mL	2.8
12.	Serum	Carcinoembryonic antigen	Two site sandwich immunoassays	0.5-100 ng/mL	6.4
13.	Serum	Total Prostate specific antigen	Two site sandwich immunoassays	0.01-100 ng/mL	6.0
14.	Serum	Ferritin	Two site sandwich immunoassays	0.5-1650 ng/mL	9.3
15.	Serum	Folate	Competitive immunoassay	0.35-24 ng/mL	8.8
16.	Serum	Vitamin B12	Competitive immunoassay	45-2000 pg/mL	10.2
17.	Serum	Vitamin D, 25 Hydroxy	Competitive immunoassay	1.2-150ng/mL	4.8
18.	Serum	CA 125	Two site sandwich immunoassays	1.0 -1000 U/mL	3.7
19.	Serum	CA 19-9	Two site sandwich immunoassays	2.0-1200 U/mL	10.7
20.	Serum	CA 15-3	Two site sandwich immunoassays	0.5-200 U/mL	6.7
21.	Serum	Cortisol	Competitive immunoassay	0.20-75 ng/dL	6.1

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
22.	Serum	Total IgE	Two site sandwich immunoassays	1.5-3000 IU/mL	7.4
23.	Serum	Total IgM	Immunonephlometry	0.25-4.5 g/L	9.3
24.	Serum	Total IgG	Immunonephlometry	2-25 g/L	7.1
25.	Serum	Total IgA	Immunonephlometry	0.25-5.0 g/L	7.9
26.	Serum	Valproic acid	Competitive immunoassay	1-150 µg/mL	0.5
27.	Serum	Vancomycin	Competitive immunoassay	0.67-90 µg/mL	8.9
28.	Serum	Carbamazipine	Competitive immunoassay	0.25 - 18 µg/mL	7.8
29.	Serum	Phenytoin	Competitive immunoassay	0.5 – 40 µg/mL	1.7
30.	Serum	C-peptide	Sandwich immunoassay	0.05 – 30 ng/mL	9.9
31.	Serum	C-ANCA	Immunoblot	NA	NA
32.	Serum	P-ANCA	Immunoblot	NA	NA
33.	Serum	GBM	Immunoblot	NA	NA
34.	Serum	ANA	Immunoblot	NA	NA
35.	Serum	ANA	Indirect Immunofluorescence	NA	NA
36.	Serum	ds-DNA	Indirect Immunofluorescence	NA	NA
37.	Serum	Liver IgG	Immunoblot	NA	NA
38.	Serum	Anti-cyclic citrullinated peptide	Immunoassay	NA	NA

### 3.Hematology

1.	Whole blood	WBC	Light scattered	0-299 X 10 <sup>3</sup> /µL	2.3
2.	Whole blood	NE%	Flow cytometry	0- 99.9 %	2.2
3.	Whole blood	LY%	Flow cytometry	0- 99.9 %	3.4
4.	Whole blood	MO%	Flow cytometry	0- 99.9 %	23.6
5.	Whole blood	EO%	Flow cytometry	0- 99.9 %	5.8
6.	Whole blood	BA%	Flow cytometry	0- 99.9 %	7.8
7.	Whole blood	RBC	Electrical Impedence	0- 14.9 X 10 <sup>6</sup> /µL	0.8

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
8.	Whole blood	HGB	Photometry	0- 29.9 g/dl	1.0
9.	Whole blood	HCT	Calculated	0- 99.9 %	1.5
10.	Whole blood	MCV	Calculated	NA	NA
11.	Whole blood	MCH	Calculated	NA	NA
12.	Whole blood	MCHC	Calculated	NA	NA
13.	Whole blood	RDW-CV	Calculated	NA	NA
14.	Whole blood	PLT COUNT	Electrical Impedence	0- 1490 X 10 <sup>3</sup> /μL	2.5
15.	Whole blood	Absolute eosinophil count	Manual	0-2222 /μL	NA
16.	Peripheral blood smear	Peripheral blood smear examination	Light Microscopy with interpretation	Descriptive	NA
17.	Whole blood	Sickling test	Manual	Negative - Positive	NA
18.	Citrated plasma	D-dimer	Particle enhanced nephelometry	0.1-7.5 mg/l	NA

#### 4. Clinical Pathology

SI No.	Materials or items examined/ tested	Specific tests/ examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV %
1.	Urine	Colour	Visual naked eye	Descriptive	NA
2.	Urine	Transparency	Visual naked eye	Descriptive	NA
3.	Urine	Protein	Protein -error principle	Negative to 4+	NA
4.	Urine	Glucose	Glucose oxidase peroxidase	Negative to 4+	NA
5.	Urine	Specific gravity	PH Indicator	1.000-1.030	NA
6.	Urine	Ketone	Na Nitroprusside	Negative to 4+	NA
7.	Urine	Urobilinogen	Diazoium ion reaction	Negative to 4+	NA
8.	Urine	Nitrate	Griess test	Negative to 4+	NA
9.	Urine	Bilirubin	Azo - Diazo Reaction	Negative to 4+	NA
10.	Urine	Blood	Peroxidase	Negative to 4+	NA
11.	Urine	Reaction (pH)	Double Indicator	5.0-8.5	NA
12.	Urine	Leucocyte	Light Microscopy	Descriptive	NA

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
13.	Urine	Squamous Epithelial Cell	Light Microscopy	Descriptive	NA
14.	Urine	Erythrocytes	Light Microscopy	Descriptive	NA
15.	Urine	Cast	Light Microscopy	Descriptive	NA
16.	Urine	Cristal	Light Microscopy	Descriptive	NA
17.	Urine	Occult Blood	Benzidine Method	Positive / Negative	NA
18.	Stool	Colour	Light Microscopy	Descriptive	NA
19.	Stool	Consistency	Visual naked eye	Descriptive	NA
20.	Stool	Mucus	Visual naked eye	Descriptive	NA
21.	Stool	Blood	Visual naked eye	Descriptive	NA
22.	Stool	Parasite	Light Microscopy	Descriptive	NA
23.	Stool	Leukocyte	Light Microscopy	Descriptive	NA
24.	Stool	Erythrocyte	Light Microscopy	Descriptive	NA
25.	Stool	Undigested food Particles	Light Microscopy	Descriptive	NA
26.	Stool	Occult Blood	Guaiac method	Negative to ++++	NA
27.	Stool	Reducing Substances	Benedict Method	Negative to ++++	NA
28.	Urine	Drug of Abuse (DOA)	Competitive Immunochromatography	Positive / Negative	NA
29.	Urine	Pregnancy Test	Immunochromatography	Negative - Positive	NA

5. Serology

SI No.	Materials or items examined/tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV %
1	Serum	Rheumatoid Factor (RF)	Particle enhanced Immunonephelometric	20-300 IU/ml	3.8
2	Serum	CRP	Particle enhanced Immunonephelometric	2.0-150 mg/l	4.1
4	Serum	Anti-Streptolysin O	Particle enhanced Immunonephelometric	50-600 IU/ml	4.2
5	Serum	HIV 1 & 2	Immunochromatography	Non reactive -Reactive	NA
6	Serum	HBsAg	Immunochromatography	Non reactive -Reactive	NA
7	Serum	Anti- HCV	Immunochromatography	Non reactive -Reactive	NA

SI No.	Materials or items examined/ tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	CV%
8	Serum	HAV IgM	Immunochromatography	Negative -Postive	NA
9	Serum	HEV IgM	Immunochromatography	Negative -Postive	NA
11	Whole Blood	Malaria P4 Ag	Immunochromatography	Negative -Postive	NA
12	Serum	Dengue NS1 Ag, IgG, IgM Ab	Immunochromatography	Negative -Postive	NA
13	Serum	Salmonella typhi Ag	Immunochromatography	Negative -Postive	NA
14	Serum	Leishmania Ab	Membrane base Immunoassay	Negative -Postive	NA
15	Serum	TB IgG/ IgM	Lateral flow chromatography	Negative -Postive	5.5
17	Serum	Leptospira IgM	Immunochromatography	Negative -Postive	NA
18	Stool	H. pylori Ag	Immunochromatography	Negative -Postive	NA
19	Serum	H. pylori Ab	Immunochromatography	Negative -Postive	NA
20	Serum	Syphilis Ab	Immunochromatography	Negative -Postive	NA
21	Serum	HAV IgG	Immunochromatography	Negative -Postive	NA
<b>6. Molecular Biology</b>					
1.	EDTA Plasma	HLA B 27	RTPCR	Detected - Not detected	NA
2.	EDTA Plasma	HBV DNA	RTPCR	Detected - Not Detected	NA
3.	Sputum/ Urine / CSF /Body Fluid	MTB	RTPCR	Detected - Not Detected	NA
4.	EDTA Plasma	HCV RNA	RTPCR	1.00 E+09 TO 3.0E+02 IU/ml	NA
<b>7. Cytopathology</b>					
1.	Body fluids (Ascitic, pleural CSF, Synovial, pus, BAL fluid, ET Secretions, nipple discharge)	Centrifugation smear, preparation, pap, H& E and MGG staining	Light Microscopy with interpretation	Descriptive	NA
2.	Cervical and vaginal smears	PAP Stain	Light Microscopy with interpretation	Descriptive	NA
3.	Palpable or non-palpable lesion involving any organ	FNA, Smear, preparation, MGG staining with or without PAP/ H&E	Light Microscopy with interpretation	Descriptive	NA