



Scope of Accreditation for Medical Testing

As per ISO 15189:2012

Page No. 1 of 10

CAB Name : Spectrum Laboratory, Spectrum Clinical Research Pvt. Ltd.

Address : 5th floor, Manish Commercial Centre, Dr. A.B. Road Worli, Mumbai – 400030
Maharashtra, India

Certificate No: M-0004

Issue date : 05.10.2024

Validity* : 04.10.2028

Amendment date : NA

Medical Testing

Sr. No.	Parameter / Materials / Products tested	Type of Test/Properties measured/Range of measurement	Standard specifications / Equipment/Techniques used
Discipline: Clinical Biochemistry		Facility: Permanent	
1	Serum / plasma	Glucose (20 - 625 mg/dL)	Glucose Oxidase
2	Serum	Creatinine (0.05 - 14.0 mg/dL)	Enzymatic Method
3	Serum	Urea Nitrogen/ BUN (2-120 mg/dL)	Urease End point technique
4	Serum	Uric Acid (0.5 -17 mg/dL)	Enzymatic uricase / peroxidase
5	Serum	Cholesterol (50 - 325 mg/dL)	Enzymatic using cholesterol oxidase and ester hydrolase & peroxidase
6	Serum	D-HDL Cholesterol (5 - 110 mg/dL)	Non-HDL precipitation method followed by enzymatic detection.
7	Serum	Triglycerides (10 - 525 mg/dL)	Combination of enzymes LIP& GK; GPO / POD
8	Serum	Calcium (1 - 14 mg/dL)	Arsenazo Method
9	Serum	Total Bilirubin (0.1 - 27.0 mg / dL)	Modification of classic Diazo reaction using Dyphylline
10	Serum	Bu(Unconjugated/ Indirect bilirubin) (0.0 – 27.0 mg/dL)	Modified Jendrassik Grof method
11	Serum	Bc(Conjugated/ Direct Bilirubin)	Calculated

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Page No. 2 of 10

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12	Serum	Aspartate Amino Transferase (AST/SGOT) (3 - 750 U/L)	UV method using coenzyme pyridoxal-5-phosphate(P5P)
13	Serum	Alanine Amino Transferase (ALT/SGPT) (6 - 1000 U/L)	UV method using coenzyme pyridoxal-5-phosphate(P5P)
14	Serum	Alkaline Phosphatase (ALKP) (20 - 1500 U/L)	Method by Bowers and Mc Comb using p-NPP
15	Serum	Gamma Glutamyl Transpeptidase (GGT) (10 - 1400 U/L)	Using γ -glutamyl-4-nitroanilide technique
16	Serum	Total Protein (2 - 11 gm/dL)	Biuret End point reaction
17	Serum	Albumin (1.0 – 6.0 gm /dL)	Bromcresol Green Dye Binding method
18	Serum	Globulin	Calculated
19	Serum	LDL	Calculated (Friedwald's)
20	Serum	VLDL	Calculated (Friedwald's)
21	Serum	Sodium (75 – 250 mmol/L)	ISE Direct
22	Serum	Potassium (1 – 14 mmol/L)	ISE Direct
23	Serum	Chloride (50 – 175	ISE Direct

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Page No. 3 of 10

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		mmol/L)	
24	Serum	Phosphorous (0.5 – 13.0 mg/dL)	Ammonium Molybdate method
25	Whole Blood	Glycated hemoglobin (HbA1c) (2.7% - 19.7 %)	HPLC
26	Serum	Total T3 (Total Triiodothyronine) (10 – 800 ng/dL)	Competitive Immunoassay using Direct Chemiluminescent technology
27	Serum	Total T4 (Total Thyroxine) (0.3 – 30 µg/dL)	Competitive Immunoassay using Direct Chemiluminescent technology
28	Serum	TSH (Thyroid Stimulating Hormone) (0.010 – 150 µIU/ml)	Sandwich Immunoassay using Direct Chemiluminescent technology
29	Serum	PSA (Prostate Specific Antigen) (0.01 – 100 ng/ml)	Sandwich Immunoassay using Direct Chemiluminescent technology
30	Serum	Vitamin B12 (45 – 2000 pg/ml)	Competitive Immunoassay using Direct Chemiluminescent technology
31	Serum	Vitamin D (Total) (3.7 – 150 ng/ml)	Chemiluminescent Assay

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Page No. 4 of 10

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32	Serum	Free T3 (0.88 – 30.0 pg/ml)	Competitive Immunoassay
33	Serum	Free T4 (0.25 – 6.0 ng/dL)	Competitive Immunoassay
34	Serum	Luteinizing Hormone (LH) (0.2 – 250 mIU/ml)	Sandwich Immunoassay
35	Serum	Follicle-Stimulating Hormone (FSH) (0.2 – 200 mIU/ml)	Sandwich Immunoassay
36	Serum	Prolactin (PRL) (0.25 – 200 ng/ml)	Chemiluminescent Assay
37	Serum	Insulin (0.03 – 300 µIU/ml)	Sandwich Immunoassay
38	Serum	Human Chorionic Gonadotropin (HCG) (0.5 – 1000 mIU/ml)	Sandwich Immunoassay
39	Serum	Carcinoembryonic Antigen (CEA) (0.1 – 1000 ng/ml)	Sandwich Immunoassay
40	Serum	CA125 (0.5 – 5000 U/ml)	Sandwich Immunoassay

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41	Serum	CA 19.9 (0.8 – 2000 U/ml)	Chemiluminescent Assay
42	Serum	Alpha-Fetoprotein (AFP) (0.5 – 3000 ng/ml)	Sandwich Immunoassay
43	Serum	Immunoglobulin E (IgE) (5.7 – 1500 IU/ml)	Immunoturbidimetric Assay
Discipline: Clinical Pathology		Facility: Permanent	
44	Urine	Physical Examination (Colour)	Visual
45	Urine	Physical Examination (Volume)	Measuring Cylinder
46	Urine	Chemical Examination (pH) (5-8)	pH indicator principle
47	Urine	Chemical Examination (Specific Gravity)	Polymeric ionic exchanger
48	Urine	Chemical Examination (Albumin)	Dye binding indicator
49	Urine	Chemical Examination (Occult blood)	Peroxidase activity
50	Urine	Chemical Examination (Glucose)	Glucose oxidase
51	Urine	Chemical Examination (Ketones)	Nitroprusside test

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Page No. 6 of 10

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52	Urine	Chemical Examination (Urobilinogen)	Modified Ehrlich reaction
53	Urine	Chemical Examination (Bile Pigments)	Faucher's reaction
54	Urine	Chemical Examination (Bile salts)	Hay's sulphur flower test
55	Urine	Microscopic Examination after centrifugation (Pus Cells) (leukocytes)	Microscopy
56	Urine	Microscopic Examination after centrifugation (Epithelial Cells)	Microscopy
57	Urine	Microscopic Examination after centrifugation (Red Cells)	Microscopy
58	Urine	Microscopic Examination after centrifugation (Casts)	Microscopy
59	Urine	Microscopic Examination after centrifugation (Crystals)	Microscopy
60	Urine	Microscopic Examination after centrifugation (Miscellaneous will include	Microscopy

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Page No. 7 of 10

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		yeast, parasites and bacteria.)	
61	Urine	Pregnancy Test	Detection of Beta HCG
62	Stool	Physical Examination (Colour)	Visual
63	Stool	Physical Examination (form)	Visual
64	Stool	Chemical Examination (Occult Blood)	Haemtest TM Kit (Non-Benzidine Kit)
65	Stool	Chemical Examination (pH)	pH indicator paper
66	Stool	Microscopic Examination (Pus Cells)	Microscopy of Saline and Iodine smears
67	Stool	Microscopic Examination (Epithelial Cells)	Microscopy of Saline and Iodine smears
68	Stool	Microscopic Examination (Red Cells)	Microscopy of Saline and Iodine smears
69	Stool	Microscopic Examination (Ova)	Microscopy of Saline and Iodine smears
70	Stool	Microscopic Examination (Cysts)	Microscopy of Saline and Iodine smears
71	Stool	Concentration method (Ova)	Microscopy after Formalin – Ether sedimentation method

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Page No. 8 of 10

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72	Stool	Concentration method (Others)	Microscopy after Formalin – Ether sedimentation method
Discipline: Haematology		Facility: Permanent	
73	EDTA Whole Blood	Haemoglobin (0.0 – 30.0 g/dL)	Sysmex XN 1000 Photometry
74	EDTA Whole Blood	Red Blood Cells Count (0.00 - 10.00 x10 ⁶ /μL)	Sysmex XN 1000 Electrical Impedance
75	EDTA Whole Blood	Packed Cell Volume (PCV or Hematocrit) (0.0 - 80.0 HCT %)	Sysmex XN 1000 Electrical Impedance
76	EDTA Whole Blood	Indices	Sysmex XN 1000 Calculation
77	EDTA Whole Blood	White Blood Cells Count (0.0 - 100.0 x10 ³ /μL)	Sysmex XN 1000 Flow cytometry
78	EDTA Whole Blood	Platelets (0.0-1500.0 x10 ³ /μL)	Sysmex XN 1000 Electrical Impedance
79	EDTA Whole Blood	Differential Count (0 – 100 %)	Sysmex XN 1000 Flow cytometry
80	EDTA Whole Blood	Other parameters RDW PDW	Sysmex XN 1000 Electrical Impedance

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Page No. 9 of 10

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		P-LCR	
81	EDTA Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Capillary Photometry
82	EDTA Whole Blood	Blood Grouping	Tube agglutination
83	EDTA Whole Blood	Blood Rh factor	Tube agglutination
84	Citrated Plasma	Prothrombin Time (PT) (0 – 120 Seconds)	Tissue Thromboplastin in presence of Calcium initiating clotting mechanism
85	EDTA Whole Blood	Glucose-6- Phosphate Dehydrogenase (G6PD)	Dye decolouration using indophenol dye
Discipline: Microbiology & Infectious Disease Serology			Facility: Permanent
86	Serum	Hepatitis B surface antigen (HBsAg) (Reactive / Non- Reactive)	Immunochromatographic assay for the detection of Hepatitis B Surface Antigen
87	Serum	Venereal Disease Research Laboratory Test (VDRL) (Reactive / Non- Reactive)	Detection of Anti-lipoidal antibodies by flocculation method
88	Serum	Widal (Reactive / Non- Reactive)	Antigen - Antibody reaction

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89	Serum	Anti-hepatitis C virus (Anti-HCV) (Reactive / Non-Reactive)	Immunochromatographic assay for the detection of Hepatitis C virus

*This certificate will cease on 31.12.2025 in accordance with ILAC directive related to new ISO 15189:2022 version of the standard.

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