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to 13 October 2022
Issued on 17 December 2021



ISO 15189
ML 033-01

Schedule of Accreditation

Accreditation Scheme for Medical/Clinical Laboratories
Sri Lanka Accreditation Board for Conformity Assessment

Accreditation Number: ML 033-01

Ninewells Hospitals (Pvt) Ltd
55/1 Kirimandala Mawatha
Colombo 00500

Scope of Accreditation: Performing Medical/Clinical testing under the fields of Clinical Biochemistry/Chemical Pathology, Clinical Pathology and Haematology

The laboratory is accredited for the following tests.

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference Range/Detection Limit
01	Clinical Biochemistry / Chemical Pathology	Albumin	Colorimetric assay, Bromocresol Green method	Cobas C III	0.2 – 6.0 g/dl
		Alkaline Phosphatase	Colorimetric assay (PNPP, AMP, IFCC reference method)		3– 1200 U/L
		Amylase	Enzymatic colorimetric assay (G7PNP IFCC reference method)		3 - 1500 U/L
		Bilirubin (Total)	Colorimetric assay Diazotization method		0.1– 38 mg/dl
		Bilirubin (Direct)	3,5-dichlorophenyl diazonium method		0.09 – 17 mg/dl
		Serum Total Calcium	5-nitro-5'-methyl-BAPTA		0.8 – 20.1 mg/dl
		Cholesterol – HDL	Homogeneous enzymatic colorimetric assay		3– 120 mg/dl

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference Range/Detection Limit
01	Clinical Biochemistry / Chemical Pathology	Cholesterol – LDL	Homogeneous enzymatic colorimetric assay	Cobas C III	3– 550 mg/dl
		Cholesterol (Total)	Enzymatic colorimetric assay		9.7 – 800 mg/dl
		Triglycerides	Enzymatic colorimetric assay		8.8 -885 mg/dl
		Creatinine (Serum)	Enzymatic standardized IFCC IDMS		0.06 -30.5 mg/dl
		CRP	Particle enhanced turbidimetric assay		1 - 200 mg/dl
		Plasma Glucose (Fasting Blood Glucose, Random Blood Glucose, <i>postprandial</i> Blood Glucose, Glucose Challenge, Glucose Tolerance, Glucose Tolerance Extended, Blood Glucose Series)	Enzymatic reference method with Hexokinase method		2- 500 mg/dl
		AST	Colorimetric Kinetic assay		2 - 700 U/L
		GGT	Enzymatic colorimetric assay (G-Glutamyl carboxynitroanilide IFCC)		3 - 1200 U/L
		ALT	Colorimetric Kinetic assay (according to IFCC)		2 - 700 U/L
		Phosphorus	Colorimetric end point assay		0.3 – 20 mg/dl
		Potassium (Serum)	ISE		1.5 - 15 mmol/l
		Sodium (Serum)			40 -205 mmol/l
		Chloride (Serum)			50 -200 mmol/l
		Total Protein (Serum)	Colorimetric assay		2 - 120 g/dl
Urea	Colorimetric Kinetic assay	3 – 240 mg/dl			
Uric acid	Enzymatic Colorimetric	0.2– 25 mg/dl			

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference Range/Detection Limit
01	Clinical Biochemistry / Chemical Pathology	Ferritin	Sandwich <i>Chemiluminescence</i> immunoassay	Liaison XL	0.25 – 3000 ng/ml
		Follicle Stimulating Hormone (FSH)			0.25 – 400 mIU/ml
		Free triiodothyronine 3 (FT3)	Solid phase antigen linked technique (APALT) <i>Chemiluminescence</i> immunoassay		0.3 -30 pg/ ml
		Free thyroxine 4 (FT4)	Solid phase antigen linked technique (APALT) <i>Chemiluminescence</i> immunoassay		0.1 – 10 ng/ dl
		Luteinizing Hormone (LH)	Sandwich <i>Chemiluminescence</i> immunoassay		0.2 – 250 mIU/ ml
		Progesterone	Competitive Sandwich <i>Chemiluminescence</i> (<i>CLIA</i>) immunoassay		0.12– 60 ng/ ml
		Prolactin	Sandwich <i>Chemiluminescence</i> immunoassay		2 – 8000 mIU/l
		Thyroid Stimulating Hormone (TSH)	Sandwich <i>Chemiluminescence</i> immunoassay		0.04 – 100 mIU/L
		CA125	Sandwich <i>Chemiluminescence</i> immunoassay		0.3 - 1000 U/mL
		b-HCG	Sandwich <i>Chemiluminescence</i> immunoassay		0.3–10000 mIU/L
Estradiol	Competitive Sandwich <i>Chemiluminescence</i> (<i>CLIA</i>) immunoassay	10 – 10000 Pg/ml			

SI No	Field of Testing	Test	Test Method	Test Instrument	Reference Range/Detection Limit	
02	Clinical Pathology	Urine Full Report				
		Specific Gravity	Strip Method		1.000-1.030	
		pH			5-9	
		Protein			Negative -1000 mg/dl	
		Sugar (Glucose)			Negative -1000 mg/dl	
		Ketone Bodies			Trace/+/-	
		Urobilinogen			Normal/slightly increased/increased	
		Bilirubin			+/-	
		Nitrite			+/-	
		Pus cells			/hpf	
		Red cells			/hpf	
		Epithelial cells			+	
		Casts			Nil/+ /++	
		Crystals			Nil/+ /++	
Urine Pregnancy test	Chromatographic immunoassay		Positive/Negative			

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference Range/Detection Limit	
03	Haematology	ESR	Westergren Manual	Manual	10-200 mm/hr	
		Full Blood Count				
		WBC count	Hydrodynamic focussing and flow cytometer	Nihon Kohdon, Celltac ES	0.3-299 $10^3 \mu\text{L}$	
		RBC			0.4 -9.9 $10^{12}/\text{L}$	
		LYM			3-90 %	
		NE			2 – 99.9%	
		MO			4 - 99.9%	
		EO			1-99.9%	
		BA			0.5-99.9%	
		PLT			-0.9-1490 $10^3 / \mu\text{l}$	
		HGB			0.6-29.9 g/dl	
		PCV			0-99.9%	
		WBC count			Hydrodynamic focussing and flow cytometer	Sysmex XN-330
		RBC	0.01-8.60 $10^6 \mu\text{L}$			
		LYM	0.0 – 100%			
		NE	0.0 – 100%			
		MO	0.0 – 100%			
		EO	0.0 – 100%			
		BA	0.0 – 100%			
		PLT	2-5000 $10^3 \mu\text{L}$			
		HGB	0.1 – 26 g/dl			
		PCV	0.1– 75.0%			

Director/CEO
Sri Lanka Accreditation Board for Conformity Assessment
Colombo, Sri Lanka