

As an accredited laboratory, this laboratory is entitled to use the following accreditation symbol.



Valid from 20 March 2024
to 19 March 2028
Issued on 04 April 2024



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 Hospital (Pvt) Ltd
No 55/1 Kirimandala Mawatha
Colombo 05

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 (Serum)	Colorimetric assay, Bromocresol Green	Cobas C111	0.2 – 6.0 g/dL
				Thermo scientific Indiko	2.0 – 45.0 g/L
				BA 400 Bio System	1.21 – 70 g/L
		Alkaline Phosphatase (Serum)	Colorimetric assay (PNPP, AMP, IFCC reference method)	Cobas C111	3– 1200 U/L
				BA 400 Bio System	8.7 – 900 U/L
				Thermo scientific Indiko	20 – 1000 U/L
		Bilirubin Total (Serum)	Colorimetric assay Diazotization method	Cobas C111	0.1– 38 mg/dL
				Thermo scientific Indiko	0.06 – 29 mg/dL
				BA 400 Bio System	0.21 – 38 mg/dL
		Bilirubin Direct (Serum)	3,5-dichlorophenyly diazonium method	Cobas C111	0.09 – 17 mg/dL
Thermo scientific Indiko	0.06 – 20 mg/dL				

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference range / Detection Limit
01	Clinical Biochemistry / Chemical Pathology		Diazo	BA 400 Bio System	0.09- 15 mg/dL
		Total Calcium (Serum)	5'-nitro-5'-methyl-BAPTA	Cobas C111	0.8 – 20.1 mg/dL
			Arsenazo III	Thermo scientific Indiko	2.8 – 16.0 mg/dL
		BA 400 Bio System		0.42 – 18 mg/dL	
		Cholesterol HDL (Serum)	Homogeneous enzymatic colorimetric assay	Cobas C111	3– 120 mg/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	6 – 108 mg/dL
			Enzymatic colorimetric Direct assay	BA 400 Bio System	1.83 – 200 mg/dL
		Cholesterol LDL (Serum)	Homogeneous enzymatic colorimetric assay	Cobas C111	3– 550 mg/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	3 – 425 mg/dL
			Enzymatic colorimetric Direct assay	BA 400 Bio System	0.44 – 990 mg/dL
		Cholesterol Total (Serum)	Enzymatic colorimetric assay	Cobas C111	9.7 – 800 mg/dL
				Thermo scientific Indiko	8 – 579 mg/dL
				BA 400 Bio System	4.2 – 1000 mg/dL
		Triglycerides (Serum)	Enzymatic colorimetric assay	Cobas C111	8.8 – 885 mg/dL
				Thermo scientific Indiko	4 – 973 mg/dL
				BA 400 Bio System	5.99 – 600 mg/dL
		Creatinine (Serum)	Enzymatic standardized IFCC IDMS	Cobas C111	0.06 -30.5 mg/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	0.11 – 28 mg/dL
				BA 400 Bio System	0.05 – 30 mg/dL
		CRP (Serum)	Particle enhanced turbidimetric assay	Cobas C111	1 - 200 mg/dL
			Immuno turbidimetric	Thermo scientific Indiko	6 – 212 mg/dl
BA 400 Bio System	1.3 – 300 mg/dL				

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01	Clinical Biochemistry / Chemical Pathology	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	Cobas C111	2- 500 mg/dL
				BA 400 Bio System	0.728 – 750 mg/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	5 – 360 mg/dL
		AST (Serum)	Colorimetric Kinetic Assay	Cobas C111	2 - 700 U/L
				Thermo scientific Indiko	4 – 350 U/L
			Enzymatic colorimetric assay	BA 400 Bio System	7.15 - 500 U/L
		GGT (Serum)	Enzymatic colorimetric assay (G-Glutamyl carboxynitroanilide IFCC)	Cobas C111	3 - 1200 U/L
				Thermo scientific Indiko	15 - 600 U/L
				BA 400 Bio System	3.07 – 600 U/L
		ALT (Serum)	Colorimetric Kinetic assay (according to IFCC)	Cobas C111	2 - 700 U/L
				Thermo scientific Indiko	4 - 300 U/L
			Enzymatic colorimetric assay	BA 400 Bio System	8.5 – 500 U/L
		Phosphorus (Serum)	Colorimetric end point assay	Cobas C111	0.3 – 20 mg/dL
			Ammonium molibdate	Thermo scientific Indiko	0.2 – 12.4 mg/dL
			Phosphomolybdate/ UV	BA 400 Bio System	0.25 – 20 mg/dL
		Total Protein (Serum)	Colorimetric assay	Cobas C111	2 - 120 g/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	3 – 100 g/L
			Enzymatic colorimetric assay - Biuret	BA 400 Bio System	0.80 – 150 g/L

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference range / Detection Limit
01	Clinical Biochemistry / Chemical Pathology	Potassium (Serum)	ISE	RVL 9180 Roche	1.5 - 15 mmol/L
		Sodium (Serum)			40 -205 mmol/L
		Chloride (Serum)			50 -200 mmol/L
		Urea (Serum)	Colorimetric assay	Cobas C111	3 – 240 mg/dL
			Enzymatic colorimetric assay	Thermo scientific Indiko	9 – 120 mg/dL
			Enzymatic colorimetric assay - urease	BA 400 Bio System	3.69 – 300 mg/dL
		Uric acid (Serum)	Enzymatic Colorimetric	Cobas C111	0.2– 25 mg/dL
				Thermo scientific Indiko	0.2– 20.0 mg/dL
			Enzymatic colorimetric assay - uricase	BA 400 Bio System	0.31 – 25 mg/dL
		Ferritin (Serum)	Sandwich Chemiluminescence immunoassay		0.25 – 3000 ng/mL
		Follicle Stimulating Hormone (FSH) (Serum)			0.25 – 400 mIU/mL
		Free Triiodothyronine (FT3) (Serum)	Solid phase antigen linked technique (APALT) <i>Chemiluminescence</i> assay		0.3 – 30 pg/ mL
		Free Thyroxine 4 (FT4) (Serum)			0.1 – 10 ng/ dL
		Luteinizing Hormone (LH) (Serum)	Sandwich <i>Chemiluminescence</i> immunoassay	Diasorin Liaison XL	0.2 – 250 mIU/ mL
		Progesterone (Serum)	Competitive <i>Chemiluminescence</i> immunoassay		0.12– 60 ng/ mL
Prolactin (Serum)		2 – 8000 mIU/L			
Thyroid Stimulating Hormone (TSH) (Serum)	Sandwich <i>Chemiluminescence</i> immunoassay	0.04 – 100 mIU/L			
CA 125 (Serum)		0.3 - 1000 U/mL			

Sl No	Field of Testing	Test	Test Method	Test Instrument	Reference range / Detection Limit	
01	Clinical Biochemistry / Chemical Pathology	β-HCG (Serum)	Sandwich Chemiluminescence immunoassay	Diasorin Liaison XL	0.3–10000 mIU/L	
		Estradiol (Serum)	Sandwich Chemiluminescence immunoassay		10 – 1000 Pg/mL	
02	Clinical Pathology	Urine Full Report				
		Specific Gravity	DipStick Method	Urinalysis 10 Para strip (Abbott)	1.000 - 1.030	
		pH			5.0 – 9.0	
		Protein			Negative - 1000 mg/dL	
		Sugar (Glucose)			Negative - 2000 mg/dL	
		Ketone Bodies			Negative -100 mg/dL	
		Urobilinogen			Normal – increased amount /++++ (12mg/dL)	
		Bilirubin			Negative to +++(3.0 mg/dL)	
		Nitrite			Not Detected / Positive > 0.5 mg/dL	
		Pus cells	Microscopic examination	Microscope		
		Red cells				
		Epithelial cells				
		Casts				
		Crystals				
Urine Pregnancy test	Rapid chromatographic immunoassay	Urine HCG test strip - CTK	Positive/Negative			

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03	Haematology	ESR	Westergren Method	Manual	10-200 mm/hr	
		Full Blood Count				
		WBC count	Flow cytometry	SYSMEX XN-330	0.03-440 10 ³ µL	
		RBC	Hydro-dynamically focused DC detection method.		0.01-8.60 10 ⁶ µL	
		LYM	Flow cytometry method using semiconductor laser WDF Channel		0.0 – 100%	
		NE			0.0 – 100%	
		MO			0.0 – 100%	
		EO			0.0 – 100%	
		BA			0.0 – 100%	
		PLT	Hydro-dynamically focused DC detection method.		2-5000 10 ³ µL	
		HGB	SLS – Hemoglobin method		0.1 – 26 g/dl	
		PCV			0.1– 75.0%	
		MCV				
		MCH				
		MCHC				
RDW-CV						

Director/CEO
Sri Lanka Accreditation Board for Conformity Assessment