

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



Valid from 14 October 2022
to 13 October 2025
Issued on 14 February 2023



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.

SI 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
				Indiko	0.2-4.5 g/dL
		Alkaline Phosphatase (Serum)	Colorimetric assay (PNPP, AMP, IFCC reference method)	Cobas C111	3– 1200 U/L
				Indiko	20 – 1000 U/L
		Amylase (Serum)	Enzymatic colorimetric assay (G7PNP IFCC reference method)	Cobas C111	3 - 1500 U/L
		Bilirubin (Total) (Serum)	Colorimetric assay Diazotization method	Cobas C111	0.1– 38 mg/dL
				Indiko	0.06 – 29 mg/dL
		Bilirubin (Direct) (Serum)	3,5-dichlorophenyl diazonium method	Cobas C111	0.09 – 17 mg/dL
				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	Total Calcium (Serum)	5'-nitro-5'-methyl-BAPTA	Cobas C111	0.8 – 20.1 mg/dL
				Indiko	2.8 – 48 mg/dL
		Cholesterol HDL (Serum)	Homogeneous enzymatic colorimetric assay	Cobas C111	3– 120 mg/dL
				Indiko	6 – 108 mg/dL
		Cholesterol LDL (Serum)	Homogeneous enzymatic colorimetric assay	Cobas C111	3– 550 mg/dL
				Indiko	3 – 425 mg/dL
		Cholesterol Total (Serum)	Enzymatic colorimetric assay	Cobas C111	9.7 – 800 mg/dL
				Indiko	8 – 579 mg/dL
		Triglycerides (Serum)	Enzymatic colorimetric assay	Cobas C111	8.8 -885 mg/dL
				Indiko	4 -973 mg/dL
		Creatinine (Serum)	Enzymatic standardized IFCC IDMS	Cobas C111	0.06 -30.5 mg/dL
				Indiko	0.11 – 28 mg/dL
		CRP (Serum)	Particle enhanced turbidimetry assay	Cobas C111	1 - 200 mg/L
		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
				Indiko	5 – 720 mg/dL
		AST (Serum)	Colorimetric Kinetic Assay	Cobas C111	2 - 700 U/L
				Indiko	4 – 350 U/L
		GGT (Serum)	Enzymatic colorimetric assay (G-Glutamyl carboxynitroanilide IFCC)	Cobas C111	3 - 1200 U/L
				Indiko	15 - 600 U/L
		ALT (Serum)	Colorimetric Kinetic assay (according to IFCC)	Cobas C111	2 - 700 U/L
Indiko	4 - 300 U/L				
Phosphorus (Serum)	Colorimetric end point assay	Cobas C111	0.3 – 20 mg/dL		
		Indiko	0.2 – 12.4 mg/dL		

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01	Clinical Biochemistry / Chemical Pathology	Potassium (Serum)	ISE	RLV 9180	1.5 - 15 mmol/L
		Sodium (Serum)			40 -205 mmol/L
		Chloride (Serum)			50 -200 mmol/L
		Total Protein (Serum)	Colorimetric assay	Cobas C111	0.2 - 12 g/dL
				Indiko	0.3 – 10 g/dL
		Urea (Serum)	Colorimetric assay	Cobas C111	3 – 240 mg/dL
				Indiko	9 – 120 mg/dL
		Uric acid (Serum)	Enzymatic Colorimetric	Cobas C111	0.2– 25 mg/dL
				Indiko	0.2– 20 mg/dL
		Ferritin (Serum)	Sandwich Chemiluminescence immunoassay	Diasorin Liaison XL	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) Chemiluminescence assay		0.3 -30 pg/ mL
		Free thyroxine 4 (FT4) (Serum)	Solid phase antigen linked technique (APALT) Chemiluminescence assay		0.1 – 10 ng/ dL
		Luteinizing Hormone (LH) (Serum)	Sandwich Chemiluminescence immunoassay		0.2 – 250 mIU/ mL
		Progesterone (Serum)	Competitive Chemiluminescence immunoassay		0.12– 60 ng/ mL
		Prolactin (Serum)	Sandwich Chemiluminescence immunoassay		2 – 8000 mIU/L
Thyroid Stimulating Hormone (TSH) (Serum)	Sandwich Chemiluminescence immunoassay	0.04 – 100 mIU/L			
CA125 (Serum)	Sandwich Chemiluminescence immunoassay	0.3 - 1000 U/mL			
β-HCG (Serum)	Sandwich Chemiluminescence immunoassay	0.3–10000 mIU/L			
Estradiol (Serum)	Sandwich Chemiluminescence immunoassay	10 – 10000 Pg/mL			

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02	Clinical Pathology	Urine Full Report				
		Colour	Manual/Visual	-	Pale yellow/ Yellow/ Dark yellow/ Blood stained	
		Appearance		-	Clear/ Slightly turbid/ Turbid	
		Specific Gravity	Strip Method	Strip (Abbott UroColor 10)	1.000-1.030	
		pH			5-9	
		Protein			Negative -1000 mg/dL	
		Sugar (Glucose)			Negative -1000 mg/dL	
		Ketone Bodies			Negative -100 mg/dL (Negative/Trace/Positive)	
		Urobilinogen			Normal/slightly increased/increased	
		Bilirubin			Nil/Trace/Positive	
		Nitrite			Positive/Negative	
		Pus cells	Microscopic	Microscope	Occasional/HPF 0 – 100 / HPF >100 (field full)	
		Red cells			Nil Occasional/HPF 0 – 100 / HPF >100 (field full)	
		Epithelial cells			Nil/Few/+/++/+++	
		Casts			Nil/Few/+/++	
		Crystals			Nil/Few/+/++	
		Urine Pregnancy test	Lateral flow Chromatographic immunoassay	Strip (onsite CTK)	Positive/Negative	

SI 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 focusing 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 %		
		NEU			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 focusing and flow cytometer	Sysmex XN-330	0.03-440 $10^3 \mu\text{L}$
		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