

# Schedule of Accreditation



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INAB Reg No	296MT
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Accreditation Standard	ISO 15189
Date Initially Awarded	06/12/2011
Scope Classification	Microbiology and virology
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Services available to the public <sup>1</sup>	Yes

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered	
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)	
Name	Address
1 Head Office	Unit 3 Sandyford Business Centre, Sandyford Business Park, Dublin, D18

# Scope of Accreditation

## Head Office

### Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine Transferase	Serum/Plasma	L-lactate and NAD+/IFCC	Roche Cobas 6000 (MLP110144 and MLP110079)	L-lactate and NAD+/IFCC	CC-48, CC-14
	Albumin		Bromcresol Green/Colourimetric	Roche Cobas 6000 (MLP110144 and MLP110079)	Bromcresol Green/Colourimetric	CC-48, CC-7
	Albumin/Globulin Ratio		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-7
	Alkaline Phosphatase		Colourimetric/ p-nitrophenol	Roche Cobas 6000 (MLP110144 and MLP110079)	Colourimetric/ p-nitrophenol	CC-48, CC-12
	Amylase		Enzymatic colourimetric assay/ IFCC	Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic colourimetric assay/ IFCC	CC-48, CC-54
	Aspartate Transferase		NADH oxidation/ L-malate (IFCC) without pyridoxal phosphate	Roche Cobas 6000 (MLP110144 and MLP110079)	NADH oxidation/ L-malate (IFCC) without pyridoxal phosphate	CC-48, CC-13
	Bicarbonate		Phosphoenolpyruvate (PEP)	Roche Cobas 6000 (MLP110144 and MLP110079)	Phosphoenolpyruvate (PEP)	CC-48, CC-6
	Bilirubin Total		Azobilirubin/Colourimetric	Roche Cobas 6000 (MLP110144 and MLP110079)	Azobilirubin/Colourimetric	CC-48, CC-10
	Calcium		Schwarzenbach with o-cresolphthalein complexone	Roche Cobas 6000 (MLP110144 and MLP110079)	Schwarzenbach with o-cresolphthalein complexone	CC-48, CC-19
	Chloride		ISE, Indirect	Roche Cobas 6000 (MLP110144 and MLP110079)	ISE, Indirect	CC-48, CC-5
	Cholesterol		Enzymatic/Colourimetric method	Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic/Colourimetric method	CC-48, CC-

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Corrected Calcium		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-19
C-Reactive Protein		Particle-enhanced immuno-turbidimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Particle-enhanced immuno-turbidimetric assay	CC-48, CC-41
C-Reactive Protein - High Sensitivity		Particle-enhanced immuno-turbidimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Particle-enhanced immuno-turbidimetric assay	CC-48, CC-42
Creatine Kinase		D-6-phosphogluconate + NADPH + H +/UV Test	Roche Cobas 6000 (MLP110144 and MLP110079)	D-6-phosphogluconate + NADPH + H +/UV Test	CC-48, CC-15
Creatinine (Jaffe)		Alkaline Picrate	Roche Cobas 6000 (MLP110144 and MLP110079)	Alkaline Picrate	CC-48, CC-9
Enzymatic Creatinine		Enzymatic	Roche Cobas 6000 (MLP110079)	Enzymatic	CC-48, CC-9
Estimated GDFR (MDRD)		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-9
Free T3		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-2
Free T4		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-3
Gamma Glutamate Transferase		Enzymatic colourimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic colourimetric assay	CC-48, CC17
Globulin		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-7
Glucose	Serum/Fluoride Oxalate	Enzymatic reference method with hexokinase	Roche Cobas c311 (MLP110044) Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic reference method with hexokinase	CC-1, CC-48, CC-22
HDL Cholesterol	Serum/Plasma	Homogeneous enzymatic colourimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Homogeneous enzymatic colourimetric assay	CC-48, CC-27
Lactate Dehydrogenase		Pyruvate + NADH + H +/UV assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Pyruvate + NADH + H +/UV assay	CC-48, CC-16
LDL Cholesterol		Homogeneous enzymatic colourimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Homogeneous enzymatic colourimetric assay	CC-48, CC-28
Lithium	Serum	Colometric	Roche Cobas 6000 (MLP110144 and MLP110079)	Colometric	CC-48, CC-59
Magnesium	Serum/Plasma	Colourimetric method with	Roche Cobas	Colourimetric method with	CC-

			Chlorophosphonazo III	6000 (MLP110144 and MLP110079)	Chlorophosphonazo III	48, CC-20
	Phosphate		Molybdate UV	Roche Cobas 6000 (MLP110144 and MLP110079)	Molybdate UV	CC-48, CC-21
	Potassium		ISE, Indirect	Roche Cobas 6000 (MLP110144 and MLP110079)	ISE, Indirect	CC-48, CC-5
	Sodium		ISE, Indirect	Roche Cobas 6000 (MLP110144 and MLP110079)	ISE, Indirect	CC-48, CC-5
	Thyroid Stimulating Hormone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-1
	Thyroxine (T4)		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-31
	Total Protein		Colourimetric	Roche Cobas 6000 (MLP110144 and MLP110079)	Colourimetric	CC-48, CC-18
	Triglyceride		Enzymatic/Colourimetric test	Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic/Colourimetric test	CC-48, CC-25
	Troponin T hs	Plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-32
	Urea	Serum/Plasma	Kinetic test with urease and glutamate dehydrogenase	Roche Cobas 6000 (MLP110144 and MLP110079)	Kinetic test with urease and glutamate dehydrogenase	CC-48, CC-8
	Uric Acid		Enzymatic colourimetric test	Roche Cobas 6000 (MLP110144 and MLP110079)	Enzymatic colourimetric test	CC-48, CC-23
1061 Clinical Chemistry - .20 Hormones	Anti-Mullerian Hormone (AMH)	Serum/Plasma/Capillary Blood	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, CC-58
	Beta-HCG	Serum/Plasma	Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-17
	Estradiol		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-15
	Follicular Stimulating Hormone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-16
	Luteinizing Hormone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-18
	Progesterone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-

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	Prolactin		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-20
	Testosterone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-21
1061 Clinical Chemistry - .40 Iron studies	Ferritin		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-4
	Iron		Colourimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Colourimetric assay	CC-48, CC-24
	Total Iron Binding Capacity		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-44
	Transferrin		Immunoturbidimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Immunoturbidimetric assay	CC-48, CC-40
	Transferrin Saturation		Calculated	Roche Cobas 6000 (MLP110144 and MLP110079)	Calculated	CC-48, CC-24
	Unsaturated Iron Binding Capacity		Direct determination with FerroZine	Roche Cobas 6000 (MLP110144 and MLP110079)	Direct determination with FerroZine	CC-48, CC-44
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-6
	Vitamin B12		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-5
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, CC-61
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Total Prostate Specific Antigen		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas 6000 (MLP110144 and MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	CC-49, EN-27
1061 Clinical Chemistry - .60 Glycohaemoglobins	Haemoglobin A1C (IFCC)	Whole Blood	Turbidimetric Inhibition Immunoassay (TINIA)	Roche Cobas c311 (MLP110044) Roche Cobas 6000 (MLP110144 and MLP110079)	Turbidimetric Inhibition Immunoassay (TINIA)	CC-1, CC-48, CC-39
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Immunochemical Testing (FIT)	Faeces	Latex agglutination	Diana QC Sensor (MLP110113) & (MLP110114)	Latex agglutination	CC-55
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative	Rheumatoid Factor	Serum/Plasma	Immunoturbidimetric assay	Roche Cobas 6000 (MLP110144 and MLP110079)	Immunoturbidimetric assay	CC-48, CC-43

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Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Counts (Including Red Cell Count, Haemoglobin, Haematocrit, Mean Cell Volume, Mean Cell Haemoglobin, Mean Cell HB CONC, White Cell Count, Total, Neutrophils (Absolute), Neutrophils (%), Lymphocytes (Absolute), Lymphocytes (%), Monocytes (Absolute), Monocytes (%), Eosinophils (Absolute), Eosinophils (%), Basophils (Absolute), Basophils (%), Platelets Count, RDW, MPV	Whole Blood	Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	Sysmex XE-2100 (Flow Cytometer) (MLP110020) & Sysmex XS-1000i (MLP110143)	Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	HM-1, HM-2, HM-19
			Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	Sysmex XE-2100 (Flow Cytometer) (MLP110020) & Sysmex XS-1000i (MLP110143)	Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	HM-1, HM-2, HM-19
			Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	Sysmex XE-2100 (Flow Cytometer) (MLP110020) & Sysmex XS-1000i (MLP110143)	Fluorescent Flow Cytometry/Hydrodynamic Focusing, DC-Sheath Flow Cytometry, Sulfolyzer (SLS)-Haemoglobin method, Calculated/Derived, Sulfolyzer (SLS)-Haemoglobin Method	HM-1, HM-2, HM-19
1030 Haematology - .02 Visual examination of blood films	Blood Film Morphology		Romanowsky	Olympus BX-45 (Microscope) (MLP110056)	Romanowsky	HM-1, HM-6
			Romanowsky	Olympus BX-45 (Microscope) (MLP110056)	Romanowsky	HM-1, HM-6
			Romanowsky	Olympus BX-45	Romanowsky	HM-1,

				(Microscope) (MLP110056)		HM-6
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate		Sedivette	Sarstedt Sedivette ESR Rack (MLP110042)	Sedivette	HM-1, HM-8
			Sedivette	Sarstedt Sedivette ESR Rack (MLP110042)	Sedivette	HM-1, HM-8
			Sedivette	Sarstedt Sedivette ESR Rack (MLP110042)	Sedivette	HM-1, HM-8
1030 Haematology - .09 Examination of malarial parasites	Examination for Malaria Parasites		Procedures for the investigation of malaria parasites	Olympus BX-45 (Microscope) (MLP110056)	Procedures for the investigation of malaria parasites	HM-18
			Procedures for the investigation of malaria parasites	Olympus BX-45 (Microscope) (MLP110056)	Procedures for the investigation of malaria parasites	HM-18
			Procedures for the investigation of malaria parasites	Olympus BX-45 (Microscope) (MLP110056)	Procedures for the investigation of malaria parasites	HM-18
1030 Haematology - .41 General haemostasis related tests	ACTIVATED PARTIAL THROMBOPLASTIN TIME	CITRATE, PLASMA	CLOTting METHOD	SYSMEX CA660	CLOTting METHOD	HM-26
	FIBRINOGEN (CLAUSS)		CLOTting METHOD	SYSMEX CA660	CLOTting METHOD	HM-27
	INR		CLOTting METHOD	SYSMEX CA660	CLOTting METHOD	HM-25
	PROTHROMBIN TIME		CLOTting METHOD	SYSMEX CA660	CLOTting METHOD	HM-25



Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1052 Cytopathology - .01 Gynaecological (cervical)	Gynaecological	Thin Prep	Hologic Panther	High Risk HPV using Hologic Panther; thin prep LBC sample mRNA (messenger Ribonucleic Acid) * Not used for Primary Screening		MB-12, MB-13
	High Risk HPV	Thinprep LBC Sample	Roche 4800 Analyser	High Risk HPV	n/a	MB-9, MB-10
			Roche 4800 Analyser	High Risk HPV	n/a	MB-9, MB-10
			Roche 4800 Analyser	High Risk HPV	n/a	MB-9, MB-10
			Roche 4800 Analyser	High Risk HPV	n/a	MB-9, MB-10
	Papanicolaou Stained LBC Slide Sample		Olympus BX-45 Microscope	Papanicolaou Stained LBC Slide Sample	n/a	CY-2, CY-3, CY-6, CY-11
			Olympus BX-45 Microscope	Papanicolaou Stained LBC Slide Sample	n/a	CY-2, CY-3, CY-6, CY-11
			Olympus BX-45 Microscope	Papanicolaou Stained LBC Slide Sample	n/a	CY-2, CY-3, CY-6, CY-11
			Olympus BX-45 Microscope	Papanicolaou Stained LBC Slide Sample	n/a	CY-2, CY-3, CY-6, CY-11
	ThinPrep LBC Sample		Hologic T5000	ThinPrep LBC Sample	n/a	CY-39
			Hologic T5000	ThinPrep LBC Sample	n/a	CY-39
			Hologic T5000	ThinPrep LBC Sample	n/a	CY-39
			Hologic T5000	ThinPrep LBC Sample	n/a	CY-39
	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining		Leica staining machine and coverslipper	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining	n/a	CY-9
			Leica staining machine and coverslipper	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining	n/a	CY-9

			Leica staining machine and coverslipper	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining	n/a	CY-9
			Leica staining machine and coverslipper	Unstained ThinPrep LBC Sample for Papanicolaou (PAP) Staining	n/a	CY-9

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Chlamydia Trachomatis (CT)	Urine/Swab	Roche Cobas 4800 (MLP1100096 & MLP110097)	Real time PCR amplification	n/a	MB-11
	Neisseria Gonorrhoeae (NG)		Roche Cobas 4800 (MLP1100096 & MLP110097)	Real time PCR amplification	n/a	MB-11
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Anti-Hepatitis B Core (HBcAb)	Serum/Plasma/CAPILLARY BLOOD	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	LOD <= 0.8 U/ml	CC-2, CC-49, SR-8
	Anti-Hepatitis C Virus (HCVAb)		Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	0.9 COI	CC-2, CC-49, SR-4
	Hepatitis B Surface Antibody (HBsAb)	Serum/Plasma	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	2-1000 IU/L	CC-2, CC-49, SR-3
	Hepatitis B Surface Antigen (HBsAg)	Serum/Plasma/CAPILLARY BLOOD	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	0.05-130 COI	CC-2, CC-49, SR-1
	HIV Combi (HIV)		Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	LOD <= 2 IU/ml	CC-2, CC-49, SR-5
	Rubella IgG (Rubella IgG)	Serum/Plasma	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	0.17 -500 IU/ml	CC-2, CC-49, SR-6
	Syphilis	Serum/Plasma/CAPILLARY BLOOD	Roche Cobas e411 (MLP110045) & Roche Cobas 6000 (MLP110144) & (MLP110079)	Electrochemiluminescence Immunoassay (ECLIA)	LOD <0.7 COI	CC-2, CC-49, SR-10

