

Schedule of Accreditation



Organisation Name	Mater Misericordiae University Hospital
Trading As	
INAB Reg No	232MT
Contact Name	Denise O'Neill
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Accreditation Standard	ISO 15189
Date of award of accreditation	09/06/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Scope Classification	Genetics

Services available to the public¹

¹ 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	Mater Misericordiae University Hospital	Pathology Laboratory, Eccles Street, Dublin, D7

Scope of Accreditation

Mater Misericordiae University Hospital

Blood Transfusion Science

Category: A

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
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	Blood grouping (ABO & RhD)	Blood with EDTA, Blood with no anticoagulant (Clotted)	Manual gel cards and tube techniques	CE	Not applicable	LP-BT-ROU-07 LP-BT-ROU-42
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods		Blood with EDTA	BioRad IH-1000	CE	Not applicable	LP-BT-ROU-33
	Blood Grouping (ABO & RhD), Confirmation of ABO and RhD groups of donor units	Red Blood Cells	BioRad IH-1000	CE	Not applicable	LP-BT-ROU-33
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Blood with EDTA, Blood with no anticoagulant (Clotted), Eluate	BioRad IH-1000	CE	Not applicable	LP-BT-ROU-33
			Manual gel cards	CE	N/A	LP-BT-ROU-08

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual gel cards	CE	Not applicable	LP-BT-ROU-09
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatching	Blood with EDTA, Blood with no anticoagulant (Clotted)	Manual gel cards	CE	Not applicable	LP-BT-ROU-11
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Blood with EDTA, Whole blood, Red blood cells	Manual gel cards and tube techniques	CE	Not applicable	LP-BT-ROU-10
1020 Transfusion science - .07 Antibody elution	Antibody Screening	Eluate	Elution	Based on standard method	N/A	LP-BT-ROU-15
	Antibody Elution Testing of EDTA specimens	Blood with EDTA	Elution	CE	Not applicable	LP-BT-ROU-15
	Antibody Identification	Eluate	Elution	Based on standard method	N/A	LP-BT-ROU-15
1020 Transfusion science - .09 Direct antiglobulin test	Direct Coombes Testing	Blood with EDTA, Whole blood, Red blood cells	Manual gel cards	CE	Not applicable	LP-BT-ROU-13

a The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

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	24 hour Urine Amylase	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Calcium		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Chloride		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Creatinine		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Magnesium		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Phosphate		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Potassium		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Sodium		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Urate		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Urea		Calculated	NA	Based on standard method	LI-CCE-0040
	Alanine Aminotransferase (ALT)	Plasma/ Serum	NADH (without P-5'-P)	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Albumin/Creatinine Ratio	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Alkaline Phosphatase	Plasma/ Serum	IFCC with PNPP	Abbott Architect	CE	LI-CCE-0003	

(ALP)			c16000 Alinity ci series		LI-CCE-0125
Ammonia	Plasma	Colorimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Amylase	Plasma/ Serum/ Fluid/ Urine	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Anion Gap	Plasma/Serum	Calculated	NA	Based on standard method	LI-CCE-0040
Aspartate Aminotransferase (AST)	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Bilirubin direct		Diazo	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Bilirubin Total		Diazo	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
BNP	Plasma	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Calcium	Plasma/ Serum/ Urine	Arsenazo III	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Calcium Creatinine Clearance	Plasma / Serum / Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Calcium Creatinine Ratio	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Chloride	Plasma/ Serum/ Urine	Ion selective electrode	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Cholesterol	Plasma/ Serum	Cholesterol oxidase	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Corrected Calcium		Calculated	n/a	Laboratory Developed Test	LI-CCE-0040
Creatine Kinase (CK)		Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

Creatinine	Plasma/ Serum/ Fluid/ Urine	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Creatinine Clearance	Plasma/ Serum/ Urine	Calculated	n/a	Based on standard method	LP-CCE-0030
eGFR	Plasma/ Serum	Calculated	n/a	Based on standard method	LI-CCE-0040
Fractional Excretion of Sodium	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Fractional Excretion of Uric Acid		Calculated	NA	Based on standard method	LI-CCE-0040
Gamma Glutamyl Transferase (GGT)	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Glucose	Plasma/ CSF/ Urine	Hexokinase	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
HDL cholesterol	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Lactate Dehydrogenase (LDH)	Serum/ Fluid	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
LDL cholesterol	Plasma/ Serum	Enzymatic/ Calculated	Abbott Architect c16000 Alinity ci series	CE and Based on standard method	LI-CCE-0003 LI-CCE-0040 LI-CCE-0125
Lipase	Serum / Plasma	Colorimetric	Abbott Alinity ci series	CE	LI-CCE-0125
Lithium	Serum	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
Magnesium	Plasma/ Serum/ Urine	Arsenazo	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Non HDL Cholesterol	Plasma/Serum	Calculated	N/A	Calculated	LI-CCE-0040
NT-proBNP	EDTA	Chemiluminescent microparticle immunoassay (CIMA) technology	Abbott Allinity/Architect	CE	LI-CCE-0003 LI-CCE-0125
Phosphate	Plasma/ Serum/	Colorimetric	Abbott Architect	CE	LI-CCE-0003

		Urine		c16000 Alinity ci series		LI-CCE-0125
	Potassium		Ion selective electrode	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Sodium		Ion selective electrode	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Total CO2	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Triglycerides	Plasma/ Serum/ Fluid	Glycerol Phosphate Oxidase	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Troponin I (High sensitivity)	Plasma	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Urea	Plasma/ Serum/ Fluid/ Urine	Urease	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Uric Acid	Plasma/ Serum/Urine	Uricase	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin	Plasma/ Serum	Bromocresol Green	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	C-Reactive Protein (CRP)		Immunoturbidimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Globulins	Plasma / Serum	Calculated	NA	Based on standard method	LI-CCE-0040
	Microalbumin	Urine	Immunoturbidimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Protein / Creatinine ratio		Calculated	NA	Based on standard method	LI-CCE-0040
	Protein -Total	Plasma/ Serum	Biuret	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
		Urine/ CSF	Benzethonium Chloride	Abbott Architect c16000	CE	LI-CCE-0003 LI-CCE-0125

				Alinity ci series		
	SHBG	Plasma / Serum	Immunoassay	Abbott Architect Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
1061 Clinical Chemistry - .05 CO-oximetry	Carboxyhaemoglobin	Blood	Cooximetry	ABL 90 Flex	Based on standard method	LP-CCE-0049
	Ionised Calcium		ISE	ABL90 Flex	CE	LP-CCE-0049
	Methaemoglobin		Cooximetry	ABL90 Flex	Based on standard method	LP-CCE-0049
	Oxyhaemoglobin		Cooximetry	ABL90 Flex	CE	LP-CCE-0049
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pO2		Potentiometric	ABL90 Flex	CE	LP-CCE-0049
	pCO2		Potentiometric	ABL90 Flex	CE	LP-CCE-0049
	pH		Potentiometric	ABL90 Flex	CE	LP-CCE-0049
	SO2		Absorption Spectroscopy	ABL 90 Flex	CE	LP-CCE-0049
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess		Calculated	ABL 90 Flex	Based on standard method	LP-CCE-0049
	Lactate		Amperometric	ABL90 Flex	CE	LP-CCE-0049
	Potassium		Ion selective electrode	ABL90 Flex	CE	LP-CCE-0049
	Sodium		Ion selective electrode	ABL90 Flex	CE	LP-CCE-0049
	Standard Bicarbonate		Calculated	ABL90 Flex	Based on standard method	LP-CCE-0049
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Acetaminophen	Plasma	Spectrophotometric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Amikacin	Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Carbamazepine		Petinia	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Corrected Phenytoin		Calculated	NA	Based on standard method	LI-CCE-0040

Cyclosporin	Whole Blood	LC-MS/MS	Waters TQD Waters Xevo TQ Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
Digoxin	Serum	Particle Enhanced Turbidimetric Assay	Abbott Alinity ci series Abbott Architect c1600	CE	LI-CCE-0003 LI-CCE-0125
Gentamicin	Plasma/ Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Methotrexate	Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Phenobarbitone		Petinia	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Phenytoin		Enzyme Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Sirolimus	Whole blood	LC-MS/MS	Waters TQD MS Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
Tacrolimus		LC-MS/MS	Waters TQD MS Waters Xevo TQ Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
Theophylline	Serum	Enzyme Immunoassay	Abbott Alinity ci series	CE	LP-CCE-0064 LI-CCE-0125
Tobramycin		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Valproate		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Vancomycin	Plasma/ Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

	Voriconazole	Serum	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0050
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol	Plasma	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
1061 Clinical Chemistry - .20 Hormones	Adrenocorticotrophic hormone (ACTH)	EDTA on ice	Immunometric Assay	Roche Cobas	CE	LP-CCE-0057
	Androstenedione	Serum	LC-MS/MS	Waters Xevo TQ	Laboratory Developed Test	LP-CCE-0055
	Cortisol	Plasma/ Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
	C-Peptide	Plasma / Serum	CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect i2000 Alinity ci series	CE	LP-CCE-0003 LI-CCE-0125
	Follicle Stimulating Hormone (FSH)		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Growth Hormone	Serum	Immunoassay	IDS iSYS	CE	LP-CCE-0051
	HCG- Total	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	IGF-1	Serum	Immunoassay	IDS iSYS	CE	LP-CCE-0035
	Insulin	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Lutenising Hormone (LH)		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Macroprolactin	PEG Precipitation		Abbott Architect i2000 Alinity ci series	Based on standard method	LP-CCE-0005 LI-CCE-0125	
Oestradiol	Immunoassay		Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	

	Parathyroid Hormone (PTH)	Plasma	Immunoassay	Roche e411	CE	LP-CCE-0048
	Progesterone	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Prolactin		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	T3 free		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	T4 free	Plasma/ Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
	Testosterone	Serum	LC-MS/MS	Waters Xevo TQ MS	Laboratory Developed Test	LP-CCE-0055
	Thyroid Stimulating Hormone (TSH)	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Urine Free Cortisol	24 hour Urine	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0029
1061 Clinical Chemistry - .40 Iron studies	Ferritin	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Iron	Plasma/ Serum	Colorimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
	Transferrin		Immunoturbidimetric	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Transferrin Saturation		Calculated	n/a	Based on standard method	LI-CCE-0040
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Folate Red Cell	Blood	Immunoassay	Abbott Architect i2000 Abbott Architect ci series	Based on standard method	LP-CCE-0010 LI-CCE-0125

	Vitamin B12	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
1061 Clinical Chemistry - .47 Vitamin assays	Active B12/ Holotranscobalamin	Serum	CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect Immunoassay Alinity ci series	Based on a standard method	LI-CCE-0115 LI-CCE-0125
	Vitamin D		LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0002
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP)	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	CA-125	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	CA-15-3		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	CA-19-9		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Calcitonin (hCT)	Serum on ice	Immunoassay	Roche Cobas	CE	LP-CCE-0058
	CEA	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	PSA Total		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Thyroglobulin	Serum	Immunoassay	Roche Cobas	CE	LP-CCE-0059
1061 Clinical Chemistry - .52 Collagen cross-link markers	C-terminal Telopeptide of Type 1 collagen (CTX-1)	Plasma	Immunoassay	Roche e411	CE	LP-CCE-0031
	Procollagen Type 1 N- Propeptide (P1NP)		Immunoassay	Roche e411	CE	LP-CCE-0032
1061 Clinical Chemistry - .56 Biogenic amines	Homocysteine		CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect Immunoassay Alinity ci series	CE	LI-CCE-0118 LI-CCE-0125
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c	EDTA	HPLC	Menarini HA-8180v	CE	LP-CCE-0060
1061 Clinical Chemistry -	Stone Analysis	Stone	FT-IR	Nicolet iS10	Based on a standard	LP-CCE-0041

.77 Calculi					method	
1061 Clinical Chemistry - .78 Intermediary metabolites	3 -Methoxytyramine	EDTA on ice	LC-MS/MS	Waters Xevo TQ MS	Laboratory Developed Test	LP-CCE-0053
	Plasma Metanephrines	EDTA Plasma on ice	LC-MS/MS	Waters Xevo TQ MS	Laboratory Developed Test	LP-CCE-0053
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Thyroglobulin Antbodies	Serum	Electrochemiluminescence immunoassay	Roche e411	Based on standard method	LP-CCE-0059
1061 Clinical Chemistry - .99 Miscellaneous tests	Free Androgen Index		Calculated	n/a	Based on standard method	LI-CCE-0040, LI- CCE-0008
	Free Testosterone		Calculated	n/a	Based on standard method	LI-CCE-0040
	Osmolality		Plasma/ Serum/ Urine	Freezing Point Depression	Advanced Osmometer 3320	CE
	Thyroid peroxidase (TPO) antibodies	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

b The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.

Chemical Pathology

Category: B

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	Glucose	Blood	Amperometric	ABL 90 Flex	CE	LP-POC-001
		Fresh Capillary Blood	Enzymatic and Amperometric	Stat Strip Nova Biomedical hand held device & docking station	Based on standard method	LP-POC-016
	Ketone		Enzymatic and Amperometric	Stat Strip Nova Biomedical hand held device & docking station	Based on standard method	LP-POC-015
1061 Clinical Chemistry - .05 CO-oximetry	Haematocrit	Blood	Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
			Impedance	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Haemoglobin		Chemometrics applied to optical absorbance	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Haemoglobin & Haemoglobin Derivatives		Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
	Ionised Calcium		ISE	ABL 90 Flex	CE	LP-POC-001
	Ionised Magnesium		ISE	Phox Ultra analyser	CE	LP-POC-005
	Standard Bicarbonate		Calculated	Prime Plus Blood Gas Analyser	CE	LP-POC-017
1061 Clinical Chemistry - .06 Blood pH and gas	pO ₂		Amperometric	Abbott i-Stat	CE	LP-POC-010

tensions						
	pCO2	Potentiometric	ABL 90 Flex	CE	LP-POC-001	
	pCO2	Potentiometric	Abbott i-Stat	CE	LP-POC-010	
	pH	Potentiometric	ABL 90 Flex	CE	LP-POC-001	
	pO2	ISE Potentiometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
	SO2	Potentiometric	ABL 90 Flex	CE	LP-POC-001	
	1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess	ISE	Abbott i-Stat	CE	LP-POC-010
		Glucose	ISE	ABL 90 Flex	CE	LP-POC-001
Ionised Calcium		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
Ionised Magnesium		ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
Ionised Calcium		Potentiometric	ABL 90 Flex	CE	LP-POC-001	
Lactate		Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001	
		Chemometrics applied to optical absorbance	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
		Calculated	ABL 90 Flex	CE	LP-POC-001	
		Calculated	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
		Amperometric	ABL 90 Flex	CE	LP-POC-001	
		ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
		ISE	ABL 90 Flex	CE	LP-POC-001	
		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017	
	Amperometric	ABL 90 Flex	CE	LP-POC-001		
	ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017		

	Potassium	ISE	Abbott i-Stat	CE	LP-POC-010
		ISE	ABL 90 Flex	CE	LP-POC-001
		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Sodium	ISE	Abbott i-Stat	CE	LP-POC-010
		ISE	ABL 90 Flex	CE	LP-POC-001
		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Standard Bicarbonate	Calculated	ABL 90 Flex	CE	LP-POC-001

b The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.

Mater Misericordiae University Hospital

Genetics

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1075 Molecular genetics - .05 Screening for unidentified pathogenic variant(s)	DNA Sequencing	Whole blood	DNA Sequencing	MagNA Pure 24, Qubit, TapeStation, SimpliAmp, NextSeq	CE	LP-NGS-9, LP-NGS-10, LP-NGS-11, LP-NGS-12, LP-NGS-14, LP-NGS-16, LP-NGS-17, LP-NGS-25, LP-NGS-26, LP-NGS-26

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	Haematocrit (Hct)	Blood	Culmulative pulse measurement	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Haemoglobin (Hb)		Sodium Lauryl Sulphate (SLS) Haemoglobin	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	MCH		Calculated from Hb and RBC	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	MCHC		Calculated from Hb and HCT	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Mean cell volume(MCV)		Indirect measurement (mean of RBC volume)	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Platelet count		Hydrodynamic Focussing Direct Current (DC)	Sysmex XN-10/XN 20	CE	LP-HAE-

		detection			0067, LP- HAE- 0068
	Red cell count(RBC)	Hydrodynamic Focussing Direct Current (DC) detection	Sysmex XN-10/XN 20	CE	LP- HAE- 0067, LP- HAE- 0068
	White cell count (WBC)	Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP- HAE- 0067, LP- HAE- 0068
1030 Haematology - .02 Visual examination of blood films	Blood film examination includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Red Cell morphology	Staining/microscopy/Digital imaging	Wescor stainer/ Sysmex SP10 stainer/Microscope/CellaVision DI-60 automated digital imaging analysis system with operator result validation	Based on standard method	LP- HAE- 004 LP- HAE- 006 LP- HAE- 070 LP- HAE- 072
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)	Photo optical based on Westergren method	Sarstedt Sediplus S2000	CE	LP- HAE- 024
1030 Haematology - .05 Automated differential leucocyte counts	Automated basophil count	Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP- HAE- 0067, LP- HAE- 0068
	Automated eosinophil count	Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP- HAE- 0067, LP- HAE- 0068

	Automated lymphocyte count		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated monocyte count		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated neutrophil count		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte count		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
1030 Haematology - .08 Blood film examinations involving special staining procedures	Iron stain (Bone marrow and Urinary haemosiderin)	Bone marrow /Urine	Staining/ microscopy	Manual staining technique/ Microscope	Based on standard method	LP-HAE-031
1030 Haematology - .09 Examination of malarial parasites	Malaria Blood film examination	Blood	Staining/ microscopy	Manual staining technique/ Microscope	Based on standard method	LP-HAE-025, LP-HAE-026
	Malaria screening test		Immunochromatographic card screening test	Manual immunochromatographic card test	CE	LP-HAE-027
1030 Haematology - .20 Bone marrow examination	Bone marrow examination	Bone marrow aspirate	Staining/ microscopy	Wescor stainer/Microscope	Based on standard method	LP-HAE-007
1030 Haematology - .30 Tests for haemoglobin	Haemoglobin Electrophoresis	Blood	Capillary Electrophoresis	Sebia Minicap Flex piercing	CE	LP-HAE-083

variants and thalassaemia						
	HPLC for Haemoglobinopathy		High performance liquid chromatography	Biorad D10	CE	LP-HAE-050
	Sickle cell screen		Qualitative solubility test for Hb S	Manual test	CE	LP-HAE-028
1030 Haematology - .36 Screening tests for G6Pd	Glucose 6 Phosphate Dehydrogenase screen		Qualitative fluorescence test	Manual test	CE	LP-HAE-029
1030 Haematology - .40 Limited haemostasis related tests	Activated Protein C resistance		Photo optical	ACL TOP 550	CE	LP-HAE-089
	Anti Xa level(LMWH)		Chromogenic	ACL TOP 550	CE	LP-HAE-092
	Anti Xa level(UFH)		Chromogenic	ACL TOP 550	CE	LP-HAE-097
	Anticoagulant drug monitoring: Rivaroxaban / Apixaban / Dabigatran		Chromogenic	ACL TOP 550	CE	LP-HAE-093, LP-HAE-095
	Antithrombin		Chromogenic	ACL TOP 550	CE	LP-HAE-089
	Factor II:C assay		Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor IX:C assay		Photo optical	ACL TOP 550	CE	LP-HAE-103
	Factor V:C assay		Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor VII:C assay		Photo optical	ACL TOP 550	CE	LP-HAE-102

	Factor VIII:C assay	Photo optical	ACL TOP 550	CE	LP-HAE-103
	Factor X:C assay	Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor XI:C assay	Photo optical	ACL TOP 550	CE	LP-HAE-103
	Factor XII:C assay	Photo optical	ACL TOP 550	CE	LP-HAE-103
	Free Protein S	Immuno-turbidimetric	ACL TOP 550	CE	LP-HAE-089
	Lupus anticoagulant	Photo optical	ACL TOP 550	CE	LP-HAE-090
	Lupus Insensitive Activated Partial Thromboplastin Time(APTT)	Photo optical	ACL TOP 550	CE	LP-HAE-096
	Protein C	Chromogenic	ACL TOP 550	CE	LP-HAE-089
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time(APTT)	Photo optical	ACL TOP 550	CE	LP-HAE-087
	D Dimer	Immuno-turbidimetric	ACL TOP 550	CE	LP-HAE-087
	Fibrinogen (Clauss)	Photo optical	ACL TOP 550	CE	LP-HAE-087
	International Normalised ratio (INR)	Photo optical	ACL TOP 550	CE	LP-HAE-087
	Prothrombin Time	Photo optical	ACL TOP 550	CE	LP-HAE-058
	Thrombin Time	Photo optical	ACL TOP 550	CE	LP-

						HAE-088
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious mononucleosis screen		Immunoassay	Manual test	CE	LP-HAE-030
1030 Haematology - .70 Immunophenotyping	Acute panel:Antigens tested; Ig G, CD7, CD10, CD45, CD2, HLADR, CD34, CD45, CD117, CD14, CD13, CD33, CD22, CD19, CD15, CD64, CD56,CD11b,CD35,CD300,CD38,CD58,CD81. cMPO, CD79a, CD3 , TdT	Blood/BMA	Flow cytometry	BD Facs Canto	CE	LP-HAE-075, LP-HAE-078
	Lymphoproliferative panel:Antigens tested; B-Cell panel: CD45, CD5, CD10, CD19, CD38, CD8, CD4, CD3, CD56, Kappa, Lambda, FMC7, CD23, CD22, Ig M, CD79, CD20, CD200,CD43,CD81. T-Cell panel: CD16, CD7, CD56, CD2, CD4, CD8, CD56,CD30,CD26,CD25,CD57. Hairy Cell (extra): CD103, CD11c, CD19, CD45, CD25. Plasma cell (extra): CD138PE		Flow cytometry	BD Facs Canto	CE	LP-HAE-075, LP-HAE-077
	PNH screen:Antigens tested;CD235, CD59, FLAER, CD15,CD33,CD14, CD24	Blood	Flow cytometry	BD Facs Canto	CE	LP-HAE-075, LP-HAE-079

Haematology

Category: B

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	Haemoglobin	Whole Blood	Modified Azidemethaemoglobin reaction	HemoCue Hb 201 DM Analyser	Based on standard method	LP-POC-002
1030 Haematology - .40 Limited haemostasis related tests	ACT +	Native whole blood	Hemochron Signature Elite Whole Blood Microcoagulation System	Hemochron Singnature Elite	Based on standard method	LP-POC-006
	ACT Lr		Hemochron Signature Elite Whole Blood Microcoagulation System	Hemochron Singnature Elite	Based on standard method	LP-POC-009
	INR	Capillary Blood Sample	Electrochemical measurement of INR	Coaguchel XS- pro	Based on standard method	LP-POC-003
1030 Haematology - .41 General haemostasis related tests	EXTEM C	Whole blood	Thromboelastometry	ROTEM sigma analysyer	CE	LP-POC-013
	FIBTEM C		Thromboelastometry	ROTEM sigma analysyer	CE	LP-POC-013
	HEPTEM C		Thromboelastometry	ROTEM sigma analysyer	CE	LP-POC-013
	INTEM C		Thromboelastometry	ROTEM sigma analysyer	CE	LP-POC-013

Histopathology and Cytopathology

Category: A

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
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Cut-up Tissue processing Embedding Microtomy Automated Haemotxylin and Eosin Staining Coverslipping Megablocks	Human tissue	Sakura VIP Processors Sakura Embedding Centre Microtomes Nikon Microscope Microwriters Bioptics Pixarray Digital Specimen Radiography System Specimen Camera Leica HistoCore SPECTRA Stainer and Coverslipper Peloris Tissue processor	Based on standard method	N/A	LP-HIS-CU-001 LP-HIS-CU-002 LP-HIS-CU-003 LP-HIS-CU-004 LP-HIS-CU-005 LP-HIS-EQ-003 LP-HIS-EQ-035 LP-HIS-EQ-038 LP-HIS-EQ-041 LP-HIS-EQ-009 LP-HIS-EQ-037 LP-HIS-EQ-011 LP-HIS-EQ-016 LP-HIS-EQ-020 LP-HIS-BO-001 LP-HIS-EQ-004 LP-HIS-RL-001 LP-HIS-RL-002 LP-HIS-RL-003 LP-HIS-RL-004 LP-HIS-EQ-001 LP-HIS-EQ-002 LP-HIS-EQ-005 LP-HIS-EQ-019 LP-HIS-EQ-026 LP-HIS-EQ-044
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Frozen Section Cryotomy and staining		Microflow BSC Class 1 Safety Cabinet Leica CM1950 Cryostat Leica Linear Stainer ST4020	CE	N/A	LP-HIS-EQ-042 LP-HIS-EQ-025 LP-HIS-RF-001 LP-HIS-EQ-015
1051 Histopathology - .03 Histochemistry	Automated and Manual	FFPE tissue	Dako Artisan Stainer Leica HistoCore	CE and based on standard method	N/A	LP-HIS-ST-001 LP-HIS-ST-002

	<p>PAS and Diastase-PAS Gomori's Trichrome Gram stain Perl's Prussian Blue Reticulin (Silver method) Ziehl-Neelsen Alcian Blue Alcian Blue-PAS Amyloid Orcein Grocott Martius scarlet blue Masson Fontana Elastic Van Gieson CAE Method Masson Trichrome Van Gieson method Warthin and Starry method Oil Red O method Delipidisation of Fresh Specimens</p>		SPECTRA Stainer and Coverslipper			<p>LP-HIS-EQ-017 LP-HIS-EQ-046 LI-HIS-022 LP-HIS-ST-014 LP-HIS-ST-016 LP-HIS-ST-009 LP-HIS-ST-011 LP-HIS-ST-007 LP-HIS-ST-012 LP-HIS-ST-017 LP-HIS-ST-015 LP-HIS-ST-008 LP-HIS-ST-006 LP-HIS-ST-013 LP-HIS-ST-003 LP-HIS-ST-005 LP-HIS-ST-004 LP-HIS-ST-010 LP-HIS-ST-018 LP-HIS-ST-019 LP-HIS-ST-020 LP-HIS-ST-027 LP-HIS-ST-021 LP-HIS-ST-022</p>
1051 Histopathology - .04 Histological interpretation-medical renal pathology	<p>Diagnostic Interpretation and reporting of Human tissue specimens.</p> <p>Specialist Areas excluded: Medical Renal Pathology Paediatric Pathology Perinatal Pathology Neuropathology</p> <p>Specialist areas included: Breast Screening Pathology</p>	Human tissue / Human fluid	Microscope	Based on standard method	N/A	LP-HIS-EQ-002
1051 Histopathology - .09 Immunohistochemistry	ACTM ACTS	Human tissue	Automated Ultraview DAB detection	CE	N/A	LP-HIS-IM-005 LP-HIS-IM-006

	<p>AE13 ALK AFP AR BCAT BCL2 BCL6 Ber EP4 CALP CA125 CAIX CAM CALC CALR C4D CD1A CD2 CD3 CD4 CD5 (4C7) CD8 CD10 CD15 CD19 CD20 CD23 CD30 CD31 CD34 CD45 CD56 CD57 CD68 CD79A CD99 CD117 CD138 CDX2 CEA CHROM CK5/6 CK7 CK19 CK20 CK34Be12 CMYC CMV</p>		<p>Ultraview APAP detectionOptiview DAB detection Inform Her2 ISH detectionIHC DS uDAB uAP Red Ventana Benchmark Ultra Microtomes Nikon Microscope Leica HistoCore SPECTRA Stainer and Coverslipper</p>			<p>LP-HIS-EQ-005 LP-HIS-EQ-002 LP-HIS-EQ-014 LP-HIS-EQ-019 LP-HIS-EQ-020 LP-HIS-EQ-022 LP-HIS-EQ-024 LP-HIS-EQ-031 LP-HIS-EQ-032 LP-HIS-EQ-046</p>
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	CYD1 DBA44 DES DOG1 D2-40 ECAD EMA ERSP1 F XIIIa GATA3 GAST HCG HER4B5 Breast HER4B5 Gastric HHV8 HMB HLO HSA HSV1 HSV2 IgG4 INH KLC LLC LYSO MAMA MELA MIB1 MLH1 MSH2 MSH6 MPO MUM1 MYF4 NAP NSE PAX8 P16 P53 P63 P120 Catenin PLD-1 (SP142) PLD-1 (SP263) PLAP PMS2 PR PSA					
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	PSMA RACE RCC SATB2 SMMS SOX-10 SOX-11 SYN S100 TDTI TG TLE TTF1 VIM WT1 Double-stain protocols CAL/BER D240/AE1-3 LCDS (KLC/LLC) P63/CK5/6 P63/SMMS PRCA (P63/CK34B/RACE) TTF1/NAP					
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	EBER Inform Her2 ISH detection List of probes: Inform HER2 Dual ISH DNA Probe cocktail	FFPE TISSUE	VENTANA BenchMark ULTRA IHC stainer Microtomes Nikon Microscope Leica HistoCore Spectra Stainer Coverslipper	CE	N/A	LP-HIS-IM-005 LP-HIS-IM-006 LP-HIS-EQ-002 LP-HIS-EQ-005 LP-HIS-EQ-014 LP-HIS-EQ-019 LP-HIS-EQ-020 LP-HIS-EQ-046
1051 Histopathology - .13 Molecular testing	Idylla BRAF Mutation Test		Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045
	Idylla KRAS Mutation Test		Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045
	Idylla MSI Mutation Test		Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045
	Idylla NRAS Mutation Test		Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045
1052 Cytopathology - .02 Non gynaecological cytology	Cytology Sample Preparation and Description	Human tissue or fluid	Thin Prep Megafuge Shandon Cytospin	Based on standard method	N/A	LP-HIS-CY-001 LP-HIS-CY-002 LP-HIS-CY-003

	<p>Cytology sample Description Cytology Sample Preparation Cytology Sample Staining</p> <p>Diagnostic interpretation and reporting of non-gynae samples</p>		<p>Microflow Class II Cabinet Leica ST5010 (XL Autostainer)</p>			<p>LP-HIS-CY-004 LP-HIS-CY-005 LP-HIS-CY-006 LP-HIS-CY-007 LP-HIS-CY-008 LP-HIS-CY-009 LP-HIS-CY-010 LP-HIS-CY-011 LP-HIS-EQ-008 LP-HIS-EQ-025 LP-HIS-EQ-029 LP-HIS-EQ-030 LP-HIS-EQ-039 LP-HIS-EQ-002 LP-HIS-EQ-024 LP-HIS-EQ-031 LP-HIS-EQ-044 ED-HIS-MAN-037</p>
1052 Cytopathology - .03 Cytochemistry	<p>Oil Red O method Delipidisation of Fresh Specimens Ziehl-Neelsen Grocott</p>		<p>Thin Prep Megafuge Shandon Cytospin Leica ST5010 (XL Autostainer) Microflow Class II Cabinet Dako Artisan Stainer Leica HistoCore Spectra Stainer Coverslipper</p>	CE	N/A	<p>LP-HIS-ST-013 LP-HIS-EQ-008 LP-HIS-EQ-030 LP-HIS-EQ-039 LP-HIS-EQ-025 LP-HIS-EQ-017 LP-HIS-EQ-046 LP-HIS-EQ-002 LP-HIS-MAN-037</p>

Immunology

Category: A

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
1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids	Investigation of individual immunoglobulin concentrations - IgG, IgA, IgM	Serum	Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
	Investigation of Monoclonal Gammopathies		Sebia Hydrasys and Capillarys 3 / Electrophoresis. Monoclonal Band calculated using INAB Accredited CCE Serum Total Protein level (Abbott Architect c16000 Alinity ci series)	Based on standard method	N/A	LP-IMM-0004 LP-IMM-0009 LP-CCE-0064
		Urine	Sebia Hydrasys and Capillarys 3 / Urinary Paraprotein Band calculated using INAB Accredited CCE Urinary Total Protein level (Abbott Architect c16000 Alinity ci series)	Based on standard method	N/A	LP-IMM-0004 LP-IMM-0009
1040 Immunology - .03 Total IgE	Quantitative determination of total IgE in serum using the Phadia Immunocap 250 analyser- Enzyme Immunoassay	Serum	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
1040 Immunology - .04 Allergen - specific IgE	Quantitative investigation of Serum		Phadia Immunocap 250 analyser/ Enzyme	Based on standard method	N/A	LP-IMM-0012

	samples for Allergen specific IgE	Immunoassay			
	Quantitative investigation of Serum samples for Allergen specific IgG	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
1040 Immunology - .06 Investigation of complement	Quantitative determination of C1 esterase inhibitor, C3 and C4 of the compliment pathway	Optilite / Turbidimetry	CE	N/A	LP-IMM-0041
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti-GAD	DS2/Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0034 LP-IMM-0015
	Anti-IFA measurment using the Phadia/Thermofisher Immunocap 250	Phadia Immunocap250 analyser	Enzyme Immunoassay	N/A	LP-IMM-0012 LI-IMM-0044
	Anti-M2	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	B-2 glycoprotein-1 IgG	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	B-2 Glycoprotein-1 IgM	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Cardiolipin IgG	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Cardiolipin IgM	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	CCP	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Centromere	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Connective Tissue Disease Screen &	Phadia Immunocap250 analyser	Enzyme Immunoassay	N/A	LP-IMM-0012 LI-IMM-0044

Confirmation using the Phadia/Thermofisher Immunocap 250				
ds-DNA	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Jo-1	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - La	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - RNP70	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Ro	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Scl-70s	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - U1RNP	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA -SmD	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
GBM	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Myeloperoxidase	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Proteinase -3	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Rheumatoid Factor	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012

	TTG IgA		Phadia Immucap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	TTG IgG		Phadia Immucap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
1040 Immunology - .14 b2-microglobulin	Beta-2-microglobulin		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes	Lymphocyte subset analysis for CD16/CD56 Count	EDTA whole blood	Becton Dickinson FACS CANTO SPA3/ Flow cytometry	Based on standard method	N/A	LP-IMM-0001 LP-IMM-0007
	Lymphocyte subset analysis for CD19 Count		Becton Dickinson FACS CANTO SPA3/ Flow cytometry	Based on standard method	N/A	LP-IMM-0001 LP-IMM-0007
	Lymphocyte subset analysis for CD3/CD4 Count		Becton Dickinson FACS CANTO SPA3/ Flow cytometry	Based on standard method	N/A	LP-IMM-0001 LP-IMM-0007
	Lymphocyte subset analysis for CD3/CD8 Count		Becton Dickinson FACS CANTO SPA3/ Flow cytometry	Based on standard method	N/A	LP-IMM-0001 LP-IMM-0007
1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes	Anti-LKM	Serum	BioRad PhD slide processor/ indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0006 LP-IMM-0030
	Investigation of ANCA		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0027 LP-IMM-0030
	Investigation of Antinuclear antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0005 LP-IMM-0030
	Investigation of ds-DNA Crithidia		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0008 LP-IMM-0030
	Investigation of Endomysial antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0026 LP-IMM-0030
	Investigation of Mitochondrial antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0006 LP-IMM-0030
	Investigation of		Biorad PhD slide	Based on standard	N/A	LP-IMM-0006

	Parietal Cell antibodies		processor/ Indirect Immunoflourescence	method		LP-IMM-0030
	Investigation of Skin antibodies		Biorad PhD slide processor/ Indirect Immunoflourescence	Based on standard method	N/A	LP-IMM-0028 LP-IMM-0030
	Investigation of Smooth muscle antibodies		Biorad PhD slide processor/ Indirect Immunoflourescence	Based on standard method	N/A	LP-IMM-0006 LP-IMM-0030
1040 Immunology - .61 Proteins, quantitative analysis	Quantitative measurement of Serum free light chains – Kappa and Lambda		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
1040 Immunology - .99 Miscellaneous tests	Alpha-1-antitrypsin		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-004
	Antistreptolysin		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
	Calprotectin	Faeces	Diasorin / Chemiluminescence	CE certified method	N/A	LP-IMM-0040
	Coeruloplasmin	Serum	Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
	Haptoglobin		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041

Category: A

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
1011 Macroscopic examination and description	Macroscopic examination and description of specimens	Sputum, Fluids, Faeces, CSF	N/A / Visual	Based on standard method	N/A	LP-MIC-ROU-02 LP-MIC-ROU-03 LP-MIC-ROU-06 LP-MIC-ROU-14
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Cell counts & Differential	Urine, fluids, CSF	Microscope / Microscopy	Based on standard method	N/A	LP-MIC-ROU-05 LP-MIC-ROU-03 LP-MIC-ROU-14 LP-MIC-IDEN-05
	Gram staining	Tissue/Fluids/ Corneal scrapings, CSF, BAL	Microscope / Staining and Microscopy	Based on standard method	N/A	LP-MIC-IDEN-08
	Implementation of the automated urine analyser Sedimax Contrast Pro for the investigation of UTIs	Urine	Sedimax Pro Contrast / Automated urine analyser for microscopy and the quantitative culture of samples that are microscopy positive	CE marked	N/A	LP-MIC-ROU-05
1012 Preparation of films on glass slides followed by microscopic	Cryptosporidium	Faeces	Microscope / Staining and Microscopy	Based on standard method	N/A	LP-MIC-ROU-26

examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites						
	Ova & Parasites	Urine, Faeces	Microscope / Concentration and Microscopy	Based on standard method	N/A	LP-MIC-ROU-26
	Trichomonas vaginalis	Vaginal swabs samples, fluids/CSF	Microscope / Microscopy	Based on standard method	N/A	LP-MIC-ROU-07
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	KOH Calcofluor white	BAL, Skin hair, nails	Microscope / Staining and Microscopy	Based on standard method	N/A	LP-MIC-ROU-02
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria	Auramine O for AFB	Respiratory samples, tissue/bone samples, fluids/CSF	Microscope / Concentration, Staining and Microscopy	Based on standard method	N/A	LP-MIC-ROU-15
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of CSF specimens	CSF	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-14
	Culture of faecal specimens	Faeces	N/A / Agar and enrichment culture	Based on standard method	N/A	LP-MIC-ROU-06 LP-MIC-ROU-12
	Culture of genital tract & associated specimens	Swabs: Vaginal, Endocervical, Urethral, Rectal, Pharyngeal. Bartholins gland aspirate, pus & IUD	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-07 LP-MIC-ROU-13
	Culture of respiratory specimens for bacterial pathogens other than	Respiratory samples	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-02 LP-MIC-

	Mycobacteria					ROU-08
	Culture of specimens from superficial & deep seated infections	Wounds/Tissue/Fluids/Swabs/IV tips	N/A / Agar and enrichment culture	Based on standard method	N/A	LP-MIC-ROU-03 LP-MIC-ROU-09
	Culture of urine specimens	Urine	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-05, LP-MIC-ROU-11
	Screening of specimens for MDRO	Swabs & Faeces	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-04 LP-MIC-ROU-10
		Swabs and Faeces	Culture	CE	NA	LP-MIC-ROU-04, LP-MIC-ROU-10
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi	Skin, Nails, Hair, Respiratory samples, Corneal scrapings, Contact lens, CSF, Tissues/Fluids, Swabs, Urines,	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-17
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of Mycobacteria	Blood culture	BACTEC FX / Automated continuously monitored liquid culture	CE marked	N/A	LP-MIC-ROU-15
		Respiratory samples, tissue/bone samples, fluids/CSF, Urine	BacTALERT 3D / Automated continuously monitored liquid culture	CE marked	N/A	LP-MIC-ROU-15
	Introduction of new BacTALERT MP bottle for the detection of mycobacteria from specimens other than blood.	Respiratory samples, tissue/bone samples, fluids/CSF, Urine	BactAlert TB / Automated continuously monitored liquid culture	CE marked	N/A	LP-MIC-ROU-15
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Salmonella & Shigella typing	Isolate	N/A / Slide agglutination	CE marked	N/A	LP-MIC-ROU-12

1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Dry spot Pnemo	Blood culture	N/A / Particle agglutination	CE marked	N/A	LP-MIC-IDEN-06
	E. coli 0157 Latex	Isolate	N/A / Particle agglutination	CE marked	N/A	LP-MIC-IDEN-07
	Pastorex		N/A / Particle agglutination	CE marked	N/A	LP-MIC-IDEN-11
	Streptococcal Grouping Latex Kit		N/A / Particle agglutination	CE marked	N/A	LP-MIC-IDEN-13
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	QuantiFERON®-TB Plus - Detection of latent tuberculosis infection using the QuantiFERON®-TB Plus Assay.	Blood	Diasorin Liason XL / Chemiluminescence assay	CE marked	N/A	LP-MIC-ROU-51
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	BD MGIT TBc	Isolates	N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-ROU-34
	Cryptococcal Antigen	CSF & serum	N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-ROU-23
	Legionella Urinary antigen	Urine	N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-ROU-25
	OLM™ Lateral Flow Device	Bronchoalveolar Lavage	Immuno-chromatographic assay	CE marked	N/A	LP-MIC-IDEN-25
	PBP 2' Kit	Isolates	N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-IDEN-12
	Resist-5 O.O.K.N.V		Immunochromatographic assay	CE Marked	NA	LP-MIC-IDEN-23
	Streptococcus pneumoniae Urinary antigen	Urine	N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-ROU-27
	Urinary hCG		N/A / Immuno-chromatographic assay	CE marked	N/A	LP-MIC-ROU-24

1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	FilmArray Meningitis/Encephalitis ME panel	CSF	Amplification and detection of target DNA and RNA on FilmArray 2.0	CE	NA	LP-MIC-ROU-45
	HAIN CM	Extract from positive culture bottles	PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-32
	HAIN MTBC		PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-32
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Chlamydia trachomatis and Neisseria gonorrhoeae	Endocervical/ Cervical swabs & FVU	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-39
	Chlamydia trachomatis and Neisseria gonorrhoea	FVU	Amplification and detection of target DNA on BD Max	Based on standard method	NA	LP-MIC-ROU-44
	CRE	Isolates & rectal swabs	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-42
	Detection of Carbenpenamse using FlowFlex Technology	Rectal	Roche FlowFlex PCR Technology	CE Marked	N/A	LP-MIC-ROU-51
	Faecal Molecular screen for Bacterial Enteric Pathogens	Faeces	Amplification and detection of target DNA on BD Max	Based on standard method	NA	LP-MIC-ROU-46
	Identification of M. tuberculosis complex direct from specimens using Xpert MTB/RIF Ultra kit on the Cepheid GeneXpert Dx System	Sputum (direct)	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-49
		Sputum sediment	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-49
Investigation of Faecal Specimens for Molecular Detection and	Faeces	Roche FlowFlex PCR Technology	CE marked	N/A	LP-MIC-ROU-53	

Differentiation of Norovirus RNA using FLOW Flex					
Molecular detection of COVID/FLU/RSV on Cepheid GeneXpert DX System	Nasopharangeal	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-68
Molecular detection of COVID/FLU/RSV using Viasure assay on Roche Flow Flex System		Roche FlowFlex System / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-67
Molecular Detection of Influenza and RSV viral RNA using the Cepheid GeneXpert DX System.	Nasopharyngeal swabs	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-48
Molecular detection of mecA and mecC in MRSA isolates using XPERT NG	Isolates/nasal swabs	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-IDEN-
Molecular detection of respiratory viruses and bacteria on BioFire RP2.1 Plus on the FilmArray	Nasopharangeal	BioFire RP2.1 Plus on the Film Array / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-65, LP-MIC-ROU-45
Molecular detection of SARS-CoV-2 on Alinity m		Alinity m / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-63
Molecular detection of SARS-CoV-2 on Cepheid GeneXpert DX System		Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-58
Molecular detection of SARS-CoV-2 on Luminex Aires		Luminex Aires / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-62
Molecular detection of SARS-CoV-2 using Viasure assay on Roche Flow Flex System		Roche FlowFlex System / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-60
Molecular detection of Trichomonas vaginalis	First void urine/ Endocervical swab	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-39
Norovirus Genogroup I and II	Faeces	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-40
Toxigenic Clostridium difficile		Amplification and detection of target DNA on BD Max	Based on standard method	NA	LP-MIC-ROU-47

			Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-22
	Xpert CARBA-R	Rectal swabs & Isolates	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-42
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	API 32C for identification of yeasts	Isolates	Biochemical reactions	CE marked	N/A	LP-MIC-IDEN-26
	API NH		N/A / Fermentation, decarboxylation etc	CE marked	N/A	LP-MIC-IDEN-01
	Dnase		N/A / Hydrolysis of DNA	Based on standard method	N/A	LP-MIC-IDEN-15
	Phenotypic confirmation of ESBL's		Disc diffusion	Based on standard method	NA	LP-MIC-IDEN-24
	VITEK Identification		VITEK 2XL / Fermentation, decarboxylation etc	CE marked	N/A	LP-MIC-ROU-19
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Lactophenol cotton blue		Microscope / Staining & Microscopy	Based on standard method	N/A	LP-MIC-ROU-17
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification using MALDI-TOF Spectroscopy		VITEK MS / Mass Spectrophotometry	CE marked	N/A	LP-MIC-ROU-19
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial susceptibility testing		N/A / Disc diffusion	CE marked	N/A	LP-MIC-ROU-20

			VITEK 2XL / Broth MIC	CE marked	N/A	LP-MIC-ROU-20
	Cefpodoxime combination disc kit		N/A / Disc diffusion	CE marked	N/A	LI-MIC-36
	KPC, MBL& Oxa 48 kit		N/A / Disc diffusion	CE marked	N/A	LP-MIC-IDEN-20
	Minimum inhibitory concentration		N/A / Minimum inhibitory strip diffusion	CE marked	N/A	LP-MIC-ROU-20
	Total ESBL confirmation kit		N/A / Disc diffusion	CE marked	N/A	LI-MIC-36
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria	HAIN MTBDRplus	Extract from positive culture bottles	PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-32
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Detection of azole resistance in Aspergillus species using the VIP check plate	Aspergillus isolates	Broth MIC	CE marked	N/A	LP-MIC-ROU-64
	Yeast one Sensititre	Isolates	N/A / Broth MIC	CE marked	N/A	LP-MIC-ROU-18
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Platelia™ Aspergillus antigen in serum and Bronchoalveolar Lavage (BAL) for the Detection of Aspergillus Galactomannan antigen.	Serum and BALs	Dynex DS2 / Immunoenzymatic sandwich microplate assay	CE marked	N/A	LP-MIC-ROU-56
	Wako™ β-D-Glucan assay for detection of 1-3 β glucans	Serum	Toxinometer / Kinetic turbidimetric method	CE marked	N/A	LP-MIC-ROU-57