

# Schedule of Accreditation



Organisation Name	Mater Misericordiae University Hospital
Trading As	
INAB Reg No	232MT
Contact Name	Denise O'Neill
Address	Pathology Laboratory, Eccles Street, Dublin
Contact Phone No	01 8545070
Email	doneill@mater.ie
Website	
Accreditation Standard	ISO 15189
Date Initially Awarded	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

Services available to the public<sup>1</sup>

<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	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) Typing).	Whole blood	Manual method using tubes and Gels	Based on standard method	N/A	LP-BT-ROU-07
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Automated method using the IH 1000 Blood Grouping Analyser	Based on standard method	N/A	LP-BT-ROU-33
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Automated method using the IH 1000 Blood Grouping Analyser	Based on standard method	N/A	LP-BT-ROU-33
			Manual method using Gels	Based on standard method	N/A	LP-BT-ROU-08
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual method using tubes and Gels	Based on standard method	N/A	LP-BT-ROU-09
1020 Transfusion science - .05 Cross match compatible donor units	Antigen Typing	Red Blood Cells	Manual method using tubes and Gels	Based on standard method	N/A	LP-BT-ROU-10
	Crossmatch Testing	Plasma	Manual method using Gels	Based on standard method	N/A	LP-BT-ROU-11
	Direct Coombs Testing	Red Blood Cells	Manual method using Gels	Based on standard method	N/A	LP-BT-ROU-13
1020 Transfusion science - .07 Antibody elution	Antibody Screening	Eluate	Elution	Based on standard method	N/A	LP-BT-ROU-15
	Antibody Identification		Elution	Based on standard method	N/A	LP-BT-ROU-15
	Direct Coombs Testing		Elution	Based on standard method	N/A	LP-BT-ROU-15

*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)*

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 Aminotransferase (ALT)	Plasma/ Serum	NADH (without P-5'-P)	Abbott Architect c16000	CE	LP-CCE-0003
	Alkaline Phosphatase (ALP)		IFCC with PNPP	Abbott Architect c16000	CE	LI-CCE-0003
	Ammonia	Plasma	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
	Amylase	Plasma/ Serum/ Fluid/ Urine	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
	Aspartate Aminotransferase (AST)	Plasma/ Serum	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
	Bilirubin direct		Diazo	Abbott Architect c16000	CE	LI-CCE-0003
	Bilirubin Total		Diazo	Abbott Architect c16000	CE	LI-CCE-0003
	BNP	Plasma	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Calcium	Plasma/ Serum/ Urine	Arsenazo III	Abbott Architect c16000	CE	LI-CCE-0003
	Chloride		Ion selective electrode	Abbott Architect c16000	CE	LI-CCE-0003
	Cholesterol	Plasma/ Serum	Cholesterol oxidase	Abbott Architect c16000	CE	LI-CCE-0004
	Corrected Calcium		Calculated	n/a	Laboratory Developed Test	LI-CCE-0040
	Creatine Kinase (CK)		Enzymatic	Abbott Architect c16000	CE	LI-CCE-0004
	Creatinine	Plasma/ Serum/ Fluid/ Urine	Enzymatic	Abbott Architect c16001	CE	LI-CCE-0004
	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
	Gamma Glutamyl Transferase (GGT)		Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
	Glucose	Plasma/ CSF/ Urine	Hexokinase	Abbott Architect c16000	CE	LI-CCE-0003
	HDL cholesterol	Plasma/ Serum	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
	Lactate Dehydrogenase (LDH)	Serum/ Fluid	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
LDL cholesterol	Plasma/ Serum	Enzymatic/ Calculated	Abbott Architect c16000	CE and Based on standard method	LI-CCE-0003, LI-CCE-0040	

	Lithium	Serum	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
	Magnesium	Plasma/ Serum/ Urine	Arsenazo	Abbott Architect c16000	CE	LI-CCE-0003
	Non HDL Cholesterol	Plasma/Serum	Calculated	N/A	Calculated	LI-CCE-0040
	Phosphate	Plasma/ Serum/ Urine	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
	Potassium		Ion selective electrode	Abbott Architect c16000	CE	LI-CCE-0003
	Sodium		Ion selective electrode	Abbott Architect c16000	CE	LI-CCE-0003
	Total CO2	Plasma/ Serum	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
	Triglycerides	Plasma/ Serum/ Fluid	Glycerol Phosphate Oxidase	Abbott Architect c16000	CE	LI-CCE-0003
	Troponin I (High sensitivity)	Plasma	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Urea	Plasma/ Serum/ Fluid/ Urine	Urease	Abbott Architect c16000	CE	LI-CCE-0003
	Uric Acid	Plasma/ Serum	Uricase	Abbott Architect c16000	CE	LI-CCE-0003
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin	Plasma/ Serum	Bromocresol Green	Abbott Architect c16000	CE	LI-CCE-0003
	C-Reactive Protein (CRP)		Immunoturbidimetric	Abbott Architect c16000	CE	LI-CCE-0004
	Microalbumin	Urine	Immunoturbidimetric	Abbott Architect c16000	CE	LI-CCE-0003
	Protein -Total	Plasma/ Serum	Biuret	Abbott Architect c16000	CE	LI-CCE-0003
		Urine/ CSF	Benzethonium Chloride	Abbott Architect c16000	CE	LI-CCE-0003
SHBG	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003	
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	CE	LI-CCE-0003
	Amikacin	Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
	Carbamezepine		Petinia	Abbott Architect c16000	CE	LI-CCE-0003
	Cyclosporin	Whole blood	LC-MS/MS	Waters TQD & Xevo TQ MS	Laboratory Developed Test	LP-CCE- 0001
	Digoxin	Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
	Gentamicin	Plasma/ Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
	Methotrexate	Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Phenobarbitone		Petinia	Abbott Architect c16000	CE	LI-CCE-0003
	Phenytoin		Enzyme Immunoassay	Abbott Architect c16000	CE	LI-CCE-0003
	Sirolimus	Whole blood	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE- 0003
	Tacrolimus		LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE- 0001
	Theophylline	Serum	Enzyme Immunoassay	Abbott Architect c16000	CE	LI-CCE-0003
	Tobramycin		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
	Valproate		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
	Vancomycin	Plasma/ Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000	CE	LI-CCE-0003
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	CE	LI-CCE-0003
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate	Plasma/ Serum	Enzymatic	Abbott Architect c16000	CE	LI-CCE-0003
1061 Clinical Chemistry - .20 Hormones	Adrenocorticotrophic hormone (ACTH)	EDTA on ice	Immunometric Assay	Roche Cobas	CE	LP-CCE- 0057
	Aldosterone	Plasma	Immunoassay	IDS iSYS	CE	LP-CCE- 0054
	Androstenedione	Serum	LC-MS/MS	Waters Xevo TQ	Laboratory Developed Test	LP-CCE- 0055
	Cortisol	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	C-Peptide		CMIA (chemiluminescent microparticle Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	FSH		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Growth Hormone	Serum	Immunoassay	IDS iSYS	CE	LP-CCE- 0051
	HCG- Total	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	IGF-1	Serum	Immunoassay	IDS iSYS	CE	LP-CCE- 0035
	Insulin	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	LH		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Macroprolactin		PEG precipitation	Abbott Architect i2000	Based on	LP-CCE-

					standard method	0005
	Oestradiol		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Parathyroid Hormone (PTH)	Plasma	Immunoassay	Roche e411	CE	LP-CCE-0048
	Progesterone	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Prolactin		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Renin	Plasma	Immunoassay	IDS iSYS	CE	LP-CCE-0054
	T3 - free	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	T4 - free		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	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	CE	LI-CCE-0003
	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	CE	LI-CCE-0003
	Iron	Plasma/ Serum	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
	Transferrin		Immunoturbidimetric	Abbott Architect c16000	CE	LI-CCE-0003
	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	CE	LI-CCE-0003
	Folate Red Cell	Blood	Immunoassay	Abbott Architect i2000	Based on standard method	LP-CCE-0010
	Vitamin B12	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D	Serum	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0002
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha feto protein (AFP)	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	CA-125		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	CA-15-3		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	CA-19-9		Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Calcitonin (hCT)	Serum on ice	Immunoassay	Roche Cobas	CE	LP-CCE-0058
	CEA	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	PSA - total	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	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 - .60 Glycohaemoglobins	HbA1c	EDTA	HPLC	Menarini HA-8180v	CE	LP-CCE-0060
1061 Clinical Chemistry - .77 Calculi	Stone Analysis	Stone	FT-IR	Nicolet 380 FT-IR	Based on standard method	LP-CCE-0041

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 Antibodies	Serum	Electrochemiluminescence immunoassay	Roche e411	Based on standard method	LP-CCE- 0059
1061 Clinical Chemistry - .99 Miscellaneous tests	Anti-thyroglobulin antibodies	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003
	Free Androgen Index	Serum	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	LP-CCE- 0009
	Thyroid peroxidase (TPO) antibodies	Plasma/ Serum	Immunoassay	Abbott Architect i2000	CE	LI-CCE-0003

*b Point of care testing, ISO 22870*

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	
	1061 Clinical Chemistry - .05 CO-oximetry		Haematocrit	Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
			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	
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pO2		Amperometric	Abbott i-Stat	CE	LP-POC-010	
			Potentiometric	ABL 90 Flex	CE	LP-POC-001	
	pCO2		Potentiometric	Abbott i-Stat	CE	LP-POC-010	
			Potentiometric	ABL 90 Flex	CE	LP-POC-001	
	pH		ISE	Abbott i-Stat	CE	LP-POC-010	
			ISE	ABL 90 Flex	CE	LP-POC-001	
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess		Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001	
		Calculated	ABL 90 Flex	N/A	LP-POC-001		
	Lactate	Amperometric	ABL 90 Flex	CE	LP-POC-001		
	Potassium	ISE	Abbott i-Stat	CE	LP-POC-010		
		ISE	ABL 90 Flex	CE	LP-POC-001		
	Sodium	ISE	Abbott i-Stat	CE	LP-POC-010		
		ISE	ABL 90 Flex	CE	LP-POC-001		
Standard Bicarbonate	Calculated	ABL 90 Flex	N/A	LP-POC-001			

*b Point of care testing, ISO 22870*



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	Cumulative 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) detection	Sysmex XN-10/XN 20	CE	LP-HAE-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, Eosinophils, Basophils, Red Cell morphology		Staining/microscopy/Digital imaging	Wescor stainer/ Sysmex SP10 stainer/Microscope/CellaVision DI-60 automated digital imaging analysis system with	Based on standard method	LP-HAE-004 LP-

				operator result validation		HAE-006 LP-HAE-070 LP-HAE-072
1030 Haematology - .03 Erythrocyte 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	Bone marrow examination	Bone marrow	Staining/ microscopy	Wescor stainer/Microscope	Based on standard method	LP-HAE-

examination		aspirate				007
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	HPLC for Haemoglobinopathy	Blood	High performance liquid chromatography	Biorad D10	CE	LP-HAE-050
	Sickle Screen (Sickledex)		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 500	CE	LP-HAE-060
	Anti Xa level(LMWH)		Photo optical	ACL TOP 500	CE	LP-HAE-061
	Anticoagulant drug monitoring: Rivaroxaban / Apixaban / Dabigatran		Photo optical	ACL TOP 500	CE	LP-HAE-073, LP-HAE-074
	Antithrombin		Photo optical	ACL TOP 500	CE	LP-HAE-060
	Free Protein S		Photo optical	ACL TOP 500	CE	LP-HAE-060
	Lupus anticoagulant		Photo optical	ACL TOP 500	CE	LP-HAE-063
	Protein C		Photo optical	ACL TOP 500	CE	LP-HAE-060
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time(APTT)		Photo optical	ACL TOP 500	CE	LP-HAE-058
	D Dimer		Photo optical	ACL TOP 500	CE	LP-HAE-058
	Fibrinogen (Claus)		Photo optical	ACL TOP 500	CE	LP-HAE-058
	International Normalised ratio (INR)		Photo optical	ACL TOP 500	CE	LP-HAE-058
	Prothrombin Time		Photo optical	ACL TOP 500	CE	LP-HAE-058
	Thrombin Time		Photo optical	ACL TOP 500	CE	LP-HAE-066
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	APTEM	Whole blood	Thromboelastometry	ROTEM delta analyser with associated pipette	CE	LP-POC-004
	EXTEM		Thromboelastometry	ROTEM delta analyser with associated pipette	CE	LP-POC-004
	EXTEM C		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	FIBTEM		Thromboelastometry	ROTEM delta analyser with associated pipette	CE	LP-POC-004
	FIBTEM C		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	HEPTEM		Thromboelastometry	ROTEM delta analyser with associated pipette	CE	LP-POC-004
	HEPTEM C		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	INTEM		Thromboelastometry	ROTEM delta analyser with associated pipette	CE	LP-POC-004
	INTEM C		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013

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	Human tissue	Sakura VIP Processors Sakura Embedding Centre MicromHM325 Microtomes Nikon Microscope Thermoshandon Microwriters Bioptics Pixarray Digital Specimen Radiography System Macropath D Specimen Camera Sakura Prisma/G2 Integrated Stainer and Coverslipper Peloris Tu=issue processor	Based on standard method	N/A	LP-HIS-CU-001 LP-HIS-CU-002 LP-HIS-CU-003 LP-HIS-EQ-003 LP-HIS-EQ-035 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
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Frozen Section cryotomy and staining		Microflow BSC Class 1 safety cabinet Leica CM1950 Cryostat	Based on standard method	N/A	LP-HIS-RF-001 LP-HIS-EQ-015
1051 Histopathology - .03 Histochemistry	Automated and Manual PAS and Diastase-PAS Gomori's Trichrome Gram stain Perl's Prussian Blue Reticulin (Silver method) Ziehl-Neelsen 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		Dako Artisan Stainer Sakura Prisma/G2 Integrated Stainer and Coverslipper	CE and based on standard method	N/A	LP-HIS-ST-001 LP-HIS-ST-002 LP-HIS-EQ-017 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-015 LP-HIS-ST-008

	Oil Red O method Delipidisation of Fresh Specimens					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-021 LP-HIS-ST-022
1051 Histopathology - .04 Histological interpretation- medical renal pathology	Diagnostic Interpretation and reporting of Human tissue specimens.  Specialist Areas excluded: Medical Renal Pathology Paediatric Pathology Perinatal Pathology Neuropathology  Specialist areas included: Breast Screening Pathology	Human tissue / Human fluid	N/A	Based on standard method	N/A	N/A
1051 Histopathology - .09 Immunohistochemistry	ACTM ACTS AE13 ALK AFP AAT AR BCAT BCL2 BCL6 Ber EP4 CALP CA125 CAM CALC CALR C4D CD1A CD2 CD3 CD4 CD5 (4C7) CD8 CD10	Human tissue	Automated Ultraview DAB detection Ultraview APAP detection Optiview DAB detection Inform Her2 ISH detection IHC DS uDAB uAP Red using Ventana Benchmark UltraVentana Benchmark XT Leica Bond III Microm HM325 Microtomes Nikon Microscope Sakura Prisma/G2 Integrated Stainer and Coverslipper	CE	N/A	LP-HIS-IM-003 LP-HIS-IM-004 LP-HIS-IM-005 LP-HIS-IM-006 LP-HIS-EQ-005 LP-HIS-EQ-012 LP-HIS-EQ-013 LP-HIS-EQ-014

CD15 CD19 CD20 CD23 CD30 CD31 CD33 CD34 CD42B CD45 CD45ro CD56 CD57 CD68 CD79A CD99 CD105 CD117 CD138 CDX2 CEA CHROM CK5/6 CK7 CK19 CK20 CK34Be12 CMV CYD1 DBA44 DES DOG1 D2-40 EBVLMP ECAD EMA ERSP1 F8 F XIIIa GAL3 GATA GAST GFAP GH GLU GLUT 1 HBCAG HBSAG HCG HER4B5 HHV8 HMB HLO HPL HPV HSA HSV1 HSV2 IgG4 IGM INH INS KLC LLC LYSO MAMA MELA MIB1 MLH1						
---	--	--	--	--	--	--



	MSH2 MSH6MT1 MPO MUM1 MYF4 MYOG MYOS NAP NFIL NK1C3 NSE PAX8 PGP9.5 P16 P53 P63 P120 Catenin PLAP PMS2 PR PSA PSMA RACE RCC SER SMMS SOM SYN S100 TDTI THROM TG TLE TTF1 VIM WT1  Double-stain protocols CAL/BER CYT CD45/AE13 D240/AE1-3 ER/CK5-6 LCDS (KLC/LLC) P120/ECAD P63/CK5/6 P63/CK34B P63/RACE P63/SMMS PRCA (CK34B/RACE) T HEPB DS T HPV/P16 TTF1/ACTM TTF1/NAP					
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	Inform Her2 ISH detection List of probes: Inform HER2 Dual ISH DNA Probe cocktail		Ventana Benchmark Ultra MicromHM325 Microtomes Nikon Microscope Sakura Prisma/G2 Integrated Stainer and Coverslipper	CE	N/A	LP-HIS-IM-006 LP-HIS-EQ-005 LP-HIS-EQ-014
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-

	<p>Cytology sample Description Cytology Sample Preparation Cytology Sample Staining</p> <p>Diagnostic interpretation and reporting of non-gynae samples</p>		<p>Stainmate Autostainer Microflow Class II Cabinet</p>			<p>002 LP-HIS-CY-003 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-CY-012 LP-HIS-EQ-008</p>
1052 Cytopathology - .03 Cytochemistry	<p>Oil Red O method Delipidisation of Fresh Specimens Ziehl-Neelsen Grocott</p>		<p>Thin Prep Megafuge Shandon Cytospin Stainmate Autostainer Microflow Class II Cabinet Dako Artisan Stainer</p>	CE	N/A	<p>LP-HIS-ST-021 LP-HIS-ST-022 LP-HIS-ST-012 LP-HIS-ST-013</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 immunoglobulin concentrations using the Dade Behring BNII analyser.	Serum	Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010
	Kappa free light chains		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
	Lambda free light chains		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
	Protein electrophoresis		Sebia Hydrasys and Capillarys 3 / Electrophoresis	Based on standard method	N/A	LP-IMM-0004 LP-IMM-0009
	Urinary electrophoresis	Urine	Sebia Hydrasys and Capillarys 3 / Electrophoresis	Based on standard method	N/A	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	Investigation of serum samples for allergy testing		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		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010
	Quantitative determination of complement components C3 and C4 of the complement pathway using the Dade Behring BNII analyser		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010
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		DS2/Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0034 LP-IMM-0023
	Anti-M2		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Aspergillus		Phadia Immunocap	Based on	N/A	LP-IMM-0012

	antibodies		250 analyser/ Enzyme Immunoassay	standard method		
	B-2 glycoprotein		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Budgerigar antibodies		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
	ds-DNA		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	ENA profile		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	ENA symphony		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Farmers lung antibodies		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
	Pigeon antibodies		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 Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	TTG IgG		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
1040 Immunology - .14 b2-microglobulin	Beta-2- microglobulin		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
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 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 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 Parietal Cell antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0006 LP-IMM-0030
	Investigation of Skin antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0028 LP-IMM-0030
	Investigation of Smooth muscle antibodies		Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0006 LP-IMM-0030
1040 Immunology - .99 Miscellaneous tests	Alpha-1-antitrypsin		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
	Antistreptolysin		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
	Coeruloplasmin		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024
	Haptoglobin		Dade Behring BNII analyser/ Nephelometry	Based on standard method	N/A	LP-IMM-0010 LP-IMM-0024

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
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Cryptosporidium	Faeces	Microscope / Staining and Microscopy	Based on standard method	N/A	LP-MIC-ROU-26
	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	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

required - .04 Microscopic examination for mycobacteria						
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 Mycobacteria	Respiratory samples	N/A / Culture	Based on standard method	N/A	LP-MIC-ROU-02 LP-MIC-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
1014 Detection of	Salmonella & Shigella	Isolate	N/A / Slide agglutination	CE marked	N/A	LP-MIC-

bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	typing					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	Blood	Interferon-g release assays/ELISA / Dynex DS2	CE marked	N/A	LP-MIC-ROU-43
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-3 O.K.N.		Immuno-chromatographic assay	CE	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
	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
	Influenzae A and Influenza B	Nasopharyngeal specimens	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-41
	M. tuberculosis Complex	Respiratory samples	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-33
	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
	Norovirus Genogroup I and II	Faeces	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	N/A	LP-MIC-ROU-40
			Amplification and detection of target DNA on BD Max	Based on standard method	NA	LP-MIC-ROU-47
	Toxigenic Clostridium difficile		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 NH	Isolates	N/A / Fermentation, decarboxylation etc	CE marked	N/A	LP-MIC-IDEN-01
	C390 discs		N/A / Selective inhibition by disc diffusion	CE marked	N/A	
	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

	Rapid CARB Blue Kit		N/A / Hydrolysis of imipenem	CE marked	N/A	LP-MIC-IDEN-19
	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
	CAT ID kit		VITEK 2XL / Broth MIC	CE marked	N/A	LP-MIC-ROU-20
	Cefpodoxime combination disc kit		N/A / Disc diffusion	CE marked	N/A	LP-MIC-IDEN-22
	KPC, MBL& Oxa 48 kit		N/A / Disc diffusion	CE marked	N/A	LI-MIC-36
	Minimum inhibitory concentration		N/A / Disc diffusion	CE marked	N/A	LP-MIC-IDEN-20
	Total ESBL confirmation kit		N/A / Minimum inhibitory strip diffusion	CE marked	N/A	LP-MIC-ROU-20
	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	Yeast one Sensititre	Isolates	N/A / Broth MIC	CE marked	N/A	LP-MIC-ROU-18