

# 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, D7
Contact Phone No	01 8545070
Email	doneill@mater.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2012
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 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	N/A	N/A, Not Applicable, Ireland
2	Mater Misericordiae University Hospital	Pathology Laboratory, Eccles Street, Dublin, Ireland, 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 BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
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, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
	Blood Grouping (ABO & RhD)		BioRad IH-500	CE	Not applicable	LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility

						procedures in blood transfusion laboratories, 2012
	Blood Grouping (ABO & RhD), Confirmation of ABO and RhD group of Blood Transfusion Service Red Blood Cells	Whole blood, Red Blood Cells	BioRad IH-1000	CE	Not applicable	LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
			BioRad IH-500	CE	Not applicable	LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
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, LP-BT-ROU-08, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
			Manual gel cards	CE	N/A	LP-BT-ROU-33, LP-BT-ROU-08, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
	Antibody Screening	Blood with EDTA	BioRad IH-500	CE	Not applicable	LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification	Blood with EDTA, Blood with no anticoagulant (Clotted), Eluate	Manual gel cards and tube techniques	CE	Not applicable	LP-BT-ROU-09, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatching	Blood with EDTA, Blood with no anticoagulant (Clotted)	Manual gel cards and electronic issue	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, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
1020 Transfusion science - .07 Antibody elution	Antibody Elution Testing of EDTA specimens	Blood with EDTA	Elution	CE	Not applicable	LP-BT-ROU-15, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
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, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012
<i>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)</i>						

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 **1,2,3,4	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Calcium **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Chloride **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Creatinine **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Magnesium **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Phosphate **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Potassium **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Sodium **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Urate **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	24 hour Urine Urea **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
Alanine Aminotransferase (ALT) **1,2,3,4	Li-Heparin Plasma / Serum	NADH (without P-5'-P)	Abbott Alinity ci series / 5 U/L to 3899 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI	

Albumin/Creatinine Ratio **1,2,3,4	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Alkaline Phosphatase (ALP) **1,2,3,4	Li-Heparin Plasma / Serum	IFCC with PNPP	Abbott Alinity ci series / 9 U/L to 4555 UL	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Ammonia **1,2,3,4	Li-Heparin Plasma	Colorimetric	Abbott Alinity ci series / 14 µmol/l to 998 µmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Amylase **1,2,3,4	Li-Heparin Plasma/ Serum/ Fluid/ Urine	Enzymatic	Abbott Alinity ci series / 3 U/L to 3300 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Anion Gap **1,2,3,4	Plasma/Serum	Calculated	NA	Based on standard method	LI-CCE-0040
Aspartate Aminotransferase (AST) **1,2,3,4	Li-Heparin Plasma/ Serum	Enzymatic	Abbott Alinity ci series / 6 U/L to 5234 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Bicarbonate (Total CO2) **1,2,3,4	Li-Heparin Plasma / Serum	Enzymatic	Abbott Alinity c series / 5 to 50 mmol/L Highest reportable value (autodilution): >100 mmol/L (1:2)	CE	LI-CCE-0125 CLSI
Bilirubin direct **1,2,3,4	Li-Heparin Plasma/ Serum	Diazo	Abbott Alinity ci series / 1.7 µmol/l to 256.5 µmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Bilirubin Total **1,2,3,4	Li-Heparin Plasma / Serum	Diazo	Abbott Alinity ci series / 1.71 µmol/l to 427.5 µmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Calcium **1,2,3,4	Li-Heparin Plasma / Serum / Urine	Arsenazo III	Abbott Alinity ci series / 0.50 mmol/l to 6.00 mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Calcium Creatinine Clearance **1,2,3,4	Plasma / Serum / Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Calcium Creatinine Ratio **1,2,3,4	Urine	Calculated	NA	Based on standard method	LI-CCE-0040

Chloride **1,2,3,4	Li-Heparin Plasma / Serum / Urine	Ion selective electrode	Abbott Alinity ci series / 50 mmol/l to 150mmol/l / Urine: 20 mmol/l to 300mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Cholesterol **1,2,3,4	Li-Heparin Plasma / Serum	Cholesterol oxidase	Abbott Alinity ci series / 0.1 mmol/l to 19.24 mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Corrected Calcium **1,2,3,4		Calculated	N/A	Laboratory Developed Test	LI-CCE-0040
Creatine Kinase (CK) **1,2,3,4		Enzymatic	Abbott Alinity ci series / 7 U/L to 4267 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Creatinine **1,2,3,4	Li-Heparin Plasma / Serum / Fluid / Urine	Enzymatic	Abbott Alinity ci series / 8.8 µmol to 3536 µmol/l Urine: 0.22 mmol/l to 35.6 mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Creatinine Clearance **1,2,3,4	Li-Heparin Plasma/ Serum/ Urine	Calculated	N/A	Based on standard method	LP-CCE-0030
eGFR **1,2,3,4	Li-Heparin Plasma / Serum	Calculated	N/A	Based on standard method	LI-CCE-0040
Fractional Excretion of Sodium **1,2,3,4	Urine	Calculated	NA	Based on standard method	LI-CCE-0040
Fractional Excretion of Uric Acid **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Li-Heparin Plasma / Serum	Enzymatic	Abbott Alinity ci series / 4 U/L to 8500 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Glucose **1,2,3,4	Fluoride EDTA Plasma / CSF / Urine	Hexokinase	Abbott Alinity ci series / 0.28 mmol/l to 44.4 mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Hight Density Lipoprotein (HDL) Cholesterol **1,2,3,4	Li-Heparin Plasma / Serum	Enzymatic	Abbott Alinity ci series / 0.13 mmol/l to 4.66 mmol/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI



Lactate Dehydrogenase (LDH) **1,2,3,4	Serum / Fluid	Enzymatic	Abbott Alinity ci series / 30 U/L to 4500 U/L	CE	LI-CCE-0003 LI-CCE-0125 CLSI
Lipase **1,2,3,4	Serum / Plasma	Colorimetric	Abbott Alinity ci series	CE	LI-CCE-0125
Lithium **1,2,3,4	Serum	Colorimetric	Abbott Architect c16000	CE	LI-CCE-0003
Low Density Lipoprotein (LDL) **1,2,3,4	Li-Heparin Plasma / Serum	Enzymatic / Calculated	Abbott Alinity ci series / 0.03 mmol/l to 20.69 mmol/l	CE and Based on standard method	LI-CCE-0003 LI-CCE-0040 LI-CCE-0125 CLSI
Magnesium **1,2,3,4	Plasma/ Serum/ Urine	Arsenazo	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Non HDL Cholesterol **1,2,3,4	Plasma/Serum	Calculated	N/A	Calculated	LI-CCE-0040
NT-proBNP **1,2,3,4	EDTA	Chemiluminescent microparticle immunoassay (CIMA) technology	Abbott Allinity/Architect	CE	LI-CCE-0003 LI-CCE-0125
Phosphate **1,2,3,4	Plasma/ Serum/ Urine	Colorimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Potassium **1,2,3,4		Ion selective electrode	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Sodium **1,2,3,4		Ion selective electrode	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Total CO2 **1,2,3,4	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Triglycerides **1,2,3,4	Plasma/ Serum/ Fluid	Glycerol Phosphate Oxidase	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
Troponin I (High sensitivity) **1,2,3,4	Plasma	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

	Urea **1,2,3,4	Plasma/ Serum/ Fluid/ Urine	Urease	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Uric Acid **1,2,3,4	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 **1,2,3,4	Li-Heparin Plasma/ Serum	Bromocresol Green	Abbott Alinity ci series / 3 g/l to 94 g/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	C-Reactive Protein (CRP) **1,2,3,4	Li-Heparin Plasma/ Serum	Immunoturbidimetric	Abbott Alinity ci series / 1 mg/l to 160 mg/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	Globulins **1,2,3,4	Plasma / Serum	Calculated	NA	Based on standard method	LI-CCE-0040
	Microalbumin **1,2,3,4	Urine	Immunoturbidimetric	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Protein / Creatinine ratio **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	Protein -Total **1,2,3,4	Plasma/ Serum	Biuret	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
		Urine/ CSF	Benzethonium Chloride	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
SHBG **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	
1061 Clinical Chemistry - .05 CO-oximetry	Carboxyhaemoglobin **1,2,3,4	Blood Heparinised	Cooximetry	ABL 90 Flex	CE	LP-CCE-0049
	Ionised Calcium **1,2,3,4		Ion selective electrode (ISE)	ABL90 Flex	CE	LP-CCE-0049
	Methaemoglobin **1,2,3,4	Blood	Cooximetry	ABL90 Flex	Based on standard method	LP-CCE-0049
	Oxyhaemoglobin **1,2,3,4		Cooximetry	ABL90 Flex	CE	LP-CCE-0049
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2 **1,2,3,4		Potentiometric	ABL90 Flex	CE	LP-CCE-0049

	pH **1,2,3,4		Potentiometric	ABL90 Flex	CE	LP-CCE-0049
	pO2 **1,2,3,4		Potentiometric	ABL90 Flex	CE	LP-CCE-0049
	SO2 **1,2,3,4		Absorption Spectroscopy	ABL 90 Flex	CE	LP-CCE-0049
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess **1,2,3,4	Blood Heparinised	Calculated	ABL 90 Flex	CE	LP-CCE-0049
	Chloride **2,4	Blood in heparin	Ion-selective Electrode (ISE)	ABL 90 Flex Plus Analyser	CE	LP-POC-018 CLSI C46-A2
	Lactate **1,2,3,4	Blood Heparinised	Amperometric	ABL90 Flex	CE	LP-CCE-0049
	Potassium **1,2,3,4	Blood	Ion selective electrode	ABL90 Flex	CE	LP-CCE-0049
	Sodium **1,2,3,4		Ion selective electrode	ABL90 Flex	CE	LP-CCE-0049
	Standard Bicarbonate **1,2,3,4		Calculated	ABL90 Flex	Based on standard method	LP-CCE-0049
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Acetaminophen **1,2,3,4	Li-Heparin Plasma / Serum	Spectrophotometric	Abbott Alinity ci series / 4 mg/l to 605 mg/l	CE	LI-CCE-0125 CLSI
	Amikacin **1,2,3,4	Serum	Particle Enhanced Turbidimetric Assay	Abbott Alinity ci series / 2.0 mg/l to 50 mg/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	Carbamazepine **1,2,3,4		Petinia	Abbott Alinity ci series / 1.9 mg/l to 20.0 mg/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	Corrected Phenytoin **1,2,3,4		Calculated	NA	Based on standard method	LI-CCE-0040
	Cyclosporin **1,2,3,4	Whole Blood	LC-MS/MS	Waters TQD Waters Xevo TQ Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
	Digoxin **1,2,3,4	Serum	Particle Enhanced Turbidimetric Assay	Abbott Alinity ci series Abbott Architect c1600	CE	LI-CCE-0003 LI-CCE-0125
	Gentamicin **1,2,3,4	Li-Heparin Plasma / Serum	Particle Enhanced Turbidimetric Assay	Abbott Alinity ci series /0.5 mg/l to 10 mg/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI

	Methotrexate **1,2,3,4	Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Phenobarbitone **1,2,3,4		Petinia	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Phenytoin **1,2,3,4		Enzyme Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Sirolimus **1,2,3,4	Whole blood	LC-MS/MS	Waters TQD MS Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
	Tacrolimus **1,2,3,4		LC-MS/MS	Waters TQD MS Waters Xevo TQ Waters TQ-XS	Laboratory Developed Test	LP-CCE-0001
	Theophylline **1,2,3,4	Serum	Enzyme Immunoassay	Abbott Alinity ci series	CE	LP-CCE-0064 LI-CCE-0125
	Tobramycin **1,2,3,4		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Valproate **1,2,3,4		Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Vancomycin **1,2,3,4	Plasma/ Serum	Particle Enhanced Turbidimetric Assay	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Voriconazole **1,2,3,4	Serum	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0050
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol **1,2,3,4	Fluoride EDTA Plasma	Enzymatic	Abbott Alinity ci series / 10 mg/dl to 600 mg/dl	CE	LI-CCE-0003 LI-CCE-0125 LP-CCE-0064 CLSI

1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate **1,2,3,4	Plasma/ Serum	Enzymatic	Abbott Architect c16000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
1061 Clinical Chemistry - .20 Hormones	Adrenocorticotrophic hormone (ACTH) **1,2,3,4	EDTA Plasma on ice	Immunometric Assay	Roche Cobas / 1.5 to 2000 ng/L	CE	LP-CCE-0057 CLSI
	Androstenedione **1,2,3,4	Serum	LC-MS/MS	Waters Xevo TQ / 0.1 nmol/L to 44.6 nmol/L	Laboratory Developed Test	LP-CCE-0055 CLSI C62-A
	Cortisol **1,2,3,4	Li-Heparin Plasma / Serum	Immunoassay	Abbott Alinity ci series / 27.5 nmol/l to 1650 nmol/l	CE	LI-CCE-0003 LP-CCE-0064 CLSI
	C-Peptide **1,2,3,4	Plasma / Serum	CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect i2000 Alinity ci series	CE	LP-CCE-0003 LI-CCE-0125
	Follicle Stimulating Hormone (FSH) **1,2,3,4		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Growth Hormone **1,2,3,4	Serum	Immunoassay	IDS iSYS / 0 µg/l to 10 µg/l	CE	LP-CCE-0051 CLSI
	HCG- Total **1,2,3,4	Li-Heparin Plasma / Serum	Immunoassay	Abbott Alinity ci series / 1.2 IU/l to 15,000 IU/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	IGF-1 **1,2,3,4	Serum	Immunoassay	IDS iSYS / 10 µg/l to 1200 µg/l	CE	LP-CCE-0035 CLSI
	Insulin **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Lutenising Hormone (LH) **1,2,3,4		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Macroprolactin **1,2,3,4		PEG Precipitation	Abbott Architect i2000 Alinity ci series	Based on standard method	LP-CCE-0005 LI-CCE-0125
Oestradiol **1,2,3,4	Immunoassay		Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	

	Parathyroid Hormone (PTH) **1,2,3,4	Plasma	Immunoassay	Roche e411	CE	LP-CCE-0048
	Progesterone **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Prolactin **1,2,3,4		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	T3 free **1,2,3,4		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	T4 free **1,2,3,4	Plasma/ Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LP-CCE-0064
	Testosterone **1,2,3,4	Serum	LC-MS/MS	Waters Xevo TQ MS	Laboratory Developed Test	LP-CCE-0055
	Thyroid Stimulating Hormone (TSH) **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Urine Free Cortisol **1,2,3,4	24 hour Urine	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0029
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4	Li-Heparin Plasma / Serum	Immunoassay	Abbott Alinity ci series / 1.98 µg/l to 1676 µg/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	Iron **1,2,3,4	Li-Heparin Plasma / Serum	Colorimetric	Abbott Alinity ci series / 0.9 µmol/l to 179 µmol/l	CE	LI-CCE-0003 LI-CCE-0125 LP-CCE-0064 CLSI
	Transferrin **1,2,3,4	Plasma/ Serum	Immunoturbidimetric	Abbott Architect c16000 Abbott Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125
	Transferrin Saturation **1,2,3,4		Calculated	n/a	Based on standard method	LI-CCE-0040
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

	Folate Red Cell **1,2,3,4	Blood in EDTA	Immunoassay	Abbott Alinity ci series / 2.2 ng/ml to 20.0 ng/ml	Based on standard method	LP-CCE-0010 LI-CCE-0125 CLSI	
	Vitamin B12 **1,2,3,4	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 **1,2,3,4	Serum	CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect Immunoassay Alinity ci series	Based on a standard method	LI-CCE-0115 LI-CCE-0125	
	Vitamin D **1,2,3,4		LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-CCE-0002	
			LC-MSMS	Waters TQ-XS 15 nmol/L to 368 nmol/L	In house developed	LP-CCE-0002	
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP) **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	
	CA-125 **1,2,3,4		Li-Heparin Plasma / Serum	Immunoassay	Abbott Alinity ci series / 1.1 KU/l to 1000 KU/l	CE	LI-CCE-0125 LI-CCE-0003 CLSI
	CA-15-3 **1,2,3,4			Immunoassay	Abbott Alinity ci series / 0.6 KU/l to 800 KU/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	CA-19-9 **1,2,3,4			Immunoassay	Abbott Alinity ci series / 2.06 KU/l to 1200 KU/l	CE	LI-CCE-0003 LI-CCE-0125 CLSI
	Calcitonin (hCT) **1,2,3,4	Serum on ice	Immunoassay	Roche Cobas / 1 to 200,000 ng/L	CE	LP-CCE-0058 CLSI	
	CEA **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	
	PSA Total **1,2,3,4		Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125	
	Thyroglobulin **1,2,3,4	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) **1,2,3,4	EDTA Plasma	Immunoassay	Roche e411 / 0.010 to 6.00 µg/L	CE	LP-CCE-0031 CLSI
	Procollagen Type 1 N- Propeptide (P1NP) **1,2,3,4	Plasma	Immunoassay	Roche e411	CE	LP-CCE-0032
1061 Clinical Chemistry - .56 Biogenic amines	Homocysteine **1,2,3,4		Li-Heparin Plasma / HCY-Z gel serum	CMIA (Chemiluminescent microparticle Immunoassay)	Abbott Architect Immunoassay Alinity ci series	CE
	Total Homocysteine	Chemiluminescent Microparticle Immunoassay (CMIA)		Alinity ci series / 1.00 µmol/l to 50.0 µmol/l Highest reportable value (autodilution): >500 umol/L (1:10)	CE	LI-CCE-0125 LI-CCE-0118 CLSI
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c **1,2,3,4	Blood in EDTA	HPLC	Arkray HA8190 / 20 mmol/mol to 150mmol/mol	CE	LP-CCE-0060 LP-CCE-0080 CLSI
			HPLC	Arkray HA8190 20 mmol/mol to 150 mmol/mol	CE	LP-CCE-0080
1061 Clinical Chemistry - .77 Calculi	Stone Analysis **1,2,3,4	Stone	FT-IR	Nicolet iS10	Based on a standard method	LP-CCE-0041
1061 Clinical Chemistry - .78 Intermediary metabolites	3 -Methoxytyramine **1,2,3,4	EDTA Plasma on ice	LC-MS/MS	Waters Xevo TQ MS / 65 pmol/L to 10087 pmol/L	Laboratory Developed Test	LP-CCE-0053 CLSI C62-A
	Plasma Metanephrines **1,2,3,4		LC-MS/MS	Waters Xevo TQ MS	Laboratory Developed Test	LP-CCE-0053
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Thyroglobulin Antibodies **1,2,3,4	Serum	Electrochemiluminescence immunoassay	Roche e411	Based on standard method	LP-CCE-0059
1061 Clinical Chemistry - .99 Miscellaneous tests	Free Androgen Index **1,2,3,4		Calculated	N/A	Based on standard method	LI-CCE-0040 LI-CCE-0008
	Free Testosterone **1,2,3,4		Calculated	N/A	Based on standard method	LI-CCE-0040



	Osmolality **1,2,3,4	Li-Heparin Plasma / Serum / Urine	Freezing Point Depression	Osmo1	CE	LP-CCE-0009 CLSI
	Thyroid peroxidase (TPO) antibodies **1,2,3,4	Plasma / Serum	Immunoassay	Abbott Architect i2000 Alinity ci series	CE	LI-CCE-0003 LI-CCE-0125

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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 **4	Fresh Capillary Blood	Enzymatic and Amperometric	Stat Strip Nova Biomedical hand held device & docking station	Based on standard method	LP-POC-016
	Ketone **4		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 **2,4	Blood	Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
			Impedance	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Haemoglobin & Haemoglobin Derivatives **2,4		Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
	Haemoglobin **2,4		Chemometrics applied to optical absorbance	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	Standard Bicarbonate **1,2,4		Calculated	Prime Plus Blood Gas Analyser	CE	LP-POC-017
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pO2 **2,4		Amperometric	Abbott i-Stat	CE	LP-POC-010
			Potentiometric	ABL 90 Flex	CE	LP-POC-001
	pCO2 **2,4		Potentiometric	Abbott i-Stat	CE	LP-POC-010

	pCO2 **2,4		ISE Potentiometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	pH **2,4		Potentiometric	ABL 90 Flex	CE	LP-POC-001
			ISE	Abbott i-Stat	CE	LP-POC-010
	pO2 **2,4		ISE	ABL 90 Flex	CE	LP-POC-001
			ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017
			ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017
			Potentiometric	ABL 90 Flex	CE	LP-POC-001
	SO2 **2,4		Absorption Spectroscopy	ABL 90 Flex	CE	LP-POC-001
			Chemometrics applied to optical absorbance	Prime Plus Blood Gas Analyser	CE	LP-POC-017
	1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser		Anion Gap **2,4		Calculated	NA
Base Excess **2,4		Calculated	ABL 90 Flex		CE	LP-POC-001
		Calculated	Prime Plus Blood Gas Analyser		CE	LP-POC-017
Chloride **2,4			ISE	ABL90	CE	LP-POC-017
Creatinine		Blood in heparin	Amperometry	ABL 90 Flex Plus Analyser / 10 to 1800 µmol/L	CE	LP-POC-018 CLSI C46-A2
Glucose **2,4		Blood	Amperometric	ABL 90 Flex	CE	LP-POC-001
Glucose **2,4			ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017
Ionised Calcium **2,4			ISE	ABL 90 Flex	CE	LP-POC-001
Ionised Magnesium **2,4			ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017
Ionised Calcium **2,4			ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017

	Lactate **2,4		Amperometric	ABL 90 Flex	CE	LP-POC-001
	Potassium **2,4		ISE Amperometric	Prime Plus Blood Gas Analyser	CE	LP-POC-017
			ISE	Abbott i-Stat	CE	LP-POC-010
			ISE	ABL 90 Flex	CE	LP-POC-001
	Sodium **2,4		ISE	Prime Plus Blood Gas Analyser	CE	LP-POC-017
			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 **2,4			Calculated	ABL 90 Flex	CE
Urea	Blood in Heparin	Potentiometry	ABL 90 Flex Plus Analyser / 1 to 50 mmol/L	CE	LP-POC-018 CLSI C46-A2	
1061 Clinical Chemistry - .61 Hb A1c	Haemoglobin A1c (HbA1c)	Fresh Capillary Whole Blood & Anticoagulated Whole Blood with EDTA, heparin, fluoride/oxalate or citrate	Latex Immune-Agglutination Inhibition & Spectrophotometry	DCA Vantage / 4 to 130 mmol/mol	CE	LP-POC-022 IFCC

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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)	NGS panels Cardiology: Arrhythmogenic Cardiomyopathy Atrial Fibrillation Aortic Diseases Arrhythmias and Sudden Death without Structural Heart Disease Brugada Syndrome Cardiac Conduction Disease Cardiomyopathies and Arrhythmias Cardiomyopathies Congenital Heart Catecholaminergic Polymorphic Ventricular Tachycardia Cardiovascular Diseases Dilated Cardiomyopathy Hypertrophic Cardiomyopathy Long QT Syndrome Non-Compaction Cardiomyopathy RASopathies Restrictive	EDTA Whole blood	Next Generation Sequencing (NGS) - screening for clinical significant germline SNPs and small (<10) indels associated with rare and inherited disorders	Illumina NextSeq 500	CE	LP-NGS-14, LP-NGS-17, LP-NGS-25, LP-NGS-26, LP-NGS-44  American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines  Association of Clinical Genomic Science (ACGS)

	Cardiomyopathy Short QT Syndrome Respiratory: Pulmonary Arterial Hypertension					
	Sanger sequencing	EDTA Whole blood, DNA	Sanger Sequencing - screening for clinically significant germline SNPs and small (<10) indels for the purposes of confirmatory testing, cascade testing & targeted genes	Applied Biosystems SeqStudio	CE	LP-NGS-44, LP-NGS-45 (Sanger Sequencing & Analysis)  American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines  Association of Clinical Genomic Science (ACGS) Practice guidelines for Sanger Sequencing Analysis and Interpretation and General Genetic Laboratory Reporting Recommendations
1075 Molecular genetics - .11 DNA extraction	DNA Isolation	EDTA Whole blood	DNA Isolation	Roche MagnaPure 24	CE	LP-NGS-10 (DNA Isolation from Peripheral Blood on the MagNa Pure 24)  American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines  Association of Clinical Genomic Science (ACGS)



Haematology

Category: A

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) **1,2,4	Blood	Culmulative pulse measurement	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Haemoglobin (Hb) **1,2,4		Sodium Lauryl Sulphate (SLS) Haemoglobin	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	MCH **1,2,4		Calculated from Hb and RBC	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	MCHC **1,2,4		Calculated from Hb and HCT	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Mean cell volume(MCV) **1,2,4		Indirect measurement (mean of RBC volume)	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Platelet count **1,2,3,4		Hydrodynamic Focussing Direct Current (DC) detection	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Red cell count(RBC) **1,2,4		Hydrodynamic Focussing Direct Current (DC) detection	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	White cell count (WBC) **1,2,4		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 **2,4		Staining/microscopy/Digital imaging	Wescor stainer/ Sysmex SP10 stainer/Microscope/CellaVision DI-60 automated digital	Based on standard method	LP-HAE-004 LP-HAE-006



				imaging analysis system with operator result validation		LP-HAE-070 LP-HAE-072
	Staining of Blood films for the examination of Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, Red Cell morphology	Blood in EDTA	Wrights Giemsa staining	N/A	CE	LP-HAE-107 BSH Guidelines
	Staining of Bone marrow aspirate slides	Bone marrow Aspirate	May Grunwald staining	N/A	CE	LP-HAE-107 BSH Guidelines
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR) **1,3,4	Blood	Photo optical based on Westergren method	Sarstedt Sediplus S2000	CE	LP-HAE-024
1030 Haematology - .05 Automated differential leucocyte counts	Automated basophil count **1,2,4		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated eosinophil count **1,2,4		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated lymphocyte count **1,2,4		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated monocyte count **1,2,4		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
	Automated neutrophil count **1,2,4		Fluorescence Flow Cytometry	Sysmex XN-10/XN 20	CE	LP-HAE-0067, LP-HAE-0068
1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte count **1,2,4		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) **2,3,4	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 **2,4	Blood	Staining/ microscopy	Manual staining technique/ Microscope	Based on standard method	LP-HAE- 025, LP- HAE-026
	Malaria screening test **2,4		Immunochemical card screening test	Manual immunochemical card test	CE	LP-HAE- 027
1030 Haematology - .20 Bone marrow examination	Bone marrow examination **1,2,4	Bone marrow aspirate	Staining/ microscopy	Wescor stainer/Microscope	Based on standard method	LP-HAE- 007
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Haemoglobin Electrophoresis **1,2,4	Blood	Capillary Electrophoresis	Sebia Minicap Flex piercing	CE	LP-HAE- 083
	HPLC for Haemoglobinopathy **1,2,4		High performance liquid chromatography	Biorad D10	CE	LP-HAE- 050
	Sickle cell screen **4		Qualitative solubility test for Hb S	Manual test	CE	LP-HAE- 028
1030 Haematology - .36 Screening tests for G6Pd	Glucose 6 Phosphate Dehydrogenase screen **1,2,4		Qualitative fluorescence test	Manual test	CE	LP-HAE- 029
1030 Haematology - .40 Limited haemostasis related tests	Activated Protein C resistance **1,4		Photo optical	ACL TOP 550	CE	LP-HAE- 089
	Anti Xa level(LMWH) **2,4		Chromogenic	ACL TOP 550	CE	LP-HAE- 092
	Anti Xa level(UFH) **2,4		Chromogenic	ACL TOP 550	CE	LP-HAE- 097
	Anticoagulant drug monitoring: Rivaroxaban / Apixaban / Dabigatran **2,4		Chromogenic	ACL TOP 550	CE	LP-HAE- 093, LP- HAE-095
	Antithrombin **1,2,4		Chromogenic	ACL TOP 550	CE	LP-HAE- 089
	Factor II:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE- 102
	Factor IX:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE- 103

	Factor V:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor VII:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor VIII:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-103
	Factor X:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-102
	Factor XI:C assay **1,4		Photo optical	ACL TOP 550	CE	LP-HAE-103
	Factor XII:C assay **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-103
	Free Protein S **1,2,4		Immuno-turbidimetric	ACL TOP 550	CE	LP-HAE-089
	Heparin Induced Thrombocytopenia screen (HIT) **1,2,3,4	Serum	Lateral flow immunoassay	N/A	CE	LP-HAE-106
	Lupus anticoagulant **1,2,4	Blood	Photo optical	ACL TOP 550	CE	LP-HAE-090
	Lupus Insensitive Activated Partial Thromboplastin Time(APTT) **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-096
	Protein C **1,2,4		Chromogenic	ACL TOP 550	CE	LP-HAE-089
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time(APTT) **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-087
	Activated Partial Thromboplastin Time (APTT) ** 1,2,3,4	Blood in Sodium Citrate	Clot based manual method	20 to 180 seconds / Waterbath	CE	LI-HAE-056 BSH Guidelines
	APPT Correction test		Photo optical	16 to 400 seconds	CE	LP-HAE-098 BSH Guidelines
	D Dimer **1,4	Blood	Immuno-turbidimetric	ACL TOP 550	CE	LP-HAE-087
	Fibrinogen (Clauss) **1,4		Photo optical	ACL TOP 550	CE	LP-HAE-087

	International Normalised ratio (INR) **1,4		Photo optical	ACL TOP 550	CE	LP-HAE-087
	Prothrombin Time **1,2,4		Photo optical	ACL TOP 550	CE	LP-HAE-058
	Prothrombin Time (PT) **1,2,3,4	Blood in Sodium Citrate	Clot based manual method	9 to 150 seconds / Waterbath	CE	LI-HAE-056 BSH Guidelines
	PT Correction test		Photo optical	8 to 320 seconds	CE	LP-HAE-098 BSH Guidelines
	Thrombin Time **1,2,4	Blood	Photo optical	ACL TOP 550	CE	LP-HAE-088
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious mononucleosis screen **3,4		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 **2,3,4	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 **2,3,4		Flow cytometry	BD Facs Canto	CE	LP-HAE-075, LP-HAE-077
	PNH screen:Antigens tested;CD235, CD59, FLAER, CD15,CD33,CD14, CD24 **2,3,4	Blood	Flow cytometry	BD Facs Canto	CE	LP-HAE-075, LP-HAE-079

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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 **2,4	Whole Blood	Modified Azidemethaemoglobin reaction	HemoCue Hb 201 DM Analyser	Based on standard method	LP-POC-002
1030 Haematology - .40 Limited haemostasis related tests	Activated Clotting Time - Plus (ACT+)	Native Whole Blood	Mechanical Endpoint Clotting Detection	GEM Hemochron 100 / 68 to 1005 s	CE	LP-POC-020 BSH Guideline: Point of Care in General Haematology & CLSI POCT14
	INR **1,4	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 **2,4	Whole blood	Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	FIBTEM C **2,4		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	HEPTEM C **2,4		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013
	INTEM C **2,4		Thromboelastometry	ROTEM sigma analyser	CE	LP-POC-013

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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 International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and

						Reporting. Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
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  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
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 Alcian Blue-PAS	Human Tissue/ Human Fluid/ FFPE tissue	Dako Artisan Link Pro Stainer Leica HistoCore SPECTRA Stainer and Coverslipper	CE and based on standard method	N/A	LP-HIS-ST-001 LP-HIS-ST-002 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



	<p>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>					<p>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> <p>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)</p>
	Histochemistry	FFPE	Dako Artisan Link Pro Special Stains Stainer	CE	N/A	<p>LP-HIS-EQ-017 International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for</p>

						the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
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 / FFPE tissue	Microscope	Based on standard method	N/A	<p>LP-HIS-EQ-002</p> <p>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)</p>
1051 Histopathology - .09 Immunohistochemistry	<p>ACTM ACTS AE13 ALK AFP AAT AR BCAT BCL2 BCL6 Ber EP4 CALP CA125 CAM CALC CALR C4D CD1A</p>	Human tissue	<p>AutomatedUltraview DAB detection Ultraview APAP detectionOptiview DAB detection Inform Her2 ISH detectionIHC DS uDAB uAP Red using Ventana Benchmark UltraVentana Benchmark XTLeica Bond III MicromHM325 MicrotomesNikon MicroscopeSakura Prisma/G2 Integrated Stainer and Coverslipper</p>	CE	N/A	<p>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</p>

CD2 CD3 CD4 CD5 (4C7) CD8 CD10 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 ERG ERSP1					
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	F8 F XIIIa GAL3 GATA GAST GFAP GH GLU GLUT 1 HBCAG HBSAG HCG HER356 HER4B5 HHV8 HMB HLO HPL HPV HSA HSV1 HSV2 IgG4 IGM INH INS KLC LLC LYSO MAMA MELA MIB1 MLH1 MSH2 MSH6MT1 MT2 MPO MUM1 MYF4 MYOG MYOS NAP NCAD NFIL NK1C3					
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	<p> NSE  PAX8  PGP9.5  P16  P53  P63  P120 Catenin  PLAP  PMS2  PNEUMO  PR  PSA  PSMA  RACE  RCC  SER  SMMS  SOM  SYN  S100  TDTI  THROM  TG  TLE  TTF1  VIM  WT1 </p> <p> 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 </p>					
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	Immunohistochemistry staining NKX 3.1 Antibody		Ventana BenchMark Ultra IHC stainer / Immunohistochemistry	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 International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting. Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	EBER Inform Her2 ISH detection. List of probes: Inform HER2 Dual ISH DNA, DNA Probe cocktail	FFPE TISSUE	VENTANA BenchMark ULTRA IHC stainer Microtomes Nikon Microscope Leica HistoCore Spectra Stainer Coverslipper / Chromogenic in situ hybridisation	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  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality

						Assurance Programme in Histopathology (Version 6.11,2018)
	Inform Kappa ISH		VENTANA BenchMark ULTRA IHC stainer Microtomes Nikon Microscope Leica HistoCore Spectra Stainer Coverslipper / Chromogenic in situ hybridisation	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  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
	Inform Lambda ISH		VENTANA BenchMark ULTRA IHC stainer Microtomes Nikon Microscope Leica HistoCore Spectra Stainer Coverslipper / Chromogenic in situ hybridisation	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  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and

					Reporting. Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
1051 Histopathology - .13 Molecular testing	Idylla BRAF Mutation Test	Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
	Idylla KRAS Mutation Test	Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of



					a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
	Idylla MSI Mutation Test	Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
	Idylla NRAS Mutation Test	Idylla RT-PCR	CE	N/A	LP-HIS-EQ-045  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)

1052 Cytopathology - .02 Non gynaecological cytology	Cytology Sample Preparation and Description  Cytology sample Description Cytology Sample Preparation Cytology Sample Staining  Diagnostic interpretation and reporting of non-gynae samples	Human tissue or fluid	Thin Prep Megafuge Shandon Cytospin Microflow Class II Cabinet Leica ST5010 (XL Autostainer)	Based on standard method	N/A	LP-HIS-CY-001 LP-HIS-CY-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-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  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
1052 Cytopathology - .03 Cytochemistry	Oil Red O method Delipidisation of Fresh Specimens Ziehl-Neelsen	Human Tissue/ Human Fluid	Thin Prep Megafuge Shandon Cytospin Leica ST5010 (XL Autostainer)	CE	N/A	LP-HIS-ST-013 LP-HIS-EQ-008 LP-HIS-EQ-030 LP-HIS-EQ-039 LP-HIS-EQ-025

	Grocott		Microflow Class II Cabinet Dako Artisan Stainer Leica HistoCore Spectra Stainer Coverslipper			LP-HIS-EQ-017 LP-HIS-EQ-046 LP-HIS-EQ-002 LP-HIS-MAN-037  International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.  Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)
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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 Monoclonal Gammopathies **1,2,3,4	Serum	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 **1,2,3,4	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 samples for Allergen specific IgE **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012

	Quantitative investigation of Serum samples for Allergen specific IgG **1,2,3,4	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 **1,2,3,4	Optilite / Turbidmetry	CE	N/A	LP-IMM-0041
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti-GAD **1,2,3,4	DS2/Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0034 LP-IMM-0015
	Anti-IFA measurment using the Phadia/Thermofisher Immunocap 250 **1,2,3,4	Phadia Immunocap250 analyser	Enzyme Immunoassay	N/A	LP-IMM-0012 LI-IMM-0044
	Anti-Liver Kidney Microsomal (Anti-LKM) **1,2,3,4	Phadia Immunocao 250 Analyser / Enzyme Immunoassay	CE	0.4-168 U/ml	LP-IMM-0012  British Society of Gastroenterology (BSG)  Sheffield PRU - Autoimmunity
	Anti-M2 **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	B-2 glycoprotein-1 IgG **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	B-2 Glycoprotein-1 IgM **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Cardiolipin IgG **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012

Cardiolipin IgM **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
CCP **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Centromere **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Connective Tissue Disease Screen & Confirmation using the Phadia/Thermofisher Immunocap 250 **1,2,3,4	Phadia Immunocap250 analyser	Enzyme Immunoassay	N/A	LP-IMM-0012 LI-IMM- 0044
ds-DNA **1,2,3,4	Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Jo-1 **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - La **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - RNP70 **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Ro **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - Scl-70s **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
ENA - U1RNP **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
Extractable Nuclear Antigen / ENA - Smd P-S **1,2,3,4	Phadia Immunocap 250 analyser / Enzyme Immunoassay	CE	0.7 U/mL to 330.0 U/mL	LP-IMM-0012 National Clinical

						Programme for pathology (NCP)
	GBM **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Myeloperoxidase **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Proteinase -3 **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	Rheumatoid Factor **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	TTG IgA **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
	TTG IgG **1,2,3,4		Phadia Immunocap 250 analyser/ Enzyme Immunoassay	Based on standard method	N/A	LP-IMM-0012
1040 Immunology - .13 Cryoglobulins	Identification of the presence of Cryoglobulin		Sebia Hydrasys / Immunofixation	CE	Presence detected visually	LP-IMM-0011 National Institute for Health and Care Excellence (NICE)
1040 Immunology - .14 b2-microglobulin	Beta-2-microglobulin **1,2,3,4		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 **1,2,3,4	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 **1,2,3,4		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 **1,2,3,4		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 **1,2,3,4		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-Liver Kidney Microsomal (Anti-LKM) **1,2,3,4	Serum	Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/10 to / 40	LP-IMM-0006 LP-IMM-0030  British Society of Gastroenterology (BSG)  Sheffield PRU - Autoimmunity
	Anti-Liver Kidney Microsomal / Anti-LKM **1,2,3,4		Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006, LP-IMM-0030  British Society of Gastroenterology (BSG)  Sheffield PRU - Autoimmunity
	Anti-Neutrophil Cytoplasmic Antibodies (ANCA) **1,2,3,4		Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/20	LP-IMM-0027 LP-IMM-0030  International Consensus on ANCA
	Anti-Neutrophil Cytoplasmic Antibodies / ANCA **1,2,3,4		Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/20	LP-IMM-0027, LP-IMM-0030  International Consensus on ANCA
	Anti-Nuclear Antibodies (ANA) **1,2,3,4		Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/40 to 1/640	LP-IMM-0005 LP-IMM-0030  National Clinical Programme for Pathology
	Antinuclear Antibodies / ANA **1,2,3,4		Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/40 to 1/640	LP-IMM-0005, LP-IMM-0030  National Clinical



				Programme for Pathology (NCP)
ds -DNA Crithidia **1,2,3,4	Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/10	LP-IMM-0008 LP-IMM-0030  National Clinical Programme for Pathology
ds-DNA Crithidia **1,2,3,4	Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/10	LP-IMM-0008, LP-IMM-0030  National Clinical Programme for Pathology (NCP)
Endomysial Antibodies (EMA) **1,2,3,4	Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/5	LP-IMM-0026 LP-IMM-0030  National Clinical Programme for Pathology
Endomysial Antibodies / EMA **1,2,3,4	Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/5	LP-IMM-0026, LP-IMM-0030  National Clinical Programme for Pathology (NCP)
Investigation of Skin antibodies **1,2,3,4	Biorad PhD slide processor/ Indirect Immunofluorescence	Based on standard method	N/A	LP-IMM-0028 LP-IMM-0030
Mitochondrial Antibodies (AMA) **1,2,3,4	Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006 LP-IMM-0030  Sheffield PRU - Autoimmunity
Mitochondrial Antibodies / AMA **1,2,3,4	Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006, LP-IMM-0030  Sheffield PRU - Autoimmunity

	Parietal Cell Antibodies (PCA) **1,2,3,4		Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006 LP-IMM-0030  Sheffield PRU- Autoimmunity
	Parietal Cell Antibodies / PCA **1,2,3,4		Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006, LP- IMM-0030  Sheffield PRU - Autoimmunity
	Smooth Muscle Antibodies (SMA) **1,2,3,4		Helmed automated IFA processor / Indirect Immunofluorescence	CE	1/10 to 1/40	LP-IMM-0006 LP-IMM-0030  Sheffield PRU- Autoimmunity
	Smooth Muscle Antibodies / SMA **1,2,3,4		Helmed Automated IFA Processor / Indirect Immunofluorescence	CE	1/10 to 1/160	LP-IMM-0006, LP- IMM-0030  Sheffield PRU - Autoimmunity
1040 Immunology - .61 Proteins, quantitative analysis	Quantitative measurement of Serum free light chains – Kappa and Lambda **1,2,3,4		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
1040 Immunology - .99 Miscellaneous tests	Alpha-1-antitrypsin **1,2,3,4		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-004
	Antistreptolysin **1,2,3,4		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
	Calprotectin **1,2,3,4	Faeces	Diasorin / Chemiluminescence	CE certified method	N/A	LP-IMM-0040
	Coeruloplasmin **1,2,3,4	Serum	Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041
	Haptoglobin **1,2,3,4		Optilite / Turbidimetry	CE certified method	N/A	LP-IMM-0041

*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures".*

*Note 1 - Range may be extended for the test*

*Note 2 – New parameters/tests may be added*

*Note 3 – New matrices may be added*  
*Note 4 – Changes to equipment/kits where the underlying methodology does not change*  
*For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory*

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	Qualitative	LP-MIC-ROU-02 LP-MIC-ROU-03 LP-MIC-ROU-06 LP-MIC-ROU-14, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards for Microbiology Investigation for Fluids from Normally Sterile Sites
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 in EDTA, CSF	Microscope / Microscopy	Based on standard method	Presence or absence of red blood cells white blood cells and epithelial cells	LP-MIC-ROU-05 LP-MIC-ROU-03 LP-MIC-ROU-14 LP-MIC-IDEN-05, PHE UK Standards UK Standards Investigation of urine, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards Investigation of Faecal

						Specimens for Enteric Pathogens
	Gram staining	Tissue/Fluids/ Corneal scrapings, CSF, Vaginal, Endocervical, Urethral swabs in Amies transport medium	Microscope / Staining and Microscopy	Based on standard method	Presence or absence of bacteria	LP-MIC-IDEN-08, PHE UK Standards UK Standards Investigation of urine, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens, PHE UK Standards Investigation of genital tract and associated specimens, PHE Guidance on the detection of gonorrhoea in England, PHE UK Standards for Microbiology Investigation of Sinus Aspirate
	Urine cell counts using analyser Sedimax Contrast Pro for the investigation of UTIs	Urine	Sedimax Pro Contrast / Bright field and phase contrast microscopy	CE marked	Particle concentration (HPF or / $\mu$ L)	LP-MIC-ROU-05, PHE UK Standards UK Standards Investigation of urine
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	Presence or absence of cysts and oocytes	LP-MIC-ROU-26, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens
	Ova & Parasites	Urine, Faeces	Microscope / Concentration and Microscopy	Based on standard method	Protozoa: presence of cysts and oocytes Helminths: presence	LP-MIC-ROU-26, PHE UK Standards Investigation of

					or absence of eggs or larvae	Specimens other than Blood for Parasites
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	Presence or absence of fungal hyphae	LP-MIC-ROU-02, PHE UK Standards for Microbiology Investigation of Dermatological Specimens for Superficial Mycoses
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	Presence or absence of acid fast bacilli (AFB)	LP-MIC-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species
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	Qualitative	LP-MIC-ROU-14, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid
	Culture of faecal specimens	Faeces	N/A / Agar and enrichment culture	Based on standard method	Qualitative	LP-MIC-ROU-06 LP-MIC-ROU-12, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens
	Culture of genital tract & associated specimens	Swabs: Vaginal, Endocervical, Urethral, Rectal, Pharyngeal in Amies transport medium. Bartholins gland aspirate, pus & IUD	N/A / Culture	Based on standard method	Qualitative	LP-MIC-ROU-07, LP-MIC-ROU-13, PHE UK Standards Investigation of genital tract and associated specimens, PHE Guidance on the detection of gonorrhoea in England

Culture of respiratory specimens for bacterial pathogens other than Mycobacteria	Respiratory samples	N/A / Culture	Based on standard method	Qualitative	LP-MIC-ROU-02, LP-MIC-ROU-08, PHE UK Standards for Microbiology Investigation of Bronchoalveolar Lavage, Sputum and Associated Specimens
Culture of specimens from superficial & deep seated infections	Wounds/Tissue/ Fluids/Swabs in Amies transport medium/IV tips	N/A / Agar and enrichment culture	Based on standard method	Qualitative	LP-MIC-ROU-03, LP-MIC-ROU-09, PHE UK Standards for Microbiology Investigation of tissues and biopsies from deep-seated sites and organs, PHE UK Standards for Microbiology Investigation for Fluids from Normally Sterile Sites, PHE UK Standards Investigation of Intravascular Cannulae and Associated Specimens, PHE UK Standards for Microbiology Investigation of Sinus Aspirate
Culture of urine specimens	Urine	N/A / Culture	Based on standard method	Qualitative	LP-MIC-ROU-05, LP-MIC-ROU-11, PHE UK Standards UK Standards Investigation of urine
Screening of specimens for MDRO	Swabs in Amies transport medium & Faeces	N/A / Culture	Based on standard method	Qualitative	LP-MIC-ROU-04, LP-MIC-ROU-10, Eucast Guidelines, PHE UK Standards Investigation of Specimens for Screening for MRSA

		Swabs in Amies transport medium & Faeces	N/A / Culture	CE marked	Qualitative	LP-MIC-ROU-04, LP-MIC-ROU-10, PHE UK Standards Investigation of Specimens for Screening for MRSA
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 (in Amies transport medium), Urines,	N/A / Culture	Based on standard method	Qualitative	LP-MIC-ROU-17, LP-MIC-ROU-02, LP-MIC-ROU-03, LP-MIC-ROU-14, LP-MIC-ROU-05, LP-MIC-ROU-07, PHE UK Standards for Microbiology Investigation of Dermatological Specimens for Superficial Mycoses, PHE UK Standards for Microbiology Investigation of Bronchoalveolar Lavage, Sputum and Associated Specimens, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards for Microbiology Investigation of tissues and biopsies from deep-seated sites and organs, PHE UK Standards Investigation of Intravascular Cannulae and Associated Specimens, PHE UK Standards for Microbiology Investigation for Fluids from Normally Sterile Sites



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 (Myco/F lytic Culture vials)	BACTEC FX / Advanced fluorescence detection technology	CE marked	Range of time to detection 8-16 days	LP-MIC-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species
		Respiratory samples, tissue/bone samples, fluids/CSF, Urine	BacTALERT 3D / Automated colorimetric microbial detection	CE marked	Mycobacterium tuberculosis ≤14 cfu Mycobacterium kansasii ≤4cfu Mycobacterium avium ≤15 cfu	LP-MIC-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Salmonella, Shigella and Vibrio typing	Isolate on nutrient agar slope	N/A / Slide agglutination	CE marked	Visible agglutination in the presence of homologous cultures	LP-MIC-ROU-12, PHE UK Standards for Microbiology for investigation of Gastroenteritis, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Dry spot Pnemo	Blood	N/A / Particle agglutination	CE marked	Visible agglutination in the presence of homologous cultures	LP-MIC-IDEN-06
	E. coli 0157 Latex	Isolate	N/A / Particle agglutination	CE marked	Visible agglutination in the presence of homologous cultures	LP-MIC-IDEN-07
	Pastorex		N/A / Particle agglutination	CE marked	Visible agglutination in the presence of homologous cultures	LP-MIC-IDEN-11

	Streptococcal Grouping Latex Kit		N/A / Particle agglutination	CE marked	Visible agglutination in the presence of homologous cultures	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 (QFT-Plus)	Diasorin Liason XL / Chemiluminescence assay	CE marked	Assay range: up to 10 IU/ml of IFN-gamma	LP-MIC-ROU-51, PHE UK Standards Investigation of specimens for Mycobacterium species, WHO Guidelines on the management of latent tuberculosis infection
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	Presence or absence of MPT64 antigen	LP-MIC-ROU-34, PHE UK Standards Investigation of specimens for Mycobacterium species
	Cryptococcal Antigen	CSF & serum	N/A / Immuno-chromatographic assay	CE marked	CSF: Qualitative Serum: semi-quantitative C5 – C95 Interval 1.0 – 1.5 ng/mL	LP-MIC-ROU-23, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid
	Legionella Urinary antigen	Urine	N/A / Immuno-chromatographic assay	CE marked	Presence or absence of L. pneumophila serogroup 1 antigen	LP-MIC-ROU-25, PHE UK Standards UK Standards Investigation of urine
	OLM™ Lateral Flow Device	Bronchoalveolar Lavage	Immuno-chromatographic assay	CE marked	Presence or absence of Aspergillus antigen	LP-MIC-IDEN-25
	Resist-5 O.O.K.N.V	Isolates	Coris Bioconcept / Immunochromatographic assay	CE marked	N/A	VT-MIC-2022-02, LP-MIC-ROU-19, ED-MIC-REF-53
	Streptococcus pneumoniae Urinary antigen	Urine	N/A / Immuno-chromatographic assay	CE marked	LOD:1:250 dilution	LP-MIC-ROU-27

	Urinary hCG		N/A / Immuno-chromatographic assay	CE marked	Samples containing <25 mIU/mL hCG may test positive, but samples containing <5 mIU/mL hCG should be negative	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 marked	Qualitative	LP-MIC-ROU-45, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
	HAIN CM	DNA Extract from positive culture bottles	PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-32, PHE UK Standards: Investigation of specimens for Mycobacterium species, Good Laboratory Practice when Performing Molecular Amplification Assays
	HAIN MTBC		PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-32, PHE UK Standards Investigation of specimens for Mycobacterium species, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
1015 Detection and/or identification of bacterial, parasite, fungal and	Chlamydia trachomatis and Neisseria gonorrhoeae	Endocervical/ Cervical Genxpert swabs/UTM viral transport media & FVU	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected	LP-MIC-ROU-39, PHE UK Standards for Microbiology Chlamydia

viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems						trachomatis Infection – Testing by Nucleic Acid, Good Laboratory Practice when Performing Molecular Amplification Assays
	CRE	Isolates & rectal swabs (Copan dual swab)	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected	LP-MIC-ROU-42, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
	Detection of Carbenpenamse using FlowFlex Technology	Rectal swab (Copan faecal swab)	Roche FlowFlex PCR Technology	CE Marked	KPC: cut off 37, OXA 48: cut off 37, VIIM cut off 38, IMP cut off 38, NDM cut off	LP-MIC-ROU-51, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
	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	Detected / Not detected	LP-MIC-ROU-49, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of specimens for Mycobacterium species
		Sputum sediment	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected	LP-MIC-ROU-49, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of specimens for

						Mycobacterium species
Molecular detection of bacteria and viruses on BioFire ME panel	CSF	Biomeriux Biofire Torch / Amplification and detection of target DNA	CE marked	Qualitative		LP-MIC-ROU-65
Molecular detection of bacteria on BioFire Joint infection panel on the Biofire Torch	Synovial fluids	Biomeriux Biofire Torch / Amplification and detection of target DNA	CE marked	Qualitative		LP-MIC-ROU-71
Molecular detection of bacteria on BioFire Joint infection panel on the FilmArray		Amplification and detection of target DNA on the FilmArray	CE marked	Qualitative		LP-MIC-ROU-71, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
Molecular detection of Carbapenemase Producing Enterobacterales (CPE) using Cepheid Genexpert system	Rectal swab (Copan faecal swab)	Cepheid Genexpert / Amplification and detection of target DNA on system	In House Developed	N/A		PHE UK Standards Good Laboratory Practice when Performing Molecular Amplification Assays LP-MIC-ROU-40
Molecular detection of COVID/FLU/RSV on Cepheid GeneXpert DX System	Nasopharangeal(Genexpert/UTM)	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected		LP-MIC-ROU-68, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
Molecular detection of mecA and mecC in MRSA isolates using XPERT NG	Isolates	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected		LP-MIC-ROU-19, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
Molecular detection of respiratory viruses and bacteria on BioFire RP2.1 Plus on the BioFire Torch	Nasopharyngeal (Genexpert/UTM)	Biomeriux Biofire Torch / Amplification and detection of target DNA	CE marked	Qualitative		LP-MIC-ROU-65

Molecular detection of respiratory viruses and bacteria on BioFire RP2.1 Plus on the FilmArray	Nasopharangeal (Genexpert/UTM)	BioFire RP2.1 Plus on the Film Array / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-65, LP-MIC-ROU-45, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
Molecular detection of Trichomonas vaginalis	First void urine/ Endocervical swab	Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected	LP-MIC-ROU-39, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
Molecular detection of Aspergillus fumigatus, Aspergillus terreus, Aspergillus flavus, Aspergillus species and azole-resistance markers TR34 and TR46	Bronchoalveolar Lavage	Pathonostics PneumoGenius Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system	CE Marked	N/A	PHE UK Standards for Microbiology Investigations Good Practice when Performing Molecular Amplification Assays LP-MIC-ROU-75
Molecular screen for Norovirus, Astrovirus, Sapovirus, Adenovirus and Rotavirus using Entericbio system	Faeces	Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system	CE Marked	N/A	PHE UK Standards for Microbiology Investigations Gastroenteritis, PHE UK Standards for Microbiology Investigations Good Practice when Performing Molecular Amplification Assays LP-MIC-ROU-74
Molecular screen for Salmonella, Shigella/Enteroinvasive E. coli (EIEC), Campylobacter, STEC/VTEC, Gardia and Cryptosporidium using Entericbio system		Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system	CE Marked	N/A	PHE UK Standards for Microbiology Investigations Gastroenteritis, PHE UK Standards for Microbiology Investigations Good Practice when Performing Molecular

					Amplification Assays LP-MIC-ROU-73
Molecular screen for Toxigenic Clostridium difficile using Entericbio system		Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system	CE Marked	N/A	PHE UK Standards for Microbiology Investigations Gastroenteritis, PHE UK Standards for Microbiology Investigations Good Practice when Performing Molecular Amplification Assays LP-MIC-ROU-72
Norovirus Genogroup I and II		Cepheid GeneXpert / Amplification and detection of target DNA	CE marked	Detected / Not detected	LP-MIC-ROU-40, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens
Toxigenic Clostridium difficile		Amplification and detection of target DNA on BD Max	Based on standard method	Detected / Not detected	LP-MIC-ROU-47, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens
Verification of VRE Viasure molecular assay on Roche Flow flex system	Rectal swabs	Roche FlowFlex system / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-69, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification

						Assays
	Verification of VRE Viasure molecular assay on Roche FlowFlex System		Roche FlowFlex Syatem / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-69
	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	Qualitative	LP-MIC-IDEN-26
	API NH		N/A / Fermentation, decarboxylation etc	CE marked	Qualitative	LP-MIC-IDEN-01
	Dnase		N/A / Hydrolysis of DNA	Based on standard method	Qualitative	LP-MIC-IDEN-15
	Phenotypic confirmation of ESBL's		Disc diffusion	Based on standard method	Qualitative	LP-MIC-IDEN-24, Eucast Guidelines
	VITEK Identification		VITEK 2XL / Fermentation, decarboxylation etc	CE marked	Qualitative	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	Fungal Isolates	Microscope / Staining & Microscopy	Based on standard method	Presence/Absence of fungal hyphae	LP-MIC-ROU-17, PHE UK Standards for Microbiology Investigation of Dermatological Specimens for Superficial Mycoses
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification using MALDI-TOF Spectroscopy	Isolates	VITEK MS / Mass Spectrophotometry	CE marked	Qualitative	LP-MIC-ROU-19
1017 Measurement of antimicrobial activity	Antimicrobial susceptibility testing	Anaerobic Bacterial isolates	Minimum inhibitory strip diffusion & disc diffusion	CE marked	Qualitative	LP-MIC-ROU-18 ED-MIC-REF-53



and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes						
		Isolates	N/A / Disc diffusion	CE marked	Refer to Eucast Guidelines	LP-MIC-ROU-20, Eucast Guidelines
			VITEK 2XL / Broth MIC	CE marked	Refer to Eucast Guidelines	LP-MIC-ROU-20, Eucast Guidelines
		Neisseria Gonorrhoea isolates	Minimum inhibitory strip diffusion	CE marked	Qualitative	LP-MIC-ROU-20 ED-MIC-REF-53
	Cefpodoxime combination disc kit	Isolates	N/A / Disc diffusion	CE marked	Refer to Eucast Guidelines	LI-MIC-36, Eucast Guidelines
	Minimum inhibitory concentration		N/A / Minimum inhibitory strip diffusion	CE marked	Refer to Eucast Guidelines	LP-MIC-ROU-20, Eucast Guidelines
Total ESBL confirmation kit		N/A / Disc diffusion	CE marked	Refer to Eucast Guidelines	LI-MIC-36, Eucast Guidelines	
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	Qualitative	LP-MIC-ROU-32, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
			PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA	CE marked	Qualitative	LP-MIC-ROU-32, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays
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	Qualitative	LP-MIC-ROU-64, HPSC National guidelines for prevention of nosocomial aspergillosis, EORTC/MSGERC criteria for diagnosis of

						invasive fungal disease
	Yeast one Sensitre	Isolates	N/A / Broth MIC	CE marked	N/A	LP-MIC-ROU-18, PHE UK Standards for Microbiology Chlamydia trachomatis Infection – Testing by Nucleic Acid, CLSI Performance Standards for AST of Yeast
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified )			Broth microdilution	CE marked	N/A	LP-MIC-ROU-18, CLSI Performance Standards for AST of Yeast
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Wako™ β-D-Glucan assay for detection of 1-3 β glucans	Serum	Toxinometer / Kinetic turbidimetric method	CE marked	All positive results (greater than or equal to 7pg/mL)	LP-MIC-ROU-57, HPSC National guidelines for prevention of nosocomial aspergillosis, EORTC/MSGERC criteria for diagnosis of invasive fungal disease