Schedule of Accreditation

Organisation Name	The Adelaide & Meath Hospital
Trading As	Tallaght University Hospital
INAB Reg No	330MT
Contact Name	Fionnuala O'Dwyer
Address	Incorporating The National Children's Hospital, Medical Testing Laboratory, Tallaght, Dublin, D24
Contact Phone No	01 4143380
Email	fionnuala.odwyer@tuh.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	24/02/2015
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Scope Classification	Assisted reproduction
Services available to the public[1]	No

[1] Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)

	Name	Address
1	Reeves Day Surgery Centre RDSC	Tallaght Cross West, Cookstown, Tallaght, Dublin 24, Dublin, Ireland
2	SIMMS Building	Tallaght Cross West, Cookstown Way, Tallaght, Dublin, Dublin, Ireland, D24TP66
3	Main Hospital (Head Office)	Adelaide and Meath Hospital Incorporating The National Children's Hospital, Tallaght Hospital, Dublin, D24

Scope of Accreditation

Main Hospital (Head Office)

Assisted Reproduction

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
1095 Assisted reproduction - .01 Semen analysis	Morphology	Bodily Fluid	Manual	Based on Standard Method	Lower reference Limit and critical value: 4%	CP-LP-0134, CP-LP-0135
	Motility		Manual	Based on standard method	Lower reference Limit and critical value: 40%	CP-LP-0134, CP-LP-0135
	Sperm Count		Manual	Based on Standard Method	Lower reference Limit and critical value:Total Sperm number 39 per 10^6 per ejaculate	CP-LP-0134, CP-LP-0135
	Vitality		Manual	Based on Standard Method	Lower reference Limit and critical value: 58%	CP-LP-0134, CP-LP-0135
1095 Assisted reproduction - .06 Sperm antibodies	Sperm Antibodies		Manual	Based on Standard Method	Lower reference Limit and critical value: 50%	CP-LP-0134, CP-LP-0135

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 & Rh Typing)	Red Blood Cells (EDTA)	Manual: Biovue Tube	Standard Method	N/A	BT-LP-0100
	Confirming ABO and Rh(D) group of donor units		Manual: Biovue	Standard Method	N/A	BT-LP-0114
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & Rh D typing)	Red Blood Cells (EDTA)	Automated: Vision Vision Max	Standard Method	N/A	BT-LP-0105 BT-LP-0100
	Confirming ABO and Rh(D) group of donor units	Red Blood Cells (EDTA)	Automated: Vision Vision Max	Standard Method	N/A	BT-LP-0114 BT-LP-0105
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma (EDTA)	Automated: Vision Vision Max	Standard Method	N/A	BT-LP-0105 BT-LP-0100
			Manual: Biovue Tube	Standard Method	N/A	BT-LP-0100
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated: Vision Vision Max	Standard Method	N/A	BT-LP-0105 BT-LP-0111

			Manual: Biovue Tube	Standard Method	N/A	BT-LP-0111
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing	Patient Plasma (EDTA) Donor Red Blood Cells	Automated: Vision Vision Max	Standard Method	N/A	BT-LP-0105 BT-LP-0101
			Manual: Biovue Tube	Standard Method	N/A	BT-LP-0101
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Cells	Automated: Vision Max	Based on standard method	N/A	BT-LP-0106 BT-LP-0105
	Antigen Typing	Red Blood Cells	Manual: Tubes Biovue BioRad	Standard Method	N/A	BT-LP-0106
1020 Transfusion science - .09 Direct antiglobulin test	Direct Coombs Test	Red Blood Cells (EDTA)	Manual: BioRad	Standard Method	N/A	BT-LP-0115
1020 Transfusion science - .99 Miscellaneous tests	Electronic Issue of Blood	N/A	Clinisys Winpath		N/A	BT-LP-0101 BT-LP-0133
The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)						

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine Transaminase (ALT) **1,2,3,4"	Blood	Roche Cobas 8000	According to IFCC (w/o P5P activation)	5-700 U/L	CC-LP-406
	Albumin **1,2,3,4"		Roche Cobas 8000	Colorimetric/Bromocresol Green	2-60 g/L	CC-LP-406
	Alkaline Phosphatase (ALP) **1,2,3,4"		Roche Cobas 8000	Colorimetric	5-1200 U/L	CC-LP-406
	Ammonia (NH3) **1,2,3,4"		Roche Cobas 8000	Enzymatic	10-1000 µmol/L	CC-LP-406
	Amylase **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	3-1500 U/L	CC-LP-406
	Aspartate transaminase (AST) **1,2,3,4"		Roche Cobas 8000	According to IFCC (w/o P5P activation)	5-700 U/L	CC-LP-406
	Bicarbonate **1,2,3,4"		Roche Cobas 8000	Enzymatic	2-50 mmol/L	CC-LP-406
	Calcium **1,2,4"	Urine	Roche Cobas 8000	Photometric/NM-BAPTA	0.20-7.5 mmol/L	CC-LP-406
			Roche Cobas 8000	Photometric/NM-BAPTA	0.20-7.5 mmol/L	CC-LP-406
	Calcium **1,2,3,4"	Blood	Roche Cobas 8000	Photometric	0.20-5.0 mmol/L	CC-LP-406
	Chloride **1,2,3,4"		Roche Cobas 8000	Indirect ISE	60-140 mmol/L	CC-LP-406
	Chloride **1,2,4"	Urine	Roche Cobas 8000	Indirect ISE	60-350 mmol/L	CC-LP-406
	Cholesterol **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic, colorimetric	0.1-20.7 mmol/L	CC-LP-406
	C-Reactive Protein (CRP) **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.3-350 mg/L	CC-LP-406

Creatine Kinase **1,2,3,4"		Roche Cobas 8000	UV, enzymatic reference with hexokinase	7-2000 U/L	CC-LP-406
Creatinine **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	5-2700 µmol/L	CC-LP-406
Direct Bilirubin **1,2,3,4"		Roche Cobas 8000	Diazo Method	1.2-236 µmol/L	CC-LP-406
Gamma glutamyl transferase (GGT) **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	3-1200 U/L	CC-LP-406
Glucose **1,2,4"	CSF	Roche Cobas 8000	Enzymatic - hexokinase	0.11-41.6 mmol/L	CC-LP-406
Glucose **1,2,3,4"	Blood	Roche Cobas 8000	UV, enzymatic reference with hexokinase	0.11-41.6 mmol/L	CC-LP-406
Haemolysis**1,3,4"		Roche Cobas 8000	Calculations of absorbance	5 - 1200nm	CC-LP-406
High density lipoprotein**1,2,3,4"		Roche Cobas 8000	Enzymatic Colorimetric	0.08 - 3.88 mmol/L	CC-LP-406
Icteric**1,3,4"		Roche Cobas 8000	Calculations of absorbance	0.5 - 60 nm	CC-LP-406
Interleukin-6 (IL6) **1,2,3,4"		Cobas 8000	1.5-5000 pg/ml	CE	CC-LP-406
Lactate **1,2,3,4"		Roche Cobas 8000	Colorimetric	0.2-15.5 mmol/L	CC-LP-406
Lactate **1,2,4"	CSF	Roche Cobas 8000	Colourimetric	0.2-15.5 mmol/L	CC-LP-406
Lactate Dehydrogenase (LDH) **1,2,3,4"	Blood	Roche Cobas 8000	UV	10-1000 U/L	CC-LP-406
Lipaemia**1,3,4"		Roche Cobas 8000	Calculations of absorbance	10 - 2000 nm	CC-LP-406
Magnesium **1,2,3,4"		Roche Cobas 8000	Colorimetric	0.10-2.0 mmol/L	CC-LP-406
Methotrexate **1,2,3,4"		Roche Cobas 8000	Immunoassay	0.04-1.20µmol/L	CC-LP-406
N- terminal pro B type natriuretic peptide (NT-pro BNP) **1,2,3,4"	Plasma/Serum	Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
Phosphate **1,2,3,4"	Blood	Roche Cobas 8000	Molybdate UV	0.10-6.46 mmol/L	CC-LP-406
Potassium **1,2,3,4"		Roche Cobas 8000	Indirect ISE	1.5-10.0mmol/L	CC-LP-406
Pro-calcitonin **1,2,3,4"		Cobas 8000	0.02-100 ng/ml	CE	CC-LP-406

Sodium **1,2,3,4"		Roche Cobas 8000	Indirect ISE	80-180mmol/L	CC-LP-406
Total Bilirubin **1,2,3,4"		Roche Cobas 8000	Colorimetric	2.5-550 µmol/L	CC-LP-406
Total Protein **1,2,3,4"		Roche Cobas 8000	Colorimetric	2.0-120 g/L	CC-LP-406
Total Protein - CSF **1,2,4"	CSF	Roche Cobas 8000	Turbidimetric	4-200 mg/dL	CC-LP-406
Total Protein - Urine **1,2,4"	Urine	Roche Cobas 8000	Turbidimetric	0.04-2.0 g/L	CC-LP-406
Triglyceride **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic, colorimetric	0.1-10 mmol/L	CC-LP-406
Troponin T hs (high sensitive) **1,2,3,4"	Plasma/Serum	Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
Urea **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic	0.5-40 mmol/L	CC-LP-406
Uric Acid (UA) **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	11.9-1487 µmol/L	CC-LP-406
Urinary Albumin **1,2,4"	Urine	Roche Cobas 8000	Immunoturbidimetric	3-400mg/L	CC-LP-406
Urinary amylase **1,2,4"		Roche Cobas 8000	Enzymatic, colorimetric	3-1500 IU/L	CC-LP-406
Urinary Creatinine **1,2,4"		Roche Cobas 8000	Enzymatic, colorimetric	0.1-54 mmol/L	CC-LP-406
Urinary Osmolality**1,4"		OsmoPro Multi-Sample Micro Osomometer	Freeze point depression osmometry	0 to 2000 mOsm/kg H2O	CC-LP-502
Urinary Phosphate **1,2,4"		Roche Cobas 8000	Molybdate UV	1.1-92.0 mmol/L	CC-LP-406
Urinary Potassium **1,2,4"		Roche Cobas 8000	Indirect ISE	3-100 mmolL	CC-LP-406
Urinary Sodium **1,2,4"		Roche Cobas 8000	Indirect ISE	60-350 mmol/L	CC-LP-406
Urinary Total Protein **1,2,4"		Roche Cobas 8000	Turbidimetric	0.04-2 g/L	CC-LP-406
Urinary Urate **1,2,4"		Roche Cobas8000	Enzymatic, colorimetric	131-16362mmol/L	CC-LP-406
Urinary Urea **1,2,4"		Roche Cobas 8000	Enzymatic	1-2000 mmol/L	CC-LP-406

1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Alpha 1 Antitrypsin **1,2,3,4"	Blood	Roche Cobas 8000	Immunoturbidimetric	0.2-6.0 g/L	CC-LP-406
	Apolipoprotein A **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.2-6.0 g/L	CC-LP-406
	Apolipoprotein B **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.2-6.0 g/L	CC-LP-406
	Calprotectin CALP **1,2,4"	Faeces	Roche Cobas 8000	Bullmann fCAL turbo	20-8000 ug/g	CC-LP-406
	Ceruloplasmin **1,2,3,4"	Blood	Roche Cobas 8000	Immunoturbidimetric	0.03-1.4 g/L	CC-LP-406
	High sensitivity CRP **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.15-20.0 mg/L	CC-LP-406
	Homocysteine **1,2,3,4"		Roche Cobas 8000	Enzymatic	3.0-50.0 µmol/L	CC-LP-406
	Immunoglobulin E Total (IgE) **1,2,3,4"	Plasma/Serum	Electro-chemiluinescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Lipoprotein (a) **1,2,3,4"	Blood	Roche Cobas 8000	Immunoturbidimetric	7.240 nmol/L	CC-LP-406
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Protein electrophoresis and immunofixation of serum/urine for the detection and quantitation of monoclonal components using the Sebia Capillarys 3 and Sebia Hydrasys systems. **1,2,3,4"	Serum Urine	Capillary Zone Electrophoresis Gel Electrophoresis Immunofixation	"Electrophoresis and Immunotyping/ Immunofixation. Sebia Capillarys 3 and Sebia Hydrasys 2 system"	CE	CC-LP-604 Capillarys SOP, CC-LP-605 Hydrasys SOP
1061 Clinical Chemistry - .05 CO-oximetry	Co-Oximetry	whole blood	Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
			Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
	Co-Oximetry-at Childrens Health Ireland Paediatric Emergency Care Unit		ABL 90 Flex plus		CE	PC-LP-015

1061 Clinical Chemistry - .06 Blood pH and gas tensions	Blood pH and gas tensions		Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
			Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
	Blood pH and gas tensions - at Childrens Health Ireland Paediatric Emergency Care Unit		ABL 90 Flex plus		CE	PC-LP-015
	Other analytes performed on a blood gas analyser		Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser			Potentiometry, Amperometry, Optical pO2:, Spectrophotometry	ABL 90 Flex plus	CE	PC-LP-015
1061 Clinical Chemistry - .09 Trace elements	Aluminium **1,2,3,4"	Plasma	GFAAS:Varian® 240Z	0.4-4.0 umol/L	In house developed	CC-LP-911
	Copper **1,2,3,4"		ICP-MS:NexION® 2000	0-50 umol/L	In house developed	CC-LP-908
	Zinc **1,2,3,4"		ICP-MS:NexION® 2000	0-50 umol/L	In house developed	CC-LP-908
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin**1,3,4"	Blood	Roche Cobas 8000	KIMS Immunoassay	0.8 - 40 µg/ml 1.4 - 68.4 µmol/L	CC-LP-406
	Carbamazepine **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	2-20 mg/L	CC-LP-406
	Cyclosporin **1,2,3,4"		Roche Cobas 8000	Immunoassay	30.0-2000 ng/ml	CC-LP-406
	Digoxin **1,2,3,4"	Plasma/Serum	Electrochemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Digoxin**1,2,3,4"	Blood	Roche Cobas 8000	ECLIA	0.2 - 5.0 ng/ml	CC-LP-406
	Lithium*1,2,3,4"		Roche Cobas 8000	Colorimetric	0.05 - 3.00 mmol/L	CC-LP-406
	Phenobarbitone **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	2.4-60 mg/L	CC-LP-406
	Phenytoin **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	0.8-40 mg/L	CC-LP-406
	Tacrolimus **1,2,3,4"		Roche Cobas 8000	Immunoassay	0.5-4.0ug/L	CC-LP-406

	Theophylline **1,2,3,4"	Roche Cobas 8000	KIMS Immunoassay	0.8-40 mg/L	CC-LP-406
	Tobramycin**1,3,4"	Roche Cobas 8000	Immunoassay	0.33 -10 µg/ml, 0.71 - 21.4 µmol/L	CC-LP-406
	Valporate **1,2,3,4"	Roche Cobas 8000	Immunoassay	2.8-150 mg/L	CC-LP-406
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol/ Acetaminophen **1,2,3,4"	Roche Cobas 8000	Enzymatic, colorimetric	1.2-500 mg /L	CC-LP-406
	Salicylate **1,2,3,4"	Roche Cobas 8000	Enzymatic, colorimetric	3.0-700mg/L	CC-LP-406
1061 Clinical Chemistry - .20 Hormones	Abott TFT **1,2,3,4"	Immunoassay:Architect i1000 sr		CE	CC-LP-205
	Cortisol**1,2,3,4"	Roche Cobas 8000	ECLIA	1.5 to 1750 nmol/L	CC-LP-406
	CPEPTID **1,2,3,4"	Roche Cobas 8000	Immunoassay	0.001-40ug/L	CC-LP-406
	Follicle-stimulating hormone (FSH) **1,2,3,4"	Roche Cobas 8000	ECLIA	0.1 - 200 mIU/ml	CC-LP-406
	Growth Hormone (GH) **1,2,3,4"	ISYS	Chemiluminescence CE	0.05-100ng/mL	CC-LP-102B
	Human chorionic gonadotrophin (HCG) **1,2,3,4"	Roche Cobas 8000	Immunoassay	0.2 - 10000 mIU/ml	CC-LP-406
	INSULIN **1,2,3,4"	Roche Cobas 8000	Immunoassay	0.2-1000nU/L	CC-LP-406
	Luteinizing Hormone (LH) **1,2,3,4"	Roche Cobas 8000	ECLIA	0.1 - 200 mIU/ml	CC-LP-406
	Macroprolactin**1,2,3,4"	Roche Cobas 8000	ECLIA	0.047 to 470 ng/ml	CC-LP-406
	Oestradiol (OEST)**1,2,3,4"	Roche Cobas 8000	ECLIA	5 -3000 pg/ml	CC-LP-406
	Parathyroid hormone (PTH)**1,2,3,4"	Roche Cobas 8000	ECLIA	1.20 -5000 pg/ml	CC-LP-406
	Progesterone (PROG)**1,2,3,4"	Roche Cobas 8000	ECLIA	0.05 - 16 ng/ml	CC-LP-406
	Prolactin (PROL)**1,2,3,4"	Roche Cobas 8000	ECLIA	0.047 - 470 ng/ml	CC-LP-406
	Testosterone**1,2,3,4"	Roche Cobas 8000	ECLIA	0.025 to 15.0 ng/ml	CC-LP-406

	Thyroid peroxidase antibody (TPO)**1,2,3,4"		Roche Cobas 8000	ECLIA	5 - 600 IU/ml	CC-LP-406
	Thyroid stimulating hormone (TSH) **1,2,3,4"		Roche Cobas 8000	ECLIA	0.005 - 100 µIU/ml	CC-LP-406
	Thyroxine (FT4) **1,2,3,4"		Roche Cobas 8000	ECLIA	0.5 - 100 pmol/L	CC-LP-406
	Tri-iodothyronine (FT3) **1,2,3,4"		Roche Cobas 8000	ECLIA	0.4 - 50 pmol/L	CC-LP-406
1061 Clinical Chemistry - .24 Hormone receptor assays	IGF-1 **1,2,3,4"		ISYS	Chemiluminescence CE	10-1200ng/mL	CC-LP-102B
	IGFBP3 **1,2,3,4"		ISYS	Chemiluminescence CE	80-10000ng/mL	CC-LP-102B
1061 Clinical Chemistry - .30 Sweat electrolytes	Chloride **1,2,4"	sweat	Coulometric	Sherwood 926S		CC-LP-501
1061 Clinical Chemistry - .40 Iron studies	Iron **1,2,3,4"	Blood	Roche Cobas 8000	Colorimetric	0.90-179 µmol/L	CC-LP-406
	Unsaturated Iron-Binding Capacity (UIBC) **1,2,3,4"		Roche Cobas 8000	Colorimetric	3-125 µmol/L	CC-LP-406
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D **1,2,3,4"	Plasma	Electrochemiluminescence immunoassay	Cobas 8000	CE	CC-LP-406
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha-Fetoprotein (AFP) **1,2,3,4"	Blood	Roche Cobas 8000	Immunoassay	0.50-1000 IU/L	CC-LP-406
	Cancer antigen 125 (C125) **1,2,3,4"	Plasma/Serum	Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Cancer antigen 15-3 (C15-3) **1,2,3,4"		Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Cancer antigen 19-9 (C19-9) **1,2,3,4"		Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Carcinoembryonic antigen (CEA) **1,2,3,4"		Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406

	Total Prostate-specific antigen (PSA) **1,2,3,4"		Electro-chemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
1061 Clinical Chemistry - .61 Hb A1c	HbA1c**1,2,4"	Blood	HPLC	Arkray HA8190V	20 to 151 mmol/mol	CC-LP-312
1061 Clinical Chemistry - .76 Simple side tests for biochemical and immunological analytes	Osmolality**1,4"	Urine/Plasma	Freezing pont depression	OsmoPRO / 0 - 2000mOsm/kgH20	CE	CC-LP-502
1061 Clinical Chemistry - .77 Calculi	24 hour Urinary Calcium	Urine	Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Chloride		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Creatinine		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Inorganic Phosphate		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Potassium		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Sodium		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Total Protein		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Urate		Roche Cobas 8000	N/A	N/A	CC-LP-802
	24 hour Urinary Urea		Roche Cobas 8000	N/A	N/A	CC-LP-802
	Calcium/Creatinine ratio		Roche Cobas 8000	N/A	N/A	CC-LP-406
	Corrected Calcium calculation	Blood	Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
	Creatinine Clearance	Urine	Roche Cobas 8000	N/A	N/A	CC-LI-402A
	EGFR calculation	Blood	Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406

	Low-density Lipoprotein (LDL) calculation		Roche Cobas 8000	N/A	N/A	CC-LP-406
	Microalbumin/Creatinine ratio	Urine	Roche Cobas 8000	N/A	N/A	CC-LP-406
	Non HDL calculation	Blood	Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
	Phosphate/Creatinine ratio	Urine	Roche Cobas 8000	N/A	N/A	CC-LP-406
	Protein/Creatinine ratio		Roche Cobas 8000	N/A	N/A	CC-LP-406
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin A (IGA) **1,2,3,4"	Blood	Roche Cobas 8000	Immuoturbidimetric	0.50-8.00 g/L	CC-LP-406
	Immunoglobulin G (IGG) **1,2,3,4"		Roche Cobas 8000	Immuoturbidimetric	3.0-50.0 g/L	CC-LP-406
	Immunoglobulin M (IGM) **1,2,3,4"		Roche Cobas 8000	Immuoturbidimetric	0.25-6.50 g/L	CC-LP-406
1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G, A, M and in body fluids	Ethanol **1,2,3,4"		Roche Cobas 8000	Enzymatic	10.1-498 mg/dL	CC-LP-406
1061 Clinical Chemistry - .86 C3 and C4	Complement C3 **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.04-5.0 g/L	CC-LP-406
	Complement C4 **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.02-1.0 g/L	CC-LP-406
1061 Clinical Chemistry - .87 Cryoglobulins	Cryoglobulin**3,4,"		N/A	N/A	<1%	CC-LP-406
1061 Clinical Chemistry - .99 Miscellaneous tests	Conductivity **1,2,4"	Sweat	Conduction	Wescor 3100	CE	CC-LP-501

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

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

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 - .05 CO-oximetry	Co-Oximetry **1,2,4"	whole blood	Ion Selective electrode (ISE)	ABL 90 Flex incl 5 new analysers	CE	PC-LP-015
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Blood pH and gas tensions **1,2,4"		Ion Selective electrode (ISE)	ABL 90 Flex incl 5 new analysers	CE	PC-LP-015
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Ionised Calcium (PHDU/Theatre/AMU/CCU/ Resus) **1,2,4"	Blood	Radiometer ABL 90	Potentiometry	0.2-2.7mmol/L	PC-LP-015
	Other analytes performed on a blood gas analyser- add ABL analyser to Tallaght Cross West Day surgery site	whole blood	Ion Selective electrode (ISE)	ABL 90 Flex	CE	PC-LP-015
1061 Clinical Chemistry - .20 Hormones	Beta HCG (POCT) **1,2,4"	Blood	Radiometer-AQT	Immunoassay	2-5000IU/L	PC-LP-020
1061 Clinical Chemistry - .61 Hb A1c	Near Patient HbA1c Testing-Paediatric outpatients, Diabetic Day Centre Simms		Roche cobas B101-photometric transmission measurement	20-130 mmol/l	CE	PC-LP-021

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

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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

Main Hospital (Head Office)

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	Full blood Count **1,2,3,4"	EDTA	Various	Sysmex XN9100	CE	HAEM-LI-0050
1030 Haematology - .02 Visual examination of blood films	Visual examination of blood films	EDTA blood film	Digital imaging	Sysmex DI60/Cellavision Software	CE	HAEM-LI-0060
	Visual examination of blood films **4"	EDTA	Microscopy	Leica microscopes	Based on a standard method	HAEM-LP-0058
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte counts **1,2,3,4"		Flow cytometry	Sysmex XN9100	CE	HAEM-LI-0050
1030 Haematology - .06 Automated reticulocyte counts	Automated reticulocyte counts **1,2,4"		Flow cytometry	Sysmex XN9100	CE	HAEM-LI-0050
1030 Haematology - .09 Examination of malarial parasites	Examination of malarial parasites **4"		Microscopy and Immunochromatographic Test	Leica Microscopes Test kit	Based on a standard method CE	HAEM-LP-0054A/B
	Screening Test for Malarial HRP-2 Antigen and LDH**1,4"		Immunochromatography CareUS Kit	Test kit	CE	HAEM-LP-0054C
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screening **4"		Turbidimetric	N/A	CE	HAEM-LP-0057
1030 Haematology - .40 Limited haemostasis related tests	Anti Factor Xa	Sodium citrate	Indirect Chromogenic	Sysmex CS5100	CE	HAEM-LP-0210
	Anti thrombin		Indirect Chromogenic	Sysmex CS5100	CE	HAEM-LP-0210

	APCR		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor II:C		Photo-optical Detection (PT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor IX:C		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor V:C		Photo-optical Detection (PT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor VII:C		Photo-optical Detection (PT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor VIII:C		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor X:C		Photo-optical Detection (PT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor XI:C		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Factor XII:C		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Lupus anticoagulant		Photo-optical Detection (APTT based)	Sysmex CS5100	CE	HAEM-LP-0210
	Protein C		Direct Chromogenic	Sysmex CS5100	CE	HAEM-LP-0210
	Protein S Free Ag		Latex Immunoassay	Sysmex CS5100	CE	HAEM-LP-0210
	Thrombin Time		Photo-optical Detection	Sysmex CS5100	CE	HAEM-LP-0210
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time **1,2,4"		Sysmex CS5100/Turbidimetric	Sysmex CS5100	CE	Haem-LP-0210
	D Dimer		Latex Photometric Immunoassay	CS5100	CE	HAEM-LI-0201P D Dimer assay using CS5100
	D Dimer **1,2,4"		Mini Vidas/Enzyme-Linked Flourescence Assay	Vidas 3	CE	HAEM- LP-0209
	Fibrinogen **1,2,4"		Sysmex CS5100/Turbidimetric	Sysmex CS5100	CE	HAEM-LP-0210
	Prothrombin Time **1,2,4"		Sysmex CS5100/Turbidimetric	Sysmex CS5100	CE	HAEM-LP-0210

1030 Haematology - .55 Iron studies	Ferritin **1,2,4"	Serum	Chemi-luminescence Immuno Assay	Abbott Architect	CE	HAEM-LP-0154
1030 Haematology - .57 Screening test for infectious mononucleosis	Screening test for infectious mononucleosis **3,4"	EDTA	Immunoassay	N/A	CE	HAEM-LP-0056
1030 Haematology - .58 Vitamin B12 and folate (serum and red cell)	Vitamin B12 and folate **1,2,4"	Serum	Chemi-luminescence Immuno Assay	Abbott Architect	CE	HAEM-LP-0151
1030 Haematology - .80 Molecular genetic studies	Molecular genetics of thrombophilia	EDTA	Microarray	EUROIMMUN® DNA Microarray Scanner	CE	HAEM-LP-0207

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Main Hospital (Head Office)

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 - .41 General haemostasis related tests	INR-POCT **1,4"	Blood	Roche-Coaguchek	INR 0.8-8.0/% Quick 120-5/ Seconds 9.6-96	Electrochemical	PC-LP-009

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".
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Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
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Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Automated Haematoxylin and Eosin Staining	Human tissue	Tissue-Tek Prisma Stainer	Based on standard method	NA	CP-LP-0056
	Coverslipping		G2 Coverslipper	Based on standard method	NA	CP-LP-0065
	Cut-up		Manual	Based on standard method	NA	CP-LP-0198 CP-LP-0035
	H& E staining		Automated Haematoxylin and Eosin Staining (change to Eosin stain)	Tissue-Tek Prisma Stainer	Based on standard method	CP-LP-0056
	Microtomy		Leica RM2255 microtome	Based on standard method	NA	CP-LP-0061
	Tissue embedding		Embedding Console Sakura Tissue Tek TEC	Based on standard method	NA	CP-LP-0052
	Tissue Processing		Magnus (Synergy) rapid tissue processor	Based on standard method	NA	CP-LP-0053
			Magnus (Synergy) rapid tissue processor	Based on standard method	NA	CP-LP-0053
			Tissue Processor Leica ASP6025	Based on standard method	NA	CP-LP-0050
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut-up		Milestone Presto Chill	Based on standard method	NA	CP-LP-0198 CP-LP-0035

	Cytology sample preparation and description	Body fluid	Hologic Thin-Prep Genesis Processor	Based on standard method	NA	CP-LP-0245, CP-VI-0246, CP-LI-0240
	Frozen section cryotomy and staining	Human tissue	Leica CM1950 cryostat	Based on standard method	NA	CP-LP-0043
1051 Histopathology - .03 Histochemistry	Alcian Blue	Human tissue/body fluid	Manual	Based on standard method	NA	CP-LI-0075
	Alcian Blue - PAS/DPAS		Manual	Based on standard method	NA	CP-LI-0076
	Automated Special Stains for: Alcian Blue,Alcian Blue-PAS/DPAS,Giemsa,Highmans Congo Red,Grocott's,Gordon and Sweets Reticulin,Millers Elastic,Massons Trichrome,PAS/DPAS/PASF,Perls Prussian Blue,Southgates Mucicarmine,Ziehl Nielson, Steiner.		VENTANA BenchMark Special Stainer	CE		CP-LP-0112 Special Stains - General Considerations CP-LP-0112A Automated Special stains
	Giemsa		Manual	Based on standard method	NA	CP-LI-0080
	Gordon and Sweet's Reticulin		Manual	Based on standard method	NA	CP-LI-0082
	Gram Twort	Human tissue /body fluid	Atom Scientific Kit	Based on standard method	NA	CP-LI-0083
	Highman's Congo Red	Human tissue/body fluid	Manual	Based on standard method	NA	CP-LI-0087
	Luxol Fast Blue		Manual	Based on standard method	NA	CP-LI-0089
	Martius Scarlet Blue	Human tissue /body fluid	Atom Scientific Kit	Based on standard method	NA	CP-LI-0090
	Masson Fontana	Human tissue/body fluid	Manual	Based on standard method	NA	CP-LI-0091
	Masson's Trichrome		Sigma Aldrich Kit HT15-1KT	Based on standard method	NA	CP-LI-0092

	Melanin Bleach		Manual	Based on standard method	NA	CP-LI-0093
	Miller Elastic		Manual	Based on standard method	NA	CP-LI-0094
	PAS/DPAS		Manual	Based on standard method	NA	CP-LI-0097
	Perl's Prussian Blue		Manual	Based on standard method	NA	CP-LI-0098
	Shikata Orcein		Manual	Based on standard method	NA	CP-LI-0102
	Southgate's Mucicarmine		Manual	Based on standard method	NA	CP-LI-0103
	Van Gieson		Manual	Based on standard method	NA	CP-LI-0105
	Von Kossa		Manual	Based on standard method	NA	CP-LI-0106
	Ziehl Nielsen		Manual	Based on standard method	NA	CP-LI-0107
1051 Histopathology - .05 Histological interpretation-paediatric pathology	General Histological interpretation including Paediatric pathology	Human tissue	Microscope BX50 Olympus	Based on standard method	NA	CP-MF-0003. CP-LP-0202
1051 Histopathology - .09 Immunohistochemistry	AE1,AE3 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	ALK **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	Alphafetoprotein **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	AMACR **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	BAP1 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

b-catenin **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
BCL-2 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
BCL-6 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
BOB1 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CAIX **2, 4	Human Tissue	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
Calcitonin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Caldesmon **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
Calretinin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Cam5.2 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD10 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD117 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD138 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD15 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

CD1a **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
CD2 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD20 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD21 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD23 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD3 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD30 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD31 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD31/AE1,3 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD31CH (CD31 Chromogranin cocktail) **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD34 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD4 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD45 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

CD5 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD56 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD61 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD68 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD79a **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD8 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CD99 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CDX2 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CEAM **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Chromogranin A **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CK19 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CK5,6 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
CMV **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

C-MYC **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Cyclin D1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
D2-40 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
D2-40 / Melan A Cocktail **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
D2-40/AE1,3 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
DESKR (Desmin AE1,3) Cocktail **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Desmin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
DOG1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
E-CAD, GFAP, HBME	Human tissue and body fluids	Ventana Benchmark Ultra	CE		CP-LP-0149
EMA **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
EPCAM **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
GATA -3 **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Glypican 3 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

Granzyme B **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
HCG **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
HepPar1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
HHV8 **2, 4	Human Tissue/Body fluid	Ventana Benchmark Ultra	Based on standard Method	N/A	CP-LP-0149
HLO **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
HMB45 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
HSV I **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
IgG4 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Immunohistochemistry tests	Human tissue and body fluids	Ventana Benchmark Ultra	CE		CP-LP-0149
Inhibin a **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Ki67 / MIB1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
KLC(plasma cells) **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
KLCP/LLCP Cocktail **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

KR20 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
KR7 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
KR903 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
LLC (plasma cells) **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Melan A **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MIB1/MelanA Cocktail **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MLH1 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MNF **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MPO **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MSA **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MSH2 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MSH6 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
MUM1 **2, 4	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

MYF4 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Napsin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
NF **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
NKX 3.1	Human Tissue/Body fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
OCT2 **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
OCT3/4 **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
OR **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
p16 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
p53 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
p63 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
p63 / AMACR Cocktail **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
P63/Napsin cocktail **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
PAX5 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

PAX8 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
PAX8/CAIX cocktail **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
PD1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
PMS2 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
PR **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
PRAME	Human tissue/ Body fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
Prostein **2, 4	Human Tissue/Body fluid	Ventana Benchmark Ultra	Based on standard Method	N/A	CP-LP-0149
S100 **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
S100/AE1,3 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
SMA **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
SOX10 **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
SOX11 **2, 4		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0149
STAT6 **2, 4	Human Tissue/Body Fluid	Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149

	Synaptophysin **2, 4	Human tissue	Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	TdT **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	Thyroglobulin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	TTF1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	TTF1 / CK5,6 Cocktail **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	Vimentin **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
	WT1 **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
1051 Histopathology - .10 Fluorescence in situ hybridisation	Lsi IGH SG/CCND1 SO (t11:14)		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155
	Lsi BCL2 Dual colour Breakapart		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155
	LSI BCL6 Dual colour Breakapart		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155
	Lsi IGH SG/BCL2 SO		Vysis VP2000 Processor	Based on standard method	NA	Cp-LP-0155
	Lsi IGH/MYC:CEP8		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155
	Lsi MALT1 Dual Clour Breakapart		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155
	Lsi MYC Breakapart		Vysis VP2000 Processor	Based on standard method	NA	CP-LP-0155

1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	INFORM EBER (Epstein-Barr Virus Early RNA) ISH **2, 4		Ventana Medical Systems Benchmark Ultra	Based on standard method	NA	CP-LP-0149
1051 Histopathology - .99 Miscellaneous tests	C3c		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0152
	Fibrinogen		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0152
	IgA		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0152
	IgG		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0152
	IgM		Automated:Ventana Medical Systems Benchmark Ultra	Based on standard method	N/A	CP-LP-0152
1052 Cytopathology - .02 Non gynaecological cytology	Cytology sample preparation and description	Body fluid	Cytospin 4 Thermo Shandon Electron Corporation. Leica Autostainer XL	Based on standard method	NA	CP-LP-0245
			Hologic Thin-Prep Genesis Processor	Based on standard method	NA	CP-LP-0245, CP-VI-0246, CP-LI-0240
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and Reporting of Non-Gynae samples	Human tissue/Body fluid	Microscope BX50 Olympus	Based on standard method	NA	CP-MF-0003

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
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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

Microbiology and Virology

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	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual	Based on standard method	Not applicable	Micro-LP-0001/Micro-LP-0002 Micro-LP-0010/Micro-LP-0011 Micro-LP-0021/Micro-LP-0022 Micro-LP-0019/Micro-LP-0020
	Procedure for the examination of a transfusion reaction	Blood packs red cell concentrates, platelets other blood components	Manual	Based on standard method	Not applicable	Micro-LP-0026
	Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than Mycobacteria	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	not applicable	Micro-LP-0012

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)	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Manual	Based on standard method	Not applicable	Micro-LP-0058
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Blood cultures	Manual	Based on standard method	Not applicable	Micro-LP-0058 Micro-LP-0025
	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual	Based on standard method	Not applicable	Micro-LP-0001/Micro-LP-0002 Micro-LP-0010/Micro-LP-0011 Micro-LP-0019/Micro-LP-0020 Micro-LP-0021/Micro-LP-0022 Micro-LP-0058
	Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Manual	Based on standard method	Not applicable	Micro-LP-0058
	Investigation of genital tract and	High vaginal swab, low vaginal swab, Vulval swab,	Manual	Based on standard method	Not applicable	Micro-LP-0016 Micro-LP-0058 UK Standards for Microbiology Investigation, Public Health England

associated specimens	labial swab, endocervical swab, Penile swab				
investigation of skin swabs and superficial wound swabs	Wound swabs, swabs from other superfical sites	Manual	Based on standard method	Not applicable	Micro-LP-0018 Micro-LP-0058
Investigation of urine samples -Microscopy	Urine, CSU. MSU, Clean catch urine, Subra pubic aspirate, bag urine	Manual & Automated Sysmex UF-5000	Based on standard method	Not applicable	Micro-LP-0058 Micro-LP-0013 Micro-LP-0211
Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	Based on standard method	Not applicable	Micro-LP-0030 Micro-LP-0058 HICPAC, Guidelines 2003 Hospital infection society guidelines 2002
Procedure for the examination of a transfusion reaction	Blood packs red cell concentrates, platelets other blood components	Manual	Based on standard method	Not applicable	Micro-LP-0058
procedure for the investigation of intravascular cannulae and associated specimens	Hickman, Vascath, portacath, Femoral line, central line, arterial line,subclavian line, Jugular line	Manual	Based on standard method	Not applicable	Micro-LP-0034 Micro-LP-0058

	Procedure for the investigation of specimens for ESBL, CRE and VRE	Rectal swab Faeces swabs from other sites as clinically indicated	Manual	Based on standard method	Not applicable	Micro-LP-0036 Micro-LP-0058 Micro-LP-0089/Micro-LP-0191
	Procedure for the Investigation of specimens for screening for MRSA	Nasal, groin Wound & other sites as clinically indicated	Manual	Based on standard method	Not applicable	Micro-LP-0035 Micro-LP-0058
	Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than mycobacteria	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	Not applicable	Micro-LP-0012 Micro-LP-0058
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	Identification of parasites from samples other than blood	Faeces, Urine, Bronchoalveolar lavages, Sellotape slide, Doudenal/jejunal aspirates, aspirates from spleen/liver	Manual	Based on standard method	Not applicable	Micro-LP-0024 UK standards for microbiology investigation, Public health england
	Investigation of genital tract and	High vaginal swab, low vaginal swab,	Manual	Based on standard method	Not applicable	Micro-LP-0016 Micro-LP-0024

	associated specimens	Vulval swab, labial swab, Penile swab				
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	Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	Based on standard method	Not applicable	Micro-LP-0058
	Procedure for the examination of a transfusion reaction	Isolates of fungi from Blood packs, red cell concentrates, platelets and other blood components	Manual	Based on standard method	Not applicable	Micro-LP-0058
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	Microscopy,culture and the use of the MGIT 960 including limited mycobacteria identification	Sputum,Bronchoalveolar lavage, pleural fluids, Urine, Cough swabs, CSF, Tissue, pus, other body fluids	Manual/Automated Aerospray stainer	Based on standard method	Not applicable	Micro-LP-0014 Micro-LP-0110 Micro-LP-0058
1013 Culture of organisms in liquid or agar based culture	Culture and sensitivity	Nasal (including per nasal), Throat, Ear, Eye (including	Manual	Based on standard method	Not applicable	Micro-LP-0004/Micro-LP-0005 Micro-LP-0006/Micro-LP-0015 Micro-LP-0008/Micro-LP-0007

media with visual or instrument monitoring for growth - .01 Culture of general bacteria		cannicular pus) and mouth				
	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual	Based on standard method	Not applicable	Micro-LP-0001/Micro-LP-0002 Micro-LP-0010/Micro-LP-0011 Micro-LP-0021/Micro-LP-0022 Micro-LP-0019/Micro-LP-0020
	Investigation of genital tract and associated specimens	High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Manual	Based on standard method	Not applicable	Micro-LP-0016
	investigation of skin swabs and superficial wound swabs	Wound swabs, swabs from other superfical sites	Manual	Based on standard method	Not applicable	Micro-LP-0018
	Investigation of urine samples -Microscopy and culture and sensitivity	Urine, CSU. MSU, Clean catch urine, Subra pubic aspirate, bag urine	Manual	Based on standard method	Not applicable	Micro-LP-0013
	Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	Based on standard method	Not applicable	Micro-LP-0030

Procedure for the examination of a transfusion reaction	Blood packs red cell concentrates, platelets other blood components	Manual	Based on standard method	Not applicable	Micro-LP-0026
Procedure for the investigation of faeces for bacterial pathogen	Faeces	Manual	Based on standard method	Not applicable	Micro-LP-0017
Procedure for the investigation of intravascular cannulae and associated specimens	Hickman, Vascath, portacath, Femoral line, central line, arterial line,subclavian line, Jugular line	Manual	Based on standard method	Not applicable	Micro-LP-0034
Procedure for the investigation of specimens for ESBL, CPE and VRE	Rectal swab Faeces swabs from other sites as clinically indicated	Manual	Based on standard method	Not applicable	Micro-LP-0036
Procedure for the investigation of specimens for screening for MRSA	Nasal, groin, Wound & other sites as clinically indicated	Manual	Based on standard method	Not applicable	Micro-LP-0035
Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	not applicable	Micro-LP-0012

	bacterial pathogens other than Mycobacteria					
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Manual	Based on standard method	Not applicable	Micro-LP-0004/Micro-LP-0005 Micro-LP-0006/Micro-LP-0015 Micro-LP-0008/Micro-LP-0007
	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual	Based on standard method	Not applicable	Micro-LP-0001/Micro-LP-0002 Micro-LP-0010/Micro-LP-0011 micro-LP-0021/Micro-LP-0022 micro-LP-0019/Micro-LP-0020
	investigation of genital tract and associated specimens	High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Manual	Based on standard method	Not applicable	Micro-LP-0016
	Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	Based on standard method	Not applicable	Micro-LP-0030
	Procedure for the examination of	Blood packs red cell concentrates, platelets	Manual	Based on standard method	Not applicable	Micro-LP-0026

	a transfusion reaction	other blood components				
	Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than Mycobacteria	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	Not applicable	Micro-LP-0012
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Microscopy,culture and the use of the MGIT 960 including limited mycobacteria identification	Sputum,Bronchoalveolar lavage, pleural fluids, Urine, Cough swabs, CSF, Tissue, pus, other body fluids	Manual/Automated MGIT 960	Based on standard method	Not applicable	Micro-LP-0014/Micro-LP-0103
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Procedure for the investigation of faeces for bacterial pathogen	Isolates of salmonella and shigella	Manual	Based on standard method	Not applicable	Micro-LP-0017
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and	Pastorex Staph-Plus Latex agglutination test	Bacterial Isolate	Manual	CE	Not applicable	Micro-LP-0064

appropriate techniques - .02 Particle agglutination						
	Streptococcal grouping		Manual/Particle agglutination	CE	N/A	Micro-LP-0065
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Detection of Clostridium difficile toxins A and B	Faeces	Manual	CE	Not applicable	Micro-LP-0071
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Detection of Cryptococcal antigen	CSF,Serum	Maunal/ Lateral Flow assay	CE	N/A	Micro-LP-0070
	Detection of Legionella pneumophilia and Streptococcus pneumoniae urinary antigens	urine	Manual	CE	Not applicable	Micro-LP-0186 Micro-LP-0180
	PBP '2' kit	Bacterial isolate	Manual/ Immunochromatographic assay	CE	N/A	Micro-LP-0203

	Procedure for detection of Helicobacter pylori stool antigen	Faeces	Manual ImmunoCard STAT HpSA Kit	CE	N/A	Micro-LP-0169
	Procedure for the detection of Helicobacter pylori stool antigen		Manual	CE	Not applicable	Micro-LP-0169
	Resist-5 O.K.N.V.I	Bacterial isolate	Manual/ Immunochromatographic assay	CE	N/A	Micro-LP-0198
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	FilmArray Respiratory panel which includes SARS CoV-2, Adenovirus, Coronaviruses 229E, HKU1, NL63 and OC43; Human metapneumovirus; Human Rhinovirus/Enterovirus Influenza A virus, Influenza A virus A/H1; Influenza A virus A/H3; Influenza A virus A/H1-2009; Influenza B virus, Parainfluenza virus 1; Parainfluenza virus 2;	Nasopharyngeal swab	Automated – FilmArray Multiplex PCR system	CE Marked	not applicable	Micro-LP-0208

	Parainfluenza virus 3; Parainfluenza 4; Respiratory Syncytial virus; Bordetella pertussis, Bordetella parapertussis; Chlamydia pneumoniae and Mycoplasma pneumoniae.					
	Investigation of CSF using the Biofire Filmarray Torch	CSF,	Automated - Biomerieux Biofire Filmarray Torch	CE	N/A	Micro-LP-0208
	Investigation of faeces samples using GeneXpert Norovirus Kit	Faeces	Automated GeneXpert	CE Marked	Not applicable	Micro-LP-0213
	Investigation of Nasopharyngeal swabs using Primer Design genesig Real-Thime PCR Coronavirus Covid-19 Kit	Nasopharyngeal swab	Automated Roche FlowFlex system	CE Marked	Not applicable	Micro-LP-0214
	Investigation of Nasopharyngeal swabs using Primer Design		Automated Roche FlowFlex system	CE Marked	Not applicable	Micro-LP-0214

genesig® Real-Thime PCR SARS CoV-2 Winterplex Kit					
Investigation of Nasopharyngeal Swabs using the Biofire Filmarray Torch		Automated Biomerieux Biofire Filmarray Torch	CE Marked	Not applicable	Micro-LP-0208
Investigation of Nasopharyngeal Swabs using the GeneXpert SARS CoV-2 Kit		Automated GeneXpert	CE Marked	Not applicable	Micro-LP-0213
Investigation of Nasopharyngeal swabs using Xpert Xpress CoV-2 Flu RSV plus Kit		Automated GeneXpert	CE Marked	Not applicable	Micro-LP-0213
Molecular Detection of M. tuberculosis using GeneXpert	Sputum	Automated - GeneXpert	CE	N/A	Micro-LP-0209
Molecular detection of salmonella, shigella, Verotoxigenic E. coli, cryptosporidiu	Faeces	Automated Enteric Bio	CE	Not applicable	Micro-LP-0193 Micro-LP-0192

	m, Giardia and Clostridium difficile					
	Molecular Screening of Rectal Swabs for CPE	Rectal Swabs	q PCR:Roche PSH PSU - Pre analytical sample	CE	N/A	Micro-LP-199
	Rapid Molecular Screening of Rectal Swabs for CPE		q PCR:Cepheid GeneXpert	CE	N/A	Micro-LP-200
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of S. pneumoniae	Bacterial isolate	Manual/Optochin disc	CE	N/A	Micro-LP-0041
	Identification of Cultured bacteria		Manual/Biomerieux API kits	CE	N/A	Micro-LP-0084, 0085,0087
	Identification of cultured bateria		Automated Vitek 2	CE	Not applicable	Micro-LP-0089,0001,0002,0004,0005,0006,0007,0008,0009,0010,0011,0012,0013,0015,0016,0017,0018,0019,0020,0021,0022,0025,0026,0030,0034,0035,0036
	Identification of Yeast	Yeast isolate	Automated Vitek 2 XL	CE	N/A	Micro-LP-0089, Micro-LP-0001, 0002, 0004, 0005, 0006, 0008, 0009, 0010, 0011, 0012, 0013, 0015, 0016, 0018, 0019, 0020, 0021, 0022, 0025, 0026, 0030, 0034
1016 Identification of cultured bacteria and fungi using non-nucleic acid based	Microscopic identification of fungal isolates	Fungal isolates	Manual/Lactophenol stain	Based on standard method	Not applicable	Micro-LP-0058

techniques - .03 Identification of fungi by microscopic morphology						
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Rapid method for microorganism identification from microbial cultures	Bacterial isolates	Automated Vitek MS	CE	Not applicable	Micro-LP-0191,0001, 0002, 0004, 0005, 0006, 0007, 0008, 0009, 0010, 0011, 0012, 0013, 0015, 0016, 0017, 0018, 0019, 0020, 0021, 0022, 0025, 0026, 0030, 0034, 0035, 0036
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial susceptibility for Enterobacteriacea (CPE)	Bacterial isolate	Manual Gradient MIC Automated Vitek 2	CE	N/A	Micro-LP-0089, 0037, 0036 Performance standards for AST using EUCAST and CLSI
	Antimicrobial susceptibility for vancomycin resistant Enterococci		Manual Gradient MIC Automated Vitek 2	CE	N/A	Micro-LP-0089, 0037, 0036 Performance standards for AST using EUCAST and CLSI
	Antimicrobial susceptibility-automated		Automated Vitek 2 XL	CE	N/A	Micro-LP-0089, 0037 Performance standards for AST using EUCAST and CLSI
	Detection of Beta Lactamase		maual/Chromogenic detection of enzyme	CE	N/A	Micro-LP-0037

	Susceptibility Testing (Disc Diffusion)		Manual Disc diffusion/Calipers/Zone measurements	CE	N/A	Micro-LP-0037	Performance standards for AST using EUCAST and CLSI
	Susceptibility Testing (MIC Method)		Manual Gradient MIC	CE	N/A	Micro-LP-0037	Performance standards for AST using EUCAST and CLSI
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	investigation of skin swabs and superficial wound swabs	Cultures of yeast	automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037 Micro-LP-0089	
	procedure for the investigation of intravascular cannulae and associated specimens	Cultures of Yeast	Automated vitek 2	Based on standard method	Not applicable	Micro-LP-0037	
	Yeast One Sensititre	Cultures of yeast	Manual/Antifungal susceptibility test	CE marked	Not applicable	Micro-LP-0210 Performance standards for AST using EUCAST and CLSI	
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing	Antimicrobial susceptibility testing	Bacterial isolate	Manual:Disc diffusion, Gradient MIC\Automated Vitek 2	CE	Not applicable	Micro-LP-0089 Micro-LP-0037 Performance standards for AST using EUCAST and CLSI	

aerobes) - .05 Other categories of organism (as specified)						
	investigation of skin swabs and superficial wound swabs	Cultures of aerobic bacteria	automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037 Micro-LP-0089
	procedure for the investigation of intravascular cannulae and associated specimens		Automated vitek 2	Based on standard method	Based on standard method	Micro-LP-0037
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Quantiferon TB gold plus (QFT ® plus) on Dynex DS2 automated ELISA system	Blood	"Automated Dynex DS2"	CE	0.05-10,000 IU/mL	Micro-LP-0197
1024 Preservation of microbial cultures	Examination of Blood cultures for micro-organisms other than mycobacterium species	Blood cultures	Manual	Based on standard method	Not applicable	Micro-LP-0028
	Examination of material	Bacterial isolates from CSF	Manual	Based on standard method	Not applicable	Micro-LP-0028

	from normally sterile sites					
	Procedure for the investigation of faeces for bacterial pathogen	Isolates of salmonella, shigella, vibrio, Yersina	Manual	Based on standard method	Not applicable	Micro-LP-0028
	Procedure for the investigation of specimens for ESBL, CRE and VRE	Isolates of CRE, VRE and ESBLs	Manual	Based on standard method	Not applicable	Micro-LP-0028
	procedure for the investigation of specimens for screening for MRSA	Isolates of MRSA	Manual	Based on standard method	Not applicable	Micro-LP-0028
1025 Measurement of antimicrobial levels by immunological methods	Antibiotic assays on the Abbott architect	Serum ,plasma	Automated Architect i1000	CE	Vancomycin: 3.0µg/ml to 100.0 µg/ml Gentamicin: 0.3 µg/ml to 10.0 µg/ml	Micro-LP-0027/Micro-LP-0183
	Receipt and reporting of amikacin and tobramycin assays			CE	Not applicable to microbiology Measurement carried put in clinical chemistry	Micro-LP-0181

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 - .05 CO-oximetry	Carboxy haemoglobin	Whole Blood	Absorption Spectroscopy	-2.0-103 %	ABL 90 Flex Plus	PC-LP-015
	Methaemoglobin		Absorption Spectroscopy	-2.0 -103 %	ABL 90 Flex Plus	PC-LP-015
	Oxyhaemoglobin		Absorption Spectroscopy	-2.0-103 %	ABL 90 Flex Plus	PC-LP-015
	Total Haemoglobin		Absorption Spectroscopy	-0.2-27 g/dl	ABL 90 Flex Plus	PC-LP-015
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2		Potentiometry	1.6-14.7 kPa	ABL 90 Flex Plus	PC-LP-015
	pH		Potentiometry	6.75-7.85	ABL 90 Flex Plus	PC-LP-015
	pO2		Potentiometry	1.3-73.3 kPa	ABL 90 Flex Plus	PC-LP-015
	sO2		Absorption Spectroscopy	-2.0-102 %	ABL 90 Flex Plus	PC-LP-015
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess		Calculated		ABL 90 Flex Plus	PC-LP-015
	Chloride		Potentiometry	70-160 mmol/l	ABL 90 Flex Plus	PC-LP-015
	Glucose		Amperometric	0-47 mmol/l	ABL 90 Flex Plus	PC-LP-015
	Ionised Calcium		Potentiometry	0.4-2.7 mmol/L	ABL 90 Flex Plus	PC-LP-015
	Lactate		Amperometric	1.1 mmol/l	ABL 90 Flex Plus	PC-LP-015
	Potassium		Potentiometry	1.5-10.5 mmol/l	ABL 90 Flex Plus	PC-LP-015

	Sodium		Potentiometry	95-190 mmol/l	ABL 90 Flex Plus	PC-LP-015
	Standard Bicarbonate		Calculated		ABL 90 Flex Plus	PC-LP-015
1061 Clinical Chemistry - .20 Hormones	HCG		Immunoassay	0-5000 iu/ml	AQT 90	PC-LP-020

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	Alanine transaminase (ALT) **1,2,3,4"	Blood	Roche C311	Enzymatic	5-700 U/L	CC-LP-S100A
	Albumin **1,2,3,4"		Roche C311	Colorimetric	2-60g/L	To follow
	Alkaline Phosphatase (ALP) **1,2,3,4"		Roche C311	Colorimetric	5-1200U/L	CC-LP-S100A
	Amylase **1,2,3,4"		Roche C311	Enzymatic,colorimetric	3-1500 U/L	CC-LP-S100A
	Calcium **1,2,3,4"		Roche C311	Colorimetric	0.2-5mmol/L	CC-LP-S100A
	Chloride**1,2,3,4"		Roche C311	Indirect ISE	60 to 140 mmol/L	CC-LP-S100A
	Cholesterol **1,2,3,4"		Roche C311	Enzymatic,colorimetric	0.1-20.7mmol/L	CC-LP-S100A
			Roche C311	Enzymatic,colorimetric	0.08-3.88mmol/L	CC-LP-S100A
	Creatinine **1,2,3,4"		Roche C311	Enzymatic	5-2700 umol/L	To follow
	Gamma-Glutamyl Transferase (GGT) **1,2,3,4"		Roche C311	Enzymatic,colorimetric	3-1200U/L	CC-LP-S100A
	Glucose **1,2,3,4"		Roche C311	UV, enzymatic reference with hexokinase	0.24-40 mmol/L	CC-LP-S100A
	Magnesium **1,2,3,4"		Roche C311	Colorimetric	0.1-2.0mmol/L	CC-LP-S100A
	Phosphate **1,2,3,4"		Roche C311	Molybdate UV	0.1-6.46 mmol/L	CC-LP-S100A
	Potassium **1,2,3,4"		Roche C311	Indirect ISE	1.5-10 mmol/L	To follow

	Sodium **1,2,3,4"	Roche C311	Indirect ISE	80-180 mmol/L	CC-LP-1005
	Total Bilirubin**1,2,3,4"	Roche C311	Colorimetric	2.5-650 umol/L	CC-LP-S100A
	Total Protein **1,2,3,4"	Roche C311	Colorimetric	2-120g/L	To follow
	Triglycerides **1,2,3,4"	Roche C311	Enzymatic,colorimetric	0.1-10mmol/L	CC-LP-S100A
	UREA **1,2,3,4"	Roche C311	Enzymatic	0.5-40 mmol/L	To follow
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	C-Reactive Protein (CRP) **1,2,3,4"	Roche C311	Immunoturbidimetric	0.6-350mg/L	CC-LP-S100A
1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4"	Roche E411	ECLIA	1.5-1750 nmol/L	CC-LP-S100B
	Estradiol **1,2,3,4"	Roche E411	ECLIA	0.05-60	CC-LP-S100B
	Follicle-stimulating hormone (FSH) **1,2,3,4"	Roche E411	ECLIA	0.1-200mIU/ml	CC-LP-S100B
	Human chorionic gonadotrophin (HCG) **1,2,3,4"	Roche E411	ECLIA	0.1-10000mIU/mL	CC-LP-S100B
	Luteinizing Hormone (LH) **1,2,3,4"	Roche E411	ECLIA	0.1-200mIU/mL	CC-LP-S100B
	Macroprolactin **1,2,3,4"	Roche E411	ECLIA	0.047-470ng/mL	CC-LP-S100B
	Parathyroid Hormone (PTH) **1,2,3,4"	Roche E411	ECLIA	1.20-5000pg/mL	CC-LP-S100B
	Progesterone **1,2,3,4"	Roche E411	ECLIA	0.05-60 ng/mL	CC-LP-S100B
	Prolactin **1,2,3,4"	Roche E411	ECLIA	0.047-470ng/mL	CC-LP-S100B
	Testosterone **1,2,3,4"	Roche E411	ECLIA	0.025-15ng/mL	CC-LP-S100B
	Thyroid stimulating hormone (TSH) **1,2,3,4"	Roche E411	ECLIA	0.005-100uIU/ml	CC-LP-S100B
	Thyroxine (FT4) **1,2,3,4"	Roche E411	ECLIA	0.5-100pmol/L	CC-LP-S100B

	Tri-iodothyronine (FT3) **1,2,3,4"		Roche E411	ECLIA	0.4-50 pmol/L	CC-LP-S100B
1061 Clinical Chemistry - .61 Hb A1c	HbA1c	Whole Blood	HPLC	Arkray HA8190V	CE	CC-LP-312
1061 Clinical Chemistry - .77 Calculi	Low Density Lipoprotein (LDL) calculation	Blood	Roche C311	N/A	N/A	CC-LP-S100A
1061 Clinical Chemistry - .99 Miscellaneous tests	Thyroid peroxidase (TPO) **1,2,3,4"		Roche E411	ECLIA	5-600 IU/ml	CC-LP-S100B

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