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	Standard Method	N/A	BT-LP-0111

			Tube			
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	ALB2 **1,2,3,4"	Blood	Roche Cobas 8000	Colorimetric/Bromocresol Green	2-60 g/L	CC-LP-406
	ALBU **1,2,4"	Urine	Roche Cobas 8000	Immunoturbidimetric	3-400mg/L	CC-LP-406
	ALP2L **1,2,3,4"	Blood	Roche Cobas 8000	Colorimetric	5-1200 U/L	CC-LP-406
	ALTL **1,2,3,4"		Roche Cobas 8000	According to IFCC (w/o P5P activation)	5-700 U/L	CC-LP-406
	AMYL2 **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	3-1500 U/L	CC-LP-406
	ASTL **1,2,3,4"		Roche Cobas 8000	According to IFCC (w/o P5P activation)	5-700 U/L	CC-LP-406
	BILD2 **1,2,3,4"		Roche Cobas 8000	Diazo Method	1.2-236 µmol/L	CC-LP-406
	BILT3 **1,2,3,4"		Roche Cobas 8000	Colorimetric	2.5-550 µmol/L	CC-LP-406
	CA2 **1,2,3,4"		Roche Cobas 8000	Photometric	0.20-5.0 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
	Chloride **1,2,3,4"	Blood	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
	CHO2I **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic, colorimetric	0.1-20.7 mmol/L	CC-LP-406
	CK **1,2,3,4"		Roche Cobas 8000	UV, enzymatic reference with hexokinase	7-2000 U/L	CC-LP-406

CO2-L **1,2,3,4"		Roche Cobas 8000	Enzymatic	2-50 mmol/L	CC-LP-406
CREA2 **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	5-2700 µmol/L	CC-LP-406
CRPL4 **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.3-350 mg/L	CC-LP-406
GGTI2 **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	3-1200 U/L	CC-LP-406
Gluc3 **1,2,3,4"		Roche Cobas 8000	UV, enzymatic reference with hexokinase	0.11-41.6 mmol/L	CC-LP-406
Glucose **1,2,4"	CSF	Roche Cobas 8000	Enzymatic - hexokinase	0.11-41.6 mmol/L	CC-LP-406
Haemolysis	Blood	Roche Cobas 8000	Calculations of absorbance	5 - 1200nm	CC-LP-406
HDLC4		Roche Cobas 8000	Enzymatic Colorimetric	0.08 - 3.88 mmol/L	CC-LP-406
HDLC4 **1,2,3,4"		Roche Cobas 8000	Enzymatic, colorimetric	0.08-3.88 mmol/L	CC-LP-406
Icteric		Roche Cobas 8000	Calculations of absorbance	0.5 - 60 nm	CC-LP-406
IL6 **1,2,3,4"		Cobas 8000	1.5-5000 pg/ml	CE	CC-LP-406
LACT2 **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
LDHI2 **1,2,3,4"	Blood	Roche Cobas 8000	UV	10-1000 U/L	CC-LP-406
Lipaemia		Roche Cobas 8000	Calculations of absorbance	10 - 2000 nm	CC-LP-406
Methotrexate **1,2,3,4"		Roche Cobas 8000	Immunoassay	0.04-1.20µmol/L	CC-LP-406
Mg-2 **1,2,3,4"		Roche Cobas 8000	Colorimetric	0.10-2.0 mmol/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
NH3L **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic	10-1000 µmol/L	CC-LP-406
Osmolality ETS 2022		OsmoPro Multi-Sample Micro Osomometer	Freeze point depression osmometry	0 to 2000 mOsm/kg H2O	CC-LP-502
Phos2 **1,2,3,4"		Roche Cobas 8000	Molybdate UV	0.10-6.46 mmol/L	CC-LP-406
PHOSU **1,2,4"	Urine	Roche Cobas 8000	Molybdate UV	1.1-92.0 mmol/L	CC-LP-406
Potassium **1,2,3,4"	Blood	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
	TP2 **1,2,3,4"		Roche Cobas 8000	Colorimetric	2.0-120 g/L	CC-LP-406
	TPC3 **1,2,4"	CSF	Roche Cobas 8000	Turbidimetric	4-200 mg/dL	CC-LP-406
	TPU3 **1,2,4"	Urine	Roche Cobas 8000	Turbidimetric	0.04-2.0 g/L	CC-LP-406
	Trig **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
	UA2 **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic, colorimetric	11.9-1487 µmol/L	CC-LP-406
	UA2-U **1,2,4"	Urine	Roche Cobas8000	Enzymatic, colorimetric	131-16362mmol/L	CC-LP-406
	UR Urea **1,2,4"		Roche Cobas 8000	Enzymatic	1-2000 mmol/L	CC-LP-406
	UreaL **1,2,3,4"	Blood	Roche Cobas 8000	Enzymatic	0.5-40 mmol/L	CC-LP-406
	Urinary amylase **1,2,4"	Urine	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 ETS 2022		OsmoPro Multi-Sample Micro Osomometer	Freeze point depression osmometry	0 to 2000 mOsm/kg H2O	CC-LP-502
	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 TP **1,2,4"		Roche Cobas 8000	Turbidimetric	0.04-2 g/L	CC-LP-406
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	AAT2 **1,2,3,4"	Blood	Roche Cobas 8000	Immunoturbidimetric	0.2-6.0 g/L	CC-LP-406
	APOAT **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.2-6.0 g/L	CC-LP-406
	APOBT **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

	CER **1,2,3,4"	Blood	Roche Cobas 8000	Immunoturbidimetric	0.03-1.4 g/L	CC-LP-406
	CRPHS **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.15-20.0 mg/L	CC-LP-406
	HCY **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
	LPA2 **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 - .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	AMIK	Blood	Roche Cobas 8000	KIMS Immunoassay	0.8 - 40 µg/ml 1.4 - 68.4 µmol/L	CC-LP-406
	CARB4 **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	2-20 mg/L	CC-LP-406
	CYCLO **1,2,3,4"		Roche Cobas 8000	Immunoassay	30.0-2000 ng/ml	CC-LP-406
	DIG		Roche Cobas 8000	ECLIA	0.2 - 5.0 ng/ml	CC-LP-406
	Digoxin **1,2,3,4"	Plasma/Serum	Electrochemiluminescence immunoassay	Roche Cobas 8000	CE	CC-LP-406
	Li	Blood	Roche Cobas 8000	Colorimetric	0.05 - 3.00 mmol/L	CC-LP-406
	LI **1,2,3,4"		Roche Cobas 8000	Colorimetric	0.05-3.00 mmol/L	CC-LP-406
	PHNO2 **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	2.4-60 mg/L	CC-LP-406
	PHNY2 **1,2,3,4"		Roche Cobas 8000	KIMS Immunoassay	0.8-40 mg/L	CC-LP-406
	TACRO **1,2,3,4"		Roche Cobas 8000	Immunoassay	0.5-4.0ug/L	CC-LP-406

	THEO2 **1,2,3,4"	Roche Cobas 8000	KIMS Immunoassay	0.8-40 mg/L	CC-LP-406
	TOBR	Roche Cobas 8000	Immunoassay	0.33 -10 µg/ml, 0.71 - 21.4 µmol/L	CC-LP-406
	VALP2 **1,2,3,4"	Roche Cobas 8000	Immunoassay	2.8-150 mg/L	CC-LP-406
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	ACETA **1,2,3,4"	Roche Cobas 8000	Enzymatic, colorimetric	1.2-500 mg /L	CC-LP-406
	SALI **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	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
	FSH	Roche Cobas 8000	ECLIA	0.1 - 200 mIU/ml	CC-LP-406
	FT3	Roche Cobas 8000	ECLIA	0.4 - 50 pmol/L	CC-LP-406
	FT4	Roche Cobas 8000	ECLIA	0.5 - 100 pmol/L	CC-LP-406
	GH **1,2,3,4"	ISYS	Chemiluminescence CE	0.05-100ng/mL	CC-LP-102B
	HCG	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
	LH	Roche Cobas 8000	ECLIA	0.1 - 200 mIU/ml	CC-LP-406
	Macroprolactin	Roche Cobas 8000	ECLIA	0.047 to 470 ng/ml	CC-LP-406
	OEST	Roche Cobas 8000	ECLIA	5 -3000 pg/ml	CC-LP-406
	PROG	Roche Cobas 8000	ECLIA	0.05 - 16 ng/ml	CC-LP-406
	PROL	Roche Cobas 8000	ECLIA	0.047 - 470 ng/ml	CC-LP-406
	PTH	Roche Cobas 8000	ECLIA	1.20 -5000 pg/ml	CC-LP-406
	Testosterone	Roche Cobas 8000	ECLIA	0.025 to 15.0 ng/ml	CC-LP-406
	TPO	Roche Cobas 8000	ECLIA	5 - 600 IU/ml	CC-LP-406
	TSH	Roche Cobas 8000	ECLIA	0.005 - 100 µIU/ml	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	Iron2 **1,2,3,4"	Blood	Roche Cobas 8000	Colorimetric	0.90-179 µmol/L	CC-LP-406
	UIBCI **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	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	Blood	Menarini	HPLC	20 to 151 mmol/mol	CC-LP-312
1061 Clinical Chemistry - .76 Simple side tests for biochemical and immunological analytes	Osmolality	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		Roche Cobas 8000	N/A	N/A	CC-LP-802

Creatinine					
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
		Roche Cobas 8000	N/A	N/A	CC-LP-406
		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
		Roche Cobas 8000	N/A	N/A	CC-LI-402A
		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
		Roche Cobas 8000	N/A	N/A	CC-LP-406
		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
			Roche Cobas 8000	N/A	N/A	CC-LP-406
			Roche Cobas 8000	N/A	N/A	CC-LP-406
	Protein/Creatinine ratio		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
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	IGA-2 **1,2,3,4"	Blood	Roche Cobas 8000	Immuoturbidimetric	0.50-8.00 g/L	CC-LP-406
	IGG-2 **1,2,3,4"		Roche Cobas 8000	Immuoturbidimetric	3.0-50.0 g/L	CC-LP-406
	IGM-2 **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	ETOH2 **1,2,3,4"		Roche Cobas 8000	Enzymatic	10.1-498 mg/dL	CC-LP-406
1061 Clinical Chemistry - .86 C3 and C4	C3C-2 **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.04-5.0 g/L	CC-LP-406
	C4-2 **1,2,3,4"		Roche Cobas 8000	Immunoturbidimetric	0.02-1.0 g/L	CC-LP-406
1061 Clinical Chemistry - .87 Cryoglobulins	Cryoglobulin		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

Main Hospital (Head Office)

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 **1,2,4"	whole blood	Ion Selective electrode (ISE)	ABL 90 Flex incl 5 new analysers	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

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
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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 **4"		Microscopy	Leica microscopes	Based on a standard method	HAEM-LP-0058
1030 Haematology - .03 Erthrocyte sedimentation rate	Erthrocyte sedimentation rate **4"		Sedimentation	Vesmatic 30	CE	HAEM-LP-0055
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		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
	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 **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

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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
	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
	Hales Colloidal Iron	Human tissue/body fluid	Manual	Based on standard method	NA	CP-LI-0086
	Highman's Congo Red		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
	Oil Red O		Manual	Based on standard method	NA	CP-LI-0096
	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
	Toluidine Blue		Manual	Based on standard method	NA	CP-LI-0104
	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	Based on standard	NA	CP-LP-0149

		Systems Benchmark Ultra	method		
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
EMA **2, 4		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		Ventana Benchmark Ultra	Based on standard Method	N/A	CP-LP-0149
HLO **2, 4		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
Inhibin a **2, 4		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	Ventana Benchmark Ultra	Based on standard Method	N/A	CP-LP-0149
S100 **2, 4		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	Based on standard method	N/A	CP-LP-0152

			Benchmark Ultra			
	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		Microscope BX50 Olympus	Based on standard method	NA	CP-MF-0003

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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 Micro-LP-0089/Micro-LP-0191
	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	Micr-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	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Manual	Based on standard method	Not applicable	Micro-LP-0058

description of human cells)						
	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 UK standards for Microbiology Investigation, Public Health England Micro-LP-0191/Micro-LP-0089 Micro-LP-0212
	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 UK Standards for Microbiology Investigation, Public Health England
	Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Manual	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0191 micro-Lp-0076/Micro-LP-0077 Micro-LP-0087/Micro-LP-0084 Micro-LP-0081/Micro-LP-0082 Micro-LP-0085
	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 Micro-LP-0058 UK Standards for Microbiology Investigation, Public Health England

Investigation of skin scraping for Gram negative Diplococci	Skin scrapings	Manual	Based on standard method	Not applicable	Micro-LP-0003 UK standards for microbiology investigation, Public health england
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 UK standards for microbiology investigation, Public health england Micro-LP-0089/Micro-LP-0191
Investigation of urine samples -Microscopy	Urine, CSU. MSU, Clean catch urine, Subra pubic aspirate, bag urine	Manual	Based on standard method	Not applicable	Micro-LP-0058 & 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 HICPAC, Guidelines 2003 Hospital infection society guidelines 2001
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 UK standards for microbiology investigation, Public health england
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 UK standards for microbiology investigation, Public

						health england 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 UK Standards for Microbiology Investigation, Public Health England
	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 UK Standards for Microbiology Investigation, Public Health England
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 associated specimens	High vaginal swab, low vaginal swab, Vulval swab, labial swab, Penile swab	Manual	Based on standard method	Not applicable	Micro-LP-0016 Micro-LP-0024
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	Manual	Based on standard method	Not applicable	Micro-LP-0058

		components				
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-0103 Micro-LP-0058 UK standards for microbiology investigation, Public health england Micro-LP-0166
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture and sensitivity	Nasal (inculuding per nasal), Throat, Ear, Eye (including cannicular 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 UK standards for microbiology investigation, Public health England Micro-LP-0089/Micro-LP-0191
	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 applicabe	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 UK standards for microbiology investigation, Public

					health England
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 UK Standards for Microbiology Investigation, Public Health England
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, CRE 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 bacterial pathogens other than	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	not applicable	Micro-LP-0012

	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 Micro-LP-0089/Micro-LP-0191
	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 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

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 appropriate techniques - .02 Particle agglutination	Culture and sensitivity	Isolates of Staphylococcus aureus from Nasal , Ear, Eye (including canalicular pus) and mouth	Manual	CE	Not applicable	Micro-LP-0064
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Isolates of staphylococcus aureus from blood cultures	Manual	Ce	Not applicable	Micro-LP-0064
	Examination of material from normally sterile sites	Isolates of staphylococcus aureus from normally sterile sites	Manual	Ce	Not applicable	Micro-LP-0064
	Investigation of genital tract and associated specimens	Isolates of Staphylococcus aureus from high vaginal swab, low vaginal swab, Vulval swab, labial swab, Penile swab	Manual	CE	Not applicable	Micro-LP-0064
	investigation of skin swabs and superficial wound swabs	Isolates of staphylococcus aureus from skin swabs and superficial wound swabs	Manual	Ce	Not applicable	Micor-LP-0064
	Investigation of urine samples -Culture and sensitivity	Isolates of Staphylococcus aureus from Urine samples, CSU, MSU, clean catch,	Manual	CE	Not applicable	Micro-LP-0064

		supra pubic aspirate, DST urine, bag urine				
	procedure for the investigation of intravascular cannulae and associated specimens	Isolates of staphylococcus aureus from intravascular cannulae and associated specimens	Manual	Ce	Not applicable	Micro-LP-0064
	procedure for the investigation of specimens for screening for MRSA	Isolates of staphylococcus aureus	Manual	Ce	Not applicable	Micro-LP-0064
	Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than Mycobacteria	Isolates of Staphylococcus aureus from Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	CE	Not applicable	Micro-LP-0064
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 legionella pneumophilia and streptococcus pneumoniae urinary antigens	urine	Manual	CE	Not applicable	Micro-LP-0186 Micro-LP-0180
	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	CE	Not applicable	Micro-LP-0166
	Procedure for the detection of	Faeces	Manual	CE	Not applicable	Micro-LP-0169 ImmunoCard STAT

	Helicobacter pylori stool antigen					HpSA Kit Insert
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Investigation of CSF and Nasopharyngeal Swabs using the Biofire Filmarray Torch	CSF, Nasopharyngeal swab	Automated - Biomerieux Biofire Filmarray Torch	CE Marked	N/A	Micro-LP-0208
	Molecular Detection of M. tuberculosis using GeneXpert	Sputum	Automated - GeneXpert	CE Marked	N/A	Micro-LP-0209
	Molecular detection of salmonella, shigella, Verotoxigenic E. coli, cryptosporidium, Giardia and Clostridium difficile	Faeces	Automated Enteric Bio	CE	Not applicable	Micro-LP-0193 Micro-LP-0192
	Molecular Screening of Rectal Swabs for CPE	Rectal Swabs	q PCR:Roche PSH PSU - Pre analytical sample	CE Marked	N/A	Micro-LP-199
	Rapid Molecular Screening of Rectal Swabs for CPE		q PCR:Cepheid GeneXpert	CE Marked	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	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Automated Vitek 2	CE	Not applicable	Micro-LP-0089
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Blood cultures	Automated Vitek 2/ Vitek MS	CE	Not applicable	Micro-LP-0089 Micro-LP-0212
	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Automated Vitek 2	CE	Not applicable	Micro-LP-0089

Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0076/Micro-LP-0077 Micro-LP-0081/Micro-LP-0082 Micro-Lp-0084/Micro-LP-0085
investigation of genital tract and associated specimens	High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Automated Vitek 2	CE	Not applicable	Micro-LP-0089
investigation of skin swabs and superficial wound swabs	Wound swabs, swabs from other superfical sites	automated Vitek 2	CE	Not applicable	Micro-LP-0089
Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	CE	Not applicable	Micro-LP-0152
Procedure for the examination of a transfusion reaction	Blood packs red cell concentrates, platelets other blood components	automated Vitek 2	CE	Not applicable	Micro-LP-0089
Procedure for the investigation of faeces for bacterial pathogen	Faeces	Automated Vitek 2	CE	Not applicable	Micro-LP-0089
procedure for the investigation of intravascular cannulae and associated specimens	Hickman, Vascath, portacath, Femoral line, central line, arterial line,subclavian line, Jugular line	Automated vitek 2	CE	Not applicable	Micro-LP-0089
Procedure for the investigation of specimens for ESBL, CRE and VRE	Rectal swab Faeces swabs from other sites as clinically indicated	Automated Vitek 2	CE	Not applicable	Micro-LP-0089

	Procedure for the investigation of specimens for screening for MRSA	Nasal, groin, Wound & other sites as clinically indicated	Automated Vitek 2	CE	Not applicable	Micro-LP-0089
	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/Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	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-0152
	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-0058
	Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Manual	Based on standard method	Not applicable	Micro-LP-0152
	investigation of skin swabs and superficial wound swabs	Fungi isolated from Wound swabs, swabs from other superfical sites	Manual	Based on standard method	Not applicable	Micro-LP-0058
	Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampleing plates	Manual	Based on standard method	Not applicable	Micro-LP-0152

	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-0152
	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-0152
	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-0058
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Blood cultures	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
	Examination of material from normally sterile sites	CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
	Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Automated Vitek MS	Based on standard method	Not applicable	Micro-LP-0191
	investigation of genital tract and associated specimens	High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Automated Vitek MS	CE	Not applicable	Micro-LP-0191

investigation of skin swabs and superficial wound swabs	Wound swabs, swabs from other superfical sites	automated Vitek MS	CE	Not applicable	Micro-LP-0191
Investigation of urine samples- Culture and sensitivity	Urine, CSU. MSU, Clean catch urine, Subra pubic aspirate, bag urine	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
Procedure for the enumeration and identification of bacteria and fungi from air sampling and settle plates	Settle plates Air sampling plates	Manual	CE	Not applicable	Micro-LP-0191
Procedure for the examination of a transfusion reaction	Blood packs red cell concentrates, platelets other blood components	automated Vitek MS	CE	Not applicable	Micro-LP-0191
Procedure for the investigation of faeces for bacterial pathogen	Faeces	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
procedure for the investigation of intravascular cannulae and associated specimens	Hickman, Vascath, portacath, Femoral line, central line, arterial line,subclavian line, Jugular line	Manual/Automated vitek 2 Vitek MS	Based on standard method	Not applicable	Micro-LP-0191
Procedure for the investigation of specimens for ESBL, CRE and VRE	Rectal swab Faeces swabs from other sites as clinically indicated	Automated Vitek MS	CE	Not applicable	Micro-LP-0191
Procedure for the investigation of specimens for screening for MRSA	Nasal, groin, Wound & other sites as clinically indicated	Automated	CE	Not applicable	Micro-LP-0191
Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial	Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Automated Vitek MS	Based on standard method	not applicable	Micro-LP-0191

	pathogens other than Mycobacteria					
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Antibiotic susceptibility testing disc diffusion, vitek 2 Determination of MIC using gradient diffusion	Cultures of yeast	Manual/automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037
	Culture and sensitivity	Cultures of yeast isolated from Nasal (including peri nasal), Throat, Ear, Eye (including canalicular pus) and mouth	Manual	Based on standard method	Not applicable	Micro-LP-0210 Micro-LP-0037
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Cultures of yeast isolated from Blood cultures	Automated Vitek 2 Manual	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037
	Examination of material from normally sterile sites	Isolates of yeast from CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual	Based on standard method	Not applicable	Micro-LP-0212
	Investigation of genital tract and associated specimens	Cultures of yeast isolated from High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Manual	Based on standard method	Not applicable	Micro-LP-0212
	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
	Investigation of urine samples - Culture and sensitivity	Urine, CSU, MSU, Clean catch urine, Subra pubic aspirate, bag urine	Manual	Based on standard method	Not applicable	Micro-LP-0210 Micro-LP-0037
	procedure for the	Cultures of Yeast	Automated	Based on standard	Not applicable	Micro-LP-0037

	investigation of intravascular cannulae and associated specimens		vitek 2	method		
	Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than mycobacteria	Isolates of yeast from Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual	Based on standard method	Not applicable	Micro-LP-0212
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antibiotic susceptibility testing disc diffusion, vitek 2 Determination of MIC using gradinet diffusion	Cultures of aerobic bacteria	Manual/automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037 Performance standards for AST using EUCAST and CLSI Vitek 2 user manual UK standards for microbiology investigation, Public health england
	Culture and sensitivity	Cultures of aerobic bacteria isolated from Nasal (including perinasal), Throat, Ear, Eye (including canalicular pus) and mouth	Manual/Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Cultures of aerobic bacteria isolated from blood cultures	automated Manual Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037
	Examination of material from normally sterile sites	isolates of aerobic bacteria CSF, fluids,Tissue, Biopsies, Bone marrow, CAPD, Prosthetic devices	Manual/automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089

Investigation of genital tract and associated specimens	Cultures of aerobic bacteria isolated from High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Automated Vitek 2	Based on standard method	Not applicable	Micor-LP-0037
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
Investigation of urine samples -Culture and sensitivity	Cultures of aerobic bacteria isolated from Urine, CSU, MSU, Clean catch urine, Subra pubic aspirate, bag urine	Manual/Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037 Micro-LP-0089
Procedure for the investigation of faeces for bacterial pathogen	Isolates of salmonella, shigella, vibrio, Yersina	Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0089 Micro-LP-0037
procedure for the investigation of intravascular cannulae and associated specimens	Cultures of aerobic bacteria	Automated vitek 2	Based on standard method	Based on standard method	Micro-LP-0037
Procedure for the investigation of specimens for ESBL, CRE and VRE	Cultures of aerobic bacteria isolated from Rectal swab,Faeces and swabs from other sites as clinically indicated	Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037
Procedure for the investigation of specimens for screening for MRSA	Cultures of aerobic bacteria	Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037 Micro-LP-0089
Procedure for the investigation of Sputum, Bronchoalveolar lavages and associated specimens for bacterial pathogens other than	Isolates of aerobic bacteria from Sputum, endotracheal aspirate, pleural fluids, cough swabs , Bronchoalveolar lavages	Manual/Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0037

	Mycobacteria					
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 from normally sterile sites	Bacterial isolates from CSF	Manual	Based on standard method	Not applicable	Micro-LP-0028
	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 UK standards for microbiology investigation, Public health england
1029 Miscellaneous - .99 Miscellaneous tests	Culture and sensitivity	Nasal (including perinasal), Throat, Ear, Eye (including	Manual	Based on standard method	Not applicable	Micro-LP-0065

		canalicular pus) and mouth				
	Examination of Blood cultures for micro-organisms other than mycobacterium species	Blood cultures	Manual	Based on standard method	Not applicable	Micro-LP-0040 (oxidase)
	Identification of bacterial and fungal isolates	Cultures of bacteria and fungi	Automated Vitek 2	Based on standard method	Not applicable	Micro-LP-0049 (urease) Micro-LP-0040 (oxidase)
	Investigation of genital tract and associated specimens- Lancefield Streptococcal Grouping	Cultures of aerobic bacteria isolated from High vaginal swab, low vaginal swab, Vulval swab, labial swab, endocervical swab, Penile swab	Manual	Based on standard method	Not applicable	Micro-LP-0065
	Investigation of urine samples -Culture and sensitivity	Urine, CSU, MSU, Clean catch urine, Subra pubic aspirate, bag urine, DST urine	Manual	Based on standard method	Not applicable	Micro-LP-0040 (oxidase)
	Procedure for the investigation of faeces for bacterial pathogen	Faeces	Manual	Based on standard method	Not applicable	Micro-LP-0040 (oxidase) Micro-LP-0049 (urease)

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: 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	ALB **1,2,3,4"	Blood	Roche C311	Colorimetric	2-60g/L	To follow
	ALP2L **1,2,3,4"		Roche C311	Colorimetric	5-1200U/L	CC-LP-S100A
	ALTL **1,2,3,4"		Roche C311	Enzymatic	5-700 U/L	CC-LP-S100A
	AMYL2 **1,2,3,4"		Roche C311	Enzymatic,colorimetric	3-1500 U/L	CC-LP-S100A
	BIL **1,2,3,4"		Roche C311	Colorimetric	2.5-650 umol/L	CC-LP-S100A
	CA **1,2,3,4"		Roche C311	Colorimetric	0.2-5mmol/L	CC-LP-S100A
	Chloride		Roche C311	Indirect ISE	60 to 140 mmol/L	CC-LP-S100A
	Chol **1,2,3,4"		Roche C311	Enzymatic,colorimetric	0.1-20.7mmol/L	CC-LP-S100A
	CREA2 **1,2,3,4"		Roche C311	Enzymatic	5-2700 umol/L	To follow
	GGTI2 **1,2,3,4"		Roche C311	Enzymatic,colorimetric	3-1200U/L	CC-LP-S100A
	Gluc3 **1,2,3,4"		Roche C311	UV, enzymatic reference with hexokinase	0.24-40 mmol/L	CC-LP-S100A
	HDLC4 **1,2,3,4"		Roche C311	Enzymatic,colorimetric	0.08-3.88mmol/L	CC-LP-S100A
	Mg-2 **1,2,3,4"		Roche C311	Colorimetric	0.1-2.0mmol/L	CC-LP-S100A
	PHOS **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
	TP **1,2,3,4"		Roche C311	Colorimetric	2-120g/L	To follow
	Trigs **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	CRP **1,2,3,4"		Roche C311	Immunoturbidimetric	0.6-350mg/L	CC-LP-S100A
1061 Clinical Chemistry - .20 Hormones	CORT **1,2,3,4"		Roche E411	ECLIA	1.5-1750 nmol/L	CC-LP-S100B
	EST **1,2,3,4"		Roche E411	ECLIA	0.05-60	CC-LP-S100B
	FSH **1,2,3,4"		Roche E411	ECLIA	0.1-200mIU/ml	CC-LP-S100B
	FT3 **1,2,3,4"		Roche E411	ECLIA	0.4-50 pmol/L	CC-LP-S100B
	FT4 **1,2,3,4"		Roche E411	ECLIA	0.5-100pmol/L	CC-LP-S100B
	HCG **1,2,3,4"		Roche E411	ECLIA	0.1-10000mIU/mL	CC-LP-S100B
	LH **1,2,3,4"		Roche E411	ECLIA	0.1-200mIU/mL	CC-LP-S100B
	MACROP **1,2,3,4"		Roche E411	ECLIA	0.047-470ng/mL	CC-LP-S100B
	PROG **1,2,3,4"		Roche E411	ECLIA	0.05-60 ng/mL	CC-LP-S100B
	PROL **1,2,3,4"		Roche E411	ECLIA	0.047-470ng/mL	CC-LP-S100B
	PTH **1,2,3,4"		Roche E411	ECLIA	1.20-5000pg/mL	CC-LP-S100B
	TSH **1,2,3,4"		Roche E411	ECLIA	0.005-100uIU/ml	CC-LP-S100B
	TSTO **1,2,3,4"		Roche E411	ECLIA	0.025-15ng/mL	CC-LP-S100B
1061 Clinical Chemistry - .77 Calculi	LDL calculation		Roche C311	N/A	N/A	CC-LP-S100A
1061 Clinical Chemistry - .99 Miscellaneous tests	TPO **1,2,3,4"		Roche E411	ECLIA	5-600 IU/ml	CC-LP-S100B

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