

# Schedule of Accreditation



Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Cork
INAB Reg No	153MT
Contact Name	Bernadette Murray
Address	College Rd, Cork, T12 DV56
Contact Phone No	021-4941960
Email	BMurray@bonsecours.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	06/09/2004
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Services available to the public <sup>1</sup>	Yes

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Pathology Department, College Road, Cork, T12 DV56

# Scope of Accreditation

## Head Office

### 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	ABO and Rh D and other antigens by manual methods <sup>a 3 4</sup>	Red Cells / Plasma / Serum	Bio-Rad Gel Technique Manual Tube Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	ABO and Rh D grouping of blood <sup>a 3 4</sup>		Biorad IH-1000 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/005
1020 Transfusion science - .03 Blood group antibody screen	Antibody screening <sup>a 3 4</sup>	Plasma	Biorad Gel Technique (Manual)	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures

						BSC/BB/SOP/002
			Biorad IH-1000 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002 BSC/BB/SOP/005
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification <sup>a 3 4</sup>		Biorad Gel Technique manual	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/003
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing <sup>a 3 4</sup>	Donor Cells / Plasma	Biorad Gel Technique manual	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping <sup>a 4</sup>	Red Cells	Bio-Rad Gel Technique Manual Tube Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/003
	Rh+K Phenotype <sup>a 4</sup>		Automated BioRad IH-1000. Ab/Ag Reaction Gel Technique	CE	N/A	BSH Guidelines Pre-Transfusion Compatability Procedures . BSC/BB/SOP/003, BSC/BB/SOP/005, BSC/BB/SOP/041
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test <sup>a 4</sup>		Biorad Gel Technique manual	CE	N/A	Ab/Ag Reaction BSH Guideline: The diagnosis and

						management of primary autoimmune haemolytic anaemia BSC/BB/SOP/003
	Direct Antiglobulin Test (DAT) <sup>a</sup> 4		Automated BioRad IH-1000. Ab/Ag Reaction Gel Technique	CE	N/A	BSH Guideline: The diagnosis and Management of Primary Autoimmune Haemolytic Anaemia BSC/BB/SOP/003, BSC/BB/SOP/005, BSC/BB/SOP/041

<sup>a</sup> 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)

*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: 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	24h creatinine clearance (adult)	Urine	Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	24h creatinine clearance (child)		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	24h urinary albumin		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	24h urinary amylase		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	24h urinary calcium (adult)		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	24h urinary calcium (child)		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines

			BSC/BIO/SOP/047
24h urinary chloride	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary creatinine	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary magnesium	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary phosphate	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary potassium	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary protein	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary sodium	Calculation	Abbott c8000	CE Based on manufacturer's guidelines BSC/BIO/SOP/047
24h urinary urate	Calculation	Abbott c8000	CE Based on manufacturer's guidelines

					BSC/BIO/SOP/047
24h urinary urea		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Albumin (Micro) <sup>1 2 3 4</sup>		Immunoturbidimetric - anti-human albumin antibody	Abbott c8000 5 – 500 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Albumin <sup>1 2 3 4</sup>	Serum	Colorimetric – BCP	Abbott c8000 3 – 110 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
AlkPhos <sup>1 2 3 4</sup>		Colorimetric - para-nitrophenyl phosphate	Abbott c8000 5 – 4555 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
ALT <sup>1 2 3 4</sup>		Colorimetric - NADH without P-5-P	Abbott c8000 5 – 942 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Ammonia <sup>1 2 3 4</sup>	EDTA Plasma	Colorimetric - glutamate dehydrogenase	Abbott c8000 5 – 997 µmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Amylase <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric - CNPG3 substrate	Abbott c8000 Serum/ urine 3 – 3010 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
AST <sup>1 2 3 4</sup>	Serum	Colorimetric - NADH without P-5-P	Abbott c8000 2 – 913 IU/L	CE	Based on manufacturer's guidelines



					BSC/BIO/SOP/134
Bilirubin Direct <sup>1 2 3 4</sup>		Colorimetric - Diazo reaction	Abbott c8000 1.7 – 256.5 µmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Bilirubin Total <sup>1 2 3 4</sup>		Colorimetric - diazonium salt	Abbott c8000 1.7 – 427.5 µmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
BNP (B-Type Natriuretic Peptide) <sup>1 2 3 4</sup>	Plasma	CMIA	Abbott i2000 10 – 5000 ng/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Body surface area	N/A	Calculation	N/A	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Calcium (Corrected)	Serum	Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Calcium Creatinine Ratio	Urine	Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Calcium <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric/ Arsenazo-III	Abbott c8000 Serum/ urine 0.5 – 6.0 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Chloride <sup>1 2 3 4</sup>		Indirect ISE	Abbott c8000 Serum 50 – 150 mmol/L	CE	Based on manufacturer's guidelines

			Urine 20 – 300 mmol/L		BSC/BIO/SOP/134
Cholesterol (Total) <sup>1 2 3 4</sup>	Serum	Colorimetric - cholesterol oxidase	Abbott c8000 0.2 – 18.2 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Cholesterol HDL <sup>1 2 3 4</sup>		Colorimetric - accelerator selective detergent	Abbott c8000 0.13 – 4.66 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Cholesterol LDL		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
CKDEPI GFR		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Creatine Kinase (Total) <sup>1 2 3 4</sup>		Colorimetric - NAC (N-acetyl-L-cystine)	Abbott c8000 7 – 4267 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Creatinine (Enzymatic) <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric - enzymatic quinonemine	Abbott c8000 Serum 9 – 3536 µmol/L Urine 0.19 – 35.36 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Creatinine Clearance		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047

Gamma GT <sup>1 2 3 4</sup>	Serum	Colorimetric - L-Gamma-glutamyl-3-carboxy-4-nitroanilide	Abbott c8000 4 – 8500 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Globulin		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Glucose <sup>1 2 3 4</sup>	Serum/ Plasma/ CSF	Colorimetric - hexokinase	Abbott c8000 Plasma/ Serum 0.3 – 44.4 mmol/L CSF 0.3 – 44.4 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
LDH <sup>1 2 3 4</sup>	Serum	Colorimetric - IFCC lactate to pyruvate	Abbott c8000 10 – 4500 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Magnesium <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric - isocitrate dehydrogenase	Abbott c8000 Serum 0.25 – 3.9 mmol/L Urine 0.74 - 10.85 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Phosphate <sup>1 2 3 4</sup>		Colorimetric - phosphomolybdate	Abbott c8000 Serum 0.21 – 8.17 mmol/L Urine 1.42 – 60.14 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Potassium <sup>1 2 3 4</sup>		Indirect ISE	Abbott c8000 Serum 1 - 10 mmol/L Urine 1 – 300 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Sodium <sup>1 2 3 4</sup>		Indirect ISE	Abbott c8000 Serum 100 - 200	CE	Based on manufacturer's

			mmol/L Urine 20 – 400 mmol/L		guidelines BSC/BIO/SOP/134
Triglycerides <sup>1 2 3 4</sup>	Serum	Colorimetric - Glycerol phosphate oxidase	Abbott c8000 0.05-16.05 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Troponin I (High Sensitivity) <sup>1 2 3 4</sup>	Plasma	CMIA	Abbott i2000 10 – 50,000 ng/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Urate (Uric Acid) <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric - uricase	Abbott c8000 Serum 13 - 1950 µmol/L Urine 0.132 – 14.75 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Urate/ Urea Index	Serum	Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Urea <sup>1 2 3 4</sup>	Serum/ Urine	Colorimetric - urease	Abbott c8000 Serum 0.5 - 44.6 mmol/L Urine 14.3 - 710.8 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Urinary albumin/creatinine ratio	Urine	Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Urinary magnesium/creatinine ratio		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047

	Urinary phosphate/creatinine ratio		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	Urinary urate/creatinine ratio		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	Urine Protein/Creatinine Ratio		Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Alpha 1 Anti trypsin <sup>1 2 3 4</sup>	Serum	Immunoturbidimetric - Anti-human alpha1- antitrypsin	Abbott c8000 0.25 - 3.00 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	C-Reactive Protein (CRP) <sup>1 2 3 4</sup>		Immunoturbidimetric - Anti-CRP polyclonal antibodies	Abbott c8000 0.2 – 320 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Protein (Total) <sup>1 2 3 4</sup>		Colorimetric - Biuret	Abbott c8000 8 – 184 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
		Urine/ CSF	Colorimetric - Benzethonium chloride	Abbott c8000 Urine 0.068 – 2.000 g/L CSF 68 - 2,000 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .05 CO-oximetry	O2 Saturation 1,2,4	Whole Blood taken into heparinised Blood Gas Syringe	Co-Oximetry Calculated	GEM 5000 0 – 100%	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141

						BSC/BIO/SOP/142
	Total Haemoglobin 1 2 4	Whole Blood taken Heparinised Blood gas Syringe	Co-Oximetry	Gem 5000  Range – 3.0 -23.0g/dL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Base Excess / Deficit 1,2,4	Whole Blood taken into heparinised Blood Gas Syringe	Potentiometric Co- Oximetry Calculated	GEM 5000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
	Bicarbonate 1,2,4		Potentiometric Calculated	GEM 5000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
	pCO2 1,2,4		Potentiometric	GEM 5000 0.8 – 16.7 kPa	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
	pH 1,2,4		Potentiometric	GEM 5000 7.00 – 7.92 pH units	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
	pO2 1,2,4		Amperometric	GEM 5000 0.8-92 kPa	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Lactate 1,2,4		Amperometric	GEM 5000 0.3 – 17 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141

						BSC/BIO/SOP/142
	Potassium 1,2,4		Potentiometric	GEM 5000 1 – 19 mmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/141 BSC/BIO/SOP/142
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin <sup>1 2 3 4</sup>	Serum	CMIA	Abbott i2000 0.3 - 10.0 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Tobramycin 1,2,3,4	Serum	PETINA	Abbott c8000 Range of measurement: 0.2 – 10mg/L	CE	Based on manufacturers guidelines BSC/BIO/SOP/134
	Vancomycin <sup>1 2 3 4</sup>	Serum	CMIA	Abbott i2000 3.0 – 100 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .20 Hormones	Cortisol <sup>1 2 3 4</sup>		CMIA	Abbott i2000 28 – 1650 nmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Follicle Stimulating Hormone (FSH) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.1 – 150 IU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	HCG (Beta Total) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 1.2 - 15,000 mIU/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Luteinising Hormone (LH) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.1 - 250 IU/L	CE	Based on manufacturer's guidelines

					BSC/BIO/SOP/134
	Oestradiol <sup>1 2 3 4</sup>		CMIA	Abbott i2000 37 – 3,670 pmol/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	Progesterone <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.4 – 127.2 nmol/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	Prolactin (PRL) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 13 – 4200 mIU/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	PTH (Parathyroid Hormone) <sup>1 2 3 4</sup>	EDTA Plasma	CMIA	Abbott i2000 1 - 3,000 pg/mL	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	T3 (Free) <sup>1 2 3 4</sup>	Serum	CMIA	Abbott i2000 0.1 - 46.1 pmol/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	T4 (Free) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 5.2 – 77.2 pmol/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
	Thyroid Stimulating Hormone (TSH) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.01 – 100 mIU/L	CE Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .24 Hormone receptor assays	HCG (Beta Total) Stat 1,2,3,4,		CMIA	Abbott i2000 1.2 - 15,000	CE Based on manufacturer's guidelines



1061 Clinical Chemistry - .40 Iron studies	Ferritin <sup>1 2 3 4</sup>
	Iron <sup>1 2 3 4</sup>
	Transferrin Saturation (Calculation)
	Transferrin <sup>1 2 3 4</sup>
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate (Folic Acid) <sup>1 2 3 4</sup>
	Vitamin B12 <sup>1 2 3 4</sup>
1061 Clinical Chemistry - .47 Vitamin assays	25-OH Vitamin D <sup>1 2 3 4</sup>
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Feto Protein (AFP) <sup>1 2 3 4</sup>

	mlU/mL		BSC/BIO/SOP/134
CMIA	Abbott i2000 1 - 2,000 µg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Colorimetric - ferrene	Abbott c8000 0.9 – 179 µmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
Calculation	Abbott c8000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
Immunturbidimetric - Anti-human transferrin goat serum	Abbott c8000 0.19 - 4.77 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
CMIA	Abbott i2000 1.6 – 20.5 µg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
CMIA	Abbott i2000 125 - 2,000 ng/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
CMIA	Abbott i2000 9 – 389 nmol/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
CMIA	Abbott i2000 1.7 – 1,660 IU/mL	CE	Based on manufacturer's guidelines

						BSC/BIO/SOP/134
	CA 125 <sup>1 2 3 4</sup>		CMIA	Abbott i2000 1 - 1,000 IU/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	CA 15-3 <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.5 – 800 IU/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Carcinoembryonic Antigen (CEA) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.5 – 1500 ng/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	PSA (Free) <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.01 – 30 ng/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	PSA (Index)		Calculation	Abbott i2000	CE	Based on manufacturer's guidelines BSC/BIO/SOP/047
	PSA <sup>1 2 3 4</sup>		CMIA	Abbott i2000 0.05 – 100 ng/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c	Whole Blood	HPLC	Tosoh G8 3 – 220 mmol/mol Hb	CE	Based on manufacturer's guidelines BSC/BIO/SOP/120
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Pregnancy Test <sup>1 4</sup>	Urine	Immunochromatographic Qualitative	N/A	CE	Based on manufacturer's guidelines BSC/HAEM/SOP/048

1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin IgA <sup>1 2</sup> <sub>3 4</sub>	Serum	Immunoturbidimetric - anti-human IgA	Abbott c8000 0.05 - 6.30 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Immunoglobulin IgG <sup>1 2</sup> <sub>3 4</sub>		Immunoturbidimetric - anti-human IgG	Abbott c8000 1.1 - 43.5 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Immunoglobulin IgM <sup>1 2</sup> <sub>3 4</sub>		Immunoturbidimetric - anti-human IgM	Abbott c8000 0.05 - 3.10 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .82 Total IgE	Immunoglobulin IgE <sup>1 2</sup> <sub>3 4</sub>		Fluoroenzyme Immunoassay	Phadia 250 2 – 5000 kU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/069
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	RF Latex (Rheumatoid Factor) <sup>1 2 3 4</sup>		Immunoturbidimetric - Denatured human IgG	Abbott c8000 2 – 200 IU/mL	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .86 C3 and C4	Complement C3 <sup>1 2 3 4</sup>		Immunoturbidimetric - anti-human complement C3	Abbott c8000 0.11 – 3.15 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
	Complement C4 <sup>1 2 3 4</sup>		Immunoturbidimetric - anti-human complement C4	Abbott c8000 0.03 – 0.58 g/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134
1061 Clinical Chemistry - .88 b2-microglobulin	B-2 Microglobulin <sup>1 2 3 4</sup>		Immunoturbidimetric - IgG fraction of an anti- human B2M	Abbott c8000 0.25 – 16 mg/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/134

*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.*

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B.*

Chemical Pathology

Category: B

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Capillary Blood Glucose 1,4	Capillary Whole Blood	Electrochemical	AccuChek Inform II 0.6 – 33 mmol/L	CE	Based on manufacturer's guidelines BSC/POC/SOP/020
	Capillary Blood Ketone	Capillary Whole Blood	Electrochemical	Abbott OptiumXceed 0 – 8 mmol/L	CE	Based on manufacturer's guidelines NUR0185 BSC/POC/SOP/009
	Creatinine1 4	Blood	Amperometric	i STAT Alinity 18 – 1768 µmol/L	CE	Based on manufacturer's guidelines BSC/POC/SOP/017
1061 Clinical Chemistry - .05 CO-oximetry	SO2 1,2,4	Whole Blood taken into heparinised Blood Gas Syringe	Co-Oximetry Calculated	GEM 5000 0 - 100%	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	Total Haemoglobin 1 2 4	Whole Blood taken Heparinised Blood gas Syringe	Co-Oximetry	Gem 5000 Range – 3.0 -23.0g/dL	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	Whole Blood Oximetry 1 4	Blood	Optical density	Avoximeter 1000E 0 - 100%	CE	Based on manufacturer's guidelines BSC/POC/SOP/016

1061 Clinical Chemistry - .06 Blood pH and gas tensions	Base Excess / Deficit 1,2,4	Whole Blood taken into heparinised Blood Gas Syringe	Potentiometric Co-Oximetry Calculated	GEM 5000	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	Bicarbonate 1,2,4		Potentiometric Calculated	GEM 5000	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	pCO2 1,2,4		Potentiometric	GEM 5000 0.8 – 16.7 kPa	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	pH 1,2,4		Potentiometric	GEM 5000 7.00 – 7.92 pH units	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	pO2 1,2,4		Amperometric	GEM 5000 0.8-92 kPa	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Lactate 1,2,4		Amperometric	GEM 5000 0.3 – 17 mmol/L	CE	Based on manufacturer's guidelines BSC/POC/SOP/018
	Potassium (Blood Gas) 1,2,4		Potentiometric	GEM 5000 1 – 19 mmol/L	CE	Based on manufacturer's guidelines BSC/POC/SOP/020
1061 Clinical Chemistry - .62 pH of urine and fluids by electrode	Urinalysis 1 2 4	Urine	Colorimetric	Clinitek Automated urinalysis	CE	Protein: Protein-error-of-indicators Blood: Peroxidase-like activity of haemoglobin Leucocytes: Hydrolysis of pyrrole amino acid ester and reaction with diazonium salt Nitrite: Reaction with p-arsanilic acid Glucose: Double sequential enzyme reaction using glucose

						oxidase Ketone: Acetoacetic acid reaction with nitroprusside pH: Double indicator principle Specific Gravity: Apparent pKa change of certain pre-treated polyelectrolytes in relation to ionic concentration Bilirubin: Diazo method with dichloroaniline reaction with p-diethylaminobenzaldehyde BSC/POC/SOP/015
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Pregnancy Test 1 4	Urine	Immuno-chromatographic Qualitative	Kit	CE	Based on manufacturer's guidelines BSC/POC/SOP/013 BSC/HAEM/SOP/048

*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.*

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B.*

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	Blood Count 2,4	Whole Blood (EDTA)	Optical Flow Cytometry/ Flourescence Flow Cytometry/ Electrical Impedence/ Spectrophotometry/ calculation	SysmexXN 3100 WBC 0.00 – 440.0 X 10 <sup>9</sup> /L RBC 0.00 – 8.60 X 10 <sup>12</sup> /L HGB 0.00 – 26.0 g/dL HCT 0.00 – 0.75 L/L PLT 0 – 5000 X 10 <sup>9</sup> /L NRBC 0.0 – 600.0 /100WBC Retic 0.00 – 720 X 10 <sup>9</sup> /L	CE	International Council for Standardisation in Haematology (ICSH)  Haemoglobin Cyanide (Hb) Impedence (WBC, RBC & Platelet) Manual Microscopy (White cell Differential Count) BSC/HAEM/SOP/059
1030 Haematology - .02 Visual examination of blood films	Visual Examination of Blood Film Morphology 1,2,4	Whole Blood (EDTA)	Staining/ Microscopy	Sysmex SP 50	CE	ICSH Recommendations Manual Microscopy BSC/HAEM/SOP/014 BSC/HAEM/SOP/059
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR) <sup>1 3 4</sup>	Whole Blood (EDTA/ Citrate)	Kenetics of Red Cell Aggregation	Alifax Test 1 0 – 120 mm/Hr	CE	ICSH Recommendations Westegren Manual BSC/HAEM/SOP/020
			Sedimentation	Westegren (Manual) 0 – 130 mm/Hr	CE	ICSH Recommendations Westegren Manual BSC/HAEM/SOP/020



1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential Leucocyte Counts 1,4	Whole Blood (EDTA)	Fluorescence Flow Cytometry/ Scattergram interpretation	Sysmex XN 3100 As per WBC	CE	ICSH Recommendations Manual Microscopy BSC/HAEM/SOP/059
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes 1,4		Fluorescence Flow Cytometry	Sysmex XN 3100 0.00 – 720.0 X 10 <sup>9</sup> /L	CE	ICSH Recommendations Manual Microscopy BSC/HAEM/SOP/059
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites <sup>4</sup>	Whole Blood (EDTA)/ Blood Film	Haematek stainer/ Microscopy	N/A	CE	ICSH Recommendations Blood Film Examination BSC/HAEM/SOP/045
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time <sup>1 4</sup>	Whole Blood (Citrate)	Coagulation	Sysmex CS-2500 20 – 180 sec	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057
	D-Dimer <sup>1 2 4</sup>		Turbidity	Sysmex CS-2500 0.19 – 80.0 mg/L FEU	CE	ICSH Recommendations Elisa BSC/HAEM/SOP/057
	Fibrinogen <sup>1 2 4</sup>		Coagulation	Sysmex CS-2500 0.3 – 9.0 g/l	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057
	International Normalised Ratio (INR)		Calculation	Sysmex CS-2500 Calculated from PT	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057
	Prothrombin Time <sup>1 2 4</sup>		Coagulation	Sysmex CS-2500 7 – 180 sec	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057

1030 Haematology - .57 Screening test for infectious mononucleosis	Screening Test for Infectious Mononucleosis (Epstein Barr Virus) <sup>1</sup> <sub>2 3 4</sub>	Whole Blood (EDTA)	Immunochromatographic	N/A	CE	EBV Ab Titre BSC/HAEM/SOP/040
---	---	--------------------	-----------------------	-----	----	----------------------------------

*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.*

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B.*

## 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	ACT ( Activated Clotting Time) 1 4	Blood	Mechanical Optical	Hemochron Signature Elite 80 – 1000 sec	CE	Based on manufacturer's guidelines BSC/POC/SOP/014

*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.*

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B.*

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Cut up,Tissue processing, Embedding, Microtomy, Automated and Manual Haematoxylin and Eosin staining, Coverslipping	Human tissue	Leica ASP 300 x 2 Processor, Tissue Tek VIP 6 Processor x 2, Embedding centre, Microtomes, Tissue Tek Prisma/Glas stainer coverslipper	CE	N/A	BSC/HIS/SOP/002/110/111 BSC/HIS/SOP/001 BSC/HIS/SOP/004 BSC/HIS/SOP/005 BSC/HIS/SOP/015
	1051 Histopathology - .02 Processing fresh specimens for frozen section examination		Cut-up Frozen section cryotomy Staining	Leica Cryostat /Manual H&E Staining	CE	N/A
1051 Histopathology - .03 Histochemistry	AFB Stain	Tissue Section	Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Alcian Blue - PAS (AB/PAS)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Alcian Blue (AB)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Congo red		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Elastic Van Gieson (EVG)		Ventana Bench mark Special Stain Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Giemsa		Tissue Tek prisma	CE	N/A	BSC/HIS/SOP/015
	Gomaris Green Trichrome (GGT)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Gram Stain		Manual	CE	N/A	BSC/HIS/SOP/020

			Manual	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Grocotts – PCP- (GMSP)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Grocotts –Fungi- (GMSF)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Periodic Acid Schiff (PAS)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Periodic Acid Schiff – Diastase (PASD)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Periodic Acid Schiff – Fungi (PASF)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Perls Prussion Blue		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Reticulin (Gordons and sweet)		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Trichrome Collagen		Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and reporting by Consultant Pathologist		Manual	CE	N/A	BSC/HIS/SOP/056 BSC/HIS/SOP/098 BSC/HIS/SOP/110 BSC/HIS/SOP/111 BSC/HIS/SOP/147
1051 Histopathology - .09 Immunohistochemistry	a Inhibin <sup>2 4</sup>	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Actin <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	AEI/ AE3 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	AFP <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-6 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Ber-EP4 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

Caldesmon <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Calretinin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Cam 5.2 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD10 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD117 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD138 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD15 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD20 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD23 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD30 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD31 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD3 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD34 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD4 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD43 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD45 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD5 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD56 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

CD68 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD79a <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD8 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CDX2 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CEA <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Chromogranin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK20 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK5/6 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK7 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK903 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Cyclin D1 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
D2 40 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Desmin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
E-Cadherin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
EMA <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
ER <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Gastrin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Gata 3 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

Her2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
HMB45 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
HPP <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Kappa <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Ki67 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Lambda <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Melan A <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MLH1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MNF116 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MOC31 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MSH2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MSH6 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MUM 1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Napsin <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
NKX3.1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Oct 4 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P16 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P40 2 4	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025



P504S <sup>2 4</sup>	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
p53 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P63, CK903, P504S (Triple Stain) <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
p63 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PAX 5 2 4	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PAX 8 <sup>2 4</sup>	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PMS2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PR <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PSA <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
S100 2 4	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
SATB2 2 4		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Smooth Muscle Myosin <sup>2 4</sup>	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
SOX10 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Synaptophysin <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
TTF1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Vimentin 2 4	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Wt-1 <sup>2 4</sup>	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
B Catenin <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

1052 Cytopathology - .02 Non gynaecological cytology	Non Gynaecological Cytology	Cell Block	Manual, Tek prisma, Glas Stainer, Coverslipper	CE	N/A	BSC/HIS/SOP/001 BSC/HIS/SOP/004 BSC/HIS/SOP/005 BSC/HIS/SOP/015 BSC/HIS/SOP/145
		Tissue Section	Manual/Tek Prisma/Glas stainer coverslipper	CE	N/A	BSC/HIS/SOP/145 BSC/HIS/SOP/015
	Non Gynaecological Cytology	Fluid	Automated - Holologic Thin Prep 2000	CE	N/A	BSC/HIS/SOP/145
1052 Cytopathology - .04 Cytopathological interpretation	Cytopathological Interpretation	Tissue Section	Microscope/ Manual	CE	N/A	BSC/HIS/SOP/145 BSC/HIS/SOP/015
1052 Cytopathology - .05 Immunocytochemistry	AE1/AE3 <sup>2 4</sup>	Cell Block	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-6 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	BerEp4 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Calretinin <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD10 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD20 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD3 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD43 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD45 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD68 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CDX2 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

Chromogranin A <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK20 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK5/6 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK7 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
EMA <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
ER <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
GATA3 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Her 2 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Ki67 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Melan A <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MOC31 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Napsin A <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P16 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P53 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P63 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PAX8 <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Progesterone Receptor <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Synaptophysin <sup>2 4</sup>	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

	TTF1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	WT1 <sup>2 4</sup>		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

*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.*

Immunology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. Ref & SOP
1040 Immunology - .02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Electrophoresis 1 2 4	Serum	Sebia Minicap Flex Piercing	CE	N/A	BSC/BIO/SOP/143
	Electrophoresis <sup>1 2 4</sup>	Serum/ Urine	Sebia Hydrasys Agarose Gel	CE	N/A	BSC/BIO/SOP/075
	Immunofixation <sup>1 2 4</sup>		Sebia Hydrasys Agarose Gel / Immunofixation	CE	N/A	BSC/BIO/SOP/076 BSC/BIO/SOP/077
1040 Immunology - .04 Allergen - specific IgE	Allergy Specific IgE <sup>1 2 4</sup>	Serum	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/BIO/SOP/069
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Cyclic Citrullinated Peptide Antibodies (CCP) <sup>1 2 4</sup>		Fluoroenzyme Immunoassay Phadia 250	CE	0.4 up to ≥340 EliA U/mL	BSC/IMM/SOP/006
	ENA Screen <sup>1 2 4</sup>		Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
	Glomerular Basement Membrane Antibodies (GBM) <sup>1 2 4</sup>		Fluoroenzyme Immunoassay Phadia 250	CE	1.5 up to ≥680 EliA U/mL	BSC/IMM/SOP/006
	Intrinsic Factor antibodies <sup>1 2 4</sup>		Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
	Jo1 Antibody <sup>1 2 4</sup>		Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006

La Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
M2 Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
MPO Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	0.2 up to $\geq 134$ IU/mL	CDC MPO ANCA Human Reference Serum No. 15 BSC/IMM/SOP/006
PR3 Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	0.6 up to $\geq 177$ IU/mL	CDC PR3 ANCA Human Reference Serum No. 16 BSC/IMM/SOP/006
RNP70 Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Ro Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Sc170 Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Sm Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Thyroid Peroxidase Antibody (TPO) <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	4 up to $\geq 1542$ IU/mL	NIBSC Research Standard for Anti Thyroid Microsome Serum Code 66/387 BSC/IMM/SOP/006
tTG IgA Antibodies <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	0.2 up to $\geq 128$ EliA U/mL	BSC/IMM/SOP/006
U1RNP Antibody <sup>1 2 4</sup>	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006

*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.*

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	Macroscopic examination and description of specimens <sup>1 2 3</sup>	Sputum, CSF, Faeces, sterile fluids	Manual Macroscopic examination and description of specimens	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/102 BSC/MIC/SOP/041 BSC/MIC/SOP/121 BSC/MIC/SOP/052
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)	Microscopic examination (General Bacteriology) <sup>1 2 3</sup>	Swabs, body fluids, pus, Pleural fluids, Tissue, Urine, Blood, CSF, Cannicular Pus, Wound Exudates, middle ear effusion, Fluid/ Pus genital tract specimens	Microscopic examination Light/ fluorescent microscope with or without fixation and staining with dyes for enumeration and description of bacteria	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/042 BSC/MIC/SOP/043 BSC/MIC/SOP/046 BSC/MIC/SOP/047 BSC/MIC/SOP/048 BSC/MIC/SOP/051 BSC/MIC/SOP/052 BSC/MIC/SOP/053 BSC/MIC/SOP/101 BSC/MIC/SOP/102 BSC/MIC/SOP/121 BSC/MIC/SOP/021 BSC/MIC/SOP/164
1012 Preparation of films on glass slides followed by microscopic	Microscopic examination (Parasites) <sup>1 2 3</sup>	Bile, urine, CSF, Corneal scraping, contact lenses and cleaning fluids Duodenal / Jejunal aspirates, Faeces, Liver and spleen	Microscopic examination Light/ fluorescent microscope with or	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology



examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites		aspirates ,Sputum,Tissues and biopsies ,Pus from abscesses, Brochoalveolar lavage	without fixation and staining with dyes for enumeration and description of parasites			Investigations BSC/MIC/SOP/021 BSC/MIC/SOP/122 BSC/MIC/SOP/164
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	Microscopic examination (Fungi) <sup>1 2 3</sup>	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Pleural fluids,sputum, Tissue, Urine, Blood, Transthoracic/Transtracheal aspirate, CSF, Middle ear effusion, Cannicular Pus Wound Exudates, Hair/Nail/skin clippings/Scrapings	Microscopic examination Light/ fluorescent microscope with or without fixation and staining with dyes for enumeration and description of fungi	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/061 BSC/MIC/SOP/164
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	Microscopic examination (Mycobacteria) <sup>1 2 3</sup>	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Pleural fluids, sputum, Tissue, Urine, Transthoracic/Transtracheal aspirate, CSF	Microscopic examination Light/ fluorescent microscope with or without fixation and staining with dyes for enumeration and description of acid fast bacilli	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/081 BSC/MIC/SOP/164
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of General Bacteria <sup>1 2 3 4</sup>	Swabs, body fluids, pus, Pleural fluids, Tissue, Urine, Blood, CSF, Faeces, Cannicular Pus, Wound Exudates, Sputum, Bronchial lavage/brushings/washings/bronchoalveolar lavage, antral washouts and sinus aspirates and washouts. Fluid/Pus genital tract specimens	Manual culture in liquid and agar based media with incubation of specimens at defined temperatures for defined periods with visual observation of growth. Automated BacT/ALERT 3D system for Blood Cultures	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/021 BSC/MIC/SOP/031 BSC/MIC/SOP/032 BSC/MIC/SOP/041 BSC/MIC/SOP/042 BSC/MIC/SOP/043 BSC/MIC/SOP/045 BSC/MIC/SOP/046 BSC/MIC/SOP/047 BSC/MIC/SOP/048 BSC/MIC/SOP/049 BSC/MIC/SOP/050 BSC/MIC/SOP/051 BSC/MIC/SOP/052 BSC/MIC/SOP/053

						BSC/MIC/SOP/101 BSC/MIC/SOP/102 BSC/MIC/SOP/121
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of Fungi <sup>1 2 3 4</sup>	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Blood, Transthoracic/Transtracheal aspirate, CSF, Middle ear effusion, Cannicular Pus Wound Exudates, Hair/Nail/skin clippings/Scrapings	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/061
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of Mycobacteria <sup>1 2 3 4</sup>	Swabs, CSF, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Transthoracic/Transtracheal aspirate, CSF	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.The MB BacT/ALERT 3D Mycobacterial Detection System	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/081
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Clostridium difficile <sup>1 2 3 4</sup>	Faeces	Enzyme Immunoassay/Kit	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/198
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Legionella Urine Antigen <sup>1 2 3 4</sup>	Urine	Immunochromatographic/Kit	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/199
	MPT64 <sup>1 2 3 4</sup>	Positive Mycobacterium cultures	Immunochromatographic/Kit	CE	N/A	Immunochromatographic Assay for the detection of M tuberculosis complex from cultivated samples using monoclonal antibodies. Abe C,Hirano

						K,Tomiyama T. Simple and rapid identification of the Mycobacterium tuberculosis complex by immunochromatographic assay using anti-MPB64 monoclonal antibodies. J Clin Microbiology 1999; 37:3693-3697 BSC/MIC/SOP/081
	NG- Test-CARBA-5 kit for detection of Carbapenemase Producing Enterobacteriaceae (CPE) 1,2,3,4	Rectal swab or suspicious colony	Immunochromographic /Kit	CE	N/A	Immunochromatographic Assay for the detection of carbapenemase enzymes in bacterial colonies using monoclonal antibodies.  Boutal H et al.2018. A multiplex lateral flow immunoassay for the rapid identification of NDM-,KPC-,IMP- and VIM-type and OXA-48-like carbapenemase-producing Enterobacteriaceae. J Antimicrob Chemother. BSC/MIC/SOP/033
	Urinary Pneumococcal Antigen <sup>1 2 3 4</sup>	Urine	Immunochromographic/Kit	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/252
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE	Enteric Bio System for the detection of Salmonella, Shigella, Campylobacter, VTEC, Cryptosporidium and Giardia	Faeces	PCR Hybridisation/ Enteric Bio system incorporating Light Cycler, Heat block , Centrifuge, Mixer and Pipetting centre.	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/121

marked commercial systems						
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Clostridium difficile <sup>1 2 3 4</sup>		PCR Amplification/Cepheid Gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/198
	Extended Respiratory Panel <sup>1 2 3 4</sup> Adenovirus	Nasal/ Throat Swab	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
			PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
	Extended Respiratory Panel <sup>1 2 3 4</sup> Bordetella parapertussis		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
	Extended Respiratory Panel <sup>1 2 3 4</sup> Bordetella pertussis		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
	Extended Respiratory Panel <sup>1 2 3 4</sup> Chlamydia pneumoniae		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
	Extended Respiratory Panel <sup>1 2 3 4</sup>		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards

Coronavirus 229E Coronavirus HKU1 Coronavirus OC43 Coronavirus NL63				for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Human Metapneumovirus	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Human Rhinovirus/Enterovirus	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Influenza A Influenza A/H1 Influenza A/H1-2009 Influenza A/H3 Influenza B	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Middle East Respiratory Syndrome CoronaVirus (Mers-CoV)	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Mycoplasma pneumoniae	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257

Extended Respiratory Panel <sup>1 2 3 4</sup> RSV		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel <sup>1 2 3 4</sup> Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Film Array Blood Culture 1,2,3,4	Blood Culture	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Influenzae A & B <sup>1 2 3 4</sup>	Swab, Nasalpharageal, washing/aspirate	PCR Amplification/Cepheid Gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/256
Meningitis/Encephalitis (ME) Panel <sup>1 2 3 4</sup> Herpes simplex virus 1 (HSV-1)	CSF	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/Encephalitis (ME) Panel <sup>1 2 3 4</sup> Cryptococcus neoformans/gattii		PCR Amplification Film Array	CE	N/A	BSC/MIC/SOP/257 Public Health England (PHE) - UK standards for Microbiology Investigations
Meningitis/Encephalitis (ME) Panel <sup>1 2 3 4</sup> Cytomegalovirus (CMV)		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257

Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Enterovirus (EV)	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Escherichia coli K1	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Haemophilus influenzae	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Herpes simplex virus 2 (HSV-2)	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Human herpesvirus 6 (HHV-6)	PCR Amplification Film Array	CE	N/A	BSC/MIC/SOP/257 Public Health England (PHE) - UK standards for Microbiology Investigations
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Human parechovirus (HPeV)	PCR Amplification Film Array	CE	N/A	BSC/MIC/SOP/257 Public Health England (PHE) - UK standards for Microbiology Investigations
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Listeria monocytogenes	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257

Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Neisseria meningitidis		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Streptococcus agalactiae		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Streptococcus pneumoniae		PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel <sup>1 2 3 4</sup> Varicella zoster virus (VZV)		PCR Amplification Film Array	CE	N/A	BSC/MIC/SOP/257 Public Health England (PHE) - UK standards for Microbiology Investigations
NoroVirus <sup>1 2 3 4</sup>	Faeces	PCR Amplification/Cepheid Gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/255 BSC/MIC/SOP/256
Respiratory Syncytial Virus (RSV) <sup>1 2 3 4</sup>	Swab, Nasal/pharyngeal, washing/aspirate	PCR Amplification/Cepheid Gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/256
SARS-CoV-2 (COVID 19) <sup>1 2 3 4</sup> (Individual patient samples only)	Nasal/ Throat Swab	PCR Amplification / Cepheid gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations



						BSC/MIC/SOP/256
	SARS-CoV-2 (COVID-19) 1 2 3 4	Swab (Nasal/ Throat)	Extraction: KingFischer Flex using the MagMax Viral/Pathogen II Nucleic Acid Isolation Kit RealTime PCR: Euroimmun EURORealTime SARS-CoV-2 assay on Bio-Rad CFX96	CE	N/A	BSC/MIC/SOP/259
			Extraction: KingFischer Flex using the MagMax Viral/Pathogen II Nucleic Acid Isolation Kit RealTime PCR: Euroimmun EURORealTime SARS-CoV-2 assay on Roche Lightcycler 480 II	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/259
	Xpert Flu/RSV/Covid Screen 1,2,3,4	Nasopharyngeal and Throat Swab	PCR Amplification/Cepheid Gene Xpert	CE	N/A	BSC/MIC/SOP/256
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of Cultured Bacteria and Fungi. 1 2 3 4	Swabs, Bone Marrow, Bronchial Lavage/brushings/washings/bronchoalveolar lavage,body fluids, pus, Pleural fluids , Sputum, Tissue, Urine, Blood, Transthoracic/transtracheal aspirate, CSF, Faeces, Middle Ear effusion, Cannalicular Pus, Wound exudates, Hair/Nail/Skin clipping/scrapings, Fallopian tube, Semen, IUCD, Bartolins gland, Cannuala lines, CVAD tips, Portacath, Culture Bottle/LJ slope and Bacterial colony.	Biochemical identification of Cultured Bacteria and Fungi using manual Identification Kits/tests including, PBP2a (MRSA) and automated Vitek 2 system	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/031 BSC/MIC/SOP/061 BSC/MIC/SOP/170 BSC/MIC/SOP/181 BSC/MIC/SOP/255
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Identification of Fungi by Microscopic morphology 1 2 3 4	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Pleural fluids,sputum, Tissue, Urine, Blood, Transthoracic/Transtracheal aspirate, CSF, Middle ear effusion, Cannicular Pus Wound Exudates, Hair/Nail/skin clippings/Scrapings	Microscopic examination Light/ fluorescent microscope with or without fixation and staining with dyes for enumeration and description of human cells	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/061

1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Measurement of Antimicrobial activity in Aerobic and Anerobic bacteria and application of clinical interpretive criteria <sup>1 2 3 4</sup>	Swabs, Bone Marrow, Bronchial Lavage/brushings/washings/bronchoalveolar lavage,body fluids, pus, Pleural fluids , Sputum, Tissue, Urine, Blood, Transthoracic/transtracheal aspirate, CSF, Faeces, Middle Ear effusion, Cannalicular Pus, Wound exudates, Hair/Nail/Skin clipping/scrappings, Fallopian tube, Semen, IUCD, Bartolins gland, Cannuala lines, CVAD tips, Portacath, Culture Bottle/LJ slope and Bacterial colony.	Manual Disc diffusion and Minimum Inhibitory Concentration (MIC) methods. Automated MIC methodology using Vitek 2 system.	CE	N/A	e Test Technical Manual BSC/MIC/SOP/163 Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/255
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Measurement of Antimicrobial activity in Yeasts and application of clinical interpretive criteria <sup>1 2 3 4</sup>	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Blood, Transthoracic/Transtracheal aspirate, CSF, Middle ear effusion, Cannicular Pus Wound Exudates, Hair/Nail/skin clippings/Scrapings	Manual Minimum Inhibitory Concentration (MIC) methods .	CE	N/A	e Test Technical Manual Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/163
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	ASOT <sup>1 2 3 4</sup>	Serum	Agglutination - Kit	CE	<200 – 6400 IU/mL	Based on manufacturer's guidelines BSC/MIC/SOP/201
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Mycoplasma Pneumoniae IgM <sup>1 2 3 4</sup>		Enzyme Immunoassay/Kit	CE	N/A	Based on manufacturer's guidelines BSC/MIC/SOP/201
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent	Hepatitis A IgM <sup>1 2 3 4</sup>		CMIA, Abbott i2000	CE	N/A	BSC/BIO/SOP134 BSC/MIC/SOP250 Public Health England (PHE) - UK standards for Microbiology

microparticle immunoassay, using CE marked commercial systems				Investigations	
	Hepatitis B Surface Antibodies <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/BIO/SOP134 BSC/MIC/SOP250
	Hepatitis B Core Antibodies <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/BIO/SOP134 BSC/MIC/SOP250
	Hepatitis B Surface Antigen (HBsAg) <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	BSC/BIO/SOP134 BSC/MIC/SOP250 Public Health England (PHE) - UK standards for Microbiology Investigations
	Hepatitis C Antibodies <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	BSC/BIO/SOP134 BSC/MIC/SOP250 Public Health England (PHE) - UK standards for Microbiology Investigations
	HIV 1/2 Ag/Ab Combo <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	BSC/BIO/SOP134 BSC/MIC/SOP250 Public Health England (PHE) - UK standards for Microbiology Investigations
Rubella IgG (immunity) <sup>1 2 3 4</sup>	CMIA, Abbott i2000	CE	N/A	BSC/BIO/SOP134 BSC/MIC/SOP250	

*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.*