Schedule of Accreditation

Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Cork
INAB Reg No	153MT
Contact Name	Bernadette Murray
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Website	
Accreditation Standard	EN ISO 15189
Standard Version	2022
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[1]	Yes

[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	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 [a] [3] [4]	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 RhD grouping of blood	Red Cells/ Plasma/Serum	Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002

	Antibody screening [a] [3] [4]	Plasma	Biorad Gel Technique (Manual)	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/002
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification	Plasma	Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/003
	Antibody Identification [a] [3] [4]	Plasma	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	Donor Cells / Plasma	Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/073
	Compatibility Testing [a] [3] [4]		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 [a] [4]	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	Red Cells	Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-

						transfusion compatibility procedures BSC/BB/SOP/068
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test		Bio-Rad IH-500 Gel Technique	CE	N/A	Ab / Ag Reaction BSH Guidelines Pre-transfusion compatibility procedures BSC/BB/SOP/069
	Direct Antiglobulin Test [a 4]	Red Cells	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

[a] The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

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Note 3 – New matrices may be added
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For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Head Office

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 - .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 Haemoglobulin 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 - .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[1] [4]	Urine	Immunochromatographic Qualitative	N/A	CE	Based on manufacturer's guidelines BSC/HAEM/SOP/048

1061 Clinical Chemistry - .82 Total lgE	Immunoglobulin IgE[1] [2] [3] [4]	Serum	Fluroenzyme Immunoassay	Phadia 250 2 – 5000 kU/L	CE	Based on manufacturer's guidelines BSC/BIO/SOP/069
1061 Clinical Chemistry - .99 Miscellaneous tests	Osmolality 1,2,3,4	Serum / Urine	CE Freezing Point Depression	Advanced Instruments Osmo1 Single-Sample Micro-Osmometer Serum: 275- 295 mOsm/KG Urine : Neonate: 75-300 mOsm/KG Child/Adult : 250-900 mOsm/KG	CE	Based on manufacturers guidelines BSC/BIO/SOP/013

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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

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 Haemoglobulin 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	Blood	Optical density	Avoximeter 1000E	CE	Based on manufacturer's

	Oximetry 1 4			0 - 100%		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	Immunochromatographic Qualitative	Kit	CE	Based on manufacturer's guidelines BSC/POC/SOP/013 BSC/HAEM/SOP/048

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Head Office

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count 2,4 1. White Blood Cell Count Including Automated White Cell Diff 2. Red Blood Cell 3. Haemoglobin 4. Haematocrit 5. Mean Cell Volume (MCV) 6. Mean Cell Haemoglobin (MCH) 7. Mean Cell Haemoglobin Concentration (MCHC) 8. Platelet Count 9. Nucleated Red Blood Cells (NRBC) 10. Reticulocyte Count	Whole Blood (EDTA)	Optical Flow Cytometry/ Fluorescence Flow Cytometry/ Electrical Impedance/ Spectrophotometry/ calculation	SysmexXN 3100 1. WBC 0.00 – 440.0 X 10^9/L 2. RBC 0.00 – 8.60 X 10^12/L 3. HGB 0.00 – 26.0 g/dL 4. HCT 0.00 – 0.75 L/L 5. N/A 6. N/A 7. N/A 8. PLT 0 – 5000 X 10^9/L 9. NRBC 0.0 – 600.0 /100WBC 10. Retic Count 0.00 – 720 X 10^9/L	CE	International Council for Standardisation in Haematology (ICSH) Haemoglobin Cyanide (Hb) Impedance (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 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)[1] [3] [4]	Whole Blood (EDTA/ Citrate)	Kinetics 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	Reticulocytes 1,4		Fluorescence Flow	Sysmex XN 3100	CE	ICSH

Automated reticulocyte counts			Cytometry	0.00 – 720.0 X 10^9/L		Recommendations Manual Microscopy BSC/HAEM/SOP/059
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites[4]	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 [1] [4]	Whole Blood (Citrate)	Coagulation	Sysmex CS-2500 20 – 180 sec	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057
	D-Dimer[1] [2] [4]		Turbidity	Sysmex CS-2500 0.19 – 80.0 mg/L FEU	CE	ICSH Recommendations Elisa BSC/HAEM/SOP/057
	Fibrinogen[1] [2] [4]		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[1] [2] [4]		Coagulation	Sysmex CS-2500 7 – 180 sec	CE	ICSH Recommendations Clotting BSC/HAEM/SOP/057
1030 Haematology - .57	Screening Test for	Whole Blood	Immunochromatographic	N/A	CE	EBV Ab Titre

Screening test for infectious mononucleosis	Infectious Mononucleosis (Epstein Barr Virus)[1] [2] [3] [4]	(EDTA)				BSC/HAEM/SOP/040

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Note 4 – Changes to equipment/kits where the underlying methodology does not change
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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

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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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Head Office

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
	Cut up, Tissue processing, Embedding, Microtomy, Automated and Manual Haematoxylin and Eosin staining, Coverslipping (Megablocks)	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	Human tissue	Leica Cryostat /Manual H&E Staining	CE	N/A	BSC/HIS/SOP/040
1051 Histopathology - .03 Histochemistry	AFB Stain	Tissue Section	Ventana Bench mark Histochemistry	CE	N/A	BSC/HIS/SOP/020
	Alcian Blue - PAS		Ventana Bench mark	CE	N/A	BSC/HIS/SOP/020

	(AB/PAS)	Histochemistry			
	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	Diagnostic Interpretation and	Manual	CE	N/A	BSC/HIS/SOP/056 BSC/HIS/SOP/098

Interpretation	reporting by Consultant Pathologist					BSC/HIS/SOP/110 BSC/HIS/SOP/111 BSC/HIS/SOP/147
1051 Histopathology - .09 Immunohistochemistry	a Inhibin[2] [4]	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Actin[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	AEI/ AE3[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	AFP[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-2[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-6[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Ber-EP4[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Caldesmon[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Calretinin[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Cam 5.2[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD10[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD117[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD138[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD15[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD20[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

CD23[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD30[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD31[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD3[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD34[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD4[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD43[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD45[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD5[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD56[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD68[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD79a[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CD8 [2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CDX2[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CEA[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Chromogranin[2,4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

CK20[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK5/6[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK7[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK903[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Cyclin DI[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
D2 40[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Desmin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
E-Cadherin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
EMA[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
ER[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Gastrin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Gata 3[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Her2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
HMB45[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
HPP[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Kappa[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

Ki67[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Lambda[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Melan A[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MLH1[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MNF116[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MOC31[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MSH2[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MSH6[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MUM 1[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Napsin[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
NKX3.1 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Oct 4[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P16 [2] [4]		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[2] [4]	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
p53[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

P63, CK903, P504S (Triple Stain)[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
p63[2] [4]		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[2] [4]	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PMS2[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PR[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
PSA[2] [4]		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[2] [4]	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
SOX10[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Synaptophysin[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
TTF1 [2] [4]		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[2] [4]	Tissue Section	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
B Catenin[2] [4]		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 [2] [4]	Cell Block	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-2[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Bcl-6[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	BerEp4 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Calretinin [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD10[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD20 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD3 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD43[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	CD45 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

CD68 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CDX2 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Chromogranin A[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK20[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK5/6 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
CK7 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
EMA [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
ER [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
GATA3 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Her 2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Ki67 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Melan A[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
MOC31 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
Napsin A [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P16 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
P53 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025

	P63 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	PAX8 [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Progesterone Receptor[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	Synaptophysin [2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	TTF1[2] [4]		Ventana Ultra Antigen/ Antibody reaction	CE	N/A	BSC/HIS/SOP/025
	WT1 [2] [4]		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
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Head Office

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[1 2 4]	Serum/ Urine	Sebia Hydrasys Agarose Gel	CE	N/A	BSC/BIO/SOP/075
	Immunofixation[1 2 4]		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 [1 2 4]	Serum	Fluoroenzyme Immunoassay Phadia 250	CE	0.1 - 100kU/L	BSC/BIO/SOP/069
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Cyclic Citrullinated Peptide Antibodies (CCP) [1 2 4]		Fluoroenzyme Immunoassay Phadia 250	CE	0.5 up to ≥340 EliA U/mL	BSC/IMM/SOP/006
	ENA Screen [1 2 4]		Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
	Glomerular Basement Membrane Antibodies (GBM) [1 2 4]		Fluoroenzyme Immunoassay Phadia 250	CE	1.5 up to ≥680 EliA U/mL	BSC/IMM/SOP/006
	Intrinsic Factor		Fluoroenzyme	CE	N/A	BSC/IMM/SOP/006

antibodies [1 2 4]	Immunoassay Phadia 250			
Jo1 Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
La Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
M2 Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
MPO Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	0.2 up to ≥134 IU/mL	CDC MPO ANCA Human Reference Serum No. 15 BSC/IMM/SOP/006
PR3 Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	0.6 up to ≥177 IU/mL	CDC PR3 ANCA Human Reference Serum No. 16 BSC/IMM/SOP/006
RNP70 Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Ro Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Scl70 Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Sm Antibody [1 2 4]	Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006
Thyroid Peroxidase Antibody (TPO) [1 2 4]	Fluoroenzyme Immunoassay Phadia	CE	4 up to ≥1542 IU/mL	NIBSC Research Standard for Anti

			250			Thyroid Microsome Serum Code 66/387 BSC/IMM/SOP/006
	tTG IgA Antibodies [1] [2] [4]		Fluoroenzyme Immunoassay Phadia 250	CE	0.2 up to ≥128 EliA U/mL	BSC/IMM/SOP/006
	U1RNP Antibody [1] [2] [4]		Fluoroenzyme Immunoassay Phadia 250	CE	N/A	BSC/IMM/SOP/006

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Head Office

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[1 2 3]	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) [1 2 3]	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 examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Microscopic examination (Parasites)[1] [2] [3]	Bile, urine, CSF,Corneal scraping, contact lenses and cleaning fluids Duodenal / Jejunal aspirates, Faeces,Liver and spleen aspirates ,Sputum,Tissues and biopsies ,Pus from abscesses, Brochoalveolar lavage	Microscopic examination Light/ fluorescent microscope with or without fixation and staining with dyes for enumeration and description of parasites	Based on standard methods	N/A	Public Health England (PHE) - UK standards for Microbiology 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)[1] [2] [3]	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Pleural fluids,sputum, Tissue, Urine, Blood, Transthoraic/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)[1] [2] [3]	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Pleural fluids, sputum, Tissue, Urine, Transthoraic/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 [1] [2] [3] [4]	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	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

			3D system for Blood Cultures			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 [1] [2] [3] [4]	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar levage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Blood, Transthoraic/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 [1] [2] [3] [4]	Swabs, CSF, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Transthoraic/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[1] [2] [3] [4]	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 [1] [2] [3] [4]	Urine	Immunochromographic/Kit	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/199
	MPT64[1] [2] [3] [4]	Positive Mycobacterium cultures	Immunochromographic/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 [1] [2] [3] [4]	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 - .03 Nucleic acid amplification tests, CE marked commercial systems	Clostridium difficile[1] [2] [3] [4]	Faeces	PCR Amplification/Cepheid Gene Xpert	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/198
	Enteric Bio System for the detection of Salmonella, Shigella, Campylobacter, VTEC, Crytosporidium and Giardia		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
	Extended Respiratory Panel[1] [2] [3] [4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] Coronavirus 229E Coronavirus HKU1 Coronavirus OC43 Coronavirus NL63	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
	Extended Respiratory Panel[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] RSV	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations BSC/MIC/SOP/257
Extended Respiratory Panel[1 2 3 4] Severe Acute Respiratory Syndrome	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations

Coronavirus 2 (SARS-CoV-2)					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[1 2 3 4]	Swab, Nasopharyngeal, 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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)	PCR Amplification Film Array	CE	N/A	Public Health England (PHE) - UK standards

Panel[1 2 3 4] Neisseria meningitidis					for Microbiology Investigations BSC/MIC/SOP/257
Meningitis/ Encephalitis (ME) Panel[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4] 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[1 2 3 4]	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 Synctial Virus (RSV)[1 2 3 4]	Swab, Nasopharyngeal, 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)[1 2 3 4]	Nasal/ Throat Swab	PCR Amplification / Cepheid gene Xpert	CE	N/A	Public Health England (PHE) - UK standards

	(Individual patient samples only)					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
	Xpert MTB/RIF Ultra 1,2,3,4	Sputum	PCR Amplification	CE	Refer to Method summary sheets	BSC/MIC/SOP/256
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identication of Cultured Bacteria and Fungi. [1] [2] [3] [4]	Swabs, Bone Marrow, Bronchial Lavage/brushings/washings/bronchoelveolar 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	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

		clipping/scrappings, Fallopian tube, Semen, IUCD, Bartolins gland, Cannuala lines, CVAD tips, Portacath, Culture Bottle/LJ slope and Bacterial colony.				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, Transthoraic/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[1] [2] [3] [4]	Swabs, Bone Marrow, Bronchial Lavage/brushings/washings/bronchoelveolar 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[1] [2] [3] [4]	Swabs, Bone marrow , Bronchial lavage/brushings/washings/bronchoalveolar lavage, body fluids, pus, Plural fluids,sputum, Tissue, Urine, Blood, Transthoraic/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	ASOT[1] [2] [3] [4]	Serum	Agglutination - Kit	CE	<200 – 6400 IU/mL	Based on manufacturer's guidelines BSC/MIC/SOP/201

systems						
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Mycoplasma Pneumoniae IgM [1 2 3 4]		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 microparticle immunoassay, using CE marked commercial systems	CMV IgM 1,2,3,4	Serum	Liaison XS	CE	N/A	Based on Manufacturers guidelines BSC/MIC/SOP/260
	Procalcitonin 1,2,3,4		Liaison XS	CE	N/A	Based on Manufacturers guidelines BSC/MIC/SOP/260
	Toxoplasma IgM 1,2,3,4		Liaison XS	CE	N/A	Based on Manufacturers guidelines BSC/MIC/SOP/260
	Varicella Zoster IgG 1,2,3,4		Liaison XS	CE	N/A	Based on Manufacturers guidelines BSC/MIC/SOP/260

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.