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	021-4542005
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Website	
Accreditation Standard	ISO 15189
Date Initially Awarded	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]

[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	Warfarin Clinic	College Road, Suite 4, Lee Clinic, Lee Road, Cork, Cork
2	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 1 3 4]	Red Cells / Plasma / Serum	Ab / Ag Reaction Manual Gel Technique / Rapid tube	CE based on standard method	Refer to method summary sheet	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 [a 1 3 4]		Automated Biorad IH-1000 ,Ab / Ag Reaction Gel Technique	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/005
1020 Transfusion science - .03 Blood group antibody screen	Antibody screening [a 1 3 4]	Plasma	Ab / Ag Reaction Manual Gel Technique	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/002/ BSC/BB/SOP/005
			Automated Biorad IH1000 Ab / Ag Reaction	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/005
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification [a 1 3 4]		Ab / Ag Reaction Manual Gel Technique	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/003
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing [a 1 3 4]	Donor Cells / Plasma	Ab / Ag Reaction Manual Gel Technique	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/002
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping [a 4]	Red Cells	Ab / Ag Reaction Manual Gel Technique	CE based on standard method	Refer to method summary sheet	BSC/BB/SOP/003
1020 Transfusion science - .09 Direct antiglobulin test	Direct Coombs Test [a 1 3 4]		Ab / Ag Reaction Manual Gel Technique	CE based on standard method	Refer to method summary sheet	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)

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories 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 laboratories 'Master 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	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h creatinine clearance (child)		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary albumin		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary amylase		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary calcium (adult)		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary calcium (child)		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary chloride		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary creatinine		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary magnesium		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary phosphate		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary potassium		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary protein		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary sodium		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary urate		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	24h urinary urea		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Albumin (Micro)[1 2 3 4]		Immunoturbidimetric - anti-human albumin antibody	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Albumin[1 2 3 4]	Serum	Colorimetric – BCP	Abbott Architect c8000	CE based on standard method	BSC/BIO/SOP/134
	AlkPhos[1 2 3 4]		Colorimetric - para-nitrophenyl phosphate	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	ALT[1 2 3 4]		Colorimetric - NADH without P-5-P	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Ammonia[1 2 3 4]	EDTA Plasma	Colorimetric - glutamate dehydrogenase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Amylase[1 2 3 4]	Serum/ Urine	Colorimetric - CNPG3	Abbott ci8000	CE based on	BSC/BIO/SOP/134

		substrate		standard method	
AST[1 2 3 4]	Serum	Colorimetric - NADH without P-5-P	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Bilirubin Direct[1 2 3 4]		Colorimetric - Diazo reaction	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Bilirubin Total[1 2 3 4]		Colorimetric - diazonium salt	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
BNP (B-Type Natiuretic Peptide)[1 2 3 4]	Plasma	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
Body surface area	N/A	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Calcium (Corrected)	Serum	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Calcium Creatinine Ratio	Urine	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Calcium[1 2 3 4]	Serum/ Urine	Colorimetric/ Arsenazo-III	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Chloride[1 2 3 4]		Indirect ISE	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Cholesterol (Total)[1 2 3 4]	Serum	Colorimetric - cholesterol oxidase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Cholesterol HDL[1 2 3 4]		Colorimetric - accelerator selective detergent	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Cholesterol LDL		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
CKDEPI GFR		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Creatine Kinase (Total)[1 2 3 4]		Colorimetric - NAC (N-acetyl-L-cystine)	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Creatinine (Enzymatic)[1 2 3 4]	Serum/ Fluid/ Urine	Colorimetric - enzymatic quinonemine	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Creatinine Clearance	Serum/ Urine	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Gamma GT[1 2 3 4]	Serum	Colorimetric - L-Gamma-glutamyl-3-carboxy-4-nitroanilide	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Globulin		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
Glucose[1 2 3 4]	Serum/ Plasma/ CSF/ Fluid	Colorimetric - hexokinase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
LDH[1 2 3 4]	Serum/ Fluids	Colorimetric - IFCC lactate to pyruvate	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Magnesium[1 2 3 4]	Serum/ Urine	Colorimetric - isocitrate dehydrogenase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Phosphate[1 2 3 4]		Colorimetric - phosphomolybdate	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Potassium[1 2 3 4]		Indirect ISE	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Sodium[1 2 3 4]		Indirect ISE	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Triglycerides[1 2 3 4]	Serum	Colorimetric - Glycerol phosphate oxidase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
Troponin I (High Sensitivity)[1 2 3 4]	Plasma	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134

	Urate (Uric Acid)[1 2 3 4]	Serum/ Urine/ Fluid	Colorimetric - uricase	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Urate/ Urea Index	Serum	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Urea[1 2 3 4]	Serum/ Urine	Colorimetric - urease	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Urinary albumin/creatinine ratio	Urine	Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Urinary magnesium/creatinine ratio		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Urinary phosphate/creatinine ratio		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Urinary urate/creatinine ratio		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Urine Protein/Creatinine Ratio		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Alpha 1 Anti trypsin[1 2 3 4]	Serum	Immunoturbidimetric - Anti-human alpha1-antitrypsin	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	C-Reactive Protein (CRP)[1 2 3 4]		Immunoturbidimetric - Anti-CRP polyclonal antibodies	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
	Protein (Total)[1 2 3 4]		Colorimetric - Biuret	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
		Urine/ CSF	Colorimetric - Benzethonium chloride	Abbott ci8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .06 Blood pH and gas tensions	O2 Saturation[1 2 4]	Heparin Blood	Co-oximetry	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
	pCO2[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
	pH[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
	pO2[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Lactate[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
	Potassium (Blood Gas)[1 2 4]		Direct ISE	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/110
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin[1 2 3 4]	Serum	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Vancomycin[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .20 Hormones	Cortisol[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Follicle Stimulating Hormone (FSH)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	HCG (Beta Total)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134

	Luteinising Hormone (LH)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Oestradiol[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Progesterone[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Prolactin (PRL)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	PTH (Parathyroid Hormone)[1 2 3 4]	EDTA Plasma	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	T3 (Free)[1 2 3 4]	Serum	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	T4 (Free)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Thyroid Stimulating Hormone (TSH)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .30 Sweat electrolytes	Chloride	Sweat	Colorimetric	Jenway Chloride Meter	CE based on standard method	BSC/BIO/SOP/015
1061 Clinical Chemistry - .40 Iron studies	Ferritin[1 2 3 4]	Serum	CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Iron[1 2 3 4]		Colorimetric - ferrene	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
	Transferrin Saturation (Calculation)		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	Transferrin[1 2 3 4]		Immunoturbidimetric - Anti-human transferrin goat serum	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate (Folic Acid)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Vitamin B12[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .47 Vitamin assays	25-OH Vitamin D[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Feto Protein (AFP)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	CA 125[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	CA 15-3[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	CA19-9[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	Carcinoembryonic Antigen (CEA)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	PSA (Free)[1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
	PSA (Index)		Calculation	N/A	CE based on standard method	BSC/BIO/SOP/047
	PSA [1 2 3 4]		CMIA	Abbott i2000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c	Whole Blood	HPLC	Tosoh G8	CE based on standard method	BSC/BIO/SOP/120

1061 Clinical Chemistry - .62 pH of urine and fluids by electrode	pH[1 2 3 4]	Pleural Fluid	Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/112
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Pregnancy Test[1 4]	Urine	Immunochromatographic Qualitative	Kit	CE based on standard method	BSC/HAEM/SOP/048
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin IgA[1 2 3 4]	Serum	Immunoturbidimetric - anti-human IgA	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
	Immunoglobulin IgG[1 2 3 4]		Immunoturbidimetric - anti-human IgG	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
	Immunoglobulin IgM[1 2 3 4]		Immunoturbidimetric - anti-human IgM	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .82 Total IgE	Immunoglobulin IgE[1 2 3 4]		Fluroenzyme Immunoassay	Phadia 250	CE based on standard method	BSC/BIO/SOP/069
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	RF Latex (Rheumatoid Factor)[1 2 3 4]		Immunoturbidimetric - Denatured human IgG	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .86 C3 and C4	Complement C3[1 2 3 4]		Immunoturbidimetric - anti-human complement C3	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
	Complement C4[1 2 3 4]		Immunoturbidimetric - anti-human complement C4	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .88 b2-microglobulin	B-2 Microglobulin[1 2 3 4]		Immunoturbidimetric - IgG fraction of an anti-human B2M	Abbott c8000	CE based on standard method	BSC/BIO/SOP/134
1061 Clinical Chemistry - .99 Miscellaneous tests	Osmolality[1 2 3 4]	Serum/ Urine	Freezing Point Depression	Advanced Micro-Osmometer	CE based on standard method	BSC/BIO/SOP/013

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Chemical Pathology

Category: B

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Capillary Blood Ketone	Capillary Whole Blood	Electrochemical	Abbott OptiumXceed	CE based on standard method	NUR0185 BSC/POC/SOP/009
	Glucose		Electrochemical	Roche Accu-ChekProforma	CE based on standard method	NUR0115 BSC/POC/SOP/005
1061 Clinical Chemistry - .05 CO-oximetry	HHb[1 2 4]	Whole Blood taken into Heparinised Blood Gas Syringe	Co-oximetry	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	COHb [1 2 4]		Co-oximetry	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	MetHb[1 2 4]		Co-oximetry	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	O^2Hb[1 2 4]		Co-oximetry	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	SO^2 b[1 2 4]		Co-oximetry	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
1061 Clinical Chemistry - .06 Blood pH and gas tensions	O2 Saturation (Blood Gas)[1 2 4]	Heparin Blood	Co-oximetry	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
	pCO2 (Blood Gas)[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
	pCO2[1 2 4]	Whole Blood taken into Heparinised Blood Gas Syringe	Potentiometric	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	pH (Blood Gas)[1 2 4]	Heparin Blood	Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
	pH[1 2 4]	Whole Blood taken into Heparinised Blood Gas Syringe	Potentiometric	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	pO2		Potentiometric	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
	pO2 (Blood Gas)[1 2 4]	Heparin Blood	Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Lactate (Blood Gas)[1 2 4]		Potentiometric	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
	Lactate[1 2 4]	Whole Blood taken into	Potentiometric	Cobas b123	CE based on standard method	BSC/BIO/SOP/138

		Heparinised Blood Gas Syringe				
	Potassium (Blood Gas)[1] [2] [4]	Heparin Blood	Direct ISE	Roche Cobas b221	CE based on standard method	BSC/BIO/SOP/113
		Whole Blood taken into Heparinised Blood Gas Syringe	Potentiometric	Cobas b123	CE based on standard method	BSC/BIO/SOP/138
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Pregnancy Test[1] [4]	Urine	Immunochromatographic Qualitative	Kit	CE based on standard method	NUR0219 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 - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)[1 3 4]	Whole Blood (EDTA/ Citrate)	Kenetics of Red Cell Aggregration	Alifax Test 1	CE based on standard method	BSC/HAEM/SOP/022
			Sedimentation	Westegren (Manual)	CE based on standard method	BSC/HAEM/SOP/022
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites[4]	Whole Blood (EDTA)/ Blood Film	Haematekstainer/ Microscopy	Manual	CE based on standard method	BSC/HAEM/SOP/045
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screen[4]	Whole Blood (EDTA)	HgB Solubility	Manual	CE based on standard method	BSC/HAEM/SOP/016
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time [1 4]	Whole Blood (Citrate)	Coagulation	Sysmex CS2100i/ CS-2500	CE based on standard method	BSC/HAEM/SOP/030
	D-Dimer[1 2 4]		Turbidity	Sysmex CS2100i/ CS-2500	CE based on standard method	BSC/HAEM/SOP/030
	Fibrinogen[1 2 4]		Coagulation	Sysmex CS2100i/ CS-2500	CE based on standard method	BSC/HAEM/SOP/030
	International Normalised Ratio (INR)		Calculation	Sysmex CS2100i/ CS-2500	CE based on standard method	BSC/HAEM/SOP/030
	Prothrombin Time[1 2 4]		Coagulation	Sysmex CS2100i/ CS-2500	CE based on standard method	BSC/HAEM/SOP/030
1030 Haematology - .57 Screening test for infectious mononucleosis	Screening Test for Infectious Mononucleosis (Epstein Barr Virus)[1 2 3 4]	Whole Blood (EDTA)	Immunochromatographic	Manual Kit	CE based on standard method	BSC/HAEM/SOP/040

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Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Cut up,Tissue processing, Embedding, Microtomy, Automated and Manual Haematoxylin and Eosin staining, Coverslipping	Human tissue	Leica ASP 300 Processor, Tissue Tek VIP 6 Processor, Embedding centre, Microtomes, Tissue Tek Prisma/Glas stainer coverslipper	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/002/110/111, BSC/HIS/SOP/001/003, 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 based on standard method	Refer to method summary sheet	BSC/HIS/SOP/040
1051 Histopathology - .03 Histochemistry	Alcian Blue - PAS (AB/PAS)	Tissue Section	Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Alcian Blue (AB)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Congo red		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Elastin Van Gieson (EVG)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Giemsa		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Gomaris Green Trichrome (GGT)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Gram Stain		Manual	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Grocotts – PCP-(GMSP)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Grocotts –Fungi-(GMSF)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Periodic Acid Schiff (PAS)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Periodic Acid Schiff – Diastase (PASD)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Periodic Acid Schiff –Fungi (PASF)		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Perls Prussion Blue		Ventana Bench mark Histochemistry	CE based on standard method	Refer to method	BSC/HIS/SOP/020

				summary sheet	
	Reticulin (Gordons and sweet)	Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
	Trichrome Collagen	Ventana Bench mark Histochemistry. Change to blue instead of light green	CE based on standard method	Not applicable	BSC/HIS/SOP/020
	Ziel Neelsen (AFB)	Ventana Bench mark Histochemistry	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/020
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and reporting by Consultant Pathologist	Manual	CE based on standard method	Not Applicable.	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[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Actin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	AEI/ AE3[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	AFP[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Bcl-2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Bcl-6[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Ber-EP4[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Caldesmon[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Calretinin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Cam 5.2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	CD10[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	CD117[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	CD138[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	CD15[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	CD20[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method	BSC/HIS/SOP/025

			summary sheet	
CD23[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD30[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD31[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD3[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD34[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD4[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD43[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD45[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD5[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD56[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD68[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD79a[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CD8 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CDX2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CEA[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Chromogranin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CK20[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CK5/6[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CK7[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
CK903[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method	BSC/HIS/SOP/025

			summary sheet	
Cyclin DI[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
D2 40[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Desmin[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
E-Cadherin[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
EMA[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
ER[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Gastrin[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Gata 3[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Glycophorin A[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Her2[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
HMB45[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
HPP[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Kappa[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Ki67[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Lambda[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Melan A[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
MLH1[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
MNF116[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
MOC31[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
MSH2[2 4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method	BSC/HIS/SOP/025

			summary sheet	
MSH6[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
MUM 1[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Myeloperoxidase[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Napsin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
NSE[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Oct 4[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
P504S[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
p53[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
P63, CK903, P504S (Triple Stain)[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
p63[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
PAX 8[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
PMS2[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
PR[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
PSA[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
RCC[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
S100[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
Smooth Muscle Myosin[2] [4]	Ventana Ultra Antigen/ Antibody reaction. Change to 1. Antibody incubation reduced from 32mins to 16mins. Change to 2. Antigen retrieval reduced from 32 to 24 mins	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
SOX10[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025

	Synaptophysin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	TTF1 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Vimentin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	Wt-1[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
	B Catenin[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Refer to method summary sheet	BSC/HIS/SOP/025
1052 Cytopathology - .02 Non gynaecological cytology	Non gynaecological cytology	Manual/Tek Prisma/Glas stainer coverslipper	CE based on standard method	Not Applicable.	BSC/HIS/SOP/145 BSC/SOP/HIS/015
1052 Cytopathology - .04 Cytopathological interpretation	Cytopathological Interpretation	Microscope/ Manual	CE based on standard method	Not Applicable.	BSC/HIS/SOP/145 BSC/HIS/SOP/015
1052 Cytopathology - .05 Immunocytochemistry	AE1/AE3 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	BerEp4 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	Calretinin [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CD20 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CD3 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CD45 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CD68 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CDX2 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CK20[2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CK5/6 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	CK7 [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	EMA [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	ER [2] [4]	Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025

	GATA3 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	Ki67 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	MOC31 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	Napsin A [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	P16 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	P53 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	P63 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	PAX8 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	RCC [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	Synaptophysin [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	TTF1[2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	BSC/HIS/SOP/025
	WT1 [2 4]		Ventana Ultra Antigen/ Antibody reaction	CE based on standard method	Not applicable	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 laboratories approved and documented procedures.
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Note 3 – New matrices may be added
Note 4 – Changes to equipment / kits where the underlying methodology does not change
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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 3 4]	Serum/ Urine	Agarose Gel	SebiaHydrasys 2	CE based on standard method	BSC/BIO/SOP/075
	Immunofixation[1 2 3 4]		Agarose Gel / Immunofixation	SebiaHydrasys 2	CE based on standard method	BSC/BIO/SOP/076, BSC/BIO/SOP/077
1040 Immunology - .04 Allergen - specific IgE	Allergy Specific IgE[1 2 3 4]	Serum	Fluroenzyme Immunoassay	Phadia 250	CE based on standard method	BSC/BIO/SOP/069
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Cyclic Citrullinated Peptide Antibodies (CCP)[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti Neutrophil Cytoplasmic Antibody (ANCA)[1 2 3 4]		Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/004
	Anti Nuclear Antibody (ANA)[1 2 3 4]		Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/002
	Beta2 Glycoprotein 1 [1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
	Cardiolipin IgG Abs[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
	Centromere[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
	DNA Antibodies[1 2 3 4]		Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/003
	ENA Screen[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
	Endomysial Antibodies[1 2 3 4]		Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/005
	Gastric Parietal Cell Antibodies[1 2 3 4]		Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/002
	Glomerular Basement Membrane Antibodies (GBM)[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
	Intrinsic Factor antibodies[1 2 3 4]		Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006

Jo1[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
La[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
LKM Ab (Liver Kidney Microsomal Antibody[1 2 3 4]	Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/002
M2 Antibody[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
Mitochondrial Antibodies[1 2 3 4]	Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/002
MPO sensitive[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
PR3 sensitive[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
RNP70[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
Ro[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
Sc170[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
Sm[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
Smooth Muscle Antibodies[1 2 3 4]	Kit/Microscope - Indirect Immunofluorecence	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/002
Thyroid Peroxidase Antibody (TPO)[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
tTG IgA Antibodies [1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006
U1RNP[1 2 3 4]	Fluoroenzyme Immunoassay Phadia 250	CE based on standard method	Refer to method summary sheet	BSC/IMM/SOP/006

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Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1011 Macroscopic examination and description	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	Refer to Method summary sheets	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	Refer to Method summary sheets	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	Refer to Method summary sheets	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 levage, 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	Refer to Method summary sheets	BSC/MIC/SOP/061, BSC/MIC/SOP/164
1012 Preparation of films on glass slides	Microscopic examination	Swabs, Bone marrow , Bronchial	Microscopic examination Light/ fluorescent	Based on standard	Refer to Method	BSC/MIC/SOP/081,

followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria	(Mycobacteria) [1] [2] [3]	lavage/brushings/washings/bronchoalveolar levage, body fluids, pus, Pleural fluids,sputum, Tissue, Urine, Transthoraic/Transtracheal aspirate, CSF.	microscope with or without fixation and staining with dyes for enumeration and description of acid fast bacilli	methods	summary sheets	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 levage, 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 temperaures for defined periods with visual observation of growth.Automated BacT/ALERT 3D system for Blood Cultures	Based on standard methods	Refer to Method summary sheets	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/SOP121.
	Culture of General Bacteria [1] [2] [3] [4] (new Carba Chromogenic Agar)	Rectal Swab or Isolate	Manual culture in liquid and agar based media with incubation of specimens at defined temperaures for defined periods with visual observation of growth.	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/033
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	Refer to Method summary sheets	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	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/081,

			System			
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	Based on standard methods	Refer to Method summary sheets	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	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/199,
	MBT64[1 2 3 4]	Positive Mycobacterium cultures	Immunochromographic/Kit	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/081,
	Urinary Pneumococcal Antigen [1 2 3 4]	Urine	Immunochromographic/Kit	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/252,
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	Enteric Bio System for the detection of Salmonella, Shigella, Campylobacter, VTEC, Crytosporidium and Giardia	Faeces	PCR Hybridisation/ Enteric Bio system incorporating Light Cycler, Heat block , Centrifuge, Mixer and Pipetting centre.	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/121,
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Respiratory Synctial Virus (RSV)	Swab, Nasalphargeal, washing/aspirate	PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/197, BSC/MIC/SOP/255
	Carba R Assay for CRE	Rectal Swab or Isolate	PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/033
	Clostridium difficile	Faeces	PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/198,
	Influenzae A & B	Swab, Nasalphargeal, washing/aspirate	PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/197, BSC/MIC/SOP/255
	NoroVirus	Faeces	PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/255, BSC/MIC/SOP/256,
	VRE		PCR Amplification/Cepheid Gene Xpert	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/032, BSC/MIC/SOP/255
1016 Identification of cultured bacteria and	Identication of Cultured	Swabs, Bone Marrow, Bronchial Lavage/brushings/washings/bronchoelveol	Biochemical identification of Cultured Bacteria and	Based on standard	Refer to Method	BSC/MIC/SOP/031,

fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Bacteria and Fungi. [1] [2] [3] [4]	ar 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.	Fungi using manual Identification Kits/tests including, PBP2a (MRSA) and automated Vitek 2 system	methods	summary sheets	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/bronchoalveola r levage, 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	Refer to Method summary sheets	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/bronchoelveol ar 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.	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/163 , e Test Technical Manual, 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/bronchoalveola r 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 Minimum Inhibitory Concentration (MIC) methods .	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/163 , e Test Technical Manual,
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	ASOT[1] [2] [3] [4]	Serum	Agglutination - Kit	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/201
	Syphillis RPR test[1] [2] [3] [4]		Agglutination - Kit	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/201
	Syphillis TPHA test[1] [2] [3] [4]		Agglutination - Kit	Based on standard methods	Refer to Method summary sheets	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	CMV IgM[1] [2] [3] [4]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/200
	Hepatitis B Core Antibodies[1] [2] [3]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary	BSC/MIC/SOP/200

	[4]				sheets	
	Hepatitis B Surface Antigen (HBsAg)[1 2 3 4]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/200
	HIV 1/ 2 Ag/ Ab Duo[1 2 3 4]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/200
	Mycoplasma Pneumoniae IgM [1 2 3 4]		Enzyme Immunoassay/Kit	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/201
	Procalcitonin		Enzyme Immunoassay/Vidas	Based on standard methods	Not applicable	BSC/MIC/SOP/200
	Toxoplasma IgM[1 2 3 4]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/200
	Varicella Zoster IgG antibodies[1 2 3 4]		Enzyme Immunoassay/ Vidas	Based on standard methods	Refer to Method summary sheets	BSC/MIC/SOP/200
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Hepatitis A IgM[1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	Hepatitis B Surface Antibodies [1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	Hepatitis B Core Antibodies[1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	Hepatitis B Surface Antigen (HBsAg)[1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	Hepatitis C Antibodies [1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	HIV 1/2 Ag/Ab Combo [1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	BSC/BIO/SOP134, BSC/MIC/SOP250.
	Rubella IgG (immunity) [1 2 3 4]		CMIA, Abbott i2000	Based on standard methods	Refer to Method summary sheets	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 laboratories 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 laboratories 'Master list of Flexible scope changes', available directly from the laboratory.

Warfarin Clinic

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	Capillary INR	Whole Blood - Capillary	Coagulation	Coagucheck Pro II	CE based on standard method	BSC/HAEM/SOP/038