

Schedule of Accreditation



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Trading As	
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Accreditation Standard	ISO 15189
Date Initially Awarded	09/12/2008
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology

Services available to the public¹

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	Castlebar, Mayo, F23 H529

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, Rh(D) Group **1,3,4	Whole Blood	BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/097
			BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/003
			Tube Methodology/ Direct Agglutination	CE	Positive/Negative	BT/LP/003
			AutoVue Ultra/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/007
			Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods						
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen **1,3,4	Plasma	Automated AutoVue Ultra/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/007
			Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/075
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/006
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/006
	rr Antibody Screen **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination	CE	Positive/Negative	BT/LP/100

			Technology			
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/008 BT/LP/102
			Manual BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/008 BT/LP/075
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/008 BT/LP/010
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/008 BT/LP/010
1020 Transfusion science - .05 Cross match compatible donor units	Investigation of Transfusion Reactions **1,3,4	Whole Blood	Automated AutoVue Ultra/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/018
			Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/018
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/018
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/018
	Red Cell Compatibility by Electronic Issue **1,3,4	Plasma	Automated Ortho Vision and AutoVue Ultra/ iLAB LIS/ Electronic Issue	CE	Positive/Negative	BT/LP/104
			Automated AutoVue Ultra/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/013
			Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/103
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/009 BT/LP/011
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/009 BT/LP/011
			Red Cell Compatibility Testing **1,3,4			
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Antigen Phenotyping **4	Red Cells	Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/015 BT/LP/100
			Manual BioVue System/ Column	CE	Positive/Negative	BT/LP/015

			Agglutination Technology			
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/015
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/012
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/012
1020 Transfusion science - .99 Miscellaneous tests	Blood Grouping including ABO, Rh(D) and DAT for Newborns **1,3,4		Automated AutoVue Ultra/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/050
			Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/014 BT/LP/097
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/014
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/014
	Estimation of Feto-Maternal Haemorrhage by the Kleihauer-Betke Test **1,2,3,4	Whole Blood	Manual Slide Staining/ Kleihauer-Betke Test	CE		BT/LP/073

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	Haematocrit **1,4	Whole Blood	RBC cumulative pulse height detection method	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Haemoglobin **1,4		Spectrophotometric (SLS Haemoglobin Method)	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	MCH **1,4		Calculated from Hb and RBC	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	MCHC **1,4		Calculated from Hb and HCT	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Mean Cell Volume **1,4		Calculated from RBC and HCT	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Platelet (Impedance/Optical) **1,4		Sheath Flow DC detection/ Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Red Cell Count **1,4		Sheath Flow DC detection	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	White Cell Count **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
1030 Haematology - .02 Visual examination of blood films	Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, White Cell & Red Cell Morphology **1,2,4		Hematek Modified Wright-Giemsa Staining/ Microscopy	Hematek Stainer, Microscope	CE	H/LP/005
1030 Haematology - .03 Erthrocyte sedimentation rate	ESR (Automated) **1,3,4		Photometric Capillary stopped flow Kinetic Analysis	ALLIFAX-Test 1	CE	H/LP/013
	ESR (Manual) **1,3,4		Sedimentation of RBCs	Manual Westergren	CE	H/LP/012
1030 Haematology - .05 Automated differential leucocyte counts	Basophil **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Eosinophil **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Lymphocyte **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
	Monocyte **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023

						H/LP/004
	Neutrophil **1,4		Laser Flow Cytometry	Sysmex XE-2100/ Sysmex XT-2000i	CE	H/LP/022 H/LP/023 H/LP/004
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes **1,4		Laser Flow Cytometry	Sysmex XE-2100	CE	H/LP/023 H/LP/004
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites by Thick and Thin Blood Films **4		Staining/ Microscopy	Microscope	CE	H/LP/001
	Malaria Screening Test (ICT Kit) **1,2,3,4		Immunochemical Test	Binax NOW® Malaria Screening Test Kit	CE	H/LP/036
			Immunochemical Test	CareStart® Malaria Rapydtest Screening Kit	CE	H/LP/044
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen Test **4		Solubility Screening Test for HbS	Sickledex® Test Kit	CE	H/LP/002
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,4	Plasma	Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/007
	D-Dimer **1,2,4		Immunoassay	Sysmex CS-2100	CE	H/LP/009
	Fibrinogen (Clauss) **1,2,4		Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/010
	International Normalised Ratio (INR)		Ratio Calculation	Sysmex CS-2100	CE	H/LP/007
	Prothrombin Time (PT) **1,2,4		Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/007
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen Test **1,2,3,4		Immunoassay	Clearview IM II® Test Kit	CE	H/LP/003

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	Human Tissue	Manual	Based on standard methods		HP/LP/031 HP/LP/035
	Cut - Up **4		Manual	Based on standard methods		HP/LP/031 HP/LP/035
	Embedding		Embedding Station/ Coldplate	Based on standard methods		HP/LP/032
	Embedding **4		Embedding Station/ Coldplate	Based on standard methods		HP/LP/032
	Haematoxylin/Eosin Staining (Automated/Manual)	Human Tissue Slides (Unstained)	Leica® Automated Staining Machine/ Manual Staining	CE		HP/LP/043 HP/LP/068
	Haematoxylin/Eosin Staining (Automated/Manual) **4		Leica® Automated Staining Machine/ Manual Staining	CE		HP/LP/043 HP/LP/068
	Immunohistochemical Tissue Staining (Automated)		Benchmark XT IHC Stainer	CE		HP/LP/038
	Immunohistochemical Tissue Staining (Automated) **4		Benchmark XT IHC Stainer	CE		HP/LP/038
	Microtomy	Human Tissue Blocks	Microtome	Based on standard methods		HP/LP/033
	Microtomy **4		Microtome	Based on standard methods		HP/LP/033
	Mounting/Coverslipping (Automated/Manual)	Human Tissue Slides (stained)	Automated Coverslipper/ Manual coverslipping	CE Based on standard methods		HP/LP/020 HP/LP/043
	Mounting/Coverslipping (Automated/Manual) **4		Automated Coverslipper/ Manual coverslipping	CE Based on standard methods		HP/LP/020 HP/LP/043
	Processing and Decalcification of Bone	Human Tissue	VIP 5/VIP6AI tissue processor	Based on standard methods		HP/LP/028 HP/LP/078
	Processing and Decalcification of Bone **4		VIP 5/VIP6AI tissue processor	Based on standard methods		HP/LP/028 HP/LP/078
	Tissue Processing		Tissue Processors (VIP5/VIP6AI)	CE		HP/LP/028 HP/LP/078
	Tissue Processing **4		Tissue Processors (VIP5/VIP6AI)	CE		HP/LP/028 HP/LP/078
1051 Histopathology - .03 Histochemistry	Congo Red Stain for Amyloid	Human Tissue Slides (Unstained)	Manual Staining	CE		HP/LP/007
	Gordon and Sweets Reticulin Stain		Manual Staining	CE		HP/LP/018
	Haematoxylin Van		Manual Staining	CE		HP/LP/012

	Gieson (HVG) Stain for Collagen					
	Martius Scarlet Blue (MSB) Stain for Fibrin		Manual Staining	CE		HP/LP/016
	Miller's Stain for Elastic Fibres		Manual Staining	CE		HP/LP/015
	Periodic Acid Schiffs (PAS) Stain for Glycogen		Manual Staining	CE		HP/LP/017
	Perls Prussian Blue Stain for Ferric Iron		Manual Staining	CE		HP/LP/008
	Ziehl-Nielsen Stain for Tubercle Bacilli		Manual Staining	CE		HP/LP/019
1051 Histopathology - .06 Histological interpretation-perinatal pathology	Diagnostic interpretation and reporting of human tissue specimens; Specialist areas include perinatal pathology (confined to histological examination of placental tissue and gravid uteri)	Human Tissue Slides (Stained)	Microscope	Based on standard methods		HP/LP/002 HP/LP/031 HP/LP/048
1051 Histopathology - .09 Immunohistochemistry	AFP alphafetoprotein	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Alpha Fetoprotein	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
	Alpha Fetoprotein **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
	Bcl2	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
		Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
	Bcl2 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
	BCL6	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	CA125		Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
		Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
	CA125 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
	CA19.9	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
		Human Tissue Slides	Benchmark XT IHC Stainer	CE		HP/LP/038

	(Unstained)				
CA19.9 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Calretinin	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Calretinin **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD10	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD10 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD138	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD138 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD15	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD15 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD20	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD20 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD23	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD23 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD3	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-	CE	Positive/Negative	HP/LP/038

		Antibody reaction)			
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD3 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD30	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD30 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD31	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD31 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD34	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD34 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD43	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD43 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD45	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD45 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD5	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD5 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038

CD56	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD56 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD68	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD68 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CD99	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CD99 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CDX2	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CDX2 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CEA	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CEA **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Chromagranin A	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Chromagranin A **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CK19	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides	Benchmark XT IHC Stainer	CE		HP/LP/038

	(Unstained)				
CK19 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CK20	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CK20 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CK5/6	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CK5/6 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
CK7	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
CK7 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
C-Kit	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
Cyclin D1		Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Cyclin D1 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Desmin	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Desmin **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
EMA	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
EMA **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038

		Stainer			
Ep Cam (Ber ep4)		Benchmark XT IHC Stainer	CE		HP/LP/038
Ep Cam (Ber ep4) **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
EpCam (ber ep4)	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
ER		Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
ER **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
GCDFP-15	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
GCDFP-15 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
GFAP	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
GFAP **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
H. Pylori	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
H.Pylori	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
H.Pylori **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Hep Par	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
HepPar	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
HepPar **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
HmB45	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides	Benchmark XT IHC Stainer	CE		HP/LP/038

	(Unstained)				
HMB45 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Inhibin Alpha	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Inhibin Alpha **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
KI67	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
KI67 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
KIT		Benchmark XT IHC Stainer	CE		HP/LP/038
KIT **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Melan A	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Melan A **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
MSA	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
MSA **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
MUM1	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
MUM1 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
NSE	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038

NSE **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
P16	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
P16 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
P53	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
P53 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Pan-Cytokeratin	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Pan-Cytokeratin **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Pax 5	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
PAX 5 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Pax 8	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
PAX 8 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
PLAP	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
PLAP **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
PR	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038

PR	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
PR **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
PSA	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
PSA **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Racemase-p504s	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Racemase-p504s **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
S100	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
S100 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Synaptophysin	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Synaptophysin **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
TdT	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
Tdt **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
TTF-1	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
	Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
TTF-1 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
Vimentin	Human Tissue	Ventana Benchmark	CE	Positive/Negative	HP/LP/038

		Slides (unstained)	Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)			
		Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
	VIMENTIN **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
	WT1	Human Tissue Slides (unstained)	Ventana Benchmark Classic IHC/ Optiview Detection Kit (Antigen-Antibody reaction)	CE	Positive/Negative	HP/LP/038
		Human Tissue Slides (Unstained)	Benchmark XT IHC Stainer	CE		HP/LP/038
	WT1 **2, 4		Benchmark XT IHC Stainer	CE		HP/LP/038
1052 Cytopathology - .02 Non gynaecological cytology	Cytology Sample preparation and description, diagnostic interpretation and reporting of non-gynae samples	Human Tissue BAL CSF Fluids Urine	Cyto-tek centrifuge Microscope	Based on standard methods		HP/LP/029 HP/LP/044 HP/LP/045

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 **1,2,3	Sputum CSF	Manual	Based on standard method	N/A	M/LP/016 M/LP/022 Relevant Standards for Microbiology Investigations, Public Health England
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 for general bacteriology (including enumeration and description of human cells) **1,2,3	Sputum Bronchoalveolar Lavage Tracheal Aspirate Fluids Bile Urine Wound Swabs Pressure Sores Abscesses Cough swabs HVS Eye Swab Conjunctiva swab Ear Swab Nasal Swabs Mouth Swabs Throat Swab Ulcer Swabs, burn, skin, superficial wound Swab, Exudates, Pus Swabs Surveillance Specimens MRSA Swabs VRE Swabs CRE Swabs Genital Tract Specimens including penile swab, Vaginal swab, endocervical, IUCD Urethral swab Cannulae CSF Human Tissue Semen Tips Cultures Slides (unstained)	Light Microscope/ Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Based on standard method	N/A	M/LP/025 M/LP/026 M/LP/022 M/LP/024 M/LP/012 Relevant Standards for Microbiology Investigations, Public Health England
1012 Preparation of films	Microscopic		Light Microscope/	Based on standard	N/A	M/LP/025

on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	examination for funghi		Microscopic examination with or without fixation and staining with dyes as required	method		M/LP/026 M/LP/022 M/LP/024 M/LP/012 Relevant Standards for Microbiology Investigations, Public Health England
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Blood Culture Analysis	Blood/body fluids- e.g joint aspirates	BacT/ALERT system for Blood Cultures/Colorimetric detection	CE	Positive/Negative	M/LP/023 M/LP/051
	Culture of General Bacteria **1,2,3,4	Sputum Bronchoalveolar Lavage Tracheal Aspirate Fluids Bile Urine Wound Swabs Pressure Sores Abscesses Cough swabs HVS Eye Swab Conjunctiva swab Ear Swab Nasal Swabs Mouth Swabs Throat Swab Ulcer Swabs, burn, skin, superficial wound Swab, Exudates, Pus Swabs Surveillance Specimens MRSA Swabs VRE Swabs CRE Swabs Genital Tract Specimens including penile swab, Vaginal swab, endocervical, IUCD Urethral swab Cannulae CSF Human Tissue Semen Tips Cultures Slides (unstained)	BacT Alert® Blood Culture Monitoring System Manual Assessment Light microscope	CE Based on standard method	Positive/Negative	M/LP/027 M/LP/006 M/LP/007 M/LP/008 M/LP/009 M/LP/010 M/LP/011 M/LP/012 M/LP/013 M/LP/014 M/LP/015 M/LP/016 M/LP/017 M/LP/018 M/LP/019 M/LP/021 M/LP/022 M/LP/023 M/LP/024 M/LP/047 M/LP/049 Relevant Standards for Microbiology Investigations, Public Health England
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring	Culture of funghi		Manual Assessment BacT Alert® Blood Culture Monitoring System	CE Based on standard method	Positive/Negative	M/LP/027 M/LP/006 M/LP/007 M/LP/008

for growth - .02 Culture of fungi			Light microscope			M/LP/009 M/LP/010 M/LP/011 M/LP/012 M/LP/013 M/LP/014 M/LP/015 M/LP/016 M/LP/017 M/LP/018 M/LP/019 M/LP/021 M/LP/022 M/LP/023 M/LP/024 M/LP/047 M/LP/049 Relevant Standards for Microbiology Investigations, Public Health England
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Staphylococcus Latex Test **1,2,3,4	Cultures	Pastorex Staph Plus®/ Slide Agglutination	CE	Positive/Negative	M/LP/028
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Identification of Neisseria gonorrhoeae **1,2,3,4		Phadebact® Monoclonal GC Test/ Particle Agglutination	CE	Positive/Negative	M/LP/028
	Meningitis Latex Test **1,2,3,4	Urine CSF Serum Cultures	Pastorex® Meningitis Latex Kit/ Particle Agglutination	CE	Positive/Negative	M/LP/028
	Streptococcus Grouping **1,2,3,4	Cultures	Prolex® Streptococcal Grouping Latex Kit/ Particle Agglutination	CE	Positive/Negative	M/LP/028
	Test for Streptococcus pneumoniae **1,2,3,4	Cultures Whole Blood	Slidex® Pneumo Kit/ Particle Agglutination	CE	Positive/Negative	M/LP/028
		Whole Blood Cultures	Pastorex Streptococcus pneumoniae®/ Latex Agglutination	CE	Positive/Negative	M/LP/028
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Carba 5 NG Test for CPE	Culture/Isolates	NG Test Carba 5 Kit/ rapid 5 enzyme immunoassay (lateral flow)	CE	Positive/Negative	M/LP/047 M/LI/065 M/RI/096
	Test for Neisseria gonorrhoeae **1,2,3,4	Cultures	Gonogen II® test kit/ Immunoassay	CE	Positive/Negative	M/LP/028
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04	Test for Legionella pneumophila	Urine CSF	Binax NOW® test kit/ Immunochromatography	CE	Positive/Negative	M/LP/024 M/LP/022

Immunochromatographic methods,						
	Test for Legionella pneumophila **1,2,3,4	Urine	Binax NOW® test kit/ Immunochromatography	CE	Positive/Negative	M/LP/024
	β-Lactamase Test **1,2,3,4	Cultures	Nitrocefin Disks/ Immunochromatography	CE	Positive/Negative	M/LP/028
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of cultured bacteria (Aerobes/Anaerobes) **1,2,3,4		API System®/ Manual	CE	N/A	M/LP/028
			Vitek 2XL®/ Automated	CE	N/A	M/LP/043 M/LP/044
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		Light Microscope	Based on standard method	N/A	M/LP/028 Relevant Standards for Microbiology Investigations, Public Health England
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification of bacterial, fungal and mycobacterial isolates **1,2,3,4		VitekMS-MALDI TOF/ Automated	CE	N/A	M/LP/041
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Sensitivity Testing **1,2,3,4		EUCAST/ MIC (Manual) ETEST/Disk Diffusion (Manual) Oxoid® Discs/Disk Diffusion (Manual)	CE Based on standard method	N/A	M/LP/042 EUCAST Guidelines
			Vitek 2XL®/ Automated Biochemical Testing	CE	N/A	M/LP/042 M/LP/044
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts			ETEST/MIC Disk Diffusion (Manual)	CE Based on standard method	N/A	M/LP/042 EUCAST Guidelines
			Vitek 2XL®/ Automated Biochemical Testing	CE	N/A	M/LP/042 M/LP/044
1024 Preservation of microbial cultures	Preservation of Isolates **1,2,3,4		Freezer/Manual	Based on standard method	N/A	M/LP/023 PATH/MP/018 Relevant Standards for Microbiology Investigations, Public Health England
1029 Miscellaneous - .99 Miscellaneous tests	Drugs for Therapeutic Monitoring: Gentamicin **1,2,3,4	Serum Plasma	Roche Cobas C311®/ Photometric	CE		M/LP/035
	Drugs for Therapeutic Monitoring: Vancomycin	Serum/ Plasma	Roche Cobas C311®/ Photometric	CE		M/LP/035

	Drugs for Therapeutic Monitoring: Vancomycin **1,2,3,4		Roche Cobas C311®/ Photometric	CE		M/LP/035
	Drugs for Therapeutic Monitoring: Vancomycin and Tobramycin **1,2,3,4	Serum Plasma	Roche Cobas C311®/ Photometric	CE		M/LP/035

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.