

Schedule of Accreditation



Organisation Name	Midland Regional Hospital Tullamore
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	07/04/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Services available to the public ¹	Yes

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Quality Office	Pathology Department, Midland Regional Hospital Tullamore, Arden Road, Tullamore, Offaly, Ireland, R35 Y2D1

Scope of Accreditation

Quality 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	Forward Blood Group, Reverse Blood Group	Red Blood Cells and Plasma	Manual method using tube and Gels cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003
		Whole Blood in EDTA	Manual method using tube and Gels cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003
Red Blood Cells and Plasma		Automated using Gel cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003, T/BTL/EQ/057	
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	Plasma	Manual method using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003
			Manual method using Gel Cards Automated using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines,

						T/BTL/LP/003, T/BTL/EQ/057
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual method using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/005
			Manual method using Gel Cards Automated using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/005, T/BTL/EQ/057
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing		Manual method using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/004
			Manual method using Gel Cards Automated using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/004, T/BTL/EQ/056
1020 Transfusion science - .06 Red cell phenotyping	Antigen typing - Patients and Donor Cells	Donor and Patient Red Cells	Manual method using tube and Gels cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/009
		Patient and Donor Red Cells	Manual method using tube and Gels cards Automated using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/009, T/BTL/EQ/057
1020 Transfusion science - .99 Miscellaneous tests	Direct coombs testing/Monospecific coombs test		Manual method using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/010
	Direct coombs testing/Monospecific coombs test		Manual method using Gel Cards Automated using Gel Cards	CE - based on standard method	Qualitative - Agglutination donates a positive reaction	Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/010, T/BTL/EQ/057

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)

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	Alanine Aminotransferase (ALT)	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/069
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/017
	Albumin		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/067
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/015
	Albumin/Creatinine Ratio (ACR)	urine	Calculation	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/007
			Calculation	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/007
	Alkaline Phosphatase (ALP)	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/068
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/016
	Amylase	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/070
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/018
	ASOT	serum/plasma	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/071
			Immunoturbidimetric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/019
	Aspartate Aminotransferase		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/072

(AST)					
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/020
Bicarbonate		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/073
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/021
Bilirubin (Direct)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/074
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/027
Bilirubin (Total)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/075
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/040
BNP	plasma	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/013
C reactive Protein (CRP)	serum/plasma	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/087
		Immunoturbidimetric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/026
Calcium		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/022
	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/079
Chloride	serum/plasma	ISE	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/081
		ISE	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/045
Cholesterol		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/082
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/023
Corrected Calcium		Calculation	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/007
		Calculation	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/007
Creatine Kinase (CK)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/083

		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/024
Creatinine (Enzymatic)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/086
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/049
Creatinine (Jaffe)	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/085
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/048
Creatinine Clearance		Calculation	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/007
		Calculation	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/007
eGFR	serum/plasma	Calculation	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/007
		Calculation	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/007
Gamma Glutamyltransferase (GGT)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/089
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/029
Glucose	serum/plasma/CSF	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/090
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/030
HDL	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/092
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/031
High Sensitivity Troponin T (HsTnT)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/103
		Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/060
Lactate	plasma	Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/032
Lactate DeHydrogenase	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/094

(LDH)					
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/033
LDL		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/095
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/034
Magnesium	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/096
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/035
Microalbumin	urine	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/097
		Immunoturbidimetric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/036
Parathyroid Hormone (PTH)	plasma	Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/100
		Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/058
Phosphate	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/098
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/037
Potassium		ISE	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/045
		ISE	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/045
Protein (Urinary/CSF)	urine/CSF	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/105
		Immunoturbidimetric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/043
Sodium	serum/plasma/urine	ISE	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/045
		ISE	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/045
Total Protein	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/104
		Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/041

	Triglyceride	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/106
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/042
	Urea		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/107
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/047
	Uric Acid		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/108
			Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/044
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2	Whole Blood	Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	pH		Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	PO2		Amperometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Calcium	Whole Blood	Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Chloride		Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Glucose		Amperometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Lactate		Amperometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Potassium		Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Sodium		Potentiometric	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	Standard Bicarbonate		Calculation	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
	TCO2		Calculation	Cobas b221 blood gas analyser	Manufacturer CE marked method	T/BIO/LP/005
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin	serum/plasma	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/013

	Vancomycin	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/013
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/088
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol	Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/028
		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/065
	Salicylate	Photometric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/014
		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/102
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Feto Protein (AFP)	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/039
		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/066
	Cancer antigen 125 (CA 125)	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/051
		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/078
	Cancer antigen 15.3 (CA 15.3)	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/053
		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/076
	Cancer antigen 19.9 (CA 19.9)	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/054
		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/077
	CarcinoEmbryonic Antigen (CEA)	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/050
		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/080
Human Chorionic Gonadotrophin Plus Beta (BHCG)	Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/055	
	Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/091	

			Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/056
	Prostate Specific Antigen (PSA)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/099
			Chemiluminescent Immunoassay	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/057
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c	Whole Blood	HPLC	Ha-8180	Manufacturer CE marked method	T/BIO/EQ/017
1061 Clinical Chemistry - .61 Hb A1c			HPLC	Ha-8180	Manufacturer CE marked method	T/BIO/EQ/017
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor	serum/plasma	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/101
			Immunoturbidimetric	Roche Modular Analyser	Manufacturer CE marked method	T/BIO/LP/038

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count	Blood	Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004
1030 Haematology - .02 Visual examination of blood films	Manual WBC Differential & Blood Film Review		Slide Stainer & Morphological	Wescor Stainer & Sysmex SP-50	Automated	T/HAE/EQ/015, T/HAE/LP/007, T/HAE/TR/001, T/HAE/LP/026
			Slide Stainer & Morphological	Wescor Stainer & Sysmex SP-50	Automated	T/HAE/EQ/015, T/HAE/LP/007, T/HAE/TR/001, T/HAE/LP/026
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR	Whole Blood in EDTA	Capillary photometry	TEST 1 Analyser	Based on standard method	T/HAE/LP/021, T/HAE/EQ/012
1030 Haematology - .05 Automated differential leucocyte counts	White Blood Cell Differential	Blood	Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004
			Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Spectrophotometry, Sheath flow (DC) detection and	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035,

			Fluorescence flow cytometry			T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004
			Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004
1030 Haematology - .09 Examination of malarial parasites	Malaria Parasites Detection		Qualitative Immuno-chromatographic Assay and Thick & Thin film	N/A	Manual (CE marked kits)	T/HAE/LP/017, T/HAE/LP/012, T/HAE/LP/013, T/HAE/LP/020
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screening test		Qualitative Turbidity Solubility Test	N/A	Manual (CE marked kit)	T/HAE/LP/009
1030 Haematology - .41 General haemostasis related tests	Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Derived Fib) , Fibrinogen (Clauss Fib), International Normalised Ratio (INR), D-Dimer (D-Dimer)	Plasma	Quantitative Turbidimetric, Chromogenic & Immunological	ACL Top 500	Automated	T/HAE/EQ/026, T/HAE/EQ/028 , T/HAE/EQ/029
	Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Derived Fib), Fibrinogen (Clauss Fib), International Normalised Ratio (INR), D-Dimer (D-Dimer)		Quantitative, Turbidimetric, Chromogenic and Immunological	ACL Top 550	Automated	ISO 15189 T/HAE/EQ/026 T/HAE/EQ/028 T/HAE/EQ/029
1030 Haematology - .57 Screening test for infectious mononucleosis	Epson Barr Virus Screening Test for Infectious Mononucleosis		Qualitative Latex Agglutination Immunoassay	N/A	Manual (CE marked kit)	T/HAE/LP/010

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Automated and Manual Haematoxylin and Eosin Staining	Paraffin Section of Human Tissue	Leica Histocore Spectra ST Stainer and Coverlipper	Based on standard method	N/A	T/HIS/LP/049
	Automated and Manual Haematoxylin and Eosin Staining		Leica Multistainer/ Manual/Automated	Based on standard method	N/A	T/HIS/LP/015,
	Coverslipping	Stained Glass Slide containing section of human tissue	Leica Coverslipper/Automated	Based on standard method	N/A	T/HIS/EQ/016
			Leica Histocore Spectra ST Stainer and Coverlipper	Based on standard method	N/A	T/HIS/LP/049
	Cut up	Formalin Fixed Human tissue	Dissection table /Manual	Manual -Based on standard method	N/A	T/HIS/LP/002
	Embedding	Paraffin Processed Human tissue	Leica Embedding Station /Manual	Manual- Based on standard method	N/A	T/HIS/EQ/005 , T/HIS/LP/033
	Microtomy	Paraffin Block of Human Tissue	Leica Microtomes/semi automatic	Based on standard method	N/A	T/HIS/LP/010, T/HIS/LP/038
	Tissue processing	Formalin Fixed Human tissue	Leica ASP 300S/ Automated Formalin Fixed Paraffin processing	Based on standard method	N/A	T/HIS/EQ/003,T/HIS/EQ/004
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut-up	Fresh Human Tissue / Formalin Fixed Human Tissue	Microm Cryostat / Manual	Based on standard method	N/A	T/HIS/LP/010 T/HIS/EQ/039
	Frozen section cryotomy and staining					

1051 Histopathology - .03 Histochemistry	Alcian Blue/PAS stain	Paraffin Section on glass slide	Semi Automated- Artisan	Non CE/Based on standard method	N/A	T/HIS/LP/047
	Congo Red		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/055
	Diastase PAS stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/046
	Giemsa		Manual	Non CE/Based on standard method	N/A	T/HIS/LP/099
	Gram Twort		Manual	CE Marked /Based on standard method	N/A	T/HIS/LP/052
	Grocott Methenamine silver		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/062
	Martius Scarlett Blue		Manual	Non CE/Based on standard method	N/A	T/HIS/LP/060
	Masson Fontana		Manual	Non CE/Based on standard method	N/A	T/HIS/LP/058
	Massons Trichrome		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/050
	May Grunwald Giemsa	Cytology cytospin Slide / Smears	Leica Multistainer/ Manual/Automated	CE Marked /Based on standard method	N/A	T/HIS/LP/029
	PAP (Papanicolou stain)	Cytology Thin Prep Slide	Leica Multistainer/ Manual/Automated	CE Marked /Based on standard method	N/A	T/HIS/LP/030
	PAS Green Stain	Paraffin Section on glass slide	Dako Artisan/ Automated	CE	N/A	T/HIS/LP/100
	PAS Stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/045
	Perls Prussian Blue		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/048
	Reticulin Nuclear Fast Red		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/049
	Toluidine Blue		Manual	Non CE/Based on standard method	N/A	T/HIS/LP/057
	Verhoeff Elastic stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/053
	Warthin and Starry		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/043

	Ziehl Neelsen		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/034
1051 Histopathology - .04 Histological interpretation- medical renal pathology	Specialist areas excluded: Breast check designated laboratories only Breast screening pathology Medical Renal Pathology Neuropathology Paediatric Pathology Perinatal Pathology					
	Specialist areas included: Diagnostic Interpretation and reporting of Human tissue specimens	Formalin fixed paraffin processed human tissue	Manual	N/A		T/HIS/LP/077 T/HIS/LP/076 T/HIS/LP/070 T/HIS/LP/078 T/HIS/LP/072 T/HIS/LP/075 T/HIS/LP/073 T/HIS/LP/074 T/HIS/LP/071 T/HIS/LP/079
1051 Histopathology - .05 Histological interpretation- paediatric pathology	CD31/AE1-AE3 dual staining	Human tissue	Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	CD34/AE1-AE3 dual staining		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	D2-40/AE1-AE3 dual staining		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	HPV staining		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	Kappa		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	Lambda		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	P63/ CK5-6 dual		Ventana Benchmark	Based on standard	Qualitative	T/HIS/LP/022

	Staining		Ultra / In situ hybridisation	method		
	TTF/Napsin Dual Staining		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
1051 Histopathology - .09 Immunohistochemistry	D2 40-Podoplanin	Paraffin Section on glass slide		CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	34 BE 12, ALK-1, Actin		Benchmark Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	BCL-2, BCL-6, BER EP4, BOB-1		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Calretenin, Cam 5.2		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CD 15,CD 20,CD 23,CD 30		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CD 3,CD 4,CD 5,CD 8,CD 10,		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CD 31,CD 34,CD 45,CD 56		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CD 68,CD 117,CD 138		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CDX 2, CEA, Chromogranin		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CK 5/6,CK 7,CK 19,CK 20		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CK AE1/AE3		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	CMV, Cyclin D1, Desmin, DOG -1		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	DOG-1, BOB-1, TdT,		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Dual Stain CD31/AE1/AE3		Benchmark Ultra/Optiview DAB Kit +Ultraview Red Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Dual Stain CD34/ AE1-3		Benchmark Ultra/ Optiview DAB Kit + Ultraview Red Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Dual stain D2-40/ AE1-3	Benchmark Ultra/ Optiview DAB Kit+	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022		

Dual stain P63/CK5-6
Dual Stain TTF/Napsin
E-Cadherin, EMA, ER,GFAP
Glycophorin A
HMB45,Melan A,
HPV 16 Probe
HSA,Ki-67,Napsin-A, Oct 2
Kappa Probe, Lambda Probe
MLH-1, MSH2, MSH6, PMS-2
MOC31, MUM-1,
Napsin-A, PLAP, GFAP
P16, P40,P53
P40, D2 40- Podoplanin
P57,P63,P504s, PLAP
PAX 8
Podoplanin (D2-40), PR,PSA
S100 Antigen, Synaptophysin
SOX 10

Ultraview Red Kit			
Benchmark Ultra/ Optiview DAB Kit + Ultraview Red Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit + Ultraview Red Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/Ultraview Red Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/iView Blue Plus Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ I View Blue Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022

	Tdt, Thyroglobulin, TTF-1		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Thyroglobulin		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Vimentin, WT-1, OCT-2		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Vimentin, WT-1		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
1052 Cytopathology - .02 Non gynaecological cytology	Cytology sample preparation and description	Human tissue or fluid	Shandon Cytospin/ Thin Prep 2000	N/A	N/A	T/HIS/LP/004, T/HIS/LP/006, T/HIS/LP/007, T/HIS/LP011, T/HIS/LP/29,T/HIS/LP/30, T/HIS/LP/36, T/HIS/EQ/002, T/HIS/EQ/036
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and reporting of non- gynae samples	Stained slide prepared from Human Tissue or Fluid	Interpretative / Manual	N/A	N/A	T/HIS/LP/098

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
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 purposes	Blood Cultures	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/006, T/MIC/EQ/007
		CRE Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/045, T/MIC/EQ/007
		CSF	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/005, T/MIC/EQ/007
		Ear Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/050, T/MIC/EQ/007
		Eye Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/012, T/MIC/EQ/007 UK Standards for Microbiology Investigations
		Fluids	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/007, T/MIC/EQ/007
		Genital Tract	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/014, T/MIC/EQ/007
		Intravascular Cannulae	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/007, T/MIC/EQ/007
		MRSA Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/016, T/MIC/EQ/007

		Throat and Mouth Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/012, T/MIC/EQ/007
		Tissues/Biopsies	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/007, T/MIC/EQ/007
		Urine	Sysmex UF-5000	Automated-Microscopy	N/A	T/MIC/LP/008 T/MIC/EQ/026
		VRE Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/017, T/MIC/EQ/007
		Wound Swab	Light Microscope	Manual - Microscopy	N/A	T/MIC/LP/009, T/MIC/EQ/007
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Microbial Culture	Blood Cultures/Swabs/Fluids/Tissues	BacTAlert 3D/Manual Culture	Automated/Manual	N/A	T/MIC/LP/005, T/MIC/LP/006, T/MIC/LP/007, T/MIC/LP/008, T/MIC/LP/009, T/MIC/LP/010, T/MIC/LP/011, T/MIC/LP/012, T/MIC/LP/013, T/MIC/LP/014, T/MIC/LP/016, T/MIC/LP/017, T/MIC/LP/019, T/MIC/LP/020, T/MIC/LP/045, T/MIC/LP/050, T/MIC/EQ/003
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	S. aureus	Isolate	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/042
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Streptococcus Groups		N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/042
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques -	Clostridium difficile	Faeces	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/020

.04 Immunochromatographic methods,						
	Helicobacter pylori		N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/023
	Legionella	Urine	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/008
	Rotavirus/Adenovirus	Faeces	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/021
	S. pneumoniae	Urine	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/008
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	Investigation of Nasopharyngeal swabs for SARS-CoV-2	Nasopharyngeal Aspirates and Nasal Swabs	EasyScreen Assay on QuantStudio Molecular System	CE Marked	N/A	T/MIC/LP/053, T/MIC/EQ/026, T/MIC/EQ/028
	Xpert Xpress SARS-CoV-2 Assay	NPA and Nasal	GeneXpert	CE Marked	N/A	T/MIC/LP/053, T/MIC/EQ/023
	Xpert Xpress SARS-CoV-2/Flu/RSV		GeneXpert	Standard Method	N/A	T/MIC/LP/048, T/MIC/EQ/023
	Xpert Xpress SARS-CoV-2/Flu/RSV Plus Assay		GeneXpert	Standard Method	N/A	T/MIC/LP/048, T/MIC/EQ/023
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	C. diff Toxin	Stool	GeneXpert- PCR	Automated	Qualitative Test	T/MIC/LP/020
	Influenza A,B and RSV	Swab	GeneXpert- PCR	Automated	Qualitative Test	T/MIC/LP/048
	Norovirus G1 and G2	Stool	GeneXpert- PCR	Automated	Qualitative Test	T/MIC/LP/047
	Screening samples for CPE by PCR	Rectal swab/faeces	Cepheid GeneXpert	Based on standard	Qualitative test	T/MIC/LP/045
	Screening samples for MRSA by PCR	Nasal Groin Swab	Cepheid GeneXpert	Based on standard	Qualitative test	T/MIC/LP/016
	Screening samples for VRE by PCR	Rectal swab/faeces	Cepheid GeneXpert	Based on standard	Qualitative test	T/MIC/LP/017

1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Organism Identification	Isolates	Vitek 2 Compact/Biochemical Methods	Automated and Manual CE Marked Kits	N/A	T/MIC/LP/041, TMIC/LP/042, T/MIC/LP/043
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Susceptibility Testing		Vitek 2 Compact/Biochemical Methods	Automated and Manual CE Marked Kits	N/A	T/MIC/LP/043
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	HCV	Blood	Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay	Automated	Qualitative Test	T/MIC/LP/046
	Hepatitis B Core Antibody		Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay	Automated	Qualitative Test	T/MIC/LP/046
	Hepatitis B Surface Antibodies		Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay	Automated	Qualitative Test	T/MIC/LP/046
	Hepatitis B Surface Antigen		Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay	Automated	Qualitative Test	T/MIC/LP/046
	HIV Ag/Ab Combo		Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay	Automated	Qualitative Test	T/MIC/LP/046

1024 Preservation of microbial cultures	Preservation of Microbial Cultures	Isolates	N/A	N/A	N/A	T/MIC/RC/007
1029 Miscellaneous - .99 Miscellaneous tests	Pregnancy Test	Urine	N/A Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/029