

Schedule of Accreditation



Organisation Name	Midland Regional Hospital Tullamore
Trading As	
INAB Reg No	221MT
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Accreditation Standard	EN ISO 15189
Standard Version	2022
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
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			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/056
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen	Plasma	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/056

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification	Patient and Donor Red Cells	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/056
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing		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		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/056
	Extended Antigen Typing - Patient and Door Cells		Manual method using Gel Cards Automated 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/009, T/BTL/EQ/056
1020 Transfusion science - .99 Miscellaneous tests	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/056
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)						

Quality Office

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .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
	Albumin		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/067
	Albumin/Creatinine Ratio (ACR)	urine	Calculation	Roche Cobas 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
	Amylase	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/070
	ASOT	serum/plasma	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/071
	Aspartate Aminotransferase (AST)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/072
	Bicarbonate		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/073
	Bilirubin (Direct)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/074

Bilirubin (Total)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/075
C reactive Protein (CRP)		Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/087
Calcium	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
Cholesterol		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/082
Corrected Calcium		Calculation	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/007
Creatine Kinase (CK)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/083
Creatinine (Enzymatic)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/086
Creatinine (Jaffe)	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/085
Creatinine Clearance		Calculation	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/007
eGFR	serum/plasma	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
Glucose	serum/plasma/CSF	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/090
HDL	serum/plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/092
High Sensitivity Troponin T (HsTnT)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/103

1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Lactate DeHydrogenase (LDH)		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/094
	LDL		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/095
	Magnesium	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/096
	Microalbumin	urine	Immunoturbidimetric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/097
	NTproBNP	Serum/Plasma	Electrochemiluminescent Assay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/109
	Parathyroid Hormone (PTH)	plasma	Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/100
	Phosphate	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/098
	Potassium		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
	Sodium	serum/plasma/urine	ISE	Roche Cobas 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
	Triglyceride		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/106
	Urea	serum/plasma/urine	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/107
	Uric Acid		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/108
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Procalcitonin	serum/plasma	Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/112

1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin	Whole Blood	Enzyme Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/111
	Vancomycin		Colourimetric Assay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/110
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 Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/065
	Salicylate		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)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/066
	Cancer antigen 125 (CA 125)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/078
	Cancer antigen 15.3 (CA 15.3)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/076
	Cancer antigen 19.9 (CA 19.9)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/077
	CarcinoEmbryonic Antigen (CEA)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/080
	Human Chorionic Gonadotrophin Plus Beta (BHCG)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/091
	Prostate Specific Antigen (PSA)		Chemiluminescent Immunoassay	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/099
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
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Quality Office

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count	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)	Sysmex XN-10/ XN-20	Automated	T/HAE/LP/025, T/HAE/LP/026,

			detection and Fluorescence flow cytometry			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 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 - .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 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	Infectious Mononucleosis Screen	EDTA, Blood/Serum/Plasma	Immunoassay	Clearview IM II Kit	Manual (CE marked kit)	T/HAE/LP/028
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Quality Office

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	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/EQ/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/EQ/050
	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 Arcadia Embedding Station /Manual	Based on standard method	N/A	T/HIS/LP/033, T/HIS/EQ/052
		Paraffin Processed Human tissue	Leica Embedding Station /Manual	Manual- Based on standard method	N/A	T/HIS/EQ/005 , T/HIS/LP/033
	Microtomy	Formalin Fixed Paraffin Embedd Human Tissue	Epredia HM355S Microtome	Based on standard method	N/A	T/HIS/EQ/056 T/HIS/LP/038

		Paraffin Block of Human Tissue	Leica Microtomes/semi automatic	Based on standard method	N/A	T/HIS/EQ/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,
			Sakura Tissue'Tek VIP 6 AI Tissue Processor	Based on standard method	N/A	T/HIS/EQ/054
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Frozen section cryotomy and staining	Fresh Human Tissue / Formalin Fixed Human Tissue	Leica CM1860UV Cryostat/Manual Staining	Based on standard method	N/A	T/HIS/LP/10 T/HIS/EQ/51
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/47 T/HIS/EQ/44
	Congo Red		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/055, T/HIS/EQ/044
	Diastase PAS stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/046, T/HIS/EQ/044
	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, T/HIS/EQ/044
	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, T/HIS/EQ/044
	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, T/HIS/EQ/044
	PAS Stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/045, T/HIS/EQ/044
	Perls Prussian Blue		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/048, T/HIS/EQ/044
	Reticulin Nuclear Fast Red		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/049, T/HIS/EQ/044
	Verhoeff Elastic stain		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/053, T/HIS/EQ/044
	Warthin and Starry		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/043, T/HIS/EQ/044
	Ziehl Neelsen		Dako Artisan/ Automated	CE	N/A	T/HIS/LP/054, T/HIS/EQ/044
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	Dual Stain P40/CK5/6	Paraffin section on glass slide	Automated Benchmark Ultra	N/A	CE Marked	T/HIS/22 T/HIS/EQ/45
1051 Histopathology - .09 Immunohistochemistry	D2 40-Podoplanin			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		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		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022

DOG-1, BOB-1,
Dual Stain CD31/AE1/AE3
Dual Stain CD34/ AE1-3
Dual stain D2-40/ AE1-3
Dual stain P63/CK5-6
Dual Stain TTF/Napsin
E-Cadherin, EMA, ER
Glycophorin A
HMB45,Melan A,
HSA,Ki-67, Oct 2
Kappa Probe, Lambda Probe
MLH1, MSH2, MSH6, PMS-2
MOC31, MUM-1,
Napsin-A, PLAP, GFAP

Benchmark Ultra/ Optiview	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 + 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 + 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/ 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

	P16, P40,P53		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	P57,P63,P504s		Benchmark Ultra/Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	PAX 8		Benchmark Ultra/ Optiview	Non-CE marked	N/A	T/HIS/EQ/045, T/HIS/LP/022
	PR,PSA		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	S100 Antigen, Synaptophysin		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	SOX 10		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Tdt, 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
1052 Cytopathology - .02 Non gynaecological cytology	Vimentin, WT-1	Human tissue or fluid	Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Cytology sample preparation and description		Shandon Cytospin/Thinprep Genesis	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/048, 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

Quality Office

Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
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
		CPE 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 Flow Cytometry	Automated- Microscopy	N/A	T/MIC/LP/008 T/MIC/EQ/027
		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/ Faeces	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 - .04 Immunochromatographic methods,	Clostridium difficile	Faeces	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/020
	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	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

hybridization, CE marked commercial systems						
	Xpert Xpress Cov-2 Plus kit	NPA and Nasal Swab	GeneXpert	CE Marked	N/A	T/MIC/EQ/023
		NPA and Nasal Swabs	Gene Xpert	CE Marked	N/A	T/MIC/EQ/023, MRHT/PPPG/MIC/37
	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	CE Marked	N/A	T/MIC/LP/048, T/MIC/EQ/023
	Xpert Xpress SARS-CoV-2/Flu/RSV Plus Assay		GeneXpert	CE Marked	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
	Central Nervous System Pathogens	CSF	FilmArray Torch - PCR	Automated	Qualitative Test	T/MIC/LP/056
	Enteric Pathogens	Stool	EasyScreen Assay on QuantStudio Molecular System	Automated	Qualitative Test	T/MIC/LP/019
	Influenza A,B and RSV	Swab	GeneXpert- PCR	CE marked	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
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis	Determination of Minimum Inhibitory Concentrations	Isolate	Gradient Strips	CE marked	N/A	T/MIC/LP/043
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
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy		Bacterial isolates/Fungi	MS-PRIME/MALDI-TOF Spectroscopy	Automated	N?A	T/MIC/LP/057 T/MIC/EQ/033
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Susceptibility Testing	Isolates	Vitek 2 Compact/Biochemical Methods	Automated and Manual CE Marked Kits	N/A	T/MIC/LP/043
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antimicrobial Resistance Testing using Disc Diffusion	Isolate	Disk Diffusion	CE marked	N/A	T/MIC/LP/043

1024 Preservation of microbial cultures	Preservation of Microbial Cultures	Isolates	N/A	N/A	N/A	T/MIC/RC/007
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