

# Schedule of Accreditation



Organisation Name	Midland Regional Hospital Tullamore
Trading As	
INAB Reg No	221MT
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Accreditation Standard	ISO 15189
Date Initially Awarded	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 <sup>1</sup>	Yes

<sup>1</sup> 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, 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
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods		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 - .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	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
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)*

## 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
	BNP	plasma	Chemiluminescent Immunoassay	Abbott Architect 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
Calcium		Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/079
Chloride		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
Lactate	plasma	Photometric	Roche Cobas Analyser	Manufacturer CE marked method	T/BIO/LP/093
Lactate DeHydrogenase (LDH)	serum/plasma	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
	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 - .06 Blood pH and gas tensions	pCO2	Whole Blood	Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	pH		Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	PO2		Amperometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	TCO2		Calculation	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Calcium		Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	Chloride		Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018



	Glucose		Amperometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	Lactate		Amperometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	Potassium		Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	Sodium		Potentiometric	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
	Standard Bicarbonate		Calculation	GEM 5000 Blood Gas Analysers	Manufacturer CE marked method	T/BIO/EQ/018
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin	serum/plasma	Chemiluminescent Immunoassay	Abbott Architect Analyser	Manufacturer CE marked method	T/BIO/LP/013
	Vancomycin		Chemiluminescent Immunoassay	Abbott Architect 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 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 - .61 Hb A1c	HbA1c	Whole Blood	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

## 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	Quantitative Flow Cytometry and CN-Free Colourimetric	Advia 2120i	Automated	T/HAE/EQ/001, T/HAE/EQ/003 & T/HAE/LP/005
1030 Haematology - .02 Visual examination of blood films	Manual WBC Differential & Blood Film Review		Slide Stainer & Morphological	Wescor Stainer	Automated	T/HAE/EQ/015, T/HAE/LP/007
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	Quantitative Flow Cytometry	Advia 2120i	Automated	T/HAE/EQ/001, T/HAE/EQ/003 & T/HAE/LP/005
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Quantitative Flow Cytometry	Advia 2120i	Automated	T/HAE/EQ/001, T/HAE/EQ/003 & T/HAE/LP/005
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	Prothrombin Time (PT), Activated	Plasma	Quantitative, Turbidimetric,	ACL Top 550	Automated	ISO 15189 T/HAE/EQ/026

haemostasis related tests	Partial Thromboplastin Time (APTT), Fibrinogen (Derived Fib), Fibrinogen (Clauss Fib), International Normalised Ratio (INR), D-Dimer (D-Dimer)		Chromogenic and Immunological			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

## 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 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
	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
	Haematoxylin Van Gieson		Manual	Non CE/Based on standard method	N/A	T/HIS/LP/051
	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 Staining		Ventana Benchmark Ultra / In situ hybridisation	Based on standard method	Qualitative	T/HIS/LP/022
	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
CK AE1/AE3
CMV, Cyclin D1, Desmin, DOG -1
DOG-1, BOB-1, TdT,
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,GFAP
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,

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 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 +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 + 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/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

	Napsin-A, PLAP, GFAP		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
	P40, D2 40- Podoplanin		Benchmark Ultra/ Optiview	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	P57,P63,P504s, PLAP		Benchmark Ultra/ Optiview DAB Kit	CE	N/A	T/HIS/EQ/045, T/HIS/LP/022
	Podoplanin (D2-40), 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
	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

## 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
		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
		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	iQ200	Automated-Microscopy	N/A	T/MIC/LP/008, T/MIC/EQ/007
		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 - .04 Immuno-chromatographic methods,	Clostridium difficile	Faeces	N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/020
	Cryptosporidium/Giardia/Ova and Parasites		N/A - Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/022
	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 - .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 -	Organism Identification	Isolates	Vitek 2 Compact/Biochemical Methods	Automated and Manual CE Marked Kits	N/A	T/MIC/LP/041, T/MIC/LP/042, T/MIC/LP/043

.01 Biochemical methods , CE marked commercial systems							
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	Faecal Occult Blood	Faeces	N/A Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/024
	Pregnancy Test	Urine	N/A Kit	Manual - CE Marked	Qualitative Test	T/MIC/LP/029