

Schedule of Accreditation



Organisation Name	HSE West and Northwest Hospitals Group, Letterkenny University Hospital, Pathology Department
Trading As	Health Service Executive
INAB Reg No	210MT
Contact Name	Mary McDaid
Address	Pathology Department, Letterkenny University Hospital, Letterkenny, Donegal
Contact Phone No	0749123726
Email	marym.mcdaid@hse.ie
Accreditation Standard	EN ISO 15189
Date of award of accreditation	09/12/2008
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	

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	Pathology Department	Letterkenny University Hospital, Letterkenny, Donegal, Ireland

Scope of Accreditation

Pathology Department

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) typing	Red Blood Cells and Plasma	Automated BIO-RAD IH500			LP-BT-0029 Operation of the Biorad IH500
		Red Blood Cells and Plasma	Manual Tube Method Manual Gel System Automated BIO-RAD IH-1000			LP-BT-017 (Manual Tube Method) LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO-RAD IH-1000)
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods		Red Blood Cells and Plasma	Automated BIO-RAD IH500, BIO-RAD IH-1000			LP-BT-0029 LP-BT-0035

1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Manual Gel System Automated BIO-RAD IH-1000			LP-BT-0015 (Manual Gel System) LP-BT- 0035 (BIO-RAD IH- 1000)
			Automated BIO-RAD IH500			LP-BT-0029 Operation of the Biorad IH500
1020 Transfusion science - .04 Identification of blood group antibodies	Identification of Antibodies		Manual Gel System Automated BIO-RAD IH-1000			LP-BT-0015 (Manual Gel System) LP-BT- 0035 (BIO-RAD IH- 1000)
			Automated BIO-RAD IH500			LP-BT-0029 Operation of the Biorad IH500
1020 Transfusion science - .05 Cross match compatible donor units	Red Cell Compatibility Testing		Computer assisted compatibility testing (electronic issue)			LP-BT-0037 Electronic issue of red cells
	Red Cell Compatibility Testing	Plasma	Manual Gel System			LP-BT-0015 (Manual Gel System)
1020 Transfusion science - .06 Red cell phenotyping	Phenotyping	Red Cells	Manual Gel System Automated BIO-RAD IH-1000, BIO-RAD IH500, Manual gel system	CE	NA	LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO- RAD IH-1000) LP-BT-0029 Operation of the Biorad IH500
			Automated BIO-RAD IH500, IH-1000, Manual gel system	CE	N/A	LP-BT-0029 Operation of the Biorad IH500 LP-BT-0015 (Manual Gel System) LP-BT-0035 (BIO- RAD IH-1000)
1020 Transfusion science - .09 Direct antiglobulin test	Direct Coombs Test (DCT)			Automated BIO-RAD IH500, BIO-RAD IH-	CE	

			1000, Manual Gel System			Gel System) LP-BT-0035 (BIO-RAD IH-1000)
<i>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)</i>						

Pathology Department

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	Adjusted Calcium	Serum	System based	Roche c702/calculated	Standard Method	LP-CHEM-004
	Alanine Aminotransferase (ALT)		Enzymatic colorimetric	Roche c 702	Standard Method	LP-CHEM-004
	Albumin		Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
	Alkaline Phosphatase		Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
	Ammonia		Enzymatic method	Roche c702	Standard Method	LP-CHEM-004
	Amylase	Serum Urine	Enzymatic Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
	Aspartate Aminotransferase (AST)	Serum	Colorimetric	Roche c 702	Standard Method	LP-CHEM-004

Bicarbonate		Enzymatic Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
Bilirubin - Direct		Diazo	Roche c 702	Standard Method	LP-CHEM-004
Bilirubin - Total		Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
C Reactive Protein (CRP)		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
CA125		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
Calcium	Serum/ Urine	Photometric	Roche c702	Standard Method	LP-CHEM-004
Calcium/ Creatinine Ratio	Urine	Calculation	Roche c702	Standard Method	LP-CHEM-004
Chloride	Serum/ Urine	Indirect (Non selective electrodes)	Roche ISE	Standard Method	LP-CHEM-004
Cholesterol	Serum	Enzymatic Colorimetric	Roche c 702	Standard Method	LP-CHEM-004
Creatine Kinase (CK)		NAS (IFCC)	Roche c702	Standard Method	LP-CHEM-004
Creatinine (Enzymatic)	Serum/ Urine	Enzymatic Colorimetric	Roche c702	Standard Method	LP-CHEM-004
eGFR	Serum	Calculated	Roche c702	Standard Method	LP-CHEM-004
Gamma Glutamyl Transferase		Enzymatic Colorimetric	Roche c702	Standard Method	LP-CHEM-004
Glucose	Flouride Oxalate/ CSF	Enzymatic Colorimetric	Roche c702	Standard Method	LP-CHEM-004
High Density Lipoprotein (HDL)	Serum	Enzymatic Colorimetric	Roche c702	Standard Method	LP-CHEM-004
Lactate	Flouride Oxalate	Colorimetric	Roche c702	Standard Method	LP-CHEM-004

	Lactate Dehydrogenase	Serum	LtoP glucamine (IFCC)	Roche c702	Standard Method	LP-CHEM-004
	LDL Cholesterol		Enzymatic Colorimtric	Roche c702	Standard Method	LP-CHEM-004
	Magnesium		Colorimtric endpoint	Roche c702	Standard Method	LP-CHEM-004
	Osmolality	Serum/ Urine	Freezing Point Depression	Osmo 1	Standard Method	LP-CHEM-0015
	Phosphate	Serum/Urine	Molydate UV	Roche c702	Standard Method	LP-CHEM-004
	Potassium		Indirect ISE	Roche c702	Standard Method	LP-CHEM-004
	Pro Calcitonin	Serum	Sandwich principle	Roche e801	Standard Method	LP-CHEM-004
	Pro-BNP		Electrochemiluminescence/SANDWICH STEP2	Roche c801	Standard Method	LP-CHEM-004
			Electrochemiluminescence/SANDWICH STEP2	Roche c801/5-35000pg/ml	Standard Method	LP-CHEM-004
	Protein Creatinine Ratio		Enzymatic colorimtric	Roche c702	Standard Method	LP-CHEM-004
	Sodium	Serum/ Urine	Indirect ISE	Roche c702	Standard Method	LP-CHEM-004
	Triglycerides	Serum	Enzymatic Colorimtric	Roche c702	Standard Method	LP-CHEM-004
	Troponin T High Sensitivity		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Urea	Serum/ Urine	KIMS	Roche c702	Standard Method	LP-CHEM-004
	Uric Acid	Serum/Urine	Enzymatic Colorimtric	Roche c 702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .02	Anti Cyclic Citrullinated Peptide (Anti-CCP)	Serum	Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004

Proteins, quantitative analysis						
	Complement C3		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
	Complement C4		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
	Cortisol		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Immunoglobulin A		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
	Immunoglobulin G		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
	Immunoglobulin M		Immunoturbidimetric assay	Roche c702	Standard Method	LP-CHEM-004
	Interleukin-6		Electrochemiluminescence Immunoassay	Roche e801	CE	LP-CHEM-004
	Thyroid Stimulating Hormone (TSH)		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Total Protein	Serum/ CSF/ Urine	Colorimetric	Roche c702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Protein Electrophoresis	Serum/Urine	Electrophoresis	Sebia Hydrasys	Standard Method	LP-CHEM-006
1061 Clinical Chemistry - .05 CO-oximetry	Carboxyhaemoglobin	Blood	Absorption Spectrophotometry	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Methaemoglobin		Absorption Spectrophotometry	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
1061 Clinical Chemistry - .06	Base Excess		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005

Blood pH and gas tensions						
	HCO3 actual		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	HCO3 standard		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	O2 Saturation		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Pco2		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Ph		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Po2		Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
			Calculation	Siemens Rapid Point 500	Standard Method	LP-CHEM-005
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Glucose			Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Ionised Calcium			Siemens Rapid Point 500	Standard Method	LP-CHEM-005
	Lactate			Siemens Rapid Point 500	Standard Method	LP-CHEM-005
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine	Serum	Agglutination Immunassay	Roche c702	Standard Method	LP-CHEM-004

	Digoxin		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Ethanol	Serum/ Urine	Enzymatic colorimetric	Roche c702	Standard Method	LP-CHEM-004
	Gentamicin	Serum	Enzymatic Immunoassay	Roche c702	Standard Method	LP-CHEM-004
	Lithium		Colorimetric	Roche c702	Standard Method	LP-CHEM-004
	Paracetamol		Enzymatic colorimetric	Roche c702	Standard Method	LP-CHEM-004
	Phenytoin		KIMS	Roche c702	Standard Method	LP-CHEM-004
	Salicylate		Enzymatic colorimetric	Roche c702	Standard Method	LP-CHEM-004
	Vancomycin		KIMS	Roche c702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .20 Hormones	Follicle Stimulating Hormone (FSH)		Electrochemiluminescence/SANDWICH-STEP2	Roche e801	Standard Method	LP-CHEM-004
	LH		Electrochemiluminescence/SANDWICH-STEP2	Roche e801	Standard Method	LP-CHEM-004
	Oestradiol		Electrochemiluminescence/COMP-STEP2	Roche e801	Standard Method	LP-CHEM-004
	Progesterone		Electrochemiluminescence/COMP-STEP2	Roche e801	Standard Method	LP-CHEM-004

	Prolactin		Electrochemiluminescence/SANDWICH-STEP2	Roche e801	Standard Method	LP-CHEM-004
	PTH	EDTA/PLASMA	Electrochemiluminescence/SANDWICH STEP2	Roche e801	Standard Method	LP-CHEM-004
	T3- Free	Serum	Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	T4- Free		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Testosterone		Electrochemiluminescence/SANDWICH STEP 2	Roche e801	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .40 Iron studies	Ferritin		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Iron		Colorimetric	Roche c702	Standard Method	LP-CHEM-004
	Transferrin		Immunoturbidimetric	Roche c702	Standard Method	LP-CHEM-004
	Transferrin Saturation		Calculated	Roche c702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	Vitamin B12		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004

	CA15-3		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	CA19-9		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	CEA		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	HCG		Electrochemiluminescence/SANDWICHSTEP2	Roche e801	Standard Method	LP-CHEM-004
	TPSA		Electrochemiluminescence/SANDWICH-STEP2	Roche e801	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .61 Hb A1c	HbA1c	Blood	HPLC	Medicon Adams A1c, HA8180	Standard Method	LP-CHEM-007
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor	Serum	Immunoturbidimetric assay	Roche C702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .88 b2-microglobulin	B2 Microglobulin		Immunoturbidimetric	Roche Cobas 702	Standard Method	LP-CHEM-004
1061 Clinical Chemistry - .99 Miscellaneous tests	Haemochromatosis	Blood			Standard Method	LP-CHEM-0021

Pathology Department

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	Haematocrit	Blood		Sysmex XN-9000	Calculation from Area of Curve	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Haemoglobin			Sysmex XN-9000	Spectrophotometric Analysis	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	MCH			Sysmex XN-9000	Calculation with RBC and HgB	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	MCHC			Sysmex XN-9000	Calculation with HCT and HgB	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU

	Mean Cell Volume
	Platelet Count
	Red Cell Count
	White Cell Count
1030 Haematology - .02 Visual examination of blood films	Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils

	Sysmex XN-9000	Calculation with RBC and HCT	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Aperture Impedance Counting	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Aperture Impedance Counting	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film

						Examination and Manual Differential
	Red Cell Morphology			Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film Examination and Manual Differential
	Visual examination of blood films	EDTA Blood Film	Sysmex DM-1200 Automated digital morphology system with operator reclassification and result validation	N/A	CE Marked	LP-HAEM-0062 Operation of the DM1200 Digital Morphology
	White Cell Morphology	Blood		Sysmex SP-10 Slide unit/ Manual Stain/ Microscope	Staining/ Microscopy	LP-HAEM-0054 Operation of the SP-10 Slide Preparation Unit LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides LP-HAEM-0001 Blood Film Preparation LP-HAEM-0003 Blood Film Examination and Manual Differential

1030 Haematology - .03 Erthrocyte sedimentation rate	ESR (Automated)
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count
	Eosinophil Count
	Lymphocyte Count
	Monocyte Count
	Neutrophil Count
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Analysis

	Interliner ESR analyser		LP-HAEM-0056 Operataion of the Interliner ESR
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000 LP-HAEM-0053 Authorisation on the EPU
	Sysmex XN-9000	Flow Cytometry using Semi Conductor Laser	LP-HAEM-0052 Operation of the XN9000

				LP-HAEM-0053 Authorisation on the EPU
1030 Haematology - .09 Examination of malarial parasites	Binax NOW Screening Test		Immuno-Qualitative Assay	LP-HAEM-0004 Identification of Malarial Parasites LP-HAEM-0014 RDT Malaria, Binax and CareUS
	Blood film examination		Staining/ Microscopy	LP-HAEM-0004 Identification of Malarial Parasites LP-HAEM-0006 Manual Staining of Blood Films and Bone Marrow Slides
	Rapid Diagnosis of Malaria	Manual Serological Test (immunochromatographic test) for Malarial Antigens, CareUS Malaria	N/A	CE Marked LP-HAEM-0004 Identification of Malarial Parasites LP-HAEM-0014 RDT Malaria, Binax and CareUS
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen (Sickledex)		Kit	Qualitative Solubility Test LP-HAEM-0011 Sickledex Screening Test
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer Test		Kit	Acid Elution/ Microscopy LP-HAEM-0008 Kleihauer Test for detection of Foetal Hb
1030 Haematology - .40 Limited haemostasis related tests	Anti Factor 10a Assay	Plasma	Sysmex CS2500	Clotting Assay LP-HAEM-0058 Operation of the CS Series Analysers LP-HAEM-0025 Biophen Heparin Anti Xa Assay

	FIX
	FVIII
	FX
	1030 Haematology - .41 General haemostasis related tests
	Activated Partial Thromboplastin Time (APTT)
	D-Dimer
	Fibrinogen (Clauss)

	Sysmex CS2500	Clotting Assay	LP-HAEM-0058 Operation of the CS Series Analysers LP-HAEM-0035 Intrinsic Factor Assay
	Sysmex CS2500	Clotting Assay	LP-HAEM-0058 Operation of the CS Series Analysers LP-HAEM-0035 Intrinsic Factor Assay
	Sysmex CS2500	Clotting Assay	LP-HAEM-0058 Operation of the CS Series Analysers LP-HAEM-0036 Extrinsic Factor Assay
	Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0024, Determination of APTT LP-HAEM-0058 Operation of the CS Series Analysers
	Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0040 DDimer Test, Innovance LP-HAEM-0058 Operation of the CS Series Analysers
	Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0037 Claus Fibrinogen LP-HAEM-0058 Operation of the CS Series Analysers

	International Normalised Ratio (INR)			Sysmex CS2500 Sysmex CS5100	Ratio Calculation	LP-HAEM-0023 Determination of PT + INR LP-HAEM-0058 Operation of the CS Series Analysers
	Prothrombin Time (PT)			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0023 Determination of the PT + INR LP-HAEM-0058 Operation of the CS Series Analysers
	Thrombin Time			Sysmex CS2500 Sysmex CS5100	Clotting Assay	LP-HAEM-0027 Thrombin Time LP-HAEM-0058 Operation of the CS Series Analysers
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screening	Plasma or serum			Qualitative detection of Heterophile antibodies	LP-HAEM-0042 Infectious Mononucleosis Screen by Clearview IM

Pathology Department

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 Haematoxylin and Eosin Staining	Human Tissue	Automated/Leica stainer	CE Marked	N/A	LP-HISTO-0134
	Coverslipping		Automated/Leica Coverslipper	CE Marked	N/A	LP-HISTO-0134
	Cut Up		Manual/AFOS Bench, Leica IPC	Based on Standard Method	N/A	LP-HISTO-0031
	Decalcification		Manual	Based on Standard Method	N/A	LP-HISTO-0031
	Embedding		Automated/Leica Embedding Centre	CE Marked	N/A	LP-HISTO-0076
	Manual Haematoxylin and Eosin Staining		Manual	Based on Standard Method	N/A	LP-HISTO-0059, LP-HISTO-0064
	Microtomy		Manual/Microtome (Microm), Eprelia Slidemate AS Printer	Based on Standard Method	N/A	LP-HISTO-0033
			Manual/Microtome (Microm), Thermo Scientific Slidemate Printer	Based on Standard Method	N/A	LP-HISTO-0033
	Tissue Processing		Automated/ Sakura VIP 6 AI	CE Marked	N/A	LP-HISTO-0128
1051 Histopathology - .02 Processing fresh	Cut Up		Manual	Based on Standard Method	N/A	LP-HISTO-0031

specimens for frozen section examination	
	Frozen Section Cryotomy & Staining
1051 Histopathology - .03 Histochemistry	Alcian Blue
	Alcian Blue/DPAS
	Alcian Blue/PAS
	Congo Red
	Diastase Periodic Acid Schiffs Reaction (DPAS)
	Gomori's Reticulin
	Gram Stain
	Grocott Technique
	Haematoxylin Van Gieson
	Martius Scarlet Blue (MSB)
	Masson Fontana
	Masson Trichrome
	Miller's EVG
	Periodic Acid Schiffs Reaction (PAS)

Manual/Cryostat	Based on Standard Method	N/A	LP-HISTO-0040, LP-HISTO-0041
Manual	Based on Standard Method	N/A	LP-HISTO-0002
Manual	Based on Standard Method	N/A	LP-HISTO-0050
Manual	Based on Standard Method	N/A	LP-HISTO-0006
Manual	Based on Standard Method	N/A	LP-HISTO-0122
Manual	Based on Standard Method	N/A	LP-HISTO-0007
Manual	Based on Standard Method	N/A	LP-HISTO-0009
Manual	Based on Standard Method	N/A	LP-HISTO-0004
Manual	Based on Standard Method	N/A	LP-HISTO-0020
Manual	Based on Standard Method	N/A	LP-HISTO-0038
Manual	Based on Standard Method	N/A	LP-HISTO-0017
Manual	Based on Standard Method	N/A	LP-HISTO-0015
Manual	Based on Standard Method	N/A	LP-HISTO-0011
Manual	Based on Standard Method	N/A	LP-HISTO-0014
Manual	Based on Standard Method	N/A	LP-HISTO-0005

	Perls Prussian Blue		Manual	Based on Standard Method	N/A	LP-HISTO-0008
	Warthin & Starry Method		Manual	Based on Standard Method	N/A	LP-HISTO-0125
	Ziehl-Neelsen (ZN)		Manual	Based on Standard Method	N/A	LP-HISTO-0012
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and reporting of Human tissue specimens. Specialist areas excluded: Medical Renal Pathology, Paediatric Pathology, Perinatal Pathology, Neuropathology, Breast Screening Pathology. Specialist areas included: Cytopathology (non-gynae)	Human Tissue Human Tissue or fluid	Manual/Microscope	Based on Standard Method	N/A	LP-HISTO-0034, LP-HISTO-0080, LP-HISTO-0081, LP-HISTO-0082, LP-HISTO-0083, LP-HISTO-0084, LP-HISTO-0085, LP-HISTO-0091, LP-HISTO-0097, LP-HISTO-0098, LP-HISTO-0099, LP-HISTO-0100
			Manual/Microscope/Nikon Eclipse Ci-L	Based on Standard Method	N/A	LP-HISTO-0034, LP-HISTO-0080, LP-HISTO-0081, LP-HISTO-0082, LP-HISTO-0083, LP-HISTO-0084, LP-HISTO-0085, LP-HISTO-0091, LP-HISTO-0097, LP-HISTO-0098, LP-HISTO-0099, LP-HISTO-0100
1052 Cytopathology - .02 Non gynaecological cytology	Cell Block Preparation	Human Tissue/ Fluid	Manual/Automated/Centrifuge	CE Marked	N/A	LP-HISTO-0130

	Coverslipping	Manual/Automated/Leica Coverslipper	CE Marked	N/A	LP-HISTO-0134, LP-HISTO-0064
	Processing	Automated/Thin Prep Genesis/Cytocentrifuge	CE Marked	N/A	LP-HISTO-0043, LP-HISTO-0027, LP-HISTO-0048, LP-HISTO-0025, LP-HISTO-0045, LP-HISTO-0111, LP-HISTO-0138
	Staining	Manual/Automated/Cytocentrifuge	CE Marked	N/A	LP-HISTO-0043, LP-HISTO-0027, LP-HISTO-0048, LP-HISTO-0025, LP-HISTO-0045, LP-HISTO-0111 LP-HISTO-0131
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and Reporting of non-gynaecological Cytology	Automated/Leica stainer	CE Marked	N/A	LP-HISTO-0134
		Manual/Automated	CE Marked	N/A	LP-HISTO-0133
		Manual/Microscope	Based on Standard Method	N/A	LP-HISTO-0034, LP-HISTO-0081, LP-HISTO-0083, LP-HISTO-0084, LP-HISTO-0091, LP-HISTO-0098, LP-HISTO-0100, LP-HISTO-0097
		Manual/Microscope/Nikon Eclipse Ci-L	Based on Standard Method	N/A	LP-HISTO-0034, LP-HISTO-0081, LP-HISTO-0083, LP-HISTO-0084, LP-HISTO-0091, LP-HISTO-0098, LP-HISTO-0100, LP-HISTO-0097

Pathology Department

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 of General bacteriology	Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CPE) IV	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells. Based on UK Standards for Microbiology Investigations, Public Health England		LP- MICRO- 0009, LP- MICRO- 0018, LP- MICRO- 0010, LP- MICRO- 0014, LP- MICRO- 0012, LP- MICRO- 0001, LP- MICRO- 0002, LP- MICRO- 0004, LP- MICRO- 0007, LP-

						MICRO-0008, LP- MICRO-0019, LP- MICRO-0016, LP- MICRO-0022, LP- MICRO-0030, LP- MICRO-0006, LP- MICRO-0020, LP- MICRO-0066, LP- MICRO-0029, LP- MICRO-0036, LP- MICRO-0037
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for	Blood Culture Analysis	Blood/body fluids	BacT/ALERT Virtuo system for Blood Cultures/Colorimetric detection	CE	Positive/Negative	EQ-MICRO-0025 LP-MICRO-0028

growth - .01 Culture of general bacteria						
	Culture of general bacteria	Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CPE)	Culture Media	Culture, sensitivity testing as required		LP-MICRO-0009, LP-MICRO-0018, LP-MICRO-0010, LP-MICRO-0014, LP-MICRO-0012, LP-MICRO-0001, LP-MICRO-0002, LP-MICRO-0004, LP-MICRO-0007, LP-MICRO-0008, LP-MICRO-0019, LP-MICRO-0016,

						LP-MICRO-0022, LP-MICRO-0030, LP-MICRO-0006, LP-MICRO-0020, LP-MICRO-0066, LP-MICRO-0029, LP-MICRO-0036, LP-MICRO-0037
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Clostridium Difficile GDH and Toxin	Faeces	Kit	Immunochromatographic.	Positive/ Negative	LP-MICRO-0099
	H. pylori /CerTest		Immunochromatographic	CE marked	Qualitative	LP-IMMUNO-002
	Legionella Urine Antigen	Urine	Kit	Immunochromatographic.	Positive/ Negative	LP-MICRO-0062

1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Rotavirus/ Adenovirus	Faeces	Kit	Immunochromographic.	Positive/ Negative	LP-MICRO-0036
	Urinary Pneumococcal antigens	Urine	Kit	Immunochromographic.	Positive/ Negative	LP-MICRO-0063
	Blood culture ID 2 panel (BCID2)	Blood culture broth	Biofire Filmarray Torch	CE	Detected/Not Detected	EQ-MICRO-0028, LP-MICRO-0121
	C difficile	Faeces	GeneXpert/ PCR	CE	Qualitative	LP-MICRO-0110
	Carbapenemase producing enterobacterales (CPE) screening	Copan fecal swabs	Roche FLOW Flex	CE	Detected/Not Detected	EQ-MICRO-0021, LP-MICRO-0108
	Carbapenemase producing enterobacterales (CPE) screening/Xpert Carba-R		GeneXpert/Real-time PCR	CE marked	Qualitative	EQ-MICRO-0023, LP-MICRO-0123
	Meningitis/encephalitis panel (ME)	CSF	Biofire Filmarray Torch	CE	Detected/Not Detected	EQ-MICRO-0028, LP-MICRO-0220
	Respiratory 2.1plus panel (RP2.1 plus)	Nasopharyngeal/oropharyngeal swabs	Biofire Filmarray Torch	CE	Detected/Not Detected	EQ-MICRO-0028, LP-

					MICRO-0119
SARS-CoV-2	Nasopharyngeal/ Oropharyngeal swabs	GeneXpert/RT-PCR	CE	Positive/Negative	EQ- MICRO- 0023 LP- MICRO- 0111
	Nasopharyngeal/oropharyngeal swabs	Roche Cobas 6800	CE	Detected/Not Detected	EQ- MICRO- 0027, LP- MICRO- 0118
SARS-CoV-2, Influenza A/B, RSV	Nasopharyngeal/ Oropharyngeal swabs	GeneXpert/RT-PCR	CE	Positive/Negative	EQ- MICRO- 0023 LP- MICRO- 0112
Tib Molbiol Lightmix modular Salmonella, Shigella, Campylobacter, Cryptosporidium, Giardia	Faeces	Roche FlowFlex/Real- time PCR	CE marked	Qualitative	EQ- MICRO- 0021, LP- MICRO- 0127
Xpert Norovirus		GeneXpert/Real-time PCR	CE marked	Qualitative	EQ- MICRO- 0023, LP- MICRO- 0131
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid	Tib Molbiol Lightmix modular Stx1/Stx2	Roche FlowFlex/Real- time PCR	In house developed	Qualitative	EQ- MICRO- 0021, LP- MICRO- 0127

amplification tests, in house developed assays						
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Commercial Biochemical Identification	Isolates from swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CPE)	Vitek 2	Vitek ID Cards		LP- MICRO-0038-44 LP- MICRO-0046, LP- MICRO-0048-58, LP- MICRO-0064-66, LP- MICRO-0068-70,
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification using MALDI-TOF		Vitek MS/ Maldi-Tof	Mass Spectrophotometry		LP- MICRO-0038-44 LP- MICRO-0046, LP- MICRO-0048-58, LP- MICRO-0064-66, LP- MICRO-0068-70,
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general	Antifungal Susceptibility	Yeast isolates	Manual	Sensititre		MP- MICRO-0015

bacteria (rapidly growing aerobes) - .03 Yeasts						
	Antifungal susceptibility testing/Micronaut		Broth microdilution	CE marked		MP-MICRO-0015
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antibiotic Susceptibility	Isolates from Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CPE)	Manual	MIC Strips		MP-MICRO-0015
			Vitek 2	Vitek Susceptibility Cards		EQ-Micro-0002, MP-MICRO-0015
		Isolates from Swabs: eye, ear, throat, genital, nose, mouth, superficial and deep seated wounds. IV Cannulae and fluids from normally sterile body sites . sputum, pus, tissue, urine, CSF, Faeces, Screening swabs (MRSA, VRE, CPE)	Zone Reader	Disc Diffusion		EQ-Micro-0015, MP-MICRO-0015
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE	Anti Hepatitis B	Serum	Roche e801	Electrochemiluminescence Immunoassay	2-1.000 IU/L	LP-CHEM-004

marked commercial systems						
	Anti Streptolysin O (ASO)		Roche c702 Immunoturbidimetric	CE		LP-CHEM-004
	Hepatitis A		Roche E801	Electrochemiluminescence Immunoassay	Standard Method	LP-CHEM-004
	Hepatitis B		Roche E801	Electrochemiluminescence SANDWICH STEP 2	Standard method	LP-CHEM-004
	Hepatitis C		Roche E801	Electrochemiluminescence SANDWICH STEP2	Standard method	LP-CHEM-004
	HIV		Roche E801	Electrochemiluminescence/SANDWICH STEP 2	Standard Method	LP-CHEM-004
	Rubella		Roche e801	Standard	Standard Method	LP-CHEM-004
	Syphilis		Roche E801	Electrochemiluminescence	Standard Method	LP-CHEM-004
1024 Preservation of microbial cultures	Preservation of microbial cultures	Isolates	Frozen	Storage Beads		LP-MICRO-0026
1029 Miscellaneous - .99 Miscellaneous tests	Automated enumeration of clinical parameters including human cells in urine and body fluids	Urine, Body fluids	UF5000/Flow cytometry	CE marked	Quantitative/semi-quantitative	EQ-MICRO-0031

