

Schedule of Accreditation



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Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2022
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	Department of Laboratory Medicine	Department of Laboratory Medicine-Quality Office, Parnell Square, Dublin, D1

Scope of Accreditation

Department of Laboratory Medicine

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 and Rh D grouping of blood	Red Cells Plasma / Serum	Manual method.	Column Agglutination Technology (CAT) Microtitre Plate, Tube Technology	N/A	LM-BT-0002
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	ABO and RhD grouping of blood	Red cells Plasma Serum	Ortho Vision	Column Agglutination Technology (CAT) CE Marked	N/A	LP-BT-0063
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma / Serum	Automated Ortho Vision.	Column Agglutination Technology (CAT) , Tube Technology	N/A	LP-BT-0063

		Plasma and serum	Manual method	Column Agglutination Technology (CAT) CE Marked	N/A	LM-BT-0003 & LM-BT-0022
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification	Plasma / Serum	Manual/BioVueand Vision	Column Agglutination Technology (CAT)		LM-BT-0004
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing		Manual / Biorad BioVue	Column Agglutination Technology (CAT)		LM-BT-0022 LM-BT-0010
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping	Red Cells	Manual BioVue and Tube	Column Agglutination Technology (CAT) , Tube Technology		LM-BT-0006
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antibody Test		Manual BioVue (CAT) and Tube	Column Agglutination Technology (CAT) , Tube Technology CE marked	N/A	LM-BT-0005
				Ortho Vision	Column Agglutination Technology (CAT) CE marked	N/A
1020 Transfusion science - .99 Miscellaneous tests	Antibody Titre	Plasma / Serum	Manual bioVue and Vision	Column Agglutination Technology (CAT)		LM-BT-0013
	FMH Estimation	EDTA red Cells	DX Flex flow cytometer	CE marked BRAD/AEVZ		LP-BT-0066, LM-BT-0019

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)

Department of Laboratory Medicine

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	Albumin **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	ALP **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	ALT		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	ALT **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Ammonia **1234	EDTA Plasma	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Amylase **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	AST **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Bile Acids **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Calcium **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Chloride **24	Lithium Heparin / Urine	Indirect ISE	Roche Cobas Pure	CE Method	LP-BIO-0034
	CK **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Corrected Calcium Calculation **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034

Creatinine **1234	Lithium Heparin / Urine	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Creatinine Clearance Calculation	24hr Urine Collection	Calculated Test	Roche Cobas Pure	CE Method	LP-BIO-0034
CRP **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Direct Bilirubin **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Folate **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
Fructosamine/Corrected Fructosamine**1234	Lithium Heparin / serum	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
GGT **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Glucose **1234	Sodium Flouride/CSF	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
IL6 **1234	Lithium Heparin	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
Indirect Bilirubin **1234		Calculated test	Roche Cobas Pure	CE Method	LP-BIO-0034
Lactate **1234	Sodium Fluoride/CSF	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
LDH **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Magnesium **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Phosphate **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Potassium **1234	Lithium Heparin / Urine	Indirect ISE	Roche Cobas Pure	CE Method	LP-BIO-0034
Protein Creatinine Ratio **1,2,3,4	Urine	Calculation	Roche Cobas Pure / LIMS	CE METHOD	LP-BIO-0020
PTH **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
Sodium **1234	Lithium Heparin / Urine	Indirect ISE	Roche Cobas Pure	CE Method	LP-BIO-0034
Total Bilirubin **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
Total Protein **1234	Lithium Heparin / Urine / CSF	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034

	Triglycerides **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Urate **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Urea **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Urinary Protein	Urine	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Androstenedione **1234	Serum	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	DHEAS **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1234	Lithium Heparin	Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	Vancomycin**1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .20 Hormones	AMH **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Bioactive Prolactin	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	FAI**1,2,3,4	Serum	Calculated Test	Roche Cobas Pure	CE Method	LP-BIO-0034
	FSH **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	FT3		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	FT4 **1234		Serum/Lithium Heparin	Immunoassay	Roche Cobas Pure	CE Method
	HCG-B **1234	Immunoassay		Roche Cobas Pure	CE Method	LP-BIO-0034
	LH **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Oestradiol **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Procalcitonin	Serum & Lithium Heparin	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Progesterone **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Prolactin **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034

	PTH **1234		Electrochemiluminescence	Roche Cobas Pure	CE Method	LP-BIO-0034
	SHBG **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Testosterone **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	TSH **1234	Serum / Lithium Heparin	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1234	Serum / Lithium Heparin	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .45 Vitamin B12 and folate	B12 **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	Folate **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D**1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP ***1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	CA-125 **1234		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	CA19.9		Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034
	CEA	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034	
	HE4	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034	
	ROMA Index Calculation		Calculated Test	Roche Cobas Pure	CE METHOD	LP-BIO-0034
1061 Clinical Chemistry - .61 Hb A1c	Haemoglobin A1C **1,2,3,4	Whole Blood EDTA	HPLC	HA-8180	CE METHOD	LP-BIO-0019
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Anti-TPO **1234	Serum	Immunoassay	Roche Cobas Pure	CE Method	LP-BIO-0034

Department of Laboratory Medicine

Chemical Pathology

Category: B

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	Glucose **1234	Whole Blood	Enzymatic	Roche AccuChek Inform II	CE Method	LP-POC-0027
1061 Clinical Chemistry - .05 CO-oximetry	Bilirubin **2,4	Whole Blood - heparinised	Spectrophotometry	Radiometer ABL90 Flex 0-690umol/L	CE	LP-POC-0035
	Hb **2,4		Spectrophotometry	Radiometer ABL90 Flex 0-270g/L	CE	LP-POC-0035
	MethHb**2,4,		Spectrophotometry	Radiometer ABL90 Flex 0-100%	CE	LP-POC-0035
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Anion gap **2,4	Whole Blood-heparinised	Calculated	Radiometer ABL90 Flex	CE	LP-POC-0035
	Base Excess **2,4	Whole Blood - heparinised	Calculated	Radiometer ABL90 Flex	CE	LP-POC-0035
	HCO3- **2,4	Whole Blood - heparinised	Calculated	Radiometer ABL90 Flex	CE	LP-POC-0035
	pCO2 **2,4		Potentiometry	Radiometer ABL90 Flex 1.6-14.7kPa	CE	LP-POC-0035
	pH **2,4		Potentiometry	Radiometer ABL90 Flex 6.750-7.850	CE	LP-POC-0035

	pO2 **2,4		Optical pO2	Radiometer ABL90 Flex 1.33-73.3kPa	CE	LP-POC-0035
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Ca++ **2,4		Potentiometry (Direct ISE)	Radiometer ABL90 Flex 0.10-2.70mmol/L	CE	LP-POC-0035
	Cl- **2,4		Potentiometry (Direct ISE)	Radiometer ABL90 Flex 70-160mmol/L	CE	LP-POC-0035
	Glucose **2,4		Amperometry	Radiometer ABL90 Flex 0-47 mmol/L	CE	LP-POC-0035
	K+ **2,4		Potentiometry (Direct ISE)	Radiometer ABL90 Flex 1.5-10.5mol/L	CE	LP-POC-0035
	Lactate **2,4		Amperometry	Radiometer ABL90 Flex 0-31	CE	LP-POC-0035
	Na+ **2,4		Potentiometry (Direct ISE)	Radiometer ABL90 Flex 94-190mmol/L	CE	LP-POC-0035
1061 Clinical Chemistry - .35 Assays of neonatal specimens	Glucose **1234	Whole Blood	Enzymatic	Roche AccuChek Inform II	CE Method	LP-POC-0027
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	CA15.3	Serum	Electrochemiluminescence Immunoassay	Roche Cobas Pure (1.5-300U/mL)	CE Method	LP-BIO-0034
1061 Clinical Chemistry - .76 Simple side tests for biochemical and immunological analytes	Glucose**1234	Whole Blood	Roche AccuChek Inform II Poc Testing	Roche AccuChek Inform II	CE Enzymatic	LP-POC-0027 Operation of the Roche AccuChek Inform II Glucose Meter

Department of Laboratory Medicine

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	Automated Basophil Count **1,2,3,4	Whole blood, EDTA, NA Citrate	Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Automated Eosinophil Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Automated Lymphocyte Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Automated Monocyte Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Automated Neutrophil Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Automated Nucleated Red Blood Cell (NRBC) Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
	Full Blood Count including reticulocytes, white cell differential (automated) includes neutrophils, lymphocytes,		Whole Blood, EDTA, Na Citrate, Thromboexact blood	Impedance counting, fluorescence analysis by flow cytometry and SLS haemoglobin measurement on automated cell counter.	Sysmex XN 2000	CE based on Standard method

eosinophils, monocytes and basophils. *1,2,3,4					
Haematocrit (HCT) **1,2,3,4	Whole blood, EDTA, NA Citrate	Hydrodynamically focussed impedance & SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Haemoglobin (Hb) **1,2,3,4		SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Impedence Platelets (PLT-I) **1,2,3,4	Whole blood, EDTA, NA Citrate, Thromboexact blood	Hydrodynamically focussed impedance	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Mean Cell Haemoglobin (MCH) **1,2,3,4	Whole blood, EDTA, NA Citrate	Hydrodynamically focussed impedance & SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Mean Cell Haemoglobin Concentration (MCHC) **1,2,3,4		Hydrodynamically focussed impedance & SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Mean Cell Volume (MCV) **1,2,3,4		Hydrodynamically focussed impedance & SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Optical Platelets (PLT-O) **1,2,3,4	Whole blood, EDTA, NA Citrate, Thromboexact blood	Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Red Cell Count (RCC) **1,2,3,4	Whole blood, EDTA, NA Citrate	Hydrodynamically focussed impedance	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Red Cell Distribution Width (RCW) **1,2,3,4		Hydrodynamically focussed impedance & SLS	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
Reticulocyte Count **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032
White Cell Count (WCC) **1,2,3,4		Fluorescence Flow Cytometry	Sysmex XN 2000	CE based on standard method	LP-HAEM-0032

1030 Haematology - .02 Visual examination of blood films	Blood Film and white cell differential (manual) includes neutrophils, lymphocytes, monocytes, eosinophils, basophils and red cell morphology. **2,4	EDTA Blood	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Aerospray stainer / microscopy	CE Marked	LM-HAEM-0007, 0008, LP-HAEM-0003, 0004, WI-HAEM-0003, LP-HAEM-0011 & 0006
	Blood Film Examination **2,4	EDTA Blood	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells.	Aerospray stainer / microscopy	CE	LM-HAEM-0007, 0008, LP-HAEM-0003, 0004, 0006 & 0011, WI-HAEM-0003
1030 Haematology - .09 Examination of malarial parasites	Malaria Parasites Examination **1,2,4	Blood Film	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites.	Manual microscopy	CE	LM-HAEM-0009, 0010 & LP-HAEM-0006
	Malaria Parasites Examination**1,2,4		Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	Manual Microscopy	CE Marked	LM-HAEM-0009, 0010 & LP-HAEM-0006
	Rapid Diagnosis of Malaria **1,2,4	EDTA Blood	Immunochromatographic using monoclonal antibodies	Manual technique	Immunochromogenic using monoclonal antibodies	LM-HAEM-0010
	Rapid Diagnosis of Malaria *1,2,4	EDTA Blood	Immuno - chromatographic using monoclonal antibodies	Manual technique	Immunochromogenic using monoclonal antibodies	LM-HAEM-0010
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Adult and Paediatric Haemoglobinopathy screening **1,2,4	EDTA Blood / Clotted Blood	Capillary Electrophoresis	Sebia Capillarys 2	CE	LM-HAEM-0033, LM-HAEM-0034 & LP-HAEM-0028

	Adult and Paediatric Haemoglobinopathy screening**1,2,4		Capillary Electrophoresis	Sebia	CE Marked	LM-HAEM-0033 and -0034, LP-HAEM-0028
	Sickle Cell Screen **4	EDTA Blood	Qualitative Solubility Test for Hb S	Manual	CE	LM-HAEM-0026
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer (tests for foetal Hb) **1,2,4		Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells.	Manual microscopy	CE	LM-HAEM-0021 & LP-HAEM-0004
	Kleihauer (tests for foetal Hb)**1,2,4		Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Manual Microscopy	CE Marked	LM-HAEM-0021 & LP-HAEM-0004
1030 Haematology - .40 Limited haemostasis related tests	Lupus Anticoagulant	Sodium Citrate	Coagulometric / Chromogenic	dRVVT Screen: 16.0-240.0 seconds; dRVVT confirm: 6.0-121.0 seconds	CE	LP-HAEM-0023 & LM-HAEM-0031
1030 Haematology - .41 General haemostasis related tests	APTT **1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
	APTT Ratio**1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
	APTT50 **1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
	Clauss Fibrinogen **1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
	INR **1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
	PT **1,2,3,4		Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023

	PT50 **1,2,3,4	Coagulometric / Chromogenic	ACL TOP 550	CE	LP-HAEM-0023
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Department of Laboratory Medicine

Haematology

Category: B

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	Haemaglobin estimation **1,2,4	Whole Blood	Photometric	Hemocue 210DM	Photometric CE Marked	LP-POC-0009
	Haemaglobin estimation**1,2,4		Photometric	Hemocue 210DM	Photometric CE Marked	LP-POC-0009
1030 Haematology - .40 Limited haemostasis related tests	Lupus Anticoagulant	Sodium Citrate	Coagulometric/Chromogenic	dRVVTScreen: 16.0-240.0 seconds dRRVT confirm: 6.0-121.0 seconds	CE MARKED	LP-HAEM-0023, LM-HAEM-0031
1030 Haematology - .41 General haemostasis related tests	APTT/APTT50 **1,2,3,4		Coagulometric/Chromogenic	16.0-400 seconds / ACL TOP 550	CE MARKED	LP-HAEM-0023
	Clauss Fibrinogen **1,2,3,4		Coagulometric/Chromogenic	Fib-C 0.8-5.0 g/l, Fib-C L: 0.35-1.20 g/L, Fib-C H: 4.0-10.0 g/L / ACL TOP 550	CE MARKED	LP-HAEM-0023
	PT/PT50 **1,2,3,4		Coagulometric/Chromogenic	8.0-320.0 seconds/ACL TOP 550	CE MARKED	LP-HAEM-0023

Department of Laboratory Medicine

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 & Eosin **2,4	Human tissue/ Cell Block	DAKEWE DP360 Stainer & DAKWE CS500 Coverslipper	CE Marked instrument	N/A	LM-HIST-0008 & LP-HIST-0079
	Cut-Up *2*4		Thermoscientific Printmate, digital recording system, Kern balance	CE Marked instrument	N/A	LP-HIST-0009, 0056,0069,0072
	Embedding *2*4		Leica Arcadia, embedding centre, heated forceps	CE MARKED	N/A	LP-HIST-0030 & LP-HIST-0072
	Microtomy *2*4		microtomes, waterbaths, incubators	CE Marked instrument	N/A	LP-HIST-0071 & 0072
	Tissue Processing **2,4		Sakura Tissue Tek VIP6 (E2) & Sakura Tissue Tek VIP 6 (AI)	CE Marked instrument	N/A	LP-HIST-0046 & 0081
1051 Histopathology - .03 Histochemistry	Special Stains: Manual H&E	Human tissue / Cell Block	Manual, DAKWE DP360 Stainer and DP360 CS500 Coverslipper	Based on Standard Method	N/A	LM-HIST-0008 & LP-HIST-0079
1051 Histopathology - .06 Histological interpretation-perinatal pathology	Diagnostic interpretation and reporting of human		Microscope	CE Marked	N/A	LP-HIST-0032, LP-HIST-0073

	tissue specimens - specialist areas included: perinatal pathology (confined to histological examination of placental tissue and gravid uteri). Specialist areas excluded: medical renal pathology, paediatric pathology, neuropathology & breast screening pathology)				
1051 Histopathology - .09 Immunohistochemistry	CD10 **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked Instrument	N/A	LP-HIST-0080, LP-HIST-0079
	CD138 **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
	CD20 **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
	CD3 **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079

CD31 **2,4
CD45 **2,4
CD68 **2,4
CEA **2,4
Ck20 **2,4
Ck7 **2,4

Microscope			
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079

	Microscope			
CMV **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	Non-CE	N/A	LP-HIST-0080, LP-HIST-0079
Desmin **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Dual Stain P16/ki67 **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE marked	N/A	LP-HIST-0080, LP-HIST-0079
EMA **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
GFAP **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
Inhibin alpha **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB	CE Marked instrument	N/A	LP-HIST-0080, LP-HIST-0079

		Microscope			
Ki-67 **2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
p16 **2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
p53 **2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
P63 *2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE marked	N/A	LP-HIST-0080, LP-HIST-0079
PanCk (AE1/AE3) **2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079
S100 **2,4		Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079

		Microscope			
	SMA *2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked Instrument	N/A	LP-HIST-0080, LP-HIST-0079
	Vimentin **2,4	Ventana Benchmark Ultra, ultraView DAB, ultraView Red, optiView DAB Microscope	CE Marked	N/A	LP-HIST-0080, LP-HIST-0079

Department of Laboratory Medicine

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 **1,2,3,4	All swabs, bronchial lavage / brushings, endotracheal tubes, other body fluids, pus, pleural fluids, sputum, tissue, urine, blood, CSF, middle ear, effusion, cannula, associated exudates, NICU surveillance, adverse transfusion environmental specimens, semen for culture.	Light microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells.	N/A	LM-MICRO-0001, 0003, 0004, 0005, 0006, 0007, 0008, 0010, 0011, 0012, 0014, 0016, 0019, 0022, 0023, 0033, 0034, 0035, 0050, 0054, 0055, 0061, 0063 & 0064.
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic	Microscopic examination of Fungi **1,2,3,4		Light microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells.	N/A	LM-MICRO-0001, 0003, 0004, 0005, 0006, 0007, 0008, 0010, 0011, 0012, 0014, 0016, 0019, 0022, 0023, 0033, 0034, 0035, 0050, 0054, 0055, 0061, 0063 & 0064.

examination for fungi						
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Adult & Paediatric Blood Cultures*2	Blood Culture	BacTAlert	CE Marked	Growth or No Growth	LM-MICRO-0023
	Culture of General Bacteria **1,2,3,4	All swabs, bronchial lavage / brushings, endotracheal tubes, other body fluids, pus, pleural fluids, sputum, tissue, urine, blood, CSF, middle ear, effusion, cannular, associated exudates, NICU surveillance, adverse transfusion environmental specimens for culture.	BacTAlert 3D System / Microscope	BacTAlert / Manual	N/A	LM-MICRO-0001, 0003, 0004, 0005, 0006, 0007, 0008, 0010, 0011, 0012, 0014, 0016, 0019, 0022, 0023, 0033, 0034, 0035, 0050, 0054, 0055, 0061 & 0063.
	Samples for Culture and Susceptibility*4	Swabs, tissue, urine, tips, sputa, blood culture, CSF, Fluids from Sterile sites, breast milk and environmental samples	Culture of Organisms	CE Marked	Growth or No Growth	LM-MICRO-0015
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Adult & Paediatric Blood Cultures*2	Blood Culture	BacTAlert	CE Marked	Growth or No Growth	LM-MICRO-0023
	Culture of Fungi **1,2,3,4	All swabs, bronchial lavage / brushings, endotracheal tubes, other body fluids, pus, pleural fluids, sputum, tissue, urine, blood, CSF, middle ear, effusion, cannular,	Culture of Organisms	CE Marked	N/A	LM-MICRO-0001, 0003, 0004, 0005, 0006, 0007, 0008, 0010, 0011, 0012,

		associated exudates, NICU surveillance, adverse transfusion environmental specimens, semen for culture.				0014, 0016, 0019, 0022, 0023, 0033, 0034, 0035, 0050, 0054, 0055, 0061, 0063 & 0064.
	Samples for Culture and Susceptibility*4	Swabs, tissue, urine, tips, sputa, blood culture, CSF, Fluids from Sterile sites, breast milk and environmental samples	Culture of Organisms	CE Marked	Growth or No Growth	LM-MICRO-0015
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Identification of Organisms **1,2,4	All swabs ,bronchiallavage/brushings,endotracheal tubes,other body fluids,pus,pleural fluids,sputum,tissue,urine,blood,CSF,middle ear effusion,cannual,associated exudates,NICU surveillance,adverse transfusion enviromental specimens,semen for culture	Strep grouping kit,staphaurexplus, Oxidase test, Catalase test, Nitrocefin kits	CE Marked Commercial Kits	N/A	LM-MIRO-0026,LM-MICRO-0062,LM-MICRO-0029,LM-MICRO0030,LM-MICRO-0057,LM-MICRO-0024.
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination			Strep grouping kit,staphaurexplus, Oxidase test, Catalase test, Nitrocefin kits	CE Marked Commercial Kits	N/A	LM-MIRO-0026,LM-MICRO-0062,LM-MICRO-0029,LM-MICRO0030,LM-MICRO-0057,LM-MICRO-0024.
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	C. diff Quik Chek Complete	Stool	Manual	CE Marked Immunoassy Kit	Detected or Not Detected	LM-MICRO-0089
1015 Detection and/or	C. diff toxin, **1,2,4	Stools	GeneXpert	PCR	N/A	LM-MICRO-00713

identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems						
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	BV plus PCR Assay**1,2,3,4	Genital Swabs	Hamilton Seegen/ Biorad CFX96	CE marked	Normal/Positive/ Intermediate	LM-MICRO-00022,0023
	4-Plex (Flu A, Flu B, RSV and SARS-CoV-2)	Deep Nasal Swab	GeneXpert	CE	Detected or Not Detected	LM-MICRO-0072 and LM-MICRO-0086
	Biofire FilmArray BCID2 **2,3,4	Positive Blood Cultures	Biofire FilmArray	Molecular	Detected or Not Detected	LM-MICRO-0081
	Detection of CT/NG PCR using GeneXpert **1,2,3,4	Urine and genital swabs	GeneXpert	PCR CE Marked	Detected or Not Detected	LM-MICRO-0080
	Detection of CT/NG/TV/MG PCR using the Seegene **1,2,3,4	First void urines and Genital Swabs	Seegene Hamilton Nimbus and Biorad CFX97	PCR CE Marked	Qualitative and Quantitative	LM-SERO-0023

	Detection of GBS on the GeneXpert **1,2,3,4	LVS and Rectal Swabs	GeneXpert	PCR CE Marked	Detected or Not Detected	LM-MICRO-0075
	Molecular Detection of HSV1/2	Skin, Genital or Eye	Luminex	CE	Detected or Not Detected	LM-MICRO-0091
	Processing Positive Blood Cultures on the BioFire FilmArray **1,2,3,4	Blood Culture	BioFire FilmArray	PCR CE Marked	Detected or Not Detected	LM-MICRO-0081
	Testing for Norovirus GI and GII by PCR	Faeces	Cepheid genexpert	CE Marked	Detected / Not Detected	LM-MICRO-0084
	Testing for Trichomonas vaginalis by PCR**1,2,3,4	Genital swabs, eye swabs and urine	Cepheid genexpert	CE KIT	Detected / Not Detected	LM-MICRO-0082
	Testing of CPE isolates **1,2,3,4	Bacterial isolates	Cepheid genexpert	Ce Marked	Detected / Not Detected	LM-MICRO-0083
	Testing of respiratory samples using RP2 plus panel**1,2,3,4	NPA	Bio Fire Film Array	CE Marked	Detected / Not Detected	LM-MICRO-0083
	Xpert Xpress GBS Testing on the GeneXpert **2,3,4	Vaginal / Rectal Swabs	GeneXpert	Molecular	Detected or Not Detected	LM-MICRO-0075
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using	Identification of Organisms **1,2,4	All swabs, bronchial lavage / brushings, endotracheal tubes, other body fluids, pus, pleural fluids, sputum, tissue, urine, blood, CSF, middle ear, effusion, cannula, associated exudates, NICU surveillance, adverse transfusion environmental specimens, semen for culture.	Vitek MaldiToF MS Vitek 2 Compact	Spectroscopy Biochemical testing	N/A	LM-MICRO-0076 & 0033 LM-MICRO-0058,0059,0060 &

MALDI-TOF Spectroscopy						0065. LP-MICRO-0027
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Aerobes / Anaerobes **1,2,4		Vitek 2 Compact	Biochemical Testing	N/A	LM-MICRO-0018, 0058 & 0059
			Vitek 2 Compact and Manual	MIC / Disk Diffusion	N/A	LM-MICRO-0018, 0058 & 0059
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Vz IgG	Serum	Mini Vidas - enzyme linked fluorescent assay	CE Marked	Negative or Positive	LM-SERO-0003
			Abbott Architect	Immunoassay	N/A	LM-SERO-0012
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .04 Line immunoassay, using CE marked	Hepatitis B Core Antibodies Anti-HBc **1,2,3,4					

commercial systems						
	Hepatitis B Surface Antigen (HBsAg) **1,2,3,4		Mini Vidas	Immunoassay	N/A	LM-SERO-0006
	Hepatitis C Antibodies Anti-HCV **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0009
	HIV Combo Ab/Ag **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0010
	Rubella IgG **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0025
	Syphilis TP (Treponema pallidum) **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0014
			Mini Vidas	Immunoassay	N/A	LM-SERO-0019
			Abbott Architect	Immunoassay	N/A	LM-SERO-0013
1029 Miscellaneous - .01 Semen analysis (Screening Test)	Semen Analysis **1,4	Semen	SAMi Computerised Assisted Semen Analysis	Artificial Intelligence CASA	N/A	LM-MICRO-0074
1029 Miscellaneous - .99 Miscellaneous tests	Pregnancy Testing **4	Urine	Alere Diagnostic Stick Chromatography immunoassay	CE Marked	N/A	LM-MICRO-0025

The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters / tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment / kits where the underlying methodology does not change

For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory.