

# Schedule of Accreditation



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Accreditation Standard	ISO 15189
Date Initially Awarded	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<sup>1</sup>

<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	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	Automated AutoVue Innova and Manual method.	Column Agglutination Technology (CAT) Microtitre Plate, Tube Technology		LM-BT-0002 & 0020
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma / Serum	Manual method and Automated AutoVue Innova	Column Agglutination Technology (CAT) , Tube Technology		LM-BT-0003 & 0020
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual / Biorad BioVue	Column Agglutination Technology (CAT)		LM-BT-0004 & 0022
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing		Manual / Biorad BioVue	Column Agglutination Technology (CAT)		LM-BT-0022
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 - .99 Miscellaneous tests	Antibody Titre	Plasma / Serum	Manual bioVue	Column Agglutination Technology (CAT)		LM-BT-0013
	Direct Antiglobulin Test	Red Cells	Automated AutoVue Innova and Manual method in tubes and BioVue.	Column Agglutination Technology (CAT) , Tube Technology		LM -BT-0005 & 0020
	FMH Estimation		Beckman Coulter FC500	Flow Cytometry		LM-BT-0019

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 **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Alkaline Phosphatase **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	ALT **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	AMH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Amylase **1,2,3,4	Heparinised plasma/fluid	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	AST **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Bile Acids **1,2,3,4	Heparinised plasma /serum	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	CA125 **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Calcium **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Chloride **1,2,3,4	Heparinised plasma / urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Creatinine (enzymatic) **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	CRP **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Ferritin **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Folate **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Fructosamine **1,2,3,4	Heparinised plasma / serum	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	FSH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	FT4 **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Gentamicin **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	GGT **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Glucose **1,2,3,4	Sodium Fluoride/CSF	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
HCG **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020	
Lactate **1,2,3,4	Sodium Fluoride /	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020	

		CSF	Immunoassay			
	LDH **1,2,3,4	Heparinised plasma/fluid	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	LH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Magnesium **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Oestradiol **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Phosphate **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Potassium **1,2,3,4	Heparinised plasma / urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Progesterone **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Prolactin **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Protein Creatinine Ratio **1,2,3,4	Urine	Calculation	Cobas 6000	CE METHOD	LP-BIO-0020
	SHBG **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Sodium **1,2,3,4	Heparinised plasma / urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Testosterone **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Total & Direct Bilirubin **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Total Protein **1,2,3,4	Heparinised Plasma / urine / CSF/fluid	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	TPO Antibody **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Triglycerides **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	TSH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Urate **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Urea **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Vitamin B12 **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
1061 Clinical Chemistry - .35 Assays of neonatal specimens	Albumin **1,2,3,4	Heparinised plasma/fluid	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Alkaline Phosphatase **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	ALT **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	AMH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
	Amylase **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	AST **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Calcium **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
	Chloride **1,2,3,4	Heparinised plasma/urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020

CK **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Creatinine (enzymatic) **1,2,3,4	Heparinised plasma/urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
CRP **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Ferritin **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Folate **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
FSH **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
FT4 **1,2,3,4	Heparinised plasma/serum	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Gentamicin **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
GGT **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Glucose **1,2,3,4	Sodium Fluoride	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Lactate **1,2,3,4	Sodium fluoride / CSF	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
LDH **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
LH **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Mg **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Na **1,2,3,4	Heparinised plasma/urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Oestradiol **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Phosphate **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Potassium **1,2,3,4	Heparinised plasma/urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Progesterone **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Prolactin **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Testosterone **1,2,3,4		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Total and Direct Bilirubin **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Total Protein **1,2,3,4	Heparinised plasma/urine	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Triglycerides **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
TSH **1,2,3,4	Heparinised plasma / serum	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Urate **1,2,3,4	Heparinised plasma	Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
Urea **1,2,3,4		Electrochemiluminescence	Cobas 6000	CE METHOD	LP-BIO-0020
		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
Vitamin B12 **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020

1061 Clinical Chemistry - .50 Protein and peptide tumour markers	CA125		Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020
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 - .99 Miscellaneous tests	Thyroid peroxidase antibody **1,2,3,4	Serum	Electrochemiluminescence Immunoassay	Cobas 6000	CE METHOD	LP-BIO-0020

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 **4	Whole Blood	Photometric	Hemocue 201 DM	CE METHOD	LP-POC-0004 LP-POC-0005
	1061 Clinical Chemistry - .05 CO-oximetry		O2Hb **2,4	Potentiometric	Cobas b221/b123	CE METHOD
tHb **2,4			Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Bicarbonate **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	CoHb **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	HHb **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	MetHb **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	PCO2 **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	PH **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	PO2 **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	SO2 **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Bilirubin **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	Calcium **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	CL **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	Glucose **2,4		Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010
	Haematocrit **2,4	Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010	
	K **2,4	Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010	
	Lactate **2,4	Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010	
	Na **2,4	Potentiometric	Cobas b221/b123	CE METHOD	LP-POC-0010	
1061 Clinical Chemistry - .76 Simple side tests for biochemical and immunological analytes	Glucose		Roche AccuChek Inform II Poc Testing	Roche AccuChek Inform II	CE Enzymatic	LP-POC-0027 Operation of the Roche AccuChek Inform II Glucose Meter

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 including reticulocytes	Blood	automated dye cellular staining optical ,impedance	NA	CE Marked instrument	LM-HAEM-0035 LP-HAEM-0029
	Full Blood Count including reticulocytes and white cell differential (automated) includes neutrophils, lymphocytes, monocytes, eosinophils and basophils.	EDTA Blood / Na Citrate / Blood / Thromboexact blood	Automated dye cellular staining optical, impedance and flow cytometry methods	Cell Dyn 3200 and Cell Dyn Sapphire	Automated dye cellular staining optical, impedance and flow cytometry methods.	LM-HAEM-0002, 0004, LP-HAEM-0016, 0017, 0003 & 0027
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.	EDTA Blood	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Aerospray stainer / microscopy	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells.	LM-HAEM-0007, 0008, LP-HAEM-0003, 0004, WI-HAEM-0003, LP-HAEM-0011 & 0006
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte counts	EDTA Blood	Automated dye cellular staining optical, impedance and flow cytometry methods	Cell Dyn 3200 and Cell Dyn Sapphire	Absorption Spectrophotometry	LM-HAEM-0002, LP-HAEM-0017, 0016, 0003 & 0027
	Automated differential leucocytes	Blood	absorption spectrophotometry	N/A	CE Marked instrument	LM-HAEM-0035 LP-HAEM-0029
1030 Haematology - .08 Blood film examinations involving special staining procedures	Manual reticulocyte estimation	EDTA Blood	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Manual Microscopy	Microscopic examiantion with staining with brilliant cresyl blue method for enumeration of human reticulocytes	LM-HAEM-0019
1030 Haematology - .09 Examination of malarial parasites	Malaria Parasites Examination	Blood Film	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	Manual Microscopy	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites.	LM-HAEM-0009, 0010 & LP-HAEM-0006
	Rapid Diagnosis of Malaria	EDTA Blood	Immuno - chromatographic using monoclonal antibodies	Manual technique	Immunochromogenic using monoclonal antibodies	LM-HAEM-0010
1030 Haematology - .30 Tests for	Adult and Paediatric Haemoglobinopathy	EDTA Blood / Clotted Blood	Capillary Electrophoreseis	Sebia	Capillary Electrophoresis	LM-HAEM-0033 &



haemoglobin variants and thalassaemia	screening					0034
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer (tests for foetal Hb)	EDTA Blood	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Manual Microscopy	Microscopic examination with or without fixation and staining with dyes for enumeration and description of adult and foetal red cells.	LM-HAEM-0021 & LP-HAEM-0004
1030 Haematology - .40 Limited haemostasis related tests	Lupus Anticoagulant Factor VIII Activated Protein C resistance Anti Thrombin Protein C activity	Sodium Citrate Blood	Colourimetric / absorbance	ACL Top 500	Colourimetric / absorbance	LM-HAEM-0030 & 0023
1030 Haematology - .41 General haemostasis related tests	Coagulation Screen: prothrombin time, prothrombin time international ration, activated partial thromboplastin time, activated partial thromboplastin ratio, fibrinogen estimation		Colourimetric / absorbance	ACL Top 500	Colourimetric / absorbance	LM-HAEM-0030 & 0023

# 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	Whole Blood	Photometric	Hemocue 210DM	Photometric	LM-POC-0007

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 **4	Human tissue	DRS stainer			LM-HIST-0008 & LP-HIST-0050
	Coverslipping **4		coverslipper, sorblin			LM-HIST-0010, LP-HIST-0025, & 0019
	Cut-Up **4		microwriter, digital recording system, Kern balance			LM-HIST-0002, 0003, 0004, LP-HIST-0009 0056 & 0065
	Embedding		embedding centre, heated forceps			LM-HIST-0006 LP-HIST-0013,0023, 0024, 0027, 0030,0044 &0063
	Microtomy **4		microtomes, waterbaths, ovens, hotplate			LM-HIST-0007, LP-HIST-0023 & 0044
	Processing	Tissue Agar /Block	Donatello Tissue Processor	CE Marked instrument	N/A	LP-HIST-0028. LM-HIST-0005
	Tissue Processing **4	Human tissue	VIP tissue processor			LM-HIST-0005 & LP-HIST-0028
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Frozen Sections		cryostat			LM-HIST-0001 & LP-HIST-0022
1051 Histopathology - .03 Histochemistry	Special Stains: Pas x 3, Alcian Blue, Grocott, , Cold ZN, Perl's Prussian Blue, M, Von Kossa's, PTAH, Masson Trichrome, Modified Grees, , Verhoeff's Elastic, Miller's Elastic, Verhoeff's Van Gieson, Oil Red O, Celestin Blue Haem Alum, Haematoxylin & Eosin, Rapid H&E, , Churukian Schenk, Papanicolaou, Grams Twort,					LM-HIST-0008 & LP-HIST-0050
1051 Histopathology - .06 Histological interpretation-perinatal pathology	Diagnostic interpretation and reporting of human		Microscope			LM-HIST-0004, & LP-HIST-0021

	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	Dual Stain P16/ki67		Ventana Benchmark & microscope	CE marked	N/A	LM-HIST-0009
	P57kip, EMA, CLA (CD45), SMA, AE1/3, GFAP, beta-inibin, alphainibin, HCG, HPL, CK7, CK20, vimentin, S100, CD68, CD8, CD20cy, CD79a, CD10, Ki67, P16, P53, Monoclonal CEA & Polyclonal CEA, Calretinin, CD31, CD3, CMV, Parovirus, P63		Ventana benchmark, & microscope			LM-HIST-0009 LP-HIST-0021, &0034
	P63	lletzes & cervical biopsies	Ventana Benchmark & microscope	CE marked	N/A	LM-HIST-0009
1052 Cytopathology - .02 Non gynaecological cytology	H&E and PAP	Non-gynaecological fluids	Thin prep 2000, & viper vortex			LM-HIST-0012, 0014, LP-HIST-0046 & 0047

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 examination for fungi	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.
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of General Bacteria **1,2,3,4		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 & 0064.
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of Fungi		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 & 0064.
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	NAAT Testing for Trich Vaginalis and mycoplasma genitalium ETS	Urine and genital swabs form female patients	COBAS4800 PCR	PCR	N/A	LM-SERO-0021
	Neisseria Gonorrhoea, chlamydia, C. Diff toxin, SA/MRSA, Influenza A and B, Group B Streptococcal	Eye / HVS Swabs, urine Stools, blood culture, nasal swabs / aspirate / washings	Cobas 480 GeneXpert	PCR	N/A	LP-SERO-0020, LM-SERO-0018, EX-SERO-0079, LM-MICRO-0032, 0071 & 0075.
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	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.	MaldiTof	Spectroscopy	N/A	LM-MICRO-0076 & 0033
			Vitek 2 Compact	Biochemical Testing	N/A	LM-MICRO-0018, 0058 & 0059
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 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 - .04 Line immunoassay, using CE marked commercial systems	CMV IgG **1,2,3,4	Serum	Abbott Architect	Immunoassay	N/A	LM-SERO-0011
	Hepatitis B Core Antibodies Anti-HBc **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0012
			Mini Vidas	Immunoassay	N/A	LM-SERO-0006
	Hepatitis B Surface Antigen (HBsAg) **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0009
	Hepatitis C Antibodies Anti-HCV **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0010

	HIV Combo Ab/Ag **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0025
	Rubella IgG **1,2,3,4		Abbott Architect	Immunoassay	N/A	LM-SERO-0014
	Syphilis RPR (rapid plasma reagin) **1,2,3,4		Mini Vidas	Immunoassay	N/A	LM-SERO-0019
	Varicella Zoster IgG Abs		Abbott Architect	Immunoassay	N/A	LM-SERO-0013
	Varicella Zoster IgG Abs **1,2,3,4		Mini Vidas	Immunoassay	N/A	LM-SERO-0003
			Diaorin Liaison	Immunoassay	N/A	LM-SERO-0020
1029 Miscellaneous - .01 Semen analysis (Screening Test)	Semen Analysis **1,4	Semen	Sperminator Equipment	Count, volume, motility.	N/A	LM-MICRO-0074
1029 Miscellaneous - .99 Miscellaneous tests	Pregnancy Testing **4	Urine	Surescreen Diagnostic Stick	Chromatography immunoassay	N/A	LM-MICRO-0025

*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.*