

# Schedule of Accreditation



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 Trading As  
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 Accreditation Standard ISO 15189  
 Date Initially Awarded 09/06/2009

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>

<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 Cavan General Hospital	Pathology Laboratory, Cavan, H12 Y7W1

# Scope of Accreditation

## Cavan General Hospital

### 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	Blood Grouping including ABO, Rh(D)	Whole Blood	Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .03 Blood group antibody screen	Blood Group Antibody Screen		Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .04 Identification of blood group antibodies	Identification of Blood Group Antibodies		Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch Testing		Ortho Vision	CE Marked	N/A	LM-BT-0014
	Crossmatching for the release of blood using electronic system		Laboratory Information System/Ortho Vision	CE Marked	N/A	LP-BT-0035
1020 Transfusion science - .06 Red cell phenotyping	Phenotyping		Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test		Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .99 Miscellaneous tests	Kleihauer Test		Manual Method	CE Marked	N/A	LM-BT-0007

Note: Cavan General Hospital has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. No. 360 of 2005 and S.I. No. 547 of 2006)

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	TRIS Buffer without PLP	Abbott Architect	CE Marked	LM-BIO-0005
	Albumin		HCG	Abbott Architect	CE Marked	LM-BIO-0005
	Albumin/Creatinine Ratio	Urine	Calculated	Abbott Architect	CE Marked	LM-BIO-0005
	Alkaline Phosphatase (ALP)	Serum	AMP Buffer not IFCC	Abbott Architect	CE Marked	LM-BIO-0005
	Amylase		TRIS Buffer without PLP	Abbott Architect	CE Marked	LM-BIO-0005
	Asparate Aminotransferase (AST)		TRIS Buffer without PLP	Abbott Architect	CE Marked	LM-BIO-0005
	BNP	EDTA	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Calcium	Serum	Arsenazo III	Abbott Architect	CE Marked	LM-BIO-0005
		Urine	Arsenazo III	Abbott Architect	CE Marked	LM-BIO-0005
	Chloride (Cl)	Serum	Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
		Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
	Cholesterol	Serum	Choesterol esterase/oxydase	Abbott Architect	CE Marked	LM-BIO-0005
	Corrected Calcium		Calculated	Abbott Architect	CE Marked	LM-BIO-0005
	Creatine Kinase		NAC	Abbott Architect	CE Marked	LM-BIO-0005
	Creatinine		Enzymatic	Abbott Architect	CE Marked	LM-BIO-0005
			Urine	Enzymatic	Abbott Architect	CE Marked
	Creatinine Clearance	Serum/Urine	Calculated	Abbott Architect	CE Marked	LM-BIO-0005
	Direct Bilirubin	Serum	UV Method	Abbott Architect	CE Marked	LM-BIO-0005
	eGFR		Calculated	Abbott Architect	CE Marked	LM-BIO-0005
	Ethanol		ADH	Abbott Architect	CE Marked	LM-BIO-0005
	Globulins		Calculated	Abbott Architect	CE Marked	LM-BIO-0005
	Glucose		Sodium Fluoride	Hexofinase + G6PD	Abbott Architect	CE Marked
	HDL Cholesterol	Serum	Accelerator Selective Detergent	Abbott Architect	CE Marked	LM-BIO-0005
High Sensitivity	Chemiluminescent		Abbott Architect	CE Marked	LM-BIO-0005	

	Troponin		Microparticle Immunoassay (CMIA)			
	Iron		Ferene	Abbott Architect	CE Marked	LM-BIO-0005
	Lactate Dehydrogenase (LDH)		Lactate to Pyruvate (NADH)	Abbott Architect	CE Marked	LM-BIO-0005
	LDL Cholesterol		Measured Light Selective Detergent	Abbott Architect	CE Marked	LM-BIO-0005
	Magnesium		Arsenazo III	Abbott Architect	CE Marked	LM-BIO-0005
	Microalbumin	Urine	Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005
	Paracetamol	Serum	Spectrophotometric	Abbott Architect	CE Marked	LM-BIO-0005
	Phosphate		Phosphomolybdate UV	Abbott Architect	CE Marked	LM-BIO-0005
	Potassium (K)		Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
		Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
	Protein		Biuret	Abbott Architect	CE Marked	LM-BIO-0005
	Salicylate	Serum	Enzymatic/Colorimetric	Abbott Architect	CE Marked	LM-BIO-0005
	Sodium (Na)		Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
		Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Architect	CE Marked	LM-BIO-0005
	Total Bilirubin	Serum	Diazo	Abbott Architect	CE Marked	LM-BIO-0005
	Total Protein		Biuret	Abbott Architect	CE Marked	LM-BIO-0005
	Triglycerides		Glycerol Phosphate Oxidase	Abbott Architect	CE Marked	LM-BIO-0005
	Urea		Kinetic Urease	Abbott Architect	CE Marked	LM-BIO-0005
	Uric Acid		Endpoint Uricase	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	C Reactive Protein (CRP)		Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin		Architect immunoturbidimetry	2 -50	CE Marked	LM-BIO-0005
	Gentamicin		Architect Immunoassay	0.3 -10	CE Marked	LM-BIO-0005
	Litium		Spectrophotometric	Abbott Architect	CE Marked	LM-BIO-0005
	Tobramycin		Particle-enhanced Turbidimetric Inhibition Immunoassay (PETINIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Vancomycin		Fluorescence Polarisation Immunoassay	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Ferritin		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .20 Hormones	Follicle Stimulating Hormone (FSH)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005

	Free T4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Gamma Glutamyl Transferase (GGT)		L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Abbott Architect	CE Marked	LM-BIO-0005
	Luteinising Hormone (LH)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Oestradiol		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Progesterone		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Thyroid Stimulating Hormone (TSH)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .40 Iron studies	Folate		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Free PSA		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Vitamin B12		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Ca 15.3		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Ca 19.9		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	CA-125		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Carcino-embryonic Antigen		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Free T3		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	Total Prostate Specific Antigen (PSA)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
	1061 Clinical Chemistry - .60 Glycohaemoglobins	HBA1C	Whole Blood	Adams A1C HA-8180V	SDFSDFSD	CDSSSDCSD
		HPLC		Adams A1C HA-8180V	CE Marked	LM-BIO-0003
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Beta Human Chorionic Gonadotrophin (Beta HCG)	Serum	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry -	IgA		Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005

.80 Quantitative investigation of immunoglobulins G, A, M and in body fluids						
	IgG		Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005
	IgM		Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor (RF)		Immunoturbidimetric	Abbott Architect	CE Marked	LM-BIO-0005

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	Blood Count	EDTA	Sysmex XN-2000	WBC 0-440 x 10(3)/uL RBC 0-8.6 x 10(6)/uL Hgb 0-26g/dl HCT: 0-75% PLT 0-5000 x 10(3)/uL NRBC# 0-20 x 10(3)/uL	CE Marked	LM-HAEM-0014
1030 Haematology - .02 Visual examination of blood films	Visual Examination of Blood Films		Manual Method	N/A	Based on Standard Method	LM-HAEM-0011
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate	Sodium Citrate	Westergren Method/Sediplus S100	N/A	Based on Standard Method	LM-HAEM-0004
			Westergren Method/Sediplus S2000	N/A	Based on Standard Method	LM-HAEM-0005
1030 Haematology - .05 Automated differential leucocyte counts	Blood Count Differential	EDTA	Sysmex XN-2000	N/A	CE Marked	LM-HAEM-0014
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Sysmex XN-2000	N/A	RET# 0.0-0.72 x 10(6)/uL	LM-HAEM-0014
1030 Haematology - .08 Blood film examinations involving special staining procedures	Blood Film Preparation	EDTA	SP20 Stainer	SP20 Stainer	CE Marked	LM-HAEM-0015
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites	EDTA	Manual/Test Kit	N/A	CE Marked	LM-HAEM-0013
	Examination for Malarial Parasites. (screening)		Manual/Test Kit	N/A	CE Marked	LM-HAEM-0013
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sicke Cell Screen		Manual/Test Kit	N/A	CE Marked	LM-HAEM-0010
1030 Haematology - .40 Limited haemostasis related tests	Activated Partial Thromboplasin Time (APTT)	Sodium Citrate	Automated/Sysmex CS-2100i	Up to 180 seconds	CE Marked	LM-COAG-0008
	D-Dimer		Automated/Sysmex CS-2100i	0.17- 4.4mg/L	CE Marked	LM-COAG-0009
	Fibrinogen		Automated/Sysmex CS-2100i	0.3 - 14g/L	CE Marked	LM-COAG-0010
	Prothombin Time (PT)		Automated/Sysmex CS-2100i	Up to 180 seconds	CE Marked	LM-COAG-0007
1030 Haematology - .57 Screening test for infectious	Infectious Mononucleosis	Plasma	Manual/Test Kit	N/A	CE Marked	LM-HAEM-0009

mononucleosis						
	Serum	Manual/Test Kit	N/A	CE Marked	LM-HAEM-0009	
	Whole Blood	Manual/Test Kit	N/A	CE Marked	LM-HAEM-0009	



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 Staining	Human Tissue	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	Coverslipping		Automated/Tissue Tek	Based on Standard Method	N/A	LM-HIST-0009
	Cut-Up		Manual	Based on Standard Method	N/A	LM-HIST-0003
	Decalcification		Manual	Based on Standard Method	N/A	LM-HIST-0002
	Embedding		Automated/Tissue Tek Embedding Centre	Based on Standard Method	N/A	LM-HIST-0005
	Labelling, Sorting & Checking of Slides		Manual	Based on Standard Method	N/A	LM-HIST-0010
	Manual Haematoxylin & Eosin Staining		Manual	Based on Standard Method	N/A	LM-HIST-0007
	Microtomy		Manual/Microtome	Based on Standard Method	N/A	LM-HIST-0006
	Routine H&E Screening		Automated/Tissue Tek Prisma	Based on Standard Method	N/A	LM-HIST-0007
	Specimen Reception & Labelling		Manual	Based on Standard Method	N/A	LM-HIST-0001
	Tissue Processing		Automated/Tissue Tek VIP	Based on Standard Method	N/A	LM-HIST-0004
1051 Histopathology - .03 Histochemistry	Alcian Blue	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	Alcian Blue/PAS	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	Congo Red for Amyloid	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	Diffquik	Automated/Tissue Tek Prisma	Based on Standard Method	N/A	LM-HIST-0007	
	Elasin Stain	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	Gram Stain	Automated/Gram Stainer	Based on Standard Method	N/A	LM-HIST-0007	
	Grocott Stain	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	HVG	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007	
	Martius Scarlet Blue	Manual	Based on Standard Method	N/A	LM-HIST-0007	
	Masson Fontana	Manual	Based on Standard Method	N/A	LM-HIST-0007	

	Masson's Trichrome Stain	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	PAS for Fungi	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	PAS for Glycogen	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	Perls Stain for Iron	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	Reticulin Stain	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
	Ziehl Neelsen Stain	Automated/Artisan	Based on Standard Method	N/A	LM-HIST-0007
1051 Histopathology - .06 Histological interpretation- perinatal pathology	Diagnostic Interpretation and Reporting	Manual/Microscope	Based on Standard Method	N/A	LM-HIST-0003
	Perinatal Pathology (Confined to histological Examination of Placental Tissue and Gravid Uterie	Manual/Microscope	Based on Standard Method	N/A	LM-HIST-0003
1051 Histopathology - .09 Immunohistochemistry	Actin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	ALK 1	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	AMACR	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Apha Feto Protein	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	BCL06	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	BCL-2	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Beta Catenin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CA125	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Calcitonin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Calretinin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD10	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD138 (Syndecan	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD15	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD20	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD23	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD3	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CD30	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD34	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016	

CD5	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD65	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CDX2	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CEA	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Chromogranin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CK20	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CK7	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
C-Kit (CD117)	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CMV	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Cyclin D1	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Desmin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Ecadherin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
EMA	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
ER	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Factor 8	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
HCG	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
HEP PAR	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
HER 2	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
HMB45	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
Inhibin	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
KI 67	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
LCA	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
MELA/MART 1	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
NSE	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
P16	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
P53	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
P63	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
PAN K	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016

	PAX 8		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	PLAP		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Podoplanin		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	PR		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	RCC		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	S100		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Somatostatin		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Synaptophysin		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Thyroglobulin		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	TTF		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Vimentin		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	Eber Probe		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Kappa		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Lambda		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
1052 Cytopathology - .02 Non gynaecological cytology	Sample preparation & description		Automated/Benchmark	Based on Standard Method	N/A	LM-CYT-0001 - 0008
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and Reporting	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LP-HIST-0032
1052 Cytopathology - .05 Immunocytochemistry	BCL-6		Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Ber EP4	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	CA125	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Calcitonin	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Calretinin	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD15	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016	

	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD20	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD23	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD3	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD30	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CD68	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CK 5/6	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CK20	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
CK7	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
ER	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
K167	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
MELA/MART 1	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
PAN K	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
PR	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
RCC	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016

		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	S100	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Somatostatin	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	Thyroglobulin	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
	TTF	Fluid	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark	Based on Standard Method	N/A	LM-HIST-0016

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	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, HVS, Eye Swab, Ear Swab, MRSA Swab, VRE Swab, CRE Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, CSF, CSF Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens	Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells/Light Microscope	CE Marked	N/A	LM-MICRO-0001 – 0020, 0022 - 0026, 0028, 0030 – 0032, 0058, 0075, 0078, 0081
	Culture of General Bacteria		Bactec FX Culture Instrument/Microscopy	CE Marked	N/A	LM-MICRO-0001 – 0020, 0022-0026, 0028, 0030, 0075, 0081
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	HIV	Blood	Enzyme Immunoassay/Test Kit	CE Marked	N/A	LM-MICRO-0073
	RSV	Nasopharyngeal Aspirate	Enzyme Immunoassay/Test Kit	CE Marked	N/A	LM-MICRO-0074
	β-Lactamase	Blood, Wound Swab, Sputum,	Enzyme Immunoassay/Test Kit	CE Marked	N/A	LM-MICRO-



		Bronchoalveolar Lavage, HVS, Eye Swab, Ear Swab, MRSA Swab, VRE Swab, CRE Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, CSF, CSF Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens				0064
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Adenovirus	Faeces	Immunochromatographic/Test Kit	CE Marked	N/A	LM-MICRO-0062
	Cryptosporidium		Immunochromatographic/Test Kit	CE Marked	N/A	LM-MICRO-0061
	Legionella	Urine	Immunochromatographic/Test Kit	CE Marked	N/A	LM-MICRO-0065
	Rotavirus	Faeces	Immunochromatographic/Test Kit	CE Marked	N/A	LM-MICRO-0062
	S. pneumoniae	Urine	Immunochromatographic/Latex Kit	CE Marked	N/A	LM-MICRO-0076
			Immunochromatographic/Test Kit	CE Marked	N/A	LM-MICRO-0055
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	C. diff Gene	Faeces	PCR/BD Max	CE Marked	N/A	LM-MICRO-0079
	Enteric Bacterial Pathogens		Nucleic-Acid Amplification/BD Max	CE Marked	N/A	LM-MICRO-0080
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques -	Aerobes/Anaerobes	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, HVS,	MIC/Disk Diffusion/Pheonix 100	CE Marked	N/A	LM-MICRO-0029 LM-



.03 Identification of fungi by microscopic morphology		Eye Swab, Ear Swab, MRSA Swab, VRE Swab, CRE Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, CSF, CSF Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens				MICRO-0057
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy			Spectroscopy/MALDI-TOF	CE Marked	N/A	LM-MICRO-0001 – 0020, 0022 - 0026, 0028, 0030, 0034, 0039, 0040, 0075, 0078, 0081
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes			Biochemical Testing/Pheonix 100	CE Marked	N/A	LM-MICRO-0029 LM-MICRO-0057
			MIC/Disk Diffusion/Manual	CE Marked	N/A	LM-MICRO-0029 LM-MICRO-0021
1024 Preservation of microbial cultures	Isolates		Freezer/Manual	CE Marked	N/A	LP-MICRO-0054
1029 Miscellaneous - .99 Miscellaneous tests	Faecal Occult Blood	Faeces	Test Kit/Manual	CE Marked	N/A	LM-MICRO-0052
	Microscopy	Urine	Particle Counter/Sedimax	CE Marked	N/A	LM-MICRO-0001
	Pregnancy Test		Test Kit/Manual	CE Marked	N/A	LM-MICRO-0053

