

Schedule of Accreditation



Organisation Name	Cavan General Hospital
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	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 public¹

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	Cavan General Hospital	Pathology Laboratory, Cavan, Ireland, 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	DCT Poly AHG DCT Anti-IgG	EDTA Sample	Ortho DAT Biovue Card, Ortho Vision	Based on Standard method	Pos/Neg	LM-BT-0001 LM-BT-014 LP-BT-0030
	Direct Antiglobulin Test	Whole Blood	Ortho Vision	CE Marked	N/A	LM-BT-0014
1020 Transfusion science - .99 Miscellaneous tests	Kleihauer Test			Manual Method	CE Marked	N/A

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)
It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.

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	24 Hour Urinary Calcium	Urine	Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	24 Hour Urinary Potassium		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	24 Hour Urinary Sodium		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	24 Hour Urinary Urate		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	Alanine Aminotransferase (ALT)	Serum	TRIS Buffer without PLP	Abbott Alinity, Range: 6 -4772 U/L	CE Marked	LM-BIO-0009
	Albumin		HCG	Abbott Alinity, Range: 4 -105 g/L	CE Marked	LM-BIO-0009
	Albumin Creatinine Ratio (ACR)	Urine	Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	Alkaline Phosphatase (ALP)	Serum	AMP Buffer not IFCC	Abbott Alinity, Range: 9 - 4555 U/L	CE Marked	LM-BIO-0009
	Amylase		TRIS Buffer without PLP	Abbott Alinity, Range: 4 - 6554 U/L	CE Marked	LM-BIO-0009

Asparate Aminotransferase (AST)		TRIS Buffer without PLP	Abbott Alinity, Range: 3 - 4202 U/L	CE Marked	LM-BIO-0009
C Reactive Protein (CRP)		Immunoturbidimetric	Abbott Alinity, Range: 1.0 - 480 mg/L	CE Marked	LM-BIO-0009
Calcium		Arsenazo III	Abbott Alinity, Range: 0.5 - 6.0 mmol/L	CE Marked	LM-BIO-0009
	Urine	Arsenazo III	Abbott Alinity, Range: 0.5 - 6.0 mmol/L	CE Marked	LM-BIO-0009
Carcino-embryonic Antigen	Serum	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 1.73 - 1500	CE Marked	LM-BIO-0009
Chloride (Cl)		Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 50 - 150 mmol/L	CE Marked	LM-BIO-0009
	Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 20 - 200 mmol/L	CE Marked	LM-BIO-0009
Cholesterol	Serum	Cholesterol esterase/oxidase	Abbott Alinity, Range: 0.18 - 18.26 mmol/L	CE Marked	LM-BIO-0009
Creatine Kinase		NAC	Abbott Alinity, Range: 7 - 4267 U/L	CE Marked	LM-BIO-0009
Creatinine			Enzymatic	Abbott Alinity, Range: 8.8 - 3536 umol/L	CE Marked
	Urine	Enzymatic	Abbott Alinity, Range: 2200 - 35360 umol/L	CE Marked	LM-BIO-0009
Creatinine Clearance	Urine/Serum	Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
Direct Bilirubin	Serum	Diazotised sulphanilic acid	Abbott Alinity, Range: 1.7 - 256.5 umol/L	CE Marked	LM-BIO-0009

Estimated Glomerular Filtration Rate (eGFR)		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009	
Free:Total Prostate Specific Antigen (PSA) Ratio		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009	
Gamma Glutamyl Transferase (GGT)		L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Abbott Alinity, Range: 4 - 9256 IU/L	CE Marked	LM-BIO-0009	
Glucose	Sodium Fluoride	Hexofinase + G6PD	Abbott Alinity, Range: 0.28 - 44.4 mmol/L	CE Marked	LM-BIO-0009	
HDL Cholesterol	Serum	Accelerator Selective Detergent	Abbott Alinity, Range: 0.13 - 4.66 mmol/L	CE Marked	LM-BIO-0009	
High Sensitivity Troponin		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 10 - 50,000 ug/L	CE Marked	LM-BIO-0009	
Lactate Dehydrogenase (LDH)		Lactate to Pyruvate (NADH)	Abbott Alinity, Range: 30 - 4500 U/L	CE Marked	LM-BIO-0009	
Low Density Lipoprotein (LDL) Cholesterol		Measured Light Selective Detergent	Abbott Alinity, Range: 0.03 - 20.69 mmol/L	CE Marked	LM-BIO-0009	
Luteinising Hormone (LH)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.12 - 250 IU/L	CE Marked	LM-BIO-0009	
Magnesium		Enzymatic	Abbott Alinity, Range: 0.25 - 3.90 mmol/L	CE Marked	LM-BIO-0009	
Microalbumin		Urine	Immunoturbidimetric	Abbott Alinity, Range: 5 - 500 mg/L	CE Marked	LM-BIO-0009
Non High Density Lipoprotein (HDL) Cholesterol		Serum	Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
NT Pro BNP			Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 8.3 - 35000pg/ml	CE Marked	LM-BIO-0009

Osmolality		Freezing Point Depression	A2O Osmeter 0 mOSM/Kg to 3,000 mOSM/Kg	CE Marked	LM-BIO-0010
	Urine	Freezing Point Depression	A2O Osmeter 0 mOSM/Kg to 3,000 mOSM/Kg	CE Marked	LM-BIO-0010
Paracetamol	Serum	Spectrophotometric, aryl acrylamidase	Abbott Alinity, Range: 1 -377 mg/L	CE Marked	LM-BIO-0009
Phosphate		Phosphomolybdate UV	Abbott Alinity, Range: 0.23 - 8.17 mmol/L	CE Marked	LM-BIO-0009
Potassium (K)		Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 1.0 - 10.0 mmol/L	CE Marked	LM-BIO-0009
	Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 1 - 300 mmol/L	CE Marked	LM-BIO-0009
Protein		Turbidimetry	Abbott Alinity, Range: 0.062 - 2.0 g/L	CE Marked	LM-BIO-0009
Protein Creatinine Ratio		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
Protein Excretion		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
Salicylate	Serum	Enzymatic/Colorimetric	Abbott Alinity, Range: 50 - 1000 mg/L	CE Marked	LM-BIO-0009
Sodium (Na)		Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 100 - 200 mmol/L	CE Marked	LM-BIO-0009
	Urine	Ion-Selective Electrode Diluted (Indirect)	Abbott Alinity, Range: 20 - 400 mmol/L	CE Marked	LM-BIO-0009
Total Protein	Serum	Biuret	Abbott Alinity, Range: 2 - 172 g/L	CE Marked	LM-BIO-0009

	Transferrin Saturation		Calculation	Laboratory Information System Interface	Based on Standard Method	LM-BIO-0009
	Triglycerides		Glycerol Phosphate Oxidase	Abbott Alinity, Range: 0.08 - 16.05 mmol/L	CE Marked	LM-BIO-0009
	Urea		Kinetic Urease	Abbott Alinity, Range: 1.1 - 44.6 mmol/L	CE Marked	LM-BIO-0009
	Uric Acid		Endpoint Uricase	Abbott Alinity, Range: 17.7 - 2220umol/L	CE Marked	LM-BIO-0009
		Urine	Endpoint Uricase	Abbott Alinity, Range: 13.0- 2410 umol/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Procalcitonin	Serum	CMIA	Abbott Alinity, Range: 0.02 - 100 ug/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin		Petinina	Abbott Alinity, Range: 2.3 - 50 mg/L	CE Marked	LM-BIO-0009
	Gentamicin		Particle-enhanced Turbidimetric Inhibition Immunoassay (PETINIA)	Abbott Alinity, Range: 0.5 - 10.0 mg/L	CE Marked	LM-BIO-0009
	Lithium		Spectrophotometric	Abbott Alinity, Range: 0.101 - 3.51 mmol/L	CE Marked	LM-BIO-0009
	Tobramycin		Particle-enhanced Turbidimetric Inhibition Immunoassay (PETINIA)	Abbott Alinity, Range: 0.3 - 10.0 ug/L	CE Marked	LM-BIO-0009
	Vancomycin		Petinina	Abbott Alinity, Range: 1.4 - 100 mg/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Ethanol		ADH	Abbott Alinity, Range: 10 - 600 mg/dl	CE Marked	LM-BIO-0009

1061 Clinical Chemistry - .20 Hormones	Follicle Stimulating Hormone (FSH)	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.11 - 150 IU/L	CE Marked	LM-BIO-0009
	Free T3	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 1.46 - 30.72 pmol/L	CE Marked	LM-BIO-0009
	Free T4	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 5.41 - 64.35 pmol/L	CE Marked	LM-BIO-0009
	Oestradiol	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 88 - 3670 pmol/L	CE Marked	LM-BIO-0009
	Progesterone	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.5 - 40 nmol/L	CE Marked	LM-BIO-0009
	Thyroid Stimulating Hormone (TSH)	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.083 - 100.0	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .40 Iron studies	Ferritin	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 1.98 - 1675 mg/L	CE Marked	LM-BIO-0009
	Iron	Ferene	Abbott Alinity, Range: 0.9 - 179.0 umol/L	CE Marked	LM-BIO-0009
	Total Bilirubin	Diazo	Abbott Alinity, Range: 1.7 - 427.5 umol/L	CE Marked	LM-BIO-0009
	Transferrin	Turbidimetry	Abbott Alinity, Range: 0.19 - 5.83 g/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 4.98 - 45.3 nmol/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin B12	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 109 - 1475 pmol/L	CE Marked	LM-BIO-0009
	Vitamin D	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 8.8 - 385.5 nmol/L	CE Marked	LM-BIO-0009

1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 2.0 - 2000 U/L	CE Marked	LM-BIO-0009
	Ca 15.3		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.6 - 800 U/ml	CE Marked	LM-BIO-0009
	Ca 19.9		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 2.06 - 1500 U/ml	CE Marked	LM-BIO-0009
	CA-125		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 1.0 - 1000 U/ml	CE Marked	LM-BIO-0009
	Free PSA		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.001 - 30.0 ng/l	CE Marked	LM-BIO-0009
	Total Prostate Specific Antigen (PSA)		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 0.025 - 100 mg/ml	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .60 Glycohaemoglobins	Glycated Haemoglobin (HbA1c)	Whole Blood	HPLC	Adams A1C HA- 8180V HbA1c: 4 – 15% NGSP (20 – 140 mmol/mol), HbF: 0.3 – 5%	CE Marked	LM-BIO-0003
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Beta Human Chorionic Gonadotrophin (Beta HCG)	Serum	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity, Range: 2.2 - 15,000 mIU/L	CE Marked	LM-BIO-0009
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor (RF)		Immunoturbidimetric	Abbott Alinity, Range: 15 - 200 iu/ml	CE Marked	LM-BIO-0009

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 and Blood Count Differential	EDTA Whole Blood	Sysmex XN-2000 Fluorescence Flow Cytometry Hydrodynamic Focusing Direct Current Sodium Lauryl Sulphate Haemoglobin Method	WBC 0 to 440 x 10(9)/L RBC 0 to 8.6 x 10(12)/L Hgb 0 to 26 g/dl HCT: 0% to 75 L/L PLT 0 to 5000 x 10(9)/L NRBC# 0 to 20 x 10(9)/L	CE Marked	LM-HAEM-0014
1030 Haematology - .02 Visual examination of blood films	Preparation and Visual Examination of Blood Films		SP10 Stainer/Microscopy Manual Method	N/A	Based on Standard Method	LM-HAEM-0011 LM-HAEM-0015
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate	Sodium Citrate Whole Blood	Westergren Method/Desaga S2000	0 mm/hr to 100 mm/hr	Based on Standard Method	LM-HAEM-0005
			Westergren Method/Sediplus S100	0 mm/hr to 100 mm/hr	Based on Standard Method	LM-HAEM-0004
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count	EDTA Whole Blood	Sysmex XN-2000 Fluorescence Flow Cytometry	0.0 to 0.72 x 10(9)/L	CE Marked	LM-HAEM-0014
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites	EDTA Plasma	Binax Kit Immunochromatographic Membrane Assay	N/A	CE Marked	LM-HAEM-0013
	Examination for Malarial Parasites. (screening)		Carestart Kit Antigen Test	N/A	CE Marked	LM-HAEM-0013
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sicke Cell Screen	EDTA Whole Blood	Sickledex Qualitative Solubility Test	N/A	CE Marked	LM-HAEM-0010

1030 Haematology - .40 Limited haemostasis related tests	Activated Partial Thromboplasin Time (APTT)	Sodium Citrate Plasma	Sysmex CS-2100i Clotting Assay	Up to 180 seconds	CE Marked	LM-COAG-0008
	D-Dimer		Sysmex CS-2100i Immunoturbidimetric Assay	0.19 mg/L to 35.2 mg/L	CE Marked	LM-COAG-0009
	Fibrinogen		Sysmex CS-2100i Clotting Assay	0.3 g/L to 10 g/L	CE Marked	LM-COAG-0010
	Prothombin Time (PT)		Sysmex CS-2100i Clotting Assay	Up to 180 seconds	CE Marked	LM-COAG-0007
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis	EDTA Plasma	Accusay Mono Test Kit Immunoassay	N/A	CE Marked	LM-HAEM-0009
		Serum	Accusay Mono Test Kit Immunoassay	N/A	CE Marked	LM-HAEM-0009
		Whole Blood	Manual/Test Kit	N/A	CE Marked	LM-HAEM-0009

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 Staining	Human Tissue	Automated/Tissue Tek Prisma	Based on Standard Method	N/A	LM-HIST-0007
	Coverslipping		Automated/Tissue Tek Glas	Based on Standard Method	N/A	LM-HIST-0009
	Cut-Up		Manual	Based on Standard Method	N/A	LM-HIST-0003
	Embedding		Automated/Histodream Embedding Centre	Based on Standard Method	N/A	LM-HIST-0005
	Fixation and Decalcification		Manual	Based on Standard Method	N/A	LM-HIST-0002
	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
			Manual/Semi-Automated Microm HM355S Microtome	CE Marked	N/A	LM-HIST-0006
	Routine H&E Staining		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 VIP6	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	Manual	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	CE Marked	N/A	LM-HIST-0007
	Masson Fonatana	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	CE Marked	N/A	LM-HIST-0007	
1051 Histopathology - .06 Histological interpretation-perinatal pathology	Diagnostic Interpretation and Reporting excluding: Breast Pathology	Manual/Microscope	Based on Standard Method	N/A	LP-HIST-0032

	Neuropathology Renal Pathology Paediatric Pathology
	Perinatal Pathology (Confined to histological Examination of Placental Tissue and Gravid Uterie)
1051 Histopathology - .09 Immunohistochemistry	Actin
	ALK 1
	Apha Feto Protein
	BCL-2
	BCL6
	Beta Catenin
	CA125
	Calcitonin
	Calretinin
	CD10
	CD138 (Syndecan)
	CD15
	CD20
CD23	

Manual/Microscope	Based on Standard Method	N/A	LP-HIST-0032
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

CD3	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD30	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD34	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD5	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD68	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CDX2	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CEA	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Chromogranin	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CK20	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CK7	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
C-Kit (CD117)	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CMV	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Cyclin D1	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Desmin	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
EMA	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
ER	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Factor 8	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
HCG	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

Hepatocyte Specific Antigen	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
HER 2	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
HMB45	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Inhibin	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
KI 67	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
LCA	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
MELA/MART 1	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
NSE	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
P16	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
P40	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
P53	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
P57	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
P63	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PAN K	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PAX 8	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PLAP	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Podoplanin (P240)	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PR	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

	RCC		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	S100		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Synaptophysin		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Thyroglobulin		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	TTF		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Vimentin		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	Eber Probe		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Kappa		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Lambda		Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
1052 Cytopathology - .02 Non gynaecological cytology	Cytology Processing	Human Tissue Fluid	Automated/Thin Prep Genesis	CE Marked	N/A	LM-CYT-0001 to 0011
	Sample preparation & description	Human Tissue	Manual/Cell Block	Based on Standard Method	N/A	LM-CYT-0001 - 0008
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic Interpretation and Reporting	Human Tissue Fluid	Automated/Benchmark XT	CE Marked	N/A	LP-HIST-0032
1052 Cytopathology - .05 Immunocytochemistry	BCL-6	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Ber EP4	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	CA125	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Calcitonin	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
Calretinin	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD15	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD20	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD23	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD3	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD30	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CD68	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CK 5/6	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CK20	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
CK7	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
ER	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
K167	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
MELA/MART 1	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PAN K	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
PR	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
RCC	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
S100	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

		Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	Thyroglobulin	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
	TTF	Fluid	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016
		Human Tissue	Automated/Benchmark XT	CE Marked	N/A	LM-HIST-0016

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	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, High Vaginal Swab, Eye Swab, Ear Swab, Methicillin Resistant Staphylococcus aureus Swab, Vancomycin Resistant Enterococcus Swab, Carbapenem Resistant Enterobacterales Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, Cerebrospinal Fluid, Cerebrospinal Fluid Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance	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

		Specimens, Adverse Transfusion, Environmental Specimens				
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	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, High Vaginal Swab, Eye Swab, Ear Swab, Methicillin Resistant Staphylococcus aureus Swab, Vancomycin Resistant Enterococcus Swab, Carbapenem Resistant Enterobacterales Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, Cerebrospinal Fluid, Cerebrospinal Fluid Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens	Bactec FX Culture Inrument/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	Human Immunodeficiency Virus (HIV)	Blood	Enzyme Immunoassay/Determine Ultra HIV Test Kit	CE Marked	N/A	LM-MICRO-0073

specific antibodies and appropriate techniques - .03 Enzyme immunoassay,						
	RSV	Nasopharyngeal Aspirate	Enzyme Immunoassay/Test Kit	CE Marked	N/A	LM-MICRO-0074
	β-Lactamase	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, High Vaginal Swab, Eye Swab, Ear Swab, Methicillin Resistant Staphylococcus aureus Swab, Vancomycin Resistant Enterococcus Swab, Carbapenem Resistant Enterobacteriales Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, Cerebrospinal Fluid, Cerebrospinal Fluid Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens	Enzyme Immunoassay/Oxoid Beta Lactamase Sticks	CE Marked	N/A	LM-MICRO-0064
1014 Detection of bacterial, parasite, viral or	Adenovirus	Faeces	Immunochromatographic/Combi i-Strip Test Kit	CE Marked	N/A	LM-MICRO-0062

fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,						
	Legionella	Urine	Immunochromatographic/Binax NOW Legionella Test Kit	CE Marked	N/A	LM-MICRO-0065
	Rotavirus	Faeces	Immunochromatographic/Combi i-Strip 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	4-Plex	Nasopharangeal Swab	Genexpert/Polymerase Chain Reaction	CE Marked	N/A	LM-MICRO-0098
	Clostridium difficile Gene	Faeces	Polymer Chain Reaction/BD Max	CE Marked	N/A	LM-MICRO-0079
	Enteric Bacterial Pathogens		Nucleic-Acid Amplification/BD Max	CE Marked	N/A	LM-MICRO-0080
	Influenza/Respiratory syncytial virus	Nasopharangeal Swab	BD Max/Nucleic Acid Amplification	CE Marked	N/A	LM-MICRO-0088
	Norovirus	Stool	Genexpert/Polymerase Chain Reaction	CE Marked	N/A	LM-MICRO-0094
	SARs-Cov-2	Nasopharangeal Swab	BD Max/Nucleic Acid Amplification	CE Marked	N/A	LM-MICRO-0097
			Genexpert/Polymerase Chain Reaction	CE Marked	N/A	LM-MICRO-0095
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Aerobes/Anaerobes	Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, HVS, Eye Swab, Ear Swab, MRSA Swab, VRE	MIC/Disk Diffusion	CE Marked	N/A	LM-MICRO-0029 LM-MICRO-0057

		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				
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy		Blood, Wound Swab, Sputum, Bronchoalveolar Lavage, High Vaginal Swab, Eye Swab, Ear Swab, Methicillin Resistant Staphylococcus aureusRSA Swab, Vancomycin Resistant Enterococcus Swab, Carbapenem-resistant EnterobacteralesRE Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular	Spectroscopy/MALDI-TOF	CE Marked	N/A	LM-MICRO-0001 – 0020, 0022 - 0026, 0028, 0030, 0034, 0075, 0078, 0081

		Cannulae, Cerebrospinal SFluid, CerebrospinalS Fluid Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens				
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes		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	MIC/Disk Diffusion/Manual	CE Marked	N/A	LM-MICRO-0029 LM-MICRO-0021
	Antimicrobial Susceptibility Testing	Isolate	Phoenix M50 /Automated Broth Microdilution	CE Marked	N/A	LM-MICRO-0057
1024 Preservation of microbial cultures	Isolates	Blood, Wound Swab, Sputum, Bronchoalveolar	Freezer/Manual	CE Marked	N/A	LP-MICRO-0054

		Lavage, High Vaginal Swab, Eye Swab, Ear Swab, Methicillin Resistant Stayphlyococcus aureus Swab, Vancomycin Resistant Entereococcus Swab, Carbapenem-resistant Enterobacterales Swab, Throat Swab, Bile, Genital Tract Specimens, Urine, Fluids, Faeces, Sinus Aspirate, Nasal Swabs, Mouth Swabs, Pressure Sores, Abscesses, Intravascular Cannulae, Cerebrospinal Fluid, Cerebrospinal Fluid Shunts, Tissues/Biopsies, Ulcer Swabs, Surveillance Specimens, Adverse Transfusion, Environmental Specimens				
1029 Miscellaneous - .99 Miscellaneous tests	Faecal Occult Blood	Faeces	Immo-Care C Test Kit/Manual	CE Marked	N/A	LM-MICRO-0052
	Microscopy	Urine	Automated/Sedimax Analyser	CE Marked	N/A	LM-MICRO-0001