

Schedule of Accreditation



Organisation Name	Mater Private Hospital
Trading As	Mater Private Hospital
INAB Reg No	191MT
Contact Name	Fiona O'Brien
Address	Pathology Department, Eccles Street, Dublin, D7
Contact Phone No	01-8858346
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Website	
Accreditation Standard	EN ISO 15189
Date of award of accreditation	22/04/2008
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 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	Head Office	Pathology Department, Eccles Street, Dublin, D7

Scope of Accreditation

Head Office

Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO Rh D Blood Grouping	Red Cells & Plasma	1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0002 LS-BT-0041
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma/Serum	1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0002 LS-BT-0041
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0010
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing	Red Cells & Plasma	1. Manual 2. Electronic Issue	1. Manual 2. Electronic Issue	N/A	LM-BT-0007 LS-BT-0047
1020 Transfusion science -	Antigen Typing	Red Cells	1. Manual	Automated &	N/A	LM-BT-0014

.06 Red cell phenotyping			2. IH500	Manual		
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs		1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0020
<i>a The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)</i>						

Head Office

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	Serum	Bromocresol green	Roche cobas® PRO	CE	LM-BIO-0014
	Alk Phos		Roche AMP Buffer	Roche cobas® PRO	CE	LM-BIO-0014
	ALT		Tris buffer with p5p	Roche cobas® PRO	CE	LM-BIO-0014
	Amylase		Roche liquid stable pnp7	Roche cobas® PRO	CE	LM-BIO-0014
	AST		Tris buffer with p5p	Roche cobas® PRO	CE	LM-BIO-0014
	Bicarbonate		Enzymatic	Roche cobas® PRO	CE	LM-BIO-0014
	Calcium	Serum/Urine	NM-BAPTA	Roche cobas® PRO	CE	LM-BIO-0014
	Calcium Corrected	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
	Chloride	Serum/Urine	ISE indirect	Roche cobas® PRO	CE	LM-BIO-0014
	Cholesterol HDL	Serum	Direct HDL	Roche cobas®	CE	LM-BIO-0014

			PRO		
Cholesterol LDL		Direct LDL	Roche cobas® PRO	CE	LM-BIO-0014
Cholesterol Total	Serum	Cholesterol oxidase	Roche cobas® PRO	CE	LM-BIO-0014
CK		CK-NAC(IFCC)	Roche cobas® PRO	CE	LM-BIO-0014
Creatinine /creatinine clearance serum / urine	Serum/Urine	Roche Creatinine Enzymatic	Roche cobas® PRO	CE	LM-BIO-0014
CRP	Serum	Immunoturbidimetric	Roche cobas® PRO	CE	LM-BIO-0014
Digoxin		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
eGFR	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
Gamma GT	Serum	Gamma glut3carb4nitro	Roche cobas® PRO	CE	LM-BIO-0014
Globulin	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
Glucose	Serum/Plasma	Hexokinase	Roche cobas® PRO	CE	LM-BIO-0014
Iron	Serum	FerroZine without deproteinization	Roche cobas® PRO	CE	LM-BIO-0014
LDH		L to P IFCC	Roche cobas® PRO	CE	LM-BIO-0014
Lp(a)			Roche Cobas 6000	CE based on standard method	LM-BIO-0014
		Immunoturbidimetric	Roche cobas® PRO	CE	LM-BIO-0014
Magnesium		Xylidyl blue	Roche cobas® PRO	CE	LM-BIO-0014

	Non-HDL Cholesterol	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
	NT-PRO-BNP	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Phosphate		Phosphomolybdate UV	Roche cobas® PRO	CE	LM-BIO-0014
	Potassium	Serum/Urine	Indirect ISE	Roche cobas® PRO	CE	LM-BIO-0014
	Protein/Creatinine Ratio	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
	Sodium	Serum/Urine	Indirect ISE	Roche cobas® PRO	CE	LM-BIO-0014
	Total Bilirubin	Serum	Dichlorophenyl Diazonium	Roche cobas® PRO	CE	LM-BIO-0014
	Triglyceride		Lipase	Roche cobas® PRO	CE	LM-BIO-0014
	Urate		Uricase	Roche cobas® PRO	CE	LM-BIO-0014
	Urea		Urease	Roche cobas® PRO	CE	LM-BIO-0014
	Urinary Albumin	Urine	Immunoturbidimetric	Roche cobas® PRO	CE	LM-BIO-0014
	Urinary Albumin/Creatinine Ratio	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
	Urine Calcium/Creatinine Ratio	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
	1061 Clinical Chemistry - .02 Proteins, quantitative analysis	hs-Troponin T	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE
Total Protein		Serum/Urine/CSF	Biuret for Serum Turbidimetric for	Roche cobas® PRO	CE	LM-BIO-0014

			Urine/CSF			
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin	Serum	EIA	Roche cobas® PRO	CE	LM-BIO-0014
	Vancomycin	Serum	KIMS	Roche cobas® PRO	CE	LM-BIO-0014
1061 Clinical Chemistry - .20 Hormones	Beta hCG	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Cortisol		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Free T4		ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	PTH		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Sex Hormone Binding Globulin		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Testosterone		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	TSH	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Ferritin		ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
1061 Clinical Chemistry - .40 Iron studies	Transferrin		Immunoturbidimetric	Roche cobas® PRO	CE	LM-BIO-0014
	Transferrin Saturation	Calculation	Calculation	Roche cobas® PRO	CE	LM-BIO-0014
1061 Clinical Chemistry - .45 Vitamin B12 and folate	B12	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Folate		ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D		Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014

1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Ca125	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	Ca153		ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	CEA		ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
	TPSA	Serum	ECLIA Immunoassay	Roche cobas® PRO	CE	LM-BIO-0014
1061 Clinical Chemistry - .61 Hb A1c	HbA1c	Whole Blood	HPLC	Roche cobas® PRO	CE	LS-BIO-0029 Operation of the Arkray A1C HA-8160 Analyser System LM-BIO-0012 Determination of HBA1C in a Patient Sample

Head Office

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 Full Blood Counts	Whole Blood	Fluorescence Flow Cytometry Method (FCM) – a semiconductor laser (639nm). Hydrodynamic Focussing DC detection – RBC and PLT analysis. • SLS Haemoglobin Method – cyanide-free HGB analysis.	Automated using Sysmex XN 2000	CE Marked	LS-HAEM-0042- FBC and Reticulocyte Analysis using Sysmex XN-2000
1030 Haematology - .02 Visual examination of blood films	Visual examination of blood films		Modified Wrights Stain	Hematek	CE Marked	LM-HAEM-0028 Preparation, Microscopic Examination & Reporting of Blood Films LM-HAEM-0043 Staining of Blood Films using the Hematek Staining Machine LS-HAEM-0016 The

						Handling of Specimens in the Haematology Department
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate		The surface layer of the erythrocytes is detected by means of a change of light intensity at the beginning of the measuring process and after one hour	Desaga S2000	CE Marked	LM-HAEM-0042 ESR Determination using the Desaga S2000 & Sedivette Back-up LS-HAEM-0016 The Handling of Specimens in the Haematology Department
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte Counts		• Fluorescence Flow Cytometry Method (FCM)	Automated using Sysmex XN 2000	CE Marked	LS-HAEM-0042 OPERATION, FBC AND RETICULOCYTE ANALYSIS USING SYSMEX XN-2000
1030 Haematology - .41 General haemostasis related tests	APTT Ratio	Calculation	Calculation	Calculation		
	General Haemostasis tests including PT, INR, APTT, Fibrinogen quantation, D-dimer, correction studies	Plasma	Mechanical clotting system	Stago compact Max	CE	LM-HAEM-0046
			Mechanical clotting system	Stago compact Max Stago Compact Max 3	CE Marked	LM-HAEM-0046 Operation of the Stago Compact Max Analysers in the Performance of the PT/INR, APTT, Fibrinogen and D-Dimers

Head Office

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 Embedding	Human Tissue	Sakura Autotec a120	Based on Standard Method	N/A	LS-HIST-0064 Operation of the Tissue Tek A120 Auto Embedder
	Automated Haematoxylin		Automated staining and coverslipping of slides on Leica Multistainer ST and Leica Coverslipper CV. Manual disposal of used chemicals and stains.	Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet	CE/Based on standard method.	Automated Haematoxylin and Eosin Staining LM-HIST-0009 Staining LM-HIST-0010 Stains & Solutions LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0037 Disposal of Chemical and Clinical Waste
			Leica Spectra ST Staining & Spectra CV Coverslipper	CE	CE/Based on standard method.	LS-HIST-0049 Operation of the Leica Spectra and

Cover slipping & sorting	
Coverslipping and Sorting	
Cut up	

			Coverslipper
Automated coverslipping of slides using Leica Multistainer ST and Leica CV. Manual checking and labelling and distribution of slides.	Leica Multistainer ST and Leica CV Nikon Microscope	CE/Based on standard method.	Coverslipping and Sorting LM-HIST-0011 Coverslipping in Histology & Cytology LS-HIST-0010 Operation of the Nikon Microscope LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0024 Labeling, Sorting and Checking Slides and Recording Numbers LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV
Automated coverslipping of slides using Leica Spectra ST and Leica Spectra CV. Manual checking, labelling and distribution of slides.	CE	CE/Based on standard method.	LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV
Manual dissection of Human tissue samples using the G2 speech system in AFOS cut up room	AFOS Cut Up Room Balances- Ohous, Denver	N/A	LM-HIST-0022 Principles of good practice and training manual for Medical Scientists involved in Cut Up LS-HIST-0016 Operation of Balances in Histology

Embedding
Microtomy
Specimen Reception Automated and Manual Haematoxylin and Eosin Staining Coverslipping

			LS-HIST-0044 AFOS Cut Up Room LS-HIST-0050 Operation of the G2speech
Manual method of impregnating Human tissue samples with paraffin wax using the Tissue Tek TEC 5 Embedding Centre, to create a wax tissue block.	Para Trimmer Tissue Tek TEC 5 Embedding Centre	CE/Based on standard method.	LM-HIST-0007 Embedding LS-HIST-0039 Operation of Para Trimmer LS-HIST-0045 Operation of Tissue Tek TEC 5 Embedding Centre
Manual and automated use of microtomes for cutting tissue sections onto glass slides.	Leica RM 2255 (1- 4) RA Lamb Waterbaths Histology Ovens	CE/Based on standard method.	Manual and motorized sectioning of processed tissue LM-HIST-0008 Cutting of Paraffin Blocks LS-HIST-0004 Operation of the Microtomes LS-HIST-0006 RA Lamb Waterbaths LS-HIST-0014 Operation of the Histology Ovens
Manual labelling and entering specimens onto LIS. Automated printing of cassettes using the Leica IPC Automated Cassette	Leica IPC Automated Cassette Printer	CE/Based on standard method.	LS-LIS-0004 Operation of the Clinisys Laboratory Information Management System in Histology LM-HIST-0001 Specimen Reception, Labelling & Charging

						LM-HIST-0004 Fixation & Decalcification LS-HIST-0055 Operation of the Leica IPC Automated Cassette Printer
	Tissue processing		Automated method of xylene, alcohol, paraffin wax infiltration of Human tissue samples using the VIP Tissue Processor/ Leica ASP6025	VIP Tissue Processor Leica ASP6025 Tissue Processor	Based on standard method	LM-HIST-0006 Tissue Processing LS-HIST-0032 Operation of VIP Tissue Processor LS-HIST-0054 Operation of the Leica ASP6025
			Automated method of xylene, alcohol, paraffin wax infiltration of Human tissue samples using the Leica Pegasus Dual Retort Processor	CE Marked		LM-HIST-0006 Tissue Processing LS-HIST-0065 Operation of the Leica Pegasus Plus Processor
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut-up Frozen section cryotomy and staining		Manual weighing, cutting of fresh tissue sample in AFOS cut up room. Manual use of Leica Cryostat to section tissue. Manual staining and coverslipping and labelling of slides. Manual entering of specimen details onto LIS, automated printing of cassette using Leica IPC Automated Cassette Printer	Leica Multistainer Spectra and Leica Coverslipper CV Leica Cryostat CM1950 Balances- Ohaus, Denver Chemflow Fume Cabinet Leica IPC Automated Cassette Printer	Based on standard method	Cryotomy and Staining LM-HIST-0002 Frozen Sections LM-HIST-0009 Staining LM-HIST- 0011Coverslipping in Histology & Cytology LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV

						LS-HIST-0009 Operation of the Leica Cryostat CM1950 LS-HIST-0044 AFOS Cut Up Room LS-HIST-0016 Operation of the Balances in Histology LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0055 Operation of the Leica IPC Automated Cassette Printer
	Specimen Reception		Manual accepting, labelling and entering of specimens onto the LIS system.	N/A	N/A	LM-HIST-0001 Reception, Labelling & Charging
	1051 Histopathology - .03 Histochemistry	Alcian Blue	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohaus, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
		Alcian Blue/PAS	Manual staining of special stain slides. Automated 'finishing	Nikon Microscope Leica Multistainer ST and Leica	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

	special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver		
Congo Red (Amyloid)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Diastase - PAS	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Millers Elastic	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

Periodic Acid Schiffs (PAS)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Perls Prussian Blue	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010 Stains & Solutions, LM-HIST-0011 Coverslipping in Histology & Cytology, LS-HIST-0016 Operation of the Balances in Histology, LS-HIST-0010 Operation of the Nikon Microscope, LS-HIST-0017 Operation of the Chemflow Fume Cabinet, LS-HIST-0024 Labeling, Sorting and Checking Slides and Recording Numbers, LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV
Reticulin (Gordon & Sweets)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

	and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Balances- Ohous, Denver		
Special stains	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	CE/Non-CE/Based on standard method	LM-HIST-0009 Staining
Trichrome (Gomoris)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Trichrome (Masson)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Van Gieson	Manual staining of special stain slides. Automated 'finishing	Nikon Microscope Leica Multistainer ST and Leica	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

			special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Coverslipper CV Chemflow Fume Cabinet Balances- Ohaus, Denver		
	Ziehl Neelsen (ZN)		Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohaus, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
1051 Histopathology - .09 Immunohistochemistry	Actin	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Actin SM		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
			Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	AE1/AE3		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology

BCL2
BCL6
BEREP4
Calretinin
CAM5.2(Cyto8/18)
CD 20 (L26)
CD10
CD117 (c-kit)

Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048

CD138
CD15 (Leu M1)
CD23
CD3
CD30 (Ki1)
CD34
CD4

			Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and

CD45 (CLA)
CD5
CD68 (KP1)
CD79a
CD8
CDX2
CEA

			Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

Chromogranin
Cyclin D1
Cyt 903(HMWCK)
Cyto 20
Cyto 5/6
Cyto 7
D240

			the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology

Desmin
Dual Ck903/racemase
Dual Napsin /TTF1
E-Cadherin
EMA
ER
GATA3

			Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology

H. pylori (HLO)		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
HMB45		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunohistochemistry staining methods	Human tissue	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and Coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Nikon Microscope Chemflow Fume Cabinet	CE/Based on standard method.	LM-HIST-0011 Coverslipping in Histology & Cytology
Kappa	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Lambda		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Melan A	Human tissue	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet.	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

		Leica Coverslipper CV. Manual checking and sorting of slides.	Manual checking and sorting of slides. Nikon Microscope		
MLH1	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
MSH2		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
MUM1	Human tissue	Immunostainer	CE	N/A	LS-HIST-0010, 0017, 0024, 0048, 0049
Napsin A		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST5020 and Leica Coverslipper CV5030. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST5020 and Leica Coverslipper CV5030. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
P16		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

			Microscope		
P53		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
PR		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
PSA		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
PSMA		Immunostainer	CE	N/A	LS-HIST-0010, 0017, 0024, 0048, 0049
Racemase		Automated staining of immuno slides using the Leica Bond III.	Leica Bond III Immunostainer Leica Multistainer	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

		Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope		
S-100		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
SMMS		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
Synaptophysin		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

				Microscope		
	TTF1		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
	Vimentin WT1		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
1052 Cytopathology - .02 Non gynaecological cytology	Non gynaecological cytology, including Smears, Cytospin Preps and Cell Blocks, Automated Staining Papanicolaou and Manual Staining MGG	Human Tissue or Fluid	Cytospin Thin Prep2000, Leica Spectra ST & CV, Chemflow Fume Cabinet	CE	CE/Based on standard method.	TBC
	Non gynaecological cytology, including Smears Cytospin preps and Cell Blocks Automated Staining		Cytospin ThinPrep2000 Leica Multistainer ST5020 and Leica Coverslipper CV5030	CE	N/A	LM-CYT-002 Specimen Preparation and Fixation LM-CYT-004 Cytology Staining Methods LM-HIST-0011

	Papanicolaou Manual Staining MGG		Chemflow Fume Cabinet			Coverslipping in Histology & Cytology LS-HIST-0024 Labeling, Sorting and Checking Slides & Recording Numbers
	Non gynaecological cytology; including Smears Cytospin Preparations and Cell Blocks. Automated Staining Papanicolaou. Manual Staining MGG	Human Tissue and Fluids	ThinPrep Genesis Processor. Cytospin centrifuge. Leica HistoCore SPECTRA ST & CV. Chemflow Fume Cabinet	CE	N/A	

Head Office

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
	Vitek MS	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/urethral, IUCD, Ear/eye/nose/throat/mouth swabs, wound swabs, tips, drains, urine, stool	Culture and sensitivity, biochemical tests, commercial, identification systems, automated sensitivity testing, manual sensitivity testing.	Vitek MS	CE Marked	LM-MICRO-0075 Identification of Organisms using the Vitek MS
1011 Macroscopic examination and description	Examination of faecal, sputa samples	Faeces, sputum	Visual assessment	None	Based on standard method	LM-MICRO-0067 Investigation of Faeces Samples LM-MICRO-0066 Investigation of Sputum, Bronchial Washings and associated specimens
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	Cell count for body fluids	Body fluids, CSF	Microscopy: cell count	Nikon microscope	Based on standard method	LM-MICRO-0019 Investigation of CSF

purposes (including enumeration and description of human cells)						
	Examination of urine samples	Urine	Microscopy: cell count	Nikon microscope	Based on standard method	LM-MICRO-0022 Investigation of Urine
	Gram stain	Body fluids, pus, CSF, HVS, Eye	Microscopy	Nikon microscope	Based on standard method	LM-MICRO-0031 Performing a Gram Stain
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Isolation of significant pathogens in clinical samples	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/ throat/ mouth swabs, wound swabs, tips, drains, urine, stool.	Culture	PolEko Incubator Euroclone CO2 Incubator Oxoid atmospheric generation system	Based on standard method	LM-MICRO-0034, 0023, 0019, 0022, 0063, 0064, 0065, 0067
		Sputum, Bronchial washing	Culture	PolEko Incubator Euroclone CO2 Incubator	Based on standard method	LM-MICRO-0066 Investigation of Sputum, Bronchial Washings and associated specimens
	Screening for MRSA, CRE, VRE	Nose, throat, groin, rectal swabs	Culture	PolEko Incubator	Based on standard method CE marked chromogenic media	LM-MICRO-0034 Investigation of Screening Specimens LM-MICRO-0023 Inoculation of Culture Media LM-MICRO-0019 Investigation of CSF LM-MICRO-0022 Investigation of Urine LM-MICRO-0063 Investigation of ENT Specimens LM-MICRO-0064 Investigation of

						Sterile Fluids LM-MICRO-0065 Investigation of Swabs, Tissue, IV Cannulae and associated specimens LM-MICRO-0067 Investigation of Faeces Samples
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Inoculation and incubation of plates	Bronchial washing, Sputa, Wound Swab, Tissue, Sterile Fluid, CSF, Ear Swab, Eye Swab, Tip	Culture	PolEko Incubator Mettler Incubator	Based on standard method	LM-MICRO-0036 Investigation of Fungal Specimens
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Anti HAV IgM	Serum	Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	Anti HAV Total		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	Anti HBc		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	Anti HBs		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO

						Analyser
	Anti HCV		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	HBsAg		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	HIVDuo (Ag/Ab)		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
	Syphilis TP		Roche cobas® PRO	CE	Immunoassay	LM-SERO-0001 Individual Tests Performed on the Roche cobas® PRO Analyser
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	Clostridium difficile (C. diff)	Stool	Cepheid GeneXpert	CE Marked	PCR	LM-MICRO-0067
	Xpert Xpress CoV- 2/Flu/RSV plus	Naso/oropharyngeal, oropharyngeal and nasopharyngeal	Cepheid GeneXpert	CE	CE Marked	LM-MICRO-0076
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods	Use of commercial identification systems for bacteria Use of Vitek 2 Compact	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/ throat/ mouth	Culture and sensitivity, biochemical tests, commercial identification systems, automated sensitivity	Vitek 2 Compact	CE Marked	LM-MICRO-0058 The Oxidase Test LM-MICRO-0054 Campylobacter Identification

, CE marked commercial systems		swabs, wound swabs, tips, drains, urine, stool.	testing, manual sensitivity testing.			LM-MICRO-0059 The Catalase Test LM-MICRO-0046 API Identification System LM-MICRO-0048 Isolate Identification using the RapID System LM-MICRO-0061 Use of Vitek Identification and Antimicrobial Susceptibility Testing Cards LM-MICRO-0060 Use of Shigella Polyvalent Agglutinating Sera LM-MICRO-0045 Use of the Streptex Kit and the PYR Test LM-MICRO-0056 Staphylococcus aureus Identification using the Staphaurex Plus Kit LM-MICRO-0050 The Wellcolex Colour Salmonella Kit LM-MICRO-0052 The E.coli O157 Test
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Determination of MIC		MIC Strip	PolEko Incubator Euroclone CO2 Incubator	CE Marked	LM-MICRO-0027 Susceptibility Testing
		MIC	MIC Strip	Oxoid Atmosphere Generation system	CE Marked	LM-MICRO-0027 Susceptibility Testing

	Disc diffusion sensitivity testing		EUCAST disc diffusion	PolEko Incubator Euroclone CO2 Incubator	Based on standard method	LM-MICRO-0027 Susceptibility Testing
	Use of the Vitek 2 Compact	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/ throat/ mouth swabs, wound swabs, tips, drains, urine, stool.	Automated sensitivity testing	Vitek 2 compact	CE Marked	LM-MICRO-0027 Susceptibility Testing
			Automated sensitivity testing	Vitek 2 compact	CE Marked	LM-MICRO-0027 Susceptibility Testing