Schedule of Accreditation

Organisation Name	St James's Hospital
Trading As	SJH Centre for Laboratory Medicine and Molecular Pathology
INAB Reg No	327MT
Contact Name	Fiona Kearney
Address	Laboratory Medicine Directorate, St. James's Hospital, James's Street, Dublin, D08 RXOX
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Website	http://www.stjames.ie
Accreditation Standard	EN ISO 15189
Date of award of accreditation	28/10/2014
Scope Classification	Microbiology and Virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Histopathology and Cytopathology
Scope Classification	Chemical Pathology

Services available to the public[1]

[1] Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	**Address**
1	Head Office	Laboratory Medicine Directorate, James's Street, Dublin, D8

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	Blood Grouping (ABO & Rh D)	EDTA Whole Blood	1. Tube technique 2. Gel Cards	CE Marked	Not applicable	1. SOP BT 3.0001 2. SOP BT 3.0002
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & RhD)		Ortho Vision Max Swift Analyser	CE marked/Automated Based on standard method	Not applicable	SOP BT 3.0057
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening		Ortho Vision Max Swift Analyser	CE marked/Automated Based on standard method	Not applicable	SOP BT 3.0057
		Plasma	Manual Gel Cards	CE Marked	Not applicable	SOP BT 3.0005

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody identification	EDTA whole blood	Ortho Vision Max Swift Analyser	CE marked/Automated Based on standard method	Not applicable	SOP BT 3.0062
		Plasma	Manual Gel cards	CE Marked	Not applicable	SOP BT 3.0016
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility analysis for the release of compatible blood by electronic means		LIS / Electronic Issue	CE Marked	Not applicable	SOP BT 3.0053
	Crossmatching		1. Manual Tubes 2. Manual Gel Cards	CE Marked	Not applicable	1.SOP BT 3.0012 2.SOP BT 3.0009
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	1. Manual Tubes 2. Manual Gel Cards	CE Marked	Not applicable	1 & 2.SOP BT 3.0027
	Antigen typing - Rh Phenotype	EDTA whole blood Red cells	Ortho Vision Max Swift Analyser	CE marked/Automated Based on standard method	Not applicable	SOP BT 3.0057
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test		Ortho Vision Max Swift Analyser	CE marked/Automated Based on standard method	Not applicable	SOP BT 3.0061
		Red Blood Cells	Manual Gel Cards	CE Marked	Not applicable	SOP BT 3.0018

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)

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 - .02 Proteins, quantitative analysis	Calprotectin	Faeces	Immunoturbidometric assay	Biosystems A15 analyser	CE Marked	LM-BIO-0253
1061 Clinical Chemistry - .08 Haemo-related pigments and precursors	ALA & PBG**1.4	Urine	Ionic column with colour reaction (Recipe™ kit)	Shimadzu 1900i	CE Marked	LM-BIO-0263
	Erythrocyte Porphyrins **1,4	EDTA Whole Blood	Scanning Fluorimeter	Shimadzu RF6000	In-house developed	LM-BIO-0270
	Plasma Porphyrins **1,4	Plasma	Scanning Fluorimeter	Shimadzu RF6000	In-house developed	LM-BIO-0270
	Porphyrins (Uroporphyrin I, Uroporpyhrin III, Heptaporphyrin, Coproporphyrin I, Coproporphyrin III, Duetero, Meso, Proto) **1,4	Faeces	HPLC	Shimadzu HPLC-2030C Plus/	In-house developed	LM-BIO-0269
		Urine	HPLC	Shimadzu HPLC-2030C Plus/	In-house developed	LM-BIO-0269
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Inflectra ADA/Infliximab ADA **1,2,4	EDTA Plasma or Serum	ELISA	Dynex DS2	CE Marked	LM-BIO-0259
	Inflectra/Infliximab		ELISA	Dynex DS2	CE Marked	LM-BIO-0258

	**1,2,4					
	Isavuconazole**1,2,3,4	Serum	LC-MS-MS	API4000	CE Marked	LM-BIO-0255
	Posaconazole **1,2,3,4	Serum/Plasma	LC-MS-MS	API4000	CE Marked	LM-BIO-0255
	Voriconazole **1,2,3,4		LC-MS-MS	API4000	CE Marked	LM-BIO-0255
1061 Clinical Chemistry - .20 Hormones	17-Alpha OH Progesterone **1,2,3,4	Serum	LC-MS-MS	ABSciex Triple Quad 4500	CE Marked	LM-BIO-0254
	Androstendione **1,2,3,4		LC-MS-MS	ABSciex Triple Quad 4500	CE Marked	LM-BIO-0254
	DHEAS **1,2,3,4		LC-MS-MS	ABSciex Triple Quad 4500	CE Marked	LM-BIO-0254
	Parathyroid Hormone (PTH) **1,2,3,4	Serum/Plasma	Sandwich Immunoassay	Cobas e411	CE Marked	LM-BIO-0260
	Procolagen III **1,2,3,4	Serum	Competitive radioimmunoassay	Wizard 2470 Gamma Counter	CE Marked	LM-BIO-0256
	Testosterone **1,2,3,4		LC-MS-MS	ABSciex Triple Quad 4500	CE Marked	LM-BIO-0254
	Thyroid Receptor Antibodies (TRAB) **1,2,3,4		Competitive Immunoassay	Brahms Kryptor Gold	CE Marked	LM-BIO-0271
1061 Clinical Chemistry - .47 Vitamin assays	25-Hydroxyvitamin D3 and D2 **1,2,3,4		LC-MS-MS	API 4000	CE Marked	LM-BIO-0074
	Vitamin A (Retinol)		HPLC	Shimadzu HPLC-2030C Plus, Chromsystems Assay 'Vitamins A and E in serum/plasma'	CE Marked	LM-BIO-0030
	Vitamin E (alpha-Tocopherol)		HPLC	Shimadzu HPLC-2030C Plus, Chromsystems Assay 'Vitamins A and E in	CE Marked	LM-BIO-0030

				serum/plasma’		
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Chromogranin A *1,2,3,4		Automated Immunofluorescent Assay	Kryptor Gold/	CE Marked	LM-BIO-0271
	Thyroglobulin **1,2,3,4		Immunoassay sandwich principle	Brahms Kryptor Gold	CE Marked	LM-BIO-0271
1061 Clinical Chemistry - .52 Collagen cross-link markers	CTX (Beta-CrossLaps) **1,2,3,4	Serum/Plasma	Immunoassay sandwich principle	Cobas e411	CE Marked	LM-BIO-0260
	Oesteocalcin **1,2,3,4		Immunoassay sandwich principle	Cobas e411	CE Marked	LM-BIO-0260
	P1NP **1,2,3,4		Immunoassay sandwich principle	Cobas e411	CE Marked	LM-BIO-0260
1061 Clinical Chemistry - .60 Glycohaemoglobins	Haemoglobin A1c**1,2,4	EDTA Whole Blood	HPLC	Arkray HA-8190V HbA1c Analysers	CE Marked	LM-BIO-0249
1061 Clinical Chemistry - .63 Breath tests	Urea Breath Test	Breath	Non-Dispersive Ion-Selective Infrared Spectrometry	Kibion Dynamic Base UBT Analyser	CE Marked	LM-BIO-0273
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Occult Blood **4	Faeces	Immunochromatographic Lateral Flow device	Biohit Colonview, Positive/Negative	CE Marked	LM-BIO-0267
1061 Clinical Chemistry - .75 Malabsorption tests, not otherwise specified	Faecal Elastase **1,2,4		ELISA	Dynex DS2	CE Marked	LM-BIO-0069
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Thyroglobulin Antibodies **1,2,3,4	Serum	Competitive Immunoassay	Brahms Kryptor Gold	CE Marked	LM-BIO-0271
1061 Clinical Chemistry - .99 Miscellaneous tests	Osmolality **1,2,3,4	Serum/Li-Hep Plasma/Urine	Freezing-point depression	Advanced Instruments OsmoPro and Fiske3320	CE Marked	LM-BIO-0248
1064 Molecular genetics - .01 Screening for unidentified pathogenic	Detection of pathogenic variants in Familial	Peripheral blood	smMIP library preparation followed by next generation	QiaSymphony SP, Hamilton Star Automated Library	Non-CE, based on standard method	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0261

variant(s)	Hypercholesterolaemia using smMIPS NGS		sequencing	preparation system, Ion Torrent (Life technologies), JSI Software SeqNext module		
	MLPA amplification of LDLR gene		Multiplex Ligation-dependent Probe Amplification (MLPA)	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser.	CE Marked	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0265
	Sequence analysis of CPOX gene associated with hereditary coproporphyria (HCP)		PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of FECH gene associated with erythropoietic protoporphyria (EPP) and of ALAS2 exon 11 associated with X-linked protoporphyria (XLP)		PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of		PCR amplification,	QIAsymphony SP,	In-House Developed	LM-SJMD-001

	HMBS gene associated with acute intermittent porphyria (AIP)	Sanger Sequencing	Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module		HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of PPOX gene associated with variegate porphyria (VP)	PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of the TTR gene associated with transthyretin (ATTR) cardiac amyloidosis	PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of UGT1A1 gene associated with Gilbert syndrome and Crigler-Najjar syndrome	PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264

				3500 Genetic Analyser JSI Software SeqPatient module		
	Sequence analysis of UROD gene associated with porphyria cutanea tarda (PCT)		PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
	Sequence analysis of UROS gene associated with congenital erythropoietic porphyria (CEP)		PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In-House Developed	LM-SJMD-001 HAEM-LP-HMD-038 LM-BIO-0264
1064 Molecular genetics - .02 Assay for identified pathogenic variant(s)	Allelic Discrimination Assay for APOE rs7412 Genotyping	EDTA whole blood	Allelic Discrimination	7500 Fast real time PCR system	In house developed	LM-BIO-0272
	Haemochromotosis Genotyping (Detection of C282Y and H63D mutations)	EDTA and Buccal swabs	Allelic discrimination assay end point PCR using Taqman probes on a real time PCR platform	7500 Fast real time PCR system	In-house developed	LM-BIO-0075
	SNP genotyping Assay for Genotyping	Peripheral blood	Allelic Discrimination	Applied Biosystems 7500	In house developed	LM-BIO-0272

	of DPYD variants			Fast real time PCR system		

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters/tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

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	Full Blood Count Including WBC, and Nucleated RBC Quantitation **1,2,3,4	EDTA Blood	Electrical impedance cell counting and sizing, fluorescent flow cytometry and spectrophotemetry	Sysmex XN10 / XN20	CE Marked	HAEM-LM-RH-0026
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination		Cytochemical Stain / Microscopy	IUL Polystainer / Microscope	CE Marked	HAEM-LM-SH-0012 HAEM-LP-SH-0009
	Blood Film Examination **1,2,3,4		Automated digital morphology system with operator reclassification and result validation	SP10 Blood Film Stainer Sysmex DI-60	Based on Standard Method	HAEM-LM-RH-0006
			Manual	SP10 Blood Film Stainer Microscope	Based on Standard Method	HAEM-LM-RH-0006
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR) **1,3,4		Westergren Sedimentation Method	Starrsed Interliner Automated ESR Analyser	CE Marked	HAEM-LP-RH-0016
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count **1,3,4		Electrical impedance cell counting and sizing, fluorescent flow cytometry and spectrophotemetry	Sysmex XN10 / XN20	CE Marked	HAEM-LM-RH-0026

1030 Haematology - .09 Examination of malarial parasites	Malaria Screen **1,3,4		Manual microscopy and Immunochromatographic Test	Test Kit Microscope	CE Marked	HAEM-LM-RH-0012
	Screening Test for Malarial HRP-2 Antigen and LDH **1,3,4	EDTA blood	Malarial HRP-2 Antigen and LDH detection using the Malaria CareUS Kit	P. falciparum; P. vivax or ovale or malariae; P. falciparum or mixed infection	CE Marked	HAEM-LM-RH-0028
1030 Haematology - .20 Bone marrow examination	Bone Marrow Iron Stain **3.4	Bone Marrow	Cytochemical Stain	Manual	Based on Standard Method	HAEM-LM-SH-0002
	MGG Stain for Bone Marrow Aspirates **3,4		Cytochemical Stain	IUL Polystainer	CE Marked	HAEM-LM-SH-0009, HAEM-LM-SH-0012
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Haemoglobin fractions **1,4	EDTA Blood	Capilliary Electrophoresis	Sebia Capillarys 2 Flex Piercing Analyser	CE Marked	HAEM-LP-SH-0028
	Hb H Inclusions **4		Supra Vital Stain	Manual	Based on Standard Method	HAEM-LM-SH-0065
	Hemoglobin fractions **1,4		HPLC	Biorad Variant II	CE Marked	HAEM-LP-SH-0012, HAEM-MP-SH-0001
	IEF of Hb **4		Isoelectric Flocussing	Multiphor Electrophoresis	CE Marked	HAEM-LM-SH-0062
	Sickle Screen **4		Solubility Test	Manual	CE Marked	HAEM-LM-SH-0058
1030 Haematology - .35 Tests to investigate haemolysis	Dapsone Screen (Heinz Body Screen) **4		Supra Vital Stain	Manual	Based on Standard Method	HAEM-LM-SH-0051
	Membrane Screen **1,3,4		Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0109
	PNH Screening GLY-A,CD59, FLAER, CD45,		Flow Cytometry	BD FACS Canto II	In-House	HAEM-LM-SH-

	CD24, CD14, CD15, CD64 `** 1,3,4				Developed	0105
	Urinary Haemosiderin **4	Urine	Cytochemical Stain	Manual	Based on Standard Method	HAEM-LM-SH-0053
1030 Haematology - .36 Screening tests for G6Pd	Glucose-6-phosphate Dehydrogenase (G6PD) Screen **4	EDTA Blood	Fluorescent Spot Test	Manual	CE Marked	HAEM-LM-SH-0069A
1030 Haematology - .40 Limited haemostasis related tests	ADAMTS13 activity assay *1,2,4	Blood in Sodium Citrate	Automated FRET analysis	Technoclone Ceveron s100 analyser	CE Marked	Haem-LM-COAG-0146
	Anticoagulant Monitoring - Apixaban **1,2,4		Photo-optical detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0124
	Anticoagulant Monitoring - Dabigatran **1,2,4		Photo-optical detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0121
	Anticoagulant Monitoring - Rivaroxaban **1,2,4		Photo-optical detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0125
	Anticoagulant Monitoring: Argatroban **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0102
	Anticoagulant Monitoring: Edoxaban		Photo-optical Detection	ACL Top	CE Marked	HAEM-LM-COAG-0140
	Antithombin Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0089
	APCR Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0092
	Assessment of VWF multimers in plasma by electrophoresis		Electrophoresis	SEBIA:HYDRASYS 2	CE Marked	HAEM-LM-COAG-0133
	Correction Tests **1,2,4		Photo-optical Detection	ACL TOP 550	Based on Standard Method	HAEM-LM-COAG-0021
	Factor II:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
	Factor IX Inhibitor Assay **1,2,4		Photo-optical Detection	ACL TOP 750	Based on Standard Method	HAEM-LM-COAG-0131

Factor IX:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor V:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor VII:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor VIII Inhibitor Assay **1,2,4		Photo-optical Detection	ACL TOP 750	Based on Standard Method	HAEM-LM-COAG-0115
Factor VIII:C Assay **1,2,4		Photo-optical Detection	ACL Top	CE Marked	HAEM-LM-COAG-0120
Factor X:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor XI:C Assay**1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor XII:C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0120
Factor XIII Assay **1,2,4		Latex Immunoassay	ACL TOP 750	CE Marked	HAEM-LM-COAG-0087
FVIII Chromogenic assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0134
Heparin Induced Thrombocytopenia Screen: IgG ELISA **1,3,4	Serum	ELISA	Memmery Hot Air Oven Labsystems Biotek 800 TS Microplate Reader	CE Marked	HAEM-LM-COAG-0085
Lupus Anticogulant Screen **1,2,4	Blood in Sodium Citrate	Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0090
Measurement of Emicizumab level *1,2,4		Photo-optical detection	ACL Top	In house developed	HAEM-LM-COAG-0141
Protein C Assay **1,2,4		Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0091
Protein S Assay (Free Antigen) **1,2,4		Latex Immunoassay	ACL TOP 750	CE Marked	HAEM-LM-COAG-0122
VWF:Ag Assay **1,2,4		Latex Immunoassay	ACL TOP 750	CE Marked	HAEM-LM-COAG-0099

	VWF:CB Assay **1,4	ELISA	Labsystems Biotek 800 TS Microplate Reader	CE Marked	HAEM-LM-COAG-0065
	VWF:CB assay *1,2,4	Chemilumiscent immunoassay	ACL AcuStar	CE Marked	HAEM-LM-COAG-0137
	VWF:FVIII binding assay **1,4	Asserachrom VWF:FVIIIB ELISA kit	Biotek 800TS microplate reader	CE marked kit	HAEM-LM-COAG-0117
	VWF:Rco Assay **1,4	Photo-optical Detection	Sysmex CS2100i	CE Marked	HAEM-LM-COAG-0100
1030 Haematology - .41 General haemostasis related tests	Anticoagulant Drug Monitoring: Heparin Anti Xa Assay **1,2,4	Photo-optical Detection	ACL TOP 750	CE Marked	HAEM-LM-COAG-0112
	APTT **1,2,4	Photo-optical Detection	ACL TOP 550/750	CE Marked	HAEM-LM-COAG-0077
	APTT ratio 1,2,4	Photo-optical detection / calculation	ACL TOP 550/750	CE Marked	HAEM-LM-COAG-0077
	D-Dimer **1,2,4	Latex Immunoassay	ACL TOP 550	CE Marked	HAEM-LM-COAG-0123
	Factor VIII:C assay	Photo-optical Detection	ACLTop 750 analyser	In-house developed	HAEM-LM-COAG-0144
	Fibrinogen **1,2,4	Photo-optical Detection	ACL TOP 550	CE Marked	HAEM-LM-COAG-0084
	Fibrinogen Antigen **1,4	Radial Immunodiffusion	Immuno-Viewer Plate Reader	CE Marked	HAEM-LM-COAG-0046
	Fibrinogen Antigen *1,2,4	Latex Immuno-assay	ACL Top	CE kit	HAEM-LM-COAG-0143
	INR 1,2,4	Photo-optical detection / calculation	ACL TOP 550/750	CE Marked	HAEM-LM-COAG-0077
	PT **1,2,4	Photo-optical Detection	ACL TOP 550/750	CE Marked	HAEM-LM-COAG-0077
	VWF:GPIbM assay	Particle agglutination	Sysmex CN3500 analyser	CE	HAEM-LM-COAG-0136

1030 Haematology - .45 Tests of platelet function	Platelet Function Tests **1,2,4	Sodium Citrate	Photo-optical Detection	Helena Biosciences Aggregation Remote Analyser Module	Based on Standard Method	HAEM-LM-COAG-0032
	Quantitation of Platelet Adenine Nucleotides Using Firefly Luminescence **1,2,4	CTAD	Luminscence	Promega Glomax 20/20 Luminometer	Based on Standard Method	HAEM-LM-COAG-0083
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis **1,3,4	EDTA Blood/serum/plasma	Immunoassay	Test Kit	CE Marked	HAEM-LM-RH-0025
1030 Haematology - .62 Plasma viscosity	Plasma Viscosity **1,3,4	EDTA Blood	Viscometry	Benson Viscometer	CE Marked	HAEM-LP-SH-0010
1030 Haematology - .70 Immunophenotyping	Acute Leukaemia Panel. Antigens Tested: CD19,CD117,CD45,CD34,CD14,CD64,CD33, CD7,CD13, HLA-DR, CD2, CD10,CD20, CD38,CD56, cMPO, cCD3, nuclear TdT, cCD79a, cCD68, cIgM, CD15,CD36,CD300e,CD4,CD11b, CD61, GLY-A, CD41, CD65,NG2, CD9,CD203c,CD2, CD8,CD3,CD99,CD1a,CD5, cBCL2, cCD61, CD43, CD123,CD21,CD58,CD66 **1,2,3,4	Bone Marrow Aspirate in RPMI-Heparin or in EDTA. FNA or Fluids in RPMI-Heparin. Edta Blood	Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0110
	Chronic Lymphoproliferative Panel. Antigens Tested: CD5,CD3,CD19,CD45,surface Kappa, surface Lambda, CD38,CD43,CD200, sIgM, FMC7, CD20, CD10, CD22,CD23,CD79b, CD103, CD11c, CD25,CD123, CD49d, ROR1, CD62L, CD7,CD2,CD4,CD26,CD8, TCRαβ, TCRγδ, CD16,CD56,CD57,CD52,CD30, CD9, CD203c, CD33, CD24, CD117, HLA-DR, CD38,CD138, cKappa, cLambda, VS38c **1,2,3,4		Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0110
	CSF Immunophenotyping. Antigens Tested: CD7, CD117, CD10, CD34, CD19, CD45, CD3, CD8, CD56, Surface Kappa, Surface Lambda, CD4, CD14, CD38, CD20 **1,2,3,4	CSF in RPMI-Heparin or Transfix	Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0114

	Detection of Minimal Residual Disease (MRD) in B Chronic Lymphocytic Leukaemia (B-CLL). Antigens Tested: CD19, CD5,CD3,CD22,CD20,CD79b,CD81,CD43 **1,2,3,4	Bone Marrow Aspirate in RPMI-Heparin or in EDTA. Edta Blood.	Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0113
	Detection of Minimal Residual Disease (MRD) in Mantle Cell Lymphoma (MCL). Antigens Tested: CD5, CD20, CD23, CD45, CD19, CD62L, CD200, CD3 **1,2,3,4	Bone Marrow Aspirate in RPMI-Heparin or in EDTA, FNA or Fluids in RPMI-Heparin, EDTA Blood	Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0113
	Detection of TRBC 1. Antigens tested: CD8, CD3, CD2, CD5, CD7, CD4, TCRgd **1,2,3,4		Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0110
	T Cell Enumeration. Antigens Tested: CD19,CD3,CD45 **1,2,3,4	EDTA Blood	Flow Cytometry	BD Facscanto II	In-house developed	HAEM-LM-SH-0112
1030 Haematology - .80 Molecular genetic studies	Copy number variation (CNV) analysis of the F8 and F9 genes.	Blood EDTA	Multiplex Ligation-dependent Probe Amplification (MLPA)	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser.	Non-CE. Based on standard method	Std. Ref: • Jan P. Schouten, Cathal J. McElgunn, Raymond Waaijer, Danny Zwijnenburg, Filip Diepvens, Gerard Pals, Relative quantification of 40 nucleic acid sequences by multiplex ligation-dependent probe amplification, Nucleic Acids Research, Volume 30, Issue 12, 15 June 2002, Page e57, SOPs: HAEM-LM-HMD-

						017, HAEM-LP-HMD-039
	Detection of Factor V Leiden variant **4	Blood in EDTA	Real Time PCR	Cepheid GeneXpert (Absent, Heterozygous, Homozygous)	CE Marked	HAEM-LM-COAG-0138
	Detection of Prothrombin G20210A variant **4		Real Time PCR	Cepheid GeneXpert (Absent, Heterozygous, Homozygous)	CE Marked	HAEM-LM-COAG-0138
	DNA sequencing to detect single nucleotide variations and small DNA deletions and duplications within the F8, F9, VWF exons 18-24, VWF exon 28, SERPINC1, MYH9, Fibrinogens (FGA, FGB, FGG) genes.	Blood EDTA	PCR amplification, Sanger Sequencing	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module	In house developed. Based on standard method	Std. Ref: Sanger F, Nicklen S, Coulson AR. DNA sequencing with chain-terminating inhibitors. Proc Natl Acad Sci U S A. 1977;74(12):5463-5467. SOPs: HAEM-LP-HMD-003, HAEM-LP-HMD-04, HAEM-LP-HMD-007, HAEM-LP-HMD-017, HAEM-LP-HMD-020, HAEM-LP-HMD-038, HAEM-LP-HMD-039
	F8 Intron 1 assay to detect F8 gene rearrangements involving intron 1		F8 Intron 1 PCR by PCR amplification and gel electrophoresis	QIAsymphony SP, Applied Biosystem Thermal Cycler, EC 105 Electrophoresis Powerpack, Electophoresis tank 1-3,	Non-CE. Based on standard method	Std. Ref: • Liu Q, Sommer SS, Biotechniques 1998 25 pp1022-1028.

				UV gel documentation system.		SOPs: HAEM-LP-HMD-006
	F8 Intron 22 assay to detect F8 gene rearrangements involving intron 22		F8 Intron 22 Inverse PCR by PCR amplification and fragment analysis	QIAsymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser.	Non-CE. Based on standard method	Std. Ref: • Rossetti LC, Radic CP, Larripa IB, De Brasi CD. Clin Chem. 2005 Jul; 51(7):1154-8; • Rossetti LC, Radic CP, Larripa IB, De Brasi CD. J Thromb Haemost. 2008 May; 6(5):830-6 SOPs: HAEM-LM-HMD-014, HAEM-LP-HMD-039
1030 Haematology - .99 Miscellaneous tests	Cyclosporin assay **1,2,3,4	Whole Blood EDTA	Chemiluminescent microparticle immunoassay (CMIA)	Abbott Alinity i	CE	HAEM-LM-NA-0036
	Erythropoietin **1,2,3,4	Serum	Chemiluminescent Immunometric Assay	Beckman Coulter Access 2	CE Marked	HAEM-LM-NA-0024
	IF (Intrinsic Factor) Antibody **1,2,3,4		Chemiluminescent Immunometric Assay	Beckman Coulter Access 2	CE Marked	HAEM-LM-NA-0024
	Serum Transferrin Receptor **1,2,3,4		Chemiluminescent Immunometric Assay	Beckman Coulter Access 2	CE Marked	HAEM-LM-NA-0024
	Tacrolimus assay **1,2,3,4	Whole Blood EDTA	Chemiluminescent microparticle immunoassay (CMIA)	Abbott Alinity i	CE	HAEM-LM-NA-0035
1033 Molecular pathology - .01 Assay for somatic variants in DNA	(11; 14) Translocation Detection of genomic rearragements associated with lymphoma	Peripheral Blood, bone marrow	PCR	QIASymphony DNA Extraction system, Dyad DNA Engine (BioRad) GeneAmp PCR System	CE Based on standard method	M-CMD-0016

sequence(s)				2700 or 2720 (Applied Biosystems)		
	BCR-ABL1 p190 RQ-PCR Monitoring of Transcripts Associated with Leukaemia		PCR	7500 Real Time PCR System (Applied Biosystems)	Non-CE, Based on standard method	M-CMD-0059
	BCR-ABL1 p210 and p190 RQ-PCR Monitoring of Transcripts Associated with Leukaemia	Bone Marrow	PCR	Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0093
		Peripheral Blood	PCR	Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0093
	BCR-ABL1 p210 fusion Detection of rearrangements associated with leukaemia	Peripheral Blood Bone Marrow	PCR	GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 7500 Real time PCR instrument (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0063
	BCR-ABL1 p210 fusion Detection of rearrangements associated with leukaemia	Bone Marrow	PCR	Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0094
		Peripheral Blood	PCR	Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0094
	BCR-ABL1 p210 RQ-PCR Monitoring of Transcripts Associated with Leukaemia	Bone Marrow	PCR	7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0059
		Peripheral Blood	PCR	7500 Real Time PCR System (Applied Biosystems)	Non-CE Based on standard method	M-CMD-0059

Chimerism, Post Allogeneic Stem Cell Transplant Monitoring	Peripheral Blood, bone marrow	PCR	QIASymphony DNA Extraction system, Veriti (Applied Biosystems) 3500xl Genetic Analyser (Applied Biosystems)	Non-CE, based on standard method	M-CMD-0018 M-CMD-0019 M-CMD-0020
Detection of somatic mutations using a smMIP Panel (MPN Panel)	Peripheral Blood	smMIP library preparation with NGS based sequencing	QIASymphony DNA Extraction system, Hamilton Star Automated Library preparation system, Ion Chef, Illumina Next Seq, Thermal cycler	Non-CE, based on standard method	M-CMD-0076 M-CMD-0092
FLT3-ITD mutations Detection of mutations associated with leukaemia	Bone marrow	PCR	QIASymphony DNA Extraction system, GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad)	Non-CE, based on standard method	M-CMD-0030
Immunoglobulin gene rearrangements. Detection of genomic rearrangements associated with leukaemia and lymphoma.	Peripheral Blood, bone marrow, Fresh Biopsy, FFPE	PCR	QIASymphony DNA Extraction system. Hamilton Microlab STAR GeneAmp PCR System 2700/2720 (Applied Biosystems) 3500xl Genetic Analyser (Applied Biosystems)	CE Based on standard method	M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013
Immunoglobulin gene somatic hypermutation. Detection of genomic rearranegments associated with leaukaemia and lymphoma	Peripheral Blood, bone marrow	PCR	QIASymphony DNA Extraction system, GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3500xl Genetic Analyser (Applied Biosystems)	Non-CE, based on standard method	M-CMD-0038

MYD88 L265P mutation test	Peripheral Blood, bone marrow, Fresh Biopsy, FFPE	Multiplex PCR	QIASymphony DNA Extraction system, 3500xl Genetic Analyser (Applied Biosystems)	Non-CE, based on standard method	M-CMD-0085
PML-RARa fusion Detection of rearrangements associated with leukaemia	Bone Marrow	PCR	GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad)	Non-CE Based on standard method	M-CMD-0068
	Peripheral Blood	PCR	GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad)	Non-CE Based on standard method	M-CMD-0068
Provenance Testing	FFPE	PCR	QIASymphony DNA Extraction system, Veriti (Applied Biosystems) 3500xl Genetic Analyser (Applied Biosystems)	Non-CE, based on standard method	M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0071 M-CMD-0048
t (11; 14) Translocation Detection of genomic rearragements associated with lymphoma	Fresh Biopsy	PCR	Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems)	CE Based on standard method	M-CMD-0016
	Paraffin Sections	PCR	Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems)	CE Based on standard method	M-CMD-0016
T Cell Chimerism Post Allogenic Stem Cell Transplant Monitoring	Peripheral Blood	PCR	QIASymphony DNA Extraction system, Veriti (Applied Biosystems) 3500xl Genetic Analyser	Non-CE, based on standard method	M-CMD-0006

			(Applied Biosystems)		
T cell receptor gene rearrangements. Detection of genomic rearrangements associated with leukaemia and lymphoma.	Peripheral Blood, bone marrow, Fresh Biopsy, FFPE	PCR	QIASymphony DNA Extraction system, Hamilton Microlab STAR, GeneAmp PCR System 2700/2720 (Applied Biosystems) 3500xl Genetic Analyser (Applied Biosystems)	CE Based on standard method	M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013
t(14;18) translocation. Detection of genomic rearrangements associated with lymphoma	Peripheral Blood, bone marrow	PCR	QIASymphony DNA Extraction system, Dyad DNA Engine (Bio-Rad), GeneAmp PCR System 2700 or 2720 (Applied Biosystems)	CE Based on standard method	M-CMD-0014 M-CMD-0015
t(14;18) translocation. Detection of genomic rearrangements associated with lymphoma.	Fresh Biopsy	PCR	Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems)	CE Based on standard method	M-CMD-0014 M-CMD-0015
	Paraffin Sections	PCR	Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems)	CE Based on standard method	M-CMD-0014 M-CMD-0015
TP53 Mutational analysis	Peripheral Blood, bone marrow	PCR with NGS based sequencing	QIASymphony DNA Extraction system, Ion Torrent s5, Ion Chef	Non-CE, based on standard method	M-CMD-0072

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

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
1055 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Analysis of solid tumours using Cancer Hotspot mutation panel. Colorectal cancer panel, Lung Adenocarcinoma Panel, GIST Panel and Melanoma Panel.	FFPE tissue	QIASymphony DNA Extraction system, Ion Torrent S5 Sequencer, Ion Chef,7500 real Time PCR System, Hamilton STARlet, Hamilton Star Automated Library preparation system	Non-CE, based on standard method	NA	M-CMD-0073, M-CMD-0074, M-CMD-0075, M-CMD-0078
	Detection of deletions or duplications in the BRCA1 and BRCA2 genes by Multiplex Ligation-Dependent Probe Amplification	Peripheral Blood	Bio-rad Thermal cycler Pre-PCR; SimpliAmp Thermal Cyclers Post PCR; QiaSymphony DNA Extraction; 3500xl; MLPA fragment analysis	Non-CE, based on standard method	NA	M-CMD-0084, F-CMD-0154
	Detection of EGFR mutations in cfDNA using NGS technology		QIASymphony DNA Extraction system, MagNAPure 24 (Roche), Hamilton Star Automated Library preparation system, Ion Torrent S5 Sequencer	Non-CE, based on standard method	NA	M-CMD-0080
	Detection of tBRCA pathogenic mutations	Peripheral Blood, FFPE	SimpliAmp Thermal Cyclers, QiaSymphony	Laboratory developed test	NA	M-CMD-0076, M-CMD-0077

	using smMIP Panels		DNA Extraction, Illumina NextSeq / Capture based smMIP sequencing			
	EGFR Mutation testing using Idylla technology	FFPE	Idylla platform (Biocartis)	Cartridge based NGS CE marked kit	N/A	M-CMD-0086, P-CMD-0045

Head Office

Immunology

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
1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids	Detection of Oligoclonal IgG in CSF **2,4	CSF	Sebia Hydrasis / Isoelectric Focussing	CE Marked	Qualitative	LM-IMM-0060
	IgG1 **1,2,3,4	Serum	Turbimetry /Optilite	CE Method	0.15-144g/L	LM-IMM-0075
	IgG2 **1,2,3,4		Turbimetry / Optilite	CE Method	0.02-28 g/L	LM-IMM-0075
	IgG3 **1,2,3,4		Turbimetry / Optilite	CE Method	0.05-8.8g/L	LM-IMM-0075
	IgG4 **1,2,3,4		Turbimetry / Optilite	CE Method	0.0043-64.8g/L	LM-IMM-0075
	Investigation of Monoclonal Gammopathies in Serum **2,4		Sebia Cappillarys 3 / Electrophoresis	CE Marked	Qualitative	LM-IMM-0064
			Sebia Hydrasis / Immunophenotyping / Immunofixation	CE Marked	Qualitative	LM-IMM-0064
	Investigation of Monoclonal Gammopathies in Urine **2,4	Urine	Sebia Hydrasis / Electrophoresis	CE Marked	Qualitative	LM-IMM-0007
			Sebia Hydrasis / Immunofixation	CE Marked	Qualitative	LM-IMM-0007

	Quantitation of IgG in CSF for the detection of Oligoclonal bands	CSF	Roche Cobas c303/Turbimetry	CE Marked	CSF IgG 4-200mg/L	LM-IMM-0080 LP-IMM-0108
	Quantitation of IgG in Serum for the detection of Oligoclonal bands	Serum	Roche Cobas c303/Turbimetry	CE Marked	IgG 0.3-50g/L	LM-IMM-0080 LP-IMM-0108
	Quantitative measurement of Immunoglobulins -IgG, IgA and IgM		Roche Cobas c303/Turbimetry	CE Marked	IgG: 0.3-50g/L, IgA: 0.05-8g/L, IgM: 0.25-6.5g/L	LM-IMM-0080 LP-IMM-0108
1040 Immunology - .03 Total IgE	Quantitative investigation of Total IgE **1,2,3,4		Phadia 2500 Enzyme Immunoassay	CE Marked	Total IgE: 2.0 - 5000 IU/mL	LM-IMM-0036
1040 Immunology - .04 Allergen - specific IgE	ALEX2 Allergy testing **1,2,3,4		Manual method, Alex Raptor analysis software	CE Method	Specific IgE 0.3-50 KUA/L, Total IgE 20-2500	LM-IMM-0076
	Quantitative investigation for Allergen specific IgG **1,2,3,4		Enzyme Immunoassay / Phadia 250	CE Marked	Specific IgE: 0 - 100 IU/L Specific IgG: 02-200 mg/L	LM-IMM-0035
	Quantitative investigation of samples for Allergen specific IgE **1,2,3,4		Phadia 2500 Enzyme Immunoassay	CE Marked	Specific IgE: 0.1 - 100 KU/L	LM-IMM-0036
1040 Immunology - .06 Investigation of complement	C1 inhibitor **1,2,3,4		Turbimetry / Optilite	CE Method	0.08-0.88 g/L	LM-IMM-0075
	Determination of C1 Esterase Inhibitor Function **2,3,4		ELISA /DS2 Analyser	CE Marked	Qualitative	LM-IMM-0008
	Evaluation of Alternative Haemolytic Complement Activity **2,3,4		Dynex DS2 /ELISA	CE Marked	Functional Assay	LM-IMM-0063

	Evaluation of Classical Haemolytic Complement Activity **2,3,4		Dynex DS2 / ELISA	CE Marked	Functional Assay	LM-IMM-0063
	Quantitative measurement of C3 complement component.		Roche Cobas c303/Turbimetry	CE Marked	0.04-5g/L	LM-IMM-0080 LP-IMM-0108
	Quantitative measurement of C4 complement component.		Roche Cobas c303/Turbimetry	CE Marked	0.02-1g/L	LM-IMM-0080 LP-IMM-0108
1040 Immunology - .08 Detection of immune complexes in body fluids and biopsy material	Quantative Determination of β-amyloid (1-42) **1,2,3,4	CSF	Dynex DS2 Analyser/Enzyme Immunoassay	CE Marked	5 - 2000pg/ml	LM-IMM-0057
	Quantitative Determination of Phospho Tau (181P) **1,2,3,4		Dynex DS2 Analyser / Enzyme Immunoassay	CE Marked	125 - 2000 pg/ml	LM-IMM-0057
	Quantitative Determination of Total Tau (hTau Ag) **1,2,3,4		Dynex DS2 Analyser / Enzyme Immunoassay	CE Marked	75 - 1200 pg/ml	LM-IMM-0057
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Quantitative measurement of Rhematoid factor.	Serum	Roche Cobas c303/Turbimetry	CE Marked	10-130 IU/ml	LM-IMM-0080 LP-IMM-0108
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Neuronal (Paraneoplastic) Immunoblot **2,3,4		Immunoblot/Euroblot One Analyser	CE Marked	Qualitative	LM-IMM-0067
	Cardiolipin IgG **1,2,3,4		Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	IgG Card: 0.5 - 418 GLPU/ml	LM-IMM-0052
			Phadia Immunocap	CE Marked	IgG Card: 0.5 - 418	LM-IMM-0052

		2500/Enzyme Immunoassay		GLPU/ml	
	CCP **1,2,3,4	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	CCP: 0.4 - 340 U/ml	LM-IMM-0052,
		Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	CCP: 0.4 - 340 U/ml	LM-IMM-0052
	Centromere Screen **1,2,3,4	Phadia 250 / Enzyme Immunoassay	CE Marked	0.4 - 240 U/ml	LM-IMM-0052
		Phadia 2500 / Enzyme Immunoassay	CE Marked	0.4 - 240 U/ml	LM-IMM-0052
	CTD Screen **1,2,3,4	Phadia 250 / Enzyme Immunoassay	CE Marked	0.03 - 32 Ratio	LM-IMM-0052
		Phadia 2500/Enzyme Immunoassay	CE Marked	0.03 - 32 Ratio	LM-IMM-0052
	Detection of Autoimmune Liver Diseases (IgG) by Immunoblot **2,3,4	Immunoblot/Euroblot One Analyser	CE Marked	Qualitative	LM-IMM-0068
	dsDNA **1,2,3,4	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	dsDNA: 0.5-379 IU/ml	LM-IMM-0052
		Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	dsDNA: 0.5-379 IU/ml	LM-IMM-0052
	ENA Profile (RNP, Sm, Ro, LA, Scl-70, Jo01) **1,2,3,4	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	RNP: 0.3 - 240 ELIA U/ml SMDP-S: 0.7-330 ELIA U/ml; Ro: 0.3-240 ELIA U/ml; La: 0.3-320 ELIA U/ml; Scl70: 0.4-240 ELIA U/ml Jo1:0.3-240 ELIA U/ml	LM-IMM-0052

		Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	RNP: 0.3 - 240 ELIA U/ml; SMDP-S: 0.7-330 ELIA U/ml Ro: 0.3-240 ELIA U/ml; La: 0.3-320 ELIA U/ml; Scl70:0.4-240 ELIA U/ml; Jo1:0.3-240 ELIA U/ml	LM-IMM-0052
	GAD **1,2,3,4	ELISA Enzyme Immunassay / Dynex DS2	CE Marked	GAD: 5 - 2000 IU/ml	LM-IMM-0047
	GBM **1,2,3,4	Manual ELISA /DS2 Analyser	CE Marked	0-200 RU/ml	LM-IMM-0079
		Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	GBM: 0.8-680 IU/ml	LM-IMM-0052
		Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	GBM: 0.8-680 IU/ml	LM-IMM-0052
	Myeloperoxidase **1,2,3,4	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	MPO: 0.2 - 134 IU/ml	LM-IMM-0052
		Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	MPO: 0.2 - 134 IU/ml	LM-IMM-0052
	Myositis Specific Antibodies **2,3,4	Immunoblot/Euroblot One Analyser	CE Marked	Qualitative	LM-IMM-0062
	Neuronal (Paraneoplastic) Immunofluorescence **2,3,4	Manual Method / Indirect Immunoflourescence	CE Marked	Qualitative	LM-IMM-0066
	Proteinase-3 **1,2,3,4	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	PR3: 0.2 - 177 IU/ml	LM-IMM-0052

			Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	PR3: 0.2 - 194 IU/ml	LM-IMM-0052
	Quantiative determination of b2-microglobulin		Roche Cobas c303/Turbimetry	CE Marked	0.1-8.0 mg/L	LM-IMM-0080 LP-IMM-0108
	Thyroid Peroxidase (TPO) **1,2,3,4		Phadia Immunocap 250 / Enzyme Immunoassay	CE Marked	TPO: 4-1542 IU/ml	LM-IMM-0052
			Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	TPO: 4-1542 IU/ml	LM-IMM-0052
	tTg (IgA) **1,2,3,4		Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	tTG: 0.1 - 128 U/ml	LM-IMM-0052
			Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	tTG: 0.1 - 128 U/ml	LM-IMM-0052
	β2 Glycoprotein **1,2,3,4		Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	β2: 0.6-532 IU/ml	LM-IMM-0052
			Phadia Immunocap 2500/Enzyme Immunoassay	CE Marked	β2: 0.6-532 IU/ml	LM-IMM-0052
1040 Immunology - .13 Cryoglobulins	Identification of the Presence of Cryoglobulins **2,3,4		Sebia Hydrasis/Immunofixation	CE Marked	Qualitative	LM-IMM-0013
1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes	Enumeration of Lymphocyte Subsets **1,2,4	EDTA Whole Blood	Becon Dickinson FacsCanto/Flow Cytometry	CE Marked	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0045
	Measurement of Activation Markers (HLA-DR, CD25, CD38) on CD4 & CD8 T cells **1,2,4		Becton Dickinson/Flow Cytometry	Based on Standard Method	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0055

	Measurement of Double-Negative T Cell receptor alpha beta and gamma delta T cells **1,2,4		Becton Dickinson/Flow Cytometry	Based on Standard Method	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0055
	Measurement of Naïve, Memory and Class Switch Memory B Cell Subsets **1,2,4		Becton Dickinson/Flow Cytometry	Based on Standard Method	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0055
	Measurement of Naïve, Memory and Effector T Cell Subsets **1,2,4		Becton Dickinson/Flow Cytometry	Based on Standard Method	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0055
1040 Immunology - .30 Assessment of neutrophils and monocytes - quantitation	Measurement of Adhesion Molecules CD18, CD11a, CD11b, CD11c on Neutrophils **1,2,4		Becton Dickinson/Flow Cytometry	Based on Standard Method	Enumeration using Becton Dickenson FacsCanto	LM-IMM-0040
1040 Immunology - .32 Assessment of neutrophils and monocytes - in vitro functional tests	Functional Analysis of Neutrophils **2,3,4		Becon Dickinson FacsCanto/Flow Cytometry	Based on Standard Method	Qualitative	LM-IMM-0029
1040 Immunology - .36 Cell markers	Assessment of T-cell proliferation to mitogenic and physiological-like stimulation **2,3,4		Becon Dickinson FacsCanto/Flow Cytometry	Based on Standard Method	Qualitative	LM-IMM-0070
1040 Immunology - .54 Tryptase	Tryptase **1,2,3,4	Serum	Phadia Immunocap 250/Enzyme Immunoassay	CE Marked	TRYP: 1.0 - 200 µg/L	LM-IMM-0037
1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes	Anti-neutrophil cytoplasmic antibodies (ANCA) **2,3,4		Helios HTC/Indirect Immunofluorescene	CE marked	Qualitative	LM-IMM-0004 LP-IMM-0104
	Anti-nuclear antibodies (ANA)		Helios HTC/Indirect Immunofluorescene	CE marked	Negative or 1/80-1/160	LM-IMM-0039 LP-IMM-0104

	**2,3,4					
	BP Autoantibodies **1,2,3,4		Manual Method/Indirect Immunofluorescence	CE Marked	Negative or 1/10 - 1/80	LM-IMM-0020
	dsDNA antibodies **1,2,3,4		Helios HTC/Indirect Immunofluorescene	CE marked	Negative or 1/20-1/160	LM-IMM-0014 LP-IMM-0104
	Encephalitis Mosaic for detection of NMDA, LGI-1, CASPR2, AMPA 1/2, GABAB and DPPX **2,3,4	Serum / CSF	Manual Method/Indirect Immunoflourescence	CE Marked	Qualitative	LM-IMM-0071
	IgA Endomysial antibodies (EMA) *2,3,4	Serum	Helios HTC/Indirect Immunofluorescene	CE marked	Qualitative	LM-IMM-0017 LP-IMM-0104
	IgG Endomysial antibodies (EMA) *2,3,4		Helios HTC/Indirect Immunofluorescene	CE marked	Qualitative	LM-IMM-0017 LP-IMM-0104
	LKS screen *1,2,3,4		Helios HTC/Indirect Immunofluorescene	CE marked	Qualitative or 1/40-1/160	LM-IMM-0005 LP-IMM-0104
	PV Autoantibodies **1,2,3,4		Manual Method/Indirect Immunofluorescence	CE Marked	1/10 - 1/80	LM-IMM-0020
1040 Immunology - .61 Proteins, quantitative analysis	Albumin	CSF	Roche Cobas c303/Turbimetry	CE Marked	36-4800 mg/L	LM-IMM-0080 LP-IMM-0108
		Serum	Roche Cobas c303/Turbimetry	CE marked	3-101 g/L	LM-IMM-0080 LP-IMM-0108
	Alpha-1 Antitrypsin (AAT)		Roche Cobas c303/Turbimetry	CE Marked	0.2-6.0 g/L	LM-IMM-0080 LP-IMM-0108
	Caeruloplasmin		Roche Cobas c303/Turbimetry	CE Marked	0.03-1.0 g/L	LM-IMM-0080 LP-IMM-0108
	CD163 **1,2,3,4	Urine	Dynex DS2/ELISA	CE marked	0-13.61ng/ml	LM-IMM-0059
	CD25/IL-2 Ra **1,2,3,4	Serum	ELISA/Dynex DS2	Based on standard method	0-5000pg/mL	LM-IMM-0074

	Cytokine Profile IL-1b **1,2,3,4		Immunoassay/Protein Simple Ella	Based on standard method	0.16-1530pg/mL	LM-IMM-0077
	Cytokine Profile IL-6 **1,2,3,4		Immunoassay/Protein Simple Ella	Based on standard method	0.28-2652 pg/mL	LM-IMM-0077
	Cytokine Profile IL-8/CXCL8 **1,2,3,4		Immunoassay/Protein Simple Ella	Based on standard method	0.19-1804pg/mL	LM-IMM-0077
	Cytokine Profile - TNFa **1,2,3,4		Immunoassay/Protein Simple Ella	Based on standard method	0.3-1160pg/mL	LM-IMM-0077
	Free Kappa/Free Lambda **1,2,3,4		Turbimetry / Optilite	CE Method	Kappa 0.6 - 127000 mg/L Lambda 1.3-139000 mg/L	LM-IMM-0075
	Haptoglobin	Serum/Plasma	Cobas Pure c303	CE Marked	0.-5.7g/L	LM-IMM-0080
	Total Protein	Serum	Roche Cobas c303/Turbimetry	CE Marked	2-120 g/L	LM-IMM-0080 LP-IMM-0108
		Urine	Roche Cobas c303/Turbimetry	CE Marked	O.O4-2 g/L	LM-IMM-0080 LP-IMM-0108
	Transferrin	Serum	Roche Cobas c303/Turbimetry	CE Marked	0.1-5.2 g/L	LM-IMM-0080 LP-IMM-0108
1040 Immunology - .99 Miscellaneous tests	Detection of Immunoglobulins and Complement by Direct Immunofluorescence **2,4	Skin Biopsy	Cryostat/Direct Immunofluorescence	Based on Standard Method	Qualitative	LM-IMM-0042
	Haemophilus Influenza Type B **1,2,3,4	Serum	ELISA/ Dynex DS2	CE Marked	HIB: 0.11 - 9.0 U/ml	LM-IMM-0023
	Interferon Gamma Release Assay **1,2,4		ELISA/ Dynex DS2	CE Marked	IGRA: 0.05 - 10.0 IU/ml	LM-IMM-0061
	Investigation and Identification of Urinary Casts **2,4	Urine	Microscope/Manual Method	Based on Standard Method	Qualitative	LM-IMM-0038
	Phospholipase A2	Serum	ELISA / Dynex DS2	CE Marked	2 - 1500 RU/ml	LP-IMM-0092

	Receptor Antibody **1,2,3,4					LM-IMM-0078
	Pneumococcus Total IgG antibodies **1,2,3,4		Dynex DS2/ELISA	CE Marked	PCP IgG: 3.3 - 270 U/ml	LM-IMM-0025
	Tetanus antibodies **1,2,3,4		ELISA/ Dynex DS 2	CE Marked	TET: 0.01 - 7 U/ml	LM-IMM-0025

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters/tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

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
1011 Macroscopic examination and description	Macroscopic Examination and Description **,3	Artificial Devices, Aspirates, BAL, BAL Washings, Bile, Biopsies, Blood Transfusion Products, Blood, Fluids, Bone Marrow, bronchial Brushings, Cerebrospinal Fluid, Cervical Swabs, Corneal Scrapings, contact lenses, Cryobiology Products, Dermal Swabs, Duodenal/Jejunal Aspirates, Ear Swabs, Endocervical Swabs, Eye Swabs, Faeces, Gastric Washings,Fluids, penile swab, Hair, High Vaginal Swabs, Liver Aspirate, Male Urethral Swabs,Mouth Swabs,	Manual	Based on Standard Method	N/A	LP-MICRO-0001 LP-IMRL-0001

		Nail, Nasal Swabs, Ocular Swabs, Perianal Swabs, Penile swabs, Pharyngeal Swabs, Pus, Rectal Swabs, Respiratory Specimens, Skin Swabs, Sputum, Throat Swabs, Tips, Tissues, Urethral Swabs, Urine,Vulval swab Wound Swabs, worm				
	Manual determination of Leucocytes and Blood in urine using Combur 7 Test **1,4	Urine	Manual/ Urine Strip test	CE Marked	Semi Quantitative: Leucocytes: Negative, +: 10-25 Leu/µl, ++: 75Leu/µl, +++ 500Leu/µl , Blood: Negative, +: 5-10 ERY/µl, ++: 25 ERY/µl, +++:50 ERY/µl, ++++ :250 ERY/µl	LM-MICRO-0019
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)	Preparation of Films on Glass Slides for General Bacteriology Purposes-Gram Stain **3,4	Artificial Devices, BAL, BAL Washings, Biopsies, , Blood, Fluids, Bone Marrow, bronchial Brushings, Cerebrospinal Fluid, Cervical Swabs, Aspirates, , Endocervical Swabs, Eye Swabs , Fluids, High Vaginal Swabs, Mouth Swabs,Pus, Respiratory	Microscope/Manual	CE Marked	Positive / Negative	LM-MICRO-0001,04, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 30, 32, 33, 37, 43, 48, 52

		Specimens, Sputum, Tissues, Urethral Swabs, Urine, Wound Swabs, Rectal Swabs				
	Red Cell Count, White Cell Count & White Cell Differential Stain **1,3,4	Cerebrospinal Fluid	Microscope/Manual	Based on Standard Method	Red Cells, White Cells per uL. Differential: % PMNs, % Monocytes	LM-MICRO-0020, 35
	Urine Microscopy **1,3,4	Urine	Microscope/Manual	Based on Standard Method	WCC,RCC <10, 10-100, >100 per ul.	LM-MICRO-0019
	Urine Microscopy automated **1,3,4		UF5000/ Flow cytometry for automated urine microscopy	CE Marked	WCC,RCC <20 to >1000 per ul.	LM-MICRO-0019,LP-MICRO-0220
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	Microscopic Examination for Fungi including Calcofluor White Stain **2,3,4	Skin scrapings, Hair, Nail, Biopsies, Tissues, Aspirates	Microscope/Manual	CE Marked	Positive / Negative	LM-MICRO-0022, 34, 41
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria	Automated GRAM and Ziehl-Neelsen (ZN) dual staining **2,3,4	Microscope slides smeared with culture material.	Dagatron Dual stainer (GRAM and ZN) instrument (AT-3002) /Gram stain/ ZN Stain.	CE Marked	Gram Positive/ Negative / ZN positive/ Negative	LM-IMRL-0008
	Microscopic examination of Mycobacterial isolates by the Ziehl-Neelsen Stain **2,3,4	Positive Mycobacterial Cultures,	Manual/Microscope	Based on Standard Method	Positive / Negative	LM-IMRL-0002, 08
	Microscopic	Respiratory samples,	Microscope/Manual	Based on	Positive / Negative	LM-IMRL-0001, 08

	screening of specimens for Mycobacteria using Auramine Stain **2,3,4	tissues, biopsies , Gastric washings, Early morning Urine, CSF, Body Fluids, Skin & tissues specimens, Abscess, Pus, Wound swab, Blood Culture, Bone Marrow, EBUS		Standard Method		
	Microscopic screening of specimens for Mycobacteria using Auramine Stain on the automated AEROSPRAY® TB Stainer (2, 3,4)	Respiratory samples, tissues, biopsies,Gastric Washings, Early morninig urine, CSF,Body FLUIDS, Skin & Tissue specimens, Abscesses, Pusm Wound swabs, Blood Cultures, Bone Marrow, EBUS	automated AEROSPRAY® TB Stainer/Manual Microscopy	CE Marked	Positive/ Negative	LM-IMRL-0008
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Automated Culture of Specimens for General Bacteria **2,3,4	Cervical Swabs, Dermal Swabs, Ear Swabs, Endocervical Swabs, Eye Swabs, , Genital Swabs, High Vaginal Swabs, Mouth Swabs,Nasal Swabs, , Perianal Swabs, Pharyngeal Swabs, Pus swab, Rectal Swabs, Skin Swabs, Throat Swabs, Urethral Swabs, Urine, Vulval Swabs, Wound Swabs, Groin Swabs	WASP Walk away specimen processor.	CE Marked	Growth / no growth.	LM-MICRO-0002, LP-MICRO-0214

Culture of screening swabs for CPE **2,3,4	Rectal Swabs and Faeces	Manual Innoculation on CPE Chromogenic agar	CE Marked	Growth/No Growth	LM-MICRO-0057
Culture of screening swabs for MRSA **2,3,4	Nasal, Throat, Groin swabs	Manual Innoculation on MRSA chromogenic agar	CE Marked	Growth / No growth	LM-MICRO-0014
Culture of screening swabs for VRE **2,3,4	Faeces, Rectal Swabs, Colonic Aspirates	Manual/ innoculation on VRE chromogenic agar	CE Marked	growth / no growth	LM-MICRO-0057
Culture of Specimens for General Bacteria **2,3,4	Artificial Devices, BAL, BAL Washings, Bronchial Brushings, Bile, Biopsies, Blood Transfusion Products, Fluids, Bone Marrow, Cerebrospinal Fluid, Cervical Swabs, Colonic Aspirates, Corneal Scrapings,CRE Screening swabs, Cryobiology Products, Dermal Swabs, Aspirates, Ear Swabs, Endocervical Swabs, Eye Swabs, Faeces, Fluids, Genital Swabs, Hair, High Vaginal Swabs, Mouth Swabs, Nasal Swabs, Perianal Swabs, Pharyngeal Swabs, Pus, Rectal Swabs, Respiratory Specimens, Skin Swabs, Spleen Aspirate, Sputum,	Manual	CE Marked	growth / no growth	LM-MICRO-0002, 04, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 55

		Throat Swabs, Tips, Tissues, Urethral Swabs, Urine, Vulval Swabs, Wound Swabs				
	Detection of organisms (other Than Mycobacterium Species) from Blood Cultures *3,4	Blood/Fluids	Bact/Alert Virtuo Blood culture microbial detection system/colorimetric detection of CO2	CE Marked	Detected/Not Detected	LM-MICRO-0030, LP-MICRO-0229
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of specimens for superficial and systemic mycoses **2,3,4	Skin, Hair, Nail, Biopsies, Tissues,any sample specifically requesting prolonged fungal culture	Manual	CE marked	Growth / no growth	LM-MICRO-0022, 41
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of isolates for Mycobacteria **3,4	bacterial isolates	Becton Dickinson Bactec MGIT 960	CE Marked	growth / no growth	LM-IMRL-0001, 02
	Culture of specimens for Mycobacteria **3,4	Sputum, Induced sputum, BAL, Bronchial Washings, Bronchial Brushings, Biopsies, Gastric Washings, Early Morning Urine, Cerebrospinal Fluid, Pleural Fluids, Peritoneal Fluids, Synovial Fluids, Pericardial Fluids, Skin, Tissue, Abscess Contents, Aspirated Pus,	Becton Dickinson Bactec MGIT 960 / Manual Lowenstein Jenson Slopes	CE Marked	Growth / no growth	LM-IMRL-0001, 02

		Wound Swabs, Blood, Bone Marrow, EBUS				
	Detection of mycobacterium species **3,4	Blood	Becton Dickinson Bactec FX40 instrument	CE Marked	Growth / No growth	LM-IMRL-0001,LM-IMRL-0002
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Salmonella & Shigella serology **3,4	Bacterial isolates	Manual / Slide agglutination	CE marked	Positive / Negative	LM-MICRO-0029
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Detecion of antibodies to Treponema pallidum (3,4)	Serum	Manual/ Particle agglutination	CE Marked	Qualitative : Positive/Negative	LM-SERO-0029
	Non-Treponemal test for the qualitative and semi quantitative detection of Syphilis-RPR **1,3,4		Manual/ Particle Agglutination	CE Marked	Qualitative: Negative or Positive & Semiquantitative: Neat to titre of >1024	LM-SERO-0007
	Pastorex Staph Plus Test **3,4	Bacterial Isolate	Manual/Particle agglutination	CE Marked	Positive / Negative	LM-MICRO-0036,LM-MRSA-0002
	Potassium Hydroxide (String) Test **3,4		Manual	Based on Standard Method	Positive / Negative	LM-MICRO-0036
	Streptococcal Grouping **3,4		Manual/Particle agglutination	CE Marked	Qualitative agglutination or non-agglutination.	LM-MICRO-0036
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme	Detection of Aspergillus Galactomannan Antigen **3,4	Blood, BAL	Manual/EIA	CE Marked	Qualitative: Negative/Positive	LM-SERO-0016

immunoassay,						
	Detection of C. difficile toxin **3,4	Faecal specimens	Manual/ Rapid Membrane Enzyme Immunoassay /Membrane Enzyme Immunoassay for the Simultaneous Detection of Clostridium difficile Glutamate Dehydrogenase Antigen and Toxins A and B in Faecal Specimens	CE Marked	Positive / Negative.	LM-MICRO-0029
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Detection of Cryptococcal antigen **1,3,4	CSF, Serum	Manual/lateral flow assay	CE Marked	Qualitative Positive/Negative , semi quantitative neat to 2560	LM-MICRO-0052
	Detection of Legionella pneumophila and Streptococcus pneumoniae urinary antigen **3,4	Urine	Manual / lateral flow assay	CE Marked	Qualitative Positive/ Negative	LM-MICRO-0055
	Geenius HIV 1/2 Confirmatory Assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2 **3,4	Serum	Immunochromatographic test for the confirmation and differentiation of individual antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2)	CE Marked	Positive/Negative	LM-SERO-0028
	Identification of Mycobacterium tuberculosis complex	Positive Mycobacterial Cultures	Becton Dickinson MGIT 960 /immunochromatographic	CE Marked	Qualitative Positive/Negative	LM-IMRL-0012

	**3,4		techniques			
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	GenoType NTM-DR Assay for subspeciation of Mycobacterium abscessus complex and detection of Macrolide and Aminoglycoside Resistance **3,4		Veriti Thermal Cyclers/ /GenoType Molecular assay	CE Marked	Detected / Not detected	LM-IMRL-0009
	GenoType NTM-DR assay to confirm the presence of M. chimaera in mycobacterial cultures **3,4		Veriti Thermal Cyclers/Line probe assay	CE marked	Detected/Not detected	LM-IMRL-0009
	Molecular Detection of M. tuberculosis Complex and Resistance Conferring Mutation **3,4	Positive Mycobacterial Cultures, Respiratory Samples	Veriti Thermal Cyclers/GT Blot 48/Line Probe Assay	CE Marked	Detected/Not detected	LM-IMRL-0009
	Molecular Identification of Mycobacterium Species **3,4	Positive Mycobacterial Cultures	Veriti Thermal Cyclers/GT Blot 48/Line Probe Assay	CE Marked	Detected/Not detected	LM-IMRL-0009
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	AdV/hMPV/RV assay *2,3,4	Respiratory sample	Panther Fusion / real-time PCR	CE Marked	Detected/Not Detected	LM-MOL-0052
	Detection and differentiation of CPE resistance genes: bla	Rectal Swabs	GeneXpert ® Instrument Systems/Real Time PCR assay for detection of	CE Marked	Detected/not detected	LM-MICRO-0057

KPC, bla NDM, bla VIM, bla OXA-48, bla IMP-1 **2,3,4		Carbapenem resistance genes			
Detection and Identification of Aspergillus species using the AsperGenius 2.0 species Multiplex real-time PCR assay (2, 3,4)	BAL	easyMAG/Roche Light Cycler/Multiplex RT PCR	CE Marked	detected/not detected	LM-MICRO-0063
Detection and Quantitation of HCV RNA using the Aptima HCV Quant Dx Assay **1,2,3,4	Serum	Hologic Panther® system/nucleic acid amplification test using target capture, TMA,	CE Marked	Not Detected, ,< 10 IU/mL Detected but not Quantified, 10-25 IU/mL detected and quantified, 25-100,000,000 IU/mL Detected and quantified, >100,000,000 IU/mL Detected and quantified	LM-MOL-0050
Detection of Adenovirus DNA **1,2,3,4	Blood: Plasma	Applied Biosystem 7500 PCRSystem,	CE Marked	Quantitative: Not detected to > 800 copies/ml	LM-MOL-0033
Detection of CPE genes (KPC, NDM, OXA 48 like, VIM, IMP, GES) **2,3,4	Rectal Swabs and Isolates	Roche Light Cycler 480 II/ EntericBio RT-PCR	CE Marked	Detected or not detected	LM-MICRO-0057
Detection of Cytomegalovirus DNA **1,2,3,4	Plasma	Applied Biosystem 7500 PCR System,	CE Marked	Quantitative: Not detected to > 250 IU/ml	LM-MOL-0033
Detection of Epstein Barr Virus DNA **1,2,3,4		Applied Biosystem 7500 PCR System	CE Marked	Quantitative: Not detected to > 800 IU/ml	LM-MOL-0033
EntericBio Gastro	Faeces, Rectal	EntericBio realtime®	CE Marked	Detected/Not	LM-MICRO-0029

Panel 2 for the detection of enteric pathogens including parasites - Giardia lamblia & Cryptosporidium parvum/hominis **2,3,4	Swabs, Colonic Aspirates	Gastro panel 2 /epMotion 5070/Roche Light Cycler 480 II/ Real Time PCR		detected	
Molecular Detection of Hepatitis B virus **1,2,3,4	Plasma	Hologic Panther® system/nucleic acid amplification test	CE Marked	Detected/ Not detected/ Quant <10 to 1,000,000,000 IU/ml or <1.00 to > 9.00 Log10 IU/mL	LM-MOL-0049
Molecular Detection of SARS-CoV-2 using the Aptima SARS-CoV-2 assay **2,3,4	Nasopharyngeal swabs/Combined Nasal/ Throat swab/BAL	Hologic Panther® system/nucleic acid amplification test using target capture, TMA,	CE Marked	Detected/Not detected	LM-MOL-0046
Molecular detection of C. difficile **2,3,4	Faeces, Rectal Swabs, Colonic Aspirates	Roche Light Cycler 480 II/ EntericBio realtime® C. difficile assay	CE Marked	Detected / Not Detected	LM-MICRO-0029,
Molecular detection of Carbapenamase genes (KPC, VIM, IMP, NDM, OXA-48-like) **2,3,4	Bacterial Isolates	AUS Diagnostics Easy Plex /High Plex Real time PCR assay	CE Marked	Detected/Not detected	LM-MICRO-0056
Molecular Detection of Chlamydia trachomatis **2,3,4	Endocervical swabs, vaginal swabs, pharyngeal swabs, rectal swabs, male urethral swabs, male and female urines	Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA/ the Aptima CT assay	CE Marked	Detected/ Not detected	LM-MOL-0048
Molecular Detection of Chlamydia trachomatis and N. gonorroheae **2,3,4		Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and	CE Marked	Detected / Not detected	LM-MOL-0048

		DKA / the Aptima Combo 2 Assay			
Molecular Detection of CSF pathogens (Bacterial, Viral & Fungal) using the BIOFIRE Filmarray ME Panel **2,3,4	Cerebrospinal fluid	BIOFIRE® FILMARRAY® TORCH Instrument, multiplex PCR system	CE Marked	Detected/Not Detected	LM-MICRO-0061
Molecular detection of M. tuberculosis Complex and Rifampicin Resistance **2,3,4	Respiratory samples	Cepheid GeneXpert, System multiplex real time RT PCR	CE Marked	Detected /Not detected.	LM-IMRL-0013
Molecular detection of M.tuberculosis Complex and isoniazid, fluoroquinolone, amikacin, kanamycin, capreomycin and ethionamide resistance **234	Positive Mycobacterial Cultures, Respiratory Samples	Cepheid GeneXpert 10-colour module, Systems multiplex real time RT PCR	CE Marked	Detected/Not detected	LM-IMRL-0013
Molecular Detection of N. gonorroheae **2,3,4	Bacterial isolates	Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA/ the Aptima GC assay	In-house developed	Detected/ Not detected	LM-MOL-0048
	Endocervical swabs, vaginal swabs, pharyngeal swabs, rectal swabs, male urethral swabs, male and female urines	Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA/ the Aptima GC assay	CE Marked	Detected/ Not detected	LM-MOL-0048
Molecular detection of SARS-CoV-2 ,	Nasopharyngeal swabs/Combined	Cepheid GeneXpert System / automated,	CE Marked	Detected / Not detected	LM-MOL-0045

	Influenza A, Influenza B, RSV **2,3,4	Nasal/ Throat swab	multiplex real-time, (RT-PCR)			
	Paraflu assay *2,3,4	Respiratory sample	Panther Fusion / Real-time PCR	CE Marked	Detected/Not Detected	LM-MOL-0052
	SARS/Flu A/B/RSV assay **2,3,4	Nose / throat swabs	Panther Fusion / Real-time PCR	CE marked	Detected, Not detected	LM-MOL-0052
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays	Detection and Characterisation of Microbial DNA/RNA (pvl/mec)	Bacterial Isolates	Applied Biosystems 7500 PCR / Real Time PCR	In House Developed	Detected / not detected.	LM-MRSA-0012
	Detection and Characterisation of Microbial DNA/RNA in MRSA (spa typing)		MiniAmp Thermal Cycler	In House Developed	N/A	LM-MRSA-0011
	Detection of Hepatitis E RNA	Serum, Plasma	Applied Biosystems AB 7500 Fast / Real-Time PCR	In-House Developed	Detected, Not Detected	LM-MOL-0037
	Detection of LGV DNA	Rectal Swabs	Applied Biosystem 7500 PCR System/Real Time PCR	In house developed	Detected/ Not detected	LM-MOL-0036
	Detection ofVaricella-zoster DNA	Anogenital,Dermal, Ocular, Oral region swabs	Applied Biosystesm 7500 PCR System, / Real Time PCR	In house developed	Qualitative ; Detected / Not detected.	LM-MOL-0034
	Real time PCR for the detection of genes associated with linezolid resistance	Staphylococci and Enterococci isolates	AB7500	In house Assay	Positive/ negative	LM-MRSA-0017
	Whole genome sequencing for drug resistance prediction in Mycobacterium tuberculosis	Mycobacterial Isolates	Illumina (MiniSeq and MiSeq) platforms /WGS	In-house developed	Drug resistance prediction	LM-IMRL-0020

	Complex.					
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis	cgMLST and whole genome sequencing identification, lineage calling and relatedness analysis of bacterial isolates	Staphylococci and Enterococci Isolates	Illumina MiSeq	In-house developed	Lineage identification & relatedness analysis	LM-MRSA-0015
	cgMLST and whole genome sequencing identification, lineage calling and relatedness analysis of Mycobacterium tuberculosis Complex	Mycobacterium Isolates	Illumina (MiniSeq and MiSeq) platforms / WGS	In-house developed	Lineage identification & relatedness analysis	LM-IMRL-0020
	Confirmation of Pyrazinamide Resistant Mycobacterium tuberculosis using DNA Sequencing Methods	Positive Mycobacterial Cultures	Veriti Thermal Cycler/AB3500 Genetic Analyser	In house developed	N/A	LM-IMRL-0018
	Confirmation of Rifampicin resistance by investigating variants in the rpoB gene using sequencing methods		Veriti Thermal cycler/AB3500 Genetic Analyser	In house developed	N/A	LM-IMRL-0019
	Identification of Non Tuberculosis Mycobacteria by Sequencing the 65kd Shock Protein (hsp65) Gene		Veriti Thermal Cyclers/GT-Blot 48	In house developed	N/A	LM-IMRL-0015
	Speciation within the MAC Complex using 16S and ITS		Veriti Thermal Cyclers/GT-Blot 48	In house developed	N/A	LM-IMRL-0014

	Sequencing					
	Whole Genome Sequencing Analysis of SARS-CoV-2 samples	SARS-CoV2 positive nasopharyngeal samples	Illumina MiSeq/Genome Sequencing	Based on standard methodology	Lineage identification	LM-MRSA-0016
	Withdrawn	n/a	n/a	n/a	n/a	n/a
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of yeast **3,4	Yeast isolate	Biomerieux Vitek 2 XL / VITEK 2 yeast identification card (YST)	CE Marked	Identification / No identification	LM-MICRO-0005.
	Identification of Cultured Bacteria **3,4	Bacterial Isolates	Biomerieux Vitek 2 XL	CE Marked	Identification / No identification	LM-MICRO-0004, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 52, LP-MICRO-0186
	Identification of S. pneumoniae **2,4	Bacterial Isolate	Manual /Optochin disc	CE Marked	Positive: Zone of inhibition; Negative: No zone of inhibition	LM-MICRO-0036
	Tube Coagulase **4	Bacterial Isolates	Manual/Test Kit	CE Marked	Positive/Negative	LM-MRSA-0002
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Microsopic identification of fungal isolates **3,4	Fungal Isolates	Microscope/ Manual lactofuschin stain	CE marked	Positive/Negative	LM-MICRO-0022, 41
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Rapid method for microorganism identification from microbial cultures **1,2,4	Bacterial / Fungal Isolates	Vitek MS Prime/Matrix-assisted laser desorption/ionization	CE marked	Identification / No Identification	LP-MICRO-0240, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 52

	Rapid method for microorganism identification from microbial cultures **1,2,4		Vitek MS/Matrix-assisted laser desorption/ionization	CE Marked	Identification / No Identification	LM-MICRO-0004, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 52, LP-MICRO-0195
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial susceptibility for Carbapenemase resistant Enterobacteriacea (CPE) **1,2,4	Bacterial Isolate	Automated: Vitek 2XL/MIC, Manual: Gradient MIC, Disc diffusion	CE Marked	S/I/R	LM-MICRO-0003 LM-MICRO-0057
	Antimicrobial susceptibility for Vancomycin resistant Enterococci **1,2,4		Automated: Vitek 2XL/ MIC, Manual: Gradient MIC	CE Marked	S/I/R	LM-MICRO-0003 LM-MICRO-0057
	Antimicrobial susceptibility testing - automated **1,2,4	Bacterial Isolates	Biomerieux Vitek 2XL	CE Marked	S/I/R	LM-MICRO-0003
	Detection of Beta Lactamase **4		Manual/Chromogenic detection of enzyme	CE Marked	Positive/Negative	LM-MICRO-0003
	Methicillin Resistance Detection By Disk Diffusion **1,2,4		Manual/ Zone measurements	CE Marked	S/I/R	LM-MRSA-0002
	Minimum Inhibitory Concentrations using Gradient MIC in MRSA isolates **1,2,4		Manual/Gradient MIC	CE Marked	S/I/R	LM-MRSA-0005
	Specialised Antibiotic Procedures for Glycopeptide Resistance Investigation **1,2,4		Manual/MIC Broth Dilution/Gradient MIC/Growth or no Growth	CE Marked	S/I/R	LM-MRSA-0006, 07

	Susceptibility Testing (Disc Diffusion) **1,2,4		Calipers/Manual/Zone Measurements	CE Marked	S/I/R	LM--MICRO-0003, LM MRSA-0003
	Susceptibility Testing (MIC Method) **1,2,4		Manual/MIC using Gradient MIC Method)	CE Marked	S/I/R	LM-MICRO-0003
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria	New and re purposed anti-TB agents (bedaquiline, clofazimine, delamanid, linezolid and levofloxacin) for susceptibility testing Of M. tuberculosis complex isolates **1,2,4	Mycobacterium Isolates	BACTEC MGIT 960 system/Susceptibility testing: proportional method at a critical concentration	CE Marked	Susceptible / Resistant	Std.ref: World Health Organization. Technical manual for drug susceptibility testing of medicines used in the treatment of tuberculosis. World Health Organization; WHO/CDS/TB/2018.24. SOP:LM-IMRL-006
	Susceptibility Testing of First and Second Line Anti-tuberculosis Drugs **1,2,4	Positive Mycobacterial Cultures	Becton Dickinson Bactec MGIT 960	CE Marked	S/I/R	LM-IMRL-0006
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Yeast One Sensititre **1,2,4	Fungal Isolate	Manual/Antifungal susceptibility test	CE Marked	S/I/R	LM-MICRO-0039
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .04 Filamentous fungi	Antifungal susceptibility **1,2,4		Manual/Antifungal Susceptibility testing (Gradient MIC)	CE Marked	S/I/R	LM-MICRO-0039
1018 Detection of antibody response to infection using appropriate CE marked	Detection of IgM specific Antibodies to Treponema pallidum	Serum	Manual/EIA using the Captia NMT Syphilis IgM	CE Marked	Qualitative : Positive/ Negative	LM-SERO-0006

commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	**1,2,3,4					
	Enzyme immunoassay for the detection of Antibodies to Human Hepatitis C Virus **1,2,3,4		Manual/EIA using the INNOGENETICS INNO-LIA Syphilis Score	CE Marked	Qualitative Positive/Negative	LM-SERO-0018
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .04 Line immunoassay, using CE marked commercial systems	Detection of antibodies against Treponema pallidum **2,3,4		Manual/Line Blot Line Immuno Assay	CE Marked	Intensity of Antigen lines: Negative to +4	LM-SERO-0009
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Qualitative detection of Anti HB core antibody **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
	Qualitative detection of Anti-HCV antibody **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
	Qualitative detection of EBV-EBNA-1 IgG **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
	Qualitative detection		Abbott Alinity i /	CE Marked	Detected / Not	LM-SERO-0027

of HAV IgG **2,3,4		chemiluminescent microparticle immunoassay (CMIA)		Detected	
Qualitative detection of HAV IgM **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
Qualitative detection of HBsAg **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
Qualitative Detection of Anti HB core IgM using the Alinity i system **2,3,4	Serum	Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE marked	Positive/Negative	LM-SERO-0027
Qualitative Detection of Anti-HBe using the Alinity i system	Serum	Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE marked	Positive/Negative	LM-SERO-0027
Qualitative detection of EBV VCA IgG **2,3,4		Abbitt Alinity i / Chemiluminescent Microparticle Immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
Qualitative detection of EBV VCA IgM **2,3,4		Abbott Alinity i / Chemiluminescent Microparticle Immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
Qualitative Detection of HBeAg using the Alinity i system		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE marked	Positive/Negative	LM-SERO-0027
Qualitative detection of HIV Ag/Ab **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027

	Qualitative detection of Syphilis Ab **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected / Not Detected	LM-SERO-0027
	Quantitative detection of Anti HBs **2,3,4		Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA)	CE Marked	Detected (mIU/mL) / Not Detected	LM-SERO-0027
1029 Miscellaneous - .99 Miscellaneous tests	Detection of β-1-3 Glucan **1,2,3,4	Blood: Serum	Biotek ELx808 Microtitre Plate Reader/ Protease zymogen-based colorimetric assay	CE Marked	Semi Quantitative. Negative: <60pg/ml, Positive: >80pg/ml, Indeterminate: 60-80pg/ml	LM-MICRO-0058

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters/tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.