

Schedule of Accreditation



Organisation Name	Mercy University Hospital
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	06/12/2011
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
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	Mercy University Hospital	Pathology Department, Grenville Place, Cork, Ireland, T12 WE28

Scope of Accreditation

Mercy University Hospital

Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO & Rh(D) typing	Whole Blood	Autovue Innova and Diamed Micro Typing Systems Autovue Innova and Diamed Micro Typing Systems	Automatic, Column Agglutination test, Tube		LP-BB-101 ABO and RhD grouping combined with reverse ABO grouping by Diamed Micro typing Systems LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova LP-BB-116, ABO and RhD grouping by tube technique
1020 Transfusion science - .03 Blood group antibody	Antibody Screen	Plasma	Autovue Innova and Diamed Micro	Automatic, Column Agglutination test,		LP-BB-103, Antibody Screening using the

screen			Typing Systems	Tube		Diamed Micro Typing Systems LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Diamed Micro Typing Systems	Column Agglutination test		LP-BB-104, Antibody investigation
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing (IAT)	Plasma Serum	Diamed Micro Typing Systems	Column Agglutination test		LP-BB-110, Compatibility Testing, LP-BB-117, Transfusion Reaction Investigation
1020 Transfusion science - .06 Red cell phenotyping	Red cell phenotyping	Red Cells	Diamed Micro Typing Systems	Column Agglutination test,	N/A	LP-BB-109, Antigen typing of donor units and patient samples
			Diamed Micro Typing Systems	Column Agglutination test, Tube		LP-BB-109, Antigen typing of donor units and patient samples
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs Test		Diamed Micro Typing Systems	Column Agglutination test		LP-BB-115, performing a DCT and investigation of a positive DCT

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).

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	24h Creatinine Clearance **1,2,3,4	Urine	Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Calcium **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Chloride **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Creatinine **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Phosphate **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Potassium **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Protein **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Sodium **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Urate **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	24H Urinary Urea **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	Adjusted Calcium **1,2,3,4	Plasma/Serum	Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-103

Alanine aminotransferase (ALT) **1,2,3,4	Plasma/Serum	NADH (without P-5'-P)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Alkaline Phosphatase (ALP) **1,2,3,4		Para-nitrophenyl Phosphate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Amylase **1,2,3,4	Plasma/Serum/Urine	CNPG3 Substrate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Aspartate Aminotransferase (AST) **1,2,3,4	Plasma/Serum	NADH (without P-5'-P)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Bilirubin (Total) **1,2,3,4		Diazonium Salt	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Calcium **1,2,3,4	Plasma/Serum/Urine	Arsenazo III	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Chloride **1,2,3,4		Ion-selective electrode diluted (Indirect)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Cholesterol (Total) **1,2,3,4	Plasma/Serum	Enzymatic	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Cholesterol LDL **1,2,3,4	Plasma/Serum	Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
Cholesterol (HDL) **1,2,3,4	Serum/ serum	Accelerator selective detergent	Architect C8000	CE Marked Assay	LP-BIO-101 LP-BIO-102
Creatine Kinase (CK) **1,2,3,4	Plasma/Serum	NAC (N-acetyl-L-cysteine)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Creatinine **1,2,3,4	Plasma/Serum/Urine	Kinetic Alkaline Picrate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Plasma/Serum	L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Glucose **1,2,3,4		Hexokinase/G-6-PDH	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Lactate Dehydrogenase **1,2,3,4		IFCC recommended forward reaction - Lactate to Pyruvate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
Magnesium **1,2,3,4		Enzymatic	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102

	MDRD GFR **1,2,3,4		Calculation	Abbott Architect	CE based on standard method	LP-BIO-101 & LP-BIO-102
	Microalbumin **1,2,3,4	Urine	Turbidimetric/Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Osmolality **1,2,3,4	Serum/Urine	Freezing Point Depression	Advanced Instruments Model 3320 Osmometer		LP-BIO-17
	Phosphorus **1,2,3,4	Plasma/Serum/Urine	Phosphomolybdate	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Potassium **1,2,3,4		Ion-selective electrode diluted (Indirect)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Sodium **1,2,3,4	Plasma/Serum/Urine	Ion-selective electrode diluted (Indirect)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Triglyceride **1,2,3,4	Plasma/Serum	Glycerol Phosphate Oxidase	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Troponin I (High Sensitivity) **1,2,3,4	Plasma	CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Urea **1,2,3,4	Plasma/Serum/Urine	Urease	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Uric acid **1,2,3,4		Uricase	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Urinary Albumin/Creatinine Ratio **1,2,3,4	Urine	Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	Urinary Calcium/Creatinine Ratio **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
	Urinary Protein/Creatinine Ratio **1,2,3,4		Calculation	N/A	CE based on standard method	LP-BIO-101 LP-BIO-102
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4	Plasma/Serum	Bromocresol Purple	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	C-reactive Protein **1,2,3,4		Turbidimetric/Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102

	Faecal Calprotectin **1,2,3,4	Faeces	Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-316
			Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-316
	Human B-type natriuretic peptide (BNP) **1,2,3,4	EDTA	CMIA	Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Total Protein ***1,2,3,4	Plasma/Serum	Biuret	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Total Protein **1,2,3,4	Urine/CSF	Benzethonium chloride	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Digoxin **1,2,3,4	Plasma/Serum	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Lithium **1,2,3,4	Serum	Colorimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4	Plasma/Serum	Enzymatic	Abbott Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Salicylate **1,2,3,4		Enzymatic/Colorimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Free T4 ***1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Parathyroid hormone (PTH) **1,2,3,4	Plasma	CMIA	Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	PTH**1,2,3,4	EDTA Plasma	chemiluminescent microparticle immunoassay	Abbott i2000	CE Marked	LP-BIO-104 LP-BIO-105
		EDTA/Plasma	CMIA	Abbott i2000/4-2500pg/ml	CE Marked	LP-BIO-104
	Thyroid Stimulating Hormone (TSH) **1,2,3,4	Plasma/Serum	CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
1061 Clinical Chemistry - .24 Hormone receptor	Beta Human Chorionic		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105

assays	Gonadotropin (BHCG) **1,2,3,4					
1061 Clinical Chemistry - .40 Iron studies	% transferrin Saturation	Plasma/Serum	Calculation	Calculation	CE based on standard method	LP-BIO-101 LP-BIO-102
	Ferritin **1,2,3,4	Plasma/Serum	CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Iron **1,2,3,4		Ferene	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Transferrin **1,2,3,4		Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4	Plasma/Serum	CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Vitamin B12 **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha-fetoprotein (AFP) **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Ca 125 **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Ca 19-9 **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Carcinoembryonic Antigen (CEA) **1,2,3,4		CMIA	Abbott Architect i2000	CE Marked Assay	LP-BIO-104 & LP-BIO-105
	Prostate Specific Antigen **1,2,3,4		Serum	CMIA	Abbott Architect i2000	CE Marked Assay
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Immunochemical test**1,2,3,4	Faeces	Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-306
	Faecal Occult Blood **1,2,4		Immunochromatographic Qualitative	Dipstick	CE Marked Assay	LP-BIO-306
1061 Clinical Chemistry - .80 Quantitative	Immunoglobulin A **1,2,3,4	Plasma/Serum	Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102

investigation of immunoglobulins G, A, M and in body fluids						
	Immunoglobulin G **1,2,3,4		Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Immunoglobulin M **1,2,3,4		Immunoturbidimetric	Architect C8000	CE Marked Assay	LP-BIO-101 & LP-BIO-102
	Paraprotein Quantitation**1,2,3,4	Serum	Densitometry	Interlab G26	CE Marked Assay	LP-BIO-300
1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G, A, M and in body fluids	Electrophoresis **1,2,3,4	Serum/Urine	Electrophoresis	Interlab G26	CE Marked Assay	LP-BIO-300
	Paraprotein type**1,2,3,4		Immunofixation	Interlab G26	CE Marked Assay	LP-BIO-300

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.

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Haemaglobin **1,2,3,4	Blood	Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
	Haematocrit **1,2,3,4		Calculated parameter	Advia 2120i	Calculated parameter	LP-HAE-106 LP-HAE-103
	MCH **1,2,3,4		Calculated parameter	Advia 2120i	Calculated parameter	LP-HAE-106 LP-HAE-103
	MCHC **1,2,3,4		Flow Cytometry	Advia 2120i	Calculated parameter	LP-HAE-106 LP-HAE-103
	Mean Cell Volume **1,2,3,4		Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
	Platelet Count **1,2,3,4		Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
	Red Cell Count **1,2,3,4		Flow Cytometry	Advia 2120i	CE	LP-HAE-103 LP-HAE-106
	White cell count **1,2,3,4		Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
1030 Haematology - .02 Visual examination of blood films	Manual Differentiation, red cell morphology and Platelet morphology **1,2,3,4		Staining/microscopy	Manual	CE	LP-HAE-122 LP-HAE-120
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR (Automated) **1,2,3,4		Sedimentation of red cells	Alifax Test-1	CE	LP-HAE-143
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count **1,2,3,4		Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103

	Eosinophil Count **1,2,3,4
	Lymphocyte Count **1,2,3,4
	Monocyte Count **1,2,3,4
	Neutrophil Count **1,2,3,4
1030 Haematology - .06 Automated reticulocyte counts	Retic count **1,2,3,4
1030 Haematology - .09 Examination of malarial parasites	Malaria Screen **1,2,3,4
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen **1,2,3,4
1030 Haematology - .40 Limited haemostasis related tests	Free Protein S **1,2,3,4
	Lupus anticoagulant **1,2,3,4
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,2,3,4
	D-Dimer **1,2,3,4
	Fibrinogen (Clauss) **1,2,3,4
	International Normalised Ratio (INR) **1,2,3,4
	Protein C activity **1,2,3,4
	Prothrombin Time

Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	LP-HAE-106 LP-HAE-103
Blood Film	Blood Film Examination	Blood Film	LP-HAE-171
Immunoassay	Carestart test kit	CE	LP-HAE-171
Haemoglobin Solubility test	Clin-tech sickle test	CE	LP-HAE-176
Immunoassay	Sysmex CA2100i	CE	LP-Hae-160
Clotting assay	Sysmex CS2100i	CE	LP-HAE-162
Clotting assay	Sysmex CS2100i	CE	LP-Hae-159
Immunoturbidimetric assay	Sysmex CS2100i	CE	LP-Hae-159
Clotting assay	Sysmex CS2100i	CE	LP-Hae-159
Ratio calculation	Sysmex CS2100i	Ratio calculation	LP-Hae-159
Chromogenic analysis	Sysmex CA2100i	CE	LP-Hae-160
Clotting assay	Sysmex CS2100i	CE	LP-Hae-159

	(PT) **1,2,3,4				
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis **1,2,3,4		Immunoassay		CE LP-HAE-147
1030 Haematology - .80 Molecular genetic studies	Detection of Factor V Leiden & Prothrombin Variant **1,2,3,4		PCR Amplification	GeneXpert	PCR LP-HAE-172
1030 Haematology - .99 Miscellaneous tests	Antithrombin **1,2,3,4		Chromogenic analysis	Sysmex CA2100i	CE LP-Hae-160
	Rheumatoid Factor **1,2,3,4		Immunoassay	Rheumajet RF kit	CE LP-HAE-155

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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**1,2,3,4	CSF, Pleural / pericardial / chest / lymphatic fluids / drains / other fluids, sputa	Manual	Based on standard method	N/A	LP-MIC-1
	Manual determination of red cells in urine using dipstick test**1,2,3,4	Urine, Catheter Specimen Urine, nephrostomy bag samples	Manual	Based on standard method	Semi-quantitative blood: negative, +, ++, +++	LP-MIC-250
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)	Gram stains**1,2,3,4	Blood cultures, CSF, Vaginal/cervical/endocervical swabs, abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies; bacterial / isolates	Microscope/Manual	Based on standard method	Gram positive / negative; cocci / bacilli including Hay's Criteria where required	LP-MIC-283 LP-MIC-290 LP-MIC-291
	Red cell count, white cell count, white cell differential**1,2,3,4	Cerebrospinal fluid, all fluids including drain, joint, pleural, pericardial, chest, lymphatic	Microscope/Manual	Based on standard method	Red cells and white cells per cmm. Differential: % polymorphs, % leucocytes	LP-MIC-231

	Urine microscopy**1,2,3,4	Urine, Catheter Specimen Urine, nephrostomy bag samples	Microscope/Manual	Based on standard method	WCC and RCC per cmm.	LP-MIC-250
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Cryptosporidium **1,2,3,4	Faeces	Fluorescent microscopic examination	Based on standard method	Seen / Not Seen	LP-MIC-244 Investigation of Cryptosporidium Species
	Microscopic examination of cryptosporidium by auromine stain**1,2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	LP-MIC-244
	Microscopic examination of cryptosporidium by Ziehl-Neelson stain**1,2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	LP-MIC-221
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	Microscopic examination of fungi**1,2,3,4	Fungal isolates	Microscope/Manual	Based on standard method	N/A	LP-MIC-234
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	Microscopic examination of mycobacteria by auromine stain**1,2,3,4	Pleural / pericardial / chest / lymphatic fluids / drains / other fluids / swabs / tissues / respiratory samples (sputa, bronchial washings)	Microscope/Manual	Based on standard method	Seen / Not Seen	LP-MIC-221
	Microscopic examination of mycobacteria by Ziehl-Neelson stain**1,2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	LP-MIC-221
	Mycobacterium Culture **1,2,3,4	Chest / lymphatic fluids / drains / other fluids	Manual Method using Staining with fluorescent	Based on standard method	N/A	LP-MIC-221

			microscope			
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Bacterial Culture**1,2,3,4	HVs	Manual	Microscope	Normal /Intermediate /Abnormal	LP-MIC-235, LP-MIC-231, LP-MIC-290 LP-MIC-291
	Culture of blood culture specimens**1,2,3,4	Blood Culture and fluids from normally sterile sites	BacTAlert Virtuo	CE Marked	N/A	LP-MIC-282, LP-MIC-284, LP-MIC-290, LP-MIC-291
			BacTAlert Virtuo	CE Marked	N/A	LP-MIC-282 LP-MIC-284, LP-MIC-290, LP-MIC-291
	Culture of CSF**1,2,3,4	CSF	Manual	Based on standard method	N/A	LP-MIC-233 LP-MIC-290 LP-MIC-291
	Culture of faeces **1,2,3,4	Faeces	Manual	Based on standard method	N/A	LP-MIC-241 LP-MIC-290 LP-MIC-291
	Culture of faeces **1,2,3,4		Manual	Based on standard method	N/A	LP-MIC-241 LPMIC-290 LP-MIC291
	Culture of miscellaneous specimens for general bacteria**1,2,3,4	Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies;	Manual	Based on standard method	N/A	LP-MIC-232 LP-MIC-290 LP-MIC-291
	Culture of respiratory specimens **1,2,3,4	Sputa, bronchial washings, BAL, ETT specimens	Manual	Based on standard method	N/A	LP-MIC-222 LP-MIC-290

						LP-MIC-291
			Manual	Based on standard method	N/A	LP-MIC-241 LPMIC-290 LP-MIC291
	Culture of screening swabs for CPE using chromogenic agar**1,2,3,4	Rectal swabs, faeces	Manual	Based on standard method	N/A	LP-MIC-232 LP-MIC-290 LP-MIC-291
	Culture of urine**1,2,3,4	Urine, Catheter Specimen Urine, nephrostomy bag samples	Manual	Based on standard method	N/A	LP-MIC-250 LP-MIC-290 LP-MIC-291
	Culture of miscellaneous specimens for general bacteria**1,2,3,4	Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies;	Manual	Based on standard method	N/A	LP-MIC-232 LPMIC-290 LP-MIC291
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of blood culture specimens**1,2,3,4	Blood Culture and fluids from normally sterile sites	BacTAlert / Manual	CE Marked	N/A	LP-MIC-282, LP-MIC-283, LP-MIC-284, LP-MIC-290, LP-MIC-291
	Culture of CSF **1,2,3,4	CSF	Manual	Based on standard method	N/A	LP-MIC-233 LP-MIC-290 LP-MIC-291
	Culture of faeces **1,2,3,4	Faeces	Manual	Based on standard method	N/A	LP-MIC-241 LP-MIC-290 LP-MIC-291
	Culture of miscellaneous specimens for Fungi**1,2,3,4	Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs;	Manual	Based on standard method	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291

		oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies;				
	Culture of respiratory specimens **1,2,3,4	Sputa, bronchial washings, BAL, ETT specimens	Manual	Based on standard method	N/A	LP-MIC-222, LP-MIC-290, LP-MIC-291
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Salmonella, shigella and vibrio serology **1,2,3,4	Bacterial isolates	Manual	Based on standard method	Pos/Neg	LP-MIC-290
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Antistreptolysin-O-Titre (ASOT) **1,2,3,4	Serum	Manual	CE	<200 Negative >200 Positive	LP-MIC-261
	Salmonella, shigella and E. Coli particle agglutination **1,2,3,4	Bacterial isolates - species of salmonella, shigella and E. Coli	Manual / Wellcolex particle agglutination kits	CE marked	Pos/Neg	LP-MIC-290
	Staphylococcal coagulase test	Bacterial isolates - staphylococcus species	Manual	CE marked	Pos/Neg	LP-MIC-290
	Streptococcal grouping **1,2,3,4	Bacterial isolates - streptococcus species	Manual	CE marked	Qualitative agglutination or non-agglutination	LP-MIC-290
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Adenovirus detection **1,2,3,4	Faeces	Manual / Lateral flow	CE marked assay	Pos/Neg	LP-MIC-242

	C difficile detection **1,2,3,4		Manual / Lateral flow	CE marked	Pos/Neg	LP-MIC-243
	Rotavirus **1,2,3,4		Manual / Lateral flow	CE marked	Pos/Neg	LP-MIC-242
	Urinary Legionella antigen detection**1,2,3,4	Urine	Sofia Reader / immunochromatographic	CE marked	Pos/Neg	LP-MIC-265
	Urinary Pneumococcal antigen detection **1,2,3,4		Sofia Reader / immunochromatographic	CE marked	Pos/Neg	LP-MIC-265
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Detection of SARS-COV-2 **1,2,3,4	Nasopharyngeal/Oropharyngeal Swabs /Sputum/BAL specimens	Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR	CE Marked	Detected/Not Detected	LP-MIC-301
		Nasopharyngeal/Oropharyngeal Swabs; nasopharyngeal only / oropharyngeal only	GeneXpert / Real-time PCR	CE Marked	Detected/Not Detected	LP-MIC-224
	Detection of bacteria / viruses / fungi in positive blood cultures using the FilmArray Blood Culture Identification 2 (BCID2) Panel Panel **1,2,3,4 Targets include 10 antimicrobial resistance genes: CTX-M, IMP, KPC, mcr-1, mecA/C, macA/C and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; 26 bacterial targets: Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus spp, Staphylococcus aureas, Staphylococcus epidermidis, Staphylococcus pneumoniae, Streptococcus pyogenes (Group A), Acinetobacter calcoaceticus-baumannii complex, Bacteroides fragilis, Enterobacterales, Enterobacter cloacaecomplex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus spp, Salmonella spp, Serratia	Positive blood culture samples	Biofire FilmArray FilmArray Blood Culture Identification 2 (BCID2) Panel / Real Time PCR	CE marked	Detected/ Not Detected	LP-MIC-300

marcesens, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Stenotrophomonas maltophilia; and 7 yeast targets; Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Cryptococcus neoformans/gattii. 43 targets in total.**1,2,3,4					
Detection of bacterial, viral, and fungal pathogens using the FilmArray Meningitis/Encephalitis Panel (ME) **1,2,3,4 Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus (CMV) Enterovirus Herpes simplex virus 1 (HSV-1) Herpes simplex virus 2 (HSV-2) Human herpes virus 6 (HHV-6) Human parechovirus Varicella zoster virus (VZV) Cryptococcus neoformans/gattii	Cerebrospinal fluid (CSF)	BIOFIRE FILMARRAY ME Panel	CE Marked	Detected / Not Detected	LP-MIC-300
Detection of Carbapenemase Producing Enterobacteriaceae genes (KPC, VIM, IMP, NDM and OXA-48) by PCR **1,2,3,4	Bacterial isolates/ Rectal swabs	GeneXpert / Real-time PCR	CE Marked	Detected/Not Detected	LP-MIC-224 LP-MIC-232
Detection of enteric pathogens by molecular methods. Targets include: Yersinia enterocolitica, Shigella, Enteroinvasive E. Coli, E. Coli 0157, C. Difficile toxin A/B, Shigatox 1/2, Salmonella, Campylobacter, Astrovirus, Norovirus G2, Adenovirus, Sapovirus, Norovirus G1, Rotavirus**1,2,3,4	Faeces	Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR	CE Marked	Detected/Not Detected	LP-MIC-301
Detection of enteric pathogens by		Nimbus and Biorad	CE Marked	Detected/Not	LP-MIC-301

molecular methods.Targets include: Yersinia enterocolitica,Shigella, Enteroinvasive E. Coli,Faeces E. Coli 0157, C.Difficile toxin A/B,Shigatox 1/2, Salmonella,Campylobacter,Astrovirus, Norovirus G2, Adenovirus, Sapovirus, Norovirus G1, Rotavirus**1,2,3,4		CFX96 / Real-time PCR		Detected	
Detection of Influenza A/Influenza B/RSV **1,2,3,4	Nasopharyngeal/Oropharyngeal Specimens	GeneXpert/PCR	CE marked	Detected/Not Detected	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
Detection of Influenza A/Influenza B/RSV/ Sars CoV2 Plus**1,2,3,4	Nasopharyngeal/Oropharyngeal Swabs	GeneXpert	CE Marked	Detected/Not Detected	LP-MIC-100, LP-MIC-224
Detection of M. Tuberculosis and rifampicin resistance by PCR **1,2,3,4	Sputum	GeneXpert / Real-time PCR	CE marked	Detected / Not Detected	LP-MIC-224
Detection of Norovirus by PCR **1,2,3,4	Faeces	GeneXpert / Real-time PCR	CE Marked	Detected / Not Detected	LP-MIC-224
Detection of respiratory pathogens using Filmarray Respiratory Panel**1,2,3,4 Targets include: 19 viral targets : Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Middle East Respiratory Syndrome CoronaVirus (Mers-CoV), Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, RSV and 4 bacterial targets: Bordetella	Nasopharyngeal /oropharyngeal swabs	Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR	CE marked	Detected/ Not Detected	LP-MIC-300

	pertussis, Bordetella parapertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae (23 targets in total)					
	Detection of SARS-CoV-2, Influenza A/Influenza B/RSV **1,2,3,4	Nasopharyngeal/Oropharyngeal Swabs	GeneXpert/ Real-time PCR	CE Marked	Detected/Not Detected	LP-MIC-224
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of bacteria**1,2,3,4	Bacterial isolates	Biomerieux Vitek 2 Compact / Biochemical methods	CE marked	N/A	LP-MIC-273
	Identification of yeast using the VITEK 2® yeast identification card (YST)**1,2,3,4	Yeast isolates	Biomerieux Vitek 2 Compact / Biochemical methods	CE marked	N/A	LP-MIC-273
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification of cultured bacteria and fungi**1,2,3,4	Bacterial and fungal isolates	Mass Spectrometry Bruker MalDI-tof	CE Marked	N/A	LP-MIC-302
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial susceptibility testing of anaerobes using disc diffusion **1,2,3,4	Anaerobic bacterial isolates	Manual / zone diameter	Based on standard method	S/I/R	LP-MIC-272
	Antimicrobial susceptibility testing of anaerobes using disc diffusion **1,2,3,4		Manual / zone diameter	Based on standard method	N/A	LP-MIC-272
	Minimum inhibitory concentration of anaerobes using MIC strips **1,2,3,4		Manual / MIC Strips	CE Marked	S/I/R	LP-MIC-272

	Minimum inhibitory concentration of anaerobes using MIC strips **1,2,3,4		Manual / MIC Strips	CE Marked	N/A	LP-MIC-272
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Minimum inhibitory concentration using MIC strips **1,2,3,4	Yeast isolates	Manual / MIC Strips	CE Marked	S/I/R	LP-MIC-272
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Antimicrobial resistance using disc diffusion **1,2,3,4	Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture	Manual	MIC Discs	N/A	LP-MIC-271 LP-MIC-272
	Antimicrobial Susceptibility Testing using VITEK 2 ® Compact**1,2,3,4	Isolate	CE Marked	VITEK 2 AST	S/I/R	LP-MIC-273
		Other bacterial isolates - to include but not limited to staphylococcus, streptococcus, enterobacterales, pseudomonads, acinetobacter, enterococcus, haemophilus, moraxella, neisseria, campylobacter, Stenotrophomonas maltophilia and other gram-negative bacilli	VITEK 2 Compact / Minimum Inhibitory Concentration	CE Marked	S/I/R	LP-MIC-273
Antimicrobial resistance using disc diffusion **1,2,3,4	Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab,	MIC Discs	Manual	N/A	LP-MIC-272, LP-MIC-271	

		Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture				
	Minimum inhibitory concentration using MIC strips **1,2,3,4	Other bacterial isolates - to include but not limited to staphylococcus, streptococcus, enterobacteriales, pseudomonads, acinetobacter, enterococcus, haemophilus, moraxella, neisseria, campylobacter, Stenotrophomonas maltophilia and other gram-negative bacilli	Manual / MIC Strips	CE Marked	S/I/R	LP-MIC-272
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	HIV Ag/Ab using Abbott Architect **1,2,3,4	Blood	Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	<1.0 S/CO = Negative ≥1.0 = Positive	LP-MIC-100, LP-MIC-101, LP-MIC-103
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Hep A IgM using Abbott Architect **1,2,3,4	Serum	Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	<0.8 Non reactive 0.8-1.2 Grayzone >1.2 Reactive	LP-MIC-100
	Hepatitis B Antibody using Abbott Architect **1,2,3,4		Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	2.5 -1000 mIU/ml	LP-MIC-100
	Hepatitis B sAg using Abbott Architect **1,2,3,4		Abbott Architect / chemiluminescent	CE Marked	<1.0 S/CO = Negative ≥1.0	LP-MIC-100

			microparticle immunoassay		= Positive	
	Hepatitis BsAg Antibody using Abbott Architect **1,2,3,4	Blood/ Serum	Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	Hepatitis C Antibody using Abbott Architect **1,2,3,4	Serum	Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	<1.0 S/CO = Negative ≥1.0 = Positive	LP-MIC-100
	HIV Ag/Ab using Abbott Architect **1,2,3,4		Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	<1.0 S/CO = Negative ≥1.0 = Positive	LP-MIC-100
1029 Miscellaneous - .99 Miscellaneous tests	Gentamycin **1,2,3,4		Abbott Architect / chemiluminescent microparticle immunoassay	CE Marked	0.11 to 11.16 mg/L	LP-MIC-100
	Pregnancy Test **1,2,3,4	Urine	Sofia Reader / immunochromatographic	CE Marked	Pos/Neg	LP-MIC-265
	Vancomycin **1,2,3,4	Serum	Abbott Architect / chemiluminescent	CE Marked	0.24 - 100.00 ug/ml	LP-MIC-100

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.