

Schedule of Accreditation



Organisation Name	Mercy University Hospital
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2022
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	Diamed Micro Typing Systems, tube technique	CE marked assay	N/A	LP-BB-101 LP-BB-116
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods		Whole Blood EDTA	Ortho Vision	CE marked assay	N/A	LP-BB-200, BSH guidelines pre transfusion compatibility procedures
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen	Plasma	Ortho Vision and Diamed Micro Typing Systems, Gel Technique	CE Marked Assay	N/A	LP-BB-103 LP-BB-200, BSH guidelines pre transfusion

						compatibility procedures
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Diamed Micro Typing Systems	Column Agglutination test		LP-BB-104,
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing (IAT)	Plasma Serum	Diamed Micro Typing Systems	CE marked assay		LP-BB-110,
1020 Transfusion science - .06 Red cell phenotyping	Red cell phenotyping	Red Cells	Diamed Micro Typing Systems	CE marked assay	N/A	LP-BB-109
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs Test		Diamed Micro Typing Systems	CE marked assay		LP-BB-115

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).

Mercy University Hospital

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	24h Creatinine Clearance	Urine	Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
	24H Urinary Calcium		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
	24H Urinary Chloride		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
	24H Urinary Creatinine		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
	24H Urinary Phosphate		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106

24H Urinary Potassium		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
24H Urinary Protein		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
24H Urinary Sodium		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
24H Urinary Urate		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
24H Urinary Urea		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
Alanine aminotransferase (ALT) **1,2,3,4	Plasma/Serum	NADH (without P-5'-P)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Alkaline Phosphatase (ALP) **1,2,3,4		Para-nitrophenyl Phosphate	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Amylase **1,2,3,4	Plasma/Serum/Urine	CNPG3 Substrate	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Aspartate Aminotransferase (AST) **1,2,3,4	Plasma/Serum	NADH (without P-5'-P)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106

Bilirubin (Total) **1,2,3,4		Diazonium Salt	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Calcium **1,2,3,4	Plasma/Serum/Urine	Arsenazo III	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Calcium Adjusted	Plasma/Serum	Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
Chloride **1,2,3,4	Plasma/Serum/Urine	Ion-selective electrode diluted (Indirect)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Cholesterol (Total) **1,2,3,4	Plasma/Serum	Enzymatic	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Cholesterol LDL	Plasma/Serum	Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
Cholesterol (HDL) **1,2,3,4	Serum/ serum	Accelerator selective detergent	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Creatine Kinase (CK) **1,2,3,4	Plasma/Serum	NAC (N-acetyl-L-cysteine)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Creatinine **1,2,3,4	Plasma/Serum/Urine	Kinetic Alkaline Picrate	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106,

		Kinetic Alkaline Picrate	Architect C8000	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
eGFR	Plasma/Serum	Calculation	Architect C8000	CE based on standard method	Based on manufacturer's guidelines LP-BIO-101 LP-BIO-102
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Plasma/Serum	L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Glucose **1,2,3,4		Hexokinase/G-6-PDH	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Lactate Dehydrogenase **1,2,3,4		IFCC recommended forward reaction - Lactate to Pyruvate	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Magnesium **1,2,3,4		Enzymatic	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Microalbumin **1,2,3,4	Urine	Turbidimetric/Immunoturbidimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
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	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106

Potassium **1,2,3,4		Ion-selective electrode diluted (Indirect)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Sodium **1,2,3,4	Plasma/Serum/Urine	Ion-selective electrode diluted (Indirect)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Triglyceride **1,2,3,4	Plasma/Serum	Glycerol Phosphate Oxidase	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Troponin I (High Sensitivity) **1,2,3,4	Plasma	CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
Urea **1,2,3,4	Plasma/Serum/Urine	Urease	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Uric acid **1,2,3,4		Uricase	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
Urinary Albumin/Creatinine Ratio	Urine	Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
Urinary Calcium/Creatinine Ratio		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
Urinary Protein/Creatinine Ratio		Calculation	N/A	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106

1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4	Plasma/Serum	Bromocresol Purple	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
	C-reactive Protein **1,2,3,4		Turbidimetric/Immunoturbidimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
	Faecal Calprotectin **1,2,4	Faeces	Immunoturbidimetric	Alinity Ci	CE Marked Assay	LP-BIO-316
	Globulin	Plasma/Serum	Calculation	Alinity C	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-101 LP-BIO-102
	NT-pro BNP (Human B-type natriuretic peptide) **1,2,3,4	EDTA	CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Total Protein ***1,2,3,4	Plasma/Serum	Biuret	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
	Total Protein **1,2,3,4	Urine/CSF	Benzethonium chloride	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Digoxin **1,2,3,4	Plasma/Serum	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
	Gentamycin **1,2,3,4	Serum	Immunoturbidimetric	Alinity	CE Marked Assay	LP-BIO-106
			Immunoturbidimetric	Alinity	CE Marked Assay	LP-BIO-106
	Lithium **1,2,3,4		Colorimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's

						guidelines LP-BIO-106
	Vancomycin **1,2,3,4		Immunoturbidimetric	Alinity	CE Marked Assay	LP-BIO-106
			Immunoturbidimetric	Alinity	CE Marked Assay	LP-BIO-106
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4	Plasma/Serum	Enzymatic	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
			Enzymatic	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
	Salicylate **1,2,3,4		Enzymatic	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Free T4 ***1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Parathyroid hormone (PTH) **1,2,3,4	Plasma	Chemiluminescent microparticle immunoassay	Architect i2000	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-104 & LP-BIO-105
	Thyroid Stimulating Hormone (TSH) **1,2,3,4	Plasma/Serum	CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107

1061 Clinical Chemistry - .24 Hormone receptor assays	Beta Human Chorionic Gonadotropin (BHCG) **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
1061 Clinical Chemistry - .40 Iron studies	% transferrin Saturation	Plasma/Serum	Calculation	Calculation	CE based on standard method	Based on manufacturer's guidelines LP-BIO-106
	Ferritin **1,2,3,4	Plasma/Serum	CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Iron **1,2,3,4		Ferene	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Transferrin **1,2,3,4		Immunoturbidimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Vitamin B12 **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha-fetoprotein (AFP) **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107

	Ca 125 **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Ca 19-9 **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Carcinoembryonic Antigen (CEA) **1,2,3,4		CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
	Prostate Specific Antigen **1,2,3,4	Serum	CMIA	Alinity i	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-107
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Occult Blood**1,2,4	Faeces	Immunoturbidimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-306
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin G, A, M **1,2,3,4	Plasma/Serum	Immunoturbidimetric	Alinity Ci	CE Marked Assay	Based on manufacturer's guidelines LP-BIO-106

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.

Mercy University Hospital

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	Haemaglobin (HB) **1,2,3,4	Blood in EDTA	Flow Cytometry	0.0 to 22.5g/dl Advia 2120i	CE	ICSH Recommendations, LP-HAE-106 LP-HAE-103
	Haematocrit (HCT)		Calculated parameter	Advia 2120i	Calculated parameter	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103
	Mean Cell Haemoglobin Concentration (MCHC)	Blood	Flow Cytometry	Advia 2120i	Calculated parameter	LP-HAE-106 LP-HAE-103
	Mean Cell Volume (MCV) **1,2,3,4	Blood in EDTA	Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103
	Mean Cellular Haemoglobin (MCH)		Calculated parameter	Advia 2120i	Calculated parameter	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103

	Platelet Count **1,2,4
	Red Cell Count **1,2,4
	White cell count **1,2,4
1030 Haematology - .02 Visual examination of blood films	Manual Differentiation, red cell morphology and Platelet morphology **1,2,4
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR (Automated) **1,2,3,4
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count **1,2,4
	Eosinophil Count **1,2,4
	Lymphocyte Count **1,2,4

Flow Cytometry	5 to 3983 x 10 ⁹ /L Advia 2120i	CE	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103
Flow Cytometry	0.0 to 6.76 x 10 ⁶ /μl Advia 2120i	CE	Based on manufacturer's guidelines, LP-HAE-103 LP-HAE-106
Flow Cytometry	0.02 to 409.55 x 10 ⁹ /L Advia 2120i	CE	Based on manufacturer's guidelines LP-HAE-106, LP-HAE-103
Manual preparation, staining and visual examination of blood films	Siemens Hematek 3000 Stainer Leica DM1000 Microscope	CE	LP-HAE-122 LP-HAE-120
Photometrical Capillary stopped flow kinetic analysis	0-120mm/min Alifax Test-1	CE	LP-HAE-143
Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines, LP-HAE-106 LP-HAE-103
Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines, LP-

						HAE-106 LP-HAE-103
	Monocyte Count **1,2,4		Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines, LP- HAE-106 LP-HAE-103
	Neutrophil Count **1,2,4		Flow Cytometry	Advia 2120i	CE	Based on manufacturer's guidelines LP- HAE-106 LP-HAE-103
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte count **1,2,3,4		Flow Cytometry	0.2 to 24.9%/ Advia 2120i	CE	Based on manufacturer's guidelines, LP- HAE-106 LP-HAE-103
1030 Haematology - .09 Examination of malarial parasites	Malaria Screen **1,2,3,4	Blood in EDTA	Blood Film	Blood Film Examination	Blood Film examination Based on Standard method	BSH Guidelines LP- HAE-171
	Malaria Screen **2,3,4	Blood in EDTA	Immunoassay	Carestart test kit	CE	BSH Guidelines LP- HAE-171
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen **3,4		Haemoglobin Solubility test	SICKLEDEX screening test	CE	BSH Guidelines, LP- HAE-176
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,2,4	Blood in Sodium Citrate (3.2%)	Clotting assay	8 to 200 seconds/ACL TOP 550 Analyser	CE	BSH Guidelines , LP- HAE-180
			Clotting assay	8 to 200 seconds/Sysmex CS2100i	CE	BSH Guidelines , LP- HAE-159
	D-Dimer **1,2,4		Immunoturbidimetric assay	0.19 to 35.2mg/L FEU/ACL TOP 550 Analyser	CE	BSH Guidelines , LP- HAE-180

			Immunoturbidimetric assay	0.19 to 35.2mg/L FEU/Sysmex CS2100i	CE	BSH Guidelines , LP-HAE-159
	Fibrinogen (Clauss) **1,2,4		Clotting assay	0.3 to 7.0g/L/Sysmex CS2100i	CE	BSH Guidelines , LP-HAE-180
			Clotting assay	0.3 to 7.0g/L/Sysmex CS2100i	CE	BSH Guidelines , LP-HAE-159
	International Normalised Ratio (INR) **1,2,4		Ratio calculation	5 to 180 seconds/ACL TOP 550 Analyser	CE	BSH Guidelines , LP-HAE-180
			Ratio calculation	5 to 180 seconds/Sysmex CS2100i	Ratio calculation	BSH Guidelines LP-HAE-159
	Prothrombin Time (PT) **1,2,4		Clotting assay	5 to 180 seconds/ACL TOP 550 Analyser	CE	BSH Guidelines , LP-HAE-180
			Clotting assay	5 to 180 seconds/Sysmex CS2100i	CE	BSH Guidelines, LP-HAE-159
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis **2,3,4	Blood in EDTA or Serum	Immunoassay		CE	LP-HAE-147
1030 Haematology - .80 Molecular genetic studies	Detection of Factor V Leiden & Prothrombin Variant **2,3,4	Blood in EDTA	PCR Amplification	GeneXpert	PCR	Based on manufacturer's guidelines LP-HAE-172
1030 Haematology - .99 Miscellaneous tests	Rheumatoid Factor **1,2,3,4	Serum	Immunoassay	Rheumajet RF kit	CE	Based on manufacturer's guidelines LP-HAE-155

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.

Mercy University Hospital

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**,2,3	CSF, Pleural / pericardial / chest / lymphatic fluids / drains / other fluids, sputa	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-1
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	Based on manufacturer's guidelines LP-MIC-283 LP-MIC-290 LP-MIC-291
	Red cell count, white cell count, **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.	Public Health England (PHE) - UK standards for Microbiology

						Investigation 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.	Public Health England (PHE) - UK standards for Microbiology Investigation 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**2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-244
	Microscopic examination of cryptosporidium by Ziehl-Neelson stain**2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	Public Health England (PHE) - UK standards for Microbiology Investigation 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 of fungi**2,4	Fungal isolates	Microscope/Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-234

Microscopic examination for fungi						
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 auramine stain**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	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-221
	Microscopic examination of mycobacteria by Ziehl-Neelson stain**2,3,4		Microscope/Manual	Based on standard method	Seen / Not Seen	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-221
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**2,3,4	Blood Culture and fluids from normally sterile sites	BacTAlert Virtuo	CE Marked	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-282, LP-MIC-284, LP-MIC-290, LP-MIC-291
			BacTAlert Virtuo	CE Marked	N/A	Public Health England (PHE) - UK standards for Microbiology

					Investigation LP-MIC-282 LP-MIC-284, LP-MIC-290, LP-MIC-291
Culture of CSF**2,3,4	CSF	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-233, LP-MIC-290, LP-MIC-291
Culture of faeces **2,3,4	Faeces	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-241 LP-MIC-290 LP-MIC-291
Culture of respiratory specimens **2,3,4	Sputa, bronchial washings, BAL, ETT specimens	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-222 LP-MIC-290 LP-MIC-291
		Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-241 LPMIC-290 LP-MIC-291

Culture of screening swabs for CPE using chromogenic agar**2,3,4	Rectal swabs, faeces	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-232 LP-MIC-290 LP-MIC-291
Culture of screening swabs for MRSA using chromogenic agar **2,3,4	Nasal / Groin / Throat / Axilla Swabs	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-232 LP-MIC-290 LP-MIC-291
Culture of urine **2,3,4	Urine, Catheter Specimen Urine, nephrostomy bag samples	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-250 LP-MIC-290 LP-MIC-291
Culture of miscellaneous specimens for general bacteria**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	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-232 LPMIC-290 LP-MIC-291

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**2,3,4	Blood Culture and fluids from normally sterile sites	BacTAlert / Manual	CE Marked	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-282, LP-MIC-283, LP-MIC-284, LP-MIC-290, LP-MIC-291
	Culture of CSF **2,3,4	CSF	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-233 LP-MIC-290 LP-MIC-291
	Culture of faeces **2,3,4	Faeces	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-241 LP-MIC-290 LP-MIC-291
	Culture of miscellaneous specimens for Fungi **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	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-231 LP-MIC-290 LP-MIC-291

	Culture of miscellaneous specimens for Fungi**2,3,4		Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-231, LP-MIC-290 LP-MIC-291
	Culture of respiratory specimens **2,3,4	Sputa, bronchial washings, BAL, ETT specimens	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-222, LP-MIC-290, LP-MIC-291
	Culture of urine **2,3,4	Urine, Catheter Specimen Urine, nephrostomy bag samples	Manual	Based on standard method	N/A	Public Health England (PHE) - UK standards for Microbiology Investigation LP-MIC-250 LP-MIC-290 LP-MIC-291
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Staphylococcal coagulase test**2,3,4	Bacterial isolates - staphylococcus species	Diamondial Staph Plus Latex reagent/Manual	CE marked	Pos/Neg	Based on manufacturer's guidelines LP-MIC-290
	Streptococcal grouping **2,3,4	Bacterial isolates - streptococcus species	Remel Streptex grouping kit/Manual	CE marked	Qualitative agglutination or non-agglutination	Based on manufacturer's guidelines LP-MIC-290
1014 Detection of bacterial, parasite, viral or fungal antigens using	C difficile detection **2,3,4	Faeces	Manual Method (TechLab)/ Lateral flow	CE marked	Pos/Neg	Based on manufacturer's

specific antibodies and appropriate techniques - .04 Immunochromatographic methods,						guidelines LP-MIC-243
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	<p>Detection of bacteria / viruses / fungi in positive blood cultures using the FilmArray Blood Culture Identification 2 (BCID2) Panel Panel **1,2,3,4</p> <p>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,</p>	Positive blood culture samples	Biofire FilmArray FilmArray Blood Culture Identification 2 (BCID2) Panel / Real Time PCR	CE marked	Detected/ Not Detected	LP-MIC-300

	Enterobacter cloacaecomplex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus spp, Salmonella spp, Serratia 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) **,2,3,4 Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae	Cerebrospinal fluid (CSF)	BIOFIRE FILMARRAY ME Panel	CE Marked	Detected / Not Detected	Based on manufacturer's guidelines LP- MIC-300

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					
Detection of Carbapenemase Producing Enterobacteriaceae genes (KPC, VIM, IMP, NDM and OXA-48) by PCR **,2,3,4	Bacterial isolates/ Rectal swabs	GeneXpert / Real-time PCR	CE Marked	Detected/ Not Detected	Based on manufacturer's guidelines 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**,2,3,4	Faeces	Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR	CE Marked	Detected/Not Detected	Based on manufacturer's guidelines LP-MIC-301
Detection of M. Tuberculosis and	Sputum	GeneXpert / Real-time PCR	CE marked	Detected / Not Detected	Based on manufacturer's

rifampicin resistance by PCR **2,3,4					guidelines LP-MIC-224
Detection of Norovirus by PCR **2,3,4	Faeces	GeneXpert / Real-time PCR	CE Marked	Detected / Not Detected	Based on manufacturer's guidelines 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 pertussis,	Nasopharyngeal /oropharyngeal swabs	Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR	CE marked	Detected/ Not Detected	LP-MIC-300

Bordetella parapertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae (23 targets in total)					
Detection of respiratory pathogens using Filmarray Respiratory Panel**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 pertussis, Bordetella		Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR	CE Marked	Detected/Not Detected	Based on manufacturer's guidelines LP-MIC-300

	parapertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae (23 targets in total)					
	Detection of SARS- CoV-2, Influenza A/Influenza B/RSV **2,3,4	Nasopharyngeal/Oropharyngeal swabs, Nasopharyngeal only	GeneXpert/ Real-time PCR	CE Marked	Detected/Not Detected	Based on manufacturer's guidelines 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**2,4	Bacterial isolates	Biomerieux Vitek 2 Compact / Biochemical methods	CE marked	N/A	Based on manufacturer's guidelines LP-MIC-273 & LP- MIC-264
	Identification of yeast using the VITEK 2® yeast identification card (YST)**2,4	Yeast isolates	Biomerieux Vitek 2 Compact / Biochemical methods	CE marked	N/A	Based on manufacturer's guidelines 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**2,3,4	Bacterial and fungal isolates	Mass Spectrometry Bruker Maldi-tof	CE Marked	N/A	Based on manufacturer's guidelines LP-MIC-302
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Minimum inhibitory concentration of anaerobes using MIC strips **1,2,4	Anaerobic bacterial isolates	Manual / MIC Strips	CE Marked	S/I/R	EUCAST guidelines/ Based on manufacturer's guidelines LP-MIC-272

	Minimum inhibitory concentration of anaerobes using MIC strips **1,2,4		Manual / MIC Strips	CE Marked	S/I/R	EUCAST guidelines 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 **1,2,4	Yeast isolates	Manual / MIC Strips	CE Marked	S/I/R	EUCAST guidelines/ Based on manufacturer's guidelines 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 **2,3,4	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	Manual Method/ zone diameter	Based on standard method	S/I/R	EUCAST guidelines LP-MIC-272
	Antimicrobial Susceptibility Testing using VITEK 2® Compact**1,2,4		CE Marked	VITEK 2 Compact / Minimum Inhibitory Concentration	S/I/R	EUCAST guidelines/ Based on manufacturer's guidelines LP-MIC-273
			VITEK 2 Compact / Minimum Inhibitory Concentration	CE Marked	S/I/R	EUCAST guidelines/ Based on manufacturer's guidelines LP-MIC-273
	Antimicrobial resistance using disc diffusion **1,2,4		Manual Method/ zone diameter	Based on standard method	S/I/R	EUCAST guidelines LP-MIC-272

	Minimum inhibitory concentration using MIC strips **1,2,4		Manual / MIC Strips	CE Marked	S/I/R	EUCAST guidelines/ Based on manufacturer's guidelines LP-MIC-272
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 **1,2,3,4	Serum	Abbott Alinity/ chemiluminescent microparticle immunoassay	CE Marked	<0.8 Non reactive 0.8-1.2 Grayzone >1.2 Reactive	Based on manufacturer's guidelines LP-MIC-100
	Hepatitis B Antibody **1,2,3,4		Abbott Alinity/ chemiluminescent microparticle immunoassay	CE Marked	2.5-1000 mIU/ml	Based on manufacturer's guidelines LP-MIC-100
			Abbott/ chemiluminescent microparticle immunoassay	CE Marked	2.5 -1000 mIU/ml	Based on manufacturer's guidelines LP-MIC-104
	Hepatitis B sAg **1,2,3,4		Abbott Alinity/ chemiluminescent microparticle immunoassay		<1.0 S/CO = Negative ≥1.0 = Positive	Based on manufacturer's guidelines LP-MIC-100
	Hepatitis BsAg Antibody using Abbott Architect **1,2,3,4		Abbott Architect	Abbott Architect / chemiluminescent microparticle immunoassay	<1.0 S/CO = Negative ≥1.0 = Positive	Based on manufacturer's guidelines LP-MIC-100
	Hepatitis C Antibody **1,2,3,4		Abbott Alinity/ chemiluminescent microparticle immunoassay	CE Marked	<1.0 S/CO = Negative ≥1.0 = Positive	Based on manufacturer's guidelines LP-MIC-100

	HIV Ag/Ab **1,2,3,4		Abbott Alinity/ chemiluminescent microparticle immunoassay	CE Marked	<1.0 S/CO = Negative ≥1.0 = Positive	Based on manufacturer's guidelines LP-MIC-100
1029 Miscellaneous - .99 Miscellaneous tests	Pregnancy Test **2,3,4	Urine	Sofia Reader / immunochromatographic	CE Marked	Pos/Neg	Based on manufacturer's guidelines LP-MIC-265

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.