

# Schedule of Accreditation



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Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	09/12/2008
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Chemical pathology

Services available to the public<sup>1</sup>

<sup>1</sup> 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	Castlebar, Mayo, F23 H529

# Scope of Accreditation

## Head Office

### Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO, Rh(D) Group **1,3,4	Whole Blood	BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/003
			Tube Methodology/ Direct Agglutination	CE	Positive/Negative	BT/LP/003
Ortho Vision/ BioVue Column Agglutination Technology			CE	Positive/Negative	BT/LP/100	
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods						
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen **1,3,4	Plasma	Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioRad System/ Gel	CE	Positive/Negative	BT/LP/109

			Agglutination Technology			
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/006
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/008
			Manual BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/008 BT/LP/109
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/008 BT/LP/010
1020 Transfusion science - .05 Cross match compatible donor units	Investigation of Transfusion Reactions **1,3,4	Whole Blood	Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/018
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/018
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/018
	Red Cell Compatibility by Electronic Issue **1,3,4	Plasma	Automated Ortho Vision/ iLAB LIS/ Electronic Issue	CE	Positive/Negative	BT/LP/104
			Manual BioRad System/ Gel Agglutination Technology	CE	Positive/Negative	BT/LP/109
			Automated Ortho Vision/ BioVue Column	CE	Positive/Negative	BT/LP/103
Red Cell Compatibility Testing						
Red Cell Compatibility Testing **1,3,4						

			Agglutination Technology			
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/009 BT/LP/011
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Antigen Phenotyping **4	Red Cells	Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/015 BT/LP/100
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/015
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/015
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/012
			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/012
1020 Transfusion science - .99 Miscellaneous tests	Blood Grouping including ABO, Rh(D) and DAT for Newborns **1,3,4		Automated Ortho Vision/ BioVue Column Agglutination Technology	CE	Positive/Negative	BT/LP/100
			Manual BioVue System/ Column Agglutination Technology	CE	Positive/Negative	BT/LP/014

			Manual Tube Methodology/ Indirect Antiglobulin & Direct Agglutination Techniques	CE	Positive/Negative	BT/LP/014
	Estimation of Feto-Maternal Haemorrhage by the Kleihauer-Betke Test **1,2,3,4	Whole Blood	Manual Slide Staining/ Kleihauer-Betke Test	CE		BT/LP/073

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

*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories 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 laboratories 'Master list of Flexible scope changes', available directly from the laboratory.*

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 Urinary Albumin **1,2,4	Urine	Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Amylase **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Chloride **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Creatinine **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Potassium **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Protein **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Sodium **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	24h Urinary Urea **1,2,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052

Alanine Amino Transferase (ALT) **1,2,3,4	Serum/Plasma	IFCC(w/o Pyr Phos)	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/012
Albumin **1,2,3,4	Serum /Plasma	Photometric-Bromo Cresol Green	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/007
Alkaline Phosphate (ALP) **1,2,3,4	Serum/Plasma	IFCC with PNPP	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/008
Amylase **1,2,3,4	Serum /Urine/Plasma	Colorimetric with CNPG3	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/013
Asparate Amino Transferase (AST) **1,2,3,4	Serum/Plasma	IFCC(w/o Pyr Phos)	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/014
Bicarbonate **1,2,3,4		Enzymatic with PEP	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/024
Bilirubin Direct **1,2,3,4		Photometric with Ferricyanide	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/016
Bilirubin Total **1,2,3,4		Photometric with Ferricyanide	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/015
C Reactive Protein (CRP) **1,2,3,4		Immunoturbidimetric with antibodies	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/021
Calcium **1,2,3,4	Serum /Urine/Plasma	Photometric with Arsenazo III	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/017
Chloride **1,2,3,4		ISE Indirect	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/036
Cholesterol **1,2,3,4	Serum/Plasma	Enzymatic with CHOD/PAP	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/018
Creatine Kinase (CK) **1,2,3,4		IFCC-Hexokinase	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/019

Creatinine **1,2,3,4	Serum /Urine/Plasma	Enzymatic	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/020
Creatinine Clearance **1,2,3,4	Urine/Serum	Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
eGFR (CKD-EPI) **1,2,3,4	Serum/Plasma	Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
Gamma Glutamyl Transferase (GGT) **1,2,3,4		Enzymatic-Szasz-Persijn	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/022
Globulin **1,2,3,4	Urine	Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
Glucose **1,2,3,4	Serum /Urine/CSF/Plasma	Enzymatic with Hexokinase	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/023
High Density Lipoprotein (HDL) **1,2,3,4	Serum/Plasma	Enzymatic	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/025
Lactate **1,2,3,4	Plasma	Enzymatic with LOX-PAP	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/026
Lactate Dehydrogenase (LDH) **1,2,3,4	Serum/Plasma	IFCC-Enzymatic with Lactate	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/027
Low Density Lipoprotein (LDL) **1,2,3,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
Magnesium **1,2,3,4	Serum /Plasma	Photometric with Xylidyl Blue	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/028
Phosphate - inorganic **1,2,3,4	Serum/Plasma	Photometric with Ammonium Molybdate	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/030

	Potassium **1,2,3,4	Serum /Urine/Plasma	ISE Indirect	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/036
	Protein (Total) **1,2,3,4	Serum/Plasma	Biuret Reaction	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/032
		Urine / CSF	Pyrogallol Red-Molybdate Complex	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/039
	Serum Indices(LIH) **1,2,3,4	Serum/Plasma	Photometric	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/040
	Sodium **1,2,3,4	Serum /Urine/Plasma	ISE Indirect	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/036
	Triglycerides **1,2,3,4	Serum/Plasma	Enzymatic-GPO/PAP	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/033
	Troponin I **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800	CE based on standard method	B/LP/064
	Urate(Uric Acid) **1,2,3,4		Enzymatic-Uricase method	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/034
	Urea **1,2,3,4	Serum /Urine/Plasma	Enzymatic-Urease method	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/035
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Procalcitonin **1,2,3,4	Serum	Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800	CE based on standard method	B/LP/057
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1,2,3,4	Serum/Plasma	Enzymatic - G6PDH	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/059
	Lithium **1,2,3,4	Serum	Photometric (substituted porphyrin compound)	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/051
	Vancomycin **1,2,3,4	Serum/Plasma	Enzymatic - G6PDH	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/053

1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Alcohol **1,2,3,4	Serum	Enzymatic Alcohol Dehydrogenase	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/062
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4	Serum/Plasma	Photometric (G6PDH) /Enzyme - Immuno Technique	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/029
	Salicylate **1,2,3,4		Photometric (G6PDH) /Enzyme - Immuno Technique	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/054
1061 Clinical Chemistry - .20 Hormones	HCG+Beta **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800	CE based on standard method	B/LP/065
	PSA – Total **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800	CE based on standard method	B/LP/066
	T4 - Free **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800 / Dxl9000	CE based on standard method	B/LP/067
	Thyroid Stimulating Hormone (TSH) **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 800 / Dxl9000	CE based on standard method	B/LP/068
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 9000	CE based on standard method	B/LP/075
	Iron **1,2,3,4		TPTZ [2,4,6-Tri-(2- pyridyl)-5-triazine]	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/069
	Total Iron Binding Capacity (TIBC) **1,2,3,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
	Transferrin **1,2,3,4		Immunoturbidimetric	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/071
	Transferrin Saturation **1,2,3,4		Calculation	Beckman Coulter AU5800 / DxC700AU	CE based on standard method	B/LP/052
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 9000	CE based on standard method	B/LP/074

	Vitamin B12 **1,2,3,4		Immunoenzymatic ("sandwich") assay (two step)	Beckman Coulter Dxl 9000	CE based on standard method	B/LP/060
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*Note 4 – Changes to equipment / kits where the underlying methodology does not change*

*For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory*

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	Haematocrit **1,4	Whole Blood	RBC cumulative pulse height detection method	Sysmex XN	CE	H/LP/046
	Haemoglobin **1,4		Spectrophotometric (SLS Haemoglobin Method)	Sysmex XN	CE	H/LP/046
	MCH **1,4		Calculated from Hb and RBC	Sysmex XN	CE	H/LP/046
	MCHC **1,4		Calculated from Hb and HCT	Sysmex XN	CE	H/LP/046
	Mean Cell Volume **1,4		Calculated from RBC and HCT	Sysmex XN	CE	H/LP/046
	Platelet (Fluorescent)		Optical Fluorescence	Sysmex XN	CE	H/LP/046
	Platelet (Impedance/Optical) **1,4		Sheath Flow DC detection/ Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
	Red Cell Count **1,4		Sheath Flow DC detection	Sysmex XN	CE	H/LP/046
	White Cell Count **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
1030 Haematology - .02 Visual examination of blood films	Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, White Cell & Red Cell Morphology		Wright-Giemsa Staining/ Microscopy	SP50 Stainer/ Microscope	CE	H/LP/005 H/LP/048

	Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, White Cell & Red Cell Morphology **1,2,4		Hematek Modified Wright-Giemsa Staining/ Microscopy	Hematek Stainer, Microscope	CE	H/LP/005 H/LP/021
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR (Automated) **1,3,4		Photometric Capillary stopped flow Kinetic Analysis	ALIFAX-Test 1	CE	H/LP/013
1030 Haematology - .05 Automated differential leucocyte counts	Basophil **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
	Eosinophil **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
	Lymphocyte **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
	Monocyte **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
	Neutrophil **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes **1,4		Laser Flow Cytometry	Sysmex XN	CE	H/LP/046
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites by Thick and Thin Blood Films **4		Staining/ Microscopy	Microscope	CE	H/LP/001
	Malaria Screening Test (ICT Kit) **1,2,3,4		Immunochromatographic Test	CareUS® Malaria Rapydtest Screening Kit	CE	H/LP/044
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen Test **4		Solubility Screening Test for HbS	Sickledex® Test Kit	CE	H/LP/002
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,4	Plasma	Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/007
	D-Dimer **1,2,4		Immunoassay	Sysmex CS-2100	CE	H/LP/009

	Fibrinogen (Clauss) **1,2,4		Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/010
	International Normalised Ratio (INR)		Ratio Calculation	Sysmex CS-2100	CE	H/LP/007
	Prothrombin Time (PT) **1,2,4		Clotting Assay/ Optical Detection Method	Sysmex CS-2100	CE	H/LP/007
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen Test **1,2,3,4		Immunoassay	Clearview IM II® Test Kit	CE	H/LP/003

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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 **1,2,3	CSF	Manual	Based on standard method	N/A	M/LP/022 Relevant Standards for Microbiology Investigations, Public Health England
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Microscopic examination for general bacteriology (including enumeration and description of human cells) **1,2,3	Bronchoalveolar Lavage Fluids CPE Swabs CSF Blood Cultures	Light Microscope/ Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells	Based on standard method	N/A	M/LP/025 M/LP/026 M/LP/022 M/LP/023 M/LP/012 Relevant Standards for Microbiology Investigations, Public Health England
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 funghi	BronchoalveolarLavage Fluids CPE Swabs  CSF Blood Cultures	Light Microscope/ Microscopic examination with or without fixation and staining with dyes as required	Based on standard method	N/A	M/LP/025 M/LP/026 M/LP/022 M/LP/012 Relevant Standards for Microbiology Investigations, Public Health England

1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Blood Culture Analysis	Blood/body fluids-e.g joint aspirates, sterile sites	BacT/ALERT VIRTUO system for Blood Cultures/Colorimetric detection	CE	Positive/Negative	M/LP/023 M/LP/051
	Culture of General Bacteria **1,2,3,4	BronchoalveolarLavage Fluids CPE Swabs  CSF Blood Cultures	BacT Alert® Blood Culture Monitoring System Manual Assessment Light microscope	CE Based on standard method	Positive/Negative	M/LP/027 M/LP/012 M/LP/016 M/LP/022 M/LP/023 M/LP/047 M/LP/049 Relevant Standards for Microbiology Investigations, Public Health England
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of funghi		Manual Assessment BacT Alert® VIRTUO Blood Culture Monitoring System Light microscope	CE Based on standard method	Positive/Negative	M/LP/027 M/LP/012 M/LP/016 M/LP/022 M/LP/023 M/LP/047 M/LP/049 Relevant Standards for Microbiology Investigations, Public Health England
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Staphylococcus Latex Test **1,2,3,4	Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	Pastorex Staph Plus®/ Slide Agglutination	CE	Positive/Negative	M/LP/028
1014 Detection of bacterial, parasite, viral or fungal antigens using	Streptococcus Grouping **1,2,3,4		Prolex® Streptococcal Grouping Latex Kit/ Particle Agglutination	CE	Positive/Negative	M/LP/028

specific antibodies and appropriate techniques - .02 Particle agglutination						
	Test for Streptococcus pneumoniae **1,2,3,4	Whole Blood Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	Pastorex Streptococcus pneumoniae®/ Latex Agglutination	CE	Positive/Negative	M/LP/028
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Carba 5 NG Test for CPE	Culture/Isolates from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	NG Test Carba 5 Kit/ rapid 5 enzyme immunoassay (lateral flow)	CE	Positive/Negative	M/LP/047 M/LI/065 M/RI/096
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	β-Lactamase Test **1,2,3,4	Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	Nitrocefin Disks/ Immunochromatography	CE	Positive/Negative	M/LP/028
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Detection of bacteria / viruses / fungi in positive blood cultures using the FilmArray Blood Culture Identification 2 (BCID2) Panel Panel 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,	Positive blood culture samples	Biofire FilmArray FilmArray Blood Culture Identification 2 (BCID2) Panel / Real Time PCR	CE	Detected/ Not Detected	M/LP/062

	<p>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 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 intotal.</p>					
<p>Detection of bacterial, viral, and fungal pathogens using the</p>		<p>Cerebrospinal fluid (CSF)</p>	<p>BIOFIRE FILMARRAY ME Panel</p>	<p>CE</p>	<p>Detected / Not Detected</p>	<p>M/LP/062</p>

<p>FilmArray Meningitis/Encephalitis Panel (ME) 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</p>					
<p>Detection of respiratory pathogens using Filmarray Respiratory Panel. Targets include: 19 viral targets : Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Middle East Respiratory Syndrome CoronaVirus (MersCoV), Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV-2), Human Metapneumovirus, Human</p>	<p>Nasopharyngeal /oropharyngeal swabs</p>	<p>Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR</p>	<p>CE</p>	<p>Detected/ Not Detected</p>	<p>M/LP/062</p>

	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 parapertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae (23 targets in total)					
	Detection of SARSCoV-2, Influenza A/Influenza B/RSV	Nasopharyngeal/Oropharyngeal Swabs; nasopharyngeal only / oropharyngeal only	GeneXpert / Real-time PCR	CE	Detected/Not Detected	M/LP/054, M/LP/065
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of cultured bacteria (Aerobes/Anaerobes) **1,2,3,4	Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	Vitek 2XL®/ Automated	CE	N/A	M/LP/043 M/LP/044
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Identification of fungi by microscopic morphology **1,2,3,4		Light Microscope	Based on standard method	N/A	M/LP/028 Relevant Standards for Microbiology Investigations, Public Health England
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using	Identification of bacterial, fungal and mycobacterial isolates **1,2,3,4	Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	VitekMS-MALDI TOF/ Automated	CE	N/A	M/LP/041 M/LP/044

MALDI-TOF Spectroscopy						
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Sensitivity Testing **1,2,3,4	Cultures from CSF/ Blood Cultures/ Bronchoalveolar Lavage/ Fluids	EUCAST/ MIC (Manual) ETEST/Disk Diffusion (Manual) Oxoid® Discs/Disk Diffusion (Manual)	CE Based on standard method	N/A	M/LP/042 EUCAST Guidelines
			Vitek 2XL®/ Automated Biochemical Testing	CE	N/A	M/LP/042 M/LP/044
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts			ETEST/MIC Disk Diffusion (Manual)	CE Based on standard method	N/A	M/LP/042 EUCAST Guidelines
			Vitek 2XL®/ Automated Biochemical Testing	CE	N/A	M/LP/042 M/LP/044
1024 Preservation of microbial cultures	Preservation of Isolates **1,2,3,4		Freezer/Manual	Based on standard method	N/A	M/LP/023 PATH/MP/018 Relevant Standards for Microbiology Investigations, Public Health England

*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories 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 laboratories 'Master list of Flexible scope changes', available directly from the laboratory*