

# Schedule of Accreditation



Organisation Name	Children's Health Ireland
Trading As	Children's Health Ireland at Temple Street
INAB Reg No	374MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	08/01/2019
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Chemical pathology
Services available to the public <sup>1</sup>	No

<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	Department of Paediatric Laboratory Medicine	Temple Street, Dublin, D01 YC67

# Scope of Accreditation

## Department of Paediatric Laboratory Medicine

### 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 and RhD grouping	Red cells and plasma	Manual method Gel cards	CE		LM-BT-0002
			Manual method, tubes	Based on standard method CE		LM-BT-0002
1020 Transfusion science - .03 Blood group antibody screen	Antibody screen	Plasma	Manual method, gel cards	Based on standard method CE		LM-BT-0004
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody identification		Manual method, gel cards	Based on standard method CE		LM-BT-0004
1020 Transfusion science - .05 Cross match compatible donor units	Red cell compatibility testing	Red cells and Plasma	Manual method, gel cards	Based on standard method CE		LM-BT-0006 LM-BT-0010
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin test	Red cells	Manual method, gel cards	Based on standard method CE		LM-BT-0011

*a The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)*

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	24 HR UR CALCIUM **1,2,4	Urine in plain container	Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
	Adjusted calcium **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
	Alanine Aminotransferase **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Albumin BCP **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Alkaline Phosphatase **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Ammonia **1,2,3,4	Blood in lithium heparin	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Amylase **1,2,3,4	Blood in lithium heparin / no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Aspartate Aminotransferase **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Beta Hydroxybutyrate **1,2,3,4	Blood in fluoride heparin	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Calcium **1,2,3,4	Blood in lithium heparin/ no	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039

	anticoagulant Urine				
Chloride **1,2,3,4	Blood in lithium heparin/ no anticoagulanturine	Ion Selective Electrodes	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Cholesterol **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
C-Reactive Protein **1,2,3,4	Blood in lithium heparin / no anticoagulant	Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Creatine Kinase **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Creatinine **1,2,3,4	Blood in lithium heparin/ no anticoagulant Urine	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Direct Bilirubin **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Direct HDL Cholesterol **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Gamma-Glutamyl Transferase (GGT) **1,2,3,4	Blood in lithium heparin	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Glucose **1,2,3,4	Blood in fluoride heparin/lithium heparin CSF in fluoride heparin	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Lactate Dehydrogenase **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Lactate **1,2,3,4	Blood in fluoride heparin CSF in fluoride heparin	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039

LDL-Cholesterol **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
Magnesium **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
NEFA **1,2,3,4		Spectrophotometric	Siemens Atellica/Wako kit	CE	LP-BIO-0039 LM-BIO-0039
Non-HDL-Cholesterol **1,2,3,4		Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
Phosphorus (inorganic) **1,2,3,4	Blood in lithium heparin/ no anticoagulant Urine	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Potassium **1,2,3,4	Blood in lithium heparin / no anticoagulant Urine	Ion Selective Electrodes	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Procalcitonin **1,2,3,4	Blood in lithium heparin / no anticoagulant	Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Sodium **1,2,3,4	Blood in lithium heparin / no anticoagulant Urine	Ion Selective Electrodes	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Total Bilirubin **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Total: HDL-Cholesterol Ratio **1,2,3,4		Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
Triglycerides **1,2,3,4		Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
Tubular Reabsorbtion of Phosphate **1,2,3,4	Blood in lithium heparin/ no anticoagulant and Urine in plain container	Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039

	Urea Nitrogen **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Uric Acid **1,2,3,4	Blood in lithium heparin / no anticoagulant Urine	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Urine calcium / creatinine ratio **1,2,4	Urine in plain container	Calculation	iLAB	CE	LP-BIO-0039 LM-BIO-0039
	Urine phosphate / creatinine ratio **1,2,4		Calculation	iLAB	CE	LP-BIO-0039 LM-BIO-0039
	Urine urate / creatinine ratio **1,2,4		Calculation	iLAB	CE	LP-BIO-0039 LM-BIO-0039
	24 HR UR PROT **1,2,4		Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Globulin **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Calculation	NA	CE	LP-BIO-0039 LM-BIO-0039
	Total Protein Urine / CSF **1,2,4	Urine / CSF in plain container	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Total Protein **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Spectrophotometric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Base Excess **2,4	Whole blood in heparinised syringe	Calculation	GEM 5000	CE	LM-BIO-0038
	pCO2 **2,4		Potentiometry	GEM 5000	CE	LM-BIO-0038
	pH **2,4		Ion Selective Electrodes	GEM 5000	CE	LM-BIO-0038
	pO2 **2,4		Amperometry	GEM 5000	CE	LM-BIO-0038

	Standard bicarbonate **2,4		Calculation	GEM 5000	CE	LM-BIO-0038
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride **2,4		Ion Selective Electrodes	GEM 5000	CE	LM-BIO-0038
	Glucose **2,4		Amperometry	GEM 5000	CE	LM-BIO-0038
	Ionised Calcium **2,4		Ion Selective Electrodes	GEM 5000	CE	LM-BIO-0038
	Lactate **2,4		Amperometry	GEM 5000	CE	LM-BIO-0038
	pH adjusted ionised calcium **2,4		Calculation	GEM 5000	CE	LM-BIO-0038
	Potassium **2,4		Ion Selective Electrodes	GEM 5000	CE	LM-BIO-0038
	Sodium **2,4		Ion Selective Electrodes	GEM 5000	CE	LM-BIO-0038
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Phenobarbital **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Phenytoin **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Tacrolimus **1,2,3,4	Whole blood in EDTA	Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Tobramycin **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Valproic Acid **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Vancomycin **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039



1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4	Blood with no anticoagulant	Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Follicle Stimulating Hormone **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Free Thyroxine **1,2,3,4		Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Insulin **1,2,3,4		Blood with no anticoagulant	Immunoassay	Siemens Atellica	CE
	Luteinising Hormone **1,2,3,4	Immunoassay		Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Parathyroid Hormone **1,2,3,4	Immunoassay		Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Thyroid Stimulating Hormone **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
1061 Clinical Chemistry - .40 Iron studies	Immunoassay		Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039	
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	Immunoglobulin A **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Immunoglobulin G **1,2,3,4		Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
	Immunoglobulin M **1,2,3,4	Turbidimetric	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039	
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Anti-Thyroid Peroxidase **1,2,3,4		Immunoassay	Siemens Atellica	CE	LP-BIO-0039 LM-BIO-0039
1061 Clinical Chemistry - .99 Miscellaneous tests	Osmolality **1,2,4	Blood in lithium heparin / no anticoagulant Urine	Freezing point depression	OsmoTECH Single Sample Micro- Osmometer	CE	LP-BIO-0030 LM-BIO-0030
	Osmolality **4	Plasma Urine	Freezing point depression	OsmoTECH Single Sample Micro- Osmometer	CE	LP-BIO-0030

1062 Biochemical genetics - .01 Metabolite analysis	Acylcarnitines (semi-quantitative)	Dried Blood Spot	Tandem Mass Spectrometry (MS/MS)	Waters Xevo TQ-S Micro Tandem Mass Spectrometer	Non CE, In house	LP-META-0047 LM-META-0007
	Allo-isoleucine **1,2,3,4	Blood in lithium heparin	LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
	Amino Acid Profile (includes taurine, aspartic acid, threonine, serine, asparagine, glutamic acid, glutamine, proline, glycine, alanine, citrulline, valine, cystine, methionine, isoleucine, leucine, tyrosine, phenylalanine, ornithine, lysine, histidine, arginine, alloseucine)	Blood, Plasma, Serum	Ion Exchange Column Chromatography	Biochrom 30+	Non CE, In house	LP-META-0049 LM-META-0003
	Creatinine **1,2,3,4	Urine	Enzymatic	Roche Cobas C311	CE	LM-META-0016 LP-META-0051
	Glycosaminoglycans	Urine	Spectrophotometric	Roche C311	Non CE, In house	LP-META-0051 LM-META-0016
	Isoleucine **1,2,3,4	Blood in lithium heparin	LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
	Leucine **1,2,3,4		LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
	Methionine **1,2,3,4		LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047

	Organic acids (qualitative screen)	Urine	Gas Chromatography Mass Spectrometry (GCMS)	Agilent 5975/6890N	Non CE, In house	LM-META-0006 LP-META-0028
	Organic acids (quantitative)		Gas Chromatography Mass Spectrometry (GCMS) with stable isotope dilution	Agilent 5975/6890N GCMS	Non CE, In house	LM-META-0008 LP-META-0028
	Phenylalanine **1,2,3,4	Blood in lithium heparin	LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
	Total homocysteine **1,2,3,4	Plasma	Enzymatic	Roche Cobas C311	CE	LP-META-0051 LM-META-0016
	Tyrosine **1,2,3,4	Blood in lithium heparin	LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
	Urate **1,2,3,4	Urine	Ezymatic (uricase)	Roche Cobas C311	CE	LM-META_0016 LP-META-0051
	Valine **1,2,3,4	Blood in lithium heparin	LC-MS/MS	XEVO TQS Micro Acquity I Class LCMSMS mass spectrometer	CE	LM-META-0017 LP-META-0047
1062 Biochemical genetics - .03 Newborn screening	ADO, D-ADO	Dried Blood Spot **1,2,3,4	Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061, LM-NNS-0016
	Amino Acids (PHE/MET/LEU) ** 1,2,4	Dried Blood Spot **1,2,3,4	Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061 LM-NNS-0016
	C16 **1,2,4	Dried Blood Spot	Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061 LM-NNS-0016
	C2 **1,2,4		Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061 LM-NNS-0016
	C5DC **1,2,4		Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061 LM-NNS-0016

	C8, C10 **1,2,4		Tandem Mass Spectrometry (MS/MS)	Xevo TQD Tandem Mass Spectrometer	CE	LP-NNS-0061 LM-NNS-0016
	Galactose-1-Phosphate-Uridyl Transferase	Dried Blood Spot	Beutler - Enzymatic Fluorescence	Wallac Victor/Multiskan Sky Fluorometer	Non CE, In house	LM-NNS-0014 LP-NNS-0040 LP-NNS-0064
1065 Molecular pathology - .99 Miscellaneous tests	Calculated Osmolality **1,2,3,4	Blood in lithium heparin/ no anticoagulant	Calculation	NA	CE	LP-BIO-0003

*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*

# Department of Paediatric Laboratory Medicine

## 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	CSF **1,2,3,4	CSF	Macroscopic	Manual		LM-MICRO-0010
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 Stain / Cell count of clinical Material **1,2,3,4	All swabs, Abscess pus & swabs, Post operative wound pus & swabs, Deep seated infection swabs & pus, Ear swabs & pus, Bronchial lavage & associated samples, CSF, Continuous Ambulatory Peritoneal Dialysis(CAPD)Fluid, Fluid from normally sterile sites, Genital tract swabs & pus, Intraocular fluids & scrapings, Skin, superficial and non-surgical wound swabs, Sputum, Endotracheal secretions, Human tissue & biopsy , Intravascluar cannulae &swabs, Blood cultures & Isolates	Manual Light Microscope	Based on Standard Methods		LM-MICRO-0014; 0017;0018;0019;0020;0021; 0024; 0027; 0028

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	Direct Microscopy using Calcofluor White for Fungal Samples **1,2,3,4	Fungal Cultures; Skin scrapings; Nail Clippings , Brushings	Manual Fluorescent Microscope	Based on Standard Methods		LM-MICRO-0043; LM-MICRO-0005
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria **1,2,3,4	As per 1012; Faeces; Screening swabs; Pernasal Swabs;	Manual & BacT Alert 3D System	Based on Standard Methods & CE Marked		LM-MICRO-0014; 0015; 0016; 0017;0018;0019;0020;0021; 0023; 0024; 0027; 0028; 0029; 0030; 0031; 0032; 0033; 0035; 0036;0037; 0038; 0039; 0040; 0041; 0049; 0050;
	Culture of general bacteria **1,2,3,4	Bacterial isolate	Manual	Based on Standard Methods		LM-IMSRL-0038 LM-IMSRL-0039
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi **1,2,3,4	Skin scrapings & Nail Clippings Relevant Swab and Fluids	Manual	Based on Standard Methods		LM-MICRO-0025
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Bordetella pertussis/parapertussis antisera **1,2,3,4	Isolates	Manual	CE Marked		LM-MICRO-0010
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Bacterial Culture **1,2,3,4	Bacterial Culture	Staphaurex identification of S. aureus Streptococcal grouping kit	Manual		LM-MICRO-0010

1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	FilmArray Respiratory Panel which includes Adenovirus, Coronavirus 229E, HKU1, NL63 & OC43, Human Metapneumovirus, Influenza A H1, Influenza A H1-2009, Human Rhinovirus/Enterovirus, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Influenza A, Influenza A H3, Influenza A (no subtypedetected), Influenza B, Bordetella pertussis **1,2,3,4	Nasopharyngeal aspirate, swabs	FilmArray Multiplex PCR system	CE		LM-MICRO-0055 LP-MICRO-0044
	FilmArray RP2 Plus Panel **1,2,3,4	Nasopharyngeal swab, Nasopharyngeal aspirate	FilmArray Multiplex PCR System	CE		LP-MICRO-0045 LM-MICRO-0056
	Meningitis Bacterial Panel	CSF Blood in EDTA	Elite InGenius analyser	CE marked assay	N/A	LM-IMSRL-0050
	Meningitis/encephalitis panel which includes Escherichia coli K1, Haemophilus influenza, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, Cytomegalovirus, Enterovirus, Herpes Simplex virus 1 & 2,	CSF	FilmArray Multiplex PCR System	CE		LM-MICRO-0056 LP-MICRO-0045

	Human herpesvirus 6, Human parechovirus, Varicella zoster virus, Cryptococcus neoformans/gattii **1,2,3,4					
	MRSA screening & confirmatory testing **1,2,3,4	Isolate	GeneXpert Multiplex PCR system	CE		LM-MICRO-0057 LP-MICRO-0044
	Norovirus **1,2,3,4	Faeces	GeneXpert Multiplex PCR system	CE		LM-MICRO-0055 LP-MICRO-0044
	RSV/FLU/SARS-CoV- 2	Nasopharyngeal swab	GeneXpert System	CE		LM-MICRO-0055 LP-MICRO-0044
	SARS COV-2		GeneXpert Multiplex PCR system	CE		LM-MICRO-0055 LP-MICRO-0044
	SARS-CoV-2		Luminex Aries System	CE		LM-MICRO-0061
			Seegene	CE		LM-MICRO-0059
	Xpert EV (Enterovirus) Xpert FLU/RSV Xpert Carba-R Xpert vanA/vanB FilmArray Respiratory Panel **1,2,3,4	CSF Nasopharyngeal Aspirate/ Swab Isolate	GeneXpert System FilmArray Multiplex PCR System	CE Marked		LM-MICRO-0055 0056; 0057; 0038; 0050; LP-MICRO-0044; LP- MICRO-0045
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays	Detection of bacterial nucleic acids, Staphylococcus aureus, Group A Streptococci	EDTA blood, CSF, Fluids/Aspirates, Pus, Tissues, Bone	DNA extraction using Tissuelyser II, Thermomixer, QIASymphony, EZ1 PCR on Advanced 7500 Fast Detection System .	In House Developed		LM-IMSRL-0014, LM- IMSRL-0002, LP-IMSRL- 0009, LP-IMSRL-0015, LP- IMARL-0025
	Detection of bacterial nucleic acids: N. meningitidis, H. influenza, S.pneumoniae, Group B streptococci, E.coli, K. kingae	EDTA blood, CSF, fluid from normally sterile sites, Isolates.	DNA extraction using QIASymphony and EZ1-PCR on the 7500 Fast Detection System	Based on standard methods		LM-IMMRL-0002, LP-IMSRL-0009, LP-IMSRL-0015, LP-IMSRL-0025, LP-IMMRL-0043



	Group B Streptococcus	CSF Blood in EDTA	Elite InGenius analyser	In-house developed assay	N/A	LM-IMSRL-0050
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Aerobe/Anaerobe Identification **1,2,3,4	Isolates	Vitek 2 Compact	CE Marked		LM-MICRO-0036
	Identification of Neisseria meningitidis and Haemophilus influenzae **1,2,3,4	Bacterial Isolates	Manual	Based on Standard Methods		LM-IMSRL-0038 LM-IMSRL-0039
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Mycology Identification using Lactophenol Cotton Blue **1,2,3,4	Fungal Isolates	Manual	Based on Standard Methods		LM-MICRO-0043
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification of organisms	Bacterial isolate **1,2,3,4	Vitek-MS Mass Spectrometry	CE		LM-MICRO-0060
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 susceptibility testing of Neisseria meningitidis and Haemophilus influenzae; Beta-lactamase testing of Haemophilus influenzae **1,2,3,4	Bacterial Isolates	Manual using Etest; Nitrocefin sticks	Based on Standard Methods		LM-IMSRL-0038 LM-IMSRL-0039
	Antimicrobial Susceptibility Testing **1,2,3,4		Vitek 2 Compact Manual	CE Marked Based on Standard Methods		LM-MICRO-0045 LP-MICRO-0036

1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Measles IgG **1,2,3,4	Serum	Mini VIDAS	CE		LP-MICRO-0046
1023 Characterisation of subtypes within species of bacteria, fungi or virus using appropriate techniques - .02 Molecular / nucleic acid analysis methods [specifying the particular techniques]	Detection of bacterial nucleic acids: N. meningitidis, group B, C, W,Y	EDTA blood, CSF, fluid from normally sterile sites, Isolates.	DNA extraction using QIA-symphony and EZ1-PCR on the 7500 Fast Detection System	Based on standard methods		LM-IMMRL-0002, LP-IMSRL-0009, LP-IMSRL-0015, LP-IMSRL-0025, LP-IMMRL-0043
1023 Characterisation of subtypes within species of bacteria, fungi or virus using appropriate techniques - .03 Immunological methods/	Neisseria meningitidis and Haemophilus influenzae antigen detection **1,2,3,4	Bacterial Isolates	Manual	Based on Standard Methods		LM-IMSRL-0038 LM-IMSRL-0039
1024 Preservation of microbial cultures	Isolate culture and preservation **1,2,3,4		Manual using bead storage	Based on Standard Methods		LM-IMSRL-0012
	Isolate Storage **1,2,3,4	Bacterial & Yeast Isolates	Manual using bead storage	Based on Standard Methods		LM-MICRO-0042

*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*

