

# Schedule of Accreditation



Organisation Name	Children's Health Ireland
Trading As	Children's Health Ireland at Crumlin
INAB Reg No	375MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	09/09/2014
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
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	Crumlin, Dublin, Ireland, D12 N512

# 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 + Rh (D) typing	Whole blood	Manual Gel Technique	CE	n/a	LP-BTS-BiovueABDD
			Manual Tube	CE	n/a	LP- BTS- ABODGPTube
			Automated method using Ortho Vision	CE	n/a	LP-BTS-SampVision
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 Screening	Plasma	Automated method using Ortho Vision	CE	n/a	LP-BTS-SampVision
			Manual Gel Technique	CE	n/a	LP-BTS-Abscreen
			Manual Tube	CE	n/a	LP-BTS-Abscreen

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated method using Ortho Vision	CE	n/a	LP-BTS-SampVision
			Manual Gel Technique	CE	n/a	LP-BTS-ABID, LP- BTS-ABOAB
			Manual Tube	CE	n/a	LP-BTS-ABID, LP- BTS-ABOAB
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility testing		Automated method using Ortho Vision	CE	n/a	LP-BTS-SampVision
			Laboratory Information System	Standard Method	n/a	LP-BTS-Crossmatch
			Manual Gel Technique	CE	n/a	LP-BTS-Crossmatch
			Manual Tube	CE	n/a	LP-BTS-Crossmatch
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing of Red Cells	Red Blood Cells	Manual Tube	CE	n/a	LP-BTS-AgId
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test (DAT)		Manual Gel Technique	CE	n/a	LP-BTS-DAT
			Manual Tube	CE	n/a	LP-BTS-DAT
1020 Transfusion science - .99 Miscellaneous tests	ABO Isohaemagglutinins	Plasma	Automated method using Ortho Vision	CE	n/a	LP-BTS-Isohmag
			Manual Tube	In house developed	n/a	LP-BTS-Isohmag
<i>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)</i>						

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 Hour Urine Albumin	Urine	Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Calcium		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Chloride		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Creatinine		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Magnesium		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Phosphate		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Potassium		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Sodium		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	24 Hour Urine Urate		Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	Alanine Amino Transferase (ALT) **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-ALT
Albumin **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-ALBUMIN	

Albumin **1,2,4	Urine	Automated Turbidometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-URINALB
Albumin / Creatinine Ratio (ACR) **1,2,4		Calculation	WinPath LIS	Based on standard method	LP-BIO-URINALB LI-BIO-CalculatedTests
Alkaline Phosphatase (ALP) **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-ALP
Ammonia **1,2,3,4	Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Ammonia
Amylase **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Amylase
Aspartate Amino Transferase (AST) **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-AST
Bilirubin Direct	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	In house method	LP-BIO-BILI
Bilirubin Total **1,2,3,4		Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-BILI
Calcium / Creatinine Ratio	Urine	Calculation	WinPath LIS	Based on standard method	LP-BIO-Calcium LI-BIO-CalculatedTests
Calcium Total **1,2,3,4	Plasma Serum Urine	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-CALCIUM
Calculated Osmolality	Plasma / Serum	Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
Chloride **1,2,3,4	Serum Plasma Urine	Indirect ISE	Beckman Coulter AU680	CE Method	LP-BIO-NAKCL
Cholesterol **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Cholest
Corrected Calcium	Plasma / Serum	Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
C-Reactive Protein **1,2,3,4	Serum Plasma	Automated turbidimetric assay	Beckman Coulter AU680	CE marked	LP-BIO-CRPLatex
Creatine Kinase (CK) **1,2,3,4		Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-CK

Creatinine **1,2,3,4	Plasma Serum Urine	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Creatinine
Creatinine Clearance	Urine / Plasma	Calculated Test	N/A	Based on Standard Method	LI-BIO- CalculatedTests
Fractional Excretion of Sodium		Calculated Test	N/A	Based on Standard Method	LI-BIO- CalculatedTests
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-GGT
Globulin	Plasma / Serum	Calculated Test	N/A	Based on Standard Method	LI-BIO- CalculatedTests
Glucose **1,2,3,4	Plasma CSF	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Glucose
LDH **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-LDH
Magnesium **1,2,3,4	Plasma Serum Urine	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-Magnesium
Phosphate **1,2,3,4		Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-PHOSPHATE
Potassium **1,2,3,4	Serum Plasma Urine	Indirect ISE	Beckman Coulter AU680	CE Method	LP-BIO-NAKCL
Protein Total **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-TotProt
Sodium **1,2,3,4	Serum Plasma Urine	Indirect ISE	Beckman Coulter AU680	CE Method	LP-BIO-NAKCL
Transtubular Potassium Gradient	Urine / Plasma	Calculated Test	N/A	Based on Standard Method	LI-BIO- CalculatedTests
Triglycerides **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-TG
Tubular Reabsorption of Phosphate	Urine / Plasma	Calculated Test	N/A	Based on Standard Method	LI-BIO- CalculatedTests
Urate **1,2,3,4	Plasma Serum Urine	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-URATE

	Urate / Creatinine Ratio	Urine	Calculated Test	N/A	Based on Standard Method	LI-BIO-CalculatedTests
	Urea **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-UREA
1061 Clinical Chemistry - .05 CO-oximetry	Carboxyhaemoglobin **1,2,4	Blood	Spectrophotometry	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Methaemoglobin **1,2,4		Spectrophotometry	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2 **1,2,4		Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	pH **1,2,4	Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+	
	pO2 **1,2,4	Optical	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+	
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Base Excess **1,2,4		Calculation	ABL 90 Flex	Based on standard method	LP-BIO-ABL90FLEX+
	Calcium Ionised **1,2,4		Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Chloride **1,2,4		Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Glucose **1,2,4		Amperometry	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Lactate **1,2,4		Amperometry	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Potassium **1,2,4		Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Sodium **1,2,4		Direct ISE	ABL90 FLEX	CE Method	LP-BIO-ABL90FLEX+
	Standard Bicarbonate **1,2,4		Calculation	ABL 90 Flex	Based on standard method	LP-BIO-ABL90FLEX+
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Cyclosporine		LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-BIO-TacCyc
	Methotrexate **1,2,3,4	Serum Plasma	Chemiluminescent Immunoassay	Abbott Architect i 2000 SR	CE Method	LP-BIO-MTX
	Tacrolimus	Blood	LC-MS/MS	Waters TQD MS	Laboratory Developed Test	LP-BIO-TacCyc



1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol (Acetaminophen) **1,2,3,4	Serum Plasma	Automated Photometric Assay	Beckman Counter AU680	CE Method	LP-BIO-PARACET
1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-Cortisol
	Follicle Stimulating Hormone (FSH) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-FSH
	Growth Hormone (GH) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-GH
	Insulin-Like Growth Factor 1 (IGF-1) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-IGF-1
	Insulin-Like Growth Factor Binding Protein 3 (IGFBP3) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-IGFBP-3
	Leutinising Hormone (LH) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-LH
	Thyroid Stimulating Hormone (TSH) **1,2,3,4		Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-TSH
Thyroxine Free (Free T4) **1,2,3,4	Chemiluminescent Immunoassay	Immulite 2000XPI	CE Method	LP-BIO-FREET4		
1061 Clinical Chemistry - .30 Sweat electrolytes	Sweat Chloride **1,2,4	Sweat	Coulometric Titration	Sherwood 926s Chloride Analyzer	CE Method	LP-BIO-SWEATTEST
1061 Clinical Chemistry - .40 Iron studies	Iron **1,2,3,4	Plasma Serum	Automated Photometric Assay	Beckman Coulter AU680	CE Method	LP-BIO-IRON
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein **1,2,3,4		Chemiluminescent Immunoassay	Abbott Architect i 2000 SR	CE Method	LP-BIO-AFP
1061 Clinical Chemistry - .61 Hb A1c	HbA1c **1,2,4	Blood	HPLC	ADAMS A1C HA- 8180V	CE Method	LP-BIO-HBA1c
1061 Clinical Chemistry - .99 Miscellaneous tests	Lipid Index	Plasma	Automated turbidimetric	Beckman Coulter AU680	In house method	LP-BIO-Lipaemia
	Osmolality **1,2,3,4	Plasma Serum Urine	Freezing-Point Depression	Advanced Micro- Osmometer Model 3320	CE Method	LP-BIO-OSMOLALITY

*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.*

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count	Blood / Bone Marrow /Fluids	Impedance/ Optical /Flow Cytometry	Sysmex XN20	CE	LP-HAE-XN20
1030 Haematology - .02 Visual examination of blood films	Blood Film microscopy	Blood/Body Fluid	Microscopy	Microscope	CE	LP-HAE-BFILM
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)	Blood	Photometric reading	Sarstedt SediPLUS	CE	LP-HAE-SEDIPLUS
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential leucocyte count		Flow Cytometry	Sysmex XN20	CE	LP-HAE-XN20
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte count		Flow Cytometry	Sysmex XN20	CE	LP-HAE-XN20
	RET-HE		Flow Cytometry	Sysmex XN20	CE	LP-HAE-XN20
1030 Haematology - .08 Blood film examinations involving special staining procedures	Blood cell location on DI-60 Sysmex Digital System		Automated cell location on DI-60 microscope	NA	CE	LP-HAE-DI60
1030 Haematology - .09 Examination of malarial parasites	Parasite Film examination		Microscopy	Microscope	CE	LP-HAE-MALARIA
1030 Haematology - .20 Bone marrow examination	Bone marrow examination		Bone Marrow	Microscopy	Microscope	CE
1030 Haematology - .30 Tests for haemoglobin	Haemoglobinopathy Screening	Blood	Capillary Electrophoresis	Sebia Capillarys 2	CE	LP-HAE-CAPILLARYS

variants and thalassaemia			HPLC (High Performance Liquid Chromatography)	BioRad Variant II	CE	LP-HAE-VARIANT2
	IEF (Iso-Electric Focusing) for haemoglobinopathy confirmatory testing	Blood, Cord, Blood Spot	Qualitative IEF	Electrophoresis gel system	CE	LP-HAE-HBRESOLVE
	Lateral Flow Sickle Scan	Blood	Lateral Flow Chromatographic qualitative immunoassay	Manual	CE	LP-HAE-SickleScan
	Neonatal haemoglobinopathy Screening	Blood/Cord Blood/ Blood Spot	Capillary Electrophoresis	Sebia Capillarys 2	CE	LP-HAE-CAPILLARYS
1030 Haematology - .36 Screening tests for G6Pd	G6PDH Deficiency Screening	Blood	Qualitative Visual Fluorescence	Manual	CE	LP-HAE-G6PDSCREEN
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)	Blood / Plasma	Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
		Blood/Plasma	Manual-semi quantitative	Manual/waterbath	CE	LP-HAE-ManAPTT
	Activated Partial Thromboplastin Time Ratio (APTR)	Blood / Plasma	Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
	Activated Protein C Resistance (APCR)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLAPCR
	Anti Factor Xa		Photo Optical	ACL Top 550	CE	LP-HAE-ACLAXA
	Antithrombin		Photo Optical	ACL Top 550	CE	LP-HAE-ACLATIII
	APTT Correction test		Photo Optical	ACL Top 550	CE	LP-HAE-ACLCorr
	D-Dimer		Photo Optical	ACL Top 550	CE	LP-HAE-ACLDDimer
	Factor II (FII)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLEFS
	Factor IX (FIX)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLIFS
	Factor IX Inhibitor		Photo Optical / semi-quantitative	ACL Top 550	CE	LP-HAE-FIXInhib

	Factor V (FV)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLEFS
	Factor VII (FVII)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLEFS
	Factor VIII Inhibitor		Photo Optical / semi-quantitative	ACL Top 550	CE	LP-HAE-F8Inhib
	Factor VIII, 1 stage (FVIII clot)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLIFS
	Factor VIII, chromogenic (FVIIIChr)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLChroF8
	Factor X (FX)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLEFS
	Factor XI (FXI)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLIFS
	Factor XII (FXII)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLIFS
	Fibrinogen (Clauss)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
	International Normalised Ratio (INR)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
	Lupus Anticoagulant		Photo Optical	ACL Top 550	CE	LP-HAE-ACLLA
	Protein C		Photo Optical	ACL Top 550	CE	LP-HAE-ACLPC
	Protein S (Free)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLFPS
	Protein S Activity		Photo Optical	ACL Top 550	CE	LP-HAE-ACLPPS
	Prothrombin Time (PT)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
		Blood/Plasma	Manual-semi quantitative	Manual /waterbath	CE	LP-HAE-ManPT
	PT Correction test	Blood / Plasma	Photo Optical	ACL Top 550	CE	LP-HAE-ACLCorr
	Reptilase		Photo Optical	ACL Top 550	CE	LP-HAE-ACLRep
	Thrombin Time (TT)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLCoagS
	Von Willebrand Factor antigen (VWF:ag)		Photo Optical	ACL Top 550	CE	LP-HAE-ACLVWF
1030 Haematology - .45 Tests of platelet function	Platelet Aggregation Studies	Blood/Plasma	Light Transmission aggregometry	Helena AggRAM Aggregometer	CE	LP-HAE-RIPA   LP-HAE-PFT

1030 Haematology - .55 Iron studies	Ferritin	Serum	Chemiluminescent Immunoassay	Beckman Coulter Access 2 Immunoassay System	CE	LP-HAE- ACCESSFER LP-HAE-ACCESS2
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen	Plasma	Immuno-Chromatic	Manual Kit	CE	LP-HAE- ACCUSAYMONO
1030 Haematology - .58 Vitamin B12 and folate (serum and red cell)	Serum Folate	Serum	Chemiluminescent Immunoassay	Beckman Coulter Access 2 Immunoassay System	CE	LP-HAE- ACCESSFOL LP-HAE-ACCESS2
	Vitamin B12		Chemiluminescent Immunoassay	Beckman Coulter Access 2 Immunoassay System	CE	LP-HAE- ACCESSB12 LP-HAE-ACCESS2
1030 Haematology - .70 Immunophenotyping	Acute Leukaemia / Lymphoma & Chronic Leukaemia / Lymphoma Flow Cytometry Panels CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD9, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD21, CD22, CD24, CD25, CD30, CD33, CD34, CD35, CD36, CD38, CD41a, CD42a, CD42b, CD43, CD44, CD45, CD45RA, CD56, CD58, CD61, CD65, CD66abce, CD66c, CD66b, CD64, CD71, CD73, CD79a, CD79b, CD81, CD99, CD103, CD105, CD117, CD123, CD133, CD200, CD203c, CD300e, CD304, ALK, FMC-7, HLADR, Smlgk, Smlgλ, Cylgμ,	Blood/ Bone Marrow /Fluids / CSF	Flow Cytometry	BD Facs Lyric, BD FacsCANTO II	In house assay	LP-HAE-LeukCANTO LP-HAE- LYMPHPHEN

	SmlgM, CyMPO, NG2, TCRαβ, CyTCRβ, TCRγδ, NuTdT, CD14/CD64, CD15/CD117, CD16/CD32, Glycophorin A, 7-AAD					
	CD34 stem cell count CD45 CD34 7-AAD Viability Dye	Blood	Flow Cytometry	BD FacsCANTO II	CE	LP-HAE-CD34SCCanto
	Immunophenotyping EMA Eosin-5-Maldemide	Blood,	Immunoflourescence	BD FACS Lyric, BD FACS Canto II	In house assay	LP-HAE-EMA
	Immunophenotyping PNH CD235a CD59 CD45 CD15 CD24 FLAER CD64 CD14	Blood	Flow Cytometry	BD FACSLyric,	Based on Standard Method	LP-HAE-PNH
1030 Haematology - .99 Miscellaneous tests	Erythropoietin (EPO)	Serum	Chemiluminescent Immunoassay	Beckman Coulter Access 2 Immunoassay System	CE	LP-HAE-ACCESSEPO LP-HAE-ACCESS2
	Malaria Rapid Detection - CareStart kit	Blood	Antigen detection	Manual Kit	CE	LP-HAE-MalCareStart
	Manual Cell count	CSF	Staining/Microscopy	manual	CE	LP-HAE-CSF
	Rheumatoid Factor Screening	Blood/Serum	Latex Agglutination	Qualitative kit	CE	LP-HAE-RF
	Soluble Transferrin Receptor (sTfR)	Serum	Chemiluminescent Immunoassay	Beckman Coulter Access 2 Immunoassay System	CE	LP-HAE-ACCESSSTFR LP-HAE-ACCESS2





# Department of Paediatric Laboratory Medicine

## Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Automated Haematoxylin & Eosin Staining **2,4	Human Tissue Slides (Unstained)	Leica Autostainer XL	CE marked	NA	LP-HIS-H&E
	Coverslipping **2,4	Human Tissue Slides (Stained)	Leica CV5030 Robotic Coverslipper	CE marked	NA	LP-HIS-LeicaCV5030Coverslipper
	Cut up **2,4	Human Tissue	Manual	Based on Standard method	N/A	LP-HIS-SpRecCutUp
	Embedding **2,4		Leica EG1140H Tissue Embedding Centre Leica EG1140C Coldplate	Based on standard method	NA	LP-HIS-TissEmb
	Microtomy **2,4		Leica Autocut, Diapath Galileo, Leica RM 2165	Based on standard method	NA	LP-HIS-Microtomy
	Tissue Processing **2,4	Fixed specimens	Histocore Pearl Tissue Processor, Leica ASP300S Advanced smart processor	CE marked	NA	LP-HIS-TissProc
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cryotomy **2,4	Human Tissue	Leica CM1860UV	Based on standard method	NA	LP-HIS-Microtomy
1051 Histopathology - .03 Histochemistry	Alcian Blue Stain, Alcian Blue/PAS stain, Fouchet Stain, Gram Stain, Grocott Stain, Giemsa Stain,		Manual technique ,Leica Autostainer XL	Based on Standard Method	N/A	LP-HIS-AlcianBlue, LP-HIS-ALBPAS, LP-HIS-Fouchet, LP-HIS-GiemsaStain, LP-HIS-GRAM, LP-HIS-

	Haematoxylin Van Gieson Stain, Masson Trichrome Stain, Long ZN Stain, Masson Fontana Stain, Miller Elastic Stain, Martius Scarlet Blue stain, Oil Red O Stain, PAS/DPAS stain, Perls Stain, Reticulin Gordon and Sweets Stain, Von Kossa Stain				Grocott, LP-HIS-HVG, LP-HIS-LZN, LP-HIS-MSB, LP-HIS-MasFon, LP-HIS-MasTric, LP-HIS-Millers, LP-HIS-ORO, LP-HIS-PAS/DPAS, LP-HIS-PERLS, LP-HIS-RETICULIN, LP-HIS-VonKossa,
1051 Histopathology - .05 Histological interpretation- paediatric pathology	Diagnostic Interpretation and Reporting of Human tissue Pathology: Specialist area included: Paediatric Pathology	N/A	N/A	N/A	MP-HIS-Reporting, MP-HIS-CritDiagCom,LP-HIS-WinPath
1051 Histopathology - .09 Immunohistochemistry	AE1/AE3(CK), Alpha Feto Protein, ALK-1, BAF 47(INI), BCOR, BCL 2, Calretinin, CD1a, CD3, CD5, CD10, CD15, CD20, CD21, CD30, CD31, CD34, CD45(CLA), CD56, CD61, CD68, CD79a, CD99(Mic2), Chromogranin A, C-KIT(CD117), CMV, c-MYC, Cytokeratin 7, Desmin, D2-40, EMA, Factor XIIIa, GFAP, GLUT-1, Glycophorin A, Herpes 1, HMB45, Ki67, HLO, Langerin, MUM-1, Myeloperoxidase, Myogenin, PAX-5, PHOX 2B, P53, PLAP, S100, Smooth	Ventana BenchMarkXT	CE	NA	LP-HIS-IMMPRO LP-HIS-BenchMarkXT

	Muscle Actin, Synaptophysin, TDT, TLE1, Vimentin, WT-1 N Terminus, WT-1C Terminus, MyoD1, NKX2.2 **2,4				
1051 Histopathology - .13 Molecular testing	Chromosomal translocation analysis for the following: t(2:13) PAX3-FKHR, t(1:13) PAX7-FKHR, t(11:22) EWSFLi1/2, t(21:22) EWSESG, t(X:18) (SYT-SSX1, SYT-SSX2, SYT-SSX-4), t(12:22) ETV6-NTRK	Step One Plus, Veriti Thermal Cycler, Qubit Fluorometer	Based on Standard method	Presence/Absence of product	LP-HIS-RT-PCR, LP-HIS-RTPCRparaffin

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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 of specimens **1,2,3,4	Respiratory samples, Fluids, Faeces, CSF	Visual	Based on standard method		LP-MIC-SPUTUM, LP-MIC-FLUID, LP-MIC-FAECES, LP-MIC-CSF, LP-MIC-PDF, LP-MIC-SinusAsp, LP-MIC-Peritonit, LP-MIC-BAL, LP-MIC-CFSputa, LP-MIC-NPA
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)	Cell counts & Differential **1,2,3,4	Urine, peritoneal dialysis fluid, CSF	Microscopy	Based on standard method		LP-MIC-URINE, LP-MIC-PDF, LP-MIC-CSF
	Gram staining **1,2,3,4	Tissue, Fluids, CSF, BAL, positive blood cultures, sputum, vaginal swab, NPA	Staining & Microscopy	Based on standard method		LP-MIC-TISSUE, LP-MIC-FLUID, LP-MIC-CSF, LP-MIC-BAL, LP-MIC-BC, LP-MIC-SPUTUM, LP-MIC-Staining, LP-MIC-Genital, LP-MIC-

						PDF, LP-MIC-SinusAsp, LP-MIC-Peritonit, LP-MIC-Bile, LP-MIC-NPA
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, modified ZN **1,2,3,4	Faeces	Staining & Microscopy	Based on standard method		LP-MIC-FAECES, LP-MIC-PARASITE, LP-MIC-Staining
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	ZN **1,2,3,4	CF Sputa, BALs, tissue, fluids, CSF	Concentration , Staining & Microscopy	Based on standard method		LP-MIC-CFSPUTA, LP-MIC-BAL, LP-MIC-FLUID, LP-MIC-TISSUE, LP-MIC-CSF, LP-MIC-Staining
		Isolate	Staining & Microscopy	Based on standard method	Pos / Neg	LP-MIC-CFSPUTA, LP-MIC-Staining
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Allograft bone **1,2,4	bone	Agar and enrichment culture	Based on standard method		LP-MIC-BoneAllo
	Blood culture **1,2,3,4	Blood	BacT/ALERT 3D, automated continuously monitored liquid culture, agar & enrichment culture	CE marked /based on standard method		LP-MIC-BacT/ALERT, LP-MIC-BC
	Culture of CSF specimens **1,2,4	CSF	Culture	Based on standard method		LP-MIC-CSF
	Culture of faecal specimens **1,2,4	Faeces	Agar and enrichment culture	Based on standard method		LP-MIC-FAECES, LP-MIC-SALMONELL, LP-MIC-SHIGELLA, LP-MIC-CAMP, LP-

					MIC-YERSINIA, LP-MIC-VIBRIO, LP-MIC-VTEC, LP-MIC-F-CDT
Culture of genital tract **1,2,3,4	Genital tract swab, high vaginal swab, cervical swab, urethral swab, IUCDs, rectal swab, throat swab, fluid, pus	Culture	Based on standard method		LP-MIC-GENITAL
Culture of respiratory specimens for bacterial pathogens **1,2,4	Respiratory samples	Culture	Based on standard method		LP-MIC-SPUTUM, LP-MIC-CFSPUTA, LP-MIC-BAL, LP-MIC-NPA
Culture of specimens from superficial & deep seated infections **1,2,3,4	Wounds, tissue, fluid, swabs, IV tips	BacT/ALERT 3D, agar and enrichment culture	CE marked, based on standard method		LP-MIC-IVCANNULAE, LP-MIC-WOU-DEEP, LP-MIC-WOUSUP, LP-MIC-TISSUE, LP-MIC-FLUID, LP-MIC-EAR, LP-MIC-EYE, LP-MIC-GASASP, LP-MIC-MOUTH, LP-MIC-NASAL, LP-MIC-THROAT, LP-MIC-HOMOGRAFT, LP-MIC-PDF, LP-MIC-BacT/ALERT, LP-MIC-Peritonit, LP-MIC-SinusAsp, LP-MIC-Bile.
Culture of urine specimens 1,2,4	Urine	Culture	Based on standard method		LP-MIC-URINE
H. pylori **1,2,3,4	Gastric Biopsy	Culture	Based on standard method		LP-MIC-HP
Homograft investigation **1,2,3,4	Tissue, fluid	BacT/ALERT 3D, automated continuously monitored liquid culture, agar & enrichment culture	CE marked/based on standard method		LP-MIC-Homograft, LP-MIC-BacT/ALERT

	Screening of specimens for MDRO **1,2,3,4	Faeces, urine, swabs	Agar and enrichment culture	Based on standard method		LP-MIC-ESBL, LP-MIC-CRE, LP-MIC-ECC, LP-MIC-URINE, LP-MIC-FAECES, LP-MIC-MRSA
	Transfusion reaction **1,2,3,4	Blood pack, platelets, blood products	BacT/ALERT 3D, automated continuously monitored liquid culture, agar & enrichment culture	CE marked /based on standard method		LP-MIC-TransReact, LP-MIC-BacT/ALERT
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, Nails, hair, respiratory samples, CSF, tissue, fluids, swabs, urines	Culture	Based on standard method		LP-MIC-FUNGI
			Culture	Based on standard method		LP-MIC-FUNGI
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	Salmonella & shigella typing, E.coli, Bordetella **1,2,3,4	Isolate	Slide agglutination	Based on standard method	Pos/Neg	LP-MIC-SALMONELL, LP-MIC-SHIGELLA, LP-MIC-VTEC, LP-MIC-BORDETELLA
			Particle agglutination	CE marked	Pos/Neg	LP-MIC-STAPHX
			Particle agglutination	CE marked	Pos/Neg	LP-MIC-STREPTX
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Staphaurex **1,2,3,4					
	Streptococcal Grouping Latex kit **1,2,3,4					
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Galactomannan **1,2,3,4	Serum	Multiskan Sky ELISA Plate Reader	CE marked	Pos / Neg	LP-MIC-GALACT

	H pylori antigen **1,2,3,4	Stool	Multiskan Sky ELISA Plate Reader	CE marked	Pos / Neg	LP-MIC-HPANTI
	Techlab C.Diff Quik Chek Complete **1,2,3,4	Faeces, isolate	Enzyme immunoassay	CE marked	Pos/Neg	LP-MIC-F-CDT
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Cepheid Xpert MRSA NxG **1,2,3,4	Isolate	Cepheid GeneXpert	CE marked	No target detected / target detected	LP-MIC-MRSA, LP-MIC-GeneXpert
	Cepheid Xpert vanA/vanB **1,2,3,4		Cepheid GeneXpert	CE marked	No target detected / target detected	LP-MIC-VRE, LP-MIC-GeneXpert
	CRE **1,2,3,4	Isolate, stool sample	Cepheid GeneXpert	CE marked	Detected / Not Detected	LP-MIC-GeneXpert
	EntericBio Gastro Panel 2 **1,2,3,4	Faeces	EpMotion 5070 and PCR Thermal Cycler, Amplification and detection of target DNA	CE marked	Detected / Not Detected	LP-MIC-EBIOGP2
	EPLEX Blood culture bacterial panels **1,2,3,4	Positive blood culture	EPLEX	CE marked	No targets detected/target detected (specific to test)	LP-MIC-Eplex
	GeneXpert Real Time PCR for SARS-CoV-2 **1,2,3,4	Pooled Nose & Throat Swab or Nasopharyngeal Swab (Viral Transport Swabs with Sponge or Swab in UTM)	GeneXpert	CE marked	Detected / Not Detected	LP-MIC-GeneXpert
	RSV, Influenzae A+B **1,2,3,4	NPA	Cepheid GeneXpert	CE marked	Detected / Not detected	LP-MIC-GeneXpert
	Seegene Real Time PCR for SARS-CoV-2 **1,2,3,4	Pooled Nose & Throat Swab or Nasopharyngeal Swab (Viral Transport Swabs with Sponge, Swab	Seegene All in One	CE marked	Detected / Not Detected	LP-MIC-COVIDSEEGENE2



		in UTM or Lysis Swab)				
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays	Bordetella bronchiseptica	Nasopharyngeal aspirates / swabs, BAL, pleural fluid, isolates	QIASymphony, QIAgility, AB7500 real time PCR instrument / Extraction and amplification of targets DNA and RNA	In-house developed	Negative / Positive	LP-MIC-BPPCR, LP-MIC-PCR-ISOBOR
	Bordetella holmesii		QIASymphony, QIAgility, AB7500 real time PCR instrument / Extraction and amplification of targets DNA and RNA	In-house developed	Negative / positive	LP-MIC-BPPCR, LP-MIC-PCR-ISOBOR
	Bordetella pertussis / parapertussis		QIASymphony, QIAgility, QuantStudio6 Flex / AB7500 real time PCR instrument / Extraction and amplification of targets DNA and RNA	In-house developed	Negative / Positive	LP-MIC-BPPCR, LP-MIC-PCR-ISOBOR
	Pseudomonas aeruginosa	CF sputum, CF throat swabs, BAL	QIASymphony, QIAgility, QuantStudio6 Flex / AB7500 real time PCR instrument / Extraction and amplification of targets DNA and RNA	In-house developed	Negative / Positive	LP-MIC-CFPCR
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	API NH **1,2,3,4	Isolate	Fermentation, decarboxylation etc	CE marked	% Identification	LP-MIC-API
	Rapid BLUE CARB Kit: Carbapenemases **1,2,3,4		Hydrolysis of imipenem	CE marked	Pos/Neg	LP-MIC-CRE
	Vitek 2XL Gram Positive and Gram Negative ID **1,2,3,4	Isolate	Vitek 2 XL	CE marked	% Identification	LP-MIC-Vitek2XL
	Vitek2 YST ID **1,2,3,4	Isolate	VITEK2 XL	CE marked	% Identification	LP-MIC-VITEK2XL

1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Lactofuscin **1,2,3,4
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	MALDI-TOF Spectroscopy **1,2,3,4
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Minimum inhibitory concentration **1,2,3,4
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified )	AmpC Confirm Kit: AmpC Enterobacteriaceae **1,2,3,4
	Antimicrobial susceptibility testing **1,2,3,4

Microscopy	Based on standard method		LP-MIC-Fungi
VITEK MS, mass spectrophotometry	CE marked	% Identification	LP-MIC-VitekMS
Minimum inhibitory strip diffusion	Based on standard method		LP-MIC-MANUALAST
Broth MIC	Based on standard method		LP-MIC-YEASTONE
Disk diffusion	CE marked	Pos/Neg	LP-MIC-ESBL
Disk diffusion	Based on standard method		LP-MIC-MANUALAST

			VITEK 2XL, Broth MIC	CE marked		LP-MIC-VITEK2XL, LP-MIC-SCS
	Extended B Lactam ID Discs **1,2,3,4		Disk diffusion	CE marked	Pos/Neg	LP-MIC-ESBL
	KPC, MBL and OXA-48 Confirm Kit: Carbapenemases **1,2,3,4		Disk diffusion	CE marked	Pos/Neg	LP-MIC-CRE
	Minimum inhibitory concentration **1,2,3,4		Minimum inhibitory strip diffusion	Based on standard method		LP-MIC-MANUALAST
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Pertussis Serology **1,2,3,4	Serum	Multiskan Sky ELISA Plate Reader	CE marked	<5 to >200 IU/ml	LP-MIC-ELISAP
1024 Preservation of microbial cultures	Isolate storage on beads **1,2,3,4	isolates	Cryogenic storage of isolates	Based on standard method		LP-MIC-Beads
1025 Measurement of antimicrobial levels by immunological methods	Amikacin- **1,2,3,4	Plasma	Thermo Scientific Indiko Plus	CE marked	1.5-50.0 µg/ml	LP-MIC-Indiko
	Gentamicin **1,2,3,4		Thermo Scientific Indiko Plus	CE marked	0.3-10.0 µg/ml	LP-MIC-Indiko
	Tobramycin **1,2,3,4		Thermo Scientific Indiko Plus	CE marked	0.4-10.0 µg/ml	LP-MIC-Indiko
	Vancomycin **1,2,3,4		Thermo Scientific Indiko Plus	CE marked	2.5-100.0 µg/ml	LP-MIC-Indiko
1029 Miscellaneous - .99 Miscellaneous tests	CSF protein **1,2,4	CSF	Jenway 6300 spectrophotometer/Biochrom Libra S6 Spectrophotometer, Pyrogallol-red-molybdate colorimetric	CE marked	From 0.022g/L	LP-MIC-CSF
	Urinary Dipstick **1,2,4	urine	Visual	CE marked		LP-MIC-URINE

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