

Schedule of Accreditation



Organisation Name	Children's Health Ireland
Trading As	Children's Health Ireland at Temple Street
INAB Reg No	374MT
Contact Name	Linda Martin
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	08/01/2019
Scope Classification	Blood Transfusion Science
Scope Classification	Chemical Pathology
Services available to the public ¹	No

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	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	Red cell compatibility testing	Red cells and Plasma	Manual method, gel cards	Based on standard method CE		LM-BT-0006 LM-BT-0010

compatible donor units						
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin test	Red cells	Manual method, gel cards	Based on standard method CE		LM-BT-0011
<i>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)</i>						

Department of Paediatric Laboratory Medicine

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
1062 Biochemical genetics - .03 Newborn screening	ADO, D-ADO **1,2,3,4	Dried Blood Spot	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	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
	C5DC **1,2,4	Dried Blood Spot	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

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