Schedule of Accreditation



Organisation Name Galway University Hospital (Blood Transfusion)

Trading As Galway Blood & Tissue Establishment

INAB Reg No 233MT

Contact Name Maeve Wallace

Address Saolta University Health Care Group, Blood Bank,

Blood & Tissue Establishment, Galway, H91 YR71

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Website

Accreditation Standard EN ISO 15189

Standard Version 2022

Date of award of accreditation 09/06/2009

Scope Classification Blood Transfusion Science

Services available to the public¹

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	Galway Blood and Tissue Establishment (GBTE)	Saolta University Healthcare Group, Galway University Hospital, Newcastle Rd, Galway, Galway, Ireland, H91 YR71					

Scope of Accreditation

Galway Blood and Tissue Establishment (GBTE)

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
	Blood Grouping (ABO & RhD) Typing	EDTA specimen- Centrifuged whole blood		Based on standard method		1)GBTE/GRP/SOP/001 & 003 2)GBTE/GRP/SOP/008
1020 Transfusion science02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	1) Automated Blood Grouping (ABO & RhD) Typing 2) Infant Forward Grouping (ABO & RhD) Typing			Based on standard method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	1)GBTE/AVUE/SOP/002 2) GBTE/VIS/SOP/002 & 005 & 006
1020 Transfusion science03 Blood group antibody screen	Antibody Screening		1) Manual Microcolumn Agglutination Biovue 2) Automated Microcolumn Agglutination Biovue - Autovue 3) Automated Microcolumn	Based on standard method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	1) GBTE/GRP/SOP/007 2)GBTE/AVUE/SOP/002 3) GBTE/VIS/SOP/002 & 005

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			Agglutination Biovue - Vision/Vision Max			
			Manual Microcolumn Agglutination Diamed	Based on Standard Method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	GBTE/GRP/SOP/007
1020 Transfusion science04 Identification of blood group antibodies	Antibody Identification		1) Manual Microcolumn Agglutination 2) Automated Microcolumn Agglutination Biovue on Autovue Innova 3) Automated Microcolumn Agglutination Biovue on Ortho Vision Max	Based on standard method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	1)GBTE/ABID/SOP/001 2)GBTE/ABID/SOP/012 3)GBTE/VIS/SOP/0002 & 005
			Manual Microcolumn Agglutination Diamed	Method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	GBTE/ABID/SOP/001 GBTE/ABID/SOP/002
1020 Transfusion science05 Cross match compatible donor units	Automated Crossmatch	EDTA-Centrifuged Whole Blood	Ortho Vision Max Analysers	Method	Positive (0.5,1,2,3,4) reaction strengths & Negative Results (0)	GBTE/VIS/SOP/009
	Compatibility Testing	EDTA specimen- Centrifuged whole blood	1) Manual Microcolumn Agglutination Biovue 2) Compatibility Analysis for the release of compatible blood by Electronic Means	Based on standard method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	1)GBTE/XM/SOP/002 2)GBTE/XM/SOP/019
1020 Transfusion science06 Red cell phenotyping	Antigen Typing		1) Manual Tubes 2) Manual Micro- column Agglutination Biovue	CE & based on standard method	(, , , , ,	1) GBTE/ABID/SOP/007 2) GBTE/ABID/SOP/007
1020 Transfusion science09 Direct antiglobulin test	Direct Coombs Test		1) Manual Microcolumn Agglutination Biovue 2) Automated Method Microcolumn Agglutination Biovue on Ortho Vision/Vision Max Analysers	method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	1) GBTE/ABID/SOP/006 2) GBTE/VIS/SOP/006

Ī	Monospecific Coombs Test	Manual Microcolumn Agglutination Biovue	method	Positive (0.5, 1,2,3,4) reaction strengths & Neg results (0)	GBTE/ABID/SOP/006		
T	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)						