

Schedule of Accreditation



Organisation Name	Galway Clinic Doughiska Unlimited Company
Trading As	Galway Clinic Doughiska Unlimited Company
INAB Reg No	222MT
Contact Name	Beryl Waldron
Address	Blood Transfusion Laboratory, Doughiska, Galway, H91HHT0
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Email	beryl.waldron@blackrockhealth.com
Website	http://www.galwayclinic.com
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	07/04/2009
Scope Classification	Blood Transfusion Science
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	Head Office	Blood Transfusion Laboratory, Doughiska, Galway, Galway

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			Ortho-Biovue/ Manual Gel Method & Manual Tube Method	Ortho-Biovue Manual Gel Method (CE Marked)	ABO & Rhesus Blood Group Systems	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-015 Manual Othro-Biovue ABO & RhD Group and Screen. GC-LAB-BT-P-016 Tube ABO & RhD Group
	Blood Grouping (ABO & RhD) Typing (Automated)	Whole Blood in EDTA	Grifols Eflexis / Automated Method	Grifols Eflexis Automated Gel Card Method (CE Marked)	N/A	ISO 15189 CL 5.5 Examination Procedures GC-LAB-BT-P-049 Operation & Maintenance of the Grifols Eflexis GC-LAB-BT-P-008 Investigation of Blood Group & IAT

						Anomalies GC-LAB-BT-P-040 Management of the LIS - Meditech
	Blood Grouping (ABO & RhD) Typing (Manual)		Grifols/Manual Method	Grifols Manual Gel Card Method (CE Marked)		GC-LAB-BT-P-050 Operation & Maintenance of the Grifols Manual System GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies GC-LAB-BT-P-040 Management of the LIS - Meditech
	Blood Grouping (ABO & RhD) Typing (Manual)	Whole Blood / EDTA (Red Blood Cells)	Grifols DG (Gel Card Technology)	CE / based on standard method	N/A	GC-LAB-BT-P-050 Operation & Maintenance of the Manual DG Equipment GC-LAB-BT-P-014 Preparation of Red Cell Suspensions GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies
Tube Technique			CE / based on standard method	N/A	GC-LAB-BT-P-016 Tube ABO & RhD Group GC-LAB-BT-P-014 Preparation of Red Cell Suspensions	
Whole Blood in EDTA		Tube / Manual Method	Manual Tube Method (CE Marked)	N/A	GC-LAB-BT-P-016 Tube ABO & RhD Group GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies GC-LAB-BT-P-040 Management of the LIS - Meditech	

1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & RhD) Typing (Automated)	Whole Blood in EDTA	Grifols Eflexis (Automated)	Grifols Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-049 Operation & Maintenance of the Grifols Eflexis. GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies. GC-LAB-BT-P-040 Management of the LIS - Meditech.
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening (Automated)		Grifols Eflexis / Automated Method	Grifols Eflexis Automated Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-049 Operation and Maintenance of the Grifols Eflexis GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies GC-LAB-BT-P-040 Management of the LIS - Meditech
	Antibody Screening (Manual)		Grifols Manual Method	Grifols Manual Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-050 Operation & Maintenance of the Grifols Manual System GC-LAB-BT-P-008 Investigation of Blood Group & IAT Anomalies GC-LAB-BT-P-040 Management of the LIS - Meditech
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification (Automated and Manual)	Whole Blood in EDTA	Grifols Eflexis (Automated) / Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures.

						GC-LAB-BT-P-049 Operation and Management of the Grifols Eflexis GC-LAB-BT-P-050 Operation and Management of the Grifols Manual System GC-LAB-BT-P-009 Antibody Investigation GC-LAB-BT-P-040 Management of the LIS - Meditech
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch (Automated and Manual)		Grifols Eflexis (Automated) / Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-049 Operation and Management of the Grifols Eflexis GC-LAB-BT-P-050 Operation and Management of the Grifols Manual System GC-LAB-BT-P-005 Compatibility Testing GC-LAB-BT-P-005 Management of Blood and Blood Products GC-LAB-BT-P-040 Management of the LIS - Meditech
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing (Phenotyping) (Automated and Manual)	Whole Blood in EDTA	Grifols Eflexis (Automated) / Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-049 Operation and Maintenance of the Grifols Eflexis. GC-LAB-BT-P-050 Operation and Maintenance of the Grifols Manual

						System. GC-LAB-BT-P-009 Antibody Investigation and Antigen Typing. GC-LAB-BT-P-040 Management of the LIS - Meditech
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing (Automated and Manual)		Grifols Eflexis (Automated) / Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	ISO15189. CL.5.5 Examination procedures. GC-LAB-BT-P-049 Operation and Maintenance of the Grifols Eflexis. GC-LAB-BT-P-050 Operation and Maintenance of the Grifols Manual System. GC-LAB-BT-P-040 Operation and Management of the LIS - Meditech.
Galway Clinic Doughiska Ltd 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)						