

Schedule of Accreditation



Organisation Name	Galway Clinic Doughiska Unlimited Company
Trading As	Blackrock Health Galway Clinic
INAB Reg No	222MT
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Website	http://www.blackrockhealth.com
Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	07/04/2009
Scope Classification	Microbiology and Virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and Cytopathology
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	Blood Grouping (ABO & RhD) Typing (Manual)	Whole Blood in EDTA	Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-008 GC-LAB-BT-P-040 GC-LAB-BT-P-050
			Manual Tube Method	Manual Tube Method (CE Marked)	N/A	GC-LAB-BT-P-008 GC-LAB-BT-P-016 GC-LAB-BT-P-040
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & RhD) Typing (Automated)		Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-008 GC-LAB-BT-P-040 GC-LAB-BT-P-049
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening (Automated)		Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-008 GC-LAB-BT-P-040 GC-LAB-BT-P-049

	Antibody Screening (Manual)	Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-008 GC-LAB-BT-P-040 GC-LAB-BT-P-050
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification (Automated)	Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-009 GC-LAB-BT-P-040 GC-LAB-BT-P-049
	Antibody Identification (Manual)	Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-009 GC-LAB-BT-P-040 GC-LAB-BT-P-050
1020 Transfusion science - .05 Cross match compatible donor units	Electronic Crossmatch	Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-005 GC-LAB-BT-P-006 GC-LAB-BT-P-040 GC-LAB-BT-P-049
	Serological Crossmatch (Automated)	Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-005 GC-LAB-BT-P-006 GC-LAB-BT-P-040 GC-LAB-BT-P-049
	Serological Crossmatch (Manual)	Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-005 GC-LAB-BT-P-006 GC-LAB-BT-P-040 GC-LAB-BT-P-050
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing / Phenotyping (Automated)	Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-009 GC-LAB-BT-P-040 GC-LAB-BT-P-049
	Antigen Typing / Phenotyping (Manual)	Grifols Manual System	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-009 GC-LAB-BT-P-040 GC-LAB-BT-P-050
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test (Automated)	Grifols Eflexis	Grifols Gel Card Method (CE Marked)	N/A	GC-LAB-BT-P-040 GC-LAB-BT-P-049
	Direct Antiglobulin Test (Manual)	Grifols Manual System	Grifols Gel Card Method (CE Marked)		GC-LAB-BT-P-040 GC-LAB-BT-P-050

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)

Head Office

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 (FBC)	Blood in EDTA	Optical Flow Cytometry, Fluorescent flow cytometry, Electrical impedance, spectrophotometry/ calculation	Sysmex XN 2000/ WBC 0.00 to 440.00 x 10 ⁹ /L RBC 0.00 to 8.60 x 10 ¹² /L HGB 0.00 to 26.0 g/dL HCT 0.00 to 75 % PLT 0 to 5000 x 10 ⁹ /L	CE	GC-LAB-HAEM-P-005 GC-LAB-HAEM-P-016 GC-LAB-HAEM-P-017
1030 Haematology - .02 Visual examination of blood films	Differential White cell, Red cell morphology and platelet checks		Staining/ Microscopy/Manual	Hematek 3000 /Microscope	CE	GC-LAB-HAEM-P-010 GC-LAB-HAEM-P-011
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte counts		Fluorescent flow cytometry/ Scattergram interpretation	Sysmex XN 2000/ As per WBC	CE	GC-LAB-HAEM-P-016 GC-LAB-HAEM-P-017
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Fluorescent flow cytometry	Sysmex XN 2000 / 0.00 to 720.0 X 10 ⁹ /L	CE	GC-LAB-HAEM-P-016 GC-LAB-HAEM-P-017
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)	Blood in Sodium Citrate	Photo-optical technology	Sysmex CN3000 / APTT 8 to 360 Seconds	CE	GC-LAB-HAEM-P-029 GC-LAB-HAEM-P-030
	Activated Partial Thromboplastin Time		Calculation	Sysmex CN3000 /APTT Calculated from APTT	CE	GC-LAB-HAEM-P-029

	Ratio (APTr)					GC-LAB-HAEM-P-030
	D-Dimer		Photo-optical technology	Sysmex CN3000 /D-Dimer 190 to 35200 ng/mL	CE	GC-LAB-HAEM-P-029 GC-LAB-HAEM-P-030
	Fibrinogen		Photo-optical technology	Sysmex CN3000 / Fibrinogen 3.0 to 9.0 g/dL	CE	GC-LAB-HAEM-P-029 GC-LAB-HAEM-P-030
	International Normalised Ratio (INR)		Calculation	Sysmex CN3000 / INR Calculated from PT	CE	GC-LAB-HAEM-P-029 GC-LAB-HAEM-P-030
	Prothrombin Time (PT)		Photo-optical technology	Sysmex CN3000 / PT 5 to 180 Seconds	CE	GC-LAB-HAEM-P-029 GC-LAB-HAEM-P-030
1030 Haematology - .57 Screening test for infectious mononucleosis	Screening test for Infectious Mononucleosis (Epstein Barr Virus)	Blood in EDTA	Immunochromatographic	N/A	CE	GC-LAB-HAEM-P-004

Head Office

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 and Manual Haematoxylin & Eosin Staining	Human Tissue	Tissue-Tek Prisma Automated Slide Stainer/ Manual	CE/based on standard method	N/A	Bancroft's Theory and Practice of Histological Techniques GC-LAB-HIS-P-057 GC-LAB-HIS-P-058
	Coverslipping		Tissue-Tek G2 Glas Automated Coverslipper/ Manual	CE/based on standard method	N/A	Bancroft's Theory and Practice of Histological Techniques GC-LAB-HIS-P-057 GC-LAB-HIS-P-058
	Cut Up		Masterline Downdraft Bench	Based on standard method	N/A	Histopathology Specimens-Clinical, Pathological and Laboratory Aspects GC-LAB-HIS-P-013 GC-LAB-HIS-P-014 GC-LAB-HIS-P-049
	Embedding		Tissue-Tek TEC 6 Embedding System/ Manual	CE/based on standard method	N/A	Bancroft's Theory and Practice of Histological Techniques GC-LAB-HIS-P-017
	Microtomy		Leica 2255/Manual Leica Histocore Autocut/ Manual	CE/based on standard method	N/A	Bancroft's Theory and Practice of Histological Techniques

					GC-LAB-HIS-P-018
	Tissue Processing	Automated Tissue-Tek VIP 6/6 AI Tissue Processors	CE/based on standard method	N/A	Bancroft's Theory and Practice of Histological Techniques GC-LAB-HIS-P-016
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and Reporting of Human Tissue Specimens	Leica DFC490 Microscope/ Microscopy Olympus BX51 Microscope/Microscopy Olympus BX52 Microscope/Microscopy	CE/based on standard method	N/A	RCPATH Standards for Integrated Reporting in Cellular Pathology GC-LAB-HIS-P-005

Head Office

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	Macroscopic examination and description of specimens	Sputum, Sterile fluids	Manual/ Macroscopic examination and description of specimens	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-017 GC-LAB-MIC-P-062
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, gram stain	Urine, Fluids, tissues, swabs	Microscopy	CE/Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-035 GC-LAB-MIC-P-004 GC-LAB-MIC-P-062 GC-LAB-MIC-P-016 GC-LAB-MIC-P-018 GC-LAB-MIC-P-032 GC-LAB-MIC-P-058
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 bacteriology	Ear, eye, throat, nasal, mouth swabs	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-019 GC-LAB-MIC-P-030 GC-LAB-MIC-P-031 GC-LAB-MIC-P-047 GC-LAB-MIC-P-027
		Genital samples	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards

						for Microbiology GC-LAB-MIC-P-049
		MRSA swabs	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-014
		Rectal swabs	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-009 GC-LAB-MIC-P-012 GC-LAB-MIC-P-034
		Sputum, BAL, respiratory specimens	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-017
		Urine	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-004
		Wound and skin swabs, abscess swabs, pus, sterile fluids, tips, tissues	Culture	Based on standard method	N/A	Public Health England (PHE)- UK standards for Microbiology GC-LAB-MIC-P-016 GC-LAB-MIC-P-018 GC-LAB-MIC-P-032 GC-LAB-MIC-P-062 GC-LAB-MIC-P-076 GC-LAB-MIC-P-058
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic	Detection of Legionella Urinary Antigen	Urine	Rapid Immunochromatographic assay / BINAX Now Legionella pneumophila kit	CE	N/A	GC-LAB-MIC-P-029

methods,						
	Detection Streptococcus pneumoniae Urinary Antigen		Rapid Immunochemical assay / BINAX Now Streptococcus pneumoniae kit	CE	N/A	GC-LAB-MIC-P-029
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods, CE marked commercial systems	Identification of organisms	Bacterial Isolates	Identification using manual and automated systems / Kits/Tests and Automated Vitek 2 60	CE	N/A	GC-LAB-MIC-P-061 GC-LAB-MIC-P-023
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI- TOF Spectroscopy	Identification using MALDI-TOF Spectroscopy		Mass spectroscopy/ Biomerieux Vitek MS (MALDI-TOF)	CE	N/A	GC-LAB-MIC-P-065 GC-LAB-MIC-P-068
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes)	Antimicrobial susceptibility testing		Automated Vitek 2 60. Manual disc diffusion and Minimum inhibitory concentration (MIC) methods	CE	N/A	GC-LAB-MIC-P-011 GC-LAB-MIC-P-023