

Schedule of Accreditation



Organisation Name	Hermitage Clinic Unlimited
Trading As	Blackrock Health Hermitage Clinic
INAB Reg No	236MT
Contact Name	Aileen Coughlan
Address	Old Lucan Road, Dublin, D20 W722
Contact Phone No	+ 353 1 845 9391
Email	acoughlan@hermitageclinic.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	09/06/2009
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Services available to the public ¹	Yes

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	Old Lucan Road, Dublin, D20

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 including ABO, Rh(D) and other antigens by manual methods	Red blood cells and plasma	Grifols DG (Gel card technology) Manual Method	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-091 HMC-BB-SOP-102
			Tube Technique	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-091
	Blood grouping including ABO, Rh(D) and other antigens by manual methods		Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology	CE Based Method	Positive Grade 1-4/ Negative 0/ Mixed Field	HMC-BB-SOP-091
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood grouping including ABO, Rh(D) and other antigens by automated methods		Grifols DG (Gel card technology) Erythra Eflexis	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-091 HMC-BB-SOP-107

1020 Transfusion science - .03 Blood group antibody screen	Antibody screening	Plasma	Automated Method using Eflexis Grifols DG Gel card system	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-093 HMC-BB-SOP-102 HMC-BB-SOP-107	
			Manual Method using Grifols DG Gel Card System				
	Blood group antibody screen		Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology	CE Based Method	Positive Grade 1-4/ Negative 0	HMC-BB-SOP-093	
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated Method using Eflexis Grifols DG Gel card system	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-094 HMC-BB-SOP-102 HMC-BB-SOP-107	
							Manual Method using Grifols DG Gel Card System
							Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology
1020 Transfusion science - .05 Cross match compatible donor units	Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions		Grifols DG (Gel card technology) Manual Method	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-095 HMC-BB-SOP-102	
			Red Blood Cells and Plasma				Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red blood cells	Automated Method using Eflexis Grifols DG Gel card system	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-085 HMC-BB-SOP-102 HMC-BB-SOP-107	
			Manual Method using Grifols DG Gel Card				

			System Tube			
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin test	Red blood cells	Automated Method using Eflexis Grifols DG Gel card system Manual Method using Grifols DG Gel Card System	CE Based Method	0 to 4+ reactivity/grading	HMC-BB-SOP-010 HMC-BB-SOP-102 HMC-BB-SOP-107
1020 Transfusion science - .99 Miscellaneous tests			Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology	CE Based Method	Positive Grade 1-4/ Negative 0	HMC-BB-SOP-010

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)

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	Blood Counts	EDTA Blood Sample	Blood Counts	Sysmex XN2000	CE Based	HMC-HAE-SOP-063
1030 Haematology - .02 Visual examination of blood films	Visual examination of blood films		Visual examination of blood films	Manual	CE Based	HMC-HAE-SOP-017
1030 Haematology - .03 Erthrocyte sedimentation rate	Erthrocyte sedimentation rate		Erthrocyte sedimentation rate	Desaga S2000	CE Based	HMC-HAE-SOP-027
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte counts		Automated differential leucocyte counts	Sysmex XN200	CE Based	HMC/HAE/SOP/061 HMC/HAE/SOP/063
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thrombin Time (APTT)	Sodium Citrate Blood Sample	Photo optical	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069
	Activated Partial Thrombin Time Ratio (APTR)		Photo optical	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069
	D-Dimer		fluoresence	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069
	Fibrinogen		Photo optical	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069
	International Normalised Ratio (INR)		Photo optical	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069
	Prothrombin Time		Photo optical	ACL Top 350	CE Based	HMC-HAE-SOP-068 HMC-HAE-SOP-069

1030 Haematology - .57 Screening test for infectious mononucleosis	Screening test for infectious mononucleosis	EDTA Blood Sample	Screening test for infectious mononucleosis	Clearview IM II	CE Based	HMC-HAE-SOP-020
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