

Schedule of Accreditation



Organisation Name	Saolta University Health Care Group Portiuncula Hospital
Trading As	Portiuncula University Hospital
INAB Reg No	202MT
Contact Name	Declan Lyons
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	28/10/2008
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Services available to the public ¹	

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 Bank, HSE West, Ballinsloe, 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	Red Blood Cells	Plasma	Immunohaematology	Not Applicable	Red Blood Cells	ISO15189: LAB-QS-SOP-091, Manual method in tubes. LAB-QS-SOP-092, Manual method using gel cards.
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Immunohaematology	Not Applicable	Red Blood Cells	ISO15189: LAB-QS-SOP-075, Automated method using gel cards.
			Immunohaematology - IH500	Not Applicable	Red Blood Cells	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser

1020 Transfusion science - .03 Blood group antibody screen	Plasma
1020 Transfusion science - .04 Identification of blood group antibodies	
1020 Transfusion science - .05 Cross match compatible donor units	
1020 Transfusion science - .06 Red cell phenotyping	
	Red Blood Cells

Immunohaematology- IH500	Not applicable	Plasma	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser
Immunohaematology	Not Applicable	Plasma	ISO15189: LAB-QS-SOP-093, Manual method using gel cards. LAB-QS-SOP-075, Automated method using gel cards.
Immunohaematology - IH500	Not Applicable	Plasma	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser
Immunohaematology	Not Applicable	Plasma	ISO15189: LAB-QS-SOP-094, Manual method using gel cards.
Immunohaematology - IH500	Not Applicable	Plasma	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser
Immunohaematology	Not Applicable	Plasma	ISO15189: LAB-QS-SOP-082, Manual method using gel cards.
Immunohaematology - IH500	Not Applicable	Plasma	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser
Immunohaematology - IH500	Not Applicable	Plasma	ISO15189 LAB-QS-SOP-1035 Operation of the IH500 Analyser
Immunohaematology	Not Applicable	Red Blood Cells	ISO15189: LAB-QS-SOP-095, Manual method using gel cards.

1020 Transfusion science - .09 Direct antiglobulin test			Immunohaematology	Not Applicable	Red Blood Cells	ISO15189: LAB-QS-SOP-074, Manual method using Gel cards.
1020 Transfusion science - .99 Miscellaneous tests			Immunohaematology	Not Applicable	Red Blood Cells	ISO15189: LAB-QS-SOP-074, Manual method using gel cards.
		Whole Blood in EDTA	Acid Elution	CE	Guest medical Kleihauer Kit Microscope	ISO15189 LAB-QS- SOP-1026: Estimation of Fetomaternal Haemorrhage using the Kleihauer-Betke method
<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>						

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) Haemoglobin Red Cell Count Haematocrit (HCT) Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Mean Cell Haemoglobin Concentration (MCHC) Red cell Distribution Width (RDW) Platelets White Cell Count (WBC)	Blood EDTA	Impedance counting, fluorescence analysis by flow cytometry and SLS haemoglobin measurement on automated cell counter	Sysmex XN2000	CE Marked	LAB-HA-SOP-002
1030 Haematology - .02 Visual examination of blood films	Blood Film examination of white cell, red cell and platelet morphology		Giemsa and May Grunwald staining technique	Sysmex SP50	CE Marked	LAB-HA-SOP-009
1030 Haematology - .03 Erythrocyte sedimentation rate	ESR Sedimentation rate		Based on Westergren method	Sarstedt ST	CE Marked	LAB-HA-SOP-005
1030 Haematology - .05 Automated differential leucocyte counts	Differential White cell count Neutrophils Lymphocytes Monocytes		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE Marked	LAB-HA-SOP-002

	Eosinophils Basophils Nucleated Red blood cell (NRBC)				
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte count Absolute count Percentage		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE marked LAB-HA-SOP-002
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites		Manual staining using Fields and Giemsa stain and CareUS Malaria Rapidtest and Binaznow Malaria kits.	Microscope	CE Marked LAB-HA-SOP-010
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle screen (Sickledex)		Qualitative Solubility Test	Manual	CE Marked LAB-HA-SOP-011
1030 Haematology - .40 Limited haemostasis related tests	D-Dimer	Sodium Citrate Plasma	Percentage detection method for chromogenic and immunoassays	Sysmex CN 3000	CE Marked LAB-HA-SOP-004
1030 Haematology - .41 General haemostasis related tests	Coagulation Screen Prothrombin Time (PT) Activated Partial Thromboplastin time (APTT) Fibrinogen		Percentage detection method for Chromogenic and Immunoassays	Sysmex CN 3000	CE Marked LAB-HA-SOP-004