

Schedule of Accreditation



Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Galway
INAB Reg No	229MT
Contact Name	Siobhan Kenny
Address	Dublin Road, Renmore, Galway, H91 KC7H
Contact Phone No	091 381960
Email	skenny@bonsecours.ie
Website	http://www.bonsecours.ie
Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	09/06/2009
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Chemical pathology
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	Pathology Department, Renmore Road, Galway, H91 KC7H

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 Rh D typing)	Red blood cells	Grifols DG Gel Card Technology and Tube Method	Manual standard method	N/A	BSG/BB/SOP/030, BSG/BB/SOP/012
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Automated method using the Erytra Eflexis analyser	Based on standard method	N/A	BSG/BB/SOP/008
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Automated method using the Erytra Eflexis analyser	Based on standard method	N/A	BSG/BB/SOP/008
			Grifols DG Gel Card Technology.	Based on standard method	N/A	BSG/BB/SOP/030
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing		Grifols DG Gel Card Technology.	Based on standard method	N/A	BSG/BB/SOP/030, BSG/BB/SOP/012

	Crossmatch Testing	Plasma / Red Blood Cells	Automated method using the Erytra Eflexis analyser	Based on standard method	N/A	BSG/BB/SOP/009
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing (Direct Coombs Testing	Red blood cells	Automated method using the Erytra Eflexis analyser	Based on standard method	N/A	BSG/BB/SOP/010
	Direct Coombs Testing		Grifols DG Gel Card Technology.	Based on standard method	N/A	BSG/BB/SOP/030
Bon Secours Hospital Galway 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	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Troponin T High Sensitive (hsTroponin T)	Serum	Immunoassay	Roche Cobas	CE Marked	BSG/BIO/SOP/004 Attachment A
1061 Clinical Chemistry - .20 Hormones	HCG- Total		Immunoassay	Roche Cobas	CE Marked	BSG/BIO/SOP/004 Attachment B

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 Counts (including Red cell count, Haemoglobin, Haemocrit, Mean cell volume, Mean cell haemoglobin, Platelet count)	Whole Blood (EDTA)	Automated - Optical Flow Cytometry/ Fluorescence Flow Cytometry/ Electrical Impedance/ Spectrophotometry/ calculation	Cell Dyn Sapphire	Standard Method	BSG/HAEM/SOP/001
			Optical Flow Cytometry/ Fluorescence Flow Cytometry/ Electrical Impedance/ Spectrophotometry/ calculation	SysmexXN WBC 0.00 – 440.0 X 10 ⁹ /L RBC 0.00 – 8.60 X 10 ¹² /L HGB 0.00 – 26.0 g/dL HCT 0.00 – 0.75 L/L PLT 0 – 5000 X 10 ⁹ /L NRBC 0.0 – 600.0 /100WBC Retic 0.00 – 720 X 10 ⁹ /L	CE Marked	BSG/HAEM/SOP/0xx
1030 Haematology - .02 Visual examination of blood films	Blood film examination		Staining/ Microscopy		Standard Method	BSG/HAEM/SOP/004
			Staining/ Microscopy	Sysmex SP 50	CE Marked	BSG/HAEM/SOP/004
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation rate	4NC ESR Sodium Citrate 3.2%	Sedimentation	Westergren (Manual)	Manual	BSG/HAEM/SOP/003
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential Leucocyte Counts	Whole Blood (EDTA)	Fluorescence Flow Cytometry/ Scattergram interpretation	Cell Dyn Sapphire	Standard Method	BSG/HAEM/SOP/001

	Automated Differential Leucocyte Counts (Basophil, Eosinophil, lymphocyte, monocyte, neutrophil)		Fluorescence Flow Cytometry/ Scattergram interpretation	Sysmex XN-10 / XN 20. -0.03 x 10 ⁹ /l to 440 x 10 ⁹ /l	CE Marked	BSG/HAEM/SOP/0xx
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes		Fluorescence Flow Cytometry	Cell Dyn Sapphire	Standard Method	BSG/HAEM/SOP/001
			Fluorescence Flow Cytometry	Sysmex XN 10/XN20 0.00 – 720.0 X 10 ⁹ /L	CE Marked	BSG/HAEM/SOP/0xx