

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	2012
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
<i>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)</i>						

Chemical Pathology

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	Adjusted Calcium	Serum	Calculation	LIMS/AMS	Standard Method	BSG/BIO/SOP/002 Attachment 24
	Alanine Aminotransferase (ALT)		Enzymatic/Spectrophotometric NADH(Without P'-5'-P)	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 1
	Albumin		Colorimetric - BCP (Bromocresol Green)	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 2
	Alkaline Phosphatase		Colorimetric - Para-Nitrophenyl Phosphate	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 3
	Aspartate Aminotransferase (AST)		Enzymatic/Spectrophotometric NADH (Without P'-5'-P)	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 4
	Bilirubin (Total)		Colorimetric/Diazonium Salt	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 5
	Calcium		Colorimetric/Arsenazo-III	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 6
	Chloride		Ion selective electrode	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 7
	Cholesterol		Enzymatic/Colorimetric	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 8
	C-Reactive Protein (CRP)		Immunoturbimetric	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 10
	Creatinine (Enzymatic)		Enzymatic/Colorimetric	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 9

	Direct LDL		Enzymatic/Colorimetric	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 26
	eGFR		Calculation	LIMS/iLAB	Standard Method	BSG/BIO/SOP/002 Attachment 25
	Gamma Glutamyl Transferase (GGT)		L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 12
	Glucose	Plasma	Hexokinase	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 11
	Magnesium	Serum	Enzymatic	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 15
	Phosphate		Ammonium Molybdate/ Phosphomolybdate	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 16
	Potassium		Ion selective electrode	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 17
	Protein (Total)		Biuret Reaction	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 19
	Sodium		Ion selective electrode	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 18
	Triglycerides		Glycerol Phosphate Oxidase	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 21
	Troponin T High Sensitive (hsTroponin T)		Immunoassay	Roche Cobas	CE Marked	BSG/BIO/SOP/004 Attachment A
	Ultra HDL		Accelerator Selective Detergent	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 13
	Urate (Uric Acid)		Uricase	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 22
	Urea		Kinetic Urease	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 23
1061 Clinical Chemistry - .20 Hormones	HCG- Total		Immunoassay	Roche Cobas	CE Marked	BSG/BIO/SOP/004 Attachment B
1061 Clinical Chemistry - .40 Iron studies	Iron		Ferene	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 14
	TIBC		Calculation	LIMS/AMS	Standard Method	BSG/BIO/SOP/002 Attachment 27
	Transferrin	Immunoturbidimetric	C4000 Architect	CE Marked	BSG/BIO/SOP/002 Attachment 20	

	Transferrin saturation		Calculation	LIMS/AMS	Standard Method	BSG/BIO/SOP/002 Attachment 28
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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)	Optical Flow Cytometry/ Flourescence Flow Cytometry/ Electrical Impedence/ 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	Sysmex SP 50	CE Marked	BSG/HAEM/SOP/004
1030 Haematology - .03 Erthrocyte 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 (Basophil, Eosinophil, lymphocyte, monocyte, neutrophil)	Whole Blood (EDTA)	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	Sysmex XN 10/XN20 0.00 – 720.0 X 10 ⁹ /L	CE Marked	BSG/HAEM/SOP/0xx

