

Schedule of Accreditation



Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Tralee
INAB Reg No	206MT
Contact Name	Cara Wrenn
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Website	http://bonsecours.ie/tralee
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	09/12/2008
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
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	Strand Street, Tralee, Kerry, W92 P663

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).	Red blood cells.	Manual Method using DiaMed Gel Cards	CE Marked DiaMed	N/A	BST/BB/SOP/002
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Automated method using DiaMed Gel Cards & IH500 instrument	CE Marked DiaMed	N/A	BST/BB/SOP/033
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Automated method using DiaMed Gel Cards & IH500 instrument	CE Marked DiaMed	N/A	BST/BB/SOP/033
	Antibody Screening.		Manual Method using DiaMed Gel Cards	CE Marked (DiaMed)	N/A	BST/BB/SOP/002
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Automated method using DiaMed Gel Cards & IH500 instrument	CE Marked DiaMed	N/A	BST/BB/SOP/033

			Manual Method using DiaMed Gel Cards	CE Marked DiaMed	N/A	BST/BB/SOP/007
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing	Plasma/Red blood cells	Automated method using DiaMed Gel Cards & IH500 instrument	CE Marked DiaMed	N/A	BST/BB/SOP/033
			Manual Method using DiaMed Gel Cards	CE Marked DiaMed	N/A	BST/BB/SOP/002
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Manual Method using DiaMed Gel Cards	CE Marked DiaMed	N/A	BST/BB/SOP/007
1020 Transfusion science - .09 Direct antiglobulin test	Direct Coombs Test (Polyspecific) Direct Coombs Test (Monospecific)		Automated method using DiaMed Gel Cards & IH500 instrument	CE Marked DiaMed	N/A	BST/BB/SOP/033
			Manual Method using DiaMed Gel Cards	CE Marked DiaMed	N/A	BST/BB/SOP/007
<i>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>						

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
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)	Microscopic examination for general bacteriology purposes **1,2,3	CSF Fluids from normally sterile sites (other than CSF), Urines, Blood Cultures, MRSA screens, Genital Tract Specimens, Faeces, Swabs from all sites, including tips Sputum, Bronchial Alveolar Lavage (BAL) & Antral Wash Out, MDRO (ESBL, VRE, CPE) Screens.	Microscope/microscopy	Standard method (PHE Guidelines)		BST/MIC/SOP/005
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 bacteria**1,2,3	CSF, Fluids from normally sterile sites (other than CSF), Urines, Blood Cultures, MRSA screens, Genital Tract Specimens, Faeces, Swabs from all sites, including tips, Sputum, Bronchial Alveolar Lavage (BAL) & Antral Wash Out, MDRO (ESBL, VRE, CPE) Screens, Human cells/fluid	Manual	Standard method (PHE Guidelines)		BST/MIC/SOP/002 BST/MIC/SOP/014 BST/MIC/SOP/008 BST/MIC/SOP/006 BST/MIC/SOP/016 BST/MIC/SOP/019 BST/MIC/SOP/015 BST/MIC/SOP/013 BST/MIC/SOP/017 BST/MIC/SOP/038

1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi **1,2,3	CSF Fluids from normally sterile sites (other than CSF) Urines Blood Cultures Genital Tract Specimens Swabs from all sites, including tips Sputum, Bronchial Alveolar Lavage (BAL) & Antral Wash Out.	Manual	Standard method (PHE Guidelines)	N/A	BST/MIC/SOP/002 BST/MIC/SOP/014 BST/MIC/SOP/008 BST/MIC/SOP/006 BST/MIC/SOP/016 BST/MIC/SOP/019 BST/MIC/SOP/015 BST/MIC/SOP/013 BST/MIC/SOP/017
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Nucleic acid amplification (PCR) for CPE **1,2,3,4	Bacterial cells	Automated (GeneXpert)	CE Marked		BST/MIC/SOP/039 BST/MIC/SOP/034
	Nucleic acid amplification (PCR) for Influenzae A/B **1,2,3,4	Human cells/fluid	Automated (GeneXpert)	CE Marked		BST/MIC/SOP/034 BST/MIC/SOP/036 BST/MIC/SOP/037
	Nucleic acid amplification (PCR) for Norovirus **1,2,3,4		Automated (GeneXpert)	CE Marked		BST/MIC/SOP/034 BST/MIC/SOP/036 BST/MIC/SOP/037
	Nucleic acid amplification (PCR) for RSV **1,2,3,4		Automated (GeneXpert)	CE Marked		BST/MIC/SOP/034 BST/MIC/SOP/036 BST/MIC/SOP/037
	Nucleic acid amplification (PCR) for SARS-CoV-2 RNA		Thermofisher Kingfisher Roche Cobas Z480 Lightcycler Primer Design GeneSig SARS-COV-2 Assay	CE Marked		BST/MIC/SOP/042
	Nucleic acid amplification (PCR) for SARS-CoV-2 RNA **1,2,3,4 (Individual patient samples)		Automated (GeneXpert)	CE Marked		BST/MIC/SOP/034 BST/MIC/SOP/040

1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Automated identification (Vitek 2) & conventional identification using biochemical methods **1,2,3,4		Manual and automated (Vitek 2)	CE marked and PHE guidelines	N/A	BST/MIC/SOP/002 BST/MIC/SOP/014 BST/MIC/SOP/008
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Manual Antimicrobial Susceptibility Testing using Disk Diffusion & EUCAST Guidelines**1,2,3,4		Manual/Automated	Standard method (EUCAST and CE)		BST/MIC/SOP/031 BST/MIC/SOP/018 BST/MIC/SOP/011 BST/MIC/SOP/022
			Manual/Automated	Standard method (EUCAST and CE)		BST/MIC/SOP/031 BST/MIC/SOP/018 BST/MIC/SOP/011 BST/MIC/SOP/022
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Direct examination of faeces specimens for C. difficile toxins (enzyme EIA)**1,3,4		Manual	CE marked kit		BST/MIC/SOP/015
1029 Miscellaneous - .99 Miscellaneous tests	Direct measurement of HCG in urine. Rapid immunochromatograph Assay Faecal Occult Blood		Manual	CE marked kit	N/A	BST/MIC/SOP/009 BST/MIC/SOP/015

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.