

# Schedule of Accreditation



Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Tralee
INAB Reg No	206MT
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	09/12/2008
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Histopathology and cytopathology
Services available to the public <sup>1</sup>	Yes

<sup>1</sup> 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	Based on standard method	N/A	BST/BB/SOP/007

*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)*

Histopathology and Cytopathology

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
1051 Histopathology - .03 Histochemistry	Special Stains: Alcian Blue PAS	Human Tissue	Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: Congo Red		Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: Masson Fontana		Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special stains: Modified Giemsa		Automated (TissueTek Prisma)	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: PAS		Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: PAS Diastase		Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: Perls Prussian Blue		Manual	Based on standard method	N/A	BST/HIS/SOP/011
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Cut up Tissue Processing Embedding Microtomy Haemotoxylin/Eosin Staining Mounting (Coverslipping)		Automated (VIP 6 Processor, Embedding Centre, Microtomes, TissueTek Prisma) & Manual	CE Marked & Standard Method	N/A	BST/HIS/SOP/029 BST/HIS/SOP/030 BST/HIS/SOP/002 BST/HIS/SOP/003 BST/HIS/SOP/004 BST/HIS/SOP/005 BST/HIS/SOP/006 BST/HIS/SOP/035 BST/HIS/SOP/036 BST/HIS/SOP/037 BST/HIS/SOP/038 BST/HIS/SOP/039 BST/HIS/SOP/043 BST/HIS/SOP/044

	Special Stains: Trichrome	Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: Van Gieson	Manual	Based on standard method	N/A	BST/HIS/SOP/011
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation & reporting of human tissue specimens  Specialist areas excluded: Medical renal pathology Paediatric Pathology Perinatal Pathology Neuropathology Breast screening pathology	Manual	Based on standard method	N/A	BST/HIS/SOP/010 BST/HIS/SOP/030 BST/HIS/SOP/031 BST/HIS/SOP/033 BST/HIS/SOP/034 BST/HIS/SOP/035 BST/HIS/SOP/036 BST/HIS/SOP/037 BST/HIS/SOP/038 BST/HIS/SOP/039 BST/HIS/SOP/040 BST/HIS/SOP/044 BST/HIS/SOP/007
1051 Histopathology - .09 Immunohistochemistry	34 BetaE12 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)	N/A	BST/HIS/SOP/013 BST/HIS/SOP/026
	AE1AE3 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	AMACR (P504S) **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	BCL-2 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	BerER4 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	Ca125 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	CD10 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	CD20 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	CD3 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	CD30 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026

CD34 **2,4	Automated (Leica BondMax)	CE Marked Leica		BST/HIS/SOP/013 BST/HIS/SOP/026
CD45 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
CD5 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
CD56 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
CD68 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
CD79a **2,4	Automated (Leica BondMax)	CE Marked Leica		BST/HIS/SOP/013 BST/HIS/SOP/026
CEA **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
Chromagranin A **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
Cytokeratin 20 **2,4	Automated (Leica BondMax)	CE Marked (Dako)		BST/HIS/SOP/013 BST/HIS/SOP/026
Cytokeratin 5/6 **2,4	Automated (Leica BondMax)	CE Marked (Dako)		BST/HIS/SOP/013 BST/HIS/SOP/026
Cytokeratin 7 **2,4	Automated (Leica BondMax)	CE Marked (Dako)		BST/HIS/SOP/013 BST/HIS/SOP/026
Cytokerin 8/18 CDX2 Chromogranin	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
Desmin **2,4	Automated (Leica BondMax)	CE Marked (Leica)		BST/HIS/SOP/013 BST/HIS/SOP/026
EMA **2,4	Automated (Leica BondMax)	CE Marked (Dako)		BST/HIS/SOP/013 BST/HIS/SOP/026
HMB45	BondMax (Leica)	CE Marked (Leica)	N/A	HIS/SOP/026 HIS/SOP/013
KI-67 (MIB-1) **2,4	Automated (Leica BondMax)	CE Marked (Leica)		BST/HIS/SOP/013 BST/HIS/SOP/026
Melan A **2,4	Automated (Leica BondMax)	CE Marked (Dako)		BST/HIS/SOP/013 BST/HIS/SOP/026
P63 **2,4	Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026

	PSA **2,4		Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	S100 **2,4		Automated (Leica BondMax)	CE Marked (Leica BondMax)		BST/HIS/SOP/013 BST/HIS/SOP/026
	Smooth Muscle Actin **2,4		Automated (Leica BondMax)	Non-CE Marked (Sigma)		BST/HIS/SOP/013 BST/HIS/SOP/026
	SOX10 **2,4		Automated (Leica BondMax)	CE Marked (Epitomics)		BST/HIS/SOP/013 BST/HIS/SOP/026
	TTF-1 **2,4		Automated (Leica BondMax)	CE Marked (Leica)		BST/HIS/SOP/013 BST/HIS/SOP/026
	Vimentin **2,4		Automated (Leica BondMax)	CE Marked (Leica)		BST/HIS/SOP/013 BST/HIS/SOP/026
1052 Cytopathology - .02 Non gynaecological cytology	Gross description, processing & staining of bodily fluids & aspirates. Stained cytology slide (PAP & MGG) Microscopic examination		Automated & Manual	CE Marked & Based on standard method (British Society for Clinical Cytology)	N/A	BST/HIS/SOP/010 BST/HIS/SOP/017

*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.*

## Head Office

### 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, 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, Swabs from all sites, including	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/013 BST/MIC/SOP/017 BST/MIC/SOP/038



		tips, Sputum, Bronchial Alveolar Lavage (BAL) & Antral Wash Out, MDRO (VRE, CPE) Screens, Human cells/fluid				
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/040
	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/040
	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	Bacterial isolates.	Manual and Automated (Vitek 2)	CE Marked and Standard method (PHE Guidelines)		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 Antibiotic Susceptibility testing using Disc Diffusion/E-tests & EUCAST Guidelines	Human cells/fluids	Manual Automated reader (Biomic)	Standard Method (EUCAST & CE Marked)		BST/MIC/SOP/022 BST/MIC/SOP/029
	Manual Antimicrobial Susceptibility Testing using Disk Diffusion & EUCAST Guidelines**1,2,3,4	Human cells/fluid	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	Faeces	Manual	CE Marked Kit		BST/MIC/SOP/015

1029 Miscellaneous - .99 Miscellaneous tests	Direct measurement of HCG in urine. Rapid immunochromatograph Assay	Human cells/fluid	Manual	CE marked kit	N/A	BST/MIC/SOP/009
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