Schedule of Accreditation

Organisation Name	Bon Secours Health System CLG
Trading As	Bon Secours Hospital Tralee
INAB Reg No	206MT
Contact Name	Cara Wrenn
Address	Strand Street, Tralee, Kerry, W92 P663
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Website	http://bonsecours.ie/tralee
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	Haematology
Scope Classification	Histopathology and Cytopathology
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	CE Marked	N/A	BST/BB/SOP/002

			DiaMed Gel Cards	(DiaMed)		
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)						

Head Office

Haematology

Category: C

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 haemoglobin, platelet count)	Whole Blood (EDTA)	Automated-RF/hydro dynamic focusing (DC Detection, detection method, sheath flow DC detection method, Fluorescence flow cytometry method, Sodium Lauryl Sulphate (SLS) Haemoglobin Method	Sysmex XN-2000	CE Marked Standard Method	BST/HAEM/SOP/015
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination		Manual Micrscopy	Siemens Hematek	CE Marked Standard Method	BST/HAEM/SOP/005
1030 Haematology - .05 Automated differential leucocyte counts	Automated Differential Leucyte Counts		Automated-Fluorescence Flow cytometry, Adaptive Flagging Algorithm based on Shape recognition (AFLAS)	Sysmex XN-2000	CE Marked Standard Method	BST/HAEM/SOP/015
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte Counts		Automated fluorescence flow cytometry.	Sysmex XN-2000	CE Marked Standard Method	BST/HAEM/SOP/015

1030 Haematology - .41 General haemostasis related tests	D-dimer	Sodium Citrate Plasma	Automated standard immunoturbidity method	Sysmex CA-600	CE Marked Standard Method	BST/HAEM/SOP/002
	Prothrombin Test/International Ratio/ Activated Partial Thromboplastin Time, Activated Partial Thromboplastin Time Ratio/ Fibrinogen Estimation		Automated scatter light detection method.	Sysmex CA-600	CE Marked Standard Method	BST/HAEM/SOP/002

Head Office

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 - .01 Processing fixed specimens for Histopathological testing	Cut up Tissue Processing Embedding Microtomy Haemotoxylin/Eosin Staining Mounting (Coverslipping)	Human Tissue	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
1051 Histopathology - .03 Histochemistry	Alcian Blue		Manual	CE Marked Based on standard method		BST/HIS/SOP/011
	Gordon-sweet reticulin stain		Manual	Based on standard method	N/A	BST/HIS/SOP/011
	Special Stains: Alcian Blue PAS		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:		Automated (TissueTek	Based on standard	N/A	BST/HIS/SOP/011

	Modified Giemsa	Prisma)	method		
	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
	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)		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
GATA 3	Automated (Leica BondMax)	CE Marked (Leica)		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
P16	Automated (Leica BondMax)	CE Marked (Leica)		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
SMA	Automated (Leica BondMax)	CE Marked (Leica)		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
Synaptophysin	Automated (Leica BondMax)	CE Marked (Leica)		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), stained cytology cell block. Microscopic examination	Body Fluids and Aspirates	Automated & Manual	CE Marked & Based on standard method (British Society for Clinical Cytology)	N/A	BST/HIS/SOP/010

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 (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,	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

		Genital Tract Specimens, Swabs from all sites, including tips, Sputum, Bronchial Alveolar Lavage (BAL) & Antral Wash Out, MDRO (VRE, CPE) Screens, Human cells/fluid				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	Nucleic acid amplification (PCR) for CPE **1,2,3,4	Bacterial cells	Automated (GeneXpert)	CE Marked		BST/MIC/SOP/039 BST/MIC/SOP/034

commercial systems						
	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/002BST/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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