

# Accreditation Certificate

## The Bon Secours Health System Ltd

College Road, Cork

### Medical Testing Laboratory

Registration number: 153MT

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 15189:2007 2<sup>nd</sup> Edition  
*“Medical laboratories - Particular requirements for quality and competence”*  
*(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)*

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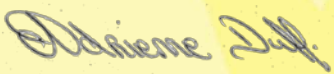
Date of award of accreditation: 06:09:2004

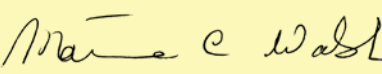
Date of last renewal of accreditation: 16:09:2009

Expiry date of this certificate of accreditation: 16:09:2014

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This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager:   
Dr Adrienne Duff

Chairperson:   
Dr Máire Walsh

Issued on 16 September 2009

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

# Schedule of Accreditation



(Annex to Accreditation Certificate)

Permanent Laboratory:  
Category A

## BON SECOURS HEALTH SYSTEM LTD

### Medical Testing Laboratory

*Initial Registration Date :* 06-September-2004  
*Postal Address:* Pathology Department  
*(Address of other locations as they apply)* College Road  
Cork

*Telephone:* +353 (021) 4542005  
*Fax:* +353 (021) 4341983  
*E-mail:* [dkeane@bonsecours.ie](mailto:dkeane@bonsecours.ie)  
*Contact Name:* Mr Dave Keane  
*Facilities:* Public Testing Laboratory

# Schedule of Accreditation



Permanent Laboratory:  
 Category A

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

## Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category C:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
  - (b) a site laboratory
  - (c) a mobile laboratory or
  - (d) equipment from a mobile or site laboratory

## Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

## Glossary of Terms

### Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will on request verify the status and scope.

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP	
1061 GENERAL CHEMISTRY	.02	Albumin	Serum/ Fluid	Bromo Cresol Green	Olympus AU640	BSC/BIO/SOP/032
	.02	Albumin (Micro)	Urine	Immunoturbimetric	Olympus AU640	BSC/BIO/SOP/032
	.01	Alk Phos	Serum	IFCC with PNPP	Olympus AU640	BSC/BIO/SOP/032
	.02	Alpha 1 Anti trypsin	Serum	Immunoturbimetric	Olympus AU640	BSC/BIO/SOP/032
	.02	Alpha Feto Protein (AFP)	Serum	Immunoassay	Olympus AU640	BSC/BIO/SOP/032
	.01	ALT	Serum	IFCC (w/o Pyr Phos)	Olympus AU640	BSC/BIO/SOP/032
	.01	Ammonia	EDTA Plasma	Enzymatic with GLDH	Olympus AU640	BSC/BIO/SOP/032
	.01	Amylase	Serum/ Fluid/ Urine	IFCC	Olympus AU640	BSC/BIO/SOP/032
	.01	AST	Serum	IFCC (w/o Pyr Phos)	Olympus AU640	BSC/BIO/SOP/032
	.02	B-2 Microglobulin	Blood	Immunoturbidimetry	Olympus AU640	BSC/BIO/SOP/032
	.01	Bilirubin Direct	Serum	Diazo	Olympus AU640	BSC/BIO/SOP/032
	.01	Bilirubin Total	Serum / Amiotic Fluid	Diazo	Olympus AU640	BSC/BIO/SOP/032
	.50	CA 125	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.50	CA 15-3	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.50	CA 19-9	Serum	MEIA	Abbott AxSym	BSC/BIO/SOP/057
	.01	Calcium	Serum/ Urine	0-Cresolphthalein	Olympus AU640	BSC/BIO/SOP/032
	.01	Calcium Creatinine Ratio	Urine	Calculation	N/A	BSC/BIO/SOP/047
	.01	Calcium (Corrected)	Serum	Calculation	N/A	BSC/BIO/SOP/047
	.50	Carcinoembryonic Antigen (CEA)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.01	Chloride	Serum/ Urine	ISE Indirect	Olympus AU640	BSC/BIO/SOP/032
	.30	Chloride	Sweat	Coulimetric	Olympus AU640	BSC/BIO/SOP/015
	.01	Cholesterol Total	Serum	CHOD/PAP	Olympus AU640	BSC/BIO/SOP/032
	.01	Cholesterol HDL	Serum	Enzymatic	Olympus AU640	BSC/BIO/SOP/032
	.01	Cholesterol LDL	Serum	Calculation	N/A	BSC/BIO/SOP/047

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1061 GENERAL CHEMISTRY	.01	CK-Total	Serum	IFCC / DGKC	Olympus AU640	BSC/BIO/SOP/032
	.02	Complement C3	Serum	Immunoturbimetric	Olympus AU640	BSC/BIO/SOP/032
	.02	Complement C4	Serum	Immunoturbimetric	Olympus AU640	BSC/BIO/SOP/032
	.20	Cortisol	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.01	Creatinine Clearance	Serum/ Urine	Calculation	N/A	BSC/BIO/SOP/047
	.01	Creatinine (Jaffe)	Serum/ Fluid/ Amniotic Fluid/ Urine	Jaffe without deproteinisation	Olympus AU640	BSC/BIO/SOP/032
	.02	C-Reactive Protein (CRP)	Serum	Immunoturbimetric	Olympus AU640	BSC/BIO/SOP/032
	.40	Ferritin	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.45	Folate (Folic Acid)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.20	Follicle Stimulating Hormone (FSH)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.01	Gamma GT	Serum	Szasz-Persijn	Olympus AU640	BSC/BIO/SOP/032
	.10	Gentamicin	Serum	Enzymatic	Olympus AU 640	BSC/BIO/SOP/032
	.01	Globulin	Serum	Calculation	N/A	BSC/BIO/SOP/047
	.01	Glucose	Plasma/ CSF/ Fluid	Hexokinase	Olympus AU640	BSC/BIO/SOP/032
	.40	Iron	Serum	Ferrazine	Olympus AU640	BSC/BIO/SOP/032
	.01	Lactate	Plasma	LOX/PAP	Olympus AU640	BSC/BIO/SOP/032
	.01	LDH	Serum/ Fluids	DGKC	Olympus AU640	BSC/BIO/SOP/032
	.20	Luteinising Hormone (LH)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.01	Magnesium	Serum	Colorimetric with CPZIII	Olympus AU640	BSC/BIO/SOP/032
	.20	Oestradiol	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



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#### BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1061 GENERAL CHEMISTRY	.01	Osmolality	Serum/ Urine	Freezing Point Depression	Gonotec Osomat 030 Osmometer	BSC/BIO/SOP/012
	.01	Phosphate	Serum/ Urine	Ammonium Molybdate	Olympus AU640	BSC/BIO/SOP/032
	.01	Potassium	Serum/ Urine	ISE Indirect	Olympus AU640	BSC/BIO/SOP/032
	.20	Progesterone	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.20	Prolactin (PRL)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.02	Protein (Total)	Serum/ Amniotic Fluid	Biuret Reaction	Olympus AU640	BSC/BIO/SOP/032
	.02	Protein (Urinary)	Urine/ CSF	Pyrogallol-Red molybdate	Olympus AU640	BSC/BIO/SOP/032
	.50	PSA (Equimolar)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.50	PSA (Free)	Serum	MEIA	Abbott AxSym	BSC/BIO/SOP/057
	.50	PSA (Index)	Serum	Calculation	N/A	BSC/BIO/SOP/047
	.01	Sodium	Serum/ Urine	ISE Indirect	Olympus AU640	BSC/BIO/SOP/032
	.20	T <sub>3</sub> (Free)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.20	T <sub>4</sub> (Free)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.20	THCG	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.20	Thyroid Stimulating Hormone (TSH)	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.40	Transferrin	Serum	Immunoturbidimetric	Olympus AU640	BSC/BIO/SOP/032
	.01	Triglycerides	Serum	GPO/PAP	Olympus AU640	BSC/BIO/SOP/032
	.02	Troponin I	Plasma	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.01	Urate (Uric Acid)	Serum/ Urine	Uricase	Olympus AU640	BSC/BIO/SOP/032
	.01	Urate/ Urea Index	Serum	Calculation	N/A	BSC/BIO/SOP/047
	.01	Urea	Serum/ Urine	Kinetic Urease	Olympus AU640	BSC/BIO/SOP/032
	.06	pH	Pleural Fluid	Potentiometric	Radiometer ABL5 Blood Gas Analyser	BSC/BIO/SOP/071
	.40	Transferrin Saturation (Calculation)	Serum	Calculation	N/A	BSC/BIO/SOP/047

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1061 GENERAL CHEMISTRY	.01	Urine Protein/ Creatine Ratio Calculation	Urine	Calculation	N/A	BSC/BIO/SOP/047
	.10	Vancomycin	Serum	FPIA	Abbott AxSYM	BSC/BIO/SOP/057
	.45	Vitamin B 12	Serum	Immunoassay	Siemens Centaur XP	BSC/BIO/SOP/055
	.06	pH	Heparin Blood	Potentiometric	Radiometer ABL5	BSC/BIO/SOP/071
	.06	pCO <sub>2</sub>	Heparin Blood	Potentiometric	Radiometer ABL5	BSC/BIO/SOP/071
	.06	pO <sub>2</sub>	Heparin Blood	Potentiometric	Radiometer ABL5	BSC/BIO/SOP/071
	.06	*pH	Heparin Blood	Potentiometric	Roche Omni 1	BSC/BIO/SOP/073
	.06	*pCO <sub>2</sub>	Heparin Blood	Potentiometric	Roche Omni 1	BSC/BIO/SOP/073
	.06	*pO <sub>2</sub>	Heparin Blood	Potentiometric	Roche Omni 1	BSC/BIO/SOP/073
1040 IMMUNOLOGY	.02	Electrophoresis	Serum	Agarose Gel	Sebia Hydrasys 2	BSC/BIO/SOP/061
	.02	Immunofixation	Serum	Agarose Gel / Immunofixation	Sebia Hydrasys 2	BSC/BIO/SOP/062
	.01	Immuno globulin IgA	Serum	Immunoturbidimetric	Olympus AU640	BSC/BIO/SOP/032
	.01	Immuno globulin IgG	Serum	Immunoturbidimetric	Olympus AU640	BSC/BIO/SOP/032
	.01	Immuno globulin IgM	Serum	Immunoturbidimetric	Olympus AU640	BSC/BIO/SOP/032
	.03	Immuno globulin IgE	Serum	Enzyme Immunoassay	Phadia Immunocap 250	BSC/BIO/SOP/069
	.04	Allergy Screen (Specific IgE)	Serum	Enzyme Immunoassay	Phadia Immunocap 250	BSC/BIO/SOP/069
	.10	RF Latex (Rheumatoid Factor)	Blood	Latex Enhanced Turbidimetry	Olympus AU640	BSC/BIO/SOP/032

\* Point of care.

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### BLOOD TRANSFUSION DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1020 IMMUNO HAEMATOLOGY	.01	ABO and Rh D grouping of blood	Red Cells / Plasma / Serum	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/002
	.03	Antibody Screening	Plasma	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/002
	.04	Antibody Identification	Plasma	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/003
	.05	Compatibility Testing	Donor Cells / Plasma	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/003
	.06	Red Cell Phenotyping	Red Cells	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/003
	.07	Antibody Elution	Red Cells	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/003
	.99	Direct Coombs Test	Red Cells	Ab / Ag Reaction Gel Technique	Manual	BSC/BB/SOP/004
Note: Transfusion reaction investigation (Blood Group Serology) is covered by the tests listed above						
1080 BLOOD TRANSFUSION	.05	Therapeutic blood donation	Whole Blood	Venepuncture	Weigher/ Mixer	BSC/PHLE/SOP/006 BSC/PHLE/SOP/007

Note: The Bon Secours Health System Ltd. Pathology Department, College Road, Cork has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (SI No 360 of 2005 and SI No 547 of 2006).

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1030 HAEMATOLOGY	.05	Full Blood Count Including White Cell, Differential (Automated) Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils	Blood	Optical Flow Cytometry/ Electrical Impedance/ Spectrophotometric/ Calculation	Cell Dyn Sapphire	BSC/HAEM/SOP/010
	.01	Haemoglobin	Blood	Spectrophotometric	Cell Dyn Sapphire / Haemocue	BSC/HAEM/SOP/010 BSC/HAEM/SOP/015
	.02	Blood Film and White Cell Differential (Manual) Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils and Red Cell Morphology	Blood	Staining / Microscopy	Manual	BSC/HAEM/SOP/014
	.06	Reticulocytes	Blood	Optical Flow Cytometry/ Fluorescence	Cell Dyn Sapphire	BSC/HAEM/SOP/010
	.03	Erythrocyte Sedimentation Rate (ESR)	Blood	Kenetics of Red Cell Aggregation	Alifax Test 1	BSC/HAEM/SOP/022
	.03	Erythrocyte Sedimentation Rate (ESR)	Blood	Sedimentation	Westgren (Manual)	BSC/HAEM/SOP/020
	.41	Activated Partial Thromboplastin Time	Blood	Coagulation	Sysmex CA 1500	BSC/HAEM/SOP/030

# Scope of Accreditation

## BON SECOURS HEALTH SYSTEM LTD



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1030 HAEMATOLOGY	.41	D-Dimer	Plasma	Latex Immuno turbidimetric	Sysmex CA 1500	BSC/HAEM/SOP/030
	.41	Fibrinogen	Blood	Coagulation	Sysmex CA 1500	BSC/HAEM/SOP/030
	.41	International Normalised Ratio (INR)	Blood	Coagulation Ratio Calculation	Sysmex CA 1500	BSC/HAEM/SOP/030
	.41	Prothrombin Time (PT)	Blood	Coagulation	Sysmex CA 1500	BSC/HAEM/SOP/030
	.41	Manual Prothrombin Time (International Normalised Ratio)	Blood	Coagulation / Tube Method	Manual	BSC/HAEM/SOP/033
	.57	Epstein Barr Virus (Heterophile Antibodies)	Blood	Immunoassay	Manual	BSC/HAEM/SOP/040
	.09	Malaria Parasites Examination	Blood Film	Staining / Microscopy	Manual	BSC/HAEM/SOP/045
	.30	Sickle Cell Screen	Whole Blood	Microscopic Examination	Manual	BSC/HAEM/SOP/016
1061 GENERAL BIOCHEMISTRY	.65	Pregnancy Test	Urine	Immunoassay (Qualitative)	Manual	BSC/HAEM/SOP/048

# Scope of Accreditation

BON SECOURS HEALTH SYSTEM LTD



## Medical Testing Laboratory

Permanent Laboratory:  
Category A

### HISTOPATHOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1051 HISTOPATHOLOGY (GENERAL)	.01	Cut-up	Tissue Biopsies for Examination	Tissue description, dissection and block selection	Manual	BSC/HIS/SOP/002 BSC/HIS/SOP/110 BSC/HIS/SOP/111
	.01	Tissue Processing	Tissue Sample	Vacuum impregnation	Vacuum Impregnation Processor x 2	BSC/HIS/SOP/001 BSC/HIS/SOP/003
	.01	Embedding	Processed Tissue Sample	Manual tissue orientation in wax	Leica Embedding Console	BSC/HIS/SOP/004
	.01	Microtomy	Paraffin Embedded Tissue Sample	Cutting and selection of representative tissue sections	Leica Microtomes	BSC/HIS/SOP/005
	.01	Automated Haematoxylin/ Eosin Staining	Tissue Section	Programmed automated application of reagents	Leica Autostainer	BSC/HIS/SOP/006
	.01	Automated Immunohistochemical Tissue Staining	Programmed automated application of reagents	Programmed automated application of reagents	Ventana Immunostainer	BSC/HIS/SOP/025 BSC/HIS/SOP/026
	.01	Mounting (Cover slipping)	Stained tissue section on glass slide	Application of coverslip to stained tissue section	Meditate Pro Mounter	BSC/HIS/SOP/007
	.01	Diagnostic Breast Pathology	Breast Tissue	Gross Descriptions, Dissections and Block Selection	Manual	BSC/HIS/SOP/110 BSC/HIS/SOP/111
			Stained Tissue Section	Microscopic Examination	Manual	BSC/HIS/SOP/056 BSC/HIS/SOP/110
	.01	Diagnostic Prostate Pathology	Prostate Tissue	Gross Descriptions, Dissections and Block Selection	Manual	BSC/HIS/SOP/110 BSC/HIS/SOP/111
			Prostate Tissue	IHC-AB P504S	Ventana	BSC/HIS/SOP/110 BSC/HIS/SOP/111
			Stained Tissue Section	Microscopic Examination	Manual	BSC/HIS/SOP/098 BSC/HIS/SOP/110 BSC/HIS/SOP/111

# Scope of Accreditation

BON SECOURS HEALTH SYSTEM LTD



Medical Testing Laboratory

Permanent Laboratory:  
Category A

## HISTOPATHOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1051 HISTOPATHOLOGY  AUTOMATED IMMUNO HISTOCHEMICAL TISSUE STAINING	.03	CD4	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD5	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD8	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD10	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD15	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD20	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD23	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD30	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD31	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD34	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD43	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD45 (LCA)	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD 68	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD79A	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD 117	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CD 138	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CEA	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Chromagranin A	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CKAE1/AE3	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CK7	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
.03	CK20	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025	

# Scope of Accreditation

BON SECOURS HEALTH SYSTEM LTD



Medical Testing Laboratory

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Category A

## HISTOPATHOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1051 HISTOPATHOLOGY  AUTOMATED IMMUNO HISTOCHEMICAL TISSUE STAINING	.03	CKMNF116	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	CK903	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Cyclin D1	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Desmin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	EMA	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	HercepTest™ Dakocytomation	Tissue Section	Ag/Ab reaction	Manual	BSC/HIS/SOP/027
	.03	HMB45	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Kappa	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Lambda	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	NSE	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Oestrogen receptor (ER)	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Progesterone receptor (PR)	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Prostate Specific Antigen (PSA)	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	S100	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Synaptophysin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	TTF-1	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
	.03	Vimentin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025
.03	Wt-1	Tissue Section	Ag/Ab reaction	Ventana Benchmark	BSC/HIS/SOP/025	

# Scope of Accreditation

BON SECOURS HEALTH SYSTEM LTD



Medical Testing Laboratory

Permanent Laboratory:  
Category A

## HISTOPATHOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1051 HISTOPATHOLOGY SPECIAL STAINS	.01	Alician Blue	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Alican Blue / PAS	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Congo Red	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Elastin Van Gieson	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Giemsa	Tissue Section	Programmed application of reagents	Leica Autostainer	BSC/HIS/SOP/006
	.01	Gordon and Sweets	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Gram Stain	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Grocott's	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Haematoxylin Van Gieson (HVG)	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Martius Scarlet Blue (MSB)	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Masson Fontana	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Masson Trichrome	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Oil Red O	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	PAS	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	PAS-D	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Perls Prussian Blue	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
	.01	Toluidine Blue	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020
.01	Ziehl Neelsen	Tissue Section	Application of Reagents	Manual	BSC/HIS/SOP/020	

# Scope of Accreditation

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1040 IMMUNOLOGY	.12	Anti Nuclear Antibody (ANA)	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/061
	.12	Anti Endomysial Antibodies	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/071
	.12	Anti tTg IgA Antibodies	Serum	Enzyme Immuno Assay	Triturus Analyser	BSC/HIS/SOP/070
	.10	Cyclic Citrullinated Peptide Antibodies (CCP)	Blood	Fluoro enzyme Immuno assay	Immunocap 250 Analyser	BSC/HIS/SOP/072
	.12	DNA Ab	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/062
	.12	ENA Screen (Extractable Nuclear Antibodies)	Serum	Enzyme Immuno Assay	Triturus Analyser	BSC/HIS/SOP/070
	.12	ENA Profile (Extractable Nuclear Antibodies)	Serum	Enzyme Immuno Assay	Triturus Analyser	BSC/HIS/SOP/070
	.12	Gastric Parietal Ab	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/061
	.12	Mitochondrial Ab	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/061
	.12	Anti LKM Ab (Liver Kidney Microsomal Ab)	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/061
	.12	Smooth Muscle Ab	Serum	Indirect Immuno fluorescence	Manual	BSC/HIS/SOP/061

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**MICROBIOLOGY DEPARTMENT**

INAB Classification Number (P9)		Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1015 MYCO BACTERIOLOGY	.01	AFB CULTURE	Swabs Bone Marrow Bronchial Lavage/ Brushings Other body fluids Pus Pleural Fluid Sputum Tissue Urine (Early morning)	Microscopy Culture (BacT Alert 3D System)	BacT Alert 3D System	BSC/MIC/SOP/081
	.02					
1011 BACTERIOLOGY	.01	BLOOD CULTURE	Blood	BacT Alert Blood Culture instrument Microscopy Culture Sensitivity	BacT Alert 3D System	BSC/MIC/SOP/101
	.03					
	.04					
	.01	BRONCHIAL LAVAGE CULTURE	Bronchial Lavage Bronchial Aspirate Bronchial Brushings Bronchial Washings Bronchoalveolar Lavage Transthoracic Aspirate Transtracheal Aspirate	Culture/ Sensitivity Microscopy (if required)	Manual	BSC/MIC/SOP/041
	.02					
	.03					
	.04					
	.01	CSF CULTURE	CSF	Culture/ Sensitivity Microscopy	Manual	BSC/MIC/SOP/102
	.02					
	.03					
	.04					
	.01	FLUID CULTURES	Amniotic Fluid Ascitic Fluid Bursa Fluid Pericardial Fluid Peritoneal Fluid Pleural Fluid Synovial Fluid	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/052
	.02					
	.03					
	.04					

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#### MICROBIOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.01 .03	Cryptosporidium stain	Faeces	Microscopy	Manual	BSC/MIC/SOP/121
	.02 .04 .06	E coli 0157	Faeces	Culture/ Sensitivity Latex for agglutination to confirm	Manual	BSC/MIC/SOP/121
	.02 .04	Faeces Culture	Faeces	Culture/ Sensitivity	Manual	BSC/MIC/SOP/121
	.01 .02 .03 .04	Cervical Culture	Cervical Swab	Culture/ Sensitivity Microscopy	Manual	BSC/MIC/SOP/048
	.02 .04	Ear Culture	Ear Swab Middle Ear Effusion	Culture/ Sensitivity	Manual	BSC/MIC/SOP/046
	.01 .02 .03 .04	Eye Culture	Eye Swab Canalicular Pus	Microscopy if Required Culture/ Sensitivity	Manual	BSC/MIC/SOP/047
	.01 .02 .03 .04	High Vaginal Culture	High Vaginal Swab (HVS) Vaginal Discharge Vulval Swab Labial Swab	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/048
	.01 .02 .03 .04	Low Vaginal Culture	Low Vaginal Swab	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/048
	.01 .02 .03 .04	Mouth Culture	Mouth Swab	Culture/ Sensitivity Microscopy if requested	Manual	BSC/MIC/SOP/042
	.02 .04	MRSA Screen	Nasal, Throat, Axilla, Groin, Perineum and other sites depending on clinical information	Culture/ Sensitivity	Manual	BSC/MIC/SOP/031
	.02 .04	Nasal Culture	Nasal Swab	Culture/ Sensitivity	Manual	BSC/MIC/SOP/043

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.01 .02 .03 .04	Penile Culture	Penile Swab	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/048
	.02 .04	Throat Culture	Throat Swab	Culture/ Sensitivity	Manual	BSC/MIC/SOP/045
	.02 .04	Ulcer Culture	Ulcer Swab	Culture/ Sensitivity	Manual	BSC/MIC/SOP/050
	.01 .02 .03 .04	Urethral Culture	Urethral Swab	Culture/ Sensitivity Microscopy	Manual	BSC/MIC/SOP/048
	.02 .04	Urethral Culture	Urethral Swab	Culture/ Sensitivity Microscopy	Manual	BSC/MIC/SOP/048
	.02 .04	VRE culture	Faeces/ Rectal Swab	Culture/ Sensitivity	Manual	BSC/MIC/SOP/032
	.01 .02 .03 .04	Sputum Culture	Aspirate Endotracheal Tube Sputum	Culture/ Sensitivity Microscopy if required	Manual	BSC/MIC/SOP/041
	.02 .04	Tip Culture	CVP or Hickman lines cannula associated swabs	Culture/ Sensitivity	Manual	BSC/MIC/SOP/049
	.01 .02 .03 .04	Tissue Culture	Tissue Biopsy	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/053
	.02 .03 .04	Urine Culture	BAG CATCH CSU MSU SUPRA PUBIC	Microscopy Culture/ Sensitivity	Manual	BSC/MIC/SOP/021
	.01 .02 .03 .04	Wound Culture	Exudates Pus Swabs	Microscopy if required Culture/ Sensitivity	Manual	BSC/MIC/SOP/050 BSC/MIC/SOP/051
1012 PARASITOLOGY	.02	Ova, Cysts & Parasites	Faeces	Microscopy	Manual	BSC/MIC/SOP/121

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#### MICROBIOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1014 MYCOLOGY .01 .02 .04 .05	Mycology Culture	Hair Samples Nail Clippings Nail Scrapings Skin Scrapings	Microscopy and Culture	Manual	BSC/MIC/SOP/061
1016 SEROLOGY	.02 Anti Streptolysin O Titre	Serum	Immuno Assay Agglutination	Manual	BSC/MIC/SOP/201
	.02 C difficile toxin A vidas test	Faeces	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 CMV IgM	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 Hepatitis A IgM	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 Hepatitis B Surface Antigen (HBsAg)	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 Hepatitis B Surface Antigen (HBsAg)	Serum	Micro particle Enzyme Immuno assay (MEIA)	Abbott Axsym	BSC/MIC/SOP/208
	.02 Hepatitis B Surface Antibodies	Serum	Enzyme immuno assay	Abbott Axsym	BSC/MIC/SOP/204
	.02 Hepatitis B Core Antibodies	Serum	Micro particle Enzyme Immuno assay (MEIA)	Abbott Axsym	BSC/MIC/SOP/209
	.02 Hepatitis B Core Antibodies	Serum	Enzyme Immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 HIV 1/ 2 Ag/ Ab Duo	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02 HIV 1/2 Ag/Ab Combo	Serum	Micro particle Enzyme Immuno assay (MEIA)	Abbott Axsym	BSC/MIC/SOP207

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1016 SEROLOGY	.02	Rubella IgG (immunity)	Serum	Enzyme immuno assay	Abbott Axsym	BSC/MIC/SOP/203
	.02	Rubella IgM	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02	Syphilis RPR Test	Serum	Antigen\ antibody reaction	Manual	BSC/MIC/SOP/201
	.02	Syphilis TPHA Test	Serum	Haema glutination test	Manual	BSC/MIC/SOP/201
	.02	Toxoplasma IgM	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200
	.02	Varicella Zoster Ig G AbS	Serum	Enzyme immuno assay	VIDAS	BSC/MIC/SOP/200