

PATHOLOGY SERVICE USER MANAUAL Policy ☐ SOP ☒ Guidelines ☐ Programme ☐	
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Author & Title:	Lyndsey O’Neill - Laboratory QA Manager Gemma Acton - Laboratory Manager
Owner & Title:	Lyndsey O’Neill – Laboratory Quality Manager
Approved By & Title:	Dr Lilian Rajan- Clinical Director Gemma Acton – Laboratory Manager Lyndsey O’Neill – Laboratory Quality Manager
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SUMMARY OF CHANGES (from previous version)			
Version/ Revision	Effective Date	Changes (list sections changes)	Change Author
19	20/08/2026	Section 11.3 states "1. The Blood Transfusion Request Form must be completed as defined in section 3 of this document." Should refer to section 8 Section 11.1 refers to section 4.3 instead of section 8.	Patten, Aoife (BSD)
19	20/08/2026	TPO is now sent to Cork. 4.9 ml of serum is required and TAT is 5 days	Morrissey, Sinead (BSD)
19	20/08/2026	Need to revise the tests available in Biochemistry - have added Vit D, Transferrin and will be adding Gents and Vancs	Byrne, Sally (BSD)
19	20/08/2026	Section 8.3 Specimen collection: "Check Patient's Medical Record Number (MRN) is on request form with the wristband" reword to include PID check for Maxims orders also	Hoyne, Andrea (BSD)
19	20/08/2026	Reference BSD/POCT/GDE/001 Point of Care Testing (POCT) Service User Manual	Kelly, Jessica (BSD)
19	20/08/2026	Update Microbiology section in table of contacts for advisory services	Morrissey, Sinead (BSD)

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1 POLICY STATEMENT

This policy statement is a reaffirmation of our commitment to a high level of ethical conduct and standards in conjunction with the Mission and Values of the Bon Secours Health System.

2 PURPOSE

The purpose of this policy and procedure is to give an overview of the services available in the Pathology Department. It is intended as a reference guide for all Pathology Service users including patients.

All Pathology services undergo continuous review through quality assurance and audit activities. The laboratory is committed to performing its activities to the highest standard and is accredited by JCI (Joint Commission International) as part of the overall Hospital accreditation process

In addition, Blood Transfusion, Haematology and Microbiology laboratories are accredited to the international standard ISO15189:2022 (registration number 201MT) and compliant with articles 14 and 15 of EU Blood Directive 2002/98/EC. The most up to date scope of accreditation can be found at : <https://inab.ie/inab-directory/laboratory-accreditation/medical-testing-laboratories/bon-secours-health-system-clg-t-a-bon-secours-hospital-dublin.html>

Clinical Chemistry, Histopathology and Point of Care analysis are currently outside the scope of INAB accreditation. Any tests not accredited to the ISO 15189 standard and not covered under the scope of INAB are clearly identified in both the user manual and on the test reports. This does not affect the validity of the results but accreditation by INAB provides organisations and their customers with confidence in the product or service being offered.

This manual is intended for users of the Pathology Services both within the Hospital and those from outside agencies.

Laboratory management are committed to:

- Provision of a patient centred diagnostic Pathology Service where all patient specimens are treated with due care and respect.

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- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.
- The use of accredited examination procedures and methods that will ensure the highest achievable quality of all tests performed.
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement. The Pathology Department participates in relevant available external third-party assessment schemes. This includes schemes operated by:
 - NEQAS (UK, National External Quality Assurance Scheme)
 - IEQAS (Irish External Quality Assurance Scheme)
 - Histopathology National Quality Improvement Programme (NQIPH).
- The Pathology Department is committed to participating in other schemes as they become available and are required to ensure comprehensive assessment of the test repertoire

3 SCOPE

This policy and procedure are relevant to all Pathology Users (Healthcare Professionals and Patients).

3.1 For Healthcare Professionals (Pathology Users)

For internal users, an electronic version of the current revision of the manual is available on the Hospital Intranet and on Q-Pulse. In addition, a copy of the manual is also posted on the hospital website under the Pathology Department information section. -

<https://www.bonsecours.ie/services/pathology>

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Revision changes are identified on the cover page under the 'Summary of Changes' section and within the document by highlighting in grey the changed sections. Updated revisions are emailed to users upon publication.

The information provided in this User Manual is correct at the time of writing and is a broad guideline to the service provided. The manual will be updated periodically; therefore, any unauthorised printed copies are uncontrolled and must not be used as the information may be incorrect.

The Bon Secours Hospital Dublin does not provide a Paediatric Service. The scope of service offered by the hospital is outlined in Bookings/Admissions Policy BSD-ADM 01

3.2 For Patients

All patient samples received in the Laboratory are treated with due care and respect. All Laboratory processes are undertaken in a way which is free from discrimination as per BSD-ORG 69 Protection and Advancement of Patient and Family Rights Policy.

This manual contains information on the following:

- Location of the Laboratory, operating hours and contact information
- Instructions for Patient Collected Samples
- A full list of tests provided and associated turnaround times are listed in accompanying document BSD/PATH/I/111. Please note that turnaround times are defined from the time the sample is received in the Laboratory to the time that results are issued to the Requesting Clinician.
- Consent process
- Confidentiality, protection of personal information and release of confidential information when required by law or authorised by contractual arrangements-
- Feedback process

Additional information for patients is available in the Patient Handbook which is available on the Hospital website <https://www.bonsecours.ie/patients/patient-handbooks>.

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The laboratory is committed to investigating all patient incidents that result in harm or could have resulted in patient harm. These are recorded as non-conformances on Q-Pulse as per BSD/QA/SOP/026 Management of Non-Conformances in the Pathology Department. This record consists of the summary of the incident, clinical significance and corrective actions. The Requesting Clinician is informed where appropriate. Open disclosure to the patient is the responsibility of the Responsible Clinician as per BSHS-QS-PP-24 (Open Disclosure Policy).

3.3 User Satisfaction, Comments and complaints

3.3.1 Comments and Complaints

The goal of Laboratory Medicine is to ensure that our users receive accurate, reliable, meaningful and timely laboratory results. It is your right as a service user to make a complaint if you believe that standards of care, treatment or practice fall short of what is acceptable. If you need to make a complaint, we want the process to be easy, effective and fair. In order to help you to do so please contact the appropriate Department, the Laboratory Manager or the Quality Manager (refer to table 1 for contact details) and ask for their complaint/suggestion to be documented or via the hospital website <https://www.bonsecours.ie/patients/patient-feedback-and-complaints>

Every effort shall be made to ensure effective resolution of client complaints in a timely fashion as per BSD/QA/SOP/028 Reporting and management of feedback and complaints.

3.3.2 User Satisfaction Surveys

The Pathology Department performs regular surveys of user satisfaction. The aim of the user satisfaction survey is to achieve continuous improvement in all aspects of the Pathology Department resulting in improved clinical effectiveness. We would encourage you to partake in these surveys so that our service can reflect your views. Results of user surveys are reviewed and if deemed appropriate, quality improvements may be implemented based on the information provided by the user.

3.4 Costs

The costs of tests can be provided at user's request.

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4 ASSOCIATED DOCUMENTS AND LEGISLATION

This policy and procedure have been developed with reference to ISO 15189:2022 Requirements for Quality and Competency, Joint Commission International (JCI) Accreditation Standards for Hospitals (8th Edition) and Health Information and Quality Authority (HIQA) National Standards for Safer Better Healthcare (Sept 2024).

4.1 Associated Documents

All pathology documents relate back to this procedure and can be found on Q-Pulse
BSD/PATH/I/111 "Table of all Tests"
BSD/PATH/I/093 "Blood Sciences Referral List"
BSD/HAEM/I/018 "Instruction for Haematology Referral Tests"
BSD/MICRO/I/002 "Microbiology Referral test list"
BSD/POCT/GDE/001 POCT User Guide

4.2 Data protection

The Bon Secours Health System is registered with the Data Commissioner in Ireland to capture and process patient information. The laboratory complies with the policy of the Bon Secours Health System relating to the legal rights of patients and staff and acts in an ethical and responsible manner in maintaining the security, confidentiality and integrity of all personal data and information.

All staff in the course of their duties may be in possession of confidential information/materials. Personal information will be collected from patients in the course of collecting samples and will usually include Name, Date of Birth and Address. The information collected is used to positively identify patients and to provide a link between historical samples.

All staff are bound by the following documents:

- BSHS-GDPR-PP-01 Data Protection and Personal Data Security Policy
- BSHS-GDPR-PP-03 Personal Data Subject Rights Policy
- BSHS-GDPR-PP-08 Personal Data Breach Management Policy
- BSHS-GDPR-PP-10 External Communications of Personal Data.

These documents provide a guide to clinical, administrative and IT staff on the implementation and operation of data protection where Bon Secours staff interact with

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patients. Staff must not disclose such information to unauthorised personnel. A breach of confidentiality is classed as gross misconduct and is subject to the invocation of the hospital disciplinary procedure.

Pathology results are issued to the Requesting Clinician as per “Reporting of Results” section of this manual . Under General Data Protection Regulations, relevant information can be made available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf Patients may request access to this information. Please visit <https://www.bonsecours.ie/data-protection-and-privacy> for further information on Data Subject Access Requests.

In certain circumstances, such as sample/report referral, data extracts to the National Cancer Registry, as required by law or court order, reporting of notifiable diseases etc., patient details/results may be disclosed to outside agencies or external bodies. This does not constitute a breach in confidentiality

4.3 Health and Safety

The Pathology department complies with national legislation regarding health and safety in the workplace. Pathology health and safety procedures are laid out in the Pathology Safety Manual BSD/PATH/SM/001 which also documents procedures for the management of health and safety in the laboratory.

To protect our staff, all patient specimens are treated as potentially infectious and appropriate personal protective equipment is used.

4.4 Quality Assurance

The department is committed to providing a high-quality service with the minimum of delay to meet the needs and requirements of our users. To ensure a high-quality service, all departments have extensive internal quality control checks and participate in recognised External Quality Assessment Schemes. The Department of Pathology services undergo continuous review through quality assurance and audit activities.

The department is committed to performing activities in accordance with the requirements of the international standard ISO15189:2022 whereby the accreditation certificate is provided by the Irish National Accreditation Board (INAB), registration number 201MT.

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Further details on INAB and its role in quality assurance and accreditation can be found at <http://www.inab.ie/>

Any tests not accredited to the ISO 15189 standard and not covered under the scope of INAB are clearly identified in both the user manual and on the test reports. This does not affect the validity of the results but accreditation by INAB provides organisations and their customers with confidence in the product or service being offered. Should you, as the user of the Pathology Service, have any queries for improvements in connection with any aspect of the service provided, staff members will be pleased to discuss these with you or alternately submit your comments/ suggestions in writing to the Laboratory Manager or Laboratory Quality Manager.

5 ROLES AND RESPONSIBILITIES

5.1 Laboratory Director

The Laboratory Manager and the Pathology Clinical Director are responsible for authorising this procedure and future revisions.

5.2 QA Manager

It is the responsibility of the Laboratory Quality Assurance Manager to ensure that this manual meets the requirements of ISO 15189:2022, JCI 8th Edition Standards and HIQA standards.

5.3 Chief Medical Scientist, Departmental Senior Scientist, Senior Phlebotomist

It is the responsibility of the Head of Department- Chief Medical Scientist/Senior Medical Scientist/Senior Phlebotomist- to review this procedure and ensure it contains accurate information for their department.

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5.4 All Pathology Staff

It is the responsibility of all Pathology Staff to adhere to this procedure

5.5 Clinical Staff (Nursing and Medical)

It is the responsibility of all clinical staff to adhere to this procedure for the collection and transport of pathology samples to the laboratory.

6 ABBREVIATIONS AND KEY DEFINITIONS

HIQA	Health Information Quality Authority
IBTS	Irish Blood Transfusion Service
INAB	Irish National Accreditation Body
JCI	Joint Commission International
POCT	Point of Care Testing

7 GENERAL INFORMATION

7.1 Location of the Pathology Department

The Pathology Department is located on the third floor of St Anthony's wing. Follow the signs from the main Hospital reception.

Pathology Office: Second Floor, St. Anthony's Wing, Bon Secours Hospital, Glasnevin

Phlebotomy: Ground Floor, Bon Secours Hospital, Glasnevin,

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7.2 Pathology Department Opening Times

Area	Opening hours		Sample receipt cut off
Phlebotomy service for inpatients	Monday to Friday Saturday Sunday	07:00 – 16:30 08:00-11:00 No Service	16:15
Phlebotomy service for outpatients	Monday to Friday Saturday Sunday	08:30 – 15:30 No service No service	15:00
Blood Sciences & Microbiology	Monday to Friday Saturday Sunday	08:30 – 16:30 09:00 – 12:30 No service	16:00 12:00
Histopathology	Monday to Friday Saturday/Sunday	08:00 – 16:30 No Routine Service	15:30*
Pathology Office	Monday to Friday Saturday/Sunday	08:00-17:00 No service	
On-call service	An emergency 'on-call' system operates outside normal hours. Note out of hours emergency service is not available in Histology		
<i>* Please contact Histopathology laboratory for urgent queries in relation to sample cut off.</i>			

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7.3 Routine Enquiries

Hospital Reception	01 - 8065300
Laboratory Area	Extension ((01)806-xxxx)
Pathology Office: all result and report enquiries	5320, 4718. 5166
Phlebotomy	5347
Clinical Chemistry	5319
Blood Transfusion	5461
Haematology	5324
Histopathology (and to book a frozen section)	5341
Microbiology	5459, 5463
Laboratory Manager	5308
Hemovigilance Officer	5445
Laboratory Quality Assurance Manager	5683
Infection Control	5386, Bleep 5529
Medical Scientist on-call	087-2513101 or via Hospital reception
Consultant Microbiologists: Dr Lilian Rajan	5369 or via hospital reception
Consultant Histopathologists: Dr David Delaney, Dr Christian Gulmann, Dr Sarah Mahon	Contact available via Histopathology Lab on 5341
Consultant Chemical Pathologist: Dr Mike Louw	Contact via Hospital Reception
Consultant Haematologists: Prof. Patrick Thornton, Prof. Siobhan Glavey, Dr John Quinn, Dr Philip Murphy	Contact details available on request to 5324 or via Hospital Reception

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7.4 Clinical advisory Services Service

The Pathology Department ensures appropriate laboratory advice and interpretation. Clinical Advice and Interpretation is available and can be obtained by contacting the appropriate laboratory or Consultant Pathologist. Scientific staff should be consulted where uncertainty exists about the availability, appropriateness, or selection of tests, the nature of the specimen required, acceptance criteria of the test, or the interpretation of results. Refer to table above for Contact Details of Key Laboratory Personnel.

7.5 Point of Care Testing (POCT)

The Hospital offers a point of care testing service. Full details of the service are described in BSD/POCT/GDE/001 Point of Care User Guide.

7.6 On-Call Service

- The laboratory operates an off-site on-call service for Blood Sciences and Microbiology outside of routine working hours. The Medical Scientist may take up to 30 minutes to arrive in the hospital therefore it is important to contact the medical scientist on call prior to drawing or sending an urgent request. *

*Time sensitive samples such as arterial blood gases or lactate should not be taken until the Medical Scientist has arrived in the laboratory to ensure specimen integrity.

7.5.1 On-call contact details

Contact	Number
Medical Scientist	087-2513101 or via Hospital reception
Consultant Advisory Services out of hours	Contact numbers available via hospital reception/ Medical Scientist as above

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7.5.2 Tests available out of hours

An on-call system operates outside normal working hours for emergency work i.e. non-deferrable tests necessary for decisions regarding patient management. The following test repertoire is available outside of routine hours.

Blood Transfusion

It is hospital policy to avoid routine transfusions out of hours. The out of hours transfusion service provided only applies to emergencies and to situations where patients cannot wait until the next routine period.

Clinical Chemistry

- Renal profile
- Liver profile
- Bone profile
- Creatinine Kinase
- Glucose
- Amylase
- CRP
- Troponin I
- NT-proBNP
- Blood Gases
- Lactate
- CSF analysis
- Gentamicin
- Vancomycin
- Immunoassays if deemed urgent

Haematology

During on call periods the following tests are routinely available:

- FBC
- Coagulation Screen/ INR
- Fibrinogen Assay/D Dimers
- ESR, (the Haematology on call medical scientist must be contacted by phone if the ESR is specifically for Temporal Arteritis and Osteomyelitis.)

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Microbiology

The Microbiology laboratory provides a limited out of hours on call test service:

- C. Difficile toxin
- Positive blood culture
- SARS-CoV-2, Flu A & B, RSV
- Antibiotic referral
- Referral of Occupational Blood Exposure
- Please inform the medical scientist on-call if any of the above tests are to be performed.
- **CSF-All CSF requests must be phoned to the Medical Scientist on-call prior to sending out of hours.**

The on-call scientist mobile number is **087 2513101**

Clinical microbiology advice is also available out of hours, contact Main Switchboard for contact details of Consultant Microbiologist.

7.7 Consent

All procedures – including phlebotomy - require the informed consent of the patient as described in BSD-ORG 16- Informed Consent policy for most routine procedures, consent can be inferred when the patient presents with a request form and agrees to a collection procedure such as venipuncture. Patients in a hospital bed should normally be afforded the opportunity to refuse.

Special procedures including invasive procedures or those with an increased risk of complications need a more detailed explanation and, in some cases, signed consent.

In emergency situations, consent might not be possible in which case it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

For a number of tests, specific consent forms are required, primarily genetic tests. Where consent forms are required to be completed, these are described in the test requirements listed in accompanying document BSD/PATH/I/111Consent for blood transfusion is described in the Blood Transfusion AND Haemovigilance section of this user manual.

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7.7.1 Patient information and signed consent for Blood Transfusion

1. The Clinical Ethics Committee has issued guidelines on obtaining informed consent including for the transfusion of blood. BSD-ORG-16 These Guidelines are on Q-Pulse. Under Joint Commission International (JCI) Accreditation Standards for Hospitals, informed consent is required before use of blood components or products.
2. Signed consent is required for transfusion for all patients capable of giving it. The provision of information is central to the consent process. For fully informed consent, the patient must receive verbal and written information on the indication for transfusion, the risks and benefits of transfusion and any alternatives available. The consent form signed by the clinician and patient is included in page 2 of the Blood Transfusion Booklet BSD-MR/F/22b/01. The patient information leaflet entitled '*Blood Transfusion Information for Patients*' (BSD/HV/I/006) should be given to all patients when consent is being obtained for transfusion. Where a transfusion occurs during a surgical procedure in theatre, the leaflet must be provided to the patient following surgery.
3. If English is not the patient's first language or where there are communication difficulties every effort will be made to communicate effectively with the patient. (Refer to BSD-ORG 14 titled 'Patient Identification')

Phlebotomy services

The Phlebotomy department operates the following schedule for inpatients.

Morning Phlebotomy Round	
Areas covered	All wards
Time	8am- 11am
Urgent Add-On Tests	11am-12pm
Afternoon Phlebotomy Round - to include all routine Add-On Tests.	
Areas Covered	All wards & DOSA
Time	2pm - 4pm

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Endoscopy	
Morning Round	11am-12.30pm
Afternoon Round	2.30pm-4pm.

Inpatients:

All blood samples should be completed via Maxims Ordercoms system. Alternatively complete the request form and place it in the designated blood request box at the nursing station on the ward. In the interest of patient safety and efficacy of the service provided by the laboratory, users are requested to avoid unnecessary repeat testing. This can be achieved by checking the maxims system prior to placing an order. Requests for tests may only be initiated by, or on behalf of, a requesting clinician.

Outpatients

Outpatient bookings are made through the SwiftQue booking system which is accessible on the hospital website. A referral letter from the patient's doctor is required

Fasting for 8-12 hours is required for fasting bloods (e.g., lipid profile, glucose)

Outpatients must be registered by the Outpatients Registration team before proceeding to Phlebotomy

Urgent requests during working hours: call the Phlebotomy staff on 5347.

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7.7.2 Add on and repeat testing

Blood Sciences and Microbiology

The laboratory should be contacted in the first instance for all add on tests. Once the laboratory has confirmed testing is possible, a completed request form must then be sent to the laboratory. Urgent verbal request will be processed on the understanding that a completed request form will follow. Results of specimens processed without a request form will not be released from the laboratory until a completed request form is received.

Histopathology

Requests for add on testing can be verbal (initially) or written. All requests are retained in Histopathology as per standard operating procedure.

7.8 Sample stability and Specimen Retention

All samples should be received into the Laboratory on the same day that they were taken. Failure to do this may render the sample unsuitable for analysis (for example potassium, FBC). In some circumstances, there is a requirement for the sample to be received within a shorter timeframe, and additional collection criteria may apply (such as transporting on ice). Storage of samples in the fridge will also render some tests unsuitable (for example QuantiFERON samples). Please ensure all samples are sent to the lab on the day of collection. Refer to Test Requirements listed in BSD/PATH/I/111 Table of tests. Specimens are retained within the laboratory according to the following table. Should additional testing be required, please contact the laboratory for advice on suitability.

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ID	Specimen description	Storage requirement	Minimum retention period of primary specimen
1.	Serum, plasma	As prescribed by test method	**48 hours after release of report
2.	Whole blood		**24 hours after release of report
3.	Body fluids/ aspirates	2-8 °C	**48 hours after release of report
	Urines for Microbiology	2-8 °C	72 hours
4.	Microbiological swabs (incl. NPS), faeces, sputa, BALs	2-8 °C	5 days
5.	24-hour urine specimens Spot urine specimens	18°C – 25°C	2-3 days
6.	Stained slides -Microbiological -Blood Films -Bone marrow smears -Cytology -Histopathology		7 days post report Microbiology slides: 1 week Minimum 10 years
7.	Surgical specimens with residual tissue	Formalin fixative 18°C – 25°C	4 weeks post authorised report
8.	Surgical specimens without residual tissue		Minimum of 3 weeks
9.	Mycology samples	2-8°C	3-4 weeks
10.	Paraffin blocks	18°C – 25°C	At least 30 years
11.	Cytology specimens	2-8 °C	4 weeks post authorised report
12.	Whole Blood for Grouping, antibody screening and/ or crossmatching	2-8 °C	7 days *

** Guidelines for the timing of sample collection prior to blood transfusion must be followed. Refer to Section 7(below) for further details.*

***Where Clinical Chemistry samples are also used for Referral Laboratories it is not always possible to retain any part of the primary sample.*

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8 SAMPLE ACCEPTANCE

Please note samples requested from Online GP's will only be accepted where full contact details are available for the communication of critical results.

The laboratory has a policy on acceptance and rejection of specimens BSD/PATH/SOP/007. The purpose of the policy is to ensure:

- Uniformity of requirements across all disciplines within the laboratory in line with INAB and ISO 15189 Standards.
- Information on both the Request Form and the corresponding clinical specimen is sufficient to unambiguously link the two together to ensure the correct results/products are issued to the correct patient.
- Information is legible and written in pen
- The Laboratory receives adequate information on the Request Form to permit correct analysis and interpretation of results such as clinical information relevant to affecting sample collection, examination performance or result interpretation e.g. medication history, travel history for Ova and parasite results
- The Laboratory records accurate and complete patient and specimen identification for each request received

Requests for laboratory testing may be electronic using the MAXIMS ordering system or in hard copy format.

8.1 Hard copy Request forms

There are a number of different request forms used for different analyses as outlined in the table below. A completed request form must accompany all samples. Please use the correct request form for the appropriate department/s as outlined below. **Requests made on unapproved forms will not be processed.**

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Request area	Form title	Form reference
Blood Transfusion	Blood Transfusion	BSD-BT/RF
Haematology, Coagulation, Clinical Chemistry, Immunology referrals, and tests referred to external laboratories	Blood Sciences	BSD-BS/RF 01
Microbiology tests, including antibiotic levels and serology TB tests	Microbiology	BSD-MM/RF 02
Histopathology/ Non-Gynaecological Cytopathology	Histopathology	HIST/RF 01
Cervical Cytology	Histopathology	PATH-RQ-FRM-9

Specific request forms must accompany referral tests including Specialist coagulation, Cytogenetics, Immunophenotyping, TB culture, QuantiFERON requests and Cancer Molecular Diagnostic testing. Copies of these forms are available from specimen reception.

The use of patient addressograph labels on request forms is recommended. Specimens cannot be processed unless the request form is completed in full.

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Minimum Acceptance Criteria for Specimens accompanied by a Request Form

	Essential Information	Desirable Information
Specimen:	Patient's full name- Mandatory	Date and time of Specimen collection
	Date of birth and or MRN - Mandatory	Signature of person taking the specimen
Request Form:	Patient's full name- Mandatory	Examination required
	Date of birth and or MRN- Mandatory	Specimen type and where relevant anatomic site of origin * *Mandatory for Microbiology and Histopathology requests
	Name of requesting GP/Destination for report- Mandatory	Clinical details
		Date and time of sample collection* * For Dynamic Function tests or other tests where timing of samples is critical this must be recorded.
		Patient's address

***Please note the patient's details must be handwritten on the specimen bottle(s) for Blood Transfusion.**

*****If a specimen is urgent, please indicate on the request form or contact the relevant department and the request will be prioritised . Overuse of the urgent service will adversely affect the turnaround time for all urgent tests.***

******* If additional copies are required by a secondary consultant, this should be clearly marked on the request form.

Where amendment/ clarification is needed (e.g., missing clinical details, test requirements), this may be established and documented by laboratory staff prior to testing. Records of forms that are incomplete are retained in the laboratory.

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8.2 Order Comms/Maxims

The Bon Secours Hospital uses the Maxims (Order Comms) software to electronically order tests for diagnostic Pathology.

Tests for the for the following disciplines can be ordered through maxims:

- Clinical Chemistry
- Haematology
- Microbiology
- Referred Tests

Refer to document BSD-DIS/SOP/002 on Q-pulse for instructions on how to order tests through Maxims. Accessing results on Maxims (Order Comms)

Once set up the User will have a username and password for Maxims.

Maxims can be accessed through the Bons Secours Homepage through a web browser. Select Maxims from the list at the top of the page.

Table: Minimum Acceptance Criteria for OCM labelled specimens

	Essential Information	Desirable Information
OCM Bar-Coded Specimen:	Intact label to include: Patient's full name Date of birth Medical Record Number Gender Destination for report Test Request	Relevant information e.g. clinical details Date and time of sample collection Identification of collector

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8.3 Specimen Collection

It is the responsibility of the person taking the sample (doctor, nurse or phlebotomist) to ensure the laboratory is provided with complete and accurate patient identification details on both the sample request form/Ordercoms request and specimen container.

In addition they must:

- Explain procedure and rationale to patient answering any questions, thus ensuring an informed verbal consent is obtained.
- Ensure that all appropriate sterile equipment is within date and all packaging is intact
- Complete positive patient identification as described below.
- Check Patient's Medical Record Number (MRN) is on request form/electronic order against the wristband
- Confirm that any special patient requirements are fulfilled i.e. Patient is fasting if required.
- Take samples into the appropriate specimen containers for the test required
- If there is a requirement for separating or dividing from the primary sample, all aliquots should be labelled as per minimum acceptance criteria policy described above.
- Ensure that sufficient specimens are collected (check with laboratory if in doubt)
- Dispose of all needles into sharps bins when finished sampling.
- Dispose of all contaminated material into biohazard bins.
- Label the specimen container as described in the table below
- Ensure the form is properly completed.
- The identity of the person collecting the sample should be stated on the request form.

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1. Patient's full name (as it is written on the identity band/ patients' chart)	
2. Date of birth	
3. Hospital number	BSH hospital number for all in-patients / day patients. Hospital number is mandatory on all Blood Transfusion specimens
4. Date and time (if appropriate to the test) of specimen collection	Mandatory for Blood Transfusion. Date mandatory for Histopathology
5. The identity of the person collecting the specimen	The signature of the person collecting Blood Transfusion specimens is mandatory Initials are required on blood specimens for Clinical Chemistry and Haematology and on blood cultures for Microbiology
6. Specimen type and/ or site of origin (anatomical site)	Where appropriate .Mandatory for Histopathology and Microbiology samples.

Patient Identification (PID) labels may be used for all specimens except for Blood Transfusion

Please note samples will not be accepted by Phlebotomy without a requesting clinician on the form.

8.3.1 Positive patient identification

Positive patient identification is completed as per BSD/PHLE/SOP/001 and BSD/PHLE/SOP/003. All in-patients must be wearing a Bon Secours Hospital Identity Band. Outpatients presenting to phlebotomy shall have their identification confirmed to the request form addressograph label by verification of first name, surname, DOB and address.

If the patient is unable to positively identify himself/herself (e.g., unconscious, confused, cannot understand etc.) the person taking the specimen must verify the identity of the patient with another person who is familiar with the patient, e.g., nurse or relative.

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8.4 Special requirements for Blood Transfusion

The Blood Transfusion Laboratory operates a zero-tolerance policy in accepting any test request where critical identifiers are not provided on the specimen and request form. Blood Type and Antibody Screen specimens will be rejected under the following circumstances.

The specimen bottle must be handwritten. The blood transfusion request form may be handwritten, or an addressograph label may be attached.

The Blood Type and Antibody Screen Specimen and Blood Transfusion Request Form MUST contain the following matching six details:

- Patient's surname and first name, including bracketed name
- MRN
- Date of birth
- Date of specimen collection
- Time of specimen collection
- Signature name of specimen taker

Other information may be included but is not essential, however details on the patient's wristband must match exactly the patient details on addressographs from the patient chart.

If the above minimum acceptance criteria are not met, the specimen will be rejected. The clinical area will be contacted where a specimen has been rejected and a new one requested.

*In an emergency /major haemorrhage a verbal request for blood/blood products from a doctor/consultant will be accepted and the form must be signed after the event by the same doctor/consultant.

Whoever signs the request form for cross matched blood is responsible for the blood transfusion and obstetric history and for checking whether CMV negative &/or irradiated products are required.

Email requests for blood are not accepted, a request form must be completed.

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Training requirements for Blood Transfusion specimen collection: Appropriately trained nursing staff are permitted to complete a request form for a blood type and antibody screen only. Appropriately trained Doctors can complete the blood request form for cross matched blood. The hospital guidelines are as follows:

- A Nurse or Doctor can complete Section A, B and C of the request form for a blood type and antibody screen.
- A Doctor must complete Section D of the request form for all blood and blood product/crossmatch requests

Where no test has been requested on the Blood Transfusion Request form, the default test will be Type and Screen.

The clinical area may be contacted by the Medical Scientist where a crossmatch has been ticked and the component/product and number of units/doses has not been specified.

The information provided on the request form can help aide the laboratory in selection of examination methods and interpretation of results.

8.5 Sample Rejection

Samples are rejected in the following circumstances:

- Do not meet the sample labelling acceptance criteria **described above**
- Leaking specimens Illegible test requests/specimens cannot be processed by the laboratory.
- Incorrect/ Insufficient specimen for test requested
- Specimen tube out of date.
- Haemolysed, lipaemic, underfilled or otherwise unsuitable for requested test(s).
- Specimens transported or stored in inappropriate pre-examination storage conditions
- Consistency of the sample: Formed Faeces or salivary sputum.

While every effort is made to contact the source location, it is the responsibility of the ward to check the electronic record in a timely fashion. Where contact is not possible, the reason for rejection is available to view electronically.

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8.6 Guidelines for Irreplaceable Specimens

In case where minimum acceptance criteria are not met, Critical/irreproducible specimens may be processed at the discretion of a Medical Scientist. In Histopathology, each specimen is considered irreplaceable.

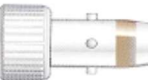
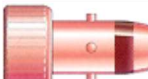
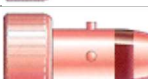
In Microbiology, irreplaceable samples include fluids, washouts, aspirates, biopsies, blood cultures, CSFs), HDU specimens (including screens) and any other specimens deemed irreplaceable by the Consultant Microbiologist.

This list is not exhaustive, and other examples may include time sensitive samples such as for blood gas analysis.

Discrepancies must be documented on **BSD/QA/F/037 Log of Non-Conforming Irreplaceable**. The requesting clinician will be required to complete **BSD/QA/F/037** stating the reason why the labelling error occurred for full accountability and traceability. Specimens will not be processed and/or the results released until this form has been completed in the **Laboratory**. A discretionary note including details of amendment and the identity of the person making the amendment will be included in the test report. A non-conformance will be reported in the laboratory QMS.

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8.6.1 Sample draw order for blood tubes

Colour code	Investigation	Order of draw
Blood Culture Bottles	ALWAYS FIRST N.B. Bottle must be filled to the line	1
	Coagulation N.B. Bottle must be filled to the line	2
	ESR	3
	Most Clinical Chemistry, antimicrobials, serology, some referrals	4
	NT-proBNP, Troponin I,	5
	<u>Large Red</u> (4.9mL) Blood Transfusion	6
	<u>Small Red</u> (2.7mL) Full Blood Count, HbA1c,	7
	Glucose, Alcohol	8

As, depicted above, if several different samples are required fill the tubes in the following order:

- Blood culture bottles (fill anaerobic, purple top, bottle first)
- Citrate tubes (light-blue top, for coagulation studies)
- Dry tubes (white top) for tests on serum chemistries, fill to line.
- Heparin tubes (orange top, for NT-proBNP, Troponin I) fill to line.
- EDTA tubes (red top, for full blood counts, HbA1c and blood transfusion.)
- Fluoride oxalate tubes (yellow top, for glucose), fill to line.
- Sodium heparin (navy top, for Chromium and Cobalt referrals)

Very gently mix specimen containers by gentle inversion five times immediately following collection.

Always use the correct tube with designate preservatives to ensure the integrity of samples.

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8.6.2 Ensuring that Blood Containers (ESR, 2.7ml Coagulation) fill to the Designated Line

To ensure that ESR and 3.0ml Coagulation bottles fill to the designated line, if these samples are being collected first or on their own, the phlebotomy line must be “primed” to ensure that the vacuum is adequate to fill the bottle to the line. This is done by firstly, collecting a small amount of blood into a tube of the same type, and then proceeding to collect a second sample and filling the bottle to the designated line. The first sample can then be discarded.

Ensure Blood cultures are filled to the fill line.

8.7 Protocol for collection of blood gas specimens

In order for the laboratory to process blood gas samples as quickly and safely as possible, the following procedure must be followed.

A blood gas sample must be tested by the laboratory within 30 minutes of sample collection or 15 minutes for lactate samples. Therefore, it is of critical importance to notify Specimen Reception at extension 5634 or the Clinical Chemistry laboratory team (extension 5319) in advance of taking a blood gas sample.

Whenever possible, hand carrying of blood gas specimens without any vigorous movement is the preferred way to transport samples.

If you have any questions about the taking of blood gas samples, please contact the Clinical Chemistry laboratory at extension 5319.

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9 DELIVERY AND TRANSPORT OF SPECIMENS TO THE LABORATORY

It is the policy of the Pathology Department to treat all specimens and samples as potentially infectious or high risk. Therefore, we advise universal precautions are taken in the collection, packaging and the delivery of specimens sent to the Pathology Department for analysis. Samples should be sent directly to the laboratory as soon as possible after collection and not stored in uncontrolled storage locations. Samples are sent at Room Temperature unless otherwise specified BSD/PATH/I/111 table of all tests document which accompanies this user manual.

If specimen integrity is compromised during transport the requesting clinician/clinical area will be notified and a non-conformance will be raised.

9.1 Specimen Delivery from Within the Hospital

- During the routine Pathology opening times, samples will be delivered to the laboratory by either the Phlebotomist(s) and where suitable through the Pneumatic Chute System or hand-delivered by staff from the clinical area. The adequacy of the Chute system is reviewed periodically.
- Outside routine Pathology opening times blood specimens will be delivered to the laboratory by either the medical staff or through the Pneumatic Chute System.
- All specimens being sent to the laboratory should be placed in a plastic sample bag. The sample bag may or may not be attached to the form. This depends on the form type.
- Blood culture bottles are to be hand-delivered to the laboratory promptly after being taken (and must be within 4hrs of collection). Blood Culture bottles must be loaded directly onto the analyser and the BacT/Alert Blood Culture Loading Register must be completed at the time of loading blood cultures bottle(s). The form is placed in the designated area beside the BacT/Alert. This is the procedure to be carried out regardless of whether it is during routine or non-routine hours.
- CSFs and urgent sterile fluids are to be hand-delivered **ASAP** and within 30 minutes of being taken, to the laboratory. The person delivering the sample must ensure that a laboratory staff member has been informed and is present to take responsibility for the sample.
- Histopathology or Cytology Specimens should not be transported via the chute system.

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- Arterial Blood Gases must be delivered to the laboratory (either by pneumatic chute system using the appropriate yellow tabbed canisters (to avoid any effect on the pO₂ result) or hand delivered) within 15 minutes of collection. Arterial blood gas collection to the laboratory must be preceded by a telephone call to the laboratory to ensure that the analyser is available for use.
- SARS-CoV-2/Flu/RSV swabs collected in Wards/Clinical Areas must be delivered to the laboratory promptly. Please note that non-urgent samples can be placed in the fridge for batch testing. Urgent samples must be delivered to the Microbiology Lab.
- **Note:** Routine specimens collected and delivered to the Laboratory during the out of hours period will result in an increase in the turnaround time for the test, as testing will not be performed until the next routine working day.

9.1.1 Histopathology Specimen Transport

Histopathology specimen transport and storage is described in detail in the Histopathology Section below.

9.2 Storage of specimens outside of routine Pathology hours

Routine specimens should not be taken outside of the deadlines for receipt of such specimens by the Pathology Department. However in cases where this cannot be avoided, the medical scientist on call should be contacted .

9.3 Specimen delivery from clinical users outside of the hospital

Specimens may be delivered from:

- General Practitioners (GPs)
- Out-patients
- Outside clinical services

All such specimens should reach Pathology by 16:00 Monday to Friday or by 12:00 hrs Saturday (excluding Histology). Please do not send specimens outside of these hours.

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9.4 Packing procedure for the transport of diagnostic specimens

The following requirements apply to all non-infectious diagnostic specimens directed to Pathology from external clinical users.

Non-infectious diagnostic specimens must be packed and transported in accordance with the European Agreement concerning the *International Carriage of Dangerous Goods by Road* (UNADR; BSD/PATH/EX/080).

Specimens to be sent must be stored in a secure (preferably plastic) primary container.

- 1 Wrap the container in absorbency pad, which will act as absorbent material in the event of any spillages. Then place in a biohazard bag.
- 2 Place the biohazard bag with the sample in speci-boxes. The speci-box is labelled with "Diagnostic Specimen Category B, UN 3373".
- 3 Place the name, address, and contact number of the destination laboratory on the outside of the envelope.
- 4 The specimen can be transported or posted as appropriate.

There is no requirement for a licensed courier to transport non-infectious diagnostic samples.

All samples should be treated as potentially hazardous within the Laboratory

When the laboratory sends a sample to a referral laboratory for testing not carried out at the Bon Secours Hospital, the laboratory is responsible for packing these specimens for transport to the external laboratory in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the laboratory staff.

9.1 Disposal of Waste Material Used in Specimen Collection

All materials used in specimen collection should be treated as potentially hazardous and discarded in sharps containers and other appropriate colour coded bags. Please refer to the current hospital guidelines and the Pathology Health and Safety manual BSD/PATH/SM/001

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10 REPORTING OF TEST RESULTS

BSD/PATH/SOP/015 “Procedure for the reporting of results” describes full details of the Pathology Department’s policy on the reporting of results. Listed below is a concise guide to elements of this procedure

All reports are issued to the requesting clinician. Results are reported on the Laboratory Information System (LIS) and are available for viewing in clinical areas on Maxims (Ordercom System) by authorised personnel once released by laboratory staff. Results are only available once all requested tests on each specimen have been reviewed and released by laboratory staff.

The INAB accreditation status is displayed on hard copy and electronic versions of reports in Maxims Tests which are outside the scope of INAB accreditation are highlighted to this effect on test reports.

Hard copy reports

The hardcopy report continues to be the official copy for Histopathology, Microbiology and Blood Transfusion and referred tests. Hard copy reports are also issued to all external users including outpatients daily.

Reports for POCT are placed directly into the patients’ Medical Record at time of testing.

Electronic Reports

All results, once released in the Laboratory can be reviewed in Maxims (Order Comms Software). Hard copy reports from Clinical Chemistry and Haematology are not distributed to in-patient’s ward areas, however reports may be printed directly from Maxims if required.

Copies of results may be sent via secure email by the Pathology Administration office upon request. All critical results will be telephoned in line with BSD/PATH/I/091 Critical Results policy.

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10.1 Telephoned reports

When results for specific parameters have reached critical values or when a specimen is rejected the requestor (ward, consultant, or GP) is contacted by telephone and informed. When specifically requested, results may also be telephoned to the requestor (a contact number must be provided). Critical results for each department are documented within the department-specific section of this document and BSD/PATH/I/091

BSD-ORG 29 *Reporting of Critical Diagnostic Test Results* is the hospital policy for the communication of critical diagnostic test results. This policy requires the receiver to document the results in the patient's notes (including the notification date, time, and their name), to read back the result to the caller and to ask the person giving the result to confirm that the read back is accurate.

10.2 Reference ranges (Biological Reference intervals)

Reference ranges for different analytes are generally printed with the test results. Please refer to the test result report but note that some reference ranges are dependent on age, sex, or other specific factors.

Reference ranges for laboratory tests are determined as part of test method verification, as documented in laboratory procedure BSD/QA/SOP/052 Procedure for the Verification of Test Methods. If required by laboratory users, detailed information on Reference Ranges is available by contacting the relevant laboratory department.

10.3 Interpretation of results

If clinical guidance is required to interpret results, this can be obtained by contacting the relevant Consultant Pathologist via the Hospital reception.

11 BLOOD TRANSFUSION AND HAEMOVIGILANCE

The Blood Transfusion laboratory provides routine and emergency pre-transfusion compatibility testing and provides blood components and products.

A list of performed Blood Transfusion test and Turnaround Times are available at BSD/PATH/I/111 "Table of all tests". Specimen/samples referred to external laboratories for testing are identified by addition of an asterisk * after the test name.

For safety reasons and where clinically possible, blood transfusions should only be given during normal working hours, and non-urgent requests for blood components/products

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should be limited to the laboratory routine working hours. However, there should be no delay in transfusing a patient outside routine hours if clinically indicated.

All transfusion reactions and events are documented and, where required, reported to the National Haemovigilance Office.

The Hospital Blood Transfusion Committee meets quarterly.

11.1 Blood Transfusion Request Forms, Specimen Containers and Specimen and Form Identification

Refer to BSD/PATH/I/111 for further information on Specimen Containers for individual Blood Transfusion tests.

Refer to Section 8.4 of this User Manual for information on Blood Transfusion Request Forms and identification of specimens and request forms in Blood Transfusion.

The pre-transfusion specimen must be taken by a Phlebotomist, Doctor or Registered Nurse trained and authorised to collect blood specimens.

Prior to sampling, the patient must be positively identified by following the procedure outlined in BSD/HV/SOP/012 Patient Identification and Pre-Transfusion Sampling.

11.1 Clinical advice on Blood Transfusion

For clinical advice on Blood Transfusion please contact the Consultant Haematologist on duty via switchboard.

In addition to the Consultant Haematologist, the Irish Blood Transfusion Service (01-4322800) provides a consultative and advisory service and advice is available from the National Haemovigilance office (NHO) on 01-4322825 or 01-4322891.

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11.2 Blood Products / Components Available

Blood Product	Supplier	Samples / Request Required	Special Requirements	Collection
Red cells	IBTS	<u>ABO/ Rh status must be confirmed through the grouping of 2 separate Blood Transfusion samples prior to the issue of red cells.</u> In the event that there is no historical group available, the Medical Scientist will contact the clinical area and request a second specimen to be taken.	See BSD/HV/I/012 for Guidelines concerning those patients who will require CMV Negative and / or Irradiated Blood Components. Red cells that are CMV negative / Irradiated / Antigen negative are ordered from the IBTS as required.	Blood Issue Fridge
Platelets	IBTS	Request on the BT/RF request form. An ABO/Rh group from the previous month is required to issue this product.	See BSD/HV/I/012 for Guidelines concerning those patients who will require CMV Negative and / or Irradiated Blood Components	Platelets are stored at room temperature and must be collected from the Blood Transfusion laboratory for use within 6 hours of receipt from the IBTS.
Octaplas (Octaplas™)	IBTS	Request on the BT/RF request form.	The BT laboratory	Thawed Octaplas is

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		An ABO/Rh group from the previous month is required to issue this product.	should be notified at least 30 minutes in advance, as Octaplas must be thawed at 37°C for 30 minutes	collected from the Blood Transfusion laboratory and must be transfused within 8 hours of thawing.
Albumin (20%)	BSD Pharmacy	Request on the BT/RF request form. No blood group required.	N/A	Blood Issue Fridge
Fibrinogen (Fibryga™)	IBTS	Request on the BT/RF request form. No blood group required.	N/A	Blood Transfusion laboratory
Anti-D	Fannin	Request on the BT/RF request form. <u>Rh D status must be confirmed through the grouping of 2 separate Blood Transfusion samples prior to the issue of anti-D immunoglobulin as this product is suitable for Rh D Negative patients only.</u>		Blood Issue Fridge
Octaplex / PCC (Octaplex™)	BSD Pharmacy	Request on the BT/RF request form. No blood group required.	N/A	Blood Transfusion laboratory

Blood components/products are issued for named patients only.

A small stock of the above products are maintained on site. Other Blood components/products are ordered from the supplier on request.

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All routine crossmatch specimens must be received in the Blood Transfusion laboratory before 15:00 on the day preceding surgery to guarantee the availability of blood for surgery the following day.

Requests for blood type and antibody screens and crossmatched blood should adhere to the guidelines outlined in the Maximum Surgical Blood Order Schedule (MSBOS) BSD/HV/I/001, unless if otherwise clinically indicated. If deviating from MSBOS the Blood Transfusion laboratory must be phoned with an explanation.

Crossmatched blood will be held in the Blood Transfusion Issue Fridge for 24 hours post-surgery. It will then be returned to stock unless notification to “hold” the blood is received from the nursing staff/clinician looking after the patient.

Blood type & antibody screen specimens are only valid for crossmatch for 72 hours post phlebotomy.

If a second sample is required for a crossmatch the 2nd specimen must be taken separately to the 1st specimen. The patient must be phlebotomized for a second time and the procedure for taking a specimen is followed. The 2nd specimen is placed in a new biohazard bag attached to a new request form and sent to Blood Transfusion. Under no circumstances should the 1st and 2nd specimen be taken together – this compromises patient safety.

Telephone requests for blood components or products or for additional blood components or products must be followed up by a written request on a Blood Transfusion Request Form before they can be issued. The phoned request must state the patient’s first name, surname, date of birth and hospital number. A register of telephoned requests (BSD/BT/F/009) is maintained within the laboratory.

Email requests for blood or blood products are not accepted, a written request on a Blood Transfusion request form must be sent.

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11.3 Timing of specimen collection pre-transfusion

11.3.1 Pre-surgery

Patients who have had a blood type & antibody screen specimen taken during pre-admission (for example, in advance of routine elective surgery) must be wearing a wristband during blood collection. The wristband is applied by the Outpatients Registration team when the patient arrives and then removed by the phlebotomist when the blood specimen has been taken.

A duplicate wristband is retained in the patient's notes and is applied at the time of admission. This policy is to ensure that such patients are wearing a wristband during the entire transfusion process.

11.3.2 Previous transfusion or pregnancy

Transfusion or pregnancy may stimulate the production of antibodies. The timing of specimens selected for crossmatch or antibody screening must take account of this, as it is not possible to predict when or whether such antibodies will appear. Transfusion history and pregnancy/obstetric history must be provided on the blood transfusion request form. Transfusion blood type & antibody screen sample is only valid for crossmatch for 72 hours post phlebotomy.

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11.1 Detection of antibody (s) in a blood type & antibody screen specimen

Clinically significant antibodies are capable of causing patient morbidity due to accelerated destruction of a significant proportion of transfused red cells.

Where an antibody has been detected in the Blood Type and Antibody Screen specimen (TS specimen), an Antibody Notification Alert is put on the PIMS system by the Medical Scientist. Two special Blood Transfusion notice stickers BT/SR-1 are attached to the outside of the patient's chart which indicates special requirements for Blood Transfusion.

This sticker is placed on the front of the patient's Medical Chart by the HVO Officer under Drugs and Sensitivities. and a sticker should be placed on the inside the front cover. Always check the patient's chart/records for these stickers. Please give 24 hours' notice prior to transfusion or surgery. BT/SR-1 LABEL states "This patient has special requirements for Blood Transfusion"

11.2 Result Reporting

Hard copy reports are issued for all Blood Transfusion testing activities. The transfusion compatibility/suitability report is issued with blood components/products and is used in the pre-transfusion identification check of the patient to be transfused and is then filed in the patient's medical records.

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11.2.1 Critical results in Blood Transfusion

As documented in BSD/PATH/I/091 Pathology Critical Results, the following Blood Transfusion critical results are phoned to the Key Contact:

BLOOD TRANSFUSION Ref: BSD/BT/SOP/074		
Result/Situation	Key Contact	Urgency
Positive Antibody Screen Communicate that there will be a delay in the provision of blood	Clinical Area Pre-Admission Clinic	Within 10 minutes
Antibody Identified Communicate that there will be a delay in blood availability for crossmatch/pre-operative patients	Clinical Area	Within 10 minutes
ABO/RhD mismatch Current sample does not match historical sample, request repeat sample	Clinical Area	Within <u>one</u> minute
Crossmatch Request Special requirements request with no history/reason	Clinical Area	Within 10 minutes
Positive Crossmatch post issue Communicate need to stop transfusion immediately	Clinical Area / Requesting Clinician	Within <u>one</u> minute
Platelet Requests Out of group platelet ordering authorisation	Requesting Clinician	Within 10 minutes
Recall message received from IBTS regarding blood product Communicate need to stop transfusion immediately and return unit to the lab	Clinical Area	Within <u>one</u> minute
Specimen Unsuitable for Testing Haemolysed or mislabelled sample	Clinical Area	Within 10 minutes

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11.3 Emergencies

In an emergency, the urgent need for blood transfusion may preclude the performance of standard compatibility testing prior to the issue of blood/ blood components. Refer to the BSD/BT/SOP/073 *Release of Blood Components and Products during Major Haemorrhage Protocol*.

Four units of group confirmed Group O Rh D Negative, C-, E-, K- red cells are available in the Blood Issue Fridge at all times for use in emergency situations. These can be used in situations where time does not permit any form of pre-transfusion testing or where a second blood type and antibody screen cannot be taken for blood group confirmation.

Female patients older than 55 years of age and all male patients may be issued with Group O Rh D Positive red cells in massive haemorrhage / emergency situations. It is a clinical decision to transfuse these units.

The provision of crossmatch compatible blood for patients with circulating/historic antibodies to red cell antigens can take a considerable amount of time. As this may result in an unexpected delay in the provision of compatible blood, the Blood Transfusion Laboratory will inform the appropriate clinical area if the situation should arise.

The responsibility for administering blood to patients prior to completion of pre-transfusion testing rests with the medical doctor who requested the blood.

Please note: If blood is required in 40-60 minutes from the time of requesting, a full crossmatch can be completed provided the units of blood are serologically compatible and the patient has a negative antibody screen and has no historical record of an antibody(ies) on file.

11.4 Collection of blood components/products from the laboratory

All personnel involved in collecting blood and blood components from the transfusion laboratory i.e., clinical staff and health care assistants (HCAs) must be fully trained and competent in the procedures for collection, transport and administration of these components or products.

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11.4.1 Blood Issue Fridge and blood component/product collection box

Red Cells, Albumin and anti-D for collection are stored in the Blood Issue Fridge which is located in the central area of the laboratory. Access to the fridge is restricted to staff with swipe card access to the pathology department. This fridge must be closed immediately after removal of blood. Platelets, LG Octaplas, Fibrinogen concentrate, and PCC must be collected from the Blood Transfusion laboratory **once issued by the Medical Scientist**. Access is restricted to staff with swipe card access to the Pathology department.

The Blood/Blood Components Signing out chart is available at the Issue Fridge.

The laboratory report is available attached to the blood sign-out form. Signature and printed name must be provided in full i.e., forename and surname along with the date and time of sign-out. Single units for transfusion in the hospital, are collected are transported in designated plastic blood transit bags available next to the Blood Issue fridge. For infection prevention and control reasons, these bags are for single use only. A pre-labelled envelope for staff to return the traceability label to the Blood Transfusion laboratory is in all bags. Dispose of the single use transport bag in the appropriate waste bin, as per hospital guidelines.

11.4.2 Emergency O Negative Units

Four Units of confirmed group **O RhD Negative, C-, E-, K- confirmed group** red cells are available for emergency use for patients.

These units are stored in the Blood Issue Fridge in the Laboratory.

The units have computer generated Suitability Labels affixed with peel-off Unit Details Label for affixing to the Administration Record in the ward and detachable traceability labels for return to the Blood Transfusion Laboratory for fating of these un-crossmatched units.

There is a Blood Transfusion Laboratory Report Form and a Blood Sign-Out Form available in the fridge for each unit.

Red labels stating **UNCROSSMATCHED BLOOD ISSUED AT MEDICAL OFFICER'S REQUEST** should be affixed to the four units on collection.

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11.4.3 Return of unused blood component/product

If an unused blood component or product is returned to the laboratory, the person returning it must state the time of return on the Blood Sign-Out Form.

Red cells and anti-D must not be stored outside a controlled storage environment for greater than 30 minutes. If the units may not be transfused they must be returned to the Blood Transfusion laboratory immediately and Medical Scientist notified. The time the units are returned to the lab must be noted on the blood sign out sheet.

PCC, Albumin and Fibrinogen concentrate can be returned if not already reconstituted/opened.

LG Octaplas must be used within 8 hours post thawing, and platelets must be used within 6 hours post receipt from the IBTS.

11.5 Transfusion traceability label

All blood components and products for transfusion have a traceability label attached to the donor unit to confirm its fate. On commencement of the transfusion episode, the traceability label must be completed, signed, dated, and timed by a clinical staff member confirming that the transfusion took place. The traceability label must then be returned immediately to the Blood Transfusion laboratory. The record of transfusion is kept for at least 30 years.

11.6 Transfusion reaction reporting and follow-up

In the event of a transfusion reaction, follow the procedure outlined in BSD/HV/SOP/014 BS Dublin: Blood Administration and Care and Monitoring of the Transfusion Recipient and BSD/HV/SOP/016 BS Dublin: Management of Serious Adverse Reactions and Serious Adverse Events (Clinical Areas) - Mandatory Reporting (Including Rapid Alert Procedure).

11.7 Reporting of adverse occurrences and near misses

All near misses and non-conformances relating to blood transfusion practices must be reported to the Haemovigilance Officer as outlined in BSD/HV/SOP/016 *BS Dublin: Serious Adverse Reactions and Events (Clinical Area) Mandatory Reporting (Including Rapid Alert Procedure)*.

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11.1 Emergency Blood Management Protocol

BSD/BT/SOP/107 Emergency Blood Management Protocol describes the contingency plan in place to ensure the effective use of available blood components when national blood stocks have fallen to very low levels. The purpose of this procedure is to ensure transfusion support for patients on such occasions.

11.2 Haemovigilance information

Copies of the following documents are available on Q-Pulse, in Nursing Administration office and in Theatre:

- BSD/HV/SOP/001 The Haemovigilance System in the Bon Secours Hospital Dublin
- BSD/HV/SOP/002 Management of Haemovigilance Incidents in the Hospital
- BSD/HV/SOP/003 The Hospital Blood Transfusion Committee
- BSD/HV/SOP/005 Procedure for the Management of Blood Components or Products, which are recalled by the Irish Blood Transfusion Service
- BSD/HV/SOP/008 Procedure for the Training and Education of all Staff Involved in the Transfusion Process
- BSD/HV/SOP/010 Prescription of Blood Components and Products and requesting from the Laboratory including completion of Blood Transfusion Request Form
- BSD/HV/SOP/012 Patient Identification and Pre-Transfusion Sampling (taking a Blood Type and Screen)
- BSD/HV/SOP/014 Blood Administration and Care and Monitoring of the Transfusion Recipient
- BSD/HV/SOP/016 Serious Adverse Reactions and Serious Adverse Events (Clinical Area) Mandatory Reporting (Including Rapid Alert Procedure)
- BSD/HV/SOP/018 Haemovigilance Management of Serious Adverse Reactions and Serious Adverse Events (Including Reporting to the NHO)
- BSD/HV/SOP/020 Disposal of Used Transfusion Packs
- BSD/HV/SOP/021 Collection of Blood Components/Products from the Blood Transfusion Laboratory
- BSD/HV/SOP/022 Emergency Reversal of Warfarin
- BSD/HV/SOP/023 Adult Life-Threatening Haemorrhage Protocol - CODE RED

The Haemovigilance Procedures as outlined above should be read in conjunction with this User Manual as they provide detailed information and instructions concerning the clinical practice in Blood Transfusion.

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12 HISTOPATHOLOGY

The department provides a routine histopathology and non-gynae cytopathology service. Specialist services (including cervical cytology, molecular diagnostics, renal pathology, neuropathology, ophthalmic pathology, and direct immunofluorescence on skin biopsies) are provided using external laboratories. The Histopathology Department welcomes queries about available investigations or the correct requirements for ordering or handling unusual or rare requests (e.g., electron microscopy or molecular studies). The Department also provides an advisory service on interpretation of examination results.

12.1 Histopathology Request Forms, Specimen Containers and Specimen and Form Identification

Refer to BSD/PATH/I/057 Instruction on Laboratory Pre-examination Requirements for Clinical Staff for further information on Specimen Containers for individual Histopathology tests.

12.2 Emergency on-call service

No service is provided usually outside of routine Monday to Friday working hours (08:00 to 16:30).

12.3 Department telephone numbers

Department telephone numbers are available in section 2 above. In addition, the consultant histopathologists may be contacted by mobile phone if required urgently (mobile phone numbers available in Histopathology laboratory).

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12.4 Collection and delivery of specimens

1. Histopathology provides a collection service from the Operating Theatres, Minor Procedures Suite and Endoscopy at 08.00 in the morning and an afternoon collection from endoscopy. Staff will reject specimens which are not labelled correctly due to form or specimen identification issues if they are leaking or soiled specimens or forms. If there is no visible specimen, the lab will inform a member of staff (e.g., theatre nurse), raise a non-conformance and follow the relevant laboratory procedure.
2. During working hours, specimens from other locations (e.g., Radiology or inpatient wards) must be placed in a Biohazard bag and delivered by clinical staff to the Histopathology laboratory. They must be handed to a Histopathology staff member. On no account should specimens simply be left in the Histopathology laboratory outside of normal working hours.
3. Histopathology and cytology specimens are not suitable for transport in the Pneumatic Tube System.

12.5 Urgent specimens

1. Specimens from the Operating Theatres, Minor Procedures Suite or Endoscopy taken after the routine collection may be submitted for urgent processing. Small biopsy specimens (including appropriate non-gynaecological cytology specimens) received in the laboratory will be available for reporting within 48 hours. Larger specimens will require an extra 24 hours for adequate fixation. The latest time for receipt of an urgent small biopsy specimen to ensure that it will be processed on that night's overnight processing cycle for next day reporting is 15:30.
2. Any such urgent specimens should be clearly marked as "Urgent" with a contact telephone number for phoning the result, placed in a Biohazard bag, and delivered by clinical staff to the Histopathology Laboratory. They must be handed to a histopathology staff member. On no account should specimens simply be left in the Histopathology Laboratory outside of normal working hours.

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12.6 Specimens from external sources

Specimens from outside the Bon Secours Hospital must be delivered to the Histopathology Laboratory during routine working hours 08.00 to 16:30. If this is not possible, the specimens should be delivered during the next working day. Histopathology specimens fixed in formalin require no special storage conditions and are entirely stable at room temperature. For cytology specimens, please see under “Storage of specimens taken out of hours” below.

12.7 Delivery of fresh tissue specimens

Fresh specimens for frozen section or for muscle, nerve, renal or skin DIF biopsies must be placed in a Biohazard bag and delivered immediately by clinical staff to the Histopathology Laboratory and handed to a histopathology staff member. See section 7.10 for specimen requirements for muscle, renal and skin DIF specimens. On no account should such specimens simply be left in the Histopathology Laboratory. See below under specific specimen requirements for each of these tests.

12.8 Storage of specimens taken out of hours

1. Outside of routine Pathology Department working hours (08.00 to 16:30), histopathology and cytopathology specimens should not be delivered to the laboratory.
2. Histopathology specimens fixed in formalin or fixed cytology specimens (e.g., fixed smears, FNA specimens in Cytofix collection fluid or Thinprep cervical specimens) require no special storage conditions and are entirely stable at room temperature.
3. Unfixed (fresh) material for cytology (e.g., fluids, washings, or urine) should be stored at 2 to 8°C in a fridge and delivered to the Histopathology Department the next working day. However, in general, unfixed (fresh) material for cytology should not be collected outside of routine Pathology Department working hours.

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12.9 Specimen requirements

12.9.1 Specimen containers

The laboratory does not supply specimen containers (including ThinPrep vials for cervical cytology) or fixative. These are obtained from the hospital stores.

Specimen containers or request forms should never be visibly soiled with body fluids. Leaking specimen containers or specimen containers without an appropriate matching lid should never be used. All such specimens will be rejected.

12.9.2 Routine Histopathology

1. Specimens must be fixed in an adequate volume of 10% neutral buffered formalin and placed in a specimen container of adequate size. Adequate fixation optimises tissue preservation and minimises the risk to laboratory staff from infectious hazards in tissue (e.g., TB, HIV, HBV, or HCV) that may remain viable in poorly fixed specimens.
2. An adequate volume of formalin for fixation is twice the volume of the specimen to be fixed as an absolute minimum but should be ten times the specimen volume for optimal fixation. If a specimen has to be squeezed or pushed into a specimen container in order to fit, the container is too small and must not be used.
3. Placing a specimen in a container of inadequate size or using inadequate volumes of formalin is a false and dangerous economy. Pathological analysis of the tissue is likely to be compromised and/or delayed and infectious hazards to laboratory staff may remain viable.

12.9.3 Frozen section service

1. A frozen section service is available during normal working hours. Unscheduled frozen section requests during working hours will be facilitated if possible. Specimens for frozen section should be fresh and delivered immediately by clinical staff to the Histopathology Laboratory. Specimens for frozen section should be received by 15:30 at the latest. If possible, cases for frozen section should be done as early as is practicable on an operating list.
2. Frozen sections should be booked at least 48 hours in advance by the requesting clinician by contacting the Histopathology Laboratory with the following details: patient name, hospital no., type and estimated time of surgery, name and contact telephone number of the consultant surgeon.

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3. If an unscheduled frozen section is requested, please contact the Histopathology Laboratory as soon as possible in order to ensure that personnel are available to perform the frozen section.
4. Contact details for the relevant operating theatre extension are required on the request form accompanying the frozen section in order to phone the result.

12.9.4 Muscle, Nerve, Renal or DIF Skin Biopsies

1. Specimens for the above indications must be notified in advance to the Histopathology Laboratory and once taken they must be delivered immediately by clinical staff to the Histopathology Laboratory.
2. Muscle and nerve specimens should be wrapped in saline-soaked gauze. The minimum amount of saline possible should be used, just enough to prevent the biopsy drying into the gauze. Loosely fold the gauze over the biopsy. Do not roll into a tight ball and do not flood the specimen with saline.
3. Renal biopsies should be placed in a pot of saline solution and delivered immediately to the Histology lab.
4. Skin DIF biopsies should be placed directly into the vial of Micehl's medium, labelling the vial directly with the patient's demographics as per normal procedure and stored in the specimen cabinet overnight along with the routine samples. The histology department will collect these specimens during the normal specimen collection carried out each morning,
5. Muscle, nerve, and renal specimens should reach the Histopathology Laboratory by 14:00 at the latest to ensure adequate time for transport on to the external laboratory where analysis is performed (specimens must reach the relevant external laboratories by 16:00 at the latest).
6. In the exceptional circumstance of delayed transportation of muscle, nerve, or a renal specimen to the Laboratory, it should be stored at 2 to 8°C. However, failure to submit such fresh specimens in a timely fashion usually results in significant or complete compromise of tissue analysis.

12.9.5 Cervical cytology

Cervical cytology specimens are obtained using a liquid-based method. Specimens are submitted in ThinPrep vials.

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12.9.6 Non-cervical cytopathology specimens

- *Urine*

Urine specimens for cytology are submitted in 50ml containers. Spontaneously voided urine specimens should be fresh. The first morning specimen of urine is unsuitable for cytology as the cells present may be degenerate. The whole urine sample should be collected for cytology, not just a mid-stream sample. Urine specimens for cytology should not be stored for more than 24 hours and should generally be obtained during routine Pathology Department working hours. If the urine specimen is not spontaneously voided, the nature of the specimen (e.g., catheter sample or bladder washings) should be indicated on the request form.

- *Serous fluids*

Serous fluid specimens (such as pleural fluid, ascites fluid or peritoneal washings) are submitted in 50ml containers (as used for urine samples). If an aliquot of a large volume of effusion/ascites fluid is submitted for cytology, care should be taken to ensure that the effusion/ascites fluid is well-distributed (that is, has not been allowed to settle) prior to aliquoting. Any solid or semi-solid fragments should always be submitted.

- *Other fluids*

All other fluid samples, such as bronchial washings, broncho-alveolar lavages, joint aspirates, or cyst aspirates, should be submitted in sterile universal containers. Joint aspirates for crystal analysis are sent to the Microbiology Laboratory.

- *Sputum*

Sputum samples for cytology are considered to be of limited diagnostic value. They should only be submitted from patients in whom bronchoscopic assessment might be indicated but who are unsuitable for the procedure for some reason. If sputum samples are submitted, they should be early morning ("first thing") specimens and deeply coughed in order to try and improve yield.

- *Brushings*

Bronchial or endoscopic brushings are usually submitted as alcohol-fixed direct smears. Alternatively, the brush itself in a sterile universal container or a sterile universal container of Cytofix solution (in preference) or saline in which the brush has been agitated may be submitted.

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- *Fine needle aspirates*

Fine needle aspiration specimens may be submitted as either alcohol-fixed and/or air-dried slides and/or in a sterile universal container of Cytolyt solution (in preference) or saline (needle washout specimens included).

- *Fresh cytology specimens from “high risk” patients*

For these purposes, any patients who also have specimens sent for TB microbiology should **always** be considered as having suspected TB infection until proved otherwise. Handling such specimens as routine by laboratory staff entails a risk from these infections.

12.10 Specimen types, specimen requirements and special requirements

Specimen type	Specimen requirements	Special requirements
All Histopathology specimens (biopsies, skins, small and large surgical specimens)	Minimum patient ID criteria (full name, DOB, MRN) and specimen site/type on specimen container & request form Relevant clinical details	Standard precautions apply to all specimens
	Container of adequate size Adequate volume of 10% buffered formalin (ideally 10x tissue volume but at least 2x)	Store at room temperature
Urgent histopathology & non-gynae cytology specimens	As above but indicate “urgent “on request form	Clinical staff deliver to lab if taken after 08.00 collection; must be received in lab by 15:30
Frozen section specimens	Deliver fresh to laboratory staff member Provide contact phone extension on request form Book 48 hours in advance if possible	Must be received in lab by 15:30
Renal biopsy	Place in container of saline solution	Must be received in lab by 14.00 as must be transported to external lab by 16.00

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Specimen type	Specimen requirements	Special requirements
Muscle biopsy Nerve biopsy	Deliver fresh to laboratory staff member Wrap in loosely folded saline-moistened gauze Do not flood with saline or roll tightly into a ball	Must be received in lab by 14.00 as must be transported to external lab by 16.00
Skin biopsy for DIF	Skin Biopsies for DIF should be collected into Michel's medium - submerge biopsy specimen into the fixative without delay. Will be collected by Histology staff as part of routine collection.	Must be received in lab by 14.00 as must be transported to external lab by 16.00
Cervical cytology	Use ThinPrep collection system	
All fresh cytology specimens	Collection and delivery to laboratory during routine working hours (08.00-16:30) Otherwise store at 2-8°C and deliver next working day	
Urine for cytology	Collect in 50ml container Freshly voided/collected specimen Do not store for more than 24 hours	Do not submit first morning specimen Submit all of a voided specimen (not just MSU)
Serous fluids for cytology (incl. pleural & ascites fluids)	Collect in 50ml container	If aliquoted from larger fluid sample, ensure that fluid is well distributed before aliquoting. Submit all clots/ solid fragments separately
Other fluids and washings incl. FNA needle washouts	Collect in prefilled cytolyt container	Use Cytolyt for FNA needle washouts or if agitating endoscopic brushes
Cytology smears of brushings and FNAs	Label slides in pencil with patient name & DOB or MRN	

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12.11 Result reporting

12.11.1 Critical results in Histopathology

As documented in BSD/PATH/I/091 Pathology Critical Results, the following Histopathology Critical Results are phoned by the Consultant Histopathologist to the Clinical Consultant:

HISTOPATHOLOGY	
Unexpected/Discrepant Findings	○ Unexpected invasive malignancy (except non-melanoma skin cancer) ○ Unexpected disease process of major clinical significance (e.g., amyloidosis) ○ Significant disagreement/change between in-house pathologist's interim report and final opinion of an external expert referral pathologist ○ Significant change between frozen section diagnosis and final diagnosis ○ Cases where an amended report has been issued.
Infections	○ Identification of acid-fast bacilli ○ Identification of pathogenic organisms in immuno-compromised patients
Findings of Immediate Clinical Significance	○ Unexpected large vessel vasculitis ○ Free fragments of fat in an endometrial curettage or colonic polypectomy ○ Segment of ureter in a hysterectomy specimen ○ Large vessel in needle biopsy ○ Neoplasms associated with paralysis or SVC syndrome ○ Any other clinically urgent report where a clinician requests direct communication of the result

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12.12 Turnaround times

Turnaround times in histopathology refer to the time in working days between receipt of a specimen in the laboratory and the availability of an authorised report (either on the LIS or as a printed copy).

Turnaround times are guided by targets set by the Histopathology National Quality Improvement Programme, although the aim is to exceed, rather than meet, these targets (see 'Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology Version 5.0).

The Histopathology NQI Programme divides specimens into six categories with which turnaround times are analysed:

- Small biopsy specimens (e.g., skin punch and shave biopsies, curetting's, bronchial biopsies, prostate needle biopsies and needle core biopsies, excluding GI biopsies) (P1)
- GI biopsy specimens (P2)
- Non-biopsy, cancer resection specimens (includes resections done for possible cancer or masses) (P3)
- Non-biopsy, other specimens (includes all other specimens, including skin excisions and re-excisions, TURP, LLETZ, gall bladder and benign hysterectomy specimens) (P4)
- Non-gynaecological cytology, exfoliative (P5) and FNA (P6), combined for analysis due to the small number of FNA specimens.

The laboratory handles small numbers of specimens in the P3 category (non-biopsy, cancer resection specimens) and hence unexpected variation in the turnaround time for individual cases may have a disproportionate effect on the turnaround times overall for this category of specimens.

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Specimen type	Turnaround time from receipt in laboratory
Frozen sections	20 minutes, assuming only one specimen per case. Multiple specimens may take longer
Urgent small/GI biopsy or cytology specimens	24-48 hours post specimen delivery
Small biopsy specimens	80% reported by day 20
GI biopsy specimens	80% reported by day 20
Non-biopsy, cancer resection specimens	80% reported by day 20
Non-biopsy, other specimens	80% reported by day 20
Non-gynaecological cytology, exfoliative and FNA	80% reported by day 10

In general, whilst most specimens may be reported within the turnaround times stated above, specimens may take longer to report due to:

- Requirement for time for adequate fixation (e.g., many larger or predominantly fatty specimens)
- Routine diagnostic/ technical issues (typically, +1-2 days if levels or special stains required, more if multiple levels or submission of additional tissue from the specimen is required, to clarify diagnosis).
- When specific procedures are routine on some categories of specimens (for example, bone marrow biopsies requiring decalcification or liver biopsies requiring a panel of histochemical stains).
- When immunohistochemical staining is required (typically +1-2 days) or an intra-departmental consultation is sought (typically +1-2 days).
- When an external expert/specialist referral opinion is required, results may take significantly longer.
- When extensive decalcification is required or where specimens may be difficult to process (e.g., nail specimens), results may take significantly longer.

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The turnaround times for Histopathology are under review will be amended if required.

If it is anticipated that a report will be unduly delayed or if a provisional report expedites clinical management (e.g., through appropriate referral onwards), a provisional report may be issued for guidance in lieu of a final definitive report.

Occasionally some cases may require a second opinion from an external source. These cases are to be reported within 6 weeks from referral.

12.13 Tests referred to external hospitals

1. Muscle and nerve biopsies are sent fresh via the Histopathology Laboratory to Beaumont Hospital Neuropathology Department (Neuropath Office for report enquiries 8092631, Laboratory 8092633).
2. Renal biopsies are sent fresh via the Histopathology Laboratory to Beaumont Hospital Renal Pathology Department (Renal Pathology Office for report enquiries 8092008, Laboratory 8092634).
3. Skin biopsies for DIF testing are sent fixed in Michel's medium via the Histopathology Laboratory to St Thomas' Hospital, London, Immunodermatology Laboratory.
4. Ophthalmic pathology specimens (e.g., corneas) are sent fixed to The Eye and Ear Hospital and addressed to Dr. Susan Kennedy.
5. Cervical cytology specimens (collected using the ThinPrep method) are sent via the Histopathology Laboratory to Eurofins Biomnis.
6. Molecular testing for MSI, K-RAS mutation and Her-2 is performed when required by Poundbury Institute.

13 MICROBIOLOGY

The Microbiology Department offers a fully consultant-led diagnostic, surveillance, and clinical advisory service to a range of specialties, services and clinicians within the hospital and community. The microbiology laboratory examines specimens from patients to detect the presence of potentially pathogenic organisms ,performs antimicrobial susceptibility testing as appropriate and facilitates the referral of samples to external laboratories as required.. We work closely with infection prevention and control, occupational Health, Public health, and the health protection Surveillance Centre (HPSC).

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13.1 Microbiology Request Forms, Specimen Containers and Specimen and Form Identification

Refer to table of all tests BSD/PATH/I/111 for further information on Specimen Containers or section 9 of the User Manual for individual Microbiology tests.

13.2 General requirements

- Collect the right sample in the correct way, ideally before commencing antimicrobial treatment.
- Always give full clinical details, travel history and details of antimicrobial therapy on the request form.
- Discuss unusual specimen requirements and results with the Consultant Microbiologist
- Specimen test requests for ova, cysts and parasites are evaluated on receipt. Only test requests satisfying the following criteria are processed:
 - a. Patient has chronic or persistent diarrhoea
 - b. Recent history of travel to endemic area
 - c. Requesting clinician is a Gastroenterologist
 - d. Requesting Consultant is Haematologist or Oncologist
 - e. Only semi-solid or liquid specimens are processed unless clinical details indicate the presence of a worm for identification

13.3 Delivery of samples to the laboratory and pre-examination storage

13.3.1 Blood Culture specimens

- Inoculated blood culture bottles must always be transported to the laboratory by hand as soon as possible.

13.3.2 Cerebrospinal Fluid (CSF)

- The Microbiology laboratory and Consultant Microbiologist must be advised prior to the collection of a CSF sample and before sending it to the laboratory.
- During routine hours, CSF specimens must be delivered by hand **as soon as possible** by hospital staff to the Microbiology laboratory and handed to a Microbiology staff member.

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- CSF samples are received by the Microbiology laboratory first. Microbiology staff will then pass on the relevant specimens to Clinical Chemistry and Histology as needed.
- **On no account** should such specimens be left in the Microbiology Laboratory without alerting a Medical Scientist
- For an out of hours CSF samples, the Scientist on call must be contacted prior to CSF delivery. The CSF sample must be handed to the scientist on call. The CSF sample is sent to the Microbiology laboratory in Beaumont for processing of the cell count and culture out of hours. The CSF Glucose is processed in the Clinical Chemistry laboratory in Bon Secours Hospital and the CSF protein is referred to the Clinical Chemistry laboratory in Beaumont hospital.

13.3.3 Nasopharyngeal swabs

- Nasopharyngeal swabs for SARS-CoV-2/Influenza/RSV testing should be hand delivered or sent in the chute to the laboratory as soon as possible.
- The on-call Scientist must be contacted via the hospital switchboard for out of hours urgent samples. ,

13.3.4 All other Microbiology specimens

- All other specimens for microbiology investigation must be transported immediately to the Microbiology laboratory. If there is an unexpected or overnight delay all samples (**except Blood Cultures, QuantiFERON's and CSF samples**) should be stored in a fridge at 2°C to 8°C
- Turnaround times quoted are based on routine specimens. In some cases, additional testing and/ or referral may be required. This will extend expected turnaround times.

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13.4 Special requirements for Microbiology sampling and testing

13.4.1 *Mycobacteria tuberculosis (TB) Staining and Culture (AFB Culture)*

Specimens required

Sputum:	As available, <u>not salivary</u>
Pus:	As much pus as possible in sterile container
Pleural Fluid:	As available
Synovial Fluid	As available
Other Body Fluids:	As available
Bone Marrow:	As much material as possible. Do not add Formalin.
Urine (EMU):	Three early morning specimens on consecutive days only if renal TB is suspected
Tissue:	As available. Do not add Formalin.
Bronchoalveolar lavage (BAL):	Minimum volume is 5-10ml or as available. If TB and C/S requested; two samples are required. The routine culture is performed in-house. An additional sample is required if viral studies, PCP or Cystic Fibrosis culture are requested. These tests are referred externally.

Please note: 'Swab' samples are not useful for the demonstration or isolation of mycobacteria. Fluid or tissue samples should be sent.

Blood Culture

- Blood Culture Bottles

The blood culture system in use is the BacT/Alert system. Unused stored Blood Culture bottles should be kept at a cool room temperature in the wards.

The number of bottles stored in each ward should be limited to their general usage and excessive stocks avoided.

Ensure fluid is clear and sensor at the bottom of the bottle is grey. There is an **expiry date** on each bottle, and they **should not be used after this date**.

Two bottles are available:

A blue (aerobic) top and a pink top (anaerobic) bottle.

Wash hands thoroughly and put on gloves. Remove the plastic flip top and sterilise using an alcohol swab.

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- *Method of collection*

1. Clean the venepuncture area with an alcohol swab, beginning at the centre of the site and cleaning in a circular motion outward to a diameter of three or four inches for about 30 seconds. Do not go back over the previously cleaned areas. Allow the alcohol to dry. Do not touch the venepuncture area after this. Using an aseptic non touch technique to collect 10mls of blood into each bottle.
2. Inoculate the ANAEROBIC (PINK) bottle first (10mls of blood), and then the AEROBIC (BLUE) bottle (10mls of blood to the indicated line).
3. Label each bottle with the patient's name, DOB, hospital number, date and time of collection and **initials of person taking the specimen**.
4. Complete the request form stating clinical details, antibiotic therapy and whether peripheral or central culture.
5. 2-3 cultures are sufficient in certain settings, such as endocarditis, ideally prior to the commencement of antimicrobial therapy.
6. For the diagnosis of catheter related blood stream infection (CRBSI), paired blood cultures obtained through the device and from a separate venepuncture is recommended.
7. For ascetic or joint fluid infections: It is recommended to inoculate small volumes into blood culture bottles to aid recovery of organisms.
8. Bring the bottles in a biohazard bag with the Microbiology Request Form to the Microbiology Laboratory during normal working hours. **During 'Out of Hours' load inoculated Blood Culture Bottles directly onto the BacT/ALERT Blood Culture monitoring system.** *Please note: Do not send blood cultures through the pneumatic tube.*

- *Turnaround times*

Most organisms will be detected within 24 - 48 hrs . Routine blood cultures are incubated for up to 5 days, but this time may be extended to 10 days in specific cases e.g., infective endocarditis. Please contact the Microbiology Laboratory/ Consultant Microbiologist to discuss such cases.

As a critical result, if blood cultures flag positive within the incubation period, the appropriate clinical team / staff will be notified by the Consultant Microbiologist / Laboratory scientist.

Sterile cultures: A report is issued after 48hrs of incubation or as soon as possible if this occurs at the weekend. Blood cultures will continue to be incubated for the appropriate incubation period and a further report will only be issued where the cultures flag positive during this period.

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13.4.2 Cerebrospinal Fluid (C.S.F.)

Samples should hand delivered to the Microbiology laboratory as soon as possible and preceded by a phone call to alert the Microbiology staff especially for samples taken out of hours.

Bacteraemia is sometimes associated with meningitis, and a blood culture should be taken when meningitis is suspected.

If in doubt, the Consultant Microbiologist should be contacted for advice.

- *Specimen required*

CSF sample - as much sample as possible divided into:

- a. Three Sterile universal container bottles sequentially marked I, II and III in order of collection.
- b. Send specimens I and III to the Microbiology laboratory for microscopy, culture or any additional Microbiology tests e.g., virology, culture for mycobacteria etc.
- c. Send specimen II to Blood Sciences Specimen Reception for CSF glucose, protein or other investigations e.g., oligoclonal bands.
- d. Ensure that a blood glucose sample is simultaneously sent to the Clinical Chemistry laboratory (to compare with CSF glucose value)
- e. Send EDTA blood sample for PCR for *Neisseria meningitidis*, *Haemophilus influenzae* and *Streptococcus pneumoniae* if this is suspected.
- f. Send a throat swab for culture if meningococcus is suspected.
- g. Sending specimens to the correct laboratory will ensure results are available more promptly.

- *Normal findings*

White Cell Count: 0 - 5 x10⁶ /L
Protein: 0.15 - 0.45 G/L
Glucose: 3 - 5 mmol/L or approx. 60-75% of plasma glucose.

- *Viral meningitis*

If clinical and laboratory findings suggest viral meningitis, the CSF may be referred for Herpes Simplex Virus and Herpes Zoster Virus. A faeces should be sent for PCR for Enterovirus. Results are phoned to the ward as soon as they are available.

If patient has been on recent foreign travel, discuss with Consultant Microbiologist.

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13.4.3 Fluids from normally sterile sites

Specimens should be transported and processed as soon as possible.
If processing is delayed, refrigeration is preferable to storage at ambient temperature.
Delays of over 48 hours are undesirable.

- *Samples required*

Send a sample for culture in a sterile universal container (Flat Base).

In addition to the sterile universal container, collect fluid into an EDTA (red) sample, 2.7ml Potassium EDTA blood tube (🩸) for white cell count.

,It is recommended to inoculate small volumes of normally sterile fluids (ascitic and joint) into blood culture bottles to aid recovery of organisms.

- *Normal findings*

Peritoneal / Ascitic Fluid	White Cell Count:	0 - 200 /cmm
Synovial / Joint Fluid	White Cell Count:	0 - 200 /cmm

13.4.4 Mycology (fungal) examination and culture

- *Systemic fungal infections*

If systemic fungal disease is suspected, please contact the Consultant Microbiologist for clinical advice and notify the laboratory to ensure the correct samples are taken and that fungal culture is specifically requested on the request form.

- *Superficial/ skin fungal infections*

Specimens Required: Skin Scrapings, Hairs, Nail Clippings, BAL etc.

- *Taking of samples*

1. Preliminary cleansing of the lesion with 70% alcohol reduces bacterial contamination.
2. Scales of skin are scraped with a scalpel or the side of a microscope slide from the active periphery of the inflamed area. Infected nails should be clipped off for examination and scrapings taken from deeper areas of the nail bed. Infected hairs must be carefully chosen to avoid submitting healthy hair. BAL specimens from a Bronchoscopy procedure may be submitted for testing.
3. All samples should be sent to the laboratory in a sterile universal container.

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13.4.5 Sputum culture/ broncho-alveolar lavage / bronchial washings/ antral washout

- *Samples required*

A good quality sputum sample should be submitted.

Salivary or muco-salivary samples may give misleading results as these samples will be contaminated by normal mouth flora.

Sputum and Antral washout are cultured for all likely Lower Respiratory Tract (LRT) pathogens.

Broncho-alveolar lavage (BALs) are routinely cultured for bacterial pathogens as well as Mycobacteria and Fungi if requested. They are also referred, if indicated, for examination for CMV, other viruses and staining/PCR testing for *Pneumocystis jirovecii* for Cystic Fibrosis culture.

13.4.6 Eye scrapings or swabs

- *Samples required*

1. For investigation of conjunctivitis a culture swab should be taken by retracting the lower eye lid and stroking the tarsal conjunctiva using the general transport swab removing all purulent material.

Use a viral transport swab if viral infection is suspected.

Contact the Microbiology Laboratory for the APTIMA swab if chlamydia infection is suspected.

2. For investigation of endophthalmitis an aspirate from the aqueous humour (anterior chamber tap) is required. Please discuss with the Consultant Microbiologist for clinical advice and notify the Microbiology Laboratory prior to sampling to ensure prompt processing of the sample.

Transport all plates, slides, and swabs immediately to the laboratory.

13.4.6 Throat swab

- *Samples required*

Using a tongue depressor take a swab sample from the tonsil or inflamed area using a blue cap transport swab. Use a pink cap transport swab if viral infection is suspected.

Transport swabs immediately to the laboratory.

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13.4.7 Nasal swab and Nasopharyngeal Swabs

A nasal swab is not usually useful for the investigation of sinusitis.

Antral lavage or pus from sinus should be sent if acute maxillary sinusitis is suspected. Nasal swabs are useful for the investigation of carriage of Staphylococci, including MRSA. Use a pink cap transport swab if viral infection is suspected.

- *Method of collection for nasal swabs*

Rotate one swab twice round each of the anterior nares.

Transport swabs immediately to the laboratory.

Nasopharyngeal swab for respiratory viruses including Influenza, RSV and SARS-CoV-2

Method of collection for nasopharyngeal swabs

Insert the swab into either nostril, passing it into the posterior nasopharynx. Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into a viral transport tube (3 mL). Break swab at the indicated break line and cap the specimen collection tube tightly.

13.4.8 Genital infections

- *Sexually Transmitted Diseases*

Samples required

Females: Cervical or High Vaginal, Urethral, Rectal and Throat Swabs

Males: Urethral Swab, Urethral Smear, Rectal and Throat Swabs

Genital tract swabs

Endocervical and high vaginal swabs are taken with the aid of a speculum. Avoid vulval contamination of the swab. For suspected Trichomonas, sample the posterior fornix and for the investigation of "Thrush" sample any obvious plaques of query Candida.

If **Gonorrhoea/ Chlamydia** are suspected use the APTIMA unisex swab for all endocervical and male urethral samples, together with the APTIMA urine collection kit available from the Microbiology Laboratory. Follow the manufacturer's instructions on the kits for correct specimen collection and handling.

High vaginal swabs

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After the introduction of the speculum, the swab should be rolled firmly over the surface of the vaginal vault. The blue cap swab should then be placed in the transport medium.

Cervical swabs

After introduction of the speculum into the vagina, the swab should be rotated inside the endocervix. The blue cap swab should then be placed in the transport medium.

Urethral swabs

Contamination with micro-organisms from the vulva or the foreskin should be avoided. The patient should not have passed urine for at least 1 hour. For males, the swab is gently passed through the urethral meatus and rotated.

Intrauterine contraceptive devices (IUCDs)

The entire device should be sent for C/S

Rectal swabs

Rectal swabs should be inserted into the 1st part of the anus and if possible, have visible faecal matter.

Molecular testing for CPR/VRE is available upon request/discussion with Infection Prevention and Control Team (IPC) or the Microbiology Consultant. For molecular testing please collect specific molecular swabs from the Microbiology laboratory.

Transport all swabs immediately to the laboratory.

If *Herpes simplex* infection is suspected use a red cap viral swab.

13.4.9 Pus samples / wound swabs

A pus sample is the preferred sample type. Deep swabs rather than superficial will give a more accurate representation of bacteria/ fungi present which may be causing infection. Please indicate clearly on the request form and the swab the anatomical site of the wound otherwise interpretation of culture results may be difficult.

- *Samples required*

1. Pus sample in sterile universal container.
2. Wound swab in transport swab. .
3. The inclusion of relevant clinical information on the request form assists in deciding the relevance of some bacterial isolates.

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13.4.10 MRSA screens

Screens for colonisation by Methicillin-Resistant *Staphylococcus aureus* (MRSA) are required for infection prevention and control reasons. The Consultant Microbiologist and the infection control Clinical Nurse Specialist will initiate and monitor this screening as appropriate.

A full MRSA screen consists of:

- Nasal Swab: Rotate one swab twice round each of the anterior nares.
- Throat Swab: Using a tongue depressor take a swab sample from the tonsil or back of pharynx.
- Groin/perineum Swab: Use one swab for each groin/perineum.

If present, also consider wounds, sites of non-intact skin, intravenous line insertion sites, catheter urine samples, suprapubic catheter sites, peg tube sites and sputum if expectorating.

Please note nasal, groin/perineum and throat swabs are pooled for MRSA screening.

13.4.11 Urine

A clean mid-stream specimen is essential

Urine samples should be transported to the lab as soon as possible. . Any sample which may be subject to delay of more than 2 hrs before being sent to the lab should be refrigerated.

- *Samples required*

MSU: A mid-stream urine is the recommended sample and requires careful collection. Collect after the initial stream is voided.

CSU: Samples should only be sent if clinically indicated i.e., patient symptomatic or systemically unwell or having a catheter change or urinary tract instrumentation. The sample should be taken aseptically through the sampling port close to the patient.

- *Tests available*

1. Microscopy

White cell count: Normal range 0-10 / c.mm

Red cell count (normally absent)

Comment on the presence of bacteria, casts, crystals, yeasts, etc.

2. Urine Culture

Bacterial Colony Count: should be less than 1,000 orgs/ml ($<10^3$ orgs/ml)

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1,000 - 100,000 orgs/ml may indicate UTI
 >100,000 orgs/ml of (one or two organisms with one strain predominating) is usually indicative of UTI

13.4.12 CPE and VRE Screens

Patient screens or environmental screens for colonisation with Carbapenemase Producing Enterobacteriales (CPE), Vancomycin-Resistant *Enterococcus* species (VRE) are required for infection prevention and control of these organisms. The Consultant Microbiologist and the Infection Prevention and Control clinical nurse specialists will initiate and monitor this screening as appropriate.

Molecular testing for CPR/VRE is available upon request/discussion with Infection Prevention and Control Team (IPC) or the Microbiology Consultant. For molecular testing please collect specific molecular swabs from the Microbiology laboratory.

CPE and VRE screening is carried out on a rectal swab (should be stained with faeces) or faeces sample.

13.4.13 Faeces

Samples may be sent for C.difficile, culture for enteric pathogens or for the detection of Norovirus. Diarrhoeal or liquid stool samples are acceptable sample types. Please include as much clinical information as possible, particularly any history of foreign travel. Multiple samples may be required to exclude e.g., giardiasis. Please see BSD/MICRO/SOP/028 "Investigation of Faeces for Ova, Cysts and Parasites" for further details.

13.4.14 Antibiotic assay

Refer to the Bon Secours Hospital, Dublin Antimicrobial Policy available on Hospital Q-Pulse. (Therapeutic Monitoring). Antibiotic assays for therapeutic drug monitoring are referred to the Mater Public Hospital .

13.4.15 Serology/ Virology general comments and requesting guide

Please discuss with the Consultant Microbiologist if a tropical infection or fever in a returned traveller is suspected. Also, if an opportunistic or viral infection is suspected in an immune-compromised patient, please contact the Consultant Microbiologist for advice.

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13.4.16 Pneumonia and Atypical Pneumonia Screen (APS)

If a patient presents with a severe or atypical pneumonia infection, the following pathogens should be considered.

Streptococcus pneumoniae

Send urine for pneumococcal antigen detection (in addition to sending sputum for C&S).

Legionella pneumophila

In an acute setting, please send urine for urinary antigen. This test is useful in the early detection of Legionnaires' disease (*Legionella pneumophila* serogroup 1), however a negative result does not rule out the disease.

ELISA screening for IgG and IgM antibodies for subgroups 1 to 6 is performed on serum. Antibodies appear 2 to 4 weeks after onset of illness.

Chlamydia pneumoniae

Send a respiratory sample or throat and nasal swabs for PCR test.

***Coxiella burnetii* (Q. Fever)**

Send a serum or EDTA sample for antibody tests

***Mycoplasma pneumoniae* (in under 20 years old patients only)**

This is an EIA test for the detection of IgM antibodies in this age-group only. IgM antibodies usually appear 10 days after onset of illness. For patients >20 years old, send a respiratory sample or nasal and throat swab for molecular tests.

Influenzae A and B, RSV and SARS-COV-2

Serology is not appropriate. A nasopharyngeal swab or nasopharyngeal aspirate (NPA) is required for PCR.

13.4.17 General notes on serology

- *Serological tests*

For a serological diagnosis, i.e., antibody tests based on the appearance of IgM, acute (as early as possible in the illness) and convalescent sera (2-3 weeks after on-set) should be taken for antibody titration. A four-fold rise in titre is considered significant. Single samples for serology are of limited value unless used for detection of IgM antibody when such tests are available. Always specify the date of onset of illness and travel history if relevant.

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13.4.18 General notes on virology

- *Virus isolation*

Where virus isolation is attempted, specimens must be taken early in the illness in the correct manner (contact Microbiology department).

Please note: Samples marked 'virus studies' or 'viral screen' will not be processed. Please specify requests and give clinical details. Failure to supply the required information will lead to delays in reporting. The patient's date of birth must be supplied in all cases.

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- *Requesting guide*

NVRL syndromic testing guide, www.ucd.ie/nvrl

Clinical syndrome	Serum	Swab/NPA, CSF	Faeces
Acute Hepatitis, Jaundice, Abnormal LFTs	Hepatitis A IgM Hepatitis B surface Antigen (HbsAg) Hepatitis C Ab/Ag Hepatitis E IgM CMV IgM EBV VCA IgM/IgG +/- Leptospira IgM If clinical features suggestive		
Chronic Hepatitis	Hepatitis BsAg/core Ab Hepatitis C Ab/Ag		
Conjunctivitis/keratitis (NVRL PCR Panel)		Eye Swab Adenovirus DNA PCR Enterovirus RNA PCR HSV DNA PCR VZV DNA PCR +/- <i>C trachomatis</i> / <i>N gonorrhoeae</i> Aptima Collection Device	
Gastroenteritis (NVRL PCR panel)			Norovirus Rotavirus Adenovirus Type F Sapovirus Astrovirus
Myocarditis/Pericarditis	CMV IgM /IgG	Throat Swab/NPA Enterovirus RNA PCR Adenovirus DNAPCR +/- Influenza A/B RNA PCR in season	Enterovirus RNA PCR Adenovirus DNA PCR

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Clinical syndrome	Serum	Swab/NPA, CSF	Faeces
Lymphadenopathy	HIV Ag/Ab EBV VCA IgM/IgG EBV VCA IgG CMV IgM/IgG Toxoplasma IgM		

Clinical syndrome	Serum	Swab/NPA, CSF	Faeces
Arthritis/ Arthralgia	<i>Parvovirus B19</i> IgM Rubella IgM +/- <i>Borrelia burgdorferi</i> (Lyme) serology if clinical features/history suggestive		
Guillain Barre Syndrome	CMV IgM/IgG <i>Hepatitis E</i> IgM EBV VCA IgM/IgG HIV Ag/Ab	Throat Swab/NPA Enterovirus RNA PCR Influenza A/B RNA PCR (in season)	Enterovirus RNA PCR
Vesicular Skin Rash		Swab Blister Fluid <i>Herpes simplex</i> Virus DNA PCR <i>Varicella zoster</i> Virus DNA PCR Enterovirus RNA PCR	
Macular/Papular Rash	<i>Parvovirus B19</i> IgM EBV VCA IgM/IgG CMV IgM/G +/- Measles IgM +/- Rubella IgM +/- HIV Ag/Ab +/- <i>T pallidum</i> (Syphilis)		Enterovirus RNA PCR
Pyrexia of Unknown Origin	CMV IgM/IgG EBV VCA IgM/IgG Toxoplasma IgM/IgG HIV Ag/Ab		
Meningitis/Encephalitis (NVRL Panel)		CSF	Enterovirus RNA PCR

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Clinical syndrome	Serum	Swab/NPA, CSF	Faeces
		<i>Herpes simplex</i> Virus 1&2 DNA PCR Enterovirus RNA PCR <i>Varicella zoster</i> Virus DNA PCR +/- Mumps RNA PCR if clinically features suggestive	

Clinical Syndrome	Serum	Swab/NPA, CSF	Faeces
Viral Respiratory Illness Suspect SARS-CoV-2 Local PCR panel Extended respiratory panel on request (NVRL PCR Panel)		NPA/BAL/ Combined Nose & Throat Swab NPS: SARS-CoV-2 RNA NPS: Influenza A RNA Influenza B RNA <i>Respiratory syncytial virus</i> RNA Adenovirus DNA Parainfluenza Viruses 1-4 RNA <i>Human metapneumovirus</i> RNA Additional testing for Rhinovirus, Enterovirus, Coronavirus can be arranged on discussion if clinically indicated. +/- Consider CMV if immunocompromised, send EDTA blood for CMV	

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Clinical Syndrome	Serum	Swab/NPA, CSF	Faeces
		DNA PCR in addition to NPA/BAL sample.	
Genital Infection	Syphilis (<i>Treponema pallidum</i>) serology And full STI screen to include serology for HIV, HepB & Hep C etc.	Ulcer / blister fluid viral swab for <i>Herpes simplex</i> Virus 1&2 DNA PCR Urine, Urethral or endocervical swab for <i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> Aptima Collection Device	

13.5 Result reporting

13.5.1 Critical results in Microbiology

Extracted from BSD/PATH/I/091 Pathology Critical Results, the following are Microbiology critical results.

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MICROBIOLOGY CRITICAL RESULTS

Critical positive results reported by the Consultant Microbiologist (or appropriate designee) to the Clinician and /or ward:
(Within 2*- 24 hours, as deemed appropriate)

Test	Result	Urgency	Responsibility
Blood culture*	Gram result or culture (clinically significant)	Within 2 hours	Consultant Microbiologist
CSF*	Elevated white cell count or positive gram or culture	Within 2 hours	Consultant Microbiologist
Other sterile sites, as deemed appropriate	Gram or culture	Within 24 hours	Consultant Microbiologist
New alert organisms, clinically relevant sites	Culture or molecular result	Within 24 hours	Consultant Microbiologist
Faecal culture /PCR <i>C. difficile</i>	Positive result	Within 24 hours	Consultant Microbiologist
Mycobacterium	Positive AFB or positive culture/PCR	Within 24 hours	Consultant Microbiologist
Legionella /Streptococcus pneumonia urinary antigen	Positive result	Within 24 hours	Consultant Microbiologist
Leptospira	IgM positive	Within 24 hours	Consultant Microbiologist
Toxoplasma	IgM positive in a pregnant patient	Within 24 hours	Consultant Microbiologist
Treponema pallidum	first detection in a pregnant patient	Within 24 hours	Consultant Microbiologist
CMV	IgM positive or low avidity IgG	Within 24 hours	Consultant Microbiologist
HIV 1 or 2	new detection	Within 24 hours	Consultant Microbiologist
Acute viral hepatitis	new acute or new chronic infection	Within 24 hours	Consultant Microbiologist

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HSV DNA	from eye swab	Within 24 hours	Consultant Microbiologist
Influenza PCR positive	New infective episode	Within 24 hours	Consultant Microbiologist
Parvovirus B19	IgM positive in a pregnant patient	Within 24 hours	Consultant Microbiologist
Measles	Serology IgM positive Oral fluid/ urine RNA positive	Within 24 hours	Consultant Microbiologist
Rubella	Serology IgM positive Oral fluid RNA positive	Within 24 hours	Consultant Microbiologist
SARS-CoV-2 PCR	Positive new infective episode	Within 24 hours	Consultant Microbiologist
Varicella Zoster	IgG negative in a pregnant or immunocompromised patient with a history of recent exposure to VZV	Within 24 hours	Consultant Microbiologist
Antibiotic Assays	All antimicrobial assay levels (with interpretation range where available)	When initial result (verbal, electronic or paper) available	Laboratory staff to the clinical team / CNM
Screening Samples	Alert organisms from screening samples.	When preliminary / final result available	IPC CNM to the relevant clinical area CNM

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13.5.2 Storage of Examined Specimens for Archive and Look Back Purposes

The table below outlines the Storage of Examined Specimens for archive and look-back purposes.

ID	Specimen Description	Storage Requirement	Storage Location	Minimum Retention Period	Responsibility
1.	Serum	Store 2-8°C	Fridge at specimen reception in Microbiology laboratory	48 hours after release of reports	Chief Medical Scientist
2.	Urine Specimens	2-8°C	Fridge at specimen reception in Microbiology laboratory	72 hrs	Chief Medical Scientist
3.	Body fluids/ aspirates/ CSF	2-8°C	Fridge at specimen reception in Microbiology laboratory	2 weeks	Chief Medical Scientist
4.	Microbiological Swabs, faeces, sputa, BALs	2-8°C	Fridge at specimen reception in Microbiology laboratory	5 days	Chief Medical Scientist
5.	Stained Slides	18°C – 25°C	Stained slide box beside hotplate in Microbiology Laboratory	7 days	Chief Medical Scientist
6.	Positive Blood Cultures	18°C – 25°C	Fume hood in Microbiology Laboratory	1 week	Chief Medical Scientist

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ID	Specimen Description	Storage Requirement	Storage Location	Minimum Retention Period	Responsibility
7.	Culture Plates	18°C – 25°C	Shelf area at swab bench in Microbiology Laboratory	5 days	Chief Medical Scientist
8.	Mycology samples	2-8°C	Fridge at specimen reception in Microbiology laboratory	3-4 weeks	Chief Medical Scientist

13.6 Microbiology Tests performed on-call/out of hours

- *Clostridioides difficile* toxin
- Positive blood culture
- SARS-CoV-2, Flu A & B, RSV
- CSF
- Referral of Occupational Blood Exposure
- Please inform the medical scientist on-call if any of the above tests are to be performed.
- The on-call scientist mobile number is **087 2513101**

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14 CLINICAL CHEMISTRY

14.1 Department Profile

Clinical Chemistry involves the use of biochemical measurements to support the diagnosis, treatment, prevention and monitoring of disease. Measurements are made in blood, urine, cerebrospinal fluid and other body fluids. Biochemical measurements can assist in determining the function of the kidneys, liver, heart, thyroid and other endocrine organs as well as assessing cardiovascular risk and diagnosing and monitoring diabetes.

14.2 Clinical Chemistry Request Forms, Specimen Containers and Specimen and Form Identification

Refer to (BSD/PATH/I/111) for further information on Specimen Containers for individual Clinical Chemistry tests.

14.3 Clinical Advice and Service

Clinical advice and interpretation are available from the Consultant Chemical Pathologist via hospital reception.

14.4 Index of Laboratory Tests

Information on all tests carried out in Clinical Chemistry can be found in BSD/PATH/I/111 "Table of all Tests".

14.5 External Laboratory Tests

Information on tests sent to referral laboratories can be found in BSD/PATH/I/111 "Table of all Tests". Specimen/samples referred to external laboratories for testing are identified by addition of an asterisk * after the test name. If you require a diagnostic test that is not listed, please contact us and we will endeavour to find a quality provider to meet your requirements.

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14.6 Profiles/Tests available in-house & Reference Ranges

In addition to the tests listed in the index of laboratory tests (BSD/PATH/I/111), the following profiles (including reference ranges) are available:

Test Name	Reference Interval	Source
Renal profile		
Sodium, serum	136 – 145 mmol/L	Abbott IFU (BSD/CC/EX/338)
Potassium, serum	Serum 3.5 – 5.1 mmol/L Plasma Male 3.5 – 4.5 mmol/L* Plasma Female 3.4 – 4.4 mmol/L* *Coded comment KP on LIS	Abbott IFU (BSD/CC/EX/338)
Chloride, serum	98 – 107 mmol/L	Abbott IFU (BSD/CC/EX/338)
Urea, serum	Male: <50yrs 3.2 – 7.4 mmol/L >50yrs 3.0 – 9.2 mmol/L Female:<50 yrs 2.5 – 6.7 mmol/L >50 yrs 3.5 – 7.2 mmol/L	Abbott IFU (BSD/CC/EX/338)
Creatinine (enz), serum	Male: 64 – 104 µmol/L Female: 49 – 90 µmol/L	Abbott IFU (BSD/CC/EX/338)
eGFR	Refer to Irish CKD guidelines	Irish CKD Guidelines (BSD/CC/EX/179)
Liver profile		
Total protein, serum	Ambulatory 64 – 83 g/L >60yrs 62 – 81 g/L	Abbott IFU (BSD/CC/EX/338)
Albumin, serum	14 – 18 yrs 32 – 45 g/L < 60 yrs 35 – 52 g/L 60– 90 yrs 32 – 46 g/L > 90 yrs 29 – 45 g/L	Abbott IFU (BSD/CC/EX/338)
Globulin, serum	19 – 35 g/L	Interpretation of Diagnostic Tests 7 th Edition. Wallack J Lippincott Williams and Wilkins 2000
Total Bilirubin, serum	3.4 – 20.5 µmol/L	Abbott IFU (BSD/CC/EX/338)
AST, serum	Adult 11 – 34 U/L	Abbott IFU (BSD/CC/EX/338)
ALT, serum	Adult Male < 45 U/L Adult Female <34 U/L	Abbott IFU (BSD/CC/EX/338)
GGT, serum	Male <55 U/L Female <38U/L	Abbott IFU (BSD/CC/EX/338)
ALP, serum	Male: 16 – 21yrs 55 - 167 U/L >22yrs 50 – 116 U/L Female: 16 – 29 yrs 44 – 107 U/L >30yrs 46 – 122 U/L	Abbott IFU (BSD/CC/EX/338)
Bone profile		

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Calcium, serum	2.20 – 2.60 mmol/L	Pathology UK Harmony (BSD/CC/EX/178)
Adjusted Calcium	2.20 – 2.60 mmol/L	Pathology UK Harmony (BSD/CC/EX/178)
Albumin, serum	As above	As above
Phosphate, serum	0.81 – 1.45 mmol/L	Abbott IFU (BSD/CC/EX/338)
ALP, serum	As above	As above
Test Name	Reference Interval	Source
Iron profile		
Iron, serum	Male: 14-19 yrs 5.5 – 30.3 µmol/L ≥19 yrs 11.6 – 31.3 µmol/L Female: 14-19 yrs 3.6 – 29.0 µmol/L ≥19 yrs 9.0 – 30.4 µmol/L	Abbott IFU (BSD/CC/EX/338)
Transferrin, serum	Male: 14-60yrs 1.74 – 3.64 g/L 60-80yrs 1.63 – 3.44 g/L Female: 14-60yrs 1.80 – 3.82 g/L 60-80yrs 1.73 – 3.60 g/L	Abbott IFU (BSD/CC/EX/338)
Transferrin Saturation, serum	Male: 20 – 50% Female: 15 – 50 %	Tietz (4 th edition)
Lipid profile		
Cholesterol, serum	Desirable < 5.0 mmol/L	National Laboratory Handbook Lipid Testing (BSD/CC/EX/251)
Triglycerides, serum	Desirable < 1.7 mmol/L	National Laboratory Handbook Lipid Testing (BSD/CC/EX/251)
HDL cholesterol, serum	Male Desirable > 1.0 mmol/L Female Desirable > 1.3 mmol/L	NCEP ATP III (BSD/CC/EX/252)
LDL cholesterol, serum	Desirable < 3.0 mmol/L	National Laboratory Handbook Lipid Testing (BSD/CC/EX/251)
High Sensitivity Troponin I, plasma	Male: <34 ng/L Female: <16 ng/L	Abbott IFU (BSD/CC/EX/338)
NT-proBNP, plasma	<75 yrs <125 pg/mL ≥75 yrs <450 pg/mL	Abbott IFU (BSD/CC/EX/338)
CK, serum	Male: 30 – 200 U/L Female: 29 – 168 U/L	Abbott IFU (BSD/CC/EX/338)
LDH, serum	125 - 220 U/L	Abbott IFU (BSD/CC/EX/338)
Amylase, serum	Adult 28– 100 U/L	Abbott IFU (BSD/CC/EX/338)
Magnesium, serum	0.66 – 1.07 mmol/L	Abbott IFU (BSD/CC/EX/338)
Urate, serum	Male: 220 - 450 µmol/L Female: 150 - 370 µmol/L	Abbott IFU (BSD/CC/EX/338)
Lactate (whole blood)	Arterial 0.4 – 0.8 mmol/L Venous 0.6 – 1.4 mmol/L	Tietz (4 th edition)
Glucose		

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Glucose, plasma	Fasting 2hr PP	< 6.1 mmol/L < 7.8 mmol/L	WHO Guidelines (BSD/CC/EX/253)
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Test Name	Reference Interval	Source
HbA1c		
HbA1c	20-42 mmol/mol	IFCC (BSD/CC/EX/254)
Proteins		
CRP	≤ 5 mg/L	Abbott IFU (BSD/CC/EX/338)
CSF specimen		
CSF glucose	2.22 – 3.89 mmol/L	Abbott IFU (BSD/CC/EX/338)
Arterial Blood Gas		
pH	7.35 – 7.45 (Arterial)	Tietz (4 th edition)
PO ₂	11.1 – 14.4 kPa (Arterial)	Tietz (4 th edition)
PCO ₂	4.5 – 6.0 kPa (Arterial)	Tietz (4 th edition)
Standard bicarbonate	24 – 29 mmol/L (Arterial)	Tietz (4 th edition)
O ₂ saturation	94 – 98 % (Arterial)	Tietz (4 th edition)
Base excess	N/A	N/A
24 hour urine		
24 hr urinary Sodium	Male: 40 – 200 mmol/24hr Female: 27 – 287 mmol/24hr	Abbott IFU (BSD/CC/EX/338)
24 hr urinary Creatinine	Male: 7.7 – 21.3 mmol/24hr Female: 5.9 – 14.1 mmol/24hr	Abbott IFU (BSD/CC/EX/338)
Creatinine Clearance	Male: 61 – 147 ml/min Female: 59 – 151 ml/min	Abbott IFU (BSD/CC/EX/338)
Haematinics		
Ferritin, serum	Male: 22 – 275 µg/L Female: 5 – 204 µg/L	Abbott IFU (BSD/CC/EX/338)
B12, serum	187- 883 ng/L	Abbott IFU (BSD/CC/EX/338)
Folate, serum	3.1 – 20.5 µg/L	Abbott IFU (BSD/CC/EX/338)
Thyroid Hormones		
TSH, serum	0.4 – 5 mIU/L	Abbott IFU (BSD/CC/EX/338)
FT ₄ , serum	9 – 19 pmol/L	Abbott IFU (BSD/CC/EX/338)
Cortisol		
Cortisol, serum	AM 102 – 535 nmol/L PM 80 – 477 nmol/L	Abbott IFU (BSD/CC/EX/338)
Tumour markers		
PSA, serum	Caucasian <50 yrs <2µg/L 50-59 yrs <3µg/L 60-69 yrs <4µg/L >70 yrs <5 µg/L	NCCP Guidelines (BSD/CC/EX/179)

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CEA, serum	<5 ug/L	Abbott IFU (BSD/CC/EX/338)
CA 125, serum	<35 kU/L	Abbott IFU (BSD/CC/EX/338)
CA 153, serum	<31 kU/L	Abbott IFU (BSD/CC/EX/338)
AFP, serum	<7.3 kU/L	Abbott IFU (BSD/CC/EX/338)

14.7 Turnaround times

Turnaround time is defined in hours or working days. Working days means Monday to Friday and excludes out-of-hours periods including weekends and bank holidays. Turnaround time for routine samples is within 4 hours and for urgent samples within 90 minutes on working days. Working days do not include weekends or public holidays or the on-call period.

14.8 Interferences

Many tests are subject to interference. This may be biological, where the offending substance alters the true concentration within the body, or analytical, where the method is not specific. The report may mention some of the more common interferences e.g., haemolysis, lipaemia and icterus. A list of known substances that interfere with each method is available from the Clinical Chemistry laboratory. Please be mindful of drug interactions that may alter or affect laboratory results as scientific staff are unlikely to be aware of patients medications/ treatments which may impact on results.

14.9 Retrospective Requesting

Routine Clinical Chemistry specimens are archived for up to 1 week at a temperature of 2 °C - 8°C. If you need further tests on a specimen that is already in the laboratory, please contact the Clinical Chemistry laboratory at ext. 5319. Analysis for additional tests is subject to stability of the analyte and availability of sufficient sample.

14.10 Result Reporting

14.10.1 Critical Results in Clinical Chemistry

As documented in BSD/PATH/I/091 Pathology Critical Results, the first instance of the following Clinical Chemistry critical results are phoned to the clinical area as soon as the result becomes available.

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Test	Unit	Lower Limit	Upper Limit
ALT (Female)	U/L	-	510
ALT (Male)	U/L	-	675
AST	U/L	-	510
Amylase	U/L	-	500
Adjusted Calcium	mmol/L	≤1.8	≥ 3.0
CK	U/L	-	≥5000
Cortisol	nmol/L	≤ 50	-
C Reactive Protein	mg/L	-	≥ 300
Creatinine	μmol/L	-	≥ 354
eGFR	mL/min	≤ 15	-
Gentamicin	mg/L	-	>2
Glucose	mmol/L	≤ 2.5	≥ 25.0
Lactate	mmol/L	-	≥2.0
Magnesium	mmol/l	≤ 0.4	1.2
Phosphate	mmol/L	≤ 0.45	3.0
Potassium	mmol/L	≤ 2.5	≥ 6.0
Sodium	mmol/L	130	150
PSA (total)	μg/L	-	10
Triglyceride	mmol/L	-	≥ 20
hs Troponin I	ng/L	-	m>34, f>16
TSH	mIU/L	-	30
T4 (free)	pmol/L	5	35
Urea	mmol/L	-	≥ 30
Vancomycin	mg/L	-	>25

In addition to the above:

- Haemolysed samples are phoned if tests in addition to AST are unsuitable for testing (AST only impacted – no phoning required)
- Any results which show a clinically significant change are phoned

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- All critical results phoned from external laboratories are phoned to the appropriate clinician/ward area by the medical scientist who receives the call within 24 hours.

15 HAEMATOLOGY

15.1 Department Profile

A frontline haematology service is provided which includes full blood count with blood film examination, routine coagulation screening which includes PT-INR, APTT, Fibrinogen and D-Dimer tests. Reticulocyte counts, ESR and Infectious Mononucleosis screening tests are also carried out in-house. Specialised tests are referred to external laboratories as per BSD/HAEM/I/018 "Instruction for Haematology Referral Tests"

15.2 Clinical Advice and Service

Clinical advice and interpretation are available from the Consultant Haematologists by contacting the Hospital reception via the switchboard.

15.3 Index of Laboratory Tests

Information on all tests carried out in Haematology can be found in BSD/PATH/I/111 "Table of all Tests" and BSD/HAEM/I/018 "Instruction For Haematology Referral Tests".

15.4 External laboratory testing

Information on tests sent to referral laboratories can be found in BSD/PATH/I/111 "Table of all Tests".

Specimen/samples referred to external laboratories for testing are identified by addition of an asterisk * after the test name. If you require a diagnostic test that is not listed, please contact us: we will endeavour to find a quality provider to meet your requirements.

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15.5 Profiles available in-house and Turnaround Times

The following profiles are available from the Haematology Department. Please refer to BSD/PATH/I/111 "Table of All Tests" for further information on specimen containers for individual Haematology tests.

Turnaround time is defined in hours or working days. Working days means Monday to Friday and excludes out-of-hours periods including weekends and bank holidays.

Profile	Tests	Sample requirements	Turnaround time (TAT)
Full Blood Count	White cell count, red cell count, Haemoglobin, Platelet count, Red cell indices, 5-part WCC Differential	2.7 ml EDTA tube Sample received within 24 hrs if stored at 2-8°C	Routine 4 hours Urgent 1 hour
Reticulocyte Count	Reticulocyte Count	2.7 ml EDTA tube Sample received within 24 hrs if stored at 2-8°C	Routine 4 hours Urgent 1 hour
Erythrocyte Sedimentation Rate	ESR	Sarstedt ESR 4NC 2ml tubes. Sample received within 4-6 hrs at room temp or 24 hrs at 2-8°C	Routine 4 hours
Infectious Mononucleosis Screening Test	Infectious Mononucleosis Screening Test	2.7 ml EDTA tube or 4.5 serum tube. Plasma must be tested within 24 hours of blood collection. Serum may be tested up to 8 days after collection.	Routine 4 hours
Blood Film Review - Scientist	TFILM	2.7 ml EDTA tube	Routine:1 working day Urgent: 4 hrs

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Profile	Tests	Sample requirements	Turnaround time (TAT)
Coagulation Screen	Prothrombin Time (PT) International Normalised Ratio (INR) Activated Partial Thromboplastin Time (APTT)	Blood Tube (3mL) containing Sodium Citrate, received within 4 hours of collection.	Routine 4 hours Urgent 70 mins
Fibrinogen and / or D- dimers	Fibrinogen / D-Dimers	Blood Tube (3mL) containing Sodium Citrate, received within 4 hours of collection.	Routine 4 hours Urgent 70 mins,
Heparin monitoring	Activated Partial Thromboplastin Time (APTT) Activated Partial Thromboplastin Time Ratio (APTTR)	Blood Tube (3mL) containing Sodium Citrate, received within 4 hours of collection.	Routine 4 hours Urgent 70 mins
Warfarin monitoring	Prothrombin Time (PT) International Normalised Ratio (INR)	Blood Tube (3mL) containing Sodium Citrate, received within 4 hours of collection.	Routine 4 hours Urgent 70 mins

Note - for any add on test requests, the time of initial sample collection will be taken into account as per the table above.

Please contact the Haematology lab (ext. 5324) for information on other tests that may be referred to external laboratories.

Sample stability established by Haematology Laboratory as per BSD/Haem/I/036 Stability Study for Haematology tests – Information available upon request.

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15.6 Reference ranges

Source of FBC reference ranges: BSD/HAEM/EX/123 Dacie and Lewis, Practical Haematology, B. J. Bain, I. Bates, M. A. Laffan, 12th edition.

FBC Reference Ranges

Parameter	Units	Male	Female
White cell count	x10 ⁹ /L	4.0-10.0	4.0-10.0
Haemoglobin	g/dL	13.0-17.0	12.0-15.0
Platelet count	x10 ⁹ /L	150-410	150-410
Red cell Count	x10 ¹² /L	4.5-5.5	3.8-4.8
Haematocrit	L/L	0.400-0.500	0.360-0.460
Mean Cell Volume	fL	83-101	83-101
Mean Cell Haemoglobin	pg	27-32	27-32
Mean Cell Haemoglobin Concentration	g/dl	31.5-34.5	31.5-34.5
RDW	%	11.6-14	11.6-14
Neutrophils	x10 ⁹ /L	2.0-7.0	2.0-7.0
Lymphocytes	x10 ⁹ /L	1.0-3.0	1.0-3.0
Monocytes	x10 ⁹ /L	0.2-1.0	0.2-1.0
Eosinophils	x10 ⁹ /L	0.02-0.5	0.02-0.5
Basophils	x10 ⁹ /L	0.02-0.1	0.02-0.1
Reticulocytes	x10 ⁹ /L	50-100	50-100
Reticulocytes	%	0.5-2.5	0.5-2.5

Source of PT/APTT/Fibrinogen reference ranges: locally derived.

Source of D-Dimer reference ranges: BSD/HAEM/EX/113 Application Sheet for D-Dimer with Innovance D-Dimer.

Coagulation Reference Ranges

Parameter	Units	Range
PT	sec	10.1-12.9
INR		*
APTT	sec	22.1-29.6
D-Dimer	mg/L	<0.5
Fibrinogen	g/L	1.5-4.0

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*The INR should only be used for monitoring warfarin therapy.

Source of ESR reference ranges: BSD/HAEM/EX/123 Dacie and Lewis, Practical Haematology, B. J. Bain, I. Bates, M. A. Laffan, 12th edition.

ESR Reference Ranges

Age (Men)	Range	Units
17-50	0-10mm	mm/Hr
51-61	0-12mm	
61-70	0-14mm	
>70	0-30mm	

Age (Women)	Range	Units
17-50	0-12mm	mm/Hr
51-61	0-19mm	
61-70	0-20mm	
>70	0-35mm	

Reference interval sources for Haematology tests are available on Q-Pulse: BSD/HAEM/I/028 Haematology Reference Ranges Instruction.

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15.7 Guidelines for Warfarin use and target INR:

<u>Target INR 2.5</u>	<u>Target INR 3.5</u>	<u>Not indicated</u>
Pulmonary embolus Proximal DVT Calf Vein thrombosis Recurrence of venous Thromboembolism Non–rheumatic atrial Fibrillation Atrial fibrillation other Causes Mural thrombus Cardiomyopathy Cardioversion (or 3.0) Symptomatic inherited Thrombophilia Antiphospholipid syndrome Bio prosthetic valve if anticoagulated Arterial grafts if anticoagulated Mechanical prosthetic aortic valve (or 3.0)	Recurrence of venous thromboemb olism whilst on Warfarin therapy Mechanical prosthetic valve (or 3.0)	Ischaemic stroke without AF Retinal vein occlusion Peripheral arterial thrombosis and grafts Coronary artery thrombosis Coronary artery graft thrombosis Coronary angioplasty and stents

The indications and targets are taken from the British Society of Haematology guidelines, Keeling D et al: Guidelines on oral anticoagulation with warfarin – Fourth edition BJ Haem August 2011; Volume 154; Issue 3; 311-324.

Refer to local Guidelines for Heparin monitoring and target range

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15.8 Result reporting

15.8.1 Critical results in Haematology

As documented in BSD/PATH/I/091 Pathology Critical Results, the following Haematology critical results are phoned by laboratory staff to the ward within 30 minutes on first presentation:

	Units	Lower Limit	Higher Limit
Haemoglobin	g/dL	< 8.0	> 20
Platelet Count	(X10 ⁹ /L)	< 50	>600
Absolute White Cell Count	(X10 ⁹ /L)	N/A	> 30
Absolute Neutrophil Count	(X10 ⁹ /L)	< 1.0	N/A
INR	RATIO	N/A	> 5.0
APTT	Time in Seconds	N/A	>40 seconds
Fibrinogen	g/L	< 1.5	N/A
D-Dimer	mg/L	N/A	>0.5
Blast cells	Blast cells seen on blood film will be phoned after discussion with consultant haematologist.		

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