Beaumont Hospital Clinical Directorate of Laboratory Medicine

Guide to Use of Laboratory Services for GP/Nursing Home Users

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DEPARTMENTAL INFORMATION

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Blood Transfusion	Clinical Guidelines Laboratory Information	
Haematology & Coagulation & Flow Cytometry	Clinical Guidelines Laboratory Information	
Chemical Pathology	Clinical Guidelines Laboratory Information	
Immunology	Clinical Guidelines Laboratory Information	
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NHISSOT	Clinical Guidelines Laboratory Information	

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1 INTRODUCTION

This user guide is designed to enable Laboratory users to obtain the maximum benefits from the services provided by the Clinical Directorate of Laboratory Medicine in Beaumont Hospital.

The information provided is a broad guideline to the use of more commonly used tests. However the Consultant Pathologists and staff of the individual Laboratory Departments are always happy to discuss the service & individual patients in more detail.

1.1 UPDATES OF USER'S HANDBOOK

This Handbook is available on the Hospitals Internet site, and will be updated on a regular basis. If you have any suggestions for improvements please contact the Laboratory Manager or Quality Manager.

Please note the most up to date version of this manual will be available online. It is policy within the Clinical Directorate of Laboratory Medicine to notify external users of updates to this manual by email.

Changes between revisions of the user guide will be highlighted in grey text to alert users of changed information.

2 TESTING GUIDELINES

2.1 BLOOD TRANSFUSION & HAEMOVIGILANCE

Beaumont Hospital Blood Transfusion Department is fully licensed by the Health Products Regulatory Authority (HPRA). The Blood Transfusion Department is also accredited to ISO 15189 by the Irish National Accreditation Board (INAB). It incorporates the Blood Transfusion Laboratory, the Haemovigilance Office and Traceability functions.

The department supplies blood components and blood products on site to patients and red blood cells to off-site Beaumont Hospital patients in St Joseph's Raheny. It also supplies red cells to St Francis Hospice (Raheny & Blanchardstown) and to St Luke's Radiation and Oncology Centre on Beaumont Hospital campus.

NOTE: Comprehensive policies and procedures are available on the Blood Transfusion intranet page.

Related documents: available on hospital intranet

BTD-HVO-041:	Indications for Blood components and blood products.
BTD-HVO-026	Patient Identification
BTD-HVO-004	Pre-Transfuison Group & Screen Sampling
BTD-HVO-007	Prescription of Blood Components and Products
BTD-HVO-039	Ordering Blood components and products from the Blood Bank
BTD-HVI-001:	Quick Reference Blood Transfusion Product Administration Guidelines
BTD-HVO-009:	Administration.
BTD-HVO-008	Care and monitoring of Transfusion recipents
BTD-HVO-011	Fateing/Disposal of Blood Components and Products
BTD-HVI-007	Guidelines for use of CMV and irradiated Blood Components
BTD-HVI-008:	Maximum Surgical Blood Ordering Schedule
BTD-HVO-042:	Emergency/Massive transfusion protocol (MTP) MTP Poster
BTD-F-0283:	MTP Poster
BTD-HVO-040:	Blood Track for Users.
BTD-HVO-031:	Transport of Blood Components and products from the Blood Transfusion Department
BTD-HVO-015:	Serious Adverse Reactions (Clinical Areas)
BTD-HVO-016	Serious Adverse Events (Clinical Areas)
BTD-HVO-002	Haemovigilance Management of Serious Adverse Events (Including Reporting to the NHO)
BTD-HVI-005	Non Blood Transfusion staff required training

2.2 SERVICE PROVISION HOURS AND CONTACT DETAILS:

- Routine hours: 8am to 5pm Monday to Friday, 9am to 1pm Saturday. Ext: 2705
- Emergency out of hours: 5pm to 8am Monday to Friday, 1pm Saturday to Monday 8am. Bleep: 252

Contact details:

- Consultant Haematologist: Dr Philip Murphy
  Email: philipmurphy@beaumont.ie

- Chief Medical Scientist: Janice O Shaughnessy. Ext: 2705
  Email: janiceoshaughnessy@beaumont.ie

- Haemovigilance. Ext: 2034
  Email: haemovigilance@beaumont.ie

Training:

Blood Transfusion training is mandatory in order to partake in any aspect of transfusion. Details of staff specific training can be found on BORIS and the hospital Intranet Blood Transfusion page. (See BTD-HVI-005)

2.3 BLOOD PRODUCTS/ COMPONENTS AVAILABLE

- Red Blood Cells
- Platelets
- Frozen Plasma
- Fibrinogen
- Flexbumin 20% and Albumin 5%
- Factor Concentrates (human & recombinant) e.g. factor VIIa, factor VIII, factor VIII/ human von Willebrand factor, factor IX, Prothrombin Complex Concentrate, PCC.
- Other Products on request

See BTD-HVO-041 Indications for Blood components and blood products

2.4 TURNAROUND TIMES

On receipt, specimens are logged into the LIS by the receiving Scientist. Turnaround Times are defined as the length of time taken from receipt of the sample to release of the report /product. This may be a manual report, electronic report visible on the LIS or verbal report via phone call. Turnaround time for products requested by users will be reflected by clinical need. If the patient has

an antibody, turnaround time will vary from above depending on the serological investigations required to identify the antibody.

2.5 PATIENT IDENTIFICATION

All patients admitted to Beaumont Hospital require a patient identification band applied to their dominant wrist (and ankle where patients are admitted to theatre) by the admitting Registered Nurse. In the event of removal of an ID Band, it is the responsibility of the person who removed it to ensure that the patient is re-identified and the ID Band is repositioned on the patient as per PPCC-NCAR-080

2.5.1 *Positive Patient Identification (PPID)*

Ask the patient to state, without prompting, his/her full name and date-of-birth and verify these details with the patient's ID band. If the patient is unable to state their name, etc, then verify the patient's full name, date-of-birth and Medical record Number in the patient's Healthcare Record/Emergency Department notes with the patient's ID Band and verify these details with parent/ guardian/ nurse/carer if present.

If any of the information does not correspond, the attending nurse must be contacted to clarify and amend the details before any blood transfusion transactions occur.

PPID must be carried out by an appropriately trained member of Beaumont Hospital staff:

- Before a Beaumont Hospital ID Band is placed on a patient's wrist or ankle.
- Before taking a blood specimen for Group and Screen testing (manual / Bridge Specimen Collection Device). This procedure is described in the SOP BTD-HVO-004 Pre-transfusion Group & Screen Sampling.
- At the start of the Pre-transfusion Checking Procedure, (manual/ Blood Track™ PDA Device). This procedure is described in the SOP BTD-HVO-009 Administration of Blood Components and Products.
- After a transfusion is stopped due to a suspected Serious Adverse Reaction or suspected Serious Adverse Event, in order to determine that the correct blood has been given.

2.5.2 *Unidentified Patient*

A list of unique identification codes will be maintained by the managers and supervisors in the emergency department designed for use in correlating positive identification for blood transfusion purposes, of an unidentified patient. These are designed for use in an emergency/life threatening situation for an unidentified patient(s) Where details are unknown, a unique computer generated ID is entered as a first name, 'Trauma' is entered as the surname and the pseudo DOB is 01/01/1901as per ED-SOP-1.

2.6 BEAUMONT HOSPITAL MAJOR EMERGENCY PLAN

In the event of a Major Incident where there are multiple unidentified casualties, pre assigned hospital records will be used.

On being advised that the Beaumont Major Incident Plan is in operation, patients will initially be assigned Medical Record Numbers and pseudonyms on admission into the Emergency Department using the Major Emergency Patient Identification Pack (MEPIP). This contains a pre-printed ID Bracelet as per PPCC-ED-11.

The Bridge PDA/Desktop device, where possible, should be used to label Group&Screen sample and for transfusion purposes, scanning the 2D barcode on patients wristabnd band that they are wearing.

2.7 PATIENT INFORMATION / CONSENT:

Signed consent for transfusion is not a legal requirement in the UK and Ireland. However, the patient should be informed of the reason for transfusion and associated risks / benefits. A record of this discussion should be documented in the patients' medical notes. The blood transfusion prescription (BTD-HVF-018) question on consent should also be answered by the prescribing Doctor. Patient Information leaflets are available in all wards and on the Hospital intranet site and on the HSE website in various languages. Patient's decision to refuse transfusion should also be documented in the medical notes.

2.8 GROUP AND SCREEN SAMPLE:

- A Group and Screen determines the patients' blood group (Group) and if they have any antibodies in their plasma (Screen).
- A G/S is required if a patient needs: Red Cells, Platelets, Plasma or granulocytes.
- Once processed a G/S is valid for 72 hours

- Check if patient already has an in-date G/S to save time and avoid unnecessary phlebotomy.
- In emergencies, G/S should be hand delivered to avoid delays.
- You should only order a G/S if your patient is likely to require transfusion within the next 3-6 days (please refer to the Maximum Surgical Blood Ordering Schedule for pre-operative patients and the GAIN Guidelines for Red Cell Transfusion for haemoglobin transfusion triggers. All guidelines are available on the Hospital intranet under Blood Transfusion Department.

2.8.1 *Extending a GS*

A G/S is valid for:

1. 72 hours (expiring at midnight of the 3rd day) - if the patient has been transfused or pregnant in the last 3 months

2. 7 days - Once a Doctor has confirmed that a patient has not had a transfusion or pregnancy within the last 90 days, they can phone the Blood Transfusion Laboratory with this information whereby the GS can be extended.

2.8.2 *Pre-Transfusion Type and Screen Sampling*

The Blood Transfusion Dept. has strict sample acceptance criteria for Group & Screen samples.

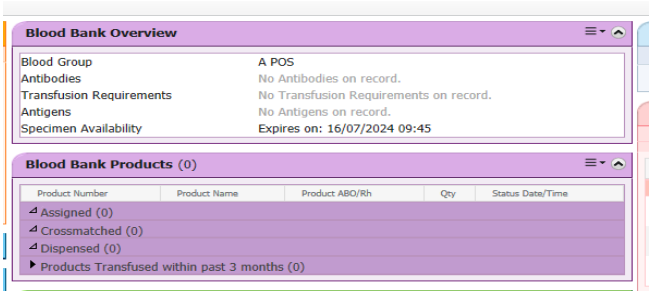
Group & Screen sampling must be performed as one continuous, uninterrupted procedure at the patient's bedside by a fully trained member of staff. (BSH 2017). The Patient must be wearing a Beaumont Hospital ID band or St Francis Hospice ID band. ***Please do not take a GS sample if patient is not wearing an ID band or if ID band details are incorrect***. *See SOP BTD-HVO-4 Pre-Transfusion Group and Screen sampling*

The GS requests from GPs are not tested in the BTD as they do not satisfy patient identification criteria as detailed in ISO15189.

2.9 **ELECTRONIC RESULTS:**

2.9.1 *Blood Transfusion Widget on PowerChart*

The BTD widget is viewable in the MedLIS summary view in PowerChart which is supplementary to results review - see below.



It displays the following data items:

- Blood Group
- Antibodies.
- Transfusion Requirements.

Requirements	Purpose	When is it added
2nd Specimen needed if blood required	Informs users on PowerChart that a 2nd specimen is required (first time non-O)	BTD staff add requirement on first time non-O patient
Previous Transfusion Reaction	Inform users that patient has a TRX	BTD add requirement when patient has had a TRX as a final result when HVO complete investigation
HLA platelets		Clinician can add requirement at time of ordering or can be added by BTD
Serological XM: expect red cell delays	Informs users patient is not eligible for computer crossmatch	
Use CMV negative		Clinician can add requirement at time of ordering or can be added by BTD
Use Irradiated		Clinician can add requirement at time of ordering or can be added by BTD
CMV- Pregnancy		Added by clinician when they select pregnant when ordering or can be added by BTD

- Antigens.
- Specimen availability: 72hrs from date/time collected (unless changed in the BTD).
- A history of blood bank products within the last 3 months in various states up to transfused.
    - Assigned: **not used in BTD**
    - Crossmatched: should be no products here as all products dispensed
    - Dispensed: products in Issue Fridge
    - Products transfused within the past 3 months: as per description.

2.9.2 *Blood Transfusion Test Requests Reports on Powerchart*

All specimens with test requests are received in lab.Specimen status is visible once received in lab from collected to verified. All results are viewable on Powerchart in Results Review. All report results are printable from Powerchart. SFH report will be emailed. .

2.9.3 *Group & Screen Results (Including Antibody ID)*

Computer Crossmatch Eligible:

- In **Results Review test comments** it will NOT state serological crossmatch required on test and a date/time will appear in specimen availability
- In **Blood Bank Overview at Transfusion Requirements**: will either be blank or say "2nd Specimen needed if blood required" for first time non O Patients
- Blood can be crossmatched in 20 minutes in urgent situations with product requisitions.

Serological Crossmatch required on current specimen:

- In **Results review** the following test comment will state "*A serological crossmatch is required. Please give at least 3 hours' notice prior to transfusion or surgery"*.
- In **Blood Bank Overview at Transfusion Requirements** it will state Serological XM: expect Red Cells delay.

A Serological Crossmatch is required due to the patient having clinically significant antibody.

- In **Results review** the following comment will state: "*A serological crossmatch is required due to the patient having clinically significant antibody. Please give 24 hours' notice prior to transfusion or surgery"*
- In **Blood Bank Overview at Transfusion Requirements** it will state Serological XM: expect Red Cells delay **AND** antibodies will be visible in widget.

Specimen referred to the IBTS for further serological investigations and crossmatching and other

- Group & Screen test will have a Ref Lab test added on. Generally the GS will be cancelled with reason.

- In **Results Review** the Reference Laboratory results test comments are variable but generally contain one or more of the following:
    - *"A serological crossmatch is required due to the patient having clinically significant antibody. Please give 24 hours' notice if red cells are required."*
    - *"Testing performed in the IBTS. The results of these tests referred to IBTS are not covered by the scope of the Blood Bank Departments ISO15189 accreditation"*
    - A scanned copy of IBTS ref lab report will be viewable on Powerchart.
- In **Blood Bank Overview at Transfusion Requirements** it will state Serological XM: expect Red Cells delay where applicable.
- In **Blood Bank Overview Antibodies** will be present where applicable
- IBTS reports are signed by IBTS Medical Scientist. Where the IBTS issues cross-matched blood the final compatibility report is signed by the IBTS Medical Scientist and subsequently reviewed by an IBTS Consultant Haematologist.

2.9.4 *Direct Antiglobulin Test (DAT)*

- DAT Results are available on Powerchart
- In **Results Review** test results will be viewable along with any comments added.

2.9.5 *ABO Titrations*

- ABO Titrations results are available on Powerchart
- Clinical Staff will see Result in **Results Review** Section where any comments attached will be visible also
- Critical Results: An IgG and/or an IgM ABO Titre result of >1:32 post-transplant is deemed a critical result and will be phoned to Colm Magee, Renal Consultant, through switch. If unable to contact Colm Magee, the result will be phoned to the transplant Coordinators office on Ext 4884. Transfusion Reaction Investigation

Reporting is in two forms on Powerchart;

- Preliminary Transfusion Reaction Result: details the conclusion of serological work-up in text format.
- Transfusion Reaction Report (Final): contains full details of the reaction with NHO and Consultant Haematologist sign-off.

2.9.6 ***Cold Agglutinins***

Cold agglutinins tests are not carried out in the hospital Blood Bank and are referred to the IBTS. The result is reported on Powerchart.

The scanned result from IBTS is viewable in results review.

2.9.7 ***Unsuitable specimen reports for Rejected Specimens***

- If the quality of the specimen received renders it unsuitable for analysis/duplicate e.g. haemolysed, no PPID, insufficient etc the specimen will be rejected

- Rejected specimens will be reported with an accession add-on of **Test Not Done**. ***Rejected***: Reason for rejection will be stated in a comment.

2.10 SECOND SAMPLE POLICY

A second sample is only required when the patient is for red cell transfusion, is not group O and has no other historical group on file, however group O compatible red cells can be issued without delay. This applies exclusively to 1st time non-blood group O patients (i.e. group A, B and AB) requiring a transfusion. A second sample is required for group verification and must be taken independently of 1st TS sample. Duplicate sample taken at the same time will be rejected.

2.11 CROSSMATCH

A valid GS is required for red blood cell crossmatch, a historical GS is required for platelets and plasma.

There are two types of red cell crossmatch performed in the lab:

Computer crossmatch/Issue: Computer cross-match is the selection and issue of red cell units where compatibility is determined by the laboratory information systems (LIMS) without serological testing of donor cells against patient plasma. This allows for the immediate issue of blood and applies to patients who have a valid TS and have no history of antibodies and no blood group anomalies.

Serological crossmatch is carried out when patients has or had antibodies/blood group anomalies: red cells may take from 60 minutes up to 24 hours. The indirect

antiglobulin test is used to detect ABO and non ABO antibody incompatibility between donor red cell and patient plasma.

2.12 ORDERING AND PRESCRIBING BLOOD COMPONENTS AND PRODUCTS

Decision to transfuse:

The decision to transfuse should be based on the clinical assessment of the patient and individual needs. Promotion of a single unit transfusion policy is recommended by National Institute of Health and Care Excellence (NICE) 2015 in adult non bleeding patients – "Don't give two without review"

The clinical assessment of the patient should include an evaluation of risk factors when determining whether to transfuse, for example, risk of transfusion-associated circulatory overload (TACO) in vulnerable patient groups e.g. low body weight, patients > 70 years of age, pre-existing conditions, such as cardiac failure or renal impairment (British Society for Haematology 2017)

The prescribing Doctor is responsible for checking the patient's previous transfusion history and any special requirements, such as CMV-/ Irradiated. They are also responsible for checking whether the patient has a valid G/S prior to transfusion

All blood products should be ordered electronically on Powerchart see SOP on hospital intranet BTD-HVO-039 Ordering Blood Components/Products from Blood Bank, and followed up with a phone order to the Hospital Blood Bank.

Ensure:

- Prescription is filled out completely. Details when ordering should include all patient details (*name, MRN number and location*), blood product and quantity required, Doctors full name, IMC and contact number. .
- Consent: it is a general ethical principle that valid consent is obtained from a patient before they receive a blood transfusion. Verbal consent suffices and can be documented in chart. Patient information leaflets are available on each ward.
- Special requirements are considered. Pre-meds for patients with history of previous transfusion reactions, fluid overload etc.
- Maximum Surgical Blood Ordering Schedule is referred to: This is a guide to blood ordering for routine/elective surgical procedures.
- Risk of Transfusion Associated Circulatory Overload (TACO) has been assessed: patient weight, cardiac history, fluid balance, etc.
- Once prescription is completed, an electronic request from the clinical area must be followed up with a verbal request by phoning the Blood Bank.

St Francis Hospice:

- Symptoms suggestive of anaemia noted and Palliative care Outcome Score (POS) recorded for dyspnoea and fatigue in patient's healthcare record.
- Once prescription is completed, email the request for red cells to bloodbank@Beaumont.ie. This must be followed up with a verbal request by phoning the Blood Bank.

2.13 REQUESTING OF BLOOD PRODUCTS WITH SPECIAL REQUIREMENTS

See guidelines for use of CMV- and/or Irradiated blood components on hospital intranet refer to BTD-HVI-007

2.14 MAXIMUM SURGICAL BLOOD ORDERING SCHEDULE

The Maximum Surgical Blood Order Schedule (M.S.B.O.S) should be adhered to when taking TS samples and ordering Blood for surgical procedures. The M.S.B.O.S is available for review as a Clinical Policy on Hospital intranet. Each member of staff has a professional responsibility to avoid over exposure of patients to blood / blood products. Over ordering of blood / blood products and unnecessary GS sampling should be avoided in order to prevent wastage and over phlebotomising patients. Blood / Blood Products are extremely costly and are frequently in short supply. Where a patient has allo-antibodies, please give the Hospital Blood Bank 24 hours' notice prior to surgery. (Refer to BTD-HVI-008).

The MSBOS is a guide only and should never replace expert clinical judgement.

2.15 BLOODTRACK

Bloodtrack is used to monitor and record all transactions in the relation to movement of Red Cells, Platelets, Plasma and Granulocytes. It allows a full electronic audit trail of these components. Users of the BloodTrack System must be trained in such prior to use.

All blood components and products are processed for electronic move out / move in to fridges / platelet agitators respectively via the Blood Track system. If Blood Track is non-functional all products must be manually signed out of the Blood and Blood Products register. (Refer to BTD-HVO-040 on hospital intranet).

2.16 EMERGENCY ISSUE OF BLOOD COMPONENTS AND PRODUCTS

If no GS or testing is incomplete and patient is unable to wait for compatible red blood cells, the lab can issue uncrossmatched RCCs immediately once requested by clinician.

- O NEG uncrossmatched units are available in the Blood Transfusion Issue fridge for use in emergencies.
- Ensure a Group and Screen specimen is taken before the O NEG uncrossmatched units are transfused.
- O NEG uncrossmatched units are not antigen negative specific to antibodies that a patient may have and therefore may result in incompatible units being transfused.
- O NEG stock is limited. Once these stocks are depleted it may be necessary to switch to O POS if patient is
  - Male
  - Female > 55 years

2.17 MASSIVE TRANSFUSION PROTOCOL

A successful Massive Transfusion Protocol can provide a timely, coordinated, delivery of blood products to the bleeding patient refer to BTD-HVO-042 Emergency/Massive transfusion protocol (MTP) and MTP Poster BTD-F-0283

- Accurate patient identification is of paramount importance. Every patient must wear an identification wristband (beware of external wristbands!).
- The Serious Hazards of Transfusion (SHOT) report suggests that the risk of error may be particularly high in an emergency situation. It is important that a correctly labelled TS specimen is taken before any blood products are administered. Use ED TRAUMA numbers if required and PDA device to ensure safe transfusion.
- One person should be nominated to liase with the BTD ensuring clear communication and to avoid confusion and unnecessary phone calls.
- When the MTP has ceased, communicate this to the Blood Bank.
- Traceability of blood products is a legal requirement – ensure traceability has been recorded / maintained for all blood products transfused or discarded in the event.
- Early administration of Tranexamic acid (Crash2 study)
- The use of rapid infusers / blood warmers are recommended for RCCs and fluids in major haermorrhage to avoid hypothermia which can exacerbate the clinical situation.

Bleeding in patients on anticoagulant therapy. **Discuss with Consultant Haematologist**. (Refer to Q pulse document PPCC-HAEM-24)

A&E / Pharmacy:

- Dabigatran- specific reversal agent Praxbind (Idarucizumab)
- Direct Factor-Xa Inhibitors (Rivaroxaban, Apixaban) – Ondexxya (Andexanet Alpha).

Bloodbank:

- In life threatening bleeds the products available from the BTD are PCC, rFactor VIIa - under the direction of the haemotology team.

2.18 COLLECTION FROM THE BLOOD TRANSFUSION LABORATORY

Only collect the Components/Products from the Hospital Blood Bank when required, as Components/Products must not be stored outside strictly controlled storage conditions or in areas such as ward refrigerators

Theatre are the only department with a remote temperature controlled fridge to store crossmatched red cells only.

Blood components and products are transported within Beaumont Hospital and St Lukes Radiation Oncology Centre by trained porters and healthcare assistants. Blue cabs transfer to St. Francis Hospice sites & St. Joseph's Hospital Raheny refer to BTD-HVO-031

2.19 BLOOD / BLOOD PRODUCT ADMINISTRATION

Bloodtrack PDAs are used to transfuse Red cells, platelets and plasma. The product barcodes and patient ID band are scanned on commencement of transfusion of Red cells, Platelets and plasma to a patient. Any discrepancies will be highlighted on PDA device and the transfusion cannot proceed. Contact the Blood Transfusion Dept for any alerts / alarms.

The manual method is used for all other blood products or can used for blood and platelets if bloodtrack is unavailable or undergoing upgrade. This requires 2 fully trained staff members checking and signing transfusion documentation independent of each other.

**See quick reference blood transfusion product administration guidelines on hospital Intranet refer to BTD-HVI-001 and BTD-HVO-009 Blood Administration.

2.20 TRACEABILITY

It is a legal requirement to maintain 100% traceability of all blood components. If Bloodtrack is used, traceability is electronically updated. Following commencement of transfusion the labels generated should be placed in the patient transfusion record.
For manual transfusions, the middle pink portion of the compatibility label must contain the signatures of both administrators and the date and time of transfusion. This section is then removed and placed in the designated traceability box in the clinical area and / or returned to the blood bank as soon as possible for fating of

the product. The lower portion of the compatibility label is also signed by both administrators, including the date and time. This lower portion is then placed in the patient's medical record. The patient transfusion record must also be signed and updated by both staff members with record of the transfusion.

2.21 MANAGEMENT OF TRANSFUSION REACTIONS

Serious adverse Events & Reactions

It is mandatory to report all serious errors, incidences and reactions related to transfusion to Haemovigilance / Blood Transfusion Department. This data is then reviewed by the Consultant Haematologist and Hospital Transfusion Committee and may be submitted to the NHO (National Haemovigilance Office) in collaboration with the HPRA (Health Products Regulatory Authority) for further review.

Please refer to Transfusion reaction information on the Hospital intranet site refer to BTD-HVF-023 Transfusion Reaction Notification Form.

Also: BTD-HVO-015 Serious Adverse Reactions (Clinical Areas) –Mandatory Reporting including Rapid Alert Procedure), BTD-HVO-016*:* Serious Adverse Events (Clinical Areas) –Mandatory Reporting including Rapid Alert Procedure), Guidelines on the investigation and management of acute transfusion reactions, British Society of Haematology, 2023 (BSH website).

2.22 CLINICAL ADVICE

A Consultant Haematologist with Administrative Charge for the Blood Transfusion Department is in place. This Consultant Haematologist provides an extensive advisory service and clinical advice. Examples include indications for platelet transfusion, management of massive transfusion and the appropriate use of blood products.

Issues relating to Haemovigilance policies and protocols are referred to the Haemovigilance officers. Examples include sample labelling and management of transfusion reactions.

Comments or suggestions relating to the service should be addressed to the Chief Medical Scientist

Further information on all aspects of Blood Transfusion including blood product information, administration guidelines, relevant policies and procedures, forms etc are all available on the Beaumont Blood Transfusion Intranet page. Please email haemovigilance@beaumont.ie with any questions or queries.

2.23 BLOOD TRANSFUSION

2.23.1 *Test Repertoire*

Test	Sample Type	Minimum Volume	TAT	Comment	Mnemonic
Group & Screen	4.9ml EDTA Specimen bottle labelled: "EDTA - FOR BLOOD BANK" (Blue top tube)	2.5ml	**Routine:** Same day if received before cut off time of 17:00 during routine hours. **Emergency:** 1 hour	GS specimens should be taken using the Bridge Medical devices/Powerchart for OPD either desktop or PDA. Equipment must be brought to patient bedside. When the Bridge medical device is not available the patient details must be handwritten on the specimen bottle. Unavoidable delays in the provision of results can occur when a patient has a positive antibody screen and/ or when a specimen is referred to the IBTS.	Group and Antibody screen
Direct Antiglobulin Test	EDTA Specimen (2.7 ml)	2.5ml	**Routine:** Same day if received before cut off time of 17:00 during routine hours. **Emergency:** 1 hour	DAT specimens should be taken using the Bridge Medical devices either desktop or PDA/Powerchart for OPD. Equipment must be brought to patient bedside. When the Bridge medical device is not available the patient details must be handwritten on the specimen bottle.	DAT
Transfusion Reaction Investigation	4.9ml EDTA Specimen + 7.5ml clotted serum specimen	2.5ml	Depends on the complexity of investigation.	Should be sent to the hospital Blood Bank as soon as possible after taking the specimens.	TRX

Test	**Sample Type**	**Minimum Volume**	**TAT**	**Comment**	**Mnemonic**
ABO Antibody titration	4.9ml EDTA Specimen.	4.0ml	**Routine:** 24 hours from time of receipt during routine hours **Urgent:** Same day if received before 1400.	This test is requested only under the instruction of the Nephrology team. Specimens should be taken using the Bridge Medical devices either desktop or PDA/Powerchart for OPD. Equipment must be brought to patient bedside. When the Bridge medical device is not available the patient details must be handwritten on the specimen bottle.	Anitbody TITR
Cold Agglutinins	2 X 4.9ml EDTA specimen bottle.	4.9ml.	5 working days from sample receipt by NHSBT As per Specimen User Manual IBTS	Referred to IBTS Specimens should be taken using the Bridge Medical devices either desktop or PDA/Powerchart for OPD. Equipment must be brought to patient bedside. When the Bridge medical device is not available the patient details must be handwritten on the specimen bottle.	COLDAGGS
ABO Rh D grouping for Living donor and H&I	4.9ml EDTA Specimen.	2.5ml.	**Routine:** Same day if received before cut off time of 17:00 during routine hours. **Emergency:** 1 hour		Ext Blood Group

2.23.2 *Blood Components/Products Available*

Power chart Mnemonic	Turnaround Time	Comment
Red Blood Cells	With valid TS: 15 mins to 3hours * From receipt of TS: up to 4 hours* Emergency • Uncrossmatched RC: <10 mins • Crossmatched RC: 60 min from receipt of GS*	
Frozen Plasma	40min to 3 hours	
Platelete Concentrate	15mins to 12hours **	The blood bank strives to maintain 2 stock platelets at all times for emergency issue. However this depends on demand and supply. Non-emergency orders should be placed prior to 14:00 hrs during routine working hours and will be available from 16:30 hrs the same day and before 22:00 hrs for approx. 11am next day delivery.
Fibrinogen Product	15min to 60mins	
Albumin 5% Albumin 20%	15min to 60mins	
Factor Concentrates • Novoseven	15 mins to 60 mins	Discussion with Haematology Medical Team required

• Factor VIII • vWF • Factor IX • Prpthrombin Concentrate • Factor XIII		
Other Anti-D Anti-Thromin Granulocytes	60min to 4 hours	Discussion with Haematology Medical Team required

*Turnaround Time provided the patient has no Antibodies or blood group discrepancies. **Availability is dependent on national supply

Specimens referred to the IBTS for antibody investigation, serological crossmatch or/and Cold Agglutinins, the results of these tests are not covered by the scope of Beaumont Hospital Blood Bank Department ISO15189 accreditation

2.23.3 ***Specialised Tests Referred to the National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)***

Test Referred	Power chart Mnemonic	Specimen Required
Human Leucocyte Antigen (HLA Typing) for Matcheded platelets	Ref Lab HLA typing for matched platetes	5-10mls EDTA
Screening for Platelet Allo-antibodies	Ref lab platelete allo Ab investigation	5-10mls clotted
Human Platelet Antigen Typing (HPA) (Genotyping)	Ref Lab HPA genotyping	5mls EDTA
Platelet Refractoriness	Ref Lab platelet refractoriness	5-10mls EDTA and Citrate
HLA Class 1&11 typing of transplant patients and family for BMT	Not on Powerchart	5-10mls EDTA

These samaples must be accompanied by form BT255-6 for reference lab send out.

2.24 HAEMATOLOGY

2.24.1 *Thrombophilia Screening*

Beaumont Hospital's specialist coagulation laboratory has a test repertoire which includes **Inherited Thrombophilia Screens, Lupus Anticoagulant, Clotting Factor Assays and von Willebrand Screens**. In the majority of cases, patients do not meet the clinical criteria for testing.

When there is a clinical indication for testing, specialist interpretation is required so that patients can be counselled appropriately, and the ability to interpret these tests correctly requires knowledge of the clinical scenario.

The Hematology Department has introduced a demand management protocol to limit access to these specialised tests.

From 1St May 2023 onwards General Practitioners will no longer be able to request the following tests directly:

- **Inherited Thrombophilia Screen** (Antithrombin, Protein C, Protein S,
- Activated Protein C Resistance (+/-Factor V Leiden Mutation if required)
- **Lupus Anticoagulant**

Testing will be reserved for specific patients who are deemed to meet the clinical criteria after being reviewed and sanctioned by the Haematology team.

If you believe your patient meets the criteria for testing, they should be referred to the relevant specialist, e.g.:

- If you suspect your patient has a bleeding disorder or an inherited thrombophilia, they can be referred to Dr Karl Ewins' Specialist Coagulation Clinic (Department of Haematology).
- If the patient has a family member with a known bleeding disorder who already attends the National Coagulation Centre (NCC) in St James's Hospital, they should be referred directly to the NCC for family screening.
- Please note that Antiphospholipid Syndrome is <u>not</u> an inherited disorder, so family screening is not required.
- Please note that recurrent miscarriage is <u>not</u> an indication for inherited thrombophilia testing and such requests will not be processed.

If you believe your patient warrants <u>urgent</u> investigation, please contact the Haematology Registrar on consults via Beaumont Hospital switch 01-8093000.

The current national thrombophilia laboratory testing guideline can be accessed at:
https://www.hse.ie/eng/about/who/cspd/ncps/pathology/resources/national%20laboratory%20handbook.html

WHAT SAMPLES ARE REQUIRED IF APPROVED ?

- Complete the Request Form with the Patient's name, DOB, unique Number, Ward/Location and Thrombophilia Screen requested
- Include patient relevant clinical information on the form
- Include anticoagulant status.
- Date and sign
- Take FOUR 2.9 mL Tri-sodium citrate 9NC (green) samples and
- Take ONE 2.6 mL EDTA (pink) sample
- Send the samples to the Coagulation Laboratory
- **Please note:** Anti Cardiolipin Antibodies are processed by Immunology and are not part of this screen.
- **If a patient is on anticoagulation at the time of testing, certain assays within the Thrombophilia profile may be rejected, see above.**

2.24.2 *Referral of Thrombophilia samples from an External Hospital*

If sending Separated Samples:

Plasma samples must be separated by a double centrifugation procedure according to the following instruction in order to prepare platelet poor plasma (plt< 10 x10^9/L).

- Frozen samples must be sent in appropriate frozen transport containers. All samples must remain in these containers.

2.24.3 *ESR*

ESR

The clinical Haematology team have listed the following conditions as the only times an ESR is indicated. In all other cases, C - reactive protein (CRP) is the preferred test.

- *Giant cell arteritis, Temporal arteritis*
- *Polymyalgia rheumatica.*
- *'Suspected myeloma'*
- *Hodgkins Lymphoma*
- *Prosthetic joint infection,*

- *Osteomyelitis,*
- *Rheumatoid Arthritis*

2.24.4 *Blood Film Examination*

All FBCs are screened to see if a blood film will be of benefit to the patient/clinician. If the FBC results and instrument flags obtained meet the criteria required for blood film examination as set down by the Haematology Consultants, a film will be examined irrespective of whether one was ordered or not.
All FBCs with results/flags which do not meet these criteria will not have a blood film added on unless clinical details are provided. The following comment will be added in such instances 'Due to the volume of FBC and blood film requests received form GP practices, blood film requests will no longer be processed unless they meet the laboratory criteria for blood film examination as set down by the Haematology Consultant.'

2.24.5 *Haematology Molecular Tests*

- **All requests** for Haematology Molecular testing will not be processed unless accompanied by the fully completed request form, Thrombophilia Request form HAEMC-LF-023 or Haemochromatosis Genetic Screening request form HAEMC-LF-077 available on the intranet.
- **Changes to genetic consent for all haematology molecular tests (HFE, Fator V Leiden and PT mutation)**. From the 04/07/2022, the laboratory will no longer take receipt or store the form containing patient genetic consent. It is the responsibility of the ordering clinician to obtain and file a copy of genetic consent in the patient's record.

- A new form HAEMP-LF-003 "*Haematology Genetic Consent Form"* is available on the Beaumont Hospital Internet/Intranet site and must be printed and kept in the patient's record by the ordering clinician.

If this form is received in the lab it will be disposed and not returned to the sender.

2.24.5.1 Haemochromatosis Testing

Due to the significant increase in orders for Haemochromatosis HFE genotypes, the Haematology Department is introducing a demand management protocol to address unnecessary ordering of this test. From the 04/07/2022 all HFE test requests **must** fulfill the following criteria:

- Testing of adult siblings (brothers and sisters) and adult offspring of **p.C282Y homozygotes** is recommended owing to increased risk of p.C282Y homozygosity and related increased morbidity. **Please indicate on the form if there is a First Degree Relative (SIBLING/PARENT) with p.C282Y homozygosity. Stating both relationship and genotype.**

- The results of iron studies: Iron, Ferritin and Transferrin Saturation (%) are available and meet certain criteria. In particular, the Transferrin Saturation should be raised (> 45%).

- **It is required to confirm elevated Transferrin Saturation on two occasions before HFE genetic diagnosis testing.**

- **Note: if Transferrin Saturation <45% and/or no first degree relative with p.C282Y homozygosity, the sample will not be processed.**

- Samples must be sent to the laboratory with the updated form *HAEMC-LF-077 "Haemochromatosis Genetic Screening Request Form" Version 3.* **If any form other than this version is sent to the laboratory, the samples will be rejected and not processed.**

Note: these guidelines are formed in line with Best Practice Guidelines "EMQN best practice guidelines for the molecular genetic diagnosis of hereditary haemochromatosis (HH) European Journal of Human Genetics (2016) 24, 479–495".

2.24.6 *Clinical Advice & Laboratory Test Interpretation*

Interpretation of Laboratory Tests / procedures may be obtained by phoning any of the telephone numbers in section 3.1.2 and asking for the Chief Medical Scientist or by requesting a senior member of staff 09:00- 17:00 Mon-Fri excluding Bank Holidays

2.25 CHEMICAL PATHOLOGY

See section 3.3 below

2.26 IMMUNOLOGY

Information on the tests available to order via Healthlink by Beaumont GPs is given below. Other tests performed in the Immunology department may be ordered by GPs once pre-approved by a named Beaumont Consultant. This must be noted on the Healthlink request form in order for the sample to be processed. The Immunology laboratory does not offer a referral service for GPs for tests not performed in-house. The assays available on Healthlink are:

Order Name	Components
Acute Allergic Reaction Investigation	As per clinical details provided by clinician.
Specific IgE: House dust mite (d1)	n/a
Specific IgE: Grass Pollen Mix 1	n/a
Specific IgE: Tree Pollen Mix	n/a
Specific IgE: Cat dander	n/a
Specific IgE: Dog dander	n/a
Anti-Tissue Transglutaminase Antibodies (IgA)	n/a
Connective Tissue Disease Screen (CTD)	n/a
Anti-Streptolysin O Titre	n/a
Rheumatoid Arthritis Antibodies	Anti-Cyclic Citrullinated Peptide Antibody
	Rheumatoid Factor
Pernicious Anaemia Antibodies	Anti-Gastric Parietal Cell Antibodies
	Anti-Intrinsic Factor Antibodies
Liver Disease Associated Antibodies	Anti-Nuclear Antibodies
	Anti-Smooth Muscle Antibodies
	Mitochondrial Antibodies
	Anti-Liver Kidney Microsomal Antibodies

2.26.1 *Rheumatoid Factor*

INDICATIONS

- Inflammatory arthritis
- Suspected vasculitis
- Interstitial lung disease
- Pleural/pericardial effusions

INTERPRETATION OF RESULTS

Negative rheumatoid factor, <14 IU/mL: A negative Rheumatoid factor makes diagnosis of Rheumatoid disease less likely, however as 10% of patients are RF negative, it does not exclude this diagnosis. Where there is a strong clinical suspicion of Rheumatoid Disease anti-CCP should be ordered.

Weak positive, 14-70 IU/mL: Some patients with Rheumatoid Disease will be only weakly positive and will fall into this range. However at this level Rheumatoid Factor is not specific for a diagnosis of Rheumatoid disease and a number of patients with weakly positive Rheumatoid Factor will have other inflammatory conditions. Anti-CCP will automatically be ordered and this will give more specific information. We generally suggest that you repeat the test in approximately 3-6 months time if clinical symptoms have persisted and only RF is positive. In Rheumatoid disease the assay should remain consistently positive, or may even be more strongly positive. However infection induced Rheumatoid Factor usually clears within weeks following successful treatment of the infection.

Significantly positive rheumatoid factor, 71-250 IU/mL: In an appropriate clinical setting a significantly positive Rheumatoid Factor is consistent with diagnosis of Rheumatoid disease. Anti-CCP will automatically be ordered.

Strongly positive rheumatoid factor, >250 IU/mL: Strongly positive Rheumatoid Factor is suggestive of Rheumatoid disease. The presence of a high level of Rheumatoid Factor at presentation is considered an adverse prognostic marker. Patients with Sjogren's syndrome may have very high levels of RF despite only minor joint symptoms. Occasionally a similar level may be seen in patients with cryoglobulinaemia and if features suggestive of this disorder are present an appropriate sample should be sent to the Proteins Laboratory in Clinical Chemistry. Anti-CCP will automatically be ordered.

Serial measurement of Rheumatoid factor is generally not useful in monitoring the response to therapy. Measurement of acute phase reactants e.g. CRP is more useful.

2.26.2 *Anti-Cyclic Citrullinated Peptide antibodies (CCP)*

INDICATIONS

- Inflammatory Arthritis
- Interstitial lung disease
- Suspected extra-articular rheumatoid disease

INTERPRETATION OF RESULTS

If result is <7 U/ml = Negative CCP

Anti-CCP has a sensitivity of 80% for detection of Rheumatoid arthritis (RA). It appears less sensitive for detection of extra-articular disease. If RA is strongly suspected, RF should be measured, as at least 10% of RA patients are negative for CCP, but positive for RF.

If result is 7 – 10 U/ml = Equivocal

If patient has evidence of an inflammatory arthropathy, suggest referral to Consultant Rheumatologist.

If result is >/= 11 U/ml = Positive CCP

Anti-CCP antibodies appear to be relatively specific for rheumatoid disease (Specificity 96%). Suggest referral to Consultant Rheumatologist

To date it is unclear whether monitoring changes in anti-CCP antibody levels is helpful. However, given that the half-life of IgG is 3 weeks, we do not recommend repeat testing more frequently than 3-monthly.

2.26.3 *Connective Tissue Disease (CTD) Screen*

INDICATIONS

- Inflammatory arthritis
- Suspected vasculitis/ connective tissue disease
- Photosensitive/other typical skin rash
- Pleural/pericardial effusions.
- Query autoimmune haemolytic anaemia, ITP, leucopenia
- Renal impairment, proteinuria, haematuria
- Unexplained CNS disease

The CTD Screen by EliA was introduced in February 2014 as an alternative method for the detection of anti-nuclear antibodies (also referred to as ANA). The CTD screen tests for anti-DNA and clinically relevant anti-ENA such as anti-Ro, anti-La, anti-Sm, and anti-RNP. For assessment of liver autoimmune diseases, the liver antibodies panel is recommended and the ANA component of this panel will remain tested using immunofluorescence (IIF) method in the Liver Disease Associated Antibodies panel In patients with negative CTD screen but strong clinical suspicion please liaise with lab as ANA by immunofluorescence is available if clinically indicated.

In most cases, a positive CTD screen result would also yield a positive result for anti-DNA and/or anti-ENA. The lab will automatically test for anti-DNA and anti-ENA on all equivocal & positive CTD screen results.

Once a diagnosis of connective tissue disease has been made, repeated measurement of CTD screen is rarely helpful in monitoring disease activity.

INTERPRETATION OF CTD RESULTS

If CTD screen is negative, connective tissue disease is unlikely.

If CTD screen is positive or equivocal, follow on testing for anti-ENA and anti-DNA will be done.

2.26.4 *Anti-Nuclear Antibodies (ANA) by immunofluorescence*

INDICATIONS

- Autoimmune liver disease
- Suspected vasculitis/ connective tissue disease**

ANA (also known as anti-nuclear antibody) is one of the main serological markers for autoimmune hepatitis and most data in the literature is based on the immunofluorescence method. Therefore we have retained the immunofluorescence method (using Hep2 cells as substrate) as the ANA method in the Liver Disease Associated Antibodies panel.

***From February 2014, we introduced the CTD screen by EliA as the method for the detection of anti-nuclear antibodies for connective tissue disease and vasculitis screens. Please refer to section above for information on CTD screen.*

INTERPRETATION OF RESULTS

Negative ANA: ANA is the commonest autoantibody found in autoimmune hepatitis but a negative ANA does not exclude the diagnosis.

Positive ANA (titre >1:80): A positive ANA is one of the serological markers for autoimmune hepatitis. Results should be interpreted within the context of clinical history, imaging and other laboratory parameters.

PATTERNS OF ANA

Both the homogenous and the speckled pattern are commonly seen in patients with autoimmune hepatitis. Anti-nucleolar pattern which is typically associated with scleroderma, is also frequently seen in autoimmune hepatitis.

Anti-Centromere antibody pattern is seen in about 13% of patients with primary biliary cirrhosis (also known as primary biliary cholangitis/PBC). Anti-centromere antibody is also typically found in CREST syndrome (Calcinosis, Raynaud's phenomenon, Oesophageal dysmotility, Sclerodactyly & Telangiectasia).

2.26.5 *Anti-Smooth Muscle Antibodies*

INDICATIONS

- Persistently abnormal Liver Function Tests
- Other signs of chronic liver disease
- Investigation of hypergammaglobulinaemia

INTERPRETATION OF RESULTS

Negative: Normal result

Weak Positive 1/40: Weak positive anti-smooth muscle antibody is of doubtful clinical significance. Common in the elderly or in patients with infection/inflammation of any cause.

Positive 1/80: Weak positive value, not specific for autoimmune hepatitis.

Positive 1/160: Moderate positive value is consistent with but not specific for autoimmune hepatitis. Other causes of liver disease should be excluded.

Strong Positive 1/320 or greater: Strongly positive value is suggestive of autoimmune hepatitis.

2.26.6 *Anti-Liver-Kidney Microsomal (LKM) Antibodies*

Note: When IIF results demonstrate an anti-LKM antibody, the specificity of this result is confirmed by an immunoblotting system using the specific antigen cytochrome P450.

INDICATIONS

- Persistently abnormal Liver Function Tests
- Other signs of chronic liver disease
- Investigation of Hypergammaglobulinaemia

Type II autoimmune hepatitis (associated with LKM antibodies) can progress rapidly. The history is often considerably shorter than with Type I autoimmune hepatitis, which is much more common and associated with the presence of anti-smooth muscle antibodies.

INTERPRETATION OF RESULTS

Negative: No serological evidence of type II autoimmune hepatitis.

Positive IIF, Positive Immunoblot: The presence of anti-LKM antibodies is associated with type II autoimmune hepatitis or hepatitis C. The titre of the

antibody is not helpful in distinguishing these disorders, and hepatitis serology should be performed.

Positive IIF, Negative Immunoblot: There are a small number of antibodies which generate a pattern (positivity) on IIF which is indistinguishable from LKM antibodies, but the staining is due to binding to antigens other than cytochrome P450. Such antibodies include anti-endoplasmic reticulin antibodies. The clinical significance, if any, of such antibodies is uncertain.

Serial measurement of anti-LKM titre can be useful in monitoring a patient's response to therapy.

Because of the rapidity with which Type II autoimmune hepatitis progresses, it is departmental policy to telephone clinicians when a new positive result is detected and contact details are available.

2.26.7 *Anti-Mitochondrial Antibody & M2 subtyping*

All newly detected anti-mitochondrial antibodies are tested for reactivity to pyruvate dehydrogenase (M2 subtype) using an ELISA system. M2 type anti-mitochondrial antibodies are highly specific for primary biliary cirrhosis (also known as primary biliary cholangitis/PBC).

INDICATIONS

- Persistently abnormal Liver Function Tests
- Other signs of chronic liver disease
- Investigation of hypergammaglobulinaemia
- Pruritis

INTERPRETATION OF RESULTS

Negative: Normal value

Positive IIF, Positive M2: Suggestive of PBC. Occasionally may be seen in undifferentiated connective tissue disease. The titre of the anti-mitochondrial antibody is usually high (1/320 or greater). However even when the antimitochondrial antibody titre is lower, detection of the M2 subtype is suggestive of PBC. Occasionally M2 positive anti-Mitochondria can be seen in undifferentiated Connective Tissue Disease

Positive IIF, Negative M2: The IIF pattern of staining is frequently atypical (less granular than an M2 type, and with different staining of tissues). This combination of results is not specific for PBC, and may be seen in a wide variety of conditions including undifferentiated connective tissue disease, anti-phospholipid syndrome, infections and other inflammatory conditions.

Note: When an anti-mitochondrial antibody is present granular staining of mitochondria in the liver, kidney tubules and gastric parietal cells is seen. In the presence of a strong anti-mitochondrial antibody, it is not possible to exclude the presence of an anti-gastric-parietal cell antibody, which is obscured.

2.26.8 *Anti-Gastric-Parietal Cell Antibodies (Anti-GPC)*

INDICATIONS

- Low B12
- Macrocytic anaemia
- Suspected subacute combined degeneration of the spinal cord

INTERPRETATION OF RESULTS

Negative: Normal value

Positive: Anti-GPC antibodies are present in about 90% of people with atrophic gastritis or pernicious anaemia, however these antibodies are relatively non-specific. Anti-GPC antibodies are present in 20% of relatives of patients with pernicious anaemia, 20% of patients with other autoimmune endocrine disease, as well as 25% of patients with iron deficiency anaemia. They are also present in 16% of females over the age of 60 years. It is recommended that vitamin B12 levels be checked. Sera in which anti-GPC antibodies are found are automatically tested for antibodies to intrinsic factor.

Obscured: When an anti-mitochondrial antibody is present granular staining of mitochondria in the liver, kidney tubules and gastric parietal cells is seen. In the presence of a strong anti-mitochondrial antibody, it is not possible to exclude the presence of an anti-gastric-parietal cell antibody, which is obscured. If pernicious anaemia is suspected, an anti-intrinsic factor antibody should be requested.

2.26.9 *Anti-Intrinsic Factor Antibodies*

INDICATIONS

- Low B12
- Macrocytic anaemia
- Suspected subacute combined degeneration of the spinal cord

INTERPRETATION OF RESULTS

In September 2020 we changed the method for anti-intrinsic factor antibodies from ELISA to EliA. The Intrinsic Factor assay will continue to be reported qualitatively with the introduction of an equivocal range in addition to negative & positive. Interpretative comments will be added on all reports.

Negative: Negative anti-Intrinsic Factor antibody does not exclude a diagnosis of pernicious anaemia, as this antibody is only found in approximately 60% of subjects with pernicious anaemia.

Equivocal: The clinical significance of intrinsic factor results that fall in the equivocal range is uncertain. Correlation with clinical history and B12 level is advised.

Positive: Positive result is suggestive of pernicious anaemia, and measurement of vitamin B12 is recommended. Patients with a normal vitamin B12 may have latent pernicious anaemia, and follow-up with at least annual measurement of Vitamin B12 level is recommended.

2.26.10 *Anti- Tissue Transglutaminase Antibodies (anti-tTG)*

Please note that anti-tTG is the appropriate screening test for coeliac disease. Equivocal or positive sera will be automatically tested for anti-endomysial antibodies. Our assay and reference ranges have been extensively validated internally, to ensure that an appropriately low threshold for triggering anti-endomysial antibody testing is in place.

INDICATIONS

- Suspected coeliac disease
- Malabsorption (including low iron, Vit B12 or albumin)
- Anaemia
- Gastrointestinal symptoms
- Trisomy 21 syndrome (increased risk of coeliac disease)
- IDDM (increased risk of coeliac disease)
- Dermatitis Herpetiformis
- Osteoporosis & Osteomalacia

- Peripheral Neuropathy
- Unexplained Infertility
- Unexplained weight loss

In addition to classical presentations with GI symptoms and malabsorption, coeliac disease is found in about 3.4% of those with osteoporosis, 12% of those with Type I diabetes mellitus and up to 1% of the general population.

tTG has been identified as the target antigen against which anti-EMA is directed. The anti-tTG EliA is used as an initial screening test and all equivocal/positive sera will be further tested for EMA antibodies. IgA deficiency is excluded by using the background reading on the EliA or measurement of total IgA. Total IgA is measured on all children with a negative TTG. In cases of IgA deficiency, IgG EMA testing or other IgG serological testing is performed. Anti-tTG has a high sensitivity for untreated coeliac disease, while the anti-endomysial antibody is more specific. Sequential testing offers optimal diagnostic utility.

Please refer to NCPP Serological Testing for Coeliac Disease Guideline from National Laboratory Handbook for further guidance available on www.beaumont.ie.

INTERPRETATION OF RESULTS

Negative (<4 U/ml): Coeliac disease unlikely if the patient is on a normal diet. If clinical suspicion is high, should be repeated in 3-6 months, ensuring that the patient is on a diet with a normal gluten content.

Equivocal 4-10 U/ml: All equivocal results will be further tested for IgA anti-EMA.

Positive >10 U/ml: Suggestive of Coeliac Disease. However false positives may occur therefore all samples with positive anti-tTG by EliA will be further tested for EMA antibodies by indirect immunofluorescence.

2.26.11 *IgA Anti-Endomysial Antibodies (EMA)*

INDICATIONS

- Positive anti-tTG (automatically added as reflex test)
- Biopsy suggestive of coeliac disease, despite negative tTG**
- Strong clinical suspicion of coeliac disease, despite negative tTG**

** Discussion with clinical team essential to have test performed for these indications.

In patients with normal levels of IgA, IgA anti-endomysial antibodies are more than 90% sensitive (up to 98% sensitive in some studies) and relatively specific

(>95%) for coeliac disease. When an anti-endomysial antibody request is received in this laboratory, we also measure IgA levels to exclude IgA deficiency. If IgA deficiency is identified serum is sent to the Proteins Laboratory in Clinical Chemistry for further assessment of immunoglobulins.

IgA deficiency is present in about 1:30 patients with coeliac disease (and about 1:600 of the general population). When IgA deficiency is present serology is less helpful in assessing the likelihood of coeliac disease. However in patients with IgA deficiency we perform an IgG anti-endomysial antibody which if strongly positive is suggestive of coeliac disease.

INTERPRETATION OF RESULTS

Negative IgA anti-endomysial antibodies: Coeliac disease is unlikely if patient is on a normal diet. However false negative results may be seen in IgA deficiency, and also in patients on a gluten free diet. The clinical significance of a negative EMA in a patient with a positive anti-tTG is uncertain, however an expert GI opinion should be sought in this situation, as biopsy may still be indicated.

Positive IgA anti-endomysial antibodies: Suggestive of coeliac disease

Negative IgA anti-endomysial antibodies, Low IgA: In this setting, negative anti-endomysial antibody does not exclude coeliac disease. If there is a high clinical suspicion of coeliac disease, or if the IgG anti-endomysial antibody is strongly positive, biopsy is indicated.

Negative IgA and IgG anti-endomysial antibodies, Low serum IgA: The negative predictive value of serology in this setting is not well established, and if there is a strong clinical suspicion of coeliac disease, biopsy is necessary to exclude coeliac disease.

If a low IgA is detected, serum is sent to the Proteins Laboratory in Clinical Chemistry for immunoglobulins and SPEP. This is to exclude a more extensive hypogammaglobulinaemia. However patients with isolated IgA deficiency are at risk of infections, allergy and autoimmune disease. You may wish to arrange for a Clinical Immunology appointment for further assessmen

2.26.12 *Allergen Specific IgE*

INDICATIONS – ALLERGEN SPECIFIC IGE

- Known allergic disease, to identify allergens
- Suspected allergic bronchopulmonary aspergillosis (ABPA)

National & international guidelines state that testing for allergen specific IgE (sIgE) should be based on an allergy focussed clinical history.

Specific allergens which are directly orderable on Healthlink are listed below. For other additional allergens which might be clinically indicated please order Acute Allergic Reaction Investigation (AARI) on Healthlink ensuring all relevant clinical information is provided associated with the episode(s).

If allergen specific IgE is positive, Total IgE will automatically be ordered to aid the interpretation of results.

Order Name
Specific IgE: House dust mite (d1)
Specific IgE: Grass Pollen Mix 1
Specific IgE: Tree Pollen Mix
Specific IgE: Cat dander
Specific IgE: Dog dander

2.26.13 *Acute Allergic Reaction Investigation - Beaumont GP Service only*

INDICATIONS – Clinical symptoms suggestive of acute allergy. (Service provided to Beaumont GPs only).

Despite advances in testing, allergy remains a clinical diagnosis, based on an allergy focussed history, supported by evidence of allergic sensitisation. Recent national and multiple international guidelines emphasise the need for allergy testing to only be performed as indicated by the allergy focussed history.

Specific IgE blood tests (when available to the allergen in question) can be helpful to indicate allergic sensitisation. However as specific IgEs are only markers of sensitisation, not necessarily a clinical allergy; results require interpretation within the context of the clinical history. Sensitised patients may be clinically

allergic OR may be sensitised and tolerant, with on-going tolerance depending on on-going exposure. Unfortunately we continue to see patients that have had their diet restricted solely based on specific IgE test results; some of whom have lost tolerance as a result.

Since 1st of March 2020 we changed the pathway for requesting specific IgE testing, to facilitate the implementation of the recommendations of these guidelines, align with MedLIS requesting and contribute to improving patient safety.

Since MedLIS GoLive in August 2024, Acute Allergic Reaction Investigation (AARI) is available to order directly on Healthink. Since February 2025 it is only available to order electronically, there is no need for the old AARI paper request form.

Specific IgEs to inhalants e.g. grass and tree pollens, cat, dog, house dust mite remain available for direct ordering (i.e. no AARI test required for these). AARI requesting pathway is only required to request specific IgEs to other allergens not listed above.If further clinical details are required, you may be contacted by a member of the Immunology team. If we are not successful in making contact, you will receive a report requesting that you make contact for discussion of clinical details. The sample will be stored for 2 weeks pending this discussion.

Reference:

https://www.hse.ie/eng/about/who/cspd/lsr/resources/indications-for-measurement-of-total-ige-in-general-practice-and-non-specialist-settings.pdf
https://www.hse.ie/eng/about/who/cspd/lsr/resources/indications-for-measurement-of-allergen-specific-ige-in-general-practice-and-non-specialist-settings.pdf

The Acute Allergic Reaction Investigation will be resulted to you in one of the following ways:

1. Based on clinical details provided, relevant specific IgEs have been requested. Report to follow.

2. Specific IgE test is not available for the suspected allergen based on the provided clinical details. If there are any queries regarding this, please contact us at immunologylab@beaumont.ie (quoting the patient's accession number and AARI in the subject line). For patient confidentiality, please ensure that only a secure healthmail email account is used. Sample will be stored for 2 weeks from date of receipt.

3. Specific IgE not indicated based on clinical details provided. If there are any queries or updates of the clinical information please contact us at immunologylab@beaumont.ie (quoting the patient's accession number and AARI in the subject line). For patient confidentiality, please ensure that only a secure healthmail email account is used. Samples will be stored for 2 weeks from date of receipt.

4. Incomplete clinical information provided in the accompanying request form. Please email us at immunologylab@beaumont.ie (quoting the patient's accession number and AARI in the subject line) to confirm contact details and suitable times between Tuesdays and Thursdays for clinical discussion. For patient confidentiality, please ensure that only a secure healthmail email account is used. Serum sample will be stored for 2 weeks pending this discussion. If no email is received within the next 2 weeks, it will be assumed that specific IgE testing is no longer required and serum will be discarded.

5. Further discussion of the clinical details is required to guide specific IgE testing if appropriate. We have not been successful in making contact using the provided contact details. Please email us at immunologylab@beaumont.ie (quoting the patient's accession number and AARI in the subject line) to confirm contact details and suitable times between Tuesdays and Thursdays for clinical discussion. For patient confidentiality, please ensure that only a secure healthmail email account is used. Serum sample will be stored for 2 weeks pending this discussion. If no email is received within the next 2 weeks, it will be assumed that specific IgE testing is no longer required and serum will be discarded.

6. Please note that a separate AARI request is not required to order specific IgEs to the common inhalant allergens i.e. cat dander, dog dander, grass pollen, tree pollen and house dust mite. These can be requested directly. Please see results of the individual specific IgE to these inhalants.

7. No specific allergen identified in clinical history provided and frequent urticaria episodes noted. Please consider the possibility of spontaneous urticaria which is an allergy mimic but not allergic in nature. More information regarding spontaneous urticaria is available on the Clinical Immunology homepage on the Beaumont Hospital website.

INTERPRETATION OF RESULTS

Interpretation of allergen-specific IgE is linked with the level of total IgE, as well as the class of allergen specific IgE. Interpretation of both types of tests are considered below.

Normal Total IgE: Excludes atopy. However, a normal IgE does not exclude sensitisation to individual allergens. As a general rule even weakly positive allergen-specific IgE may be clinically relevant in patients with a low normal IgE. However the relevance of allergen specific IgE must be carefully assessed in the context of the clinical history.

Raised Total IgE: Consistent with atopy. Atopy denotes a genetic susceptibility to make IgE responses. This does not imply that atopic disease is present. The possible role of atopy in the patients clinical presentation should be carefully assessed. False positive results for allergen-specific IgE, particularly of class 1 & 2 become more common the higher the total IgE. In patients with a raised IgE >1000kUA/L, even class 3 allergen-specific IgEs may be false positives. The clinical relevance of allergen-specific IgE measurements must be considered in the clinical context. If uncertain, you may consider referring the patient to the immunology clinic. Raised IgE may also be due to parasitic infection (eosinophilia usually also present) and Churg-Strauss syndrome.

Total IgE > 5000kUA/L: If patient has infections consider the Hyper-IgE syndrome. If this is a diagnostic possibility, please contact the Immunology Department to arrange accurate quantification of level (and clinical consultation if required).

Values of IgE > 5000kUA/L are not uncommon in patients with atopic eczema alone. In such patients allergen-specific IgE results must be assessed with extreme caution.

2.26.14

2.26.15 *Anti-Streptolysin-O Titre (ASOT)*

INDICATIONS

- Suspected current or recent streptococcal infection
- Possible rheumatic fever
- Glomerulonephritis & acute renal failure
- Reactive arthritis

Anti-streptolysin-O antibodies may be produced following infection with Group A Streptococci. Only a proportion of the subtypes of group A Strep can cause rheumatic fever or glomerulonephritis in genetically susceptible individuals, usually with an onset 2-4 weeks after the infection. The ASOT does not distinguish between nephritogenic and non-nephritogenic strains – a positive result merely indicates current or recent infection with streptococcus.

If rheumatic fever is suspected, evidence of recent streptococcal infection is required for diagnosis. If cultures and ASOT are negative, it may be of value to measure anti-DNAase, an additional antibody which may be produced following a Streptococcal infection.

INTERPRETATION OF RESULTS

In October 2020 we changed the method for ASOT from Nephelometry to Immunoturbidimetry. There was no change in reference range.

Negative ASOT (<200 IU/mL): Negative result does not exclude Group A Streptococcal infection as this antibody is present in only 80-85% of patients with Streptococcal pharygitis. A smaller proportion of patients with skin infection are antibody positive.

Positive ASOT (>200 IU/mL): Indicates current or recent infection with Group A Streptococci.

2.27 MICROBIOLOGY

2.27.1 *General Sample Collection Guidelines*

As per MEMO-MIC-0375 circulated in 2024 on 08/11/20242, due to a national shortage of medical scientists, courier delivered samples from General Practitioners and Nursing Homes for microbiological investigations other than virology bloods are currently being outsourced to Eurofins Biomnis Ireland for processing until further notice. Practices will be provided with purple bags. All samples for Microbiology must be placed directly into this bag. Drivers will take the samples directly to Eurofins Biomnis in Sandyford. There will be no change to practice with samples for NVRL, please continue to package separately and place with blood samples.

- Collect specimens aseptically in appropriate CE-marked leak-proof containers and transport in sealed plastic bags.
- A sufficient volume of material must be submitted (See Section 3.6)
- Swabs in transport media are acceptable for throat, eye, ears, vaginal and urethral specimens. Otherwise, pus, fluid or tissue is preferable to a swab.
- Swabs with special transport media are available where applicable, e.g., for viral and chlamydia investigation.
- If a diagnosis of a viral haemorrhagic fever (Lassa, Ebola, Marburg, Congo-Crimean fever), or CJD is suspected, the consultant microbiologist must be informed before any specimens are collected.
- If a potentially cytotoxic specimen is being sent, the chief or senior medical scientists in microbiology must be informed.
- Samples must be delivered to the hospital for transport to Eurofins Biomnis laboratory as soon as possible to prevent samples becoming compromised and rejected. If this is not possible, store specimens in fridge until they can be transported.

2.27.2 *Guidelines for Routine Specimens*

See table 2 and 3 below for specimen acceptance and rejection

PUS

Pus sent in sterile containers give the best results for both Gram stain and culture and is essential for the diagnosis of TB or actinomycosis. If a swab is taken, it should be sent in transport medium after it has been thoroughly soaked in the pus or exudate.

ULCERS

For the best results, ulcers should be cleaned with sterile saline to remove surface contamination, prior to obtaining the sample.

EYES

- Discharging eyes should be swabbed for bacterial culture in the usual way.
- When viral conjunctivitis or corneal lesions are suspected, a swab must be collected using viral transport medium.
- If fungal or amoebic infections are suspected, please contact the clinical microbiology team.

THROAT SWABS

- Even though viruses account for over 70% of sore throats, the most common bacterial cause of sore throat in this country is group A β-haemolytic streptococcus.
- Throat swabs should be taken from the tonsillar region.
- If a throat swab is being taken for other pathogens e.g. *C. diphtheriae, N. gonorrhoea* or *N. meningitidis*, it must be clearly requested.
- If whooping cough (pertussis) is suspected, please send a nasopharyngeal swab.
- Specimens for virology should be taken early in the course of a suspected viral illness. Virus transport medium should be used.

FAECES - ENTERIC PATHOGENS

- Testing for enteric pathogens is not part of a routine septic screen and faeces specimens should only be sent when gastrointestinal infection is suspected.
- Faeces investigation for enteric pathogens is only performed on specimens which take the shape of the container. (www.hpsc.ie)
- Faecal culture assay now includes *Cryptosporidium parvum/hominis and Giardia lamblia* as standard.
- It is important that clinical details or suspected diagnoses are included on the request form. Relevant information includes: travel history, prolonged diarrhoea, antibiotic use and suspected outbreak. Investigations for pathogens such as *Yersinia, Vibrio, or Aeromonas* etc. are only performed if indicated by clinical details.
- Specimen may be passed into a clean, dry, disposable bedpan or similar container and transferred into an appropriate CE-marked leak-proof container and place in sealed plastic bags.
- Please note the possibility of Norovirus infection and state whether vomiting is a feature or whether an outbreak is suspected. Please send a separate specimen for Norovirus testing, as this test is performed by an external laboratory.

FAECES – OVA AND PARASITES

- **The patient's travel history or other relevant clinical details must be provided.**
- Three specimens should be collected over no more than a 10-day period. It is recommended that specimens are collected every other day.
- Unless the patient has severe diarrhoea or dysentery, no more than one specimen should be examined within a single 24-hour period, as shedding of cysts and ova tends to be intermittent.
- If *E. histolytica* suspected and the first three samples are negative, ideally four additional samples should be submitted at weekly intervals.

FAECES – CLOSTRIDIOIDES DIFFICILE

- Testing for *Clostridioides difficile* is performed on all faecal samples except in the following cases:
  - Patients less than 2 years of age
  - Specimens that do not take the shape of the container
  - If specimen was positive for *C. difficile* within the last 14 days,

These criteria are in compliance with national guidelines (www. hpsc.ie)

FAECES - HELICOBACTER PYLORI

- Freshly collected samples should be sent to the laboratory for testing.
- *H. pylori* testing is not carried out on blood samples in the laboratory.

When to send a stool specimen: Send a stool specimen to the laboratory when there are ≥3 liquid or very loose stools per day. There may be other symptoms suggestive of infectious diarrhoea e.g., abdominal pain or discomfort, nausea, faecal urgency, tenesmus, fever, blood or mucus in stools.

How many samples to send: One stool specimen is normally all that is required for routine testing. As microscopy for parasites is less sensitive, please send 3 specimens (but no more than 3) on different days, as some parasites are excreted intermittently. If a worm is excreted, please send the worm and faeces sample.

How much to send: Please fill the specimen container to between ¼ and ½ full. Please do not fill to the brim.

URINE SPECIMENS

In the elderly (>65 years):

- Do not send urine for culture in asymptomatic elderly patients with a positive dipstick.
- Only send urine for culture if signs of urinary tract infection, especially dysuria, fever >38°C or new incontinence. A change in colour or odour of urine is not a sufficient indication for sending urine in the absence of clinical symptoms

- Do not treat asymptomatic bacteriuria in the elderly, as it is very common. Treating it does not reduce mortality nor prevent symptomatic episodes, but increases the risk of antimicrobial side effects, antibiotic resistance and *C. difficile* infection.
- Rapid transport, or measures to preserve the sample aid reliable laboratory diagnosis. Delays and storage at room temperature allow organisms to multiply, which generate results that do not reflect the true clinical situation

What type of specimen should you send?

Send a mid-stream specimen of urine (MSU) where possible. Patients should be instructed to pass a little urine into the toilet first, then pass enough urine into the specimen container.

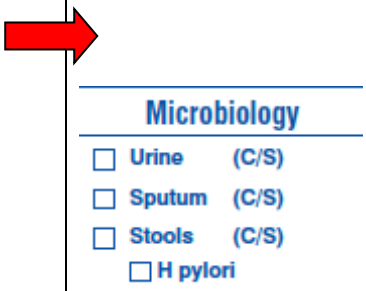
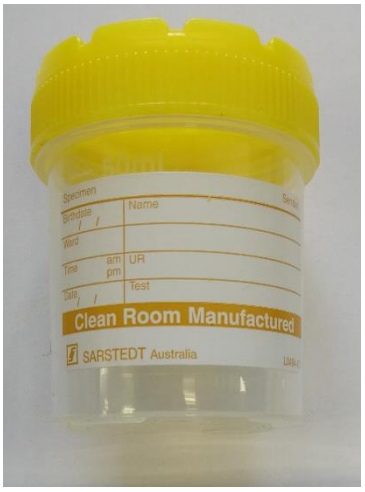
Urines for culture and sensitivity and pregnancy testing are now collected via the The Sarstedt NFT (Needle Free Transfer) system. This consists of a 100ml NFT primary container (Sarstedt Product Reference 75.562.900) and a 10mL Monovette tube (Sarstedt Product reference 10.252)

This system allows for the spill free collection and transfer of urine samples to the required 10mL Monovette tube (SeeTable 1 below).

- The 10mL Monovette **tube** is to be sent to the Microbiology lab for microbiology urine investigations (URCULT).
- ONLY 10mL Monovette tubes will be accepted and other container types will be rejected
- Both products are available from the Stores Department, Beaumont Hospital

Specimens should be processed within 4 hours. If transport to the laboratory has to be delayed, the specimen can be stored at 4°C for up to 24 hours.

Table 1. Approved urine specimen collection containers.

Department	Test	Container
Microbiology	Urine culture and sensitivity Urine hCG	
Microbiology Select C/S **or** *H pylori* only	Non-Urine Samples: Eg: Sputum Stool samples: *H.pylori* or culture and sensitivity  	

Biochemistry	Urines for ACR PCRs etc	

Urine specimens for TB
Urine specimens should be collected in the early morning on three consecutive days in a CE-marked leak-proof container (that does not contain boric acid), and placed in a sealed plastic bag. If there are no appropriate containers for a whole Early Morning Urine (EMU) sample, a midstream EMU sample is an acceptable, but not ideal alternative.

RESPIRATORY SPECIMENS

Sputum for culture and sensitivity:

- A good quality purulent or mucopurulent sputum specimen should be obtained, preferably before antimicrobial therapy, although antimicrobial therapy should not be delayed unnecessarily while awaiting a sputum specimen.
- The specimen should be transported to the laboratory within 2 hours.
- Salivary specimens are unsuitable and as such are not processed.
- If transport is delayed up to 24 hours, refrigeration is preferable to storage at ambient temperature. Specimens are not processed if they are >48hours old at time of receipt in laboratory

Sputum for investigation of *Mycobacterium* spp.:

- Sputum specimens should be relatively fresh (less than 1 day old) to minimise contamination. Purulent specimens are best.
- Two to three samples of ≥5mL should be collected approximately 8-24 hours apart with at least one from early morning
- Samples taken early morning (that is, shortly after patient waking) have the greatest yield.

- When the cough is dry, physiotherapy, postural drainage or inhalation of nebulised saline ('sputum induction') before expectoration may be helpful.

HIGH VAGINAL SWABS:

Obtain a high vaginal swab by use of a speculum and a Trans swab and submit to the laboratory.

CERVICAL / ENDOCERVICAL SWABS:

Use a speculum without lubricant. Wipe the cervix clean of vaginal secretions and mucus. Gently insert a swab into the endocervical canal and rotate to obtain any exudate and submit to the laboratory.

MOLECULAR TESTING:
for *Chlamdia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis*

Samples should be collected in the APTIMA unisex Swab Specimen Collection Kit for endocervical and male urethral swab specimens and the Urine Collection kit for male and female urine specimens as per instructions on www.nvrl.ie.

All are available from the NVRL on request and the test is referred to Eurofins Biomnis Ireland for processing by the NVRL Swab and urine specimens are stable at room temperature for 60 and 30 day post collection respectively.

2.27.3 *Serological Investigations*

Serology/virology samples from General Practitioners and nursing homes are referred to external laboratories from the Microbiology laboratory

All test requests to be ordered via the Health link system

All reports available electronically

HIV- VIRAL LOADS AND HEPATITIS C PCR.

- For HIV viral load, blood should be collected in an EDTA blood collection tube as per instructions on www.nvrl.ie.
- For hepatitis C PCR, a serum sample is required as per instructions on www.nvrl.ie.
- Hepatitis C PCR and HIV viral load investigations should be sent to the laboratory immediately for processing. **The serum must be frozen within 6 hours of taking the patient's blood,** as per instructions on www.nvrl.ie.
- Specimens are transported at -20˚C by courier each Friday to the NVRL.

ANTIBODY DETECTION.

- In order to establish a diagnosis of acute or recent viral infection by serology, viral specific IgM needs to be detected as per instructions on www.nvrl.ie.
- Before laboratory investigations are performed, paired sera must be submitted. The first should be taken as early as possible in the illness, and the second 14-21 days later and a four-fold rise in titre is required to confirm recent infection.
- A single specimen of serum is required to determine immune status or past infection.
- For serological investigations, a serum specimen of more than 1ml is required. One container of clotted blood should be sent to Beaumont Microbiology department for transport to the NVRL.
- For results enquiries, please phone the NVRL 01- 7161354.
- Results are available electronically via Healthlink

VIRAL SCREENING

- Samples for routine viral investigations are transported to the NVRL thrice daily by courier: 10.30am, 12.30pm and 2.30pm
- Please order test on Healthlink
- Clotted blood is the specimen of choice for most other external investigations.
- Please include relevant clinical details, travel history (including destinations visited and travel dates), complete demographics and inform laboratory if urgent.
- For serology referral tests, when an aliquot is required for sending out, the following is adhered to:

-Sufficient sample available

-Appropriate container for aliquot

-Labelling criteria (same information as original sample) See section 2.1.6

-Stability and storage conditions correct

Table 2: Specimen acceptance criteria

Test ordered	Container	Volume	Stability	Comments
Urine culture with microscopy	10 ml Monovette tube,	2 mls	4 hours at room temperature48 hours at 4℃	
HCG Pregnancy	10 ml Monovette tube60 ml sterile container	2 mls	4 hours at room temperature48 hours at 4℃	
TB culture	60 ml sterile container	10 mls	24 hours at room temperature, If delay store at 4 ℃	

Test ordered	Container	Volume	Stability	Comments
Ova and Parasites	60 ml sterile container	10 mls	1 hour without the addition of undiluted formalin	
C diff and Enteric Path	60 ml sterile container	1-2 ml/g	48 hours at 4℃	Liquid or semi-formed samples only processed
Enteric Path	60 ml sterile container	1-2 ml/g	48 hours at 4℃	Liquid or semi-formed samples only processed
Rotavirus/Adenovirus combi test	60 ml sterile container	1-2 ml/g	48 hours at 4℃	Children <5 years
Ova and Parasites	60 ml sterile container	1-2 ml/g	24 hours at room temperature	Travel details essential or CMT Request
Helicobacter pylori antigen	60 ml sterile container	1-2 ml/g	48 hours at 4 ℃	
Norovirus	60 ml sterile container	1-2 ml/g	48 hours at 4 ℃	Dispatched to NVRL
Respiratory culture	60 ml sterile container	15 mls	48 hours at 4℃	
TB culture	60 ml sterile container	1 ml	24 hours at room temperature, If delay store at 4 ℃	
Fungal culture (Skin scrapings/Nail clippings/Hair)	Dermapak 60 ml sterile container	As much as possible	Several months stored at room temperature	Any hair specimens must contain root of the hair
MRSA Screen Culture	Charcoal Transswab, (Nasal, Groin or Wound site)	N/A	24 hours at room temperature 72 hours at 4 ℃	
Swab/Wound/Eye/Ear/Throat/Mouth/Nasal/Pus culture	Charcoal Transswab (Wound, Eye, Ear, Throat, Mouth, Nasal, Pus),NT swab (orange)For ear, nose, throat only	N/A	24 hours at room temperature 72 hours at 4 ℃	
Genital culture	Charcoal Transswab	N/A	24 hours at room temperature	

Test ordered	Container	Volume	Stability	Comments
	(Cervical/Endocervical/Urethral/Throat/Rectal/Pus or Discharge from penis		72 hours at 4 ℃	
HVS Culture	Charcoal Transswab (HVS)	N/A	24 hours at room temperature 72 hours at 4 ℃	
Fluid/Aspirate culture	60 ml sterile container	Minimum of 1 ml in 60 ml sterile container	24 hours at room temperature 48 hours at 4 ℃ for 60 ml sterile container	
TB culture	60 ml sterile container	1 ml	24 hours at room temperature,If delay store at 4 ℃	
Pus culture	60 ml sterile container	1 ml	24 hours at room temperature If delay store at 4 ℃	
Cryptococcal antigen	CSF	100 µl	72 hours at 4 ℃ Longer at -20 ℃	
Cryptococcal antigen	White Topped Serum Tube	7.5 ml	72 hours at 4 ℃,Longer at -20 ℃	
Amikacin levels	White Topped Serum Tube	7.5 ml	Separated at 4 ℃ within 48 hours	Dispatched to Biochemistry MMUH
Adenovirus PCR	EDTA tube (pink top)	2.6 ml	Separated at -20 ℃ within 24 hours	Dispatched to NVRL State clearly on label Serum or Plasma
CMV PCR	EDTA tube (pink top)	2.6 ml	Separated at -20 ℃ within 24 hours	
EBV Serology	EDTA tube (pink top)	2.6 ml	Separated at -20 ℃ within 24 hours	
Hep B Viral Load/PCR/DNA	White Topped Serum Tube	7.5 ml	Separated at -20 ℃ within 24 hours	
Hep C PCR/Genotype/DNA/Viral Load	White Topped Serum Tube	7.5 ml	Separated at -20 ℃ within 24 hours	
HIV Viral Load/PCR	White Topped Serum Tube	7.5 ml	Separated at -20 ℃ within 24 hours	
HIV Viral Load/PCR	EDTA tube (pink top)	2.6 ml	Separated at -20 ℃ within 24 hours	
Beta-D-glucan	White Topped Serum Tube	7.5 ml	Separated at 4 ℃ for 15 days	Dispatched to Southmead, Bristol

Test ordered	Container	Volume	Stability	Comments
			Separated at -20 ℃ for 27 days	
Norovirus	60 ml sterile container	1-2 ml/g	48 hours stored at 4℃	
Parvovirus PCR	White Topped Serum Tube	7.5 ml	Separated at -20 ℃ within 24 hours	Dispatched to NVRL,State clearly on label Serum or Plasma
Teicoplanin levels	White Topped Serum Tube	7.5 ml	Separated at 4 ℃ within 48 hours	Dispatched to Eurofins Biomnis
Tobramycin levels	White Topped Serum Tube	7.5 ml	Separated at 4 ℃ within 48 hours	Dispatched to Biochemistry SVUH
Voriconazole levels	White Topped Serum Tube	7.5 ml	Separated at -20 ℃ within 24 hours	Dispatched to MMUH

Table 3: Specimen rejection criteria

Specimen	Label	Test ordered	Container	Volume	Stability	Comments
Urine						
Specimen unlabelled or mislabelled with incorrect patient details Leaking specimen	Urine	Incorrect Healthlink order Specimen with request form, not ordered on Healthlink	Sarstedt "Urine NFT" primary sample container	< 2 ml (manual microscopy & culture will be performed)	> 4 hours at room temperature > 48 hours at 4 ℃	
	HCG		60 ml sterile container without red sticker on lid	< 2 ml	24 hours at RT > 48 hours at 4 ℃	
	TB,			< 10 mls		
	O&P			< 10 mls		
Faeces						
Specimen unlabelled or mislabelled	C diff toxin & Enteric Path	Incorrect Healthlink order	Sarstedt "Urine NFT" primary sample container 10 ml Monovette tube	< 1 ml/g	>48 hours at 4℃	Formed samples & < 2 years old for C.diff
	C diff toxin PCR			< 1 ml/g		

Specimen	Label	Test ordered	Container	Volume	Stability	Comments
with incorrect patient details Leaking specimen		Specimen with request form, not ordered on Healthlink	Sarstedt "Urine NFT" primary sample container 10 ml Monovette tube		>48 hours at 4℃	Will only be processed for Crypto/Giardia if no travel details have been received or no request from CMT
	EntericPath			< 1 ml/g		
	ROT/ADV			< 1 ml/g		
	O&P			< 1 ml/g	> 48 hours at 4℃ without addition of 10% formalin-water	
	H. pylori Ag			< 1 ml/g	> 48 hours unless stored at – 20 ℃	
Respiratory						
Specimen unlabelled or mislabelled with incorrect patient details Leaking specimen	Respiratory/Sputum/ CF Resp	Incorrect Healthlink order Specimen with request form, not ordered on Healthlink	Sarstedt "Urine NFT" primary sample container	< 15 mls	> 48 hours stored at 4℃ except CF specimens	Salivary samples (except CF) are rejected.
	TB		Sarstedt "Urine ,FT" primary sample container	< 1 ml (Culture only)	> 24 hours at room temperature	
Fungal						
Specimen unlabelled or mislabelled with incorrect patient details Leaking specimen	Fungal	Incorrect Healthlink order, Specimen with request form, not ordered on Healthlink	Non sterile container	No visible sample present Culture only performed on insufficient sample	Stored at 4 ℃ > Several months	
Screens						
Specimen unlabelled or mislabelled with incorrect patient details	MRSA	Incorrect Healthlink order	Viral swab (pink)ENT swab (orange)Pertussis swab (blue)Liquid Amies eSwab	N/A	> 24 hours at room temperature > 72 hours at 4 ℃	
Swabs						
	C Swab/C Wound/C Eye/C Ear/C Throat/C Mouth/C Nasal/C Pus	Incorrect Healthlink order	Viral swab (pink)	N/A	> 24 hours at room temperature	

Specimen	Label	Test ordered	Container	Volume	Stability	Comments
Specimen unlabelled or mislabelled with incorrect patient details		Specimen with request form, not ordered on Healthlink	Pertussis swab (blue)		> 72 hours at 4 ℃	
	Genital		liquid Amies eSwab,ENT swab (orange) for any site other than ear, nose, throat	N/A	> 24 hours at room temperature > 72 hours at 4 ℃	
	GC		Agar plate other than VCAT	N/A	N/A	
	HVS		Viral swab (pink),ENT swab (orange),Pertussis swab (blue),Liquid Amies eSwab	N/A	> 24 hours at room temperature > 72 hours at 4 ℃	
Fluids						
Specimen unlabelled or mislabelled with incorrect patient details Leaking specimen, (If possible clean & process)	Fl/Asp	Incorrect Healthlink order Specimen with request form, not ordered on Healthlink	Non sterile container	< 1 ml in 60 sterile container	> 24 hours at room temperature > 48 hours at 4 ℃ for 60 ml sterile container	
	TB		Non sterile container	<1 ml (Culture only performed on insufficient volume)	> 24 hours at room temperature If delay store at 4 ℃	
Pus						
Specimen unlabelled or mislabelled with incorrect patient details Leaking specimen,	Pus	Incorrect Healthlink order Specimen with request form, not ordered on Healthlink	Non sterile container	< 1 ml	> 24 hours at room temperature > 48 hours at 4 ℃	If < 1 ml charcoal swab can be processed
Tips						
Virology (External laboratories)						

Specimen	Label	Test ordered	Container	Volume	Stability	Comments
Specimen unlabelled with MedLIS label or mislabelled with incorrect patient details Leaking specimen	AmikR	Specimen with request form, not ordered on Healthlink)	Blood bottle other than white topped serum tube	Visibly no blood in bottle	Not separated at 4 ℃ within 48 hours	
	ADVADNA VRL ADVDNAL VRL		Blood bottle other than EDTA tube (pink top)			
	CMVDNA VRL					
	EBV DNA VRL					
	HBVL VRL HBGER VRL		Blood bottle other than white topped serum tube			
	HCVGE VRL HCVVL VRL					
	HIVGER VRL					
	HIV1VL VRL		Blood bottle other than EDTA tube (pink top)	Visibly no blood in bottle	Not separated at 4 ℃ within 24 hours	
	B-D GLUCAN		Blood bottle other than white topped serum tube	Visibly no blood in bottle	Not separated at 4 ℃ for 15 days,not separated at -20 ℃ for 27 days	
	NORXPERT VRL		Non sterile container	Visibly no faeces	> 48 hours at 4 ℃	
	PARVDNA VRL		Blood bottle other than white topped serum tube	Visibly no blood in bottle	Not separated at 4 ℃ within 24 hours	
	Teicoplanin Level					
	Tobra Trough					
	Voriconazole					

2.28 HISTOPATHOLOGY/CYTOPATHOLOGY/NEUROPATHOLOGY

As per communication previously circulated, due to a national shortage of medical scientists, the Histopathology laboratory is currently outsourcing some paraffin embedded blocks to Hibernian Testing Services Ltd. for Histopathological staining and cutting as documented in the quality management system documentation.

2.28.1 *Current Best Practice for Renal Biopsies*

Two cores of tissue should be taken to ensure that there are sufficient numbers of glomeruli for examination – not less than 10 for light microscopy and immunofluorescence. This applies to native and allograft kidneys. Both cores can be placed in the same container.

2.28.2 *Handling of Tissue after Biopsy has been taken.*

Tissue must be fresh in order to allow immunological assessment to be performed. In Beaumont Hospital biopsies are carried out in the X-Ray Dept. by one of the Radiologists. The biopsy cores are placed in a universal container which is at least half full of normal saline. The container is placed in a biohazard bag and the Renal Biopsy Request form which should have been filled in by the Nephrology team on the ward prior to transfer of the patient to X-Ray is placed in the outer pouch of the bag.

2.28.3 *Coroners's Post Mortem*

In all cases the Information Sheet on Post-Mortem Examination (Lab 360A) should be given to families. (http://dms.beaumont.ie/sections/medical/procedures-for-medical1263)

Circumstances where a death should be reported to the Coroner are listed below.

If an autopsy is required, the clinical staff must inform the Anatomical Pathology Technician at extension 2679 or Mortuary Service Co-Ordinator at extension 8180. Information relating to consent is available on request.

For "consented" autopsies (so called non-Coroners or "House Cases") it is the responsibility of the individual who requests the autopsy to ensure the completed consent form (LAB 358B), patient case notes and a concise clinical summary are delivered to the Mortuary/Pathology in order for the autopsy to be performed. Case should be discussed with Pathologist where possible. (Ext 2638)

In the case of deaths outside normal working hours, the individual who obtained consent for autopsy must ensure that the relevant documentation is given to the Anatomical Pathology Technician or Autopsy/Mortuary Manager (Ext 8354) the following morning.

In Coroner's cases it is the responsibility of the clinical team to notify the Coroner and to ensure that the Coroner Autopsy Post Mortem Examination Form (LAB 357B) is completed.

DEATHS WHICH MUST BE REPORTED TO THE CORONER

(a) Deaths occurring at home or other place of residence:

- Where the deceased was not attended by a doctor during the last illness;
- Where the deceased was not seen and treated by a doctor within one month prior to the date of death;
- Where death was sudden or unexpected;
- Where death may have resulted from an accident (regardless of length of time
- between injury and death), suicide or homicide;
- Where the cause of death is unknown or uncertain;
- Where concerns are expressed by any person in relation to a death.
- Where the cause of death is suspected to be CJD.

(b) Deaths occurring in hospital:

- Deaths occurring in the accident and emergency department and individuals dead on arrival at hospital;
- Deaths occurring within 24 hours of admission;
- Where a patient dies before a diagnosis is made and the general practitioner is also unable to certify the cause;
- When death occurred while a patient was undergoing an operation or under anaesthesia or within 24 hours of same;
- Where death occurred during or as a result of any procedure;
- Where any question of negligence or misadventure arises in relation to the treatment of the deceased;
- Where death resulted from an industrial disease;
- Where death was due to neglect or lack of care (including self neglect);
- Where death occurred in a Mental Hospital;
- Where death may have resulted from an accident (regardless of length of time
- between injury and death), suicide or homicide.
- Where a patient has MRSA, C. Diff. or VRE if this is a contributing factor
- Where a patient is resident in a long stay unit or nursing home (e.g. Rockfield Unit)
- Where the cause of death is suspected to be CJD.

(c) A death is reported to the coroner by a member of the Garda Siochana:

- Where death may have resulted from an accident, suicide or homicide;
- Where death occurred in suspicious circumstances;
- Where death is unexpected or unexplained;
- Where a dead body is found;
- Where there is no doctor who can certify the cause of death.

(d) Other Circumstances

- Sudden infant deaths;
- Where a body is to be removed out of Ireland.

A detailed list of reportable deaths is available in the "The Role of the Coroner in Death Investigation", a copy of which is available on request.

It is the responsibility of the most senior member of the medical staff attending the patient to ensure that the death is reported to the Coroner.

2.29 MOLECULAR PATHOLOGY

2.29.1 *Sample selection*

All samples for solid tumour mutation analysis should be submitted as FFPE blocks. Samples for testing must arrive with a completed request form and a report on the patient sample.

All samples for Neuromolecular mutation analysis should be submitted as FFPE blocks with an accompanying H&E-stained slide. The H&E stained slide must be representative of the material in the block so a recent H&E is advised. The slide will be held in the Molecular laboratory in case the result needs to be queried in the future, for this reason a slide cut specifically for molecular testing is advised. Samples for testing must arrive with a completed request form and a report on the patient sample.

For germline BRCA testing, a peripheral blood sample should be submitted with the BRCA request form. Signed Patient consent must be obtained on this request form, the assay cannot be performed without this and will be rejected.

All samples should be sent to the following:

Molecular Pathology Laboratory
c/o Pathology Specimen Reception
Beaumont Hospital
Beaumont Road
P.O. Box 9063
Dublin 9

2.29.2 *Reporting of results*

External results are reported by email. Reports are sent to at least two recipients by email. It is common practice to add the treating clinician or practice nurse to the email list to ensure that the result arrives to the clinic as rapidly as possible. As well as any individual's email a generic laboratory email (that can be checked by different individuals to cover periods of leave) should also be provided. This facilitates integration of the result into the sending hospital's laboratory information system (LIS). All email addresses must be specified in the recipients section of the test request form.

2.29.3 ***Contacting The Department***

Teresa Loftus	Chief Medical Scientist	018092856	molecular@beaumont.ie teresaloftus@beaumont.ie

The Molecular Pathology laboratory provides a molecular pathology diagnostic and consultative service for hospitals throughout Ireland.

The information provided below is a broad guideline to the use of more commonly provided tests. However the Consultant Pathologists and staff are always happy to discuss the service & individual patients in more detail.

The Molecular Pathology Department is staffed from 08:00 – 17:00, Monday – Friday. The laboratory does not operate on Saturdays, Sundays or Bank Holidays.

2.30 **NHISSOT**

The National Histocompatibility and Immunogenetics Service for Solid Organ Transplantation (NHISSOT) provides a nationwide transplant immunology service for solid organ transplantation, including HLA typing and crossmatching of both donors and recipients, HLA antibody screening for post transplant monitoring and HLA typing for disease association.

NHISSOT or H&I (Histocompatibility & Immunogenetics) is an accredited laboratory awarded by The European Federation for Immunogenetics (EFI). EFI is a European organisation that focuses on immunogenetics, tissue typing and transplantation. The EFI Accreditation Programme provides an internationally recognised accreditation scheme for laboratories providing Histocompatibility & Immunogenetics testing services in support of solid organ transplantation.

The H&I Department is committed to providing and maintaining a service of the highest quality by strictly adhering to policies and procedures that are in place to ensure the EFI standards are being maintained and updated.

We actively participate in well established external and internal quality control programmes to ensure best practice is being followed. We are continuously implementing ways to improve the service by assessing and validating new assays and techniques to provide the best level of service for our patients.

The NHISSOT provides H&I support for:

- The National Kidney Transplant Services at Beaumont Hospital
- The National Liver /Pancreas Transplant Services at St Vincent' s University Hospital
- The National Heart/ Lung Transplant Services at the Mater Misericordiae University Hospital
- Organ Donation Transplant Ireland

This document is intended as a guide to the services and tests available in the H&I Department. It provides details of the tests available, their specimen requirements, as well as appropriate background information.

3 LABORATORY SERVICES PROVIDED

3.1 GENERAL INFORMATION

3.1.1 *Location of Department*

The Clinical Directorate of Laboratory Medicine is located between the lower ground and ground floors of Beaumont Hospital.

The postal address of the Directorate is:

Clinical Directorate of Laboratory Medicine
Beaumont Hospital
PO Box 1297
Beaumont Road
Dublin 9
D09 V2N0

Visitors to any laboratory should go to the Pathology Reception Desk on the Lower Ground Floor. Staff at pathology reception will contact the Department and a member of staff will accompany them to the relevant Laboratory.

3.1.2 *Contacting the Department/Telephone Numbers*

FUNCTION	CONTACT	TELEPHONE/EMAIL
Beaumont Hospital Reception	Switchboard	01-8093000/8377755
Directorate Management	Clinical Director	01-8092644
	Laboratory Manager	01-7977925
	Business Manager	01-8092508
Quality Management	Quality Manager	01-8092978

FUNCTION	CONTACT	TELEPHONE/EMAIL
Appointments	Phlebotomy Appointements	01-7974675
BLOOD TRANSFUSION & HAEMOVIGILANCE		
Medical Enquiries	Prof. Philip Murphy	01-8093382
	Prof. John Quinn	01-8092664
	Prof Patrick Thornton	01-8092664
	Dr. Siobhan Glavey	01-8092664
	Haematology Registrar	Bleep 276
	SP Registrar	Bleep 887
	For Out-Of- Hours Service	Contact Switch Board
Scientific Enquiries	Chief Medical Scientist	01-8094733
	Senior Medical Scientists	01-8094734
	Senior Scientist	01-8094734
	Routine Laboratory	01-8092705
	On Call	Bleep 252
Haemovigilance Enquiries	Haemovigilance Officers	01-8093334/2034 / Bleep 649
HAEMATOLOGY DEPARTMENT		
General Enquiries	HaematologyOffice-secretary/general enquiries Central Reception	01-8092655 haemtologyadmin@beaumont.ie 01-8093914/2674/2669/4075
Results	Phone number for the GP/External Lab Results Line	01-8092690

FUNCTION	CONTACT	TELEPHONE/EMAIL
Medical Enquiries	Prof. Philip Murphy	01-8093382
	Prof. John Quinn	01-8092664
	Prof. Patrick Thornton	01-8092644
	Prof. Siobhan Glavey	01-8092664
	Dr Karl Ewins	018528832
	Dr Jeremy Sargent	01-8092150/2622
	Dr Elizabeth Smyth	01-8092150/2622
Clinical Advice and Laboratory Test Interpretation	Coleman. K. Byrne Unit	01-8092150/2622
	Haematology Registrars	'Contactable through switch'
	Haematology Senior House Officers	'Contactable through switch'
	Chief Medical Scientist	01-8092662
Clinic	Coleman. K. Byrne Unit	01-8092150/2622
	Warfarin Clinic	01-8092083/3982
Scientific Enquiries	Chief Medical Scientist	01-8092662
	Seniors office	01-8093952
	Haematology Laboratory	01-8092703
	Coagulation Laboratory	01-8092656
	Flow Cytometry Laboratory	01-8092763
	Morphology Special Haematology	01-8093226
IMMUNOLOGY DEPARTMENT		
General Enquiries	Departmental Secretary	01-8093026
	Secretary to Prof. Keogan/ Dr Khalib/Dr Cox	01-8092652
	Specialist Registrar	Bleep 797

FUNCTION	CONTACT	TELEPHONE/EMAIL
Appointment Information	Secretary to Prof. Keogan/ Dr Khalib/Dr Cox	01-8092652
Clinical Advice and Laboratory Test Interpretation	Specialist Registrar	immunologydepartment@beaumont.ie Bleep 797
Lab Enquiries	Lab Reception	01-809 3914/2674/2669/4075
Results	Pathology Reception	01-8092690
Scientific Enquiries	Chief Medical Scientist	01-8093174
	Immunology Laboratory	01-8092635/2421 immunologylab@beaumont.ie
CHEMICAL PATHOLOGY DEPARTMENT		
General Enquiries	Pathology Reception	01-8092507
Test Results	Pathology Reception	01-8092507
Medical Enquiries	Dr.Shari Srinivasan	01-8092676
	Dr. Clodagh Loughrey	01-8092035
	Specialist Registrar	01-8092666 Bleep 332
Scientific Enquiries	Chief Medical Scientist	01-8092670
	Chief Medical Scientist	01-7977811
	General Clinical Biochemistry	01-8092704/2668/2671 01-8528675
	Proteins	01-8092305
	Mass Spectrometry Laboratory	01-8092351 or 01-7977333
Out of Hours	Via Switchboard	Bleep 251 or DECT 8727
MICROBIOLOGY DEPARTMENT		
All Enquiries	Microbiology office	01-8092646

FUNCTION	CONTACT	TELEPHONE/EMAIL
Results	Microbiology office	01-8092646
Medical Enquiries	Prof. B. Dinesh	01-8092646
	Prof. F. Fitzpatrick	01-8092646
	Prof. K. Burns	01-8092646
	Dr. Ciara O' Connor	01-8092646
	Dr. Sinead O' Donnell	01-809 2646
	Dr. Helene McDermott	01-809 2646
	Registrars	01 -8093320/3321/2667
	Out of Hours	Through Switchboard
Scientific Enquiries	Chief Medical Scientist	01-8092645
	Main Laboratory	01-8092647
HISTOPATHOLOGY & CYTOPATHOLOGY DEPARTMENT		
General Enquiries	Department Office	01-8092636/2353
	Department Email	histo@beaumont.ie
Medical Enquiries	Dr. Clíona Ryan	01-80922284
	Dr. Marie Staunton	01-8092997
	Dr. Brian Pierce	01-8094240/ Bleep 322
	Prof. Brendan Doyle	01-8092636
	Dr. Anne Marie O'Shea	01-8093910
	Dr. Maeve Redmond	01-8092998
	Dr. Helen Barrett	01-8092641
	Dr. Christian Gulmann	01-8092078
	Dr. Keith Pilson	01-8093986
	Dr. Clive Kilgallen	01-8092284
	Dr. Odharnaith O'Brien	01-8094218
	Dr. Laura Mc Kenna	01-8093286

FUNCTION	CONTACT	TELEPHONE/EMAIL
	Registrars Office	01-8092638/3435/ Bleep 448
Scientific Enquiries	Chief Medical Scientist	01-8092555
	Main Laboratory	01-8092353
	Specimen Reception	01-8092659
	Cytology Laboratory	01-8092640
Reports	Histopathology Office	01-8092636/2632/3919/3150/2154
RENAL PATHOLOGY		
Medical Enquiries	Dr. Brian Pierce	01-8094240/ Bleep 322
	Prof. Brendan Doyle	01-8092636
Scientific Enquiries	Renal Pathology Laboratory	01-8528633 (dect phone)
General Enquiries	Renal Pathology Secretary	01-8092008
NEUROPATHOLOGY		
Medical Enquiries	Dr Jane Cryan	01-8093973
	Dr. Francesca Brett	01-8093143/ Bleep 324
	Dr. Alan Beausang	01-8092615
	Dr. Abel Devadass	01- 8097775
	Specialist Registrar	01-8092706
Scientific Enquiries	Senior Medical Scientist	01-8092633
	Senior Medical Scientist (CJD)	01-8092633
	Research Scientist	01-8092706/ 3798
	Brain Bank	01-8092706
	Molecular Neuropathology	01-8098452/8453
Reports	Neuropathology Office	01-8092631/2072
NHISSOT		

FUNCTION	CONTACT	TELEPHONE/EMAIL
General Enquires	Main Laboratory	01-8092650
	Chief Medical Scientist	01-8092661
Scientific Enquiries	Main Laboratory	01-8092650
	Molecular	01-8093955
	Scientists Office	01-8093238/2960
	Reporting Room	01-8092651/4246
	Antibody Screen	01-8094248
Email Addresses	General enquires	crossmatch@beaumont.ie
	Patient enquires	transplantlab@beaumont.ie
	Post transplant enquires	posttransplant@beaumont.ie
On-Call	Medical Scientist on duty	087-2615112
Clinical Enquiries	Consultant Immunologist	01-8092652
	Out of Hours	Through Switchboard
Renal Transplant Co-Ordinators Beaumont Hospital	Office	01-8092759
	E-Mail	transplantcoordina@beaumont.ie
	Urgent Call via Switch	01-809300/8377755
MOLECULAR PATHOLOGY		
General Enquiries	Chief Medical Scientist	01-8092856
Email Address	General enquiries	molecular@beaumont.ie
HEALTHLINK SYSTEM		
General Enquiries/Test Result Issues	Project Manager	01-8825720 info@healthlink.doh.ie

3.1.3 ***Department Opening Hours***

The Clinical Directorate of Laboratory Medicine is open 8am to 8pm, Monday to Friday. There is no routine Saturday/Sunday/Bank Holiday service.

- Immunology laboratory hours are from 9.00 am to 5.00pm, on Monday to Friday.
- Blood Transfusion laboratory routine hours are 8am -5pm Monday to Friday and 9am-1pm on Saturday contactable on Ext. 2705. An Emergency On –Call service from 5pm -8am Monday to Friday and 1pm - 8am Saturday to Monday contactable on Bleep. 252
- Haematology Laboratory routine hours 8am to 8pm, Monday to Friday. There is a routine Saturday, 09.00 – 13.00. An Emergency On –Call service from 8pm -8am Monday to Friday and 1pm - 8am Saturday to Monday. Contactable on Bleep. 852. A reduced service is offered between Christmas, New Year and Easter
- Chemical Pathology Laboratory routine hours 8am to 8pm, Monday to Friday and Saturday, 09.00 – 13.00. An Emergency On –Call service from 8pm -8am Monday to Friday and 1pm - 8am Saturday to Monday. Contactable on Bleep #251. A reduced service is offered between Christmas, New Year and Easter
- Only a limited Histopathology/Cytopathology/Neuropathology service is provided between 5pm to 8am and scientists on call can be contacted through switch.
- Microbiology laboratory hours are from 08:00am to 8.00pm, Monday to Friday and 9:00am to 1.00pm on Saturdays. After 8pm on weekdays, and from 1pm Saturday until 8:00am Monday morning, Microbiology provides emergency on-call service only.
- NHISSOT Laboratory hours are from 8:00am to 600pm Monday to Friday. After 6pm, it is an emergency on call service. The laboratory is closed on Saturday, Sunday and Bank Holidays

- Molecular Pathology Laboratory hours are from 8am to 5pm Monday to Friday. The laboratory does not operate at weekends/bank holidays.

There is no clerical support outside Mon-Fri 09:00-17:00

Please ensure samples arrive in the laboratory as early as possible in the working day.

Arrangements are put in place each year regarding the specific services available over the Easter, Christmas and New Year periods and issued to service users with reports.

3.1.4 ***Consent***

The laboratory shall obtain the informed consent of the patient for all procedures carried out on the patient. For most routine procedures, consent can be inferred when the patient presents himself or herself with a request form and willingly submits to the collecting procedure e.g. venepuncture. Patients in a hospital bed should normally be given the opportunity to refuse.

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

If obtaining consent is not possible in emergency situations, the laboratory may carry out necessary procedures, provided they are in the patient's best interest

The requirement for consent for individual tests performed is outlined in the relevant departmental sections of this laboratory manual.

3.1.5 *Specimen Collection Guidelines & Order Of Draw*

3.1.5.1 Patient Preparation

Patients should adhere strictly to any conditions which are required prior to and during primary sample collection. Caregivers and phlebotomists should ensure that patients are informed of the procedure required for specialist primary sample collection and that they have the required equipment e.g. 24hr urine collection containers. For further information on patient preparation for primary sample collection, please contact the relevant laboratory using the contact details provided in section above.

3.1.5.2 Venepuncture Instructions

The collection of a venous sample means the identification of the best vein to source the sample. The arm veins are normally the first choice for a phlebotomist. The most commonly used veins are the cephalic, medial cubital or basilic veins.

1. The Limb should be supported on a pillow or armrest of a phlebotomy chair.
2. Apply the tourniquet 2 – 3 inches above the selected site.
3. Wear your disposable gloves, cleanse the patients skin with a mediswab.
4. Anchor the vein using manual traction below the site of entry. The vein should feel firm and slightly bouncy.
5. Insert the needle with the bevel facing upwards and the needle at 15° angle.
6. There should be a flashback of blood to denote a vein has been accessed.
7. The needle should be held firmly between your thumb and fingers to allow the change of the different tubes onto the needle.
8. When all blood specimens have been obtained, release the tourniquet, detach the last tube and now remove the needle smoothly and quickly.
9. Apply pressure to the venous site for as long as required. This avoids a haematoma forming.
10. Dispose of the used needle immediately into the sharps bin. Do not recap the needle

The blood bottles must now be labelled correctly and any special requirements adhered to.

3.1.5.3 Blood Sample Order of Draw

Samples must be drawn in the order as tabulated below, to avoid any cross contamination of samples.

Never pour blood from one tube into another. The preservative in the first tube could contaminate the second tube; this can greatly affect results and potentially compromise patient care.

Refer to the Test Library for information on sample requirements and the number of tubes required. Tubes CANNOT be used / shared across different platforms because of the risks involved in sample re-labelling.

The brown and white cap samples must be stood upright to clot as soon as the bottles are filled to ensure that the clot forms in the base of the tube and not the lid. The yellow and pink bottles must be inverted gently to ensure complete mixing. Place all the labelled samples into the bio-hazard bag attached to the patient request form and seal.

Please note: The order of draw is in line with approved standards. Please refer to test information available under relevant department guidelines below.

Colour Code	Tube type and Order of Draw	Investigations
 **Brown**	**1st** **Serum Gel** **STAND UPRIGHT ONCE DRAWN**	**4.9ml Chemical Pathology** (specific tests only, see label) **4.9ml Immunology**
 **White**	**2nd** **Serum** **STAND UPRIGHT ONCE DRAWN**	**4.9ml Chemical Pathology** (specific tests only, see label) **Virology** (Serological testing) **4.9ml** WHITE on ICE
 **Green**	**3rd** **Sodium Citrate Coag**	**10ml** required for **HLA27 / Tissue Typing** **2.9ml / 1.8ml** for **Coagulation Tests** ***Under-filled or over-filled tubes will be rejected***
 **Orange**	**4th** **Lithium Heparin** 4.9ml	**Troponin** only ***Under-filled tubes will be rejected***
 **Orange**	**5th** **Lithium Heparin** 4.9ml	**4.9ml Chemical Pathology** (specific tests only) **4.9ml** orange on ice Metal-free available from Specimen Reception (using special metal-free needle)

 **Pink**	**6th** **K-EDTA**	**2.6ml** Pink **FBC (Haematology tests),HbA1C** **Molecular Tests** **Virology** (Molecular Investigations eg EBV,CMV,HIV molecular)
 **Blue**	**7th** **K-EDTA** Blue 4.9ml with BTD label	**4.9 ml** EDTA for **Type and Screen** **4.9 ml** EDTA for **ACTH/PTH/Aldosterone/Renin**
 **Yellow**	**8th** **Sodium Fluoride**	**Glucose** **Alcohol**
 **Purple**	**9th** **Sodium Citrate**	**ESR** ***Under-filled tube will be rejected***

3.1.5.4 24-Hour Urine Collection: General Information for Patients:

You will receive

- A large plastic container in which to store urine.
- A request form with your details on it.
- A plastic bag in which to return your collection and request form.

1. You may need more than one storage container to contain all of your urine for the 24-hour period.

2. Make sure each storage container is labelled with your full name and hospital number written on it. **If your container is not labelled properly, you may be asked to repeat the 24-hour collection.**
3. Keep your storage container cool throughout the 24-hour collection period until you bring it back
4. For certain collections, a blood sample may need to be taken within the 24 hour collection period; you will be informed if this is the case.

How to collect your sample.

1. Start the 24-hour urine test by urinating directly into the toilet. Do not save this urine.
2. After you urinate, write the date and time on your storage container, **this is the start of your test.** Write this time & date on the container.
3. For the next 24 hours, collect all your urine into your storage container.
4. Exactly 24 hours after you started the test, urinate one last time and place the urine in your storage container. **This is the end of your test.** Write the date and time the test ended on your storage container.
5. If you need to use more than one container during the 24-hour period, use one container at a time. When it is full, collect your urine in the next container.
6. Please bring the urine to the hospital as soon as possible. To prevent leaks, make sure the lid is on tightly, and that the container is transported upright inside a plastic bag.
7. If you are an inpatient, your nurse will tell you what time to begin and end the collection and will set up more containers, as needed. If you have questions about the procedure, please ask.

3.1.5.5 24-Hour Urine Collection (Acidified): Information for Patients

HCl can cause burns and irritate the respiratory system. It is designated harmful and corrosive and bears the following hazard warnings.

Harmful Corrosive

You will receive

- A large plastic container with acid in which to store urine.
- A request form with your details on it.
- A plastic bag in which to return your collection and request form.

1. You may need more than one storage container to contain all of your urine for the 24-hour period.
2. Make sure each storage container is labelled with your full name and hospital number written on it. **If your container is not labelled properly, you may be asked to repeat the 24-hour collection.**
3. Keep your storage container in a cool place throughout the 24-hour collection period and until you return it to the laboratory.
4. For certain collections, a blood sample may need to be taken within the 24 hour collection period; you will be informed if this is the case.

How to handle acid safely.

1. Your storage container is supplied with a small volume of acid, do not throw this out.
2. You should open the container in a well ventilated area as fumes may escape from the acid.
3. Do not urinate directly into an acidified container.
4. Pour the urine slowly down the inside wall of the container, trying not to splash the acid.
5. Close the lid and swirl the container gently, to mix the acid and the urine.
6. Repeat steps 2~4 each time you add urine to the container.
7. Should you spill any acid on your skin, wash it off at once with plenty of running water.
8. If you experience soreness or reddening of your skin, as a result of a splash, consult your doctor & take these instructions with you.
9. **Keep the container in a safe place and out of the reach of children at all times.**

How to collect your sample.

1. Start the 24-hour urine test by urinating directly into the toilet. Do not save this urine.

2. After this urination, write the date and time on your storage container, **this is the start of your test.**
3. For the next 24 hours, collect all your urine into your storage container.
4. Exactly 24 hours after you started the test, urinate one last time and collect this urine in your storage container. **This is the end of your test.** Write the date and time the test ended on your storage container.
5. If you need to use more than one container during the 24-hour period, use one container at a time. When it is full, collect your urine in the next container.
6. Please bring the urine to the hospital as soon as possible. To prevent leaks, make sure the lid is on tightly, and that the container is transported upright inside a plastic bag.
7. If you are an inpatient, your nurse will tell you what time to begin and end the collection and will set up more containers, as needed. If you have questions about the procedure, please ask.

3.1.5.6 Mid-Stream Urine

Male: Clean the glans penis with soap and water. Commence micturition and when a few ml of urine has been passed, introduce a widemouthed container into the stream

Females: If the patient is able to collect urine without assistance from the nursing staff, instruct them as follows:
1. Separate the labia and with cotton wool or a sponge moistened with water, wipe the vulva from the front to the back. Disinfectants must not be used.
2. With the labia still separated allow some urine to pass into the toilet, and then, without stopping, allow some to pass into a sterile container.
3. Pass the remaining urine into the toilet.

3.1.5.7 Swabs

Collect the specimen by passing the swab twice over the relevant area. Label and send to the laboratory as soon as possible after collection

3.1.5.8 Endocervical Swab for GC Culture

Clean the cervical os with a large sterile swab and discard. Insert a new swab into the endocervix and rotate 360 degrees.17 Swab the external os 360 degrees if os stenosed

3.1.5.9 Sputum

Instruct the patient to remove dentures, rinse mouth and gargle with tap water and not with antiseptic mouthwash. Instruct the patient to expectorate saliva or postnasal discharge and discard, before expectorating a deep lung sputum sample into a specimen container. Specimens must be submitted in a wide-mouthed container and sent to the laboratory without delay.

3.1.5.10 Stool Samples

Stool specimens should be collected in a clean container with a secure lid, labeled, and sent to the laboratory as soon as possible after collection

3.1.5.11 Disposal of Materials Used

Dispose of all clinical waste must be in accordance with National Guidelines.

- Universal precautions must be adhered to at all times.
- Gloves must be worn at all times.
- Gloves must be changed after each patient.
- Needles must not be recapped after use.
- Dispose of sharps in a suitable sharps container.
- Dispose of all clinical waste into yellow bag.

3.1.6 ***Specimen Labelling***

The following details must be recorded clearly on specimen containers:

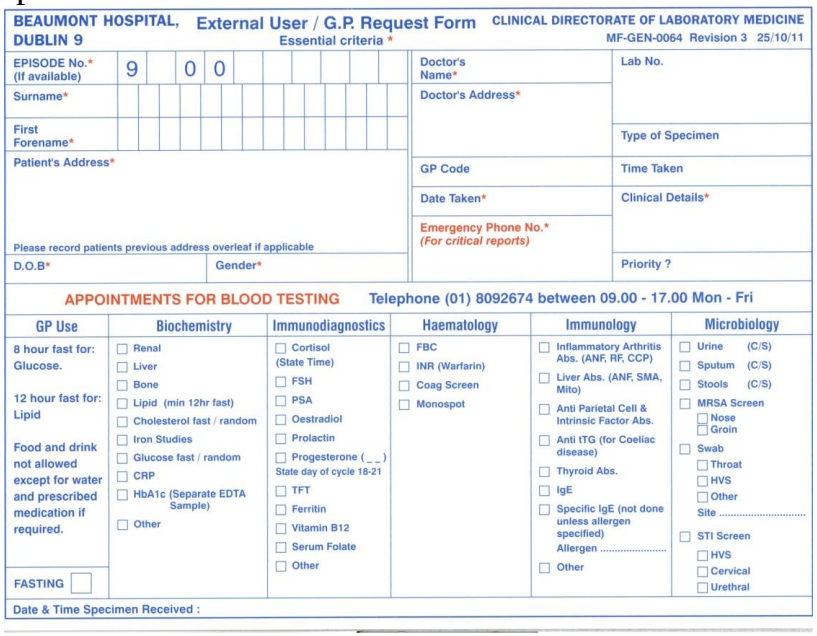
- Name
- Date of Birth
- Medical Record Number where available
- Date and time of specimen collection
- For 24 hour urine collections the date and time that the collection commenced and finished
- For Histopatholoy/Cytopathology/Neuropathology, anatomical location of specimen. If multiple specimens on the patient are taken, the specimen containers must be individually labelled as to the site of origin.
- For Microbiology, nature and site of specimen

3.1.7 ***Specimen Request Forms***

All orders are to be electronically ordered where the system is available to the GP practice. Full training has been provided to users on implementation of the GP eOrdering system. The requesting clinician is responsible for the ordering of specimens including addition of all relevant clinical details and are responsible for correct labelling of specimens. Specimens must be accompanied by a fully completed electronic request.

Where electronic ordering is not available in your GP practice or in the rare event that the system is down, the below request form may be used on instruction from Beaumont Hospital.

Approved request forms are distributed by First Direct Couriers on behalf of Beaumont Hospital. The Hospital does not have supplies of request forms. An example is shown below.



BEAUMONT HOSPITAL, DUBLIN 9 — **External User / G.P. Request Form** (Essential criteria *) — CLINICAL DIRECTORATE OF LABORATORY MEDICINE — MF-GEN-0064 Revision 3 25/10/11

EPISODE No.* (If available) 9 0 0 | Doctor's Name* | Lab No.

Surname* | Doctor's Address*

First Forename* | Type of Specimen

Patient's Address* | GP Code | Time Taken

Please record patients previous address overleaf if applicable | Date Taken* | Clinical Details*

D.O.B* | Gender* | Emergency Phone No.* (For critical reports) | Priority ?

APPOINTMENTS FOR BLOOD TESTING Telephone (01) 8092674 between 09.00 - 17.00 Mon - Fri

GP Use	Biochemistry	Immunodiagnostics	Haematology	Immunology	Microbiology
8 hour fast for: Glucose. 12 hour fast for: Lipid Food and drink not allowed except for water and prescribed medication if required. FASTING ☐	☐ Renal ☐ Liver ☐ Bone ☐ Lipid (min 12hr fast) ☐ Cholesterol fast / random ☐ Iron Studies ☐ Glucose fast / random ☐ CRP ☐ HbA1c (Separate EDTA Sample) ☐ Other	☐ Cortisol (State Time) ☐ FSH ☐ PSA ☐ Oestradiol ☐ Prolactin ☐ Progesterone (_ _) State day of cycle 18-21 ☐ TFT ☐ Ferritin ☐ Vitamin B12 ☐ Serum Folate ☐ Other	☐ FBC ☐ INR (Warfarin) ☐ Coag Screen ☐ Monospot	☐ Inflammatory Arthritis Abs. (ANF, RF, CCP) ☐ Liver Abs. (ANF, SMA, Mito) ☐ Anti Parietal Cell & Intrinsic Factor Abs. ☐ Anti tTG (for Coeliac disease) ☐ Thyroid Abs. ☐ IgE ☐ Specific IgE (not done unless allergen specified) Allergen ..... ☐ Other	☐ Urine (C/S) ☐ Sputum (C/S) ☐ Stools (C/S) ☐ MRSA Screen ☐ Nose ☐ Groin ☐ Swab ☐ Throat ☐ HVS ☐ Other Site ..... ☐ STI Screen ☐ HVS ☐ Cervical ☐ Urethral

Date & Time Specimen Received :

When ordering, submit separate samples for each laboratory department. Refer to the individual sections of this manual to ascertain number of specimens required for each sub-laboratory area. If there any problems please contact the department for clarification.

The following details must be recorded on the request:

- Name of Patient
- Date of Birth
- Hospital/Practice Name/Address
- Requesting Clinician
- Tests requested
- Contact number also an out-of hours contact number.
- Clinical details (where appropriate/relevant and including details of recent antimicrobial therapy)
  NOTE: For ESR requests, full clinical details are required
- Specimen Type for Histopathology/Cytopathology/Neuropathology
- Nature and exact body site and source of the specimen for Microbiology

The following details should be recorded on the request:

- Patients Address (and previous address where applicable)
- A current Episode number or medical record number if available
- Gender (this may have a bearing on a reference range)
- Date of collection/time
- Drawing doctor's or phlebotomist's signature
- When requesting a thromboexact specimen to be tested, please indicate on the request form that this sample needs to be processed in addition to the FBC.

Note: It is imperative that contact details of the requesting doctor and/or location of the patient are attached to the test request so that critical results can be phoned immediately.
NHISSOT request and consent forms for HLA typing and HLA Antibody screening can be obtained by emailing crossmatch@beaumont.ie

3.1.8 ***Specimen Acceptance Criteria***

The name on the request and accompanying specimen(s) must match e.g. do not use Pat on one and Patrick or Patricia on other. Please ensure that writing is legible - BLOCK CAPITALS. The requesting clinician is responsible for the correct labelling of specimens and requests. Incorrectly or inadequately labelled specimens are not accepted by the laboratory and will be returned to the source of origin.

Where additional samples are received and are not required to process the tests requested, these samples will be discarded without notification on the day of receipt.

Specimens/request will be rejected in the following situation

- Electronic request not received
- Electronic request does not match the details on specimen
- Unlabelled / Incorrectly labelled specimens i.e. without two unique patient identifiers
- Name or date of birth missing on specimen
- Specimen illegible
- Leaking or improperly sealed containers.

- Overfilled specimens
  ESR samples where blood is collected into the lid of the container.
  Coagulation containers where the blood is filled beyond the marking on the label.
- Underfilled specimens:
  ESR samples must be 85mm full. 2.7 ml
  FBC and Retic samples must have a minimum of 1mL of blood. 1.8 ml samples should have at least 500µL for FBC
  Coagulation samples must be filled to the marking on the label
- No suitable sample received for test requested
- Sample not suitable for analysis (e.g. vomit or MRSA on axilla)
- Incorrect transport media/container used (e.g. viral swab sent for C&S, MRSA requested on Chlamydia swab)
- Specimen Clotted, Underfilled, Overfilled or Haemolysed
- ESR requested with lack of clinical details
- Inherited Thrombophilia and Lupus requests if the patient is on anticoagulation.
- Factor V Leiden sample, if the screening test APCR is not also requested. Exceptions allow for family history,
- Obvious inadequacy of specimen for the test(s) required i.e. only one coagulation specimen for a Thrombophilia screen.
- If a patient is on anticoagulation at the time of testing, certain assays within the Thrombophilia profile may be rejected.
- Haematology Molecular testing cannot be performed unless patient consent has been obtained and HAEMG-LF-084 Request form has been completed in full
- HbA1c is analysed in the Biochemistry Laboratory. Patients requiring a FBC and HbA1c will require 2 EDTA 2.6mL samples sent with the test request.
- Aged Specimens:
    - Coagulation samples must be <4 hours old. In samples greater than 4 hours old. The clotting factors begin to deteriorate which lead to inaccurate results, with the exception of patients on Warfarin. In such cases, samples are stable for 24 hours.
    - D-Dimer/: Request for D-Dimer add-on, must be <8 hours old post sample collection
    - ESRs should be < 6 hours old. Samples >6 hours can lead to a false lowering of results.
    - FBC: EDTA samples must be <24hours

- Blood film preparation: samples must be <8 hours old

In the case of a sample being rejected, the requesting clinician will be informed by means of a 'test not done' being added to the original test with the reason why. A written record of all discarded samples is kept in the laboratory.

3.1.9 ***Specimen Tubes & Containers***

With the exception of swabs, specimen tubes and containers are available from Beaumont Hospital Stores Department. Contact number: 01 809 3030. All orders must be accompanied by a requisition form. These are also available from the Stores Department.

Swabs are available for collection from Pathology Reception every Friday afternoon from 2 – 4pm only, on a walk-in basis. Supplies of non-standard phlebotomy accessories are available to purchase from Sarstedt, 053-9144922, www.sarstedt.com.

Sarstedt brand tubes are ESSENTIAL as their size and shape are compatible with our laboratory analysers. Tubes supplied by other hospital laboratories are not compatible with the requirements of Beaumont Hospital. It is important to check expiry dates on all tubes. Tubes MUST BE FILLED to ensure the appropriate concentration of any anticoagulant. Do not use Paediatric tubes.

BLOOD SAMPLES

Tube colour	Anticoagulant	Volume (ml)
Orange	Lithium Heparin	4.9
Orange	Lithium Heparin For Troponin Only	2.7
Orange	Lithium Heparin in FOIL	4.9
White	White Serum ,in FOIL	4.9
Pink	EDTA wrapped in FOIL	
Random Urine	Random urine wrapped in FOIL	
Faecal Sample	Faecal Sample, foil wrapped.	

Tube colour	Anticoagulant	Volume (ml)
Brown	Plain, With Gel Separator	4.9
White	Plain, 4.9 mL volume	4,9
White	Plain	7.5
White On Ice	Plain White	7.5
Orange On Ice	Lithium Heparin	4.9
Pink	Potassium EDTA	2.6
Pink on ICE	Potassium EDTA on ICE	2.6
Yellow	Sodium Fluoride	2.7
Pink- Large	Potassium edta	7.5
N/A	plain	
**Orange	Special Metal Free Tube & Needle	7.5
N/A	Plain	
N/A	Pre-Acidfied	
N/A	CSF Plain	
CSF – Brown	Plain-Protect From Light	At least 1ml
Arterial syringe	Lithium heparin	
Purple	Tri-sodium citrate 4NC	3.5 mL
Pink	EDTA-KE (Tri-potassium Ethylenediaminetetra-acetic acid)	2.6 mL 1.8 mL- Paediatric
Green	Tri-sodium citrate 9NC	2.9 mL 1.8 mL- Paediatric
Red	0.82mg Magnesium/mL	2.7mL
n/a	Salivette	

Never pour blood from one tube into another. The preservative in the first tube will contaminate the second tube; this can greatly affect results.

URINE SAMPLES

Both 24 hour urine collections and random spot urine samples are analysed in the laboratory.

Random spot urine samples are collected into The Sarstedt NFT (Needle Free Transfer) system. This consists of a 10ml NFT primary container (Sarstedt Product Reference 75.562.900) and a 10mL Monovette tube (Sarstedt Product reference 10.252)

- A 24 hour urine collection is either taken in a plain 3L container or an acidified 3L container, depending on the test required. Pre-acidified containers with either 50% acid or concentrated acid are available from phlebotomy. If known in advance that the patient has an unusually large output, please request 2 containers for the test. Results are normally expressed per 24 hour period. Where two tests are desired, each requiring a different container, two separate 24 hour collections must be obtained. If in doubt please contact the relevant laboratory prior to commencement of the test.

APTIMA GENPROBE COLLECTION DEVICES

Aptima GenProbe Collection Devices (swabs and urine containers) are only available from the NVRL. Contact number: (01) 7161354

3.1.10 *Delivery of Specimens for Analysis*

Specimens can be delivered directly to Pathology Specimen Reception or posted to the relevant laboratory department. If posting specimens, the guidelines outlined in section 3.1.16 on page 99 must be adhered to.

3.1.10.1 GP Courier Service

A courier collects samples from each GP practice within the Beaumont Hospital catchment area. The samples are brought to Pathology Reception where request forms are reviewed and scanned, labels printed and samples are labelled prior to analysis. The final courier delivery to Pathology reception is 1:30pm Monday to Friday.

3.1.11 *Specimen Reception Process*

Samples are received in the central pathology reception where they are distributed to the relevant laboratory department. Where appropriate, specimens are centrifuged. This process separates the cells from the serum / plasma. Samples left unseparated for a number of hours / overnight (sample 'on cells'), causes a gradual leakage of red cell contents and produces spurious results for some assays including potassium, phosphate, magnesium, transaminases, LDH and Folic Acid. Therefore accurate information on date and time of sampling is very important and saves many unnecessary phone calls to busy clinicians.

3.1.12 *Test Results*

Beaumont Hospital participates in the Healthlink service, which provides the secure transfer of patient results over the internet. This service is available free of charge to all GPs and is the preferred method of result transmission. Beaumont Hospital Pathology Department does not issue paper reports unless specifically requested by a GP practice.Beaumont Hospital uploads patient reports to the Healthlink service every 10minutes.

Departmental reports going outside the hospital to GPs or external agencies are included in pathology composite reports, which include all test results validated that day from all disciplines. Interpretative comments are routinely included where appropriate.

If you have any queries in relation to a report, please contact the relevant laboratory area to discuss the result. Feedback from users about difficulty with reports helps us to improve the service. Contact details are available in Section 3.1.2 of this manual.

Despite our best efforts, it is possible that an error can occur. If you have concerns about a report please draw it to our attention without delay, and we will investigate immediately.

If you are interested in accessing this service please contact The National Healthlink Project. Tel. (01) 8825606. Email info@healthlink.doh.ie

PLEASE NOTE: It is the responsibility of the laboratory to ensure that tests are performed to the highest possible standard and reported in the time specified within this User Manual. It is the responsibility of the requesting clinician to follow up on the test results.

3.1.12.1 Requests for Results

A dedicated results telephone line is in place for blood sciences and a copy of a report can be emailed by administration staff to a secure email account (e.g @hse @healthmail etc.). The laboratory has previously issued details on obtaining a secure email account and this information is available at http://www.beaumont.ie/media/July20181.pdf. The dedicated results line details are as follows:

Tel: 01 809 2690
Monday to Friday 9.30-12:30 and 14:30-16:00

Please note this does not affect the reporting of critical results or request for clinical interpretation. Requests for clinical interpretation will be handled as outlined in section 3.1.12 above

Other useful numbers:
Microbiology reports : 01 809 2646 (lines open 9am-4pm)
Histopathology reports: 01 809 2632 (lines open 9am-4pm
NVRL results: 01 716 4414 (lines open 8am-6pm)

3.1.12.2 Critical Values

Results falling outside defined alert limits will be telephoned to the appropriate GP/Nursing Home/External personnel. Given the hundreds of specimens received each day, sample analysis often continues into the 'out-of-hours' period, it is vital that the laboratory has a mobile phone contact number for each GP so that urgent results can always be phoned.

Reports that are critical to care, requiring immediate attention will be phoned to the requesting practice as soon as they are authorised.To avoid inappropriate phone calls it is essential that the time and date of sample draw is clear on both the sample

and request form. Chemical Pathology Samples that are received that were not drawn on the day of delivery to the department will have all labile tests reported as 'on cells'.

3.1.12.3 Flagged Results.

Abnormal and flagged results are highlighted on the laboratory information system. However, each GP practive management system differs on how these messages are received. As previously communicated to GP practices by the Clinical Directorate of Laboratory Medicine in Beaumont Hospital in Dec 2024 (MEMO201), during testing carried out during implementation of the new laboratory information system and its interface with GP practice management systems, some risks were identified due to differences in how results are viewed compared to previous systems. The risks for each system are highlighted below.

A full risk assessment has been completed by the Clinical Directorate of Laboratory Medicine in Beaumont and the HSE.

The risks have been highlighted to the vendors involved. Where possible these issues will be updated.

Socrates:

1. Clinical viewing of abnormal results: shows 'abnormal' tick, even if a non-abnormal result is included in battery of results

Healthone:

1. Abnormal results only indicated by red colour, and colour changes back to default on screen change
2. No header for reference ranges
3. Microbiology result may appear in duplicate if sent multiple times.
4. Microbiology results with multiple organisms and susceptibilities can look confusing in the default view.

GP Socrates, Helix & HealthOne:

1. Amended results don't overwrite / invalidate previous. In these cases, the result previous to amendment is also visible.
2. Some symbols aren't supported by the interface (mostly uncommon symbols such as | ^ ~ and accented letters like á). These characters are not correctly represented and can appear as a 'question mark'

3. Results flagged on the lab system as 'critical' are only flagged as 'abnormal'. Note that abnormal results may be beyond critical limits

To minimise these risks, it is advised that the Healthlink view is always used to view results.

Mapping between Healthlink and GP Practice Management Systems remains the responsibility of each GP practice, contact your GP Practice Management vendor for training if required.

3.1.12.4 Turn Around Times

Turnaround times are quoted in each departmental section. Turnaround times are constantly monitored by The Clinical Directorate of Laboratory Medicine and we aim to meet the quoted turnaround times at all times. However, if the laboratory is experiencing any deays in turn around times which affect our users and patients, this will be notified to laboratory users via written communication from the laboratory management team.

3.1.13 *Telephoning GP/Results Out of Hours*

Where a GP is not contactable by mobile telephone, the dedicated GP Results Out of Hours telephone may be used to alert the GP by text that urgent results are awaiting them.
If a mobile number for the GP is not available, a non-conformance will be raised. It will be passed to the relevant Consultant Pathologist for signing and the scanned documentation will be emailed to the relevant GP's healthmail account.
Paper copies of patient reports are available from the Pathology Office, 8092507.
Beaumont Hospital has no access to the Healthlinks service.

3.1.14 *Attendance at Phlebotomy:*

An online appointment system for Phlebotomy is in place for the GP phlebotomy clinic. GP patients and family members of patients can go to www.beaumont.ie and select the 'Patient Information' link to make a blood test appointment. Alternateively, GPs can go to www.swiftqueue.com/gp to make an appointment for a patient after registering using the code 'sw1ft45'.

Telephone appointments can be made between 10.30am and 12.30pm Monday to Friday at 01-2910993 (standard local call rates), for a limited period of time. Outside these times, telephone appointments can be made by calling 1517 345 333. NOTE: This is a premium rate service with calls charged at €2.03 inclusive of VAT (calls from some mobiles may be higher with a maximum cost of €2.50).

A Phlebotomy Appointments Online User Guide is available on the hospital website.

3.1.15 *Specimen Referral*

When we are unable to provide a clinically important assay, we will attempt to source a referral laboratory, to which specimens may be sent. We welcome input from interested clinicians in this process. The choice of laboratory is primarily based on quality grounds, with accredited laboratories being chosen preferentially. Other factors such as cost and turnaround times are also considered. A list of referral laboratories in use is available from the Directorate on request. The Directorate does not refer samples for GPs or other external units. Only samples for tests that are conducted in-house, and included in the National Clinical Pathology Programme/ Beaumont Hospital approved test catalogue will be processed. In exceptional circumstances, where a patient attends a GP for bloods on the request of a Beaumont Hospital Consultant, **AND** the Consultants name and the Test required is written legibly on the Healthlink Request form, we will process the test.

3.1.16 *Specimen Transportation Guidelines*

It is essential that all specimens are transported to the laboratory under conditions which

- Comply with the Hospital Safety Statement, as well as relevant National Postal and Health and Safety legislation and IATA regulations
- Protect postal workers, couriers, porters and laboratory staff
- Ensure the integrity of the analyte to be measured

Specimens where the external surface is contaminated with blood or other body fluids will not be accepted for analysis – another specimen must be collected.

Send specimens in the bag attached to the request form. Up to 10 specimens may be placed in the bag. It is the responsibility of referring hospitals to ensure that packaging complies with relevant legislation.

The international regulations for the transport of infectious materials by any mode of transport are based upon the recommendations of the United Nations Committee of Experts on the Transport of Dangerous Goods (UN), The Universal Postal Union (UPU), the International Civil Aviation Organisation (ICAO) and the International Air Transport Association (IATA) have also incorporated the UN Recommendations in their respective regulations.

The specimen should be placed in watertight containers containing 10% Neutral Buffered Formalin (volumes larger than 125ml should not be transported by post but hand delivered to the laboratory), the lid must be securely closed to avoid leakages. Patient's details entered on container and request form as above. Specimens must be packaged in a UN-approved packaging system (UN3373/4GU/Class 6.2/ 05 GB) which consists of three layers:

1. Primary Receptacle: a labeled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.
2. Secondary Receptacle: A second durable, watertight leak-proof container to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles

3. Outer Packaging: The secondary container is placed in an outer shipping package which protects its contents from outside influences such as physical damage and water while in transit.
4. Both the recipient's and the sender's name and address must be shown on the packaging so that contact can be made in the event of a leakage.

Specimens should be addressed to the laboratory, and never to an individual member of staff. If there have been prior discussions the form (not the envelope) should state which member of staff should be informed of the specimen's arrival.

If a specimen arrives in a condition which places staff at risk, we regret that it cannot be processed. Where contact details are provided the requesting clinician will be informed, however we can take no responsibility for delays which occur due to the lack of contact details.

If diagnostic specimens in 10% formalin are posted the following guidelines and instructions must be adhered to:

Please note: Glass specimen tubes are not acceptable due to Health and Safety regulations. Please refer to page 91 for correct specimen tubes to be used.

3.1.17 ***Specimen Storage Conditions***

- Store blood samples at room temperature, unless otherwise specified. Note that blood samples stored in a refrigerator may have falsely elevated results e.g. potassium. The exception to this is FBC samples which may be stored in a refrigerator for up to 24 hours (however, should there be a delay in an FBC reaching the laboratory the sample must be <24 hours old in order for it to be processed)
- 24 hour urine collections should be refrigerated throughout the collection and brought to the laboratory ASAP.
- Samples for auto antibody crossmatches for NHISSOT should reach the laboratory within 24 hours' and **should not** to be refrigerated.
- Addition of test requests to existing samples is not recommended due to issues of sample integrity. Contact individual laboratory for advice and to book in the samples for testing.

- Malaria tests must be examined within 2 hours of sample collection. Therefore, it is recommended that patients attend the Phlebotomy Department in Beaumont Hospital for sample collection.
- In most cases, if delays are unavoidable, microbiology specimens can be preserved by refrigeration at 2-8˚C in a designated specimen fridge, as this maintains the viability of the pathogens present and prevents the overgrowth of non-pathogenic bacteria. This is of particular importance if quantitative or semi-quantitative culture is required, for example during microbiological analysis of sputum and urine.
  Exceptions to this include:
  1) Blood cultures should be promptly brought to the laboratory by a porter or sent via chute
  2) CSF should be held at room temperature.
  3) Samples specifically for the isolation of *Neisseria gonorrhoea.* (i.e. cervical or urethral specimens) should be stored at room temperature.

3.1.18 *Data Protection Policy*

The Clinical Directorate of Laboratory Medicine complies with the policy of the HSE regarding the legislation pertaining to the rights of the patient and staff and to act in an ethical and responsible manner in maintaining the security and integrity of all personal information
The Directorate retains the following information in relation to each test request received, for a minimum of 30 years, in order to ensure patient history is maintained and that sufficient information is available to staff responsible for the interpretation and reporting of results from the laboratory:

1. Patient full name
2. Patient Address
3. Patient medical record number/episode number
4. Patient date of birth
5. For each specimen: date/time of collection, date/time of receipt in the laboratory and date/time of report, specimen type, priority.
6. Clinical information provided by clinicians
7. The results and where appropriate, interpretation of each test requested.

8. Requesting clinician and address

3.1.19 *Placing Patient Information in the Public Domain*

It is laboratory policy that information obtained or created during the performance of laboratory activities is not placed in the public domain unless agreed by the patient. If the laboratory is required by law or authorised by contractual arrangements to do so, the patient's clinician will be informed and they will inform the patient (unless this is prohibited by law). Further details are outlined in the relevant departmental standard operating procedures.

Information about the patient from a source other than the patient (e.g. complainant, regulator) is kept confidential by the laboratory. The identity of the source is kept confidential by the laboratory and is not shared with the patient, unless agreed by the source.

3.1.20 *Time Limits for Requesting Additional Examinations*

Please note that verbal requests for any examinations must be followed by a fully completed request, by email request in order for results to be issued. Request forms must be received within the timeframe outlined for each department below.
Requests for Chemical Pathology add-on tests must be e-mailed to: chemicalpathology@beaumont.ie.
Requests for Haematology add-on tests must be e-mailed to: Haematology@beaumont.ie

3.1.21 *Repeat Examination due to Analytical Failure*

In the event of an analytical failure, if the system returns to normal within the test cut-off time, the samples are processed accordingly. However, if this time exceeds the test cut-off limit, the users are notified and repeat samples are requested, where applicable

3.1.22 ***Uncertainty of Measurement (MOU)***

Every measurement, including a laboratory result, is subject to a level of uncertainty. For example blood pressure measured a few times within a single clinical visit may vary. This variation is made up of biological variation together with the uncertainty of measurement (and may be compounded further if any error is made). Systems in the laboratory are designed to minimise error – however if you are concerned that an error has occurred please contact us to let us investigate this. Even when error is eliminated, uncertainty of measurement affects all results.

When interpreting the results of a laboratory test the uncertainty of measurement (UM) of that result needs to be considered. UM is a numerical value & is an expression of the magnitude of uncertainty of a result. It characterizes the dispersion of values reasonably attributed to measurement. If not understood may lead to over interpretation of results.

e.g. If the UM is 10% & the result is 100, then the true result probably lies between 90-110. Therefore is the result obtained due to clinical changes in the patient or imprecision of the test method itself?

Uncertainty is not error. Error tells us the difference between the true value & the measured value. Error can be corrected, uncertainty cannot. UM is the quantitative expression of doubt (uncertainty) & spread of a particular measurement. It is an estimate of the confidence in the result produced by the laboratory.

Uncertainty is a parameter associated with every result & is specific to each result. The uncertainty associated with any assay performed in the laboratory is available on request.

3.1.23 ***Accreditation/Quality Standards***

Beaumont Hospital Clinical Directorate of Laboratory Medicine's current scope of Accreditation to ISO15189 is available from the INAB website, https://www.inab.ie/FileUpload/Medical-Testing/Beaumont-Hospital-225MT.pdf
The H&I Department is accredited by EFI (European Federation for Immunogenetics).

Specimens referred out from Beaumont Hospital are not covered by the scope of Beaumont Hospital ISO15189 accreditation.

3.1.24 ***Complaints***

Beaumont Hospital is committed to responding to patient and user feedback both positive and negative. The hospital endeavors to respond to concerns and identify and manage any deviation from high quality care.

Complaints and feedback may be given directly to any member of staff in the laboratory or through the Patient Advisory Liaison Service (PALS) In any case, there may be a resolution at point of contact or the case may be of a serious nature that requires further action. All complaints (verbal or written) are recorded directly onto Q-Pulse, and are classified as per Non-conformity procedure. The medical significance of each complaint is decided upon by the departmental Consultant Pathologist. The Head of Department or Laboratory Manager may deal with the complaint depending on its severity. Records of complaints are maintained for periods as defined in schedule for record retention.

If a complaint cannot be resolved at local level it will be forwarded to the hospital's Patient Liaison officer.

The laboratory actively seeks feedback from its patients, users and personnel which is used to analyse and improve the laboratory management system, activities and services provided to users as demonstrated below.This is achieved through regular user satisfaction surveys, complaints and compliments that are received and through it's annual management review. All of these contribute to the laboratory continual improvement process.

3.1.25 ***Open Disclosure***

Beaumont Hospital follows the HSE National Policy for Open Disclosure. Open Disclosure is a requirement of the HIQA National Standards for Safer Better Healthcare. Open Disclosure "an open, consistent approach to communicating with patients when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event."Open Disclosure should happen when a service user has experienced an "adverse event" but also when a service user experiences a "no harm event" or is exposed to a "near miss event".

3.2 HAEMATOLOGY

Same day turnaround times refer to results being available to the requesting clinician on the same working day. Results are available on ward look-up or on Healthlink. Clinicians receiving results by post will incur an added delay.

3.2.1 *Repertoire of Haematology Tests*

Test	**Specimen Container**	**Minimum/ Container Volume**	**Adult Reference Range** (See Reports for Paediatric Ranges)			**TAT**	**Comment**
Full Blood count	EDTA (pink capped)	2.6ml standard	*Parameter*	*Male*	*Female*	1 Working Day	7.5ml and 10ml EDTA samples are not acceptable *Female >50 years
			Hb	13-17.5 g/dL	11.5-16.5 g/dL 11.7-16.0 *		
			PCV	0.37-0.54 L/L	0.335-0.54 L/L 0.355-0.52*		
			RCC	4-6.5 $x10^{12}$/L	3.8-5.8 $x10^{12}$/L 3.8-5.6*		
			RDW	11-15 %			
			MCV	79 -96 fL			
			MCH	27 -32 pg			
			MCHC	32.0-36.5 g/dL			
			PLTS	140 -400 $x10^{9}$/L			
			WBC	4.0 -11.0 $x10^{9}$/L			
			Neut	2.0 -7.5 $x10^{9}$/L			
			Lymph	1.0 -4.0 $x10^{9}$/L			
			Mono	0.2- 1.0 $x10^{9}$/L			
			Eosin	0.04- 0.4 $x10^{9}$/L			
			Baso	0.01- 0.1 $x10^{9}$/L			

Test	**Specimen Container**	**Minimum/ Container Volume**	**Adult Reference Range** (See Reports for Paediatric Ranges)	**TAT**	**Comment**
Platelet Check (Thromboexact)	0.82mgMg^{2+}/mL (Red)	2.7mL	140 -400 x10^9/L	1 Working Day	Arrange in advance with laboratory to obtain sample tube. Please write on the request form that a platelet count from a Thromboexact tube is required
ESR	Trisodium citrate 4NC /3.5 (purple)	3.5 ml **must** be filled to the line	*Male*: 1- 12 mm/hr; *Female*: 1-20 mm/hr	1 Working Day	Only indicated for the following • *Giant cell arteritis,* • *Polymyalgia rheumatica.* • *'Suspected myeloma'* • *-Hodgkins Lymphoma* • *Prosthetic joint infection,* • *Osteomyelitis,* • *Rheumatoid Arthritis*
Infectious mononucleosis Screen	EDTA (pink capped)	2.6ml standard	Negative	1 Working Day	

3.2.2 ***Repertoire of Coagulation Tests***

Test	**Specimen Container**	**Number of Samples**	**Minimum Volume**	**Reference Range**	**TAT**	**Comment**
Coagulation Screen Prothrombin Time Activated Partial Thromboplastin Time	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	PT: 10-13.2 seconds INR should only be used for monitoring Warfarin therapy. Refer to local treatment algorithm. APTT: 24 – 36 seconds	1 working Day	Sample must be <4 hours old
INR	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	The INR should only be used for monitoring Warfarin therapy. Refer to local treatment algorithm.	1 working Day	INR only requests are stable for 24 hrs Warfarin Office contact no. 01-8092083
D-Dimer	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	Under 50 yrs<0.5 µg/ml Then increases in 5 year increments by 0.5. i.e 55-60 (<0.6) and 85-90 (<0.9)	1 working Day	Sample must be <8 hours old

Test	Specimen Container	Number of Samples	Minimum Volume	Reference Range	TAT	Comment
Fibrinogen	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	1.9 – 3.5 g/L	1 working Day	Sample must be <4 hours old For patients on Argatroban a Clauss Fibrinogen test is not appropriate & will be reported as follows: "Fibrinogen result is unavailable as the patient is on Argatroban which may cause a false low fibrinogen result in the Clauss fibrinogen assay. Please discuss with the Haematology team".

Test	Specimen Container	Number of Samples	Minimum Volume	Reference Range	TAT	Comment
Thrombophilia screen	Trisodium citrate 9 NC/2.9 mL (green capped)	4	**Must** be filled to the line	See individual requests APCR, PC, Prot S Act, , AT and LA.	4 weeks.	From 1St May 2023 onwards General Practitioners will no longer be able to request the following tests directly: • **Inherited Thrombophilia Screen** (Antithrombin, Protein C, Protein S, • Activated Protein C Resistance (+/- Factor V Leiden Mutation if required) Testing will be reserved for specific patients who are deemed to meet the clinical criteria after being reviewed and sanctioned by the Haematology team. If sanctioned then a Thrombophiliarequest form HAEMC-LF-023 **MUST fully** be completed. This form can be obtained from the Beaumont Hospital website, under Haematology Dept. Batch tested. The Inherited Thrombophilia screen (Thr philia) includes the following tests: PT, APTT, FIB-C, ATPC, Prot S Act, APCR 5LEIDEN*. A Lupus screen is not on this profile.

Test	Specimen Container	Number of Samples	Minimum Volume	Reference Range	TAT	Comment
Lupus anticoagulant	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	DRVVS < 1.17 DRVVTR: <1.23 SCT TR < 1.14	4 weeks	• From 1St May 2023 onwards General Practitioners will no longer be able to request the **Lupus Anticoagulant** directly: Testing will be reserved for specific patients who are deemed to meet the clinical criteria after being reviewed and sanctioned by the Haematology team. If sanctioned then a Thrombophiliarequest form HAEMC-LF-023 **MUST fully** be completed. This form can be obtained from the Beaumont Hospital website, under Haematology Dept. Batch tested. Patients must not be on any anticoagulation as they interfere with the interpretation of the assay.

3.2.3 ***Repertoire of Haematology Molecular Tests***

Test	**Specimen Container**	**Number of Samples**	**Minimum/ Container Volume**	**Reference Range**	**TAT**	**Comment**
Factor V Leiden mutation (5Leiden) And APCR	EDTA sample (pink)	1	2.6ml Standard	Negative	6 weeks	Only tested if the Activated Protein C (APCR) is positive or a family history is indicated on the request form. For APCR sample requirements see previous table. Thrombophilia request form HAEMC-LF-023 **MUST fully** be completed. This form can be obtained from the Beaumont Hospital website, under Haematology Dept. If genetic consent is not obtained the molecular test will be rejected. The laboratory will no longer take receipt or store the form containing patient genetic consent. It is the responsibility of the ordering clinician to obtain and file a copy of genetic consent in the patient's record.
	Trisodium citrate 9 NC/2.9 mL (green capped)	1	**Must** be filled to the line	Negative		

Test	Specimen Container	Number of Samples	Minimum/ Container Volume	Reference Range	TAT	Comment
HFE Haemo-chromatosis	EDTA (PINK cap) Whole blood	1	2.6ml	Not detected	4weeks	Must be accompanied by completed Haemachromatosis Genetic Screening Request Form (HAEMC-LF-077) This form can be obtained from the Beaumont Hospital website, under Haematology Dept. If genetic consent is not obtained the molecular test will be rejected. The laboratory will no longer take receipt or store the form containing patient genetic consent. It is the responsibility of the ordering clinician to obtain and file a copy of genetic consent in the patient's record.

3.2.4 ***Requests for Additional Analysis***

Verbal requests for additional examinations from GPs will be reviewed on a case-by-case basis and are dependent on suitable specimen availability and the appropriateness of the test request. GP verbal requests accepted by phone will then need to be emailed to haematologyadmin@beaumont.ie for the additional test.

Refer to table below for test cut-off times when requested to add a test to a sample already received in the Laboratory. Processing an additional request depends on the sample having the correct anti-coagulant, not too old for analysis, correct storageand not discarded.

3.2.4.1 Test Cut-Off Times

Test	Test Cut-off Times
FBC	<24 hours
Blood Film preparation	<8 hours
Platelet Exact for platelet clumping	<24 hours
Malaria	< 2 hours (test should be performed within 2 hours of phlebotomy hence patient should present themselves to the Phlebotomy Department or AE with a request for a "malaria screen")
IM	<24 hours
Sickle Screen	<14 days if stored @ 2-8ºC
PNH	< 48 hours if stored at @ 2-8°C
Lymphoproliferative Panel, T-Panel, , Lymphoid Screening Tube	All EDTA samples must be <48 hours old.
Acute Screen, Acute Leukaemia Panel, Blast Count	Sodium Heparin (orange capped - BMA) with 1ml RPMI must be < 48 hours old
Coagulation Samples	< 4hours
D-dimer	<8 hours
INR	<24 hours
Factor V Leiden, PT mutation	<28 days once stored at 2-8°C

In cases where the Haematology consultants have reviewed a blood film, these are reported under 'HBFC. 'Bld film F' and 'HBFC can only be ordered in the Laboratory.

3.2.5 ***Critical Values***

- GP results are available on Healthlink.
- Results falling outside defined alert limits are telephoned to the appropriate personnel.

- It is imperative that the mobile phone number of the requesting doctor is on the request form so that critical results can be phoned when surgeries are closed.

- **If a mobile phone number is not available or contact number unanswered, the critical alert value will be telephoned the following day.**

The following are the different catagories as defined by the Communicationof Critical Results for Patients in the Community, National Laboratory Handbook, HSE National Clinical Programme for Pathology

- **Category A**: Result MUST be telephoned that day as soon as possible – resort to Ddoc if all else fails **Consider all results on this list Category A unless stated otherwise**

- **Category B**: Every attempt to be made to telephone result on same day but if not possible do not contact Medical SHO and instead wait for next day(if next day is weekend or bank-hol, need to contact MED-SHO after all other avenues have been exhausted.

The Following Table is a list of these results that will be phoned:

Test	OPD(except CKB) GP/ Nursing Homes/ External Hospitals
Hb	<7.0 g/dL N/N* Normochromic/ Normocytic 5-7 g/dL H/M* (**Category B**) >20.0 g/dL
PLT	<30 x 10^9/L 31-50 x 10^9/L (**Category B**) >1000 x 10^9/L
WCC	>30 x 10^9/l (**Category B**)
Neutrophils	<0.5 x 10^9/L & >50 x 10^9/L (1st time)
FBC	Results indicating possible leukaemia i.e. numerous flags (especially blast), increase WCC, DIFF vote-out or very abnormal, plt<100 and low Hb. Phone ward/clinical team responsible for the patient and to bring these results to their attention.
INR/	>5.0
Fibrinogen	<1.5 g/l
Flow Cytometry	New Acute Leukaemia/PNH patients CHB Blast counts >5%, contact Prof. Thornton/Dr Quinn directly
Morphology	New Acute Leukaemia TTP/MAHA

3.3 CHEMICAL PATHOLOGY

3.3.1 *Services Offered*

The Chemical Pathology Department provides a comprehensive suite of routine and specialised tests including;

- General biochemistry, including test profiles for renal, liver, bone, cardiac, muscle, lipid disorders and glucose homeostasis.
- Immunoassay tests of thyroid, gonadal, adrenal and pituitary function, haematinics, therapeutic drug monitoring.
- Urine tests for total protein and albumin, calcium, phosphate, magnesium and uric acid.
- Biochemical tests for phaeochromocytoma, neuroblastoma and carcinoid tumours including Plasma Free Metanephrines, urinary fractionated catecholamines, metanephrines and 5HIAA.

3.3.2 *Contact Details for Medical / Clinical Advice*

For test results please contact the dedicated results telephone line on (01) 8092690.

For medical advice contact;
Consultant Chemical Pathologist; Dr. Shari Srinivasan on (01) 8092676
Consultant Chemical Pathologist: Dr. Clodagh Loughrey on (01) 8092053

During working hours medical advice can also be obtained by contacting;
Chemical Pathology Specialist Registrar; (01) 8092666 or 8093000 Bleep #332

During working hours scientific advice can be obtained by contacting;
Chief Medical Scientist; Alison Griffin (01) 8092670
Chief Medical Scientist; Miriam Shinners (01) 7977811
For information on test requirements please see below.

3.3.3 *Requests for Additional Tests*

To request additional tests please contact the relevant laboratory.
Samples are retained in the Department for 72 hours and are validated for testing only up to this time. Requests for additional analysis must be made to the laboratory within this validity period. The laboratory will advise on the suitability of the sample for additional testing if appropriate and if agreed an e-mail outlining the request must then be sent to Chemical Pathology chemicalpathology@beaumont.ie for the attention of the relevant chemical pathology staff member following the discussion.

Table D: Routine Profiles and their Components

Description	Mnemonic	Tests
Renal Profile	Renal	Urea, Na, K, Cl,Creatinine
Liver Profile	Liver	Bilirubin, ALT, ALK, γGT, AST, ALB, TP, Globulin
Lipid Profile - Fasting Lipid Profile - Non-fasting	FHDL HDL	Cholesterol, Triglyceride, HDL, Calculated LDL, non HDL Cholesterol
Bone Profile	Bone	Ca, ALB, Phosphate, Ca Adjusted, ALK
Thyroid Function Test	TFT	FreeT4 and TSH

3.3.4 *Therapeutic Drug Monitoring (TDM) samples*

- All samples must be drawn into a white cap serum tube, 4.9mL.
- Samples should be taken immediately prior to next dose – trough sample.
- **Digoxin:** samples must be taken pre-dose or at least 6 hours post-dose.
- **Lithium:** samples must be collected 12 hours post dose.

3.3.5 *Tumour Marker Analysis*

Tumour markers should not be used to diagnose disease. Their use is to monitor / follow-up known disease states. If a patient is attending Beaumont Public Hospital for Oncology treatment, we can accept samples for Tumour marker analysis, at the request of the attending clinician and this MUST be indicated on the request form – or a copy of the Consultants request included.

Patients that are being treated and followed-up at other facilities must have tumour markers analysed at that laboratory as there can be very significant variations in results between assay platforms.

Please refer to relevant NCCP guidelines.

3.3.6 *Externally Referred Tests*

Samples from General Practitioners or other external service users are not referred to external laboratories. Beaumont Hospital is not funded to provide this service.

If a clinician of Beaumont Public Hospital requests a GP to organise a test not provided in Beaumont Hospital this will be facilitated **if** the request from the clinician is sent with the test request form or noted very clearly on the request form.

3.3.6.1 Reports from External Laboratories

External test reports are issued on paper only. They will not be available on Healthlinks. However, they will be available electronically within Beaumont Hospital to the requesting clinician. The result will also be scanned into the patient file and available from the Consultant secretary.

3.3.7 *Fertility Clinics*

Chemical Pathology does not provide testing services for patients attending fertility clinics.

3.3.8 *Critical phoning limits*

- Results falling outside defined alert limits will be telephoned to the requesting GP or referring laboratory.
- Note: If it is not possible to contact the relevant GP out of hours the result will be communicated to the nominated out-of-hours service.
- It is the responsibility of the healthcare professional who requests a laboratory test to ensure that the result is reviewed and appropriate action taken.
- Results apply to the **current episode number.**
- **Urgency A** – rapid communication of results within 2 hours.
- **Urgency B**- results require communication within 24 hours, and preferably on the same working day. This would also apply to outpatients. For outpatients if there is no facility to phone on a Saturday then discuss with the on-call senior to determine the urgency.
- **Urgency C**- communication of these results on the next working day is deemed satisfactory.

RESULTS FOR URGENT COMMUNICATION						
	Units	**Action Limits**		**Urgency**	**Ref.**	**Comments**
Analyte		**Lower**	**Upper**			
Sodium	mmol/L	120 130 if< 16 yrs 125 GP/OPD	155	A A A	1 2 3	**Note different phoning limits for in-patients and GP/OPD**
Potassium	mmol/L	2.5 2.7 GP/OPD	6.5 6 GP/OPD	A A A	2 1 3	Check for haemolysis, age of sample & EDTA contamination. **Note different limits for in-patients and GP/OPD**
Urea	mmol/L	-	30 10 if< 16 yrs 35 CKD patients	A A A	1 2 3	
Creatinine	µmol/L	-	354 200 if < 16 yrs 800 CKD patients	A A A	1,2 2 3	
Glucose	mmol/L	2.5	25 30 GP/OPD/known diabetics 15 if < 16 yrs	A A A	1,2,3 2 2	
Calcium Adjusted (Total Calcium if no calculation available)	mmol/L	1.8*	3.5 3 GP/out-patients 3.2 CKD patients	A B A	1,2 1 3	*report with Albumin Request and perform U&E. All calcium results above upper action limit to be phoned regardless of previous critical result.
Phosphate	mmol/L	0.3 0.45 GP/OPD	-	A B	2 1	
Magnesium	mmol/L	0.4		A	1,2	
Creatine Kinase	U/L	-	5000 400 if <16 yrs	A A	1,2 3	
Amylase	U/L	-	500	A	1,2	
CRP	mg/L	-	300	A	1,2	
AST	IU/L	-	500 female	A	1,2	

RESULTS FOR URGENT COMMUNICATION						
	Units	**Action Limits**		**Urgency**	**Ref.**	**Comments**
Analyte		**Lower**	**Upper**			
			600 male	A	1,2	
ALT	IU/L	-	500 female 600 male	A A	1,2 1,2	
Cortisol	nmol/l	50	-	A	1	Unless part of dexamethasone suppression test **Do not assume a dexamethasone test has been undertaken.**
Cortisol (SST)	nmol/L	250		A	2	As part of short synacthen test
Bicarbonate	mmol/L	10	-	A	2	Excluding ICU patients
Ethanol	mg% (mg/dL)		400 All levels in <16 yrs	A A	2 3	
CSF results	All Xanthochromia results to be phoned			A	3	
Paracetamol	mg/L	All results		A	2	
Digoxin	ug/L	-	2.5	A inpatients B GP/OPD	2 1,2	Check timing > 6 hrs from last dose. Give U&E results also. More urgent if K^+< 3 mmol/L. Phone **immediately** to GP/OPD requestor if overdose suspected or K^+ low
Carbamazepine	mg/L		15	A inpatients B GP/OPD	3 3	
Phenobarbitone	mg/L	-	70	A inpatients B GP/OPD	3	
Phenytoin	mg/L	-	25	A inpatients B GP/OPD	2,3 1,2,3	
Valproate (Valproic acid)	mg/L	-	120	A inpatients B GP/OPD	3	
Theophylline	mg/L		25	A inpatients B GP/OPD	2 2	
Lithium	mmol/L	-	1.5	A inpatients B GP/OPD	2 1,2	
Salicylate	mg/L	-	300	A	2	
Triglycerides	mmol/L	-	20	B	1	If specimen lipaemic, measure and report

RESULTS FOR URGENT COMMUNICATION						
	Units	**Action Limits**		**Urgency**	**Ref.**	**Comments**
Analyte		**Lower**	**Upper**			
						direct ISE Sodium and Potassium.
Haem 4+ samples	Phone all URGENT haem 4+ (this will include all ED)			A	3	
PSA	ng/mL	-	40	C	3	If no previous critical result
Ferritin	ng/mL	-	5000	C	3	
TSH	mU/L		30	C	3	
fT4	pmol/L	-	50	C	1,3	
Prolactin	mU/L	-	2000	C	3	
Testosterone female	nmol/L	-	5	C	3	
Gamma-globulins	g/L	IgG<3		C	1	With low IgA and IgM
Serum FLC Ratio		-	>100	C	3	First time detection
Paraprotein	g/L	Any IgE/IgD	IgG>15 IgA>10 IgM>10	C	1	First time detection
		Monoclonal free light chain- any size, whether or not with intact paraprotein		C	3	First time detection

3.3.8.1 Reference Intervals

All reference intervals and/or clinical decision values apply only to non-pregnant adults unless specifically stated otherwise.

3.3.8.2 Interference in Laboratory Tests

Many laboratory tests are subject to interference by endogenous or exogenous factors which may alter the true concentration of a substance within the body, or cause an analytical interference giving a potentially erroneous or misleading result.

All samples are routinely checked for Haemolysis, Lipaemia and Icterus which can interfere with laboratory tests to varying extents. Significant levels of any of these may affect the quality of some test results which will be highlighted and/or removed from the individual report.

Test results should be interpreted in conjunction with clinical findings and if interference is suspected please contact the laboratory where further information on each test method is available.

Drug interferences are also commonly encountered, a summary list is available at http://www.beaumont.ie/media/Interference_in_Laboratory_Tests1.pdf.

3.3.8.3 Repertoire of Test Services - Routine Chemistry

Test	Sample Required	Specimen Container	Minimum Volume	Reference Range/ Unit of Measurement	TAT	Comment
5HIAA	24 hour Urine collection	Pre-acidified (50% acid)	N/A	2.5 - 50 µmol/24hr	12 working days	If the patient is <15 years old, please contact the laboratory (01-7977333) for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples.
Alpha1 Antitrypsin	Plasma	Orange Cap	4.9ml	0.9 – 2.0 g/L	72 hours	
Adrenocortico-trophic Hormone (ACTH)	EDTA PLASMA on Ice	Blue Cap	4.9mL	7.2-63.3 pg /mL	10 days STAT-Contact laboratory	Patient must attend Beaumont Hospital phlebotomy for sample collection. Sample is labile, must be sent to lab immediately on ice for separation.
Adrenaline	24 hour Urine collection	Pre-acidified (50% acid)	N/A	See Table Below	24 working days	If the patient is < 15 years old, please contact the laboratory (01-7977333) for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples
Alanine aminotransferase (ALT)	Plasma	Orange Cap	4.9 mL	Female: < 33 IU/L Male: < 41 IU/L	24 hours	
Albumin	Plasma	Orange Cap	4.9 mL	35 – 52 g/L	24 hours	
Albumin Creatinine Ratio	Spot urine sample	Plain MSU	N/A	mg/mmol Creatinine Males: <2.5 Females: <3.5	96 hours	

Test	Sample Required	Specimen Container	Minimum Volume	Reference Range/ Unit of Measurement	TAT	Comment
Aldosterone	Whole blood	EDTA (Blue Cap)	4.9ml	Female: 0 – 1179pmol/L Male: 0 - 670pmol/L	20 days	Patient must be seated for 10mins prior to sample draw. Sample must be spun and separated immediately.
Alkaline Phosphatase (Total Alk Phos)	Plasma	Orange Cap	4.9 mL	Female 35 – 104 IU/L Male 40 – 129IU/L	24 hours	
Amylase	Plasma	Orange Cap	4.9mL	28 - 100 IU/L	24 hours	
Amylase Urine	Spot urine sample	Plain MSU container	N/A	M: 16 – 491IU/L F: 21 – 447 IU/L	24 hours	
Aspartate aminotransferase (AST)	Plasma	Orange Cap	4.9mL	Female < 32 IU/L Male < 40 IU/L	24 hours	
B12 (Vitamin)	Plasma	Orange Cap	4.9mL	197 – 771 ng/L	3days	
B2M	Plasma	Orange Cap	4.9mL	<60yrs 0.8 – 2.4mg/L >60yrs ≤3.0mg/L	72 hours	
bHCG	Serum	Brown Cap	4.9mL	Non-pregnant,pre-menopausal women: <1 Postmenopausal women: <7	72 hours	For preganacy testing purposes only.
Bicarbonate (TCO2)	Plasma	Orange Cap	4.9mL	22 – 29 mmol/L	24 hours	Fresh sample required – patient should attend Beaumont Hospital phlebotomy for sample collection.
Bilirubin - total	Plasma	Orange Cap	4.9mL	< 21 µmol/L	24 hours	
Bilirubin Direct	Plasma	Orange Cap 22 wrapped in foil to exclude light	4.9mL	<5.0µmol/L	72 hours	Only analysed if total bilirubin is elevated. Patient must attend Beaumont Hospital phlebotomy so that a fresh sample can be taken and protected from light.

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
BNP (Nt-Pro BNP)	Plasma or serum	Orange Cap or White Cap	4.9ml	35y-45y M 0-115 35y-45y F 0-237 45y-55y M 0-173 45y-55y F 0-284 55y-65y M 0-386 55y-65y F 0-352 65y-75y M 0-879 65y-75y F 0-623	24hrs	
CRP C Reactive Protein	Plasma	Orange Cap	4.9ml	0 – 5mg/L	24hrs	
CA 12-5	Serum	Brown Cap	4.9ml	<35 kU/L	72 hours	Refer to Ovarian Cancer GP Referral For Symptomatic Women May 2016
Caeruloplasmin	Plasma	Orange Cap	4.9ml	Male 0.15 – 0.30g/L Female 0.16 – 0.45g/L	72 hours	
Calcium	Plasma	Orange Cap	4.9mL	18-60yrs: 2.15 – 2.50mmol/L 60-90yrs: 2.20 – 2.55mmol/L >90yrs: 2.05 – 2.40mmol/L	24 hours	
Calcium Adjusted	Plasma	Orange Cap	4.9ml	2.21 – 2.52mmol/L	24 hours	Locally derived equation.
Calcium 24 Hour Urine	24 hour Urine collection	No Preservative	N/A	2.5 - 7.5 mmol/24hrs	72 hours	Container available from Phlebotomy Department
Carbamazepine	Serum	Plain (White Cap)	4.9mL	4.0 – 12.0 mg/L	24 hours	Samples should be taken immediately prior to next dose.
Catecholamines (Noradrenaline, Adrenaline & Dopamine)	24 hour Urine collection	Pre-acidified (50% acid)	N/A	See Table Below	24 working days	If the patient is <15 years old, please contact the laboratory (01-7977333) for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples.
Chloride	Plasma	Orange Cap	4.9mL	95 – 108 mmol/L	24 hours	
Cholesterol	Plasma	Orange Cap	4.9mL	< 5.0 mmol/L	24 hours	

<table>
<tr><th>Test</th><th>Sample Required</th><th>Specimen Container</th><th>Minimum Volume</th><th>Reference Range/ Unit of Measurement</th><th>TAT</th><th>Comment</th></tr>
<tr><td>Cortisol AM (8-10AM)</td><td>Serum</td><td>Brown Cap</td><td>4.9mL</td><td>166-507 nmol/ L</td><td>24hrs</td><td></td></tr>
<tr><td>Creatine Kinase (CK)</td><td>Plasma</td><td>Orange Cap</td><td>4.9mL</td><td>Males 39-308 IU/L Females 26 – 192 IU/L</td><td>24 hours</td><td></td></tr>
<tr><td>Creatinine</td><td>Plasma</td><td>Orange Cap</td><td>4.9mL</td><td>Male: 59-104µmol/L
Female: 45-84µmol/L</td><td>24 hours</td><td></td></tr>
<tr><td>Creatinine Urine - 24 Hour</td><td>24 hour Urine collection</td><td>Plain</td><td>N/A</td><td>Female: 6000-13000 µmol/ 24hrs
Male: 9000-19000 µmol/ 24hrs</td><td>72 hours</td><td>Container available from Phlebotomy Department</td></tr>
<tr><td>Creatinine Clearance (GFR)</td><td>24 hour Urine collection</td><td>Plain</td><td>N/A</td><td>80 – 125 mL/min (adults)</td><td>72 hours</td><td>Blood creatinine level also required for GFR calculation.</td></tr>
<tr><td>Cyclosporin A</td><td>Whole blood</td><td>EDTA (Pink Cap)</td><td>2.6mL</td><td>N/A (ng/ml)</td><td>10days</td><td>Trough level sample.</td></tr>
<tr><td>Dehydroepi-androsterone Sulphate (DHEAS)</td><td>Serum</td><td>Plain (White Cap)</td><td>4.9mL</td><td>(µmol/L)
<table>
<tr><th>Years</th><th>Female</th><th>Male</th></tr>
<tr><td>15-20y</td><td>1.8-10.0</td><td>1.9-13.4</td></tr>
<tr><td>20-25y</td><td>4.0-11.0</td><td>5.7-13.4</td></tr>
<tr><td>25-35y</td><td>2.7-9.2</td><td>4.3-12.2</td></tr>
<tr><td>35-45y</td><td>1.7-9.2</td><td>2.4-11.6</td></tr>
<tr><td>45-55y</td><td>1.0-7.0</td><td>1.2-9.0</td></tr>
<tr><td>55-65y</td><td>0.5-5.6</td><td>1.4-8.0</td></tr>
<tr><td>65-75y</td><td>0.3-6.7</td><td>0.9-6.8</td></tr>
<tr><td>≥ 75y</td><td>0.3-4.2</td><td>0.4-3.3</td></tr>
</table></td><td>3days</td><td>Age and gender specific ranges are applied to individual reports.</td></tr>
<tr><td>Dexamethasone overnight</td><td>Serum</td><td>Brown Cap</td><td>4.9 mL</td><td></td><td>24hrs</td><td></td></tr>
<tr><td>Digoxin</td><td>Serum</td><td>Plain (White Cap)</td><td>4.9mL</td><td>0.6 -1.2 µg/L</td><td>24 hours</td><td>With hypokalaemia toxicity may occur within the therapeutic range</td></tr>
</table>

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Estimated Glomerular Filtration Rate (eGFR)	Lithium Heparin	Lithium Heparin (Orange Top)	4.9ml	>90ml/min/1.72m^2	24 hours	Addition to Renal Profile
Dopamine	24 hour Urine collection	Pre-acidified (50% acid)	N/A	See Table Below	24 working days	If the patient is <15 years, please contact the laboratory [(01)7977333)] for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples.
Ethanol	Plasma	Fluoride oxalate (Yellow Cap)	2.7 mL	Unit: mg %	24 hours	
Ferritin	Plasma	Orange Cap	4.9mL	Female (17-60yr) 13-150ng/mL Male (20-60yr): 30-400ng/mL	3days	No reference range for >60yr.
Folate/ Folic Acid	Plasma	Orange Cap	4.9mL	3.9 – 26.8µg/L	3days	Affected by light and recent food intake. Please note, results reported as >20 µg/L.
Follicle Stimulating Hormone (FSH)	Serum	Brown Cap	4.9mL	Male : 1.5 – 12.4 U/L Female: Follicular : 3.5-12.5 U/L Mid Cycle : 4.7 – 21.5 U/L Luteal : 1.7-7.7 U/L Post Menopausal : 25.8-134.8 U/L	3days	
Free T3	Plasma	Orange Cap	4.9ml	3.1 - 6.8 pmol/L	3days	
Free Thyroxine (fT4)	Plasma	Orange Cap	4.9mL	11.9-21.6 pmol/L	3days	

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Gamma-glutamyl transferase (GGT)	Plasma	Orange Cap	4.9mL	Males < 59 I.U/L Females < 39 I.U/L	24 hours	
Glucose - Fasting	Plasma	Fluoride Oxalate (YELLOW cap)	2.7mL	Normoglycaemia = 3.5 - 5.5 mmol/L Impaired Fasting Glucose = 5.6 –6.9 mmol/L Diabetes = ≥7.0 mmol/L	24 hours	Fast for at least 8 hours. See Interpretive Comment (ADA 2019)
Glucose- Random	Plasma	Fluoride Oxalate (YELLOW cap)	2.7mL	Values >7.8 and <11.1 recommend Fasting Glucose Values ≥ 11.1 (with symptoms of hyperglycaemia) are consistent with Diabetes.	24 hours	See Interpretive Comment (ADA 2019)
Growth Hormone (hGH)	Serum	Brown Cap	4.9mL	N/A (ng/ml) See Interpretive Comment	20 days	HGH test is most useful in dynamic tests where states of hypoglycaemia or hyperglycaemia are induced. Samples need to be separated and frozen immediately.
HbA1c	Whole blood	EDTA (PINK cap)	2.6mL	IFCC: 20–42 mmol/mol Reference range for people without diabetes. The target range for patients with diabetes will be set by the clinician.	96 hours	
HMMA (VMA)	24 hour Urine collection	Pre-acidified (50% acid)		< 45 µmol/24 hr (Adult)	12 working days	If the patient is <15 years, please contact the laboratory [(01)7977333)] for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples.

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
HVA	24 hour Urine collection	Pre-acidified (50% acid)		< 40 µmol/24 hr (Adult)	12 working days	If the patient is <15 years, please contact the laboratory [(01)7977333)] for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples.
Immmunoglobulin G, A, M	Serum	Brown Top	4.9ml	IgG: 7.0 - 16.0g/L IgA: 0.7 - 4.0 g/L IgM: 0.4 - 2.3 g/L	35 days	

<table>
<tr><th>Test</th><th>Sample Required</th><th>Specimen Container</th><th>Minimum Volume</th><th>Reference Range/ Unit of Measurement</th><th>TAT</th><th>Comment</th></tr>
<tr><td>IGF1</td><td>Serum</td><td>White Cap</td><td>4.9mL</td><td>(ng/ml)
<table><tr><th>Years</th><th>Female</th><th>Male</th></tr><tr><td>0-1y</td><td>17.9-125.6</td><td>27.0-157.0</td></tr><tr><td>1-2y</td><td>19.5-132.3</td><td>29.7-166.8</td></tr><tr><td>2-3y</td><td>22.2-145.4</td><td>33.9-183.9</td></tr><tr><td>3-4y</td><td>25.9-164.2</td><td>39.0-204.5</td></tr><tr><td>4-5y</td><td>30.7-187.8</td><td>44.3-225.0</td></tr><tr><td>5-6y</td><td>26.2-214.4</td><td>50.0-245.5</td></tr><tr><td>6-7y</td><td>42.0-240.4</td><td>56.2-267.1</td></tr><tr><td>7-8y</td><td>48.6-269.6</td><td>63.4-291.9</td></tr><tr><td>8-9y</td><td>56.9-305.3</td><td>72.4-323.1</td></tr><tr><td>9-10y</td><td>67.2-349.4</td><td>83.6-361.6</td></tr><tr><td>10-11y</td><td>79.5-400.3</td><td>96.9-406.6</td></tr><tr><td>11-12y</td><td>92.6-452.6</td><td>111.6-454.4</td></tr><tr><td>12-13y</td><td>105.3-499.1</td><td>126.1-498.7</td></tr><tr><td>13-14y</td><td>115.9-533.4</td><td>138.6-532.5</td></tr><tr><td>14-15y</td><td>123.4-552.0</td><td>147.5-551.2</td></tr><tr><td>15-16y</td><td>127.4-554.2</td><td>152.2-553.5</td></tr><tr><td>16-17y</td><td>127.9-541.5</td><td>152.9-541.8</td></tr><tr><td>17-18y</td><td>125.3-517.3</td><td>150.6-520.6</td></tr><tr><td>18-19y</td><td>120.5-485.8</td><td>146.2-493.6</td></tr><tr><td>19-20y</td><td>114.4-450.8</td><td>140.2-462.7</td></tr><tr><td>20-21y</td><td>107.8-416.0</td><td>133.1-430.0</td></tr><tr><td>21-26y</td><td>92.9-342.0</td><td>115.2-354.8</td></tr><tr><td>26-31y</td><td>78.4-270.0</td><td>97.9-281.6</td></tr><tr><td>31-36y</td><td>73.1-243.0</td><td>88.3-246.0</td></tr><tr><td>36-41y</td><td>69.0-227.0</td><td>83.4-232.7</td></tr><tr><td>41-46y</td><td>61.5-204.4</td><td>74.9-216.4</td></tr><tr><td>46-51y</td><td>56.8-194.5</td><td>66.9-205.1</td></tr><tr><td>51-56y</td><td>53.0-189.6</td><td>60.6-200.3</td></tr><tr><td>56-61y</td><td>45.6-172.4</td><td>54.3-194.2</td></tr><tr><td>61-66y</td><td>42.2-169.0</td><td>48.8-187.7</td></tr><tr><td>66-71y</td><td>38.3-162.5</td><td>46.5-191.9</td></tr><tr><td>71-76y</td><td>36.6-164.7</td><td>40.9-179.2</td></tr><tr><td>76-81y</td><td>34.7-164.8</td><td>37.1-172.0</td></tr><tr><td>81-86y</td><td>34.4-172.4</td><td>33.8-165.4</td></tr><tr><td>86-91y</td><td>33.6-177.8</td><td>32.2-166.1</td></tr></table></td><td>20days</td><td>Sample must be spun and separated immediately.</td></tr>
</table>

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Iron	Plasma	Orange Cap	4.9mL	5.8 – 34.5µmol/L	24 hours	
Lactate Dehydrogenase (LDH)	Plasma	Orange Cap	4.9mL	Males 135 – 225 U/L Females 135 – 214 U/L	24 hours	Significantly increased by haemolysis and/or if sample is left on cells overnight.
Lithium	Serum	Plain (White Cap)	4.9mL	0.6 – 1.2 mmol/L	24 hours	Therapeutic range: Up to 1.3 in acute mania. Severe Toxicity likely if level > 2.0
Lipid Profile (Fasting)	Plasma	Orange Cap	4.9ml	Cholesterol ≤ 5.0mmol/L LDL(calculated) ≤ 3.0mmol/L HDLCholesterol ≥ 1.0mmol/L Triglycrides ≤ 1.7mmol/L Non HDL Cholesterol ≤ 3.8mmol/L	24 hours	Refer to National Pathology Handbook: Laboratory Testing for Lipids
Lipid Profile (Non Fasting)	Plasma	Orange Cap	4.9ml	Cholesterol ≤ 5.0mmol/L LDL (calculated) ≤3.0mmol/L HDLCholesterol ≥ 1.0mmol/L Triglycrides ≤ 2.0mmol/L Non HDL Cholesterol ≤ 3.8mmol/L	24 hours	Refer to National Pathology Handbook: Laboratory Testing for Lipids
Luteinising Hormone (LH)	Serum	Brown Cap	4.9mL	Male: 1.7 – 8.6 U/L Female: Follicular: 2.4 - 12.6 U/L Ovulation: 14.0 - 95.6 U/L Luteal: 1.0 - 11.4 U/L Post-Menopausal: 7.7-58.5 U/L	3days	
Magnesium	Plasma	Orange Cap	4.9mL	0.66 – 1.07 mmol/L	24 hours	Increased by haemolysis or if sample is left on cells overnight.
Magnesium 24 Hour Urine	24 hour Urine collection	No Preservative		3.0 – 5.0 mmol/24hr	72 hours	Container available from Phlebotomy Department

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Metanephrine (Urine Total)	24 hour Urine collection	Pre-acidified (50% acid)		See Table Below	24 working days	Container available from Phlebotomy Department
Neuroblastoma Screen (HMMA, HVA, Dopamine, Adrenaline and Noradrenaline).	Spot Urine Sample carefully acidified to pH 4 or less.	Plain container but sample should be protected from light	1-2 mLs	All results are reported in mmol/Mol of Creatinine	12 days for Routine samples 1-2 working days for Urgent samples- must be discussed with laboratory	
Noradrenaline	24 hour Urine collection	Pre-acidified (50% acid)	N/A	See Table Below	24 working days	If the patient is <15 years, please contact the laboratory (01-7977333) for information regarding sample collection. Age-related reference ranges will accompany results for paediatric samples. Samples should be taken immediately prior to next dose.
Normetanephrine (Urine Total)	24 hour Urine collection	Pre-acidified (50% acid)	N/A	See Table Below	24 working days	Container available from Phlebotomy Department
Oestradiol	Serum	Brown Cap	4.9mL	Follicular: 114-332 pmol/L Ovulation: 222-1959 pmol/L Luteal: 222-854 pmol/LPost Menopausal:18.4-505 pmol/L Male: 41.4 – 159 pmol/L	3days	
Osmolality	Plasma	(Orange Cap)	4.9mL	275 – 295 mOsm/Kg	24 hours	

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Osmolality Urine	Spot urine sample	Plain MSU container	N/A	400 – 1000 mOsm/Kg	24 hours	Results are interpreted in conjunction with the plasma Osmolality
Paracetamol	Serum	Plain (White Cap)	4.9 mL	Units: mg/L	24 hours	In suspected overdose, take sample more than 4 hours post ingestion.
Parathyroid Hormone (PTH)	Whole blood	EDTA (Blue cap)	4.9ml	17 - 74pg/ml	3days	
Phenobarbital	Serum	Plain (White Cap)	4.9mL	10.0 – 40.0 mg/L	24 hours	Therapeutic range ill-defined due to 'tolerance'
Phenytoin	Serum	Plain (WhiteCap)	4.9mL	5.0 – 20.0 mg/L	24 hours	Severe toxicity likely if >40.0mg/L
Phosphate	Plasma	Orange Cap	4.9mL	0.81 – 1.45 mmol/L	24 hours	Can be dramatically increased if sample is left on cells overnight.
Phosphate 24 Hour Urine	24 hour Urine collection	No Preservative	N/A	13.00 – 42.00 mmol/24hr	72 hours	Container available from Phlebotomy Department
Plasma Free Metanephrines	Plasma	EDTA 7.5ml	7.5ml	See table Section 3.4.11	12 working days	Sample must be taken on ice, spun within 1hr of collection aliquoted, frozen for transport.
Potassium	Plasma	Orange Cap	4.9mL	3.5 – 5.3 mmol/L	24 hours	Greatly increased if sample is left on cells overnight or refrigerated.
Potassium 24 Hour Urine	24 hour Urine collection	Plain	N/A	30.0 – 100.0 mmol/24hr (for person on average diet)	72 hours	Container available from Phlebotomy Department
Potassium Urine	Spot urine sample	Plain MSU container	N/A	N/A See Interpretive Comment	24 hours	Reference ranges are not available for spot urine tests, results must be considered in conjunction with the age, sex and hydration status of the patient

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Prolactin	Serum	Brown Cap	4.9mL	(mIU/L) **Total Prolactin** Female: 102-496 mIU/L Male: 86-324 mIU/L **Bioactive Prolactin:** Female: 75-381mIU/L Male: 63-245 mIU/L	7 days	Bioactive prolactin is the biologically active form of prolactin. For further information please consult the National Laboratory Handbook- Laboratory Testing for Hyperprolactinaemia 2019.
Progesterone	Brown	Brown Cap	4.9mL	Male: 0.159 - 0.474 nmol/L Female: Follicular: 0.159 – 0.616 nmol/L Ovulation: 0.175– 13.2nmol/L Luteal: 13.1 - 46.3 nmol/L Post Menopasal: 0.159 - 0.401 nmol/L	3days	Note date of cycle on test request form.
Protein (Total)	Plasma	Orange Cap	4.9mL	60 – 80 g/L	24 hours	
Protein (TUP) 24 Hour Urine	24 hour Urine collection	Plain	N/A	0.05 – 0.140 g/24 hour	72 hours	
Protein : Creatinine Ratio	Spot urine sample	Plain MSU container	N/A	3 – 14 mg/mmol	96hours	
Protein Electrophoresis	Serum	Brown Cap	4.9mL	N/A See Interpretive Comments	35 days	

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
PSA (total) Roche Method (e801)	Plasma	Orange Cap	4.9mL	**Age related PSA (non-suspicious DRE)** <50 = <2ug/L 50 – 59 = <3ug/L 60 – 69 = <4ug/L 70+ = <5ug/	3days	Specimens for PSA should not be drawn immediately after digital rectal examination, prostatic massage or transrectal ultrasound. PSA sampling should not be carried out for at least 6 weeks after prostatic biopsy. Refer to National Pathology Handbook: National Prostate Cancer GP Referral Guideline
Renin	Whole blood	EDTA (Blue Cap)	4.9ml	Female: 6.1 – 62.7mIU/L Male: 9.0 – 103.5mIU/L	20 days	Sample must be spun and separated immediately.
Salicylate	Serum	Plain (White Cap)	4.9 mL	Units: mg/L	24 hours	Concern level 280 mg/L if age <5 years; Severe toxicity likely if level >700 mg/L
SHBG	Serum	Plain (White Cap)	4.9ml	Male (20-49yr): 18.3 – 54.1nmol/L Male (≥ 50yr): 20.6 – 76.7nmol/L Female (20-49yr): 32.4 – 128.0nmol/L Female (≥ 50yr): 27.1 – 128.0nmol/L	3days	No SHBG reference intervals for <20yr old.
Sodium	Plasma	Orange Cap	4.9mL	133 – 146 mmol/L	24 hours	
Sodium 24 Hour Urine	24 hour Urine collection	Plain	N/A	40.0 – 220.0 mmol/24hr	72 hours	

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Sodium Urine	Spot urine sample	Plain MSU container	N/A	N/A See Interpretive Comment	24 hours	Reference ranges are not available for spot urine tests, results must be considered in conjunction with the age, sex and hydration status of the patient
Tacrolimus (FK506)	Whole blood	EDTA (Pink Cap)	2.6mL	(ngml) N/A See Interpretive Comment	72 hours	Trough level sample.
Testosterone	Serum	Plain (White cap)	4.9mL	Male: 19 - 50y: 8.6 - 29.0 nmol/L ≥50y: 6.7 - 25.7 nmol/L Female: 19 - 50y: 0.3 - 1.7 nmol/L ≥50 y: 0.1 –1.4 nmol/L	3 days	
Theophylline	Serum	Plain (White Cap)	4.9mL	10.0 – 20.0 mg/L	24 hours	Lower levels ≥ 5.0mg/L may be effective. Concern level 14.0mg/L if age < 3months. Severe toxicity likely if > 60.0mg/L.
Total Thyroxine (TT4)	Lithium Heparin	Lithium Heparin (Orange Top)	4.9ml	66 – 181nmol/L	72 hours	
Transferrin	Plasma	Orange Cap	4.9mL	A Fasting Transferrin Saturation > 55% in Males OR > 50% in Females indicates Iron accumulation.	24 hours	If Transferrin Saturation > 50% Please repeat on a morning fasting sample. Refer to: BCSH Guidelines.
Thyroid Stimulating Hormone (TSH)	Plasma	Orange Cap	4.9mL	0.27- 4.20 mU/L	72 hours	

Test	**Sample Required**	**Specimen Container**	**Minimum Volume**	**Reference Range/ Unit of Measurement**	**TAT**	**Comment**
Triglycerides	Plasma	Orange Cap	4.9mL	0.5 -2.0nmol/L (Non fasting) 0.5 - 1.7mmol/L (Fasting)	72 hours	Refer to National Pathology Handbook: Laboratory Testing for Lipids
Troponin T (TNT) Must have a dedicated sample	Lithium Heparin	Lithium Heparin (Orange Top)	2.7mL	< 14 ng/L	1.5 hours	
Urate/Uric Acid	Plasma	Orange Cap	4.9mL	Males 202 - 416µmol/L Females 143 - 340µmol/L	24 hours	
Urate 24 Hour Urine	24 hour Urine collection	Plain	N/A	1.20 – 5.90 mmol/24hr	72 hours	
Urea	Plasma	Orange Cap	4.9mL	2.8 – 8.1 mmol/L	24 hours	
Urea 24 Hour Urine	24 hour Urine collection	Plain	N/A	428.0 – 714.0 mmol/24hr	72 hours	
Valproic Acid	Serum	Plain (White Cap)	4.9mL	50 – 100 mg/L	24 hours	Therapeutic range ill-defined as toxic effects shows no clear relationship to plasma levels.
Xanthochromia	CSF	Brown cap wrapped in foil to exclude light	1mL	N/A See Interpretive Comment	24 hours (Mon-Fri)	See Protocol for Sending CSF Samples to Beaumont for Xanthochromia Analysis Beaumont Hospital - Chemical Pathology **Service available during routine working hours only.**

3.3.8.4 Calculated / Derived Tests

Calculated Parameter	Formula	Reference Range	Units	Important Notes
Calcium Adjusted	[Ca] + (46.18 – [Alb]) * 0.01516 (Locally derived equation)	2.21 – 2.52	mmol/L	The calculation is unsuitable if the albumin result is < 30g/L or > 52g/L
Globulin	Total Protein - Albumin	N/A	g/L	Interpret in conjunction with Total Proteim amd Albumin values.
LDL (Low Density Lipoprotein) Cholesterol	Cholesterol – HDL – (triglyceride / 2.2) (Friedwald Equation)	See Above	mmol/L	The calculation is unsuitable if the triglyceride level is > 4.5mmol/l Refer to National Pathology Handbook: Laboratory Testing for Lipids
Non-HDL Cholesterol	Total Cholesterol – HDL Cholesterol.	See Above	mmol/L.	Refer to National Pathology Handbook: Laboratory Testing for Lipids
Transferrin saturation (TfS)	(Iron / Transferrin) * 398	See Interpretive Comment	%	If transferrin saturation > 50% please repeat on a morning fasting sample. Refer to: BSCH guidelines. A fasting transferrin saturation > 55% in males or >50% in females indicates iron accumulation.
Unconjugated Bilirubin	Total Bilirubin – Conjugated (Direct) Bilirubin	N/A		Patient must attend Beaumont Hospital phlebotomy so that a fresh sample can be taken and protected from light. Must be interpreted in conjunction with Total and Conjugated Bilirubin.

3.3.9 ***Urinary Catecholamines and Metabolites Reference Ranges:***

Adult reference ranges:

Analyte	Reference Interval
Noradrenaline	< 0.900 umol/24hrs
Adrenaline	< 0.230 umol/24hrs
Dopamine	< 3.300 umol/24hrs
Metanephrine	< 1.80 umol/24 hrs
Normetanephrine	< 2.80 umol/24 hrs

Paediatric Reference Ranges: Units are mmol/mol Urinary Creatinine.

Age Group (yrs)	Noradrenaline	Adrenaline	Dopamine
< 1	< 0.43	< 0.08	< 1.95
1 – 3	< 0.20	< 0.08	< 1.45
3 – 5	< 0.19	< 0.08	< 0.95
5 – 8	<0.18	< 0.08	< 0.85
8 – 11	<0.17	< 0.08	< 0.75
> 11	<0.13	< 0.08	< 0.65

3.3.10 ***Plasma Metanephrine Reference Ranges***

Analyte	Reference Interval (Seated)
Plasma Free Methanephrine	0 – 510 pmol/L
Plasma Free Normetanephrine	0 – 1180 pmol/L
Plasma Free 3-Methyoxytyramine	0 – 180 pmol/L

The below table provides Supine Reference Intervals, i.e. after 30 minutes rest.

Analyte	Reference Interval (Supine)
Plasma Free Methanephrine	0 – 450 pmol/L
Plasma Free Normetanephrine	0 – 730 pmol/L
Plasma Free 3-Methyoxytyramine	0 – 180 pmol/L

Endocrinology Reference Ranges

Where age and cycle reference ranges apply to females, 50 years has been agreed by the Endocrinologists as the age to apply a post-menopausal range.

3.4 IMMUNOLOGY

The Immunology Department provides both Clinical and Laboratory Services. Additionally we are keen to assist with the development of guidelines for investigations of potential immunological disorders, clinical audit and other educational activities.

3.4.1 *Clinical Service*

There is a general immunology outpatients clinic held in Clinic A on Monday mornings and an allergy clinic held in Clinic F on Thursday afternoons. Additionally, various ANP led allergy clinics are held in the department throughout the week. The Department also has an established home therapy programme for patients on immunoglobulin replacement therapy and an ANP-led review clinics for these patients are held in the department..

Referrals are accepted from hospital teams and GPs. Self-referrals from patients cannot be accepted. Appropriate referrals include known or suspected immunodeficiency, recurrent infections, serious allergy (anaphylaxis) or angioedema, as well as difficult autoimmune disease. A detailed referral letter including current medications, previous treatments and laboratory investigations with results should be sent to Prof. Keogan/Dr Khalib/Dr Cox. Please ensure that the patients' correct address and phone number is included. Appointments are allocated on the basis of clinical urgency. Due to the long waiting time, we do not routinely offer second appointments to patients who fail to attend without cancelling their appointment.

3.4.2 *Laboratory Service*

The Laboratory provides a large range of immunological investigations focussing on investigations for autoimmune and allergic disorders. Some immunology tests are carried out in the Protein chemistry and Haematology laboratories.

3.4.3 ***Repertoire of Tests & Test Profiles***

All tests are performed on serum samples. Up to 5 tests can be performed on a 10 mL sample. However separate samples are required for some tests to facilitate optimum handling.

Test	**Specimen**	**Minimum Volume**	**Method**	**Reference Range**	**TAT**	**Urgent Service**	**Comment**	**Frequency of Retesting**
Acute Allergic Reaction Investigation AARI (Service for Beaumont GP's only)	Serum Gel Brown tube	4.9 mls Note 200µl serum plus an extra 50µl serum per specific allergen needed	FEIA (IMMUNOCAP)	N/A	N/A		See Section 2.4.28 for reporting pathway	As requested and discussed as per interpretive comments
Anti-CCP	Serum Gel Brown tube	4.9 mls	EliA (IMMUNOCAP)	< 7 U/ml	8 days			3 Months
Anti-Endomysial (IgA) Antibodies	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence	Negative	8 days			>3 months
Anti-Endomysial (IgG) Antibodies	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence	Negative	8 days		Only performed when IgA deficiency	
Anti-Gastric-Parietal Cell antibodies (Anti-GPC)	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence	Negative	3-5 days			>3 months
Anti-Intrinsic Factor Antibodies	Serum Gel Brown tube	4.9 mls	EliA (IMMUNOCAP)	Negative: <7 U/ml Equivocal: 7- 10U/ml Positive: >10 U/ml	8 days			>6 months

Test	Specimen	Minimum Volume	Method	Reference Range	TAT	Urgent Service	Comment	Frequency of Retesting
Anti-Liver-Kidney Microsomal (LKM) Antibodies	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence + Immunoblot if IIF positive	Negative	3-5 days			>1 month
Anti-Mitochondrial Antibody (including M2 subtyping)	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence + ELISA if positive	Negative M2 ELISA <10 IU/ml	3-5 days (1 month if IIF positive)			>3 months M2 performed only once
Anti-Nuclear Antibodies	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence	Negative. Weak positive (1:80) are commonly seen particularly in healthy older women.	3-5 days			No more than 3 monthly
Anti-Smooth Muscle Antibodies	Serum Gel Brown tube	4.9 mls	Indirect Immunofluorescence	Negative	3-5 days			>3 months
Anti-Streptolysin-O Titre (ASOT)	Serum Gel Brown tube	4.9 mls	Immunoturbidimetry	<200IU/ml	3-5 days			3 weeks
Anti-Tissue Transglutaminase Antibodies (anti-tTG)	Serum Gel Brown tube	4.9 mls	EliA (IMMUNOCAP)	Negative: < 4 U/ml Equivocal: 4-10 U/ml Positive: 10 U/ml	8 days			>3 months
CTD Screen	Serum Gel Brown tube	4.9 mls	EliA (IMMUNOCAP)	Negative	2-5 days			No more than 3 monthly
Rheumatoid Factor	Serum Gel Brown tube	4.9 mls	Immunoturbidimetry	<14 IU/mL	3-6 days			>3 Months

Test	Specimen	Minimum Volume	Method	Reference Range	TAT	Urgent Service	Comment	Frequency of Retesting
Specific IgE	Serum Gel Brown tube	4.10 mls Note 200µl serum plus an extra 50µl serum per specific allergen needed	FEIA (IMMUNOCAP)	<0.35 Class 0 Negative 0.35-0.7 Class 1 Weakly Positive 0.7-3.5 Class 2Positive 3.5-17.5 Class 3 Positive 17.5-52.5 Class 4 Strongly positive 52.5-100 Class 5 Strongly positive >100 Class 6 Strongly positive	15days 21 days for sIgE to Drugs		For GP users, please order using AARI	1 year for same allergens

3.4.3.1 Test Profiles

To make test ordering more efficient we have set up a range of disease specific test profiles, for investigations of common potentially immunological disorders. Where screening tests are included in test batteries, positive screening tests lead to reflex ordering of appropriate follow-up tests.

Profile	*Tests Included*	*Indication*	*Comment*
Rheumatoid Arthritis Antibodies	RF CCP	Isolated inflammatory arthritis, in the absence of systemic features.	2 separate samples are required for RA Abs
Pernicious Anaemia Antibodies	Anti-Gastric Parietal Cell Abs Anti-Intrinsic Factor Abs		
Liver Disease Associated Antibodies	Anti-Nuclear Abs Anti-Smooth Muscle Abs Anti-Mitochondrial Abs Anti-LKM Abs	Suspected chronic liver disease.	If anti-mitochondrial antibody positive, M2 subtyping will be performed, on the first occasion only.

3.5 MICROBIOLOGY

3.5.1 *Repertoire of Test Services*

Test	Target Pathogens	Specimen	Minimum Volume	Biological reference range	TAT	Comment
URINE						
Microscopy	N/A	The Sarstedt NFT (Needle Free Transfer) system. 100ml NFT primary container Reference 75.562.900) and a 10mL Monovette tube reference 10.252)	2 mls	WBC, RBC <1 to >100 per µL	Within 24 hours of receipt	Culture is only performed on urines which meet the appropriate laboratory and clinical criteria. 'WBC ≥50/uL **OR** sediMAX bacterial count of >+. The following urines are always cultured: in pregnancy, children ≤16 years old,

Test	**Target Pathogens**	**Specimen**	**Minimum Volume**	**Biological reference range**	**TAT**	**Comment**
Culture and susceptibility	Urinary pathogens	The Sarstedt NFT (Needle Free Transfer) system. 10ml NFT primary container Reference 75.562.900) and a 10mL Monovette tube reference 10.252)	2 mls	N/A	6 days	
Pregnancy test	N/A	The Sarstedt NFT (Needle Free Transfer) system. 10ml NFT primary container Reference 75.562.900) and a 10mL Monovette tube reference 10.252)	2 mls	HCG Preg Positive 25mIU/mL HCG Preg Negative HCG Weak Positive	1 day	Repeat specimen requested within 48 hrs for weak pos results
TB culture	*Mycobacterium* spp.	Approved yellow screw-capped (Sarstedt) container	10 mls	N/A	70days	3 consecutive EMUs needed – For diagnosis of disseminated or urinary tract mycobacterial infection only
FAECES						

Test	**Target Pathogens**	**Specimen**	**Minimum Volume**	**Biological reference range**	**TAT**	**Comment**
Enteric pathogens	Enteric pathogens including *Cryptosporidium parvum/hominis and Giardia lamblia*	Approved yellow screw-capped (Sarstedt) container	1-2g	N/A	3 to 6 days	Perfomed **only** on specimens which take the shape of the container A negative disclaimer is added to 'Not Detected' results
C. difficile	*C. difficile*	Approved yellow screw-capped (Sarstedt) container	1-2mls	C diff tox Detected/not detected	2 days	Perfomed **only** on specimens which take the shape of the container and >2 years of age.
Rota/adeno virus	Rota/adeno virus	Approved yellow screw-capped (Sarstedt) container	1-2g	Adeno/Rota virus Positive Adeno/Rota virus Neg	4 days	Performed routinely on children <2years
Ova/parasites	Ova & Parasites	Approved yellow screw-capped (Sarstedt) container	1-2g	N/A	4 to 8 days	Clinical/travel details essential or discussion with CMT.
Helicobacter pylori antigen	*Helicobacter pylori*	Approved yellow screw-capped (Sarstedt) container	1-2g	H.pylori Ag Not detected/detected	4 days	A negative disclaimer is added to 'Not Detected' results
SPUTUM						

Test	Target Pathogens	Specimen	Minimum Volume	Biological reference range	TAT	Comment
Routine culture	Respiratory pathogens	Approved yellow screw-capped (Sarstedt) container	As available	N/A	6 days	Salivary samples are unsuitable
TB	*Mycobacterium* spp.	Approved yellow screw-capped (Sarstedt) container	As available	N/A	70 days	3 consecutive morning samples
SKIN SCRAPPINGS/ NAIL CLIPPINGS						
Microscopy	Fungal Elements	Screw capped container (as above) or Dermapak	As much as Possible	N/A	7 days	
Culture	Dermatophytes, moulds & Yeasts	Screw capped container (as above) or Dermapak	As much as possible	N/A	40 days	Swabs are not an appropriate specimen for fungal culture. Hair must contain root
SWABS						
MRSA Screen	MRSA	Charcoal Transswab	N/A	N/A	10 days	MRSA- Only from Nasal, Groin & Wound sites
Non uro-genital (e.g. wound, eye, ear, nasal, throat)	Pathogens appropriate to site	Charcoal Transswab	N/A	N/A	6 days	Relevant clinical details essential, e.g. surgery, post-partum
Penile/vulval	Non -STI pathogens	Charcoal Transswab	N/A	N/A	4 days	
HVS –microscopy	Bacterial vaginosis	Charcoal Transswab	N/A	N/A	4 Days	
HVS –Culture	Bacterial vaginosis	Charcoal Transswab	N/A	N/A	4 Days	

1. Ova & parasites only performed when specifically requested **and** with relevant clinical details eg. Foreign travel.
2. Microscopy is prioritised over culture if insufficient sample is received.

Test	Target Pathogens	Specimen	Minimum Volume	Biological reference range	TAT	Comment
SUSPECTED STI SPECIMEN REQUIREMENTS						
MALE Urine	*Chlamydia trachomatis*	GenProbe Collection Device[1]	25 mls	N/A	5 days	First void urine (FVU) required
Swab - urethral	*N. gonorrhoeae*[2]	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days	Clinical details eg urethral disharge/ ?STI essential[1]
- rectal	*N. gonorrhoeae*	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days 48-72 hours	Clinical details essential[1]
- pharyngeal	*N. gonorrhoeae*	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days	Clinical details essential[1]
FEMALE Swab endocervical	*N. gonorrhoeaee*	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days	Clinical details essential[1]
	Chlamydia trachomatis	r GenProbe Collection Device[1]	N/A	N/A	5 days	Clinical details essential[1]
- cervical	*N. gonorrhoeae*	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days	Clinical details essential[1]
- urethral	*N. gonorrhoeae*	Charcoal Transwab or GenProbe Collection Device[1]	N/A	N/A	4 days	Clinical details essential[1]
- HVS	Bacterial vaginosis Candida and non-STI pathogens	Charcoal Transwab	N/A	N/A	4 days	Clinical details essential[1]

Test	Target Pathogens	Specimen	Minimum Volume	Biological reference range	TAT	Comment
1. Specimens received in Aptima Collection Devices will be sent to the NVRL for processing. The GenProbe (Aptima) collection devices (urine containers and swabs) are supplied by the NVRL. 2. In cases where *Neisseria gonorrhoeae* (GC) is suspected, clinical details of ?STI or 'DISCHARGE' must be provided on the request form. If not, samples will not be cultured for GC.						

3.5.2 ***General Notes***

- Beaumont Hospital Microbiology Laboratory does not provide a referral service for tests carried out in other centres (other than the NVRL virology/serology tests)
- If the test you require is not on our User Guide list, we may be able to provide you with information as to possible referral centres
- If we receive a request for a test not carried out in Beaumont, the specimen will be rejected with the 'test not performed in this laboratory' comment.

3.5.3 ***Key Factors Affecting Turn Around Times:***

The main reason for extended turn-around-times in Microbiology is in follow up of positive specimens. Microbial isolation and identification can be extensive in some instances and occasionally requiring referral of an isolate to a Reference Laboratory for typing or confirmation

3.5.4 *Samples sent to External Laboratories e.g., NVRL for analysis*

Please refer to the NVRL user manual for information on range of tests available in the NVRL, the type of specimen required and turn around time information on these tests. Information available on www.nvrl.ie

3.5.4.1 Notes on Samples Sent to the NVRL

- For tests where clotted blood is required, one 10ml vial is the specimen of choice.
- Report are available electronically via the Health link system
- For results or enquiries, the NVRL can be contacted on 01 716 1354. Address: UCD National Virus Reference Laboratory, University College Dublin, Belfield, Dublin 4.
- Request forms can be printed on-line via the NVRL web site (www.nvrl.ie) – at 'How do you send samples?' prompt (for tests not ordereable on Healthlink)
- Specimens that are referred out from Beaumont Hospital are not covered by the scope of Beaumont Hospital ISO15189 accreditation.

3.5.5 *Abbreviations Used on Microbiology Reports*

CRE: Carbapenem resistant *Enterobacterales*
CPE: Carbapenemase *Enterobacterales*
ESBL: Extended spectrum Beta-lactamase producing *Enterobacterales*
MRSA: Meticillin resistant *Staphylococcus aureus*
VRE: Vancomycin resistant enterococci

3.5.6 *Time Limits for Requesting Additional Tests:*

The normal limit of acceptability for culture for most microbiology specimens is 48hrs, once the specimen is in an appropriate transport medium.

Fungal culture specimens (nail clippings and skin scrapings) have a longer 'shelf life', though any delay increases the risk of contamination of the primary specimen, thus possibly compromising the ability to culture a pathogen

3.6 HISTOPATHOLOGY/CYTOPATHOLOGY/NEUROPATHOLOGY

The Histopathology Department provides an extensive Histopathology service, including supporting the symptomatic breast service, urology and gastrointestinal units. The department provides a diagnostic Renal Pathology service in addition to supporting the renal transplant service, including an Out of Hours service. Electron Microscopy, Cytopathology and an Autopsy service are also provided by the Histopathology laboratory. The Non-Gynae Cytopathology service includes provision of assistance and support for the Fine Needle Aspirate and endoscopic ultra sound services.

The Neuropathology section provides a diagnostic service for Neurosurgery and Neurology (including paediatric neurology and paediatric neurosurgery). A rapid intra-operative service is provided for the diagnosis of intracranial and spinal lesions including brain tumour. A range of investigations are available for the interpretation of muscle and nerve biopsies including molecular screening of common mitochondrial disorders. In addition Neuropathology is the national centre for the CJD Surveillance Unit. A Neuropathology autopsy service is also available and provides pathologic diagnosis in a variety of conditions including dementia and other neurodegenerative disorders. A CSF cytology service is also provided.

Other diagnostic services are provided on a consultative basis and include CSF analysis for 14.3.3 protein and mitochondrial genetic studies.

3.6.1 *Frozen Sections*

A ***frozen section*** service is offered between 09.00 – 17.00. Twenty Four hours notice should be given to the laboratory, prior to a frozen section. Frozen sections outside usual working hours may be provided by prior arrangement with the Consultant Pathologist.

Specimens from patients with TB, HIV or Hepatitis B or C infection should not be sent for frozen section. If such a suspicion is present, the medical staff concerned must inform laboratory personnel in order to safeguard the laboratory staff from risk of infection.

In addition, if the laboratory inadvertently processes such specimens, a decontamination procedure of the equipment required for frozen sections must be carried out. Decontamination of this equipment takes 12 hours. During this time no further frozen sections can be performed.

Frozen section reports are delivered to theatre, usually via the intercom. A written report is available following subsequent routine processing of the specimen.

3.6.2 ***Other Urgent Specimens***

Other urgent specimens are dealt with on an individual basis. The laboratory should be contacted directly with these requests in order to ensure that they are handled appropriately. Overuse of the urgent service will adversely affect the turnaround times for all urgent requests.

3.6.3 ***Reports***

The Authorised report is printed and sent to the Clinical Consultant or requesting GP. Reports are available through PIPE or by phoning the Histopathology Office at 2632/2636/2687/2154, 3919 or the Neuropathology Office at 2631 or the Renal Pathology Office at 2008. Reports are not available in the laboratory. Unauthorized reports and any issues of clinical concern can be discussed with the consultant involved in the case for any clinical advice.

3.6.4 ***Specimen Requirements For Histopathology***

The following is a guideline on the requirements of the various specimen types and the appropriate manner in which they should be delivered to the laboratory. This ensures the integrity of the specimen for laboratory investigations.

Tissue Type	**Fixative Required**	**Comment**
Specimen for Frozen Section.	Send fresh to the laboratory - immediately.	24 hours notice of Frozen sections should be given where possible. Contact the Histopathology Lab Ext 2353. Details supplied with the specimen must include a bleep number or theatre intercom to deliver report to.
Renal biopsies	Send in saline (Dublin Hospitals) Send in Formalin/Zeus (Regional Centres) (full details in section 3.6.9)	Please inform Renal Office Ext. 2765 of specimen. The Main Histology Lab can be contacted @ 2353. The EM lab on 8633.
Lymph nodes (for lymphoma diagnostics)	Send fresh to the laboratory - immediately.	Please supply all relevant clinical details.
Solid Tumours (Colon, Breast, Lung etc.)	Send fresh to the laboratory - immediately.	Please supply all relevant clinical details.
Liver biopsies*	Where possible, send two specimens – one in 10% Neutral	Please supply relevant clinical details.

Tissue Type	Fixative Required	Comment
	Buffered Formalin and one wrapped in saline moistened gauze.	Referred to St. Vincents University Hospital for copper analysis where required*
Oncotyping*	Paraffin Block	Referred to Genomic HealthCare (US) for Oncotyping
Mitochondrial Studies*	Send fresh to the laboratory - Immediately	Referred to Mitochondrial Research Group in Newcastle University for analysis/St James Hospital (CMD)
CSF for RT-QuIC Analysis	CSF frozen at -70°C within 30 minutes of aspiration and transported to the Neuropathology Dept, Beaumont Hospital on dry ice.	Volume CSF: 1 - 2ml. Sample must be clear and colourless (not blood stained) with a white cell count of <10x10^6/L and have a total protein concentration of <1 g/L1. Red blood cells (>1250 x 10^6/L) inhibit the RT-QuIC response resulting in false negatives. High CSF total protein concentrations of >1.0 g/L and raised white blood cell counts can result in false positives.
Primary Ciliary Dyskinesia*	Nasal Scraping	Referred to Southhampton General Hospital for analysis
Flow Cytometry*	CSF Or Lymph Node	Referred to Haematology in St. James's Hospital Dublin for Analysis
Amyloidosis*	Paraffin Block	Referred to National Amyloidosis Centre, London, Univeristy College London
PDL1* metastatic breast carcinoma , Head & Neck Cancer & metastatic oesophageal SCC. (NCCP recommendation)	Paraffin Block	Referred to Poundbury Cancer Institute, Dorchester, London HSL-Advanced Diagnostics HEALTH SERVICES LABORATORIES (A Sonic Healthcare UK laboratory) for metastatic oesophageal SCC.
Molecular Studies* – MY88		Referred to Royal Victoria Hospital, Belfast
All other tissue	Send in 10% Neutral Buffered Formalin.	An adequate volume of formalin in a specimen container of

Tissue Type	Fixative Required	Comment
		suitable size is essential for proper fixation. The volume of formalin used should be at least twice the volume of the tissue to be fixed. Small specimens should be placed in biohazard bags.
Histology Blocks *		outsourcing of blocks for cutting & staining to HTS

***** Specimens referred out from Beaumont Hospital - the results of these tests are not covered by the scope of Beaumont Hospital Histopathology Department ISO15189 accreditation. The responsibility for sending specimens lies with the external centre (Sender).

Please Note: Sample acceptance criteria ensure adequate identification for Histopathology samples and request forms in order for them to be accepted by the laboratory. The requesting clinician is responsible for the correct completion of the request form and the correct labelling of the sample.

Failure to comply with the correct guidance may result in the sample not being accepted in the laboratory. Inadequately or inaccurately labelled samples or forms will not be accepted unless they are considered to be unrepeatable or reproducible. An assessment of acceptance will be made by the laboratory personnel/consultant on an individual bass. The risk to the patient of rejection/acceptance of the sample will be weighed against the risk of acceptance of a wrongly labelled sample and is specific to the examinations requested. Cellular Pathology will accept no responsibility for samples processed which initially failed to meet the acceptance criteria, any deviation from the established collection procedures clearly recorded and an appropriate comment will be included in the pathology report. The laboratory will make every effort to ensure patient requests are processed in a safe and timely manner, but it is essential that request forms and samples are labelled appropriately and legibly. Inadequate or inaccurate labelling results in delays and impacts patient care. If you have any doubts regarding this policy, please contact the lab.

Multiple samples taken from a patient MUST be labelled on the sample container with the number and stae the site of tissue on each. The request form should be labelled accordingly to allow clear specimen location to be identified,

3.6.5 ***REQUIREMENT FOR EXTERNAL CENTRES***

The responsibility for sending slides/blocks/material lies with the external centre (Sender). External centres may send slides/blocks/material to Pathology for review/conferences etc. Ensure that slides/blocks/material is accompanied with the appropriate request form and relevant report. When multiple slides/blocks/materials are received, all must be labelled with clear identification of case number, according to acceptance criteria. This allows for unequivabal traceability to the patient. Any discrepancies will be addressed with the relevant referring hospital.

Ensure that packaging and transportation comply with the European Agreement for the Carriage of Dangerous Goods by Road, ADR Regulations.
Address the package to:

Histopathology/Neuropathology (as appropriate to the analysis required)
Beaumont Hospital,
Dublin 9
Include the Consignee address and telephone number.

3.6.6 ***Factors Affecting Fresh/Unfixed Tissue Specimens***

The techniques that are performed on fresh tissue are affected by the length of time that the tissue is removed from the patient before it is received for analysis. Therefore it is imperative that all tissue samples required to be sent fresh should be done so immediately. Fresh samples should be sent during normal working hours and the department must be informed in advance if a fresh sample is to arrive out of hours.
NOTE: Specimens from patients with TB, HIV or Hepatitis B or C infection should not be sent "fresh". If such a suspicion is present, the medical staff concerned must inform laboratory personnel in order to safeguard the laboratory staff from risk of infection

The following may be obtained from the Histopathology laboratory.

- Specimen containers – various sizes.
- 10% Neutral Buffered Formalin (in polycubes with taps/5lt containers).
- Pre-filled 60ml 10% Neutral Buffered Formalin containers.
- Histopathology/ Cytopathology/ Neuropathology / Renal Request Cards
- Slides and slide containers with fixative for Fine Needle Aspirates (FNAs).
- EM fixative.
- Liquid nitrogen for the Dermatology clinics.

SAFETY: Formalin is a potent eye and nasal irritant and can cause respiratory distress and allergic dermatitis. Gloves, goggles and aprons should be used when

dealing with formalin. Contact the Histopathology Laboratory for any additional information that may be required and if a formalin spillage should occur.

Liquid nitrogen can cause cold burns and is dangerous to use in confined spaces as it is an asphyxiant. It can also shatter receptacles that are unsuitable for its storage. Subsequently it will only be given to Beaumont Hospital personnel and transferred into a suitable receptacle. Information on safety on any of the above may be obtained from Histopathology on request @ ext. 2353

Please note: The laboratory periodically reviews any collection sample and handling issues through feedback via MDT meetings/User feedback Survey's and any issues discussed at departmental meetings. Where compromised samples are accepted (e.g. specimen received with no specimen) the final report will indicate the nature of the problem and if applicable that caution is required when interpreting the results.

3.6.7 *Turn Around Time for Results*

The turn around time of specimens for Histopathology will vary depending on the nature of the specimen and the complexity of the investigations required. The following is an outline of estimated turn around time for different specimen types from time of receipt in the laboratory:

Biopsies – 5-10 working days (on average)
Resections – 10 working days (on average)
Renal Biopsies -7-9weeks for Electron Microscopy
– 4-6weeks for Light Microscopy
–14 days for Immunofluorescence
CSF for RT-QuIC –10-15 working days

This is only a guideline and the complexity of a case and the requirement for further investigations may lengthen the turn around time. Results can be obtained from the Histopathology office, ext. 2636/2632/3150/3919. The Consultant/NCHDs can be contacted to discuss individual patients. TAT's are routinely monitored as part of the laboratories quality improvement programme,

3.6.8 *Cytopathology Specimen Requirements*

Specimen	**Specimen requirements**
Bronchial brushings	- Place material in a sterile container labelled with patient and specimen details, including the time of specimen collection.
	-
Fluids (Pleural, Ascitic etc.)	- Place material in a sterile container labelled with patient and specimen details, including the time of specimen collection.

Specimen	Specimen requirements
	- At least 20 mls of fluid is required for diagnosis.
Urine	- Total voided specimen is required for cytology. - The first morning specimen is not suitable. - Place in a container labelled with patient and specimen details.
Fine Needle Aspiration Cytology/EUS/EBUS	Sample from EUS/EBUS is sent to the cytology lab in cytolyt (available in the lab – Ext 2640)
Cerebrospinal Fluid for Cytology.	- Specimen must be collected in a sterile container labelled with patient and specimen details and delivered to the Neuropathology laboratory.
Flow Cytometry*	- ***Cytometry placed directly into RPMI are viable for up to 18Hrs****. (Contact Cytology on Ext. 2640)*

* Specimens referred out from Beaumont Hospital - the results of these tests are not covered by the scope of Beaumont Hospital Histopathology Department ISO15189 accreditation

ITEMS THAT CAN BE OBTAINED FROM THE CYTOLOGY LABORATORY

- Slides
- Slide holders
- Spray fixative
- Coplin jars of alcohol (Fixing FNA smears)
- Cervical cytology request forms
- ThinPrep kits for cervical smears (Hospital Clinics only)
- Biohazard bags
- Cytolyt containers

- **NOTE: EACH SAMPLE SHOULD BE ACCOMPANIED BY A HISTOPATHOLOGY/CYTOPATHOLOGY REQUEST FORM (FOUND ON ALL WARDS) – PLEASE PUT AS MUCH INFORMATION AS POSSIBLE.**

TURN AROUND TIMES FOR CYTOLOGY SAMPLES

Non-Gynae Cytology Samples – 3-4 Days

3.6.9 *Specimen Requirements for Renal Pathology*

The Laboratory should be notified in advance when a renal biopsy is to be taken.

Contact the Renal Pathology Secretary or if she is not available the Medical Scientists in the Renal Pathology/EM/Histopatholgy Laboratories:

DETAILS REQUIRED FOR RENAL BIOPSIES

The following **minimum** information must be supplied LEGIBLY:

On the body of the specimen container:

A Renal Biopsy Request Form must be filled in **(use a ballpoint pen please to make details legible on all copies of the form)** and sent with each biopsy :

- Name of patient
- Date of birth
- Medical record number
- Address of patient
- Name of Consultant
- Source (Ward Name/OPD/Hospital)
- Date sample taken
- Relevant clinical details
- Time sample taken (when applicable) as this can have an impact on the integrity of the results.
- Please give ***as much clinical information on the form*** as possible, as this will be required by the Renal Pathologist when considering differential diagnoses.
- If using addressograph labels please attach one to both flimsies and to the backing card – these copies are sent with each portion of the biopsy to the three laboratories involved in the investigation.
- ***Do not*** attach labels, use date stamps or write in the portion marked for "**Laboratory use"** as this area is used by Beaumont Scientific staff for recording the gross description of the biopsy. If your despatch procedures require that stamps or bar codes be attached please use the reverse (blank side) of the form's card copy.

3.6.10 *Renal Pathology Requirements for External Centres*

- The Renal Pathology Department should be notified before sending biopsy via email to: electronmicroscopy2@beaumont.ie
- The responsibility for sending specimens rests with the external centre.
- The **minimum details** required are as set out above, including the use of the Renal Biopsy request form. Supplies of the Request Form can be obtained by contacting the Renal laboratory on 01-8528633 (Dect phone)
- Packaging and transportation should comply with current UN legislation and the Transport of Dangerous Goods Act.
- The specimen should be dispatched so as to arrive at Beaumont Hospital no later than 16.00.
- Please note: name and contact of the referring nephrologist must be on the request form. This allows for tracking sample if not received within the timeframe.

Packages should be addressed to:

Consultant Renal Pathologist
Renal Pathology/Electron Micrscopy/Histopathology,
Histopathology Department,
Beaumont Hospital,
Dublin 9

NB Beaumont Hospital does not supply containers or fixative solutions for renal biopsies to external centres.

FOR REFERRING HOSPITALS IN THE DUBLIN AREA, if the sample can be transported to Beaumont Hospital within a couple of hours of excision, then place all of the tissue in normal saline in a 60 ml specimen jar or a universal container at least half full of liquid.

FOR REFERRALS FROM REGIONAL CENTRES, tissue can be examined and divided in the Histopathology Laboratory of the hospital prior to dispatch. Fresh tissue for immunofluorescence (0.3-0.4 cm of cortical tissue) should be placed in a transport medium suitable for preserving antigenic activity such as the Tissue Fixative available from Zeus Scientific Ltd. For best results, tissue should not spend any longer than 5 days in Zeus Tissue Fixative.

The remaining cores can be placed in Formalin. It is not necessary for external laboratories to make and keep a stock of glutaraldehyde. A piece of the core can be taken for EM from the Formalin fixed tissue on arrival at Beaumont Hospital Histopathology Department.

3.6.11 *Urgent Renal Biopsies for Rapid Processing*

If a renal biopsy result is required urgently, i.e. the day of biopsy, then rapid processing can be requested:

- You must contact the renal pathologist on duty to discuss the request, and when the request has been agreed, the Histopathology Laboratory should also be informed.
- The tissue must arrive in the Histopathology Laboratory by 12.30 pm at the latest. The tissue processor is then run for this single biopsy, and cannot be used until the process is completed. The surgical and biopsy specimens from that day's cut-up must be processed daily to maintain continuity of service to all other clinical specialities, so the processor must be available for use again at 5pm.

Please note: Renal biopsy cover: from time to time there may be an arrangement with Belfast. In terms of logistics, generally biopsies can be transferred up on the same day if we receive them by 11.15, after that they will go the following day.

Please liaise with the lab or indicate clearly on the form if a biopsy needs to be sent out or if it can wait for me to come back. It is vital that the lab is contacted regarding urgent biopsies to organise the most appropriate means of transferring the sampl. Renal laboratory personnel can be reached on 01 8528633 and Prof Declan O'Rourke can be contacted on 00447746648787.

3.6.12 ***Electron Microscopy***

The Electron Microscopy (EM) Laboratory was initially set up to serve diagnostic Renal Pathology which comprises the bulk of the caseload but a small number of Neuropathology cases are also handled.

The Laboratory is equipped with a JEOL 1400 Plus Transmission Electron Microscope and an AMT XR50 4 megapixel Digital Camera system. Samples are batched and processed automatically once a week.

The EM Laboratory is not equipped or staffed to deal with Virological EM requests, and due to low frequency of request does not accept nasal brushings for analysis of Primary Ciliary Dyskinesia (PCD)*. This is a highly specialised investigation and requires expertise which cannot be gained in this hospital due the low volume of requests. Please contact the EM laboratory for instructions, request form and fixative. When the procedure has been carried out, the sample should be sent to the EM Laboratory from where it will be referred to the UK National Centre for PCD Analysis in Southampton.

*Specimens referred out from Beaumont Hospital - the results of these tests are not covered by the scope of Beaumont Hospital Histopathology Department ISO15189 accreditation.

3.6.13 *Specimen Requirements for Neuropathology*

Tissue Type	**Means of Delivery to Neuropathology**	**Comment**
Specimen for urgent frozen section	Send fresh. Hand deliver immediately.	The Neuropathology consultation form must include a bleep number or intercom number to deliver the report
Muscle Biopsy*	Send on gauze that is barely dampened in saline. Do not fix in formalin. Hand deliver immediately. See Section 3.6.10 for requirements from external centres.	Must be received during normal working hours unless previously arranged.
Nerve Biopsy	Send on gauze that is barely dampened in saline. Do not fix in formalin. Hand deliver immediately. See Section 3.6.10 for requirements from external centres.	Must be received during normal working hours unless previously arranged.
Hippocampus & Amygdala	Send fresh. Hand deliver immediately to the laboratory.	
Temporal Lobe (Epilepsy)	Send fresh. Hand deliver immediately to the laboratory.	
Temporal Artery	Send in 10% Neutral Buffered Formalin.	Send Immediately/ASAP
Laminectomy/Disc	Send in 10% Neutral Buffered Formalin.	
Tumour fluid for cytology	Hand delivery immediately.	Must be received during normal working hours.
CSF for cytology	Hand delivery immediately.	Must be received during normal working hours.
CSF for RT-QuIC Analysis	CSF frozen at -70°C within 30 minutes of aspiration and transported to the Neuropathology Dept, Beaumont Hospital on dry ice.	Must be received during normal working hours unless previously arranged. CJD Questionnaire must accompany specimen.

Tissue Type	**Means of Delivery to Neuropathology**	**Comment**
Autopsy & Biopsy tissue (e.g/ Brain / Tonsil) for Prion Protein Analysis	Hand delivery immediately.	Must be received during normal working hours. Contact Rachel Howley 017977766
All other tissue	Sent in 10% neutral buffered formalin indicating volume.	Must be received during normal working hours.

***** Specimens referred out from Beaumont Hospital - the results of these tests are not covered by the scope of Beaumont Hospital Histopathology Department ISO15189 accreditation.

REQUIREMENTS FOR EXTERNAL CENTRES

The responsibility for sending specimens lies with the external centre (Sender). Specimens must be pre-booked with the Neuropathology department (Tel. 8092633) in advance to enable the department to make arrangements should the sample arrive after hours. Ensure that packaging and transportation comply with current UN legislation.

Address the package to:

Neuropathology,
Beaumont Hospital,
Dublin 9

Include the Consignee address and telephone number. Record that the sample is an '**Urgent sample for Neuropathology'**.

Confirm by contacting the Neuropathology department when the sample has been collected.

RESULTS

Muscle Biopsies: Laboratory tests on muscle biopsies are performed on a weekly basis due to the complexity of the techniques involved. Results are generally available in the Neuropathology office on the Friday or Monday following receipt of the sample. Approximate turnaround time of 10 days

CSF Samples for RT-QuIC Analysis: There is an approximate turn around of 10-15 days from receipt of the sample to results.

Nerve Biopsies: Results are available 10 days weeks from specimen receipt.

REQUIREMENTS / FACTORS AFFECTING MUSCLE BIOPSIES

Requirements

All investigations are performed on unfixed frozen tissue. Samples must be delivered to the lab on gauze that is barely dampened with saline as excess causes swelling and separation of fibres. This makes interpretation difficult. A muscle having grade 3/5 on MRC strength scale is best. A fatty muscle ('end-stage' biopsy) may have insufficient fibres for diagnosis.

The department must be informed in advance if a sample is being delivered after hours. Ensure a requisition form is properly completed to include clinical details

Specimen Size

An open biopsy is preferable to a needle biopsy especially if mitochondrial DNA (mtDNA) and protein analysis be required. A biopsy of at least 1.5 x 1x 1cm is ideal. This allows extra samples to be banked in case it is necessary to forward any to an external centre for further studies. Biopsies less than 0.5cu cm are insufficient for this purpose.

CSF SAMPLES FOR RT-QUIC ANALYSIS

Requirements

The sample should be sent to the Neuropathology lab immediately after aspiration for freezing as sub optimal sample storage may give unpredictable results. Alternatively the CSF sample must be frozen at -70°C within 30 minutes of aspiration and transported to the Neuropathology Dept, Beaumont Hospital on dry ice. All samples must be logged in with the Neuropathology Lab prior to sending. All samples must accompany a completed questionnaire (LF-NCJD-CSF Questions), copies of which are available from the Neuropathology Laboratory (Ext. 2633) or are available for download from www.cjd.ie.

The sample volume should be between 1-2mls and be clear and colourless (not blood stained) with a white cell count of <10x10^6/L and have a total protein concentration of <1 g/L1. Red blood cells (>1250 x 10^6/L) inhibit the RT-QuIC response resulting in false negatives. High CSF total protein concentrations of >1.0 g/L and raised white blood cell counts can result in false positives.

Safety Precautions

CSF is considered to be a low risk sample for all types of Prion Disease . Take appropriate precautions when sampling..*[see www.cjd.ie]*

In the event of accidental leakage of the sample please contact the Neuropathology laboratory. There is no immediate hazard to health unless the sample is ingested or injected into the body. Disposable gloves must be worn before attempting to handle the material.

3.6.13.1 Test Request Forms

Test request forms are available to download via the Beaumont Hospital Histopathology department website at http://www.beaumont.ie/index.jsp?p=105&n=349 or by contacting the laboratory.

3.6.13.2 Delivery of Specimens for Analysis

Courier Services Specimens can be delivered via courier directly to the Department of Histopathology.

3.6.13.3 Oral Requests/Additional Requests

Requests for additional tests are made by the Consultant Histopathologists. Further molecular testing is currently being performed by Poundbury Cancer Institute (PCI). Oral/Additional requests to the lab fot these tests must be requested by email to the laboratory. The request form is available on the poundbury institute. The request form must be completed by the requesting clinician, scanned and emailed to the histology office on histo@beaumont.ie where send out of material to PCI will be arranged. Specimens submitted for Histology are retained in the department for 6 weeks and Cytology for 4 weeks. In addition, blocks and slides are retained indefinitely on all specimens processed. Contact the laboratory/Histology office for advice regarding additional examinations required.

3.6.13.4 Test Results

Despite our best efforts, it is possible that an error can occur. If you have concerns about a report please draw it to our attention without delay, and we will investigate immediately.

3.6.13.5 Specimen Referral

When we are unable to provide a request or required follow-on analysis, we will attempt to source a referral laboratory, to which specimens may be sent. We welcome input from interested clinicians in this process. The choice of laboratory is primarily based on quality grounds, with accredited laboratories being chosen preferentially. Other factors such as cost and turnaround times are also considered.

3.6.13.6 Details Required for All Specimens

Regardless of the specimen type, the minimum essential information and minimum criteria that must be supplied **legibly** include:

On the specimen block/slide:
Histopathology block number

On the request form
- Name of patient
- Date of Birth
- Requesting Clinician/Pathologist
- Referring Hospital
- Relevant clinical details
- Specimen type

Note: Please send the pathology report relating to the sample to be tested and give ***as much clinical information on the form / letter*** as possible, as this will be required by the Pathologist when considering interpretations and advice. Specimens will not be accepted without a minimum of three forms of identification on the request form and will be returned to the source of origin to be completed / labelled correctly.
All hazard labels where appropriate must be used for the health and safety of the staff that will be handling the specimen.Turnaround Times for Results (TATs)

The turnaround time of specimens will vary depending on the nature of the specimen and the complexity of the investigations required. The following is an outline of estimated turn around times for different specimen types from time of receipt in the laboratory:

Histopathology IHC or ISH	5-10 days
HER2 IHC testing	10-15 days
Histopathology (referred to external institute)	20 days

Notes
- TATs refer to working days from receipt of specimen until report has been authorised. Time refers to 95% of referrals.
- Any request forms requesting a phoned report will be phoned to the Clinician or his/her Secretary.
- There is no time limit for requesting additional examinations but requests should be made by contacting the laboratory or the Pathologist dealing with the case.
- Urgent specimens will be "fast tracked". From receipt of specimen to interim report status can be performed in two days.

3.6.13.7 Reports

Reports are not available through the laboratory.
- Reports are sent to the Clinical Consultant or GP.
- Authorised Reports are sent to the clinician and additional requests for reports are sent via the Fortimail email encryption System. Please contact the

Histology admin office if you wish to receive reports by an alternative means or email histo@beaumont.ie

- Reports are available by phoning the Histology Office at (01) 8092632/2636/2678/2154/3919.

Neuropathology reports are available by phoning the Neuropathology results office at (01) 8092636/8092672

Renal pathology reports are available by phoning the Rena pathology results office at (01) 8092008.

- Only authorised reports are available through the office/PIPE
- If an interim report, clinical advice or result interpretation is required please contact the Consultant Histopathologist

3.6.14 *Autopsy Services (Post Mortems)*

The Histopathology and Neuropathology Department provide an autopsy service. Autopsies may be performed at the request of the clinical staff responsible for the care of the patient or under the direction of the Coroner.

- .

Written consent from the next of kin on the appropriate post-mortem examination consent form is required for non-Coroner cases (i.e."Hospital" or "House" consent cases) before an autopsy is performed. This consent is the responsibility of the treating physician (LAB 358B6).

In Coroner's cases, including query CJD cases, the Coroner Autopsy Post Mortem Examination Form (LAB 357B) detailing the nature of the procedure and giving the name and number of a family member must be completed by the treating physician. Consent from the next of kin is not an option as the Coroner may, under the law, order a post mortem in certain situations to establish or clarify the cause of death".

3.7 MOLECULAR PATHOLOGY

Molecular Pathology Department

CONTACTING THE DEPARTMENT

Teresa Loftus	Chief Medical Scientist	018092856	molecular@beaumont.ie teresaloftus@beaumont.ie

The Molecular Pathology laboratory provides a molecular pathology diagnostic and consultative service for hospitals throughout Ireland.

The information provided below is a broad guideline to the use of more commonly provided tests. However the Consultant Pathologists and staff are always happy to discuss the service & individual patients in more detail.

3.7.1 ***HISTOMOLECULAR MUTATIONAL ANALYSIS***

The laboratory provides a solid tumour mutation testing service using next generation sequencing (NGS).

The AmpliSeq for Illumina Focus NGS Panel is a targeted resequencing assay for biomarker analysis of 52 genes with known relevance to solid tumours (Table 1). The Focus Panel can simultaneously analyse both DNA and RNA extracted from the same specimen. The Focus Panel is part of a workflow that includes AmpliSeq for Illumina PCR-based library preparation, Illumina sequencing by synthesis (SBS) next-generation sequencing technology and automated analysis.

Starting with 10 ng of DNA and RNA, the panel enables the analysis of genes associated with multiple cancer types, including lung, colon, breast, and melanoma. The low-input requirement allows use with various sample types, including formalin-fixed, paraffin-embedded (FFPE) tissues. As part of the AmpliSeq for Illumina targeted resequencing solution, the Focus Panel enables quick and accurate assessment of genomic variation. The reference genome against which NGS is assessed is Ch37. A similar approach is used for BRCA1&2 germline and somatic analysis. Currently germline only analysis is performed for HER2 negative locally advanced or metastatic breast cancer patients

In conjunction with germline analysis, FFPE material is required for somatic analysis for prostate cancer patients. Homologous Recombination deficiency (HRD) testing is now performed on patients who have ovarian, fallopian tube or primary peritoneal cancer. FFPE tissue is required for the test while it is advised that a blood sample is also sent for MLPA testing.. Sequencing of germline and somatic testing for these tumour types is performed in accordance with National testing guidelines.

3.7.1.1 Relevant gene content

The AmpliSeq for Illumina Focus Panel targets hundreds of mutations across 52 key genes associated with solid tumours (Table 2). Gene content for this panel was selected based on published literature, current guidelines (National Comprehensive Cancer Network [NCCN], Association for Molecular Pathology [AMP], College of American Pathologists [CAP], European Society for Medical Oncology [ESMO], etc.), and relevant clinical trials. A positive control sample is included on each run and the expected variant allele frequency (VAF) is compared to what is detected per run. For each sample the limit of detection is the following: VAF is set to detect a 2% variant allelic frequency (VAF) with at least 1000 reads.

Like most similar panels, this is a hotspot panel and does not cover all exons for all genes. Please contact the laboratory if you have a specific variant to analyse.

3.7.1.2 Colorectal Cancer (CRC) Mutation Panel:

KRAS & NRAS

KRAS & *NRAS* mutation status are critical when evaluating patients with a view to placing them on *EGFR*-targeted monoclonal antibody therapy. The presence of an activating *KRAS* or *NRAS* mutation is generally associated with a lack of response to anti-*EGFR* therapy.

BRAF

Mutations in position p.V600 in *BRAF* have been associated with poor prognosis, especially in patients with metastatic disease. Currently there is insufficient evidence to recommend *BRAF* V600 mutational status as a predictive molecular biomarker for response to anti-*EGFR* therapy but this is a rapidly evolving field.

MICROSATELLITE INSTABILITY (MSI)/MISMATCH REPAIR DEFICIENCY (DMMR)

MSI/dMMR CRC have been shown to have increased sensitivity to immune-oncological (IO) agents such as PD-L1 inhibitors. In addition, while the majority of these tumours are sporadic, MSI/dMMR tumours are more likely to be associated with Lynch syndrome than MSS/MMR intact tumours. MSI and/or immunohistochemistry (IHC) testing is performed on tumour tissue samples to predict likely response to IO agents. In addition, the results of this testing allow for risk stratification in relation to Lynch syndrome (in certain circumstances this will be the primary indication for this testing).

MSI testing is performed initially and, if required, samples will be reflexed for MMR IHC. IHC uses a panel of 4 mismatch protein IHC markers (MLH1, PMS2, MSH2 & MSH6). MSI testing is performed using a multiplex PCR approach for thirteen different microsatellite loci followed by DNA fragment analysis using the SeqStudio™ Genetic Analyser. PCR is carried out using the Applied Biosystems TrueMark™ MSI Assay which can identify microsatellite instability in FFPE samples from multiple tumour tissue types.

3.7.1.3 Lung Cancer Mutation Panel:

EGFR

EGFR mutation status is critical when evaluating patients with a view to placing them on anti-*EGFR* Tyrosine Kinase Inhibitors (TKIs). The presence of a sensitising mutation is associated with a favourable response to treatment with *EGFR* TKIs. The presence of resistance mutations need to be interpreted in the context of any previous treatment regimes.

ERBB2 (HER2) and KRAS G12C

Clinical trials are currently enrolling patients with EBRB2 exon 20 insertions and KRAS variants. The results of these trials will determine whether these treatments become part of standard care for patients with these mutations.

BRAF

BRAF mutation status is critical when evaluating patients with a view to placing them on *BRAF* targeted therapies. The presence of a mutation in codon 600 of *BRAF* is required for treatment with *BRAF* targeted therapies.

ALK

ALK translocation has been associated with response to anti-ALK targeted therapies such as crizotinib. ALK translocations can be assessed by a number of different methodologies. Any of immunohistochemistry, in-situ hybridisation or next-generation sequencing is acceptable methodologies for assessing the presence of translocations.

ROS1

ROS1 translocation has been associated with response to targeted therapies, including crizotinib. ROS1 translocations can be assessed by a number of different methodologies. Any of in-situ hybridisation or next-generation sequencing is acceptable methodologies for assessing the presence of translocations. While antibodies exist for ROS1 immunohistochemistry it is not currently an accepted method for assessing ROS1 translocations.

Note: *ALK* and ROS1 FISH testing is routinely performed on all lung cases

3.7.1.4 Melanoma Mutation Panel:

BRAF

BRAF mutation status is critical when evaluating patients with a view to placing them on *BRAF* targeted therapies. The presence of a mutation in codon 600 of *BRAF* is required for treatment with *BRAF* targeted therapies.

KIT

KIT gene analysis enables the selection of those melanoma patients with KIT variants that will benefit from TKIs.

3.7.1.5 Breast Cancer Mutation Panel:

PIK3CA

PIK3CA mutation status provides information to guide treatment with PIK3CA inhibitors. It may also have a role in predicting response to chemotherapy.

3.7.1.6 BRCA 1 & 2 analysis and Multi Ligation dependant Probe Amplification (MLPA)

This assay detects variants in BRCA1 or BRCA2, helping to identify patients that may benefit from treatment with PARP inhibitor. MLPA analysis also looks for largescale alterations in the BRCA 1 and 2 genes.

There is also an important role in BRCA testing for identifying germline variants that may be responsible for Hereditary Breast and Ovarian Cancer (HBOC). The results of these tests can then be used by clinicians to guide family testing as required. MLPA is performed on patients samples referred for germline testing.

Currently, we offer germline only analysis to HER2 negative locally advanced or metastatic breast cancer patients.

We offer somatic analysis and MLPA for patients with prostate cancer. Germline testing is performed reflexively if a significant variant is detected. Ideally, both a germline (EDTA blood) and a tumour sample (FFPE) will be provided on the same patient.

A separate request from for BRCA analysis is available on the Beaumont internet and intranet.

Service	Specimen type	Specimen Requirements
IHC & ISH	FFPE Blocks/slides	Ensure that sections are mounted on adhesive slides.
Mutational Analysis	FFPE Blocks	A representative block of tumour (resection, biopsy or cytology preparation) should be provided. The analysis can only be performed on specimens where there is adequate tumour material.

MSI	FFPE Blocks	Send representative blocks of tumour and normal tissue and if these are not available then contact us to discuss alternatives. The normal tissue sample need not be from the same specimen. If no normal tissue is available the analysis will be performed using a generic normal control. However, this can affect the interpretation of results.
Germline BRCA1 & 2 (including MLPA)	EDTA blood	Germline only analysis is currently performed for HER2 negative locally advanced or metastatic breast cancer patients. FFPE material will be required is somatic analysis is required for prostate, ovarian, fallopian tube or primary peritoneal cancer.

3.7.1.7 Homologous Recombination Deficiency

This assay gives a Genomic Instability Score (GIS) A score of ≥ 48 is positive. BRCA1 or BRCA2 are also assessed in the same assay and a positive GIS and/or positive for a pathogenic/likely pathogenic BRCA1/2 variant will identify patients that may benefit from treatment with PARP inhibitor. MLPA analysis also looks for largescale alterations in the BRCA 1 and 2 genes This is performed on the blood sample requested to accompany the FFPE block for HRD testing. The request form is available on the internet and intranet. Detailed on the request form is the sampel type required, the FFPE block and an EDTA Blood sample.

3.7.2 ***Neuromolecular Pathology Tests and Requirements:***

Molecular Test performed	**Requirement:**
1p19q Array CGH	10x5micron sections of requested block on unbaked glass slides.
MGMT methylation analysis	10x5micron sections of requested block on unbaked glass slides.
BRAF Fusion qPCR	5x5micron sections of requested block on unbaked glass slides.

IDH 1&2 sequencing analysis	10x5micron sections of requested block on unbaked glass slides.
DNA Methylation profiling	10x5micron sections of requested block on unbaked glass slides.
FusionPlex NGS	10x5micron sections of requested block on unbaked glass slides.
DNA/RNA NGS CNS Tumours (External Referral to SIHMDS-AG)	10x5micron sections of requested block in two separate labelled sterile 1.5mL tubes.

From an external referral centre the samples must arrive with adequate documentation and request form, outlining patient details as detailed in 10 below.

3.7.2.1 Array CGH

Microarray - Comparative Genomic Hybridization (array-CGH) is a molecular cytogenetic method for analysing Copy Number Variations (CNVs) relative to ploidy level in the DNA of a test sample (eg. tumour) compared to a reference control sample. Test (eg. tumour DNA) is labelled in one fluorescent dye (eg. Cy3) while reference (sample with a normal complement of chromosomes) is labelled in another fluorescent dye (eg. Cy5). Fluorescent intensities from both dyes are then scanned and compared to each other for every locus that is represented on the microarray. The final output is a genome-wide graph of copy number gains (gain or amplification) or deletions.

3.7.2.2 MGMT methylation analysis

MGMT in gliomas is a useful predictor of the responsiveness of tumours to alkylating agents. The protein O6-methylguanine-DNA methyltransferase (MGMT) functions to repair alkylated guanine in DNA by transferring the alkyl group at the O-6 position to a cysteine residue in the enzyme. This activity confers a certain chemoresistance to tumour cells and the silencing of *MGMT* through promoter methylation results in a better response to alkylating chemotherapy. In 2005 Hegi *et al*., reported that patients with methylated *MGMT* demonstrated a significant survival advantage with temozolomide treatment in a prospective phase III trial. The assessment of the methylation status of the *MGMT* promoter has therefore become an important genetic marker which is associated with response to alkylating chemotherapy and subsequent increased overall and progression free survival in GBM patients.

Assay Principle

The MGMT assay is based on the pyrosequencing of 8 CpG sites within the MGMT gene modified from Dunn J et al. 2009. The average methylation across the 8 CpG sites is calculated automatically by the PyroMark software. Methylated samples are defined as having an average methylation of $\geq$ 9% methylation in accordance with the clinically significant thresholds reported by Dunn *et al*.

3.7.2.3 BRAF Fusion

Molecular detection of the *BRAF-KIAA1549* fusion gene on chromosome 7q32 has been identified in up to 70% of PAs and is therefore of diagnostic value in these tumours (JONES, D. T. et al, Cancer Research, 2008). A qPCR based method is employed which based on the amplification of the 3 most common fusion partners in pilocytic astrocytoma. Primers specific for each of the exons above are used to amplify the fusion product. Fluorescent probes specific for the fusion junctions are used to detect the amplified product. A positive control (*GAPDH)* is included in each analysis to ensure the quality of tumour RNA. The assay is based on the publication by Tian *et al*. Journal of Molecular Diagnostics, 2011.

3.7.2.4 IDH 1&2 Sequencing

IDH1 mutations have been reported in 60-80% of WHO grade II and III gliomas, and secondary glioblastomas, whilst 2-5% of these tumours have *IDH2* mutations. Approximately 5% of primary GBM harbour *IDH* mutations. *IDH1* mutations have been associated with better clinical outcome; they are suitable predictive markers for adult glioma patients. In terms of diagnosis the presence of an *IDH* mutation can help to distinguish oligodendrogliomas from other tumours such as clear cell ependymomas and dysembryonic neuroepithelial tumours, as well as helping to differentiate between ganglioliomas and diffuse gliomas[2-5]. Mutations affecting *IDH1* and *IDH2* have been shown to be limited to the binding site of the proteins –cDNA positions 394 and 395 in *IDH1* and 514, 515 and 516 in *IDH2*, with mutations thought to be mutually exclusive.

3.7.2.5 DNA Methylation profiling

DNA methylation plays an important and dynamic role in regulating gene expression. It allows cells to become specialized and stably maintain those unique characteristics throughout the life of the organism, suppresses the deleterious expression of viral genes and other non-host DNA elements, and provides a mechanism for response to environmental stimuli. Aberrant DNA methylation (hyper or hypomethylation) and its impact on gene expression have been implicated in many disease processes, including cancer. By providing quantitative methylation measurement at the single-CpG–site level for normal

and formalin-fixed paraffin-embedded (FFPE) samples, this assay offers powerful resolution for understanding epigenetic changes.

Following bisulfite conversion of DNA samples, DNA restoration is carried out using the Infinium HD FFPE Restoration Kit to optimise the processing of DNA previously extracted from FFPE tissue. The Illumina EPIC array Kit is then used to amplify, fragment and hybridise DNA to a beadchip which can be analysed on the Illumina iScan instrument to determine the methylation profile of the sample DNA.

3.7.2.6 FusionPlex NGS

Archer FusionPlex NGS is an RNA-based next generation sequencing panel for the identification of fusions and variants from FFPE tissue including NTRK fusions. The panel consists of 57 genes (shown below) which are assessed under the direction of the reporting neuropathologist. Any of these genes can be assessed upon request by contacting the reporting neuropathologist.

AKT1	*DDR2*	*FGFR2*	*IDH1*	*MAP3K8*	*NTRK3*	*PRKCA*	*TRIM11*
ALK	*DNAJB1*	*FGFR3*	*IDH2*	*MET*	*NUTM1*	*PRKCB*	
AXL	*EGFR*	*GNA11*	*KEAP1*	*MYB*	*PAX8*	*RAF1*	
BRAF	*ERBB2*	*GNAQ*	*KIT*	*MYBL1*	*PDGFRA*	*RET*	
BRD3	*ERBB4*	*GNAS*	*KRAS*	*NRAS*	*PIK3CA*	*ROS1*	
BRD4	*ERG*	*H3F3A*	*LTK*	*NRG1*	*POLD1*	*STK11*	
CTNNB1	*ESR1*	*HIST1H3B*	*MAP2K1*	*NTRK1*	*POLE*	*TMPRSS2*	
CYSLTR2	*FGFR1*	*HRAS*	*MAP3K3*	*NTRK2*	*PPARG*	*TP53*	

3.7.2.7 DNA/RNA NGS for CNS Tumours

CNS tumours are referred to the external laboratory listed below for the purpose of DNA and RNA next generation sequencing. The purpose of this testing is to identify variants and fusions clinically relevant to CNS tumours as either diagnostic markers or indications for treatment.

SIHMDS Acquired Genomics Laboratory,
North Thames Genomic Laboratory Hub,
Level 4 Barclay House,
37 Queen Square,

London
WC1N 3BH

Samples are referred as cut sections in sterile tubes which undergo nucleic acid extraction at the referral site. This material is then sent to the Clinical Genomics laboratory at the Royal Marsden Hospital (also part of the North Thames genomic hub), where it undergoes DNA and RNA NGS using their custom gene/fusion panels. The data output is then returned to SIHMDS-AG for analysis, interpretation and reporting. For more information regarding the NGS panels and genes included, please contact the Molecular Pathology Laboratory, Beaumont Hospital.

3.7.3 *Test Request Forms*

Test request forms are available to download via the Beaumont Hospital Molecular department website at https://www.beaumont.ie/pages/health-A-Z/laboratorypathology | or by contacting the laboratory.

3.7.4 *Delivery of Specimens for Analysis*

Courier Services Specimens can be delivered via courier directly to the Molecular Pathology Department care of Pathology Specimen reception in the Laboratory Directorate addressed to the following.

Molecular Pathology Laboratory
c/o Pathology Specimen Reception
Beaumont Hospital
Beaumont Road
P.O. Box 9063
Dublin 9

3.7.5 *Test Result Queries*

Despite our best efforts, it is possible that an error can occur. If you have concerns about a report please draw it to our attention without delay, and we will investigate immediately.

3.7.6 *Specimen Referral*

When we are unable to provide a request or require follow-on analysis, we will attempt to source a referral laboratory, to which specimens may be sent. We welcome input from interested clinicians in this process. The choice of laboratory

is primarily based on quality grounds, with accredited laboratories being chosen preferentially. Other factors such as cost and turnaround times are also considered.

3.7.7 *Details Required for All Specimens*

Regardless of the specimen type, the minimum essential information and minimum criteria that must be supplied **legibly** include:

On the specimen block/slide:
Histopathology block number

On the blood sample:

Specimen number, name and DOB

On the request form:
- Name of patient
- Date of Birth
- Requesting Clinician/Pathologist
- Referring Hospital
- Relevant clinical details
- Specimen type

Note: Please send the pathology report relating to the sample to be tested and give ***as much clinical information on the form / letter*** as possible, as this will be required by the Pathologist when considering interpretations and advice. Specimens will not be accepted without a minimum of three forms of identification on the request form and will be returned to the source of origin to be completed / labelled correctly.
All hazard labels where appropriate must be used for the health and safety of the staff that will be handling the specimen.

3.7.8 *Turnaround Times for Results (TATs)*

The turnaround time of specimens will vary depending on the nature of the specimen and the complexity of the investigations required. The following is an outline of estimated turn-around times for different specimen types from time of receipt in the laboratory:

Solid tumour mutation analysis..... 15 days

ALK & *ROS1* FISH testing ..... 15 days

Microsatellite Instability analysis (MSI) ..... 20 days

MLH1 Hypermethylation analysis ..... 20 days

BRCA 1&2 testing (including MLPA) ..... 48 days

HRD testing ..... 48 days

Neuromolecular testing (aCGH, MGMT, BRAF fusion, IDHSeq,DMET. NGS) 42 days

Notes

- TATs refer to working days from receipt of specimen until report has been authorised. Time refers to 90% of referrals.
- All reports are emailed by the secretarial staff to requesting clinical and referral site. No results are issued over the phone.
- There is no time limit for requesting additional examinations but requests should be made by emailing the laboratory at molecular@beaumont.ie including an updated request form and stating the patient's name, DOB and original sample number of available.
- Urgent specimens will be "fast tracked" as appropriate.

3.7.9 ***Reports***

Reports are available through the laboratory.

- External reports are sent to those listed on the Molecular Pathology request form or Consent form.
- Reports are normally sent via secure email System from molecular@beaumont.ie
- Only authorised reports are available
- If an interim report, clinical advice or result interpretation is required please contact the Consultant Histopathologist/Neuropathologist.

3.8 NHISSOT

3.8.1 *How to Order Tests*

As per the EFI standard for sample acceptance, all samples received and accepted into the laboratory **must** have the patient's name, date of birth and sample date.

- The Histocompatibility Testing Request and Consent Form **must** have the name, date of birth, requesting clinician/consultant, centre and sample date.
- Samples that do not comply with this EFI standard will be rejected and repeat samples for H&I will be required.

Note: It is the responsibility of the requesting clinician to ensure that the patient has read and understood the permission statement on the consent form. This must be initialled by the patient. For more information on the permission statement please contact the laboratory.

Note: Patients for HLA antibody screening only (HLA antibodies) must meet the same standards of identification. An HLA antibody Screening request form must be completed and can be emailed to crossmatch@beaumont.ie or posted with the samples to the H&I Department. This form is checked against the specimens received and the referring dialysis centre is notified if the samples are unsuitable and are rejected. For Beaumont Hosital patients the information is automatically generated on the specimen label by the Beaumont Hospital Information System

Request and Consent forms for HLA typing and HLA antibody screening are available from the H&I department. Please phone or email crossmatch@beaumont.ie if a request form is required.

3.8.2 ***Repertoire of Tests***

Test	**Specimen Type**	**Minimum Volume**
HLA typing of patients for solid organ transplants	Sodium Citrate	2.9ml
HLA antibody screening for solid organ transplants • Pre transplant [3 monthly when on waiting list] • Post Transplant [As per schedule] • Urgent Request for suspected antibody mediated rejection [AMR]	Serum Clotted	Paeds: 3ml Adult: 5ml
Autocrossmatch [Only upon request from Laboratory]	Serum Clotted Sodium Citrate	5ml 40ml
ABO blood grouping [carried out by Beaumont Blood Transfusion Laboratory]	EDTA Blood	5ml
Potential Living Donor Assessment: These tests are only available via Beaumont Hospital Transplant Co-Ordinators transplantcoordina@beaumont.ie		

3.8.3 *HLA Typing of Patients for Solid Organ Transplantation*

Human Leucocyte Antigen (HLA) type is defined by the presence of different HLA antigens on the cell surface. These antigens enable the immune system to recognise foreign organisms and destroy them.

In solid organ transplantation the major HLA antigens involved are HLA-A, HLA-B, HLA-C, HLA-DR, HLA-DQ and HLA-DP.

Mismatches between donor and recipient HLA type are a major stimulus of the development of donor specific HLA antibodies leading to rejection of the transplanted organ.

Potential recipients are HLA typed by serology and low to medium resolution molecular techniques. These techniques use commercial sera and probes and primer sets selected according to the EFI standards for HLA typing.

Note: Specimens received for HLA typing have DNA isolated and stored, serum stored and a sample sent for blood grouping. When instructed by the Transplant Co-Ordinator, HLA typing and antibody screening will be carried out. A NHISSOT patient report will be issued prior to the patient's appointment at the renal and pancreas transplant clinics.

Samples and tests required prior to a Renal Transplant Clinic appointment

- 1x 2.9ml Sodium Citrate citrated [HLA typing]
- 1x 5ml Serum Clotted sample [HLA Antibody Screening]
- 1x 5ml EDTA sample [ABO Blood Grouping]

Histocompatibility Testing Request and Consent Form [H&I-Form-509]

MOLECULAR (DNA) TYPING

Patient's DNA is isolated from citrated blood and typed by molecular techniques:

1. PCR-SSP (sequence specific primers) – these SSP primers consist of allele and group specific primers that are designed to anneal to specific sequences characteristic of a given allele or group of alleles. Amplified products of DNA are visualised by gel electrophoresis.
2. PCR-SSO (sequence specific oligonucleotides) – After PCR amplification the amplicons are denatured to form single stranded DNA which are added to a microsphere or chip containing specific SSO probes. The amplicons then hybridise to those probes that contain a complementary target sequence. Assignment of a HLA type is based on the reaction patterns associated with published HLA gene sequences.

Note: Luminex® technology for SSO typing allows for multiplex, high throughput testing. This method is therefore particularly suited for the routine HLA typing of multiple DNA samples. SSO typing is not usually done outside of routine hours but it is a backup method if required for donors on call.

Note: DNA samples may be sent to the National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL) for high resolution or sequencing for confirmation of rare HLA types.

Note: Patients are HLA typed on two separate samples taken on two different occasions.

3.8.4 *Antibody Screening*

Antibodies to HLA antigens can develop through pregnancy, transfusion, previous solid organ transplant or cardiac mechanical assist device placement. These antibodies can potentially react with a transplant organ causing graft rejection. All patients for solid organ transplantation are tested for HLA antibodies and these are recorded in the H&I database.

3.8.4.1 ScreeningTests

Luminex Single Antigen

Microbeads coated with purified HLA antigens are used to detect HLA antibodies. The Luminex flow analyser detects the fluorescent emission from the beads and the amount of fluorescence can help to estimate the amount of antibody present.

3.8.4.2 Antibody Analysis and Identifcation

The antibody screening results are analysed and any HLA antibody identified is recorded in the patient's antibody profile as an unacceptable antigen.Therefore, if a donor is identified and a recipient list is generated, any potential recipient with an antibody to the potential donors's HLA antigens are excuded. This significantly reduces the liklihood of a positive crossmatch.

3.8.4.3 Pgen

PGEN - GENERATED OR CALCULATED PRA

Using the H&I database of donor HLA types, we can calculate how many donors are unsuitable due to the presence of HLA antibody. This is referred to as generated PRA - Pgen. The Pgen value can be used as an indicator of how difficult it is to find a compatible graft.

Pgen example:

HLA-A2 is present in approx 25% of Irish donor population. If a recipient has an antibody to HLA-A2, the Pgen is calculated at 25%. This tells us that 25% of donors in the Irish population are unsuitable for this recipient. The more antibodies the patient has, the higher the Pgen.

3.8.4.4 Specimen Requirements for Antibody Screening

Renal/pancreatic patients who are active on the transplant waiting list:

- HLA antibody screening sample (clotted sample) every 90 days
- CAPD and pre-emptive patients can have the samples taken by their local GP and posted to the department -see section 3 for transport requirements
- Following a transfusion (blood products or platelets) a clotted sample is required 14 days post transfusion or as soon as possible thereafter. It is **vital** we receive these samples to monitor a patient for donor specific HLA antibodies.

Note: Routine 3 monthly samples are essential for screening and crossmatching patients on the waiting list. If we do not have a sample less than 90 days old, the patient will not be listed for transplant.

Renal/pancreatic patients who are *not yet* on the transplant waiting list:

- All patients transfused (blood products or platelets) require a clotted sample 14 days post transfusion or as soon as possible thereafter. It is **vital** we receive these samples

Cardiothoracic patients

- Patients identified as positive for HLA antibody – **Sample every month**
- Patients with no identified HLA antibody **– Sample every 3 months**

Due to time constraints in cardiothoracic transplants the following schedule applies to ensure that a sample within an acceptable time frame is available for crossmatch:

- Following a blood transfusion (blood products or platelets), we require a sample at week 2, 3 and 4

Cardiothoracic patients with cardiac mechanical assist device placement – Samples required every month unless otherwise notified.

3.8.5 ***Solid Organ Transplant Pools Work-Up***

3.8.5.1 Renal/Pancreatic Patients

If a patient is approved for the transplant waiting list at the transplant clinic by the Consultant Transplant Surgeon, the Transplant Co-ordinator will contact the laboratory by email to confirm patient's approval for activation.

The patient will appear on the monthly transplant waiting list as 'NHISSOT workup'.

A Patient is 'activated' on the transplant list when all the documentation and immunological work is completed.

A letter is then issued from the H&I Department to the patient, their Consultant Nephrologist and Transplant Co-ordinator to confirm activation on the transplant list.

3.8.5.2 Cardiothoracic Patients

On receipt of a request by email from the Cardiothoracic Transplant Co-ordinator, the patient is HLA typed and tested for HLA antibodies. The report issued will indicate if the patient will need a prospective crossmatch when listed for transplant.

Note: Additional samples are required on patients listed for lung transplant for auto crossmatch. These bloods will be requested by the Cardiothoracic Transplant Co-ordinators when the patient has been approved for the active lung transplant waiting list

3.8.5.3 LIVER PATIENTS

On receipt of a request by email from the Liver Transplant Co-ordinator, a patient is HLA-B typed and ABO blood grouped. A Confirmatory HLA-B type is performed following transplantation.

3.8.6 *Deceased Donor Work-up and Potential Recipient List Generation*

The ODTI Transplant Co-ordinator (Organ Donation and Transplant Ireland) contacts the H&I Department whena potential donor is identified. Donor bloods are sent to the laboratory.

On receipt

- Potential donor is HLA typed
- ABO blood group requested
- Match programme to identify suitable recipients is generated
- Potential recipient list is complied according to agreed criteria andcontains information on the following :

- Priority Patients/Paediatric Patients/Acceptable Mismatched Patients
- Significantly Sensitised Patients (Highly Sensitised) PGen $\geq$ 50
- Favourable Match / Reasonable Match Patients

- Longest Waiting Patients
- HLA incompatiable patients (HLAi)
- Simultaneaous Pancreas and Kidney (SPK) Patients

- The list of immunological suitable recipients is sent to the Consultant Transplant Surgeon and the Renal Transplant Co-ordinator.

3.8.7 *Matchability Scores*

A database of HLA types of previous deceased donors from the Irish population is used to calculate the chance of a patient getting a good match from our donor population.

This data is expressed as a percentage of the population and is made available to the referring clinicians on the monthly transplant waiting lists.

The ODT (Organisation for donation and transplantation in the UK)) define a favourable match as:

- 000, 100, 200, 010, 110, 210 (HLA -A, -B, -DR) – Figures represent donor mismatched antigens
- These grafts show a definite survival advantage in most large studies. Additionally, for patients likely to require a further transplant the degree of sensitisation following a well matched graft is usually less than that following a poorly matched graft.

DEFINING MATCHABILITY

For patients of blood groups A and O:

Score	Reported
5% or under	Low
5.1-7.9%	Medium
8% and over	High

3.8.8 *Living Donor Work-Up*

3.8.8.1 What is living donation?

Living donation is where a living person donates an organ (or part of an organ) for transplantation to another person. Living Donation is only considered after thorough evaluation when the donor is healthy, where the loss of the organ or part of an organ is not deemed to place their longterm health at undue risk, and where the donor understands the process and freely consents to donation.

The following forms must accompany potential donor samples for work-up:

- HLA Request form for 1st Living Donor Workup
- Activation Request form for Living Donor Workup

Samples should be forwarded to the H&I Department, either directly from the transplant co-ordinator, or by post if from abroad. Only 2 potential donors per recipient will be processed by the laboratory at any one time. If either is deemed unsuitable, two further potential donors can be evaluated once a signed activation form has been received.

3.8.8.2 What makes a Living Donor Suitable?

- **Compatible blood group**
  The living donor and recipient blood groups should be compatible.

- **Compatible HLA type**
  HLA antigens are inherited therefore blood relatives are more likely to have similar HLA type. A brother and sister have a one in four chance of having an identical type.

  Those genetically unrelated can also be assessed for living donation. Any potential living donor is HLA typed to ensure that their HLA type is compatible with the potential recipient

  HLA antigens assessed for matching are HLA-A, -B, -C, -DR, -DQ, -DP.

- **Compatible Antibody Profile**

A potential living donor can be eliminated at the first stage of living donor work-up, if the potential recipient has an antibody to the donor's HLA antigens. This antibody can pose a risk to the graft.

3.8.8.3 Summary of stages for Living Donor work-up

Note: Families who wish to donate **must** initially contact the Transplant Co-ordinators. Any samples received into the laboratory **will not be processed** without prior contact with the Transplant Co-ordinators.

Note: Samples required are listed in the repertoire of tests.

First living donor work-up – virtual crossmatch

- Potential donor HLA type and blood group
- Risk assessment issued

Second living donor work-up

2a Workup – virtual crossmatch

- Confirmatory HLA type and blood group
- Risk assessment issued

2b Workup – 'wet' crossmatch

- Confirmatory HLA type and blood group
- Crossmatch using the potential donor cells and recipient sera
- Autocrossmatch of the potential recipient
- Risk assessment issued

Final living donor work-up

- This final stage of the work-up takes place no more than one week pre-transplant
- 'Wet' crossmatch
- Risk assessment issued

3.8.8.4 Risk Assesment

Using antibody screening data, sensitisation history and crossmatch results the immunological risk for a donor/recipient pair is assigned by the Consultant Immunologist

3.8.8.5 Reporting

Reports for the first and second work-up are issued to the Transplant Co-ordinator. The final work-up report is sent to the Consultant Surgeon and Transplant Co-ordinator.

Note: Results cannot be transmitted directly to the potential recipient's Nephrologist or dialysis centre.

3.8.9 *Crossmatching for Solid Organ Transplantation*

Transplanting an organ into a patient who has circulating antibodies to donor HLA antigens could result in hyperacute rejection and immediate organ loss.

The crossmatch prior to transplantation will detect any donor specific antibodies and thus prevent hyperacute rejection, greatly reduce acute rejection and the risk of graft loss.

A positive crossmatch is not necessarily a bar to transplant. A patient's sensitisation history and antibody screening profile is also taken into account for the risk assessment.

The crossmatch uses a selection of both current and historic sera:

- Detection of historic antibody can be an indication of prior sensitisation (exposure) of the patient to donor antigen and the presence of memory T and B cells. This can lead to a rapid immunological response if challenged with the same antigen.
- Detection of current antibody, if directed against HLA antigens present on the graft, can cause hyperacute rejection of the organ, or an acute rejection.
- A day of transplant (DoTX) sample is required for crossmatch where a patient has had a recent sensitising event, graft in situ, failed graft within 12 months or borderline donor specific reactivity against donor HLA antigen.

Please note:

- **It must be stressed that all crossmatch interpretation should be done in consultation with the H&I staff and the Consultant Immunologist or designated Senior Medical Scientist**

3.8.9.1 Crossmatch tests

The crossmatch techniques used in the laboratory are flow cytometry and complement dependent cytotoxicity (CDC). They can detect both HLA class I and class II donor specific antibodies.

3.8.9.2 Virtual crossmatching

In limited circumstances a patient may be suitable for transplant without a prospective crossmatch due to theatre time constraints.

Renal and Cardiothoracic patients who fulfil **certain** criteria are suitable for consideration for virtual crossmatch in discussion with the transplant team.

Note: If the patient has had transfusion/pregnancies or has a failing transplant they may not be suitable for a virtual crossmatch.

All patients transplanted using virtual crossmatching require a flow crossmatch retrospectively in accordance with EFI standards

3.8.9.3 Autocrossmatch

This assay involves a crossmatch of the recipient's lymphocytes with autologous (own) serum. This can identify auto-reactive antibodies.

Knowledge of the presence and type of autoantibody can be helpful in interpreting positive crossmatches.

- Samples for autocrossmatches should reach the laboratory within 24 hours
- Please contact the H&I deparment to book in the samples for autocrossmatch

3.8.10 ***Post Transplant Monitoring***

Antibody testing post transplant can detect the presence of donor specific antibodies (DSA) that may develop clinical and sub-clinical. Screening for DSA post transplant and early intervention could prevent graft rejection and improve graft outcomes.

3.8.10.1 Graft Rejection

Transplant rejection occurs when a transplanted organ is rejected by the recipient's immune system, which destroys the transplanted tissue.

Rejection of solid organ grafts is conventionally classified as hyperacute, acute and chronic.

- Hyperacute rejection causes rapid activation of complement, platelet aggregation, thrombosis and ischaemic necrosis. It is mediated by pre-formed antibodies that react with many different antigens expressed on the transplanted organ. The result of hyperacute rejection is rapid destruction of the transplanted organ which must be removed immediately to prevent a severe inflammatory response.

- Acute rejection usually occurs early following transplantation (typically within 4 weeks). It is a classical cell-mediated immune response involving presentation of foreign antigens to T cells by antigen presenting cells, proliferation and activation of T cell clones and destruction of the graft by cytoxic T cells.

- Chronic rejection occurs later (typically months or years after transplantation). It leads to a gradual deterioration of renal function with biopsy appearances of fibrous intimal thickening, interstitial fibrosis and tubular atrophy. The most consistent predisposing factor is that of previous episodes of acute rejection.

3.8.10.2 Renal/Pancreatic Patients

Specimen Requirements

- Clotted sample weekly for the first month.
- Clotted sample monthly for the next two months.
- Clotted sample should then be sent at 6, 9 and 12 months post transplant.
- Clotted sample should then be sent on each subsequent anniversary of the transplant.
- Clotted sample should be sent when clinically indicated - at biopsy, when there are concerns regarding graft function or a change to the immunosuppressive regimen.

Note: Samples are tested according to their post transplant testing schedule and a post transplant report sent to the requesting Clinican.

Note: Please email posttransplant@beaumont.ie or phone the H&I department when screening is clinically indicated. Please include any clinical indicators such as creatinine levels and a contact number for urgent results. If antibody mediated rejection is suspected, this should be discussed with a Senior Medical Scientist who will contact the Consultant Immunologist with patient clinical details.

3.8.10.3 Cardiothoracic Patients

- Clotted sample weekly for the first month.
- Clotted sample monthly for the next two months.
- Clotted sample should then be sent at 6, 9 and 12 months post transplant.
- Clotted sample should then be sent on each subsequent anniversary of the transplant.
- Clotted sample should be sent when clinically indicated - at biopsy, when there are concerns regarding graft function or a change to the immunosuppressive regimen.

Note: Samples are tested according to their post transplant testing schedule and a post transplant report sent to the requesting Clinican.

3.8.10.4 Liver Patients

Graft versus Host Disease (GvHD) can pose significant risks to liver transplant patients. If GVHD is suspected, please contact the department with clinical details by phone or email posttransplantlab@beaumont.ie.

3.8.11 *HLA Typing for Partners of Recipients*

During pregnancy or birth the baby's cells can cross the placenta and expose the mother to paternal's HLA antigens.

Occasionally this can induce an immune response and the mother can subsequently develop HLA antibodies. These only become clinically relevant if the mother requires a transplant.

Paternal HLA typing is helpful to identify the antigens the mother may have been exposed to.This can aid antibody identification and help to build up an antibody profile on a patient.

3.8.12 *ABO blood group typing*

Beaumont Hospital Blood Transfusion Department carries out all donor and recipient blood grouping on request.

3.8.13 *Out of Hours services (On-Call)*

The H&I department provides an out-of-hours service for solid organ transplantation.
The services available are:

- HLA typing and crossmatching all potential donors for solid organ transplantation.
- Urgent antibody screening for cardiothoracic patients.
- Urgent antibody screening for post transplant rejection episodes.

Note:

- All requests for urgent antibody screening **out of hours must be** done in consultation with the Medical Scientist on-call
- For clinical advice **out-of-hours**, the Consultant Immunologist on-call can be contacted through the switch board.

During normal working hours urgent requests must be discussed with a Senior Medical Scientist or e-mailed to one of following e-mail addresses:

- posttransplant@beaumont.ie
- transplantlab@beaumont.ie

3.8.14 *Data Protection Act and freedom of information*

The H&I computer database is used to maintain patient data. A back-up paper copy is also retained. All data is stored in compliance with General Data Protection Regulation. .

Data can include the following:

- Name.
- Hospital chart numbers.
- Date of birth.
- Address.
- Phone number(s).
- Email address.
- Dates of dialysis.
- Type of dialysis.
- Dates of transfusions/transplants.
- Dates of sera samples received.
- Antibody screening information and results.
- HLA type.
- Molecular DNA typing information.
- Blood group.
- Number of pregnancies.
- Related donor information, where patients have been transplanted.
- Related family information, where a family study has been performed.Partner's HLA type where applicable.

3.8.15 *Reports Issued/Expected Turn Around Times (TAT)*

The following table lists the turn-around-times for H&I reports

TESTS	**TURN AROUND TIMES**
HLA typing for Solid Organ Transplant	3 weeks – *Urgent service available*
HLA Antibody Screening	2-4 weeks – *Urgent service available*
HLA Antibody Screening HLA typing requests for emergency transplantation	Same day service if requested
NHISSOT Patient report for the transplant clinic	4 weeks from request to issuing a report
Transplant pool work-up	2-6 weeks
Deceased donor work-up	6 hours
Potential donor recipient list	8 hours
Crossmatching for renal transplants	6 hours
Crossmatching for pancreatic/cardiothoracic transplants.	6.5 hours for processing a single donor with a standard workup of a maximum

TESTS	**TURN AROUND TIMES**
Time taken from receipt of bloods in H&I laboratory and potential names for crossmatch given to the on-call scientist	4 names. This time may change due to additional names or for technical issues. Users will be informed
Living donor work-up	1st work-up 4 weeks 2nd work-up 3 weeks Final work-up 48 hours
Autocrossmatch	2-3 days
Post Transplant Monitoring Non Urgent. *If contacted by the referring clinician for a more timely report the sample can be set on the next screen*. Further testing/ typing	2 weeks. 3 weeks
Post Transplant monitoring - Urgent antibody screening request for possible graft rejection *Requires discussion with Antibody Screening Senior. The level of urgency must be stated by the referring clinician*.	Same day service available if required, otherwise the sample is set on the next screen.
HLA typing for disease association	4 weeks
HLA typing for BMT/HSCT	2 weeks (unless awaiting further potential donors from overseas)
HLA typing for B57	4 weeks
HLA typing for partners	3 weeks
ABO Blood Grouping	2-3 hours

3.8.16 ***Abbreviations on H&I Reports and Printouts***

DIALYSIS CENTRES

AM Antrim Area Hospital
BE Beacon Clinic Sandyford, Dublin
BD Beacon Clinic Drogheda, Dublin
BT Beacon Clinic Tallaght, Dublin
BF Belfast City Hospital
BH Beaumont Hospital, Dublin
CA Cavan General Hospital
CB Mayo General Hospital, Castlebar
CO Cork University Hospital
CR Our Lady's Hospital for Sick Children, Crumlin, Dublin
EU Patients dialysing in hospitals overseas within the EU
FR Fresensius Limerick
GA Galway University Hospital
GW Wellstone Clinic, Galway

JA St. James's Hospital, Dublin
KK Wellstone Clinic, Kilkenny
LE Letterkenny General Hospital
LI Limerick University Hospital
MA Mater Misericordiae University Hospital, Dublin
MK Merlin Park Hospital, Galway
MW Midlands Wellstone Clinic
NC Northern Cross Clinic, Dublin
NE Daisy Hill Hospital, Newry
OM Omagh General Hospital
SL Sligo General Hospital
SV St. Vincent's University Hospital, Dublin
TA Tallaght Hospital (AMNCH), Dublin
TE Children's University Hospital, Temple Street, Dublin
TR University Hospital Kerry
TU Tullamore General Hospital
WA University Hospital Waterford
WW Wexford Wellstone

3.8.17 ***RENAL/PANCREATIC TRANSPLANT POOL PRINTOUT***

ABBREVIATIONS

Age	Age in years
Blood Grp	Blood Group
BMI	Body Mass Index
Compno	H&I computer number
Cyto Due Date	Date a sample for antibody screening is required
Days Sample	Number of days sample is due. Minus number indicates the number of days the sample is outstanding.
Dial Cen	Dialysis centre
Dial	Dialysis type: P = CAPD/CCPD H =Haemodialysis
KG	Weight in kilos
Match %	Matchability score
PGen	Generated PRA PGen4: calculated on 4 HLA loci PGen10: calculated on 10 HLA loci
Prev Tx	Previous transplant(s): Number is printed
Ref Hosp	Referring Hospital
Urgent	Highest urgency- ABO compatible kidney
Wait	Length of time on transplant pool in months

3.8.17.1 ***Crossmatch Codes***

Potential deceased donor offer list
DoTx Day of transplant sample required

Std Standard – sample(s) available in the laboratory and suitable for crossmatch

VXM Suitable for virtual crossmatch