Flow of responsibilities

**Step 1. The requesting clinician ensures:**
- The correct patient
- At the correct time
- Requesting the appropriate analysis
- Notes the patient circumstances appropriate to the analysis, e.g. fasting, prone or sitting etc.

**Step 2. The phlebotomist, nurse or clinician collecting the specimen checks and ensures** (e.g. using patient wrist band double checked against the request form and specimen label):
- The correct patient and correct time
- The analysis ordered
- The correct specimen taken
- Correct & complete labelling
- Safe handling & waste disposal

**Step 3. The ward, theatre, department or surgery ensures:**
- Safe handling & Inf. Control
- Secure and appropriate storage
- Timely onward transfer **

**Step 4. The person undertaking logistics stage (e.g. porter, transport, courier) ensures:**
- Reasonable scheduling for transit
- Safe handling
- Secure and appropriate carriage
- Meeting H&S/ADR regs. etc.
- Timely transfer to laboratory

**Step 5. The laboratory checks and ensures:**
- The correct patient
- The correct specimen received
- The correct result/advice given

**Step 6. The responsible clinician checks and ensures:**
- Receipt of the result/advice
- The correct patient
- The correct therapeutic action
- The validity of the patient record

NB: The laboratory may reject an inappropriately collected, or labelled specimen, or inappropriate specimen type
This Manual outlines guidance on laboratory services and the requirements and guidelines the safe and acceptable pre-analytical collection and handling of clinical specimens destined for analysis in the Clinical Laboratory Services. Clinical Immunology specimens are not within the scope of this manual.

References (e.g. ISO standard):
- ISO15189: 2012 Standards 5.4
- EC4 Essential Criteria 7.7 (Sample Transport & Handling)
- Safe working and the prevention of infection in clinical laboratories and similar facilities (Health Services Advisory Committee HSE Books 2003) ISBN 0 7176 25133
- British Standard BS EN 14820:2004 Single-use containers for human venous blood specimen collection
- British Standard BS 5213:1975 Specification for medical specimen containers for microbiology
- The Approved List of Biological Agents (Advisory Committee on Dangerous Pathogens). downloadable from [http://www.hse.gov.uk/pubns/misc208.pdf](http://www.hse.gov.uk/pubns/misc208.pdf)
- The Classification, Packing and Labelling of Dangerous Substances Regulations 1984 SI 1984 No 1244 HMSO ISBN 0 11 047244 6
- Human Tissue Authority, Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Licence Number 11100
- Human Tissue Authority, Post-mortem examination Licence Number 12329
- Blood Safety Quality Regulations 2005 (BSQR)
- Medicines and Healthcare Products Regulatory Agency (MHRA)

Responsibilities:
- Initial acceptance/rejection of samples and requests based on clear guidance noted in a Laboratory Procedure – all staff receiving specimens.
- Review for acceptance of equivocal or unrepeatable material referred up by Specimen Reception staff – designated staff.

Related Documentation:
- All Trust Policies & Procedures
- UHB Trust Blood Transfusion Policy & Procedures
- UHB Infection Prevention & Control Policy
- UHB Information Security Policy
- PUB_003 Guide to Specimen Containers for Pathology Requests (except Cellular Pathology)
- PUB_005 Guidance on the Carriage of Laboratory Specimens for Porters, Drivers, Couriers.
- PUB 048 Guidance Notes on Transport of Clinical Specimens by Road
- PUB_006 Guidance for Laboratory Visitors
- Trust booklet “Information about post-mortem examination for relatives”

Key Changes since last Version:
- Addition of patient information leaflets for collection of urine and faecal samples.
- Confirmations that Bethesda Assay is now UKAS Accredited.
- Confirmation that calprotectin, Lyso Gb3 analysis, Haemoglobinopathy screen is not currently included in our UKAS accreditation scope.
- Haemoglobinopathy screen is now performed by Heartlands.
- Addition of add-on tests section for Haematology.
- Vacant posts filled:
  - Cellular Pathology Manager: Martin Collard
  - Haematology Manager: Nicola Jones.
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Definitions

Chain of Custody
Each sequential participant in the act of collecting and transporting a specimen from the patient to the laboratory. The effective documentation of this chain provides a valid audit trail for the specimen for accreditation or litigation purposes.

Clinical Laboratory
In the context of this manual - ‘Clinical Laboratory Services’, or Division 4 Group A.

Phlebotomy
The removal of blood from a vein using a needle, also known as venepuncture (although this may also indicate part of the process to inject into a vein) and sometimes venesection or venotomy (although these latter may also indicate surgical incision into a vein). Phlebotomy may be used to obtain blood for the purposes of diagnostic tests or as a treatment in itself for certain conditions.

PID
Patient Identification.

Urgent
Requiring immediate action or attention. It is important that if a specimen requires urgent analysis that this status is effectively conveyed to the participants in the ‘chain of custody’ from specimen collection to the laboratory. The abuse or overuse of this status overloads the process and devalues the term when there is a truly urgent situation; it should not be used lightly.

Specimen and sample are often used interchangeably. However:

- **Specimen** usually refers to an item to be characterized chemically or biologically.
- **Sample** can refer to a finite portion of that specimen which is taken for analysis.

For simplicity the term specimen is used here to indicate the discrete biological material of whatever size sent to the laboratory for analysis.

Specimen Collection
Producing a specimen from a patient for laboratory analysis.

Specimen Handling
The process of labelling, manipulating and storing of a collected patient’s specimen or packaging prior to transportation.

Specimen Transportation
The process of transporting the collected, labelled, and packaged patient’s specimen to the Clinical Laboratory Services for analysis.

The Trust
Where the ‘Trust’ is mentioned in this publication it refers to the University Hospitals Birmingham NHS Foundation Trust. Queen Elizabeth Hospital Birmingham may be abbreviated to QEHB, Queen Elizabeth Hospital to QEH.
1. Foreword

Dear Colleague,

This handbook has been prepared by Clinical Laboratory Services (CLS) of the University Hospitals Birmingham NHS Foundation Trust. It combines the information from the previous handbooks issued separately to GPs and to the Trust. You will find details within of the various clinical pathology services provided, including help with contacts, phlebotomy and specimen collection, logistical arrangements, tests available and reporting of results.

Each request accepted by our laboratories for examination(s) shall be considered an agreement and as such must fulfil all UKAS requirements for service agreements. As such only those examination procedures which we have the skills and expertise necessary to perform the testing correctly will be carried out by our laboratories. All staff carrying out the testing must therefore be deemed competent before doing so.

In the majority of cases our procedures are UKAS accredited, where they are not this is made clear on the final report. Users will be notified of any changes to test accreditation status.

A link to The Guide to Specimen Containers for Pathology Requests is available in Appendix 5, although some guidance is given here on suitable specimen containers there may be specific exceptions so please refer to this Guide for current requirements. Each laboratory section has details about the service offered by that laboratory and some specific requirements depending on the assay/examination requested. There is also general advice about requesting and documentation, collecting and transporting of a clinical specimen for analysis to the laboratories and reporting of the result; this is contained in the series of Appendices at the end of this document. Please ensure that you understand the process and your specific responsibilities in this regard.

Clinical Laboratory Services work to all Trust Polices regarding the protection of personal information. Trust Policy and Procedures have been written to ensure compliance with the Data Protection Act 1998.

We welcome any comments on the service provided. This will enhance our programme of continuous review and upgrade of laboratory work to reflect changing clinical practice. Please direct any comments in writing to myself at the address below.

I hope you will find this information of value and trust that it will enable you to optimise your use of the services available.

Paula Hytch
Group Manager Clinical Laboratory Services
Clinical Laboratory Services Level -1
University Hospitals Birmingham NHS Foundation Trust.

Foreword
2. Introduction

Clinical Laboratory Services provides a high quality, cost-effective service to the University Hospital Birmingham NHS Foundation Trust, GPs and community hospitals mainly within the South Birmingham PCT and is a referral centre for specialist services for other local; national Trusts and international users. It is continually upgrading the test repertoire offered to reflect medical developments and user requirements. The laboratory services currently provided include:

- Department of Clinical Biochemistry
- Department of Laboratory Haematology (Including Transfusion)
- Department of Clinical Microbiology (Including Virology)
- Department of Cellular Pathology (Including Mortuary)
- Department of Molecular Pathology

All laboratories are staffed by qualified and experienced medical, scientific and technical personnel.

Please note that a Clinical Immunology service is provided by the Immunology Department of the University of Birmingham. This is based in the University Medical School and is not within the organisational structure of Clinical Laboratory Services.

2.1. Quality Management

Clinical Biochemistry, Laboratory Haematology, Blood Bank, Molecular Pathology and Clinical Microbiology laboratories are accreditation by UKAS against ISO15189:2012. The Cellular Pathology laboratory is currently working towards accreditation against ISO15189:2012.

Each of the laboratory departments runs a comprehensive quality management system, participating in all relevant National Quality Assessment Schemes, and operates a schedule of internal quality audit, corrective action and quality improvement.

The laboratories are recognised for training by the Health and Care Professions Council, the Royal College of Pathologists, the Association for Clinical Biochemistry and the Institute of Biomedical Sciences.

All work is performed with due care for the health and safety of staff and patients and with proper regard for the environment. The laboratories comply with comprehensive safety procedures and Control of Substances Hazardous to Health (COSHH) regulations.

2.2. User Satisfaction

As part of our quality management system and to ensure that we are meeting the needs of our users, we are always keen to receive any comments you may have regarding the quality of the service we provide and would welcome any suggestions on ways in which we might be able to improve the service. We also take complaints about our work, staff and levels of service very seriously. If you are not satisfied, please contact the Quality Manager to register a complaint. Details of the complaints procedure will be given to you at this time.
Clinical Laboratory Services Queen Elizabeth Hospital

Please feel free to email any of the Quality Team with any suggestions labsquality@uhb.nhs.uk or the individual department representatives.

**Group Quality Manager**  Veronica.Ridley@uhb.nhs.uk

**Individual laboratory Quality Leads**
- Clinical Chemistry  Estelle.Williams@uhb.nhs.uk
- Haematology  David.Innes@uhb.nhs.uk
- Transfusion  Paul.Whittaker@uhb.nhs.uk
- Microbiology  Verity.Pursglove@uhb.nhs.uk
- Cellular Pathology  Helen.Stokes@uhb.nhs.uk
- Molecular Pathology  Helen.Stokes@uhb.nhs.uk

2.3. *Patient Consent and Data Protection*

The Trust has many policies and procedures which the Clinical Laboratory Services (CLS) complies with including a Data Protection and Confidentiality Policy which ensures that the Trust complies with the Data Protection Act 1998 (DPA), the Caldicott principles and the duty of confidentiality in relation to all personal data held.

The Trust is committed to protecting the rights and privacy of individuals (including staff, patients, contractors, members of the public and any other groups) in accordance with the DPA to which it is subject as a controller and processor of personal data (data controller).

A copy of the Data Protection and Confidentiality Policy is available through the Trust on request under the Freedom of Information Act 2000.

There is also a Trust policy and procedure for Consent to Examination or Treatment and these are also available through the Trust on request under the Freedom of Information Act 2000.
3. Key Information

3.1. Current Locations of Departments

<table>
<thead>
<tr>
<th>Department</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Specimen Reception</td>
<td>Clinical Laboratory Services, Level-1</td>
</tr>
<tr>
<td>Clinical Biochemistry</td>
<td>Queen Elizabeth Hospital Birmingham Mindelsohn Way, Edgbaston, Birmingham, B15 2GW</td>
</tr>
<tr>
<td>Laboratory Haematology/Transfusion</td>
<td>Tel: 0121 627 2000</td>
</tr>
<tr>
<td>Clinical Microbiology</td>
<td></td>
</tr>
<tr>
<td>Microbiology Specimen Reception</td>
<td></td>
</tr>
<tr>
<td>Infection Control Nurses</td>
<td></td>
</tr>
<tr>
<td>Cellular / Molecular Pathology</td>
<td></td>
</tr>
<tr>
<td>Mortuary</td>
<td></td>
</tr>
</tbody>
</table>

3.2. Opening Hours

Please see individual department sections for opening hours and arrangements for urgent samples and services available outside of core hours.

3.3. Results

All results are electronically transferred to the PICS and Brower systems. The results of urgent requests may be notified to the requesting source if there are abnormal results that exceed critical limits.

3.4. General Contact Numbers

<table>
<thead>
<tr>
<th>Department</th>
<th>Contact Details</th>
<th>Out of Core Hours – for timings see individual department sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>All results and general enquiries for Biochemistry, Haematology &amp; Microbiology</td>
<td>0121 371 5999</td>
<td></td>
</tr>
<tr>
<td>All general enquiries for Cellular Pathology, Molecular Pathology</td>
<td>0121 371 3326</td>
<td></td>
</tr>
<tr>
<td>Biochemistry Urgent Requests</td>
<td>0121 371 5985</td>
<td>Bleep 2312</td>
</tr>
<tr>
<td>Haematology Urgent Requests</td>
<td>0121 371 5986</td>
<td>Bleep 1376</td>
</tr>
<tr>
<td>Blood Bank All Enquiries</td>
<td>0121 371 3297/8</td>
<td>Bleep 1376</td>
</tr>
<tr>
<td>Microbiology Out-of-hours</td>
<td></td>
<td>Radiopager/mobile telephone via hospital switchboard (a rota operates for this service) (This service is provided by staff from home)</td>
</tr>
</tbody>
</table>
### 4. Senior Staff Contacts

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director of Pathology Services</td>
<td>Dr Alan Jones</td>
<td>0121 371 5959</td>
</tr>
<tr>
<td>Group Manager</td>
<td>Paula Hytch</td>
<td>0121 371 5958</td>
</tr>
<tr>
<td>Group Quality Manager</td>
<td>Veronica Ridley</td>
<td>0121 371 5962</td>
</tr>
<tr>
<td>Group IT Manager</td>
<td>Colin Mason</td>
<td>0121 371 5956</td>
</tr>
<tr>
<td>Clinical Biochemistry, Clinical Lead Consultant</td>
<td>Dr Rachel Webster</td>
<td>0121 371 5997</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Helen Peat</td>
<td>0121 371 5963</td>
</tr>
<tr>
<td>Microbiology, Clinical Lead Consultant</td>
<td>Dr Miruna David</td>
<td>0121 371 6176</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Paul Arrowsmith</td>
<td>0121 371 5977</td>
</tr>
<tr>
<td>Haematology, Clinical Lead Consultants</td>
<td>Dr Percy – General Haematology &amp; Coagulation</td>
<td>0121 371 4981</td>
</tr>
<tr>
<td></td>
<td>Dr Morton – General Haematology &amp; Transfusion</td>
<td>0121 371 5725</td>
</tr>
<tr>
<td></td>
<td>Dr Clark – General Haematology</td>
<td>0121 414 6498</td>
</tr>
<tr>
<td></td>
<td>Dr Lowe – General Haematology &amp; Coagulation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laboratory Manager</td>
<td>Helen Peat</td>
</tr>
<tr>
<td>Cellular Pathology, Clinical Lead Consultant</td>
<td>Dr Shalini Chaudhri</td>
<td>0121 371 3347</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Martin Collard</td>
<td>0121 371 5960</td>
</tr>
<tr>
<td>Molecular Pathology, Clinical Lead Consultant</td>
<td>Dr Phillipe Taniere</td>
<td>0121 371 3350</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Martin Collard</td>
<td>0121 371 3343</td>
</tr>
<tr>
<td>Division A</td>
<td>Paul Jordan</td>
<td>0121 371 2789</td>
</tr>
<tr>
<td>Divisional Director</td>
<td>Yma Choudhury</td>
<td>0121 371 2787</td>
</tr>
</tbody>
</table>

There is a more comprehensive list of senior staff and their telephone numbers in the departmental sections (below). Please note the instructions given by each of the departments with respect to clinical advice as opposed to technical queries.

The following is now a corporate responsibility and no longer part of the Laboratory management structure (from 2008):

| Infection Control, Consultant responsible for Infection Control: | Dr Elisabeth Holden | 0121 371 6175 |
| Infection Control Clinical Scientist:                           | Mark Garvey          | 0121 371 3785 |
5. Clinical Biochemistry

5.1. Introduction
Clinical Biochemistry is a UKAS accredited clinical laboratory service that uses biochemical analysis to provide results used for the diagnosis and monitoring of disease. The laboratory is automated for the majority of tests but some testing requires more complex apparatus and manual techniques.

The Department actively promotes and supports Point-of-Care Testing (POCT) managing blood gas analysers across multiple hospital sites, blood glucose, ketone and INR testing meters and provides an on-site laboratory service in the Diabetes Centre.

The Department provides a comprehensive clinical biochemistry service to the Trust. In addition, a full service is provided to the South Birmingham community Trust, the Royal Orthopaedic Hospital and GP practices. The Department also provides specialist services including endocrinology to other hospitals in Birmingham, the West Midlands Region, the rest of the UK and the Republic of Ireland.

The Department provides a clinical advisory service, which includes the clinical interpretation of results, advice on the appropriate selection of laboratory tests and investigation and monitoring strategies for individual patients and for specific diseases. There is close liaison with clinicians and other healthcare personnel within the Trust, the Community and in other hospitals to ensure best practice in the use of the Clinical Biochemistry Service, for clinical governance and clinical audit purposes and ensure that the Clinical Biochemistry Service is an integrated component of patient care pathways.

This section outlines the use of the laboratory and many of the tests available. It is not completely comprehensive and advice should be sought if there are queries, from the Duty Biochemist within hours or the consultant on-call rota out-of-hours (contact the on-call Biomedical Scientist first).

5.2. Laboratory Hours
The department provides a full service from 09.00 am to 17.30hrs on Monday to Friday (core hours). A more limited out-of-hours service is available outside of these core hours. Not all tests are available outside the core hours, for further information please contact the lab directly.

5.3. Urgent Samples
Specimens requiring immediate attention on receipt should be identified by obtaining an urgent number from extension 15985. Only specimens requiring urgent analysis where there is a need for clinical management decisions that can only be taken by biochemical investigation should use this service. Many of the urgent management decisions can be taken using results supplied by the Point-of-Care instruments available in the emergency department and intensive care units.
Prior to sending any urgent specimens, you must telephone the laboratory before dispatch of the specimen so that you can be given an urgent specimen identification number. This urgent specimen number must be noted in the designated box on the request form to provide easy identification for the laboratory staff on arrival within the department, as must the correct location of the patient. This will facilitate its processing and ensure that the results are returned directly to the requesting source. It is important to do this in order that we identify urgent specimens amongst the 4,000 requests we receive daily. You must do this at any time of day or night in order to facilitate fast processing.

The following wards are seen as priority locations:

<table>
<thead>
<tr>
<th>Ward</th>
<th>Turnaround time (from receipt of specimen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED, CDU, WACT, WACB, WACE, WAST W620 QCHEMO</td>
<td>1 hour</td>
</tr>
<tr>
<td>WCCA, WCCB, WCCC, WCCD, WADM, WAMB, Oncology, W622, QCCU, QSSU, St Mary's Hospice and GP samples marked urgent.</td>
<td></td>
</tr>
</tbody>
</table>

Please note that at times of high demand or if there are instrument malfunctions we may not be able to achieve this turnaround time.

Arrangements for urgent endocrine tests, e.g. neonatal 17-hydroxyprogesterone, should be made via the Duty Biochemist on extension 16543 during normal working hours.

For pregnancy testing, a urine test is the first line investigation and will normally be done as a Point-of-Care Test (POCT) in accordance with Trust policy. The Microbiology Department is able to offer this test during normal laboratory hours, if POCT is not available. For a patient with suspected ectopic pregnancy who is being/has been referred, Birmingham Women’s Hospital have a restricted service for serum hCG on weekend early mornings but do not have an out-of-hours service. Any arrangements for a serum hCG in this situation will be made by Birmingham Women’s Hospital clinical staff.

Samples sent for serum hCG in QEH will be assumed to be for cancer monitoring as the hCG assay is not validated for pregnancy testing and we have no reference intervals for any of the trimesters of pregnancy.
5.4. Useful Contact Numbers

<table>
<thead>
<tr>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duty Biochemist</td>
<td>Ext 16543</td>
</tr>
<tr>
<td>Specimen Enquires</td>
<td>Ext 15999</td>
</tr>
<tr>
<td>Point-of-care</td>
<td>Bleep 1189 Ext 15976</td>
</tr>
<tr>
<td>Urgent Requests</td>
<td></td>
</tr>
<tr>
<td>GPs</td>
<td>0121 3715985</td>
</tr>
<tr>
<td>Hospital inpatients or out patients</td>
<td>Ext 15985</td>
</tr>
</tbody>
</table>

For a more extensive list of telephone numbers please consult the guide at the end of the Clinical Biochemistry section.
5.5. Specimens

5.5.1. Blood
In general the following blood collection bottles are required (colour reference is Greiner Vacuette® system only, other systems may vary). The collection tube required by test is given in section 5.9. Please contact the laboratory if you are unsure of the correct collection tube.

<table>
<thead>
<tr>
<th>For all analyses not described below</th>
<th>Serum - Yellow Top tube containing gel (red top serum tubes can also be accepted for many analytes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Fluoride oxalate plasma - Grey Top tube</td>
</tr>
<tr>
<td>hCG</td>
<td>Serum – Red or yellow top tube as a separate tube</td>
</tr>
<tr>
<td>Ciclosporin &amp; Tacrolimus</td>
<td>EDTA plasma - Purple Top tube</td>
</tr>
<tr>
<td>PTH</td>
<td>EDTA plasma - Purple Top tube</td>
</tr>
<tr>
<td>Trace elements</td>
<td>Serum – Navy blue top trace elements tube</td>
</tr>
</tbody>
</table>

For all tubes please mix thoroughly.

5.5.2. Urine Collections
Bottles for 24 hour urine collections can be obtained from the Clinical Biochemistry Department. Different preservatives are required for different analyses. Please ensure that ward staff/portering staff/patients who are sent to collect containers know which analyses will be required. Please ensure that patient information on the specimen bottles is complete before they are returned to the laboratory.

5.5.3. Add-on Tests
- QEHB inpatients and outpatients: Please send a request form with the patient’s details and tests required, clearly stating it is an add-on request.
- Moseley Hall Hospital, St Mary’s Hospice, Royal Orthopaedic Hospital and GP surgeries: Please telephone extension 16543 to request additional tests.

Please note that add-on tests will not be dealt with urgently. Due to sample storage procedures within the department, it may not be possible to access a sample quickly, if an add-on result is required urgently, it may be more appropriate to re-bleed the patient.

Please be aware that due to varying in vitro stability of analytes, it may not be possible to add-on further tests.

Please call extension 16543 to discuss if required.

5.6. Specific Analyses
The Department of Clinical Biochemistry performs the majority of routine assays in-house. A small number of specialist assays are forwarded on to centres elsewhere in the UK although advice and interpretation will always be available locally.
Clinical Laboratory Services Queen Elizabeth Hospital

The Department of Clinical Biochemistry has particular expertise in; the investigation of diabetes mellitus, lipid disorders, gastroenterology, rheumatology, tumour markers and endocrinology. An extensive analytical service is provided within the Diabetes Centre.

5.6.1. Diagnosis of Diabetes Mellitus

Conventionally diabetes mellitus was diagnosed by high fasting or random blood glucose concentrations, or an abnormal oral glucose tolerance test (OGTT) whilst haemoglobin A1c (HbA1c) was used to monitor longer term glycaemic control in patients with known diabetes mellitus.

In 2011, the World Health Organisation (WHO 2011) recommended that HbA1c measurements should also be used to diagnose diabetes in the majority of asymptomatic individuals, and this recommendation has been agreed in the UK (NHS Diabetes 2011).

An HbA1c of 48 mmol/mol or more is consistent with diabetes. If the patient has no symptoms then a second HbA1c result must be obtained within 2 weeks, and if it remains ≥48 mmol/mol diabetes mellitus is confirmed.

HbA1c values of 42 to 47 mmol/mol suggest a high risk of future diabetes. Such individuals should be offered structured lifestyle education and support to delay/prevent development of diabetes, and have an annual HbA1c test.

HbA1c must be measured in an accredited laboratory undertaking recommended quality assurance procedures. Near patient testing is not appropriate when HbA1c is used for the diagnosis of diabetes.

HbA1c is now the preferred method to diagnose diabetes, except in the following situations where this test would be unreliable, and in whom the traditional methods of diagnosis with blood glucose concentrations remain the method of choice:

- Haemoglobinopathies
- Increased red cell turnover
- Anaemia (haemoglobin < 80 g/L)
- ?Type 1 diabetes or acute onset of symptoms of diabetes
- ?Gestational diabetes
- Children and adolescents
- Patients taking steroids and antipsychotic or other medications that cause a rapid rise in blood glucose

Despite this new approach, if an individual has abnormally high random or fasting blood glucose levels or abnormal OGTT, which would be consistent with diabetes on the traditional criteria, then that patient should be considered to have diabetes irrespective of their HbA1c value. Without symptoms of diabetes two abnormal tests of the same type (two high fasting/random blood gluoses or a diabetic OGTT) are required to confirm diabetes mellitus.

5.6.2. Monitoring glycaemic control in patients with diabetes

HbA1c is routinely measured for this purpose. The assay is run daily on weekdays and requires an EDTA plasma sample (purple top). Fructosamine can be used as an alternative when HbA1c is not appropriate. Fructosamine reflects blood glucose over two weeks rather than 2 to 3 months as it reflects glycation of albumin rather than haemoglobin. Fructosamine is performed on serum (yellow or red top) and run daily.
5.6.3. Glucose Tolerance Tests
Contact the duty biochemist on 0121 3716543 to discuss whether an oral glucose tolerance test (OGTT) is required for a particular patient and/or to book an OGTT. The OGTT is performed at the Diabetes Centre Laboratory in Nuffield House on the QEHB site. In addition, a protocol can be provided for performing an OGTT on wards or in the community.

5.6.4. Coronary Heart Disease Risk Score
Standard 4 of the National Service Framework for Coronary Heart Disease states that: “General Practitioners and Primary Health Care teams should identify all people at significant risk of cardiovascular disease (CVD) but who have not yet developed symptoms and offer them appropriate advice and treatment to reduce their risk”.

Numerous risk calculators are available to calculate risk for coronary disease and these are all based on the Framingham model. The JBS III or the QRISK 2016 calculators are used for the calculation of cardiovascular disease risk. The South Birmingham PCT requires general practice to screen for CVD and any request for ‘CVD risk’ will generate a total cholesterol, HDL-cholesterol, creatinine and HbA1c (a yellow top and purple top bottle must be supplied). There are freely available calculators available to calculate a ‘CHD risk’ (Coronary heart disease risk) score (e.g. http://www.qintervention.org/).

Please note HDL-cholesterol is only measured when the CHD risk score is requested. We do not provide HDL-cholesterol otherwise on any request for a lipid profile.

Often we are asked to provide LDL-cholesterol calculations. For your convenience the calculation of LDL-cholesterol is provided below but you should recognise that this is only strictly valid where patients attend fasting for at least 12 hours in order to suppress triglyceride concentrations. Triglyceride concentrations >4.5 mmol/L negate the use of the calculation;

\[
\text{LDL cholesterol} = \text{Total cholesterol} - \text{HDL-cholesterol} - \left(\frac{\text{Triglyceride}}{2.19}\right)
\]

5.6.5. Thyroid Function Tests
TSH and free thyroxine (fT4) are provided as first-line tests. Since many drugs and treatments affect thyroid function tests, details of all drugs or other treatment must be provided in order that further tests can be initiated by the laboratory as appropriate. Please indicate on request form if patient is on thyroid hormone replacement.

Free T3 is analysed only according to an agreed protocol and full clinical details must be given on the request form.

Thyroid hormone measurements can be misleading in patients with acute and non-thyroid illness. Thyroid status should only be assessed after recovery from acute non-thyroidal illness. ‘Screening’ of patients in hospital for thyroid illness is not recommended.

Please see the UK Guidelines for the Use of Thyroid Function Tests at: http://www.british-thyroid-association.org/current-bta-guidelines-

5.6.6. Management of the Menopause
The menopausal transition is best diagnosed on clinical grounds. Endocrine investigation may be helpful where the pattern of age, menstrual history and features of oestrogen deficiency are unusual.
Please indicate the woman’s date of birth, recent menstrual pattern and date of last menstrual period/day of cycle on which the blood sample was collected. A rise in follicle stimulating hormone (FSH) is the earliest sign of the approaching menopause. Measurement of serum FSH is the recommended first investigation if biochemical confirmation is necessary. The measurement of luteinising hormone (LH), oestradiol or progesterone is not appropriate. A serum FSH in the reference range for the follicular phase does not exclude the perimenopause.

5.6.7. Hormone Replacement Therapy
HRT when prescribed (orally or transdermally) for the relief of menopausal symptoms does not require endocrine monitoring. Where there is unexpected failure of treatment, for example due to non-compliance or malabsorption, investigation may be useful. Different formulations of HRT may or may not be detected by oestradiol assays. Please indicate on the request form the HRT preparation prescribed.
The main indication for measuring oestradiol in women on HRT is in those receiving implants containing oestradiol. Early replacement of the implant may result in accumulation of oestradiol. Monitoring of serum oestradiol before the implant is replaced has been recommended to avoid supraphysiological concentrations. Sometimes testosterone implants are used in HRT. Measurement of testosterone in an analogous fashion to oestradiol may help to assess whether a further implant may be necessary.

5.6.8. Prolactin and Macroprolactin
The laboratory will perform a screening test for immunoglobulin bound prolactin (macroprolactin) on samples with a prolactin greater than 600 mIU/L. Please contact the laboratory for further information.

5.6.9. Troponin
Troponins are used in the diagnosis of acute myocardial infarction (AMI) and acute coronary syndrome (ACS) in patients with a short history of chest pain. Cardiac troponins are proteins that are involved in the contraction of the myocardium. Minimal myocardial damage can be reflected by large rises in cardiac troponins which are specific to cardiac muscle. The two types of troponin types commonly measured are troponin T and troponin I. The QEHB laboratory uses cardiac Troponin T (cTnT).
cTnT increases within 3-4 hours after myocardial infarction (AMI) and may be detectable for up to 2 weeks. In contrast to ST-elevation myocardial infarction (STEMI) the diagnosis of non-ST elevation myocardial infarction (NSTEMI) relies on the cTnT result. The new universal definition of myocardial infarction (MI) are blood levels of cTnT above the 99th percentile of the reference limit of a healthy population together with evidence of myocardial ischemia including typical symptoms, ECG changes and/or imaging results.
A highly sensitive cTnT assay is in use at the QEHB laboratory which shows superior detection of early release of cTnT from damaged myocardium. This means that rather than measurement of cTnT at 10-12 hours post-chest pain (as for less sensitive assays), samples can now be taken on admission followed by a second sample 3-6 hours post-admission.
From these data myocardial infarction (MI) and Acute Coronary Syndrome (ACS) can be ruled out within 6 hours provided both cTnT hs levels are <14 ng/L. A rise in cTnT hs of 100% in 6 hours is indicative of myocardial damage consistent with AMI and NSTEMI. Note patients with significant renal impairment or frank renal failure have presenting high TnT levels and must have repeat TnT measured 3h later to prove or disprove ACS or frank MI.

5.6.10. Therapeutic Drug Monitoring (TDM)

A TDM service is provided in the department of Clinical Biochemistry for some of the drugs requiring regular monitoring. Please check the time at which a sample should be collected as failure to collect the blood at the appropriate time will make it impossible to compare the measured concentration with an accepted therapeutic range. Assays are of little use under these conditions.

The monitoring of valproic acid is not recommended because of the poor correlation between plasma levels and therapeutic effect. The duty biochemist must be contacted to discuss its measurement for any other purpose.

Any request for urgent therapeutic drug analysis that is not provided by Clinical Biochemistry must be discussed with the Duty Biochemist, or when out-of-hours with the duty Biomedical Scientist who may ask you to discuss this with the Duty Consultant. In some circumstances additional discussion with a pharmacist is required. Some specimens requiring analysis out-of-hours may need to be sent to the Toxicology unit at City Hospital and if you organise this without consulting the Pharmacy department you will incur charges to the trust that will not be the responsibility of Clinical Biochemistry.

5.6.11. Overdoses/Drug Screens

Samples for a ‘Drug Screen’ are analysed at the Regional Toxicology Laboratory (RTL) at City Hospital. A request for a “drug screen” or ‘unknown drug’ requires:-

- At least 10 mL of urine in plain tube (NOT containing boric acid).
- A green top (Lithium heparin anticoagulant) tube filled with blood.
- Detailed patient information.
- Clinical condition e.g. coma grade, fitting etc.
- Current known prescribed drugs.
- Overdose drug(s) if known.
- Urine specimen type e.g. voided or catheter.

Blood samples taken for a ‘Drug Screen’ are of little use unless there is prior knowledge of the agent ingested. Discuss whether a blood sample is of use with the duty biochemist or duty consultant (via the out-of-hours Biomedical Scientist). Paracetamol, salicylate and lithium measurements are available on a 24 hr basis. All requests for other ingested drugs must be discussed with the Poisons Unit and Regional Toxicology Laboratory and samples sent only by prior arrangement. Any samples requiring urgent analysis at the Regional Toxicology Laboratory will require direct dispatch to that laboratory and must not be sent to the Clinical Biochemistry department. Charges realised by these analysis will be forwarded to the relevant division.
5.6.12. Antibiotics
Amikacin, gentamycin, tobramycin and vancomycin are measured in Clinical Biochemistry but clinical advice is given from Microbiology. For patients with liver or renal impairment, advice on antibiotic dosage is available from Clinical Microbiology. The aim is to turnaround these results within a clinical effective time from the time of receipt in the laboratory.
Assays for other antimicrobials including flucytosine, teicoplanin and streptomycin are available from Microbiology after prior consultation with the Clinical Microbiologist.

5.6.13. Porphyria Screens
The laboratory performs a urine porphyrin screen in house whilst blood samples (required for latent porphyria or cutaneous porphyria) and all samples from known porphyria patients are referred to a specialist laboratory. The sample required and interpretation depends upon the clinical scenario;
- **? acute porphyria in a symptomatic patient:** Send urine to lab for a porphyrin screen (PBG and total urine porphyrin). A negative PBG screen in a symptomatic patient excludes an acute porphyria as the cause of the symptoms.
- **? acute porphyria in an asymptomatic patient (or >3 days post-symptoms):** Send urine to lab for a porphyrin screen (PBG and total urine porphyrin) and an EDTA blood to refer to a specialist laboratory to rule out latent/resolving porphyria.
- **? bullous porphyria (skin fragility):** Send urine to lab for a porphyrin screen (PBG and total urine porphyrin). A negative total urine porphyrin excludes porphyria as a cause of skin fragility.
- **? acute photosensitivity (EPP):** Send EDTA blood to lab for referral to a specialist laboratory.
- **Asymptomatic patient with a family history of porphyria:** Send urine, blood & faecal samples to QEHB laboratory for referral to a specialist laboratory.

All samples for porphyria investigations must be protected from the light otherwise there are a risk of a false negative result. Clinical details MUST be provided with a request for investigation of porphyria. This is to enable appropriate investigation and reporting by both QEHB lab and the specialist laboratories.
In the event of a positive or equivocal urine porphyrin screen, additional samples (EDTA blood/faeces) may be requested for referral to a specialist laboratory.

5.7. Point-of-Care Testing (POCT or Near Patient Testing, NPT)
The use of all point-of-care devices from simple dip-stick tests to blood gas analysis machines is governed by a comprehensive Trust policy and procedure. Please ensure that you are aware of the requirements of this policy before you embark on point-of-care testing. The POCT services managed by the team are rapidly expanding and include:

5.7.1. Blood Glucose Meters
Ward based glucose meters that measure blood glucose using a 'dry-chemistry' stick are used throughout the Trust. These meters must only be used by authorised staff that have
received training via the scheme organised in conjunction with the meter manufacturer.

The working range of all glucose meters is limited and for accurate determination at the extremes of the range (2.5 - 20.0 mmol/L for the UHB meters), blood should be taken into a grey-top vacuette tube and sent to the laboratory. If the result is unexpected, send a sample to the laboratory or a sample can be processed on one of the blood gas analysers located throughout the Trust.

In hypoglycaemia, values below the working range must be confirmed by a laboratory glucose measurement. Consult the biochemist/consultant on duty prior to taking the blood so that appropriate samples can be collected for the investigation of insulinoma, should this be warranted.

5.7.2. Blood Gas Analysers (QEHB, Heritage Building, ROH, Moseley Hall)

The department has rationalised blood gas instrumentation in the Trust and identical instruments are sited throughout the Trust. All analysers measure pH, pCO₂, pO₂, sodium, potassium and ionised calcium. They provide full co-oximetry and derive values for base excess and bicarbonate. Glucose and lactate measurement is available on both sites, but not on all analysers.

The blood gas analysers are located throughout QEHB, Heritage Building and the POCT team also manage analysers at the Royal Orthopaedic Hospital and Moseley Hall Hospital. Ward based operators and doctors are trained by staff of the POCT team. The laboratories do not have blood-gas analysers in the department and there is no in-house lactate measurement.

5.7.3. INR Measurement

Throughout the Trust the POCT team manage the INR devices used for rapid testing. These meters have been installed in areas where a clinical need has been identified and approved. Operators are trained by the members of the POCT team.

5.7.4. Ketone Measurement

To comply with the DKA guidelines and to support the diagnosis and management of patients with DKA the POCT team manage the ketone meter service within the Trust. Meters have been installed in areas where a clinical need has been identified and approved. Training and full service report is provided by the POCT team.

5.7.5. Other POCT Services

As well as these tests the POCT team are currently managing or are reviewing the following services:
DDimer testing, urine analysis including hCG testing (pregnancy testing) and dipsticks for screening, Haemostasis testing (ACT, APTT, ROTEM, TEG), Haematology clinics, Biochemistry one stop clinics and sexual Health testing.

If any clinical areas require advice or guidance on the installation or use of POCT systems please contact us to discuss further.
5.8. Common Factors Affecting Analysis

It is not practical to list all factors that may affect all analytes however but a guide to some of the more common factors are as follows:

- Haemolysis, icteric and lipaemia interfere with certain analytes and as a consequence some analytes may not be reported. However, a comment will be included on the report to indicate why. Common analytes affected include: sodium, potassium, bilirubin, magnesium, phosphate, LDH, AST, ALT and cTnT hs.
- Serum samples should be processed (centrifuged and serum separated from the cells) within 6 hours of collection. Any undue delay, particularly more than 6 hours, can influence the potassium and enzyme results.
- Extreme temperatures (cold and hot) can cause abnormal levels of some analytes especially potassium.
- Sodium is affected by abnormal levels of protein and lipids. A direct ISE measurement will be performed and this report (plus appropriate comment) will be issued.
- A high platelet and white blood count can cause a falsely elevated potassium (a condition known as pseudohyperkalaemia). It is suggested that in these suspected cases blood is collected into both a lithium heparin tube and a yellow top serum tube and sent to the Biochemistry department as soon as possible for potassium analysis to confirm. There is a difference of approximately 0.3 mmol/L in plasma compared with serum potassium. Larger differences are consistent with blood abnormalities affecting the results.
- It is important that blood is collected in the correct tubes and in the correct order to reduce the risk of anti-coagulant interference e.g. EDTA interference with calcium assays.
- CSF samples for xanthochromia should be protected from light and should not be transported to the laboratory using the SDS. Lumbar puncture for xanthochromia should not be performed until 12 hours post onset of symptoms in order to minimise false negative results.
- HbA1c will not be reported on patients with known haemoglobinopathies. It is recommended that fructosamine is measured on these patients.

5.9. Analyses available

A guide to reference ranges are shown, but please refer to reference range (which may be age or gender related) quoted on the report form. Turnaround times quoted relate to the maximum time from receipt of the specimen in the laboratory to the reporting of the result for Trust generated requests.
5.9.1. Blood/serum

Please note preferred sample type is given. The analysis may also be available on alternative specimen types, please contact laboratory for further information.

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE</td>
<td>20 - 70 U/L</td>
<td>Serum (yellow or red top)</td>
<td>7 days</td>
</tr>
<tr>
<td>ACTH</td>
<td>7 am to 10am: 7.2 - 63.3 ng/L</td>
<td>EDTA plasma (purple top) On ice straight to lab</td>
<td>72 hours</td>
</tr>
<tr>
<td>Albumin</td>
<td>34 - 51 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Alcohol (non-legal)</td>
<td>&gt;1000 mg/L = intoxication 3500-4500 mg/L = severe intoxication &gt;5500 mg/L = usually fatal</td>
<td>Fluoride oxalate plasma (grey top) (filled)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Aldosterone</td>
<td>Standing/random samples: &lt;750 pmol/L Recumbent (min 4h): &lt;375 pmol/L</td>
<td>Serum (yellow or red top) or plasma (green or purple top)</td>
<td>10 days</td>
</tr>
<tr>
<td>Alkaline Phosphatase (ALP)</td>
<td>Adult male: 40 - 130 U/L Adult female: 35 - 105 U/L Paediatric: 1-3 yrs. (male &amp; female): &lt;281 U/L 4-6 yrs. (male &amp; female): &lt;269 U/L 7-12 yrs. (male &amp; female): &lt;300 U/L 13-17 yrs. (male): &lt;390 U/L 13-17 yrs. (female): &lt;187 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Alkaline phosphatase isoenzymes</td>
<td>Qualitative report provided</td>
<td>Serum (yellow or red top)</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Alpha-1-antitrypsin</td>
<td>1.0 1.9 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Alpha-1-antitrypsin phenotyping</td>
<td>Qualitative report provided</td>
<td>Serum (yellow or red top)</td>
<td>7 days</td>
</tr>
<tr>
<td>Test</td>
<td>Reference Range</td>
<td>Sample Type</td>
<td>Turnaround Time</td>
</tr>
<tr>
<td>----------------------</td>
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</tr>
<tr>
<td><strong>Alpha-fetoprotein (AFP)</strong></td>
<td>&lt; 6 KU/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Alpha sub-unit</strong></td>
<td>Adult (male and female) &lt;1 IU/L</td>
<td>Serum (yellow or red top)</td>
<td>21 days</td>
</tr>
<tr>
<td></td>
<td>Post-menopausal and mid-cycle &lt;3 IU/L</td>
<td>Serum (yellow or red top)</td>
<td></td>
</tr>
<tr>
<td><strong>ALT</strong></td>
<td>5 - 41 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Ammonia</strong></td>
<td>Male: 16 – 60 μmol/L</td>
<td>EDTA plasma (purple top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Female: 11 – 51 μmol/L</td>
<td><strong>On ice straight to lab</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Amylase</strong></td>
<td>&lt; 100 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Androstenedione</strong></td>
<td><em>Measured as part of a steroid profile containing testosterone and 17-OHP</em></td>
<td>Serum (yellow or red top)</td>
<td>72 hours</td>
</tr>
<tr>
<td></td>
<td>Adults;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female (pre-menopause): 0.9 – 7.5 nmol/L</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Female (post-menopause): 0.4 – 2.9 nmol/L</td>
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<tr>
<td></td>
<td>Male (18-40yrs): 1.1 – 5.6 nmol/L</td>
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<td></td>
<td>Male (41-67yrs): 0.8 – 4.7 nmol/L</td>
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<tr>
<td></td>
<td>Paediatrics;</td>
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<tr>
<td></td>
<td>Neonates: &lt;8.0 nmol/L</td>
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<tr>
<td></td>
<td>Female Tanner stage 1: &lt;1.9 nmol/L</td>
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</tr>
<tr>
<td></td>
<td>Male Tanner stage 1: &lt;1.1 nmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>AST</strong></td>
<td>5 - 43 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Bile Acid</strong></td>
<td>&lt;14 μmol/L for pregnant women</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Bilirubin (total)</strong></td>
<td>&lt;22 μmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Bilirubin (direct/conjugated)</strong></td>
<td>No reference range reported. Result should be interpreted with the total bilirubin. The assay should only be performed when total bilirubin is elevated</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>NT-pro-BNP</strong></td>
<td>Male &lt;60yrs: &lt;85 ng/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Male ≥60yrs: &lt;161 ng/L</td>
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<td></td>
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<tr>
<td></td>
<td>Female &lt;60yrs: &lt;144 ng/L</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Female ≥60yrs: &lt;203 ng/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure referral guidelines (NICE):</td>
<td>&lt;400 ng/L: Do not refer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>400-2000ng/L: Refer within 6 weeks</td>
<td></td>
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<tr>
<td></td>
<td>&gt;2000 ng/L: Refer urgently (&lt;2 weeks)</td>
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<td></td>
</tr>
<tr>
<td>Test</td>
<td>Value</td>
<td>Type</td>
<td>Referee</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Ca-125</td>
<td>&lt;36 kU/L (females)</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Ca-153</td>
<td>&lt;26 kU/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Ca-199</td>
<td>&lt;28 kU/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Caeruloplasmin</td>
<td>0.2 - 0.45 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Calcium (Total)</td>
<td>2.10 - 2.60 mmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Therapeutic ranges;</td>
<td>Pre-dose serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Used as single anti-epileptic: 8-12 mg/L</td>
<td>Pre-dose</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>&gt;1 anti-epileptic used: 4 – 8 mg/L</td>
<td>serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Not used as anti-epileptic: up to 12 mg/L</td>
<td>Pre-dose</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>*The minimum time for patient to reach steady state without loading or after dosage change is 14 days</td>
<td>Pre-dose</td>
<td>24 hours</td>
</tr>
<tr>
<td>CEA</td>
<td>&lt;5 μg/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Optimal concentration: &lt;4.0 mmol/L (JBS guidelines)</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Ciclosporin</td>
<td>Therapeutic target ranges applied on an individual basis dependent upon specialty, dosing, period in treatment regime and clinical status (contact appropriate speciality)</td>
<td>Pre-dose EDTA plasma (purple top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>CK</td>
<td>Female: 24 - 170 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Male: 24 - 195 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Cortisol</td>
<td>7 to 10am: 172 - 497 nmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Midnight: &lt;130 nmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Short synacthen test:</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Adequate response is a cortisol &gt;450 nmol/L 30 min post-synacthen</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Males (all ages): 60 - 126 μmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Females &lt;60 yrs.: 50 - 101 μmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Females ≥60 yrs.: 50 - 111 μmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>CRP</td>
<td>&lt; 10 mg/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
</tbody>
</table>
### Cryoglobulins
Qualitative report provided

- **Transport specimen to the lab at 37°C**
- **72 hours**

### CTX
- **Female:**
  - Pre-menopause: 0.025 - 0.573 ng/mL
  - Post-menopause: 0.104 - 1.008 ng/mL

- **Male:**
  - 30-50 yrs.: 0.016 - 0.584 ng/mL
  - 51-70 yrs.: <0.704 ng/mL
  - >70 yrs.: <0.854 ng/mL

- **EDTA plasma (purple top)**
- **7 days**

### DHAS
Age and gender related reference ranges, please contact laboratory

### Digoxin
Therapeutic range: 0.5 – 2.0 μg/L
Target range for heart failure: 0.5 – 2.0 μg/L

*The minimum time for patient to reach steady state without loading or after dosage change is 7 days*

- **>6h post-dose**
- serum (yellow or red top)
- **24 hours**

### Everolimus
Therapeutic target ranges applied on an individual basis dependent upon specialty, dosing, period in treatment regime and clinical status (contact appropriate speciality)

- **Pre-dose EDTA plasma (purple top)**
- **48 hours**

### Ferritin
- **Female:** 10 - 320 μg/L
- **Male:** 18-360 μg/L

*Note clinical advice is provided by Haematology*

### Free T3
3.1 - 6.8 pmol/L

*added at discretion of Duty Biochemist for non-specialists*

### Free T4
10 - 22 pmol/L

*Measured as part of a TFT including TSH*

### Folate
2.7 - 18.6 μg/L

*Note clinical advice is provided by Haematology*

### Fructosamine
200 - 285 μmol/L

### FSH
- **Female:**
  - Follicular: 3.5-12.5 IU/L
  - Mid-cycle: 4.7-21.5 IU/L
  - Luteal: 1.7-7.7 IU/L
  - Post-menopausal: 25.8-134.8 IU/L

- **Male:** 1.5-12.4 IU/L

- **Serum (yellow or red top)**
- **24 hours**
<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Ranges</th>
<th>Sample Type</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>GGT</td>
<td>Female: 9 - 40 U/L Male: 9 - 50 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Glucose</td>
<td>No reference range given, see WHO 2006 guidelines on diagnosis of diabetes.</td>
<td>Fluoride oxalate plasma (grey top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Growth hormone</td>
<td>GH secretion is pulsatile and random samples are of little diagnostic value</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Haptoglobin</td>
<td>0.46-2.60 g/L female 0.46-3.00 g/L male</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>hCG</td>
<td>Female (non-pregnant): &lt; 2 IU/L Female (post-menopausal): &lt; 7 IU/L Male: &lt; 2 IU/L Pregnancy reference ranges not available</td>
<td>Red top as seperate tube</td>
<td>24 hours</td>
</tr>
<tr>
<td>HDL-Cholesterol</td>
<td>Optimal values; Female: &gt;1.2 mmol/L Male: &gt;1.0 mmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>17-hydroxyprogesterone (17-OHP) *Measured as part of a steroid profile containing testosterone and androstenedione</td>
<td>Adults; Female (follicular phase): 0.6 – 4.0 nmol/L Female (luteal phase): 1.0 – 6.0 nmol/L Male: 1.2 – 3.7 nmol/L Paediatrics; Neonates: &lt;8.0 nmol/L Female &amp; male Tanner stage 1: &lt;5.0 nmol/L</td>
<td>Serum (yellow or red top)</td>
<td>72 hours</td>
</tr>
<tr>
<td>IgA</td>
<td>0.65 - 3.75 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>IgG</td>
<td>8.0 - 14.5 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>IgM</td>
<td>0.2 - 3.0 g/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>IGF-1</td>
<td>Age and gender related reference ranges, please contact laboratory</td>
<td>Serum (yellow or red top)</td>
<td>7 days</td>
</tr>
<tr>
<td>IGF-BP3</td>
<td>Age and gender related reference ranges, please contact laboratory</td>
<td>Serum (yellow or red top)</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Iron</td>
<td>Female: 5 - 30 μmol/L Male: 10 - 32 μmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>LDH</td>
<td>Adult females: 135 – 214 U/L Adult males: 135 – 225 U/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Test</td>
<td>Description</td>
<td>Normal Ranges</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Lithium</strong></td>
<td>Therapeutic range (for prophylactic treatment 12h post dose): 0.4 - 1.0 mmol/L</td>
<td>Females &amp; males &lt;16yrs: 120 – 300 U/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lower end of Li range for maintenance therapy &amp; elderly patients.</td>
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<tr>
<td></td>
<td>Higher end of Li range for treatment of acute mania.</td>
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<tr>
<td></td>
<td>*Minimum time for patient to reach steady state without loading or after dosage change is 3 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LH</strong></td>
<td>Female:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Follicular: 2.4 - 12.6 IU/L</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Mid-cycle: 14.0 – 95.6 IU/L</td>
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<tr>
<td></td>
<td>- Luteal: 1.0 – 11.4 IU/L</td>
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<tr>
<td></td>
<td>- Post-menopausal: 7.7 – 58.5 IU/L</td>
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</tr>
<tr>
<td></td>
<td>Male: 1.7 – 8.6 IU/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LysoGb3</strong></td>
<td>&lt;0.8 nmol/L means a diagnosis of Fabry disease is not likely.</td>
<td>Serum (yellow or red top) 4 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium</strong></td>
<td>0.70 - 0.95 mmol/L</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Methotrexate</strong></td>
<td>(for high dose IV regimes only)</td>
<td>See individual protocols 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Oestradiol</strong></td>
<td>Female:</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Follicular: 98 – 571 pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Mid-cycle: 176 - 1153 pmol/L</td>
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<tr>
<td></td>
<td>- Luteal: 122 – 1094 pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Post-menopausal: &lt;183 pmol/L</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Male: &lt;192 pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Osmolality</strong></td>
<td>274 - 294 mOsmol/Kg</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Paracetamol</strong></td>
<td>Not applicable (use in overdose only)</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Phenytoin</strong></td>
<td>Therapeutic range: 7 – 20 mg/L</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Minimum time for patient to reach steady state without loading or after dosage change is 7 days</td>
<td>Anytime</td>
<td></td>
</tr>
<tr>
<td><strong>Phosphate</strong></td>
<td>0.80 - 1.40 mmol/L</td>
<td>Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Potassium</strong></td>
<td>3.4 - 5.2 mmol/L</td>
<td>Serum (yellow top) 24 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Progesterone</strong></td>
<td>Luteal samples - collect 7 days (+/- 2 days) before onset of next menstrual cycle</td>
<td>Luteal phase progesterone &gt;30 nmol/L suggests Serum (yellow or red top) 24 hours</td>
<td></td>
</tr>
<tr>
<td>Test</td>
<td>Range</td>
<td>Sample Type</td>
<td>Result Time</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------</td>
<td>------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>adequate ovulation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prolactin</strong></td>
<td>Female: 100-500 mU/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours (longer if further screening required)</td>
</tr>
<tr>
<td>Male: 85-325 mU/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Sample will be screened for macroprolactin if initial result is &gt;600 mU/L</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Protein electrophoresis</strong></td>
<td>Qualitative report provided</td>
<td>Serum (yellow or red top)</td>
<td>72 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PSA</strong></td>
<td>Referral Thresholds:</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td>≤49 yrs.: 2.5 µg/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-59yr: 3.5 µg/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60-69yr: 4.5 µg/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70-79 yrs.: 6.5 µg/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥80yr: based on clinical suspicion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PTH</strong></td>
<td>1.6 - 6.9 pmol/L</td>
<td>EDTA plasma (purple top)</td>
<td>24 hours</td>
</tr>
<tr>
<td><em>Please send sample for calcium and albumin to enable interpretation</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Renin</strong></td>
<td>Ambulatory:</td>
<td>EDTA plasma (purple top)</td>
<td>14 days</td>
</tr>
<tr>
<td>Female: 6.1 – 62.7 mIU/L</td>
<td></td>
<td>Send within 3 hours (room temp)</td>
<td></td>
</tr>
<tr>
<td>Male: 9.0 – 103 mIU/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine: 4.2 – 59.7 mIU/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rheumatoid Factor</strong></td>
<td>&lt;14IU/mL</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Salicylate</strong></td>
<td>Not applicable (use in overdose only)</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SHBG</strong></td>
<td>Female (17–50 yrs.): 26.1 – 110 nmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Male (17–65 yrs.): 14.5 – 48.4 nmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sirolimus</strong></td>
<td>Therapeutic target ranges applied on an individual basis dependent upon specialty, dosing, period in treatment regime and clinical status (contact appropriate speciality)</td>
<td>Pre-dose EDTA plasma (purple top)</td>
<td>48 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sodium</strong></td>
<td>134 - 146 mmol/L</td>
<td>Serum (yellow or red top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tacrolimus</strong></td>
<td>Therapeutic target ranges applied on an individual basis dependent upon specialty, dosing, period in treatment regime and clinical status (contact appropriate speciality)</td>
<td>Pre-dose EDTA plasma (purple top)</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Testosterone</strong></td>
<td><em>Measured as part of a steroid profile containing</em></td>
<td>Serum (yellow or red top)</td>
<td>72 hours</td>
</tr>
<tr>
<td>Adults;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female: &lt;1.9 nmol/L</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Clinical Laboratory Services Queen Elizabeth Hospital

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Ranges</th>
<th>Sample Type</th>
<th>Result Time</th>
</tr>
</thead>
</table>
| androstenedione and 17-OHP  | Male: 7.0 – 27.0 nmol/L  
Paediatrics;  
Female Tanner stage 1: <0.6 nmol/L  
Male Tanner stage 1: <0.7 nmol/L | Serum (yellow or red top) |             |
| Theophylline                | Therapeutic range: 10 – 20 mg/L (Pre-dose)  
*Minimum time for patient to reach steady state without loading or after dosage change is 2 days* | Serum (yellow or red top) | 24 hours |
| Thyroglobulin               | No reference range reported                       | Serum (yellow or red top) | 10 days |
| Thyroid screen: FDH, HAMA, T4/T3 Antibodies etc. | Please contact the Duty Biochemist for advice on 0121 3716543 (internal: ext. 16543) | Serum (yellow or red top) x2 | 6 weeks |
| Total CO₂ (bicarbonate)    | 22 - 29 mmol/L                                    | Serum (yellow or red top) | 24 hours |
| Total protein               | 60 – 80 g/L                                       | Serum (yellow or red top) | 24 hours |
| Transferrin                 | 2.0 - 3.6 g/L                                     | Serum (yellow or red top) | 24 hours |
| Triglyceride                | Optimal level (Joint British Societies guidelines) is <1.7 mmol/L | Serum (yellow or red top) | 24 hours |
| Troponin T (high sensitivity)| <14 ng/L (99th percentile) – see section 1.6.9    | Serum (yellow or red top) | 24 hours |
| TSH                         | *Measured as part of a TFT including fT4*  
0.3 - 4.5 mIU/L                                                  | Serum (yellow or red top) | 24 hours |
| Urea                        | Females:  
<30 yrs.:      2.6 - 7.1 mmol/L  
30–39 yrs.:  2.8 - 7.1 mmol/L  
40–49 yrs.:  3.0 - 7.1 mmol/L  
50–59 yrs.:  3.2 - 7.6 mmol/L  
>60 yrs.:      3.4 - 8.0 mmol/L  
Males:  
<40 yrs.:      3.2 - 7.6 mmol/L  
40–49 yrs.:  3.4 - 7.6 mmol/L  
50–59 yrs.:  3.4 - 7.8 mmol/L  
>60 yrs.:      3.4 - 8.0 mmol/L | Serum (yellow or red top) | 24 hours |
| Urate (uric acid)           | 160 - 400 μmol/L                                  | Serum (yellow or red top) | 24 hours |
| Vitamin B12                 |                                                    | Serum                 | 24 hours |
Clinical Laboratory Services Queen Elizabeth Hospital

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin D</td>
<td>&lt;30nmol/L – Vitamin D Deficiency</td>
<td>Serum (yellow or red top)</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>30-50nmol/L – Borderline low vitamin D</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;50nmol/L – Adequate vitamin D</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;300nmol/L – may indicate Vitamin D toxicity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note clinical advice is provided by Haematology*

*Please note that IGF-BP3, LysoGb3 Renin analysis and Alpha sub-unit is not currently included in our UKAS accreditation scope.*

5.9.2. CSF

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>2.0 - 5.0 mmol/L (60% of plasma value)</td>
<td>Grey Top tube</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Concurrent plasma specimen must be sent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>0.15 - 0.45 g/L</td>
<td>Plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Xanthochromia</td>
<td>Qualitative report provided</td>
<td>Plain universal container</td>
<td>Available Mon to Fri 9-5pm Sat 9-12.30 pm</td>
</tr>
<tr>
<td></td>
<td>Protected from light. Do not use SDS to transport sample to the laboratory</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please note that thyroglobulin analysis is not currently included in our UKAS accreditation scope.*

5.9.3. Urine

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR (albumin:creatinine ratio)</td>
<td>&lt;2.3 mg/mmol creatinine</td>
<td>Random urine in plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Albumin excretion</td>
<td>&lt;0.025 g/24h</td>
<td>24h urine</td>
<td>24 hours</td>
</tr>
<tr>
<td>Test</td>
<td>Details</td>
<td>Sample Type</td>
<td>Results Time</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Amylase excretion</td>
<td>No reference ranges are reported</td>
<td>(plain bottle)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Bence-Jones Protein (BJP)</td>
<td>Qualitative report provided</td>
<td>Early morning urine in plain universal container</td>
<td>7 days</td>
</tr>
<tr>
<td>Calcium excretion</td>
<td>2.5 – 7.5 mmol/24h</td>
<td>24h urine (acid bottle)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Calcium:creatinine ratio</td>
<td>No reference ranges are reported</td>
<td>Random urine in plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Urinary free cortisol (UFC)</td>
<td>&lt;130 nmol/L /24h</td>
<td>24h urine (plain bottle)</td>
<td>7 days</td>
</tr>
<tr>
<td>Creatinine Clearance</td>
<td>Female: 75 - 115 mL/min Male: 85 - 125 mL/min</td>
<td>24h urine (plain bottle). Take a concurrent serum sample during the collection period</td>
<td>24 hours</td>
</tr>
<tr>
<td>Creatinine excretion</td>
<td>Female: 7.0 – 16.0 mmol/24h Male: 9.0 – 18.0 mmol/24h</td>
<td>24h urine (plain bottle)</td>
<td>24 hours</td>
</tr>
<tr>
<td>5-HIAA</td>
<td>5 - 45 µmol/24h *Patients should avoid serotonin-rich foods immediately prior to and during the urine collection (e.g. Banana, pineapple, tomatoes, kiwi fruit and various nuts). Please provide list of medications with request</td>
<td>24h urine (acid bottle)</td>
<td>7 days</td>
</tr>
<tr>
<td>Osmolality</td>
<td>No reference ranges are reported. Interpret in conjunction with serum osmolality and volume status.</td>
<td>Random urine in plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>pH</td>
<td>pH 4.5-7.4 (Keep sample cold during collection period)</td>
<td>Random urine in plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Phosphate excretion</td>
<td>No reference ranges are reported</td>
<td>24h urine (acid bottle)</td>
<td>24 hours</td>
</tr>
</tbody>
</table>
### Porphyria Screen (PBG and total porphyrins)

Qualitative report provided

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random urine in plain universal container</td>
<td>As required</td>
</tr>
<tr>
<td>Protected from light</td>
<td></td>
</tr>
</tbody>
</table>

### Urea and electrolytes (sodium and potassium) – 24h excretion

For investigation of electrolyte problems

Interpret urine Na and K concentration in conjunction with serum levels

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>24h urine (plain bottle)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Random urine in plain universal container</td>
<td></td>
</tr>
</tbody>
</table>

### Urea and electrolytes (sodium and potassium) – random sample

**Urea and electrolytes**

For investigation of electrolyte problems

Interpret urine Na and K concentration in conjunction with serum levels

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random urine in plain universal container</td>
<td>24 hours</td>
</tr>
</tbody>
</table>

### 5.9.4. Faeces

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faecal Elastase</td>
<td>Sufficient: &gt;200 μg/g stool</td>
<td>Plain blue top container</td>
<td>4 weeks</td>
</tr>
<tr>
<td></td>
<td>Mild deficiency: 100 – 200 μg/g stool</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe deficiency: &lt;100 μg/g stool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faecal Calprotectin</td>
<td>&lt;60 μg/g: Normal calprotectin. No evidence of GI inflammation - ?IBS</td>
<td>Plain blue top container</td>
<td>1 week</td>
</tr>
<tr>
<td></td>
<td>60-150 μg/g: Borderline raised calprotectin indicating mild inflammation. Stop any NSAIDs and repeat in 4 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;150 μg/g: Raised calprotectin. This may indicate inflammatory bowel disease. Refer to gastroenterology</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>GP screening for IBD should be carried out in accordance to the screening pathway provided by the CCG.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.9.5. Fluids

<table>
<thead>
<tr>
<th>Test</th>
<th>Adult Reference Range</th>
<th>Specimen type</th>
<th>Routine Turnaround</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylase</td>
<td>Ascitic fluid (? pancreatic fistula) only. Send concurrent serum amylase. No reference ranges are reported</td>
<td>Ascitic fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Drain fluid only (? Biliary fistula). No reference ranges are reported</td>
<td>Drain fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Test</td>
<td>Adult Reference Range</td>
<td>Specimen type</td>
<td>Routine Turnaround</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>--------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>CEA/amylase (pancreatic cyst fluid)</td>
<td>There are no applicable reference ranges for pancreatic cyst fluid CEA or amylase. Interpret according to local guidelines and imaging.</td>
<td>Pancreatic cyst fluid collected into a plain universal container</td>
<td>7 days</td>
</tr>
<tr>
<td>Chylomicrons</td>
<td>To determine if chest drain fluid contains chylomicrons (?) Chylothorax. Also request triglycerides. No reference ranges are reported</td>
<td>Chest drain fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Salivary Cortisol</td>
<td>Morning (7-9 am): 3.2-22.8 nmol/L Night (11pm-12 am): &lt;3.2 nmol/L</td>
<td>Salivette collection device (contact lab for supply)</td>
<td>14 days</td>
</tr>
<tr>
<td>Glucose</td>
<td>Pleural fluid (?) Transudate or exudate only. No reference ranges are reported</td>
<td>Grey top fluoride oxalate tube</td>
<td>24 hours</td>
</tr>
<tr>
<td>pH (pleural fluid)</td>
<td>For differentiating infective from non-infective pleural effusions (British Thoracic Society’s guidelines). Measured on fresh specimen collected anaerobically using a dedicated blood gas analyzer (W515 -respiratory)</td>
<td>Fresh specimen collected anaerobically</td>
<td>As required</td>
</tr>
<tr>
<td>Total protein</td>
<td>Pleural fluid (?) Transudate or exudate and ascitic fluid (?) cirrhotic or malignant) only. No reference ranges are reported</td>
<td>Pleural fluid or ascitic fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>To determine if chest drain fluid contains chylomicrons (?) Chylothorax. Also request chylomicrons. No reference ranges are reported</td>
<td>Chest drain fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
<tr>
<td>Urea</td>
<td>To determine if drain fluid contains urine. No reference ranges are reported</td>
<td>Drain fluid. Collected into a plain universal container</td>
<td>24 hours</td>
</tr>
</tbody>
</table>

*Please note that all fluids tests (with the exception of salivary cortisol) are not currently included in our UKAS accreditation scope.
### 5.9.6. Other analytes not listed

Any analytes not listed here may be available at other specialist centres within the region or the United Kingdom.

The duty biochemist can be contacted for advice on the availability of unlisted assays and the nature of the specimen required together with the expected turnaround times.

### 5.10. Telephone numbers

<table>
<thead>
<tr>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duty Biochemist</td>
<td>Ext 16543</td>
</tr>
<tr>
<td>Urgent Requests: Inpatients or out patients or GP</td>
<td>Ext 15985</td>
</tr>
<tr>
<td>Urgent Requests: Out of normal working hours</td>
<td>bleep: 2312 (8.00 pm - 8.00 am)</td>
</tr>
<tr>
<td>Urgent Endocrine requests</td>
<td>Ext 16543 (normal working hours)</td>
</tr>
<tr>
<td>General Office: enquires</td>
<td>Ext. 15999 (8.45 am - 6.00 pm) for results &amp; enquiries.</td>
</tr>
<tr>
<td>Consultant Clinical Scientist</td>
<td>Ext 15997</td>
</tr>
<tr>
<td>Dr RL Webster</td>
<td></td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Ext. 15963</td>
</tr>
<tr>
<td>Mrs Helen Peat</td>
<td></td>
</tr>
<tr>
<td>Point-of-care Testing</td>
<td>Ext 15976</td>
</tr>
<tr>
<td></td>
<td>Bleep 1189</td>
</tr>
</tbody>
</table>
For a list of the Haematology accredited assays please see the UKAS schedule of accreditation.

6. Laboratory Haematology

6.1. Introduction

This section of the handbook provides information about the Trust’s Haematology laboratories and how to use the haematology laboratory service. It is by no means exhaustive and should further information, clinical advice or result interpretation be required, please contact a member of the haematology staff using the contact numbers listed below. The main laboratory is situated on the Queen Elizabeth Hospital site and is divided into the following sections:

1. Routine Laboratory.
2. Specials Laboratory.

6.2. Useful Telephone Numbers

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Manager</td>
<td>Mrs Helen Peat</td>
<td>0121 371 5963</td>
</tr>
<tr>
<td>Blood Bank Manager</td>
<td>Jane Tidman</td>
<td>0121 371 3297/3298</td>
</tr>
<tr>
<td>Haematology Manager</td>
<td>Nicola Jones</td>
<td>0121 371 6529</td>
</tr>
<tr>
<td>Coagulation Manager</td>
<td>Vacant</td>
<td>0121 371 5988</td>
</tr>
<tr>
<td>Lead Transfusion Practitioner</td>
<td>Juliet Smith</td>
<td>0121 371 5971/07867 537140</td>
</tr>
<tr>
<td>Transfusion Pathway Team Leader</td>
<td>Lisa McKain</td>
<td>0121 371 5970</td>
</tr>
<tr>
<td>Haematology/Transfusion Bleep</td>
<td></td>
<td>1376</td>
</tr>
<tr>
<td>Consultants</td>
<td>Dr C Percy</td>
<td>0121 371 4981</td>
</tr>
<tr>
<td></td>
<td>Dr S Morton</td>
<td>0121 371 4379/5725</td>
</tr>
<tr>
<td></td>
<td>Dr G Lowe</td>
<td>07880021527</td>
</tr>
<tr>
<td></td>
<td>Dr F Clark</td>
<td>0121 371 5961/0121 4146498</td>
</tr>
<tr>
<td></td>
<td>Dr W Lester</td>
<td>0121 371 4995/4996</td>
</tr>
<tr>
<td></td>
<td>Haematology SpR (weekdays 9 – 5)</td>
<td>07825 822253</td>
</tr>
<tr>
<td></td>
<td>Registrars</td>
<td>Bleep through switchboard</td>
</tr>
<tr>
<td>Secretaries</td>
<td>Jan Gaffey Group Support Manager</td>
<td>0121 371 5960</td>
</tr>
<tr>
<td></td>
<td>Secretary to Dr S Morton</td>
<td>0121 371 4379</td>
</tr>
<tr>
<td></td>
<td>Secretary to Dr C Percy</td>
<td>0121 371 4996</td>
</tr>
<tr>
<td></td>
<td>Secretary to Dr G Lowe</td>
<td>0121 371 4381</td>
</tr>
<tr>
<td>Anticoagulant Office</td>
<td>Anticoagulation Clinic Secretaries</td>
<td>0121 371 8369/8370</td>
</tr>
</tbody>
</table>
6.3. **Laboratory Hours**

The Laboratory offers a 24 hour service.  
For any specialist testing please contact the laboratory first to arrange.

**Specials Assay Laboratory**
Specialist coagulation tests (including platelet investigation) are performed in this laboratory by prior arrangement. This service operates a 5 day working week (Mon-Fri)

6.4. **Routine Investigations and Factors Affecting Analysis**

The following investigations are available in the Routine Diagnostic Laboratory:

Samples should be delivered to specimen reception at the earliest opportunity.

Samples for FBC can be accepted for up to 24 h providing they have been stored at 2-8ºC. The age of the sample and incorrect storage conditions can affect the results.

Any add on requests can usually be performed on an EDTA specimen within 24 hours of the receipt of the sample.

All coagulation tests are most accurate if carried out within 4 h of venepuncture and must not be refrigerated or stored overnight.

As the stability of coagulation factors varies, add on telephone tests will be performed at the discretion of the laboratory. A repeat sample will often be requested.

6.4.1. **Automated Blood Count**

A full blood count comprising haemoglobin, red cell count, haematocrit, red cell indices (MCV, MCH and MCHC), total white cell count with differential and platelet count is generated by automated equipment from a single blood sample. **If venepuncture is difficult, or if the blood is not mixed rapidly with the anticoagulant, micro-clots may occur resulting in a falsely low platelet count.**

6.4.2. **Blood Film Examination**

Blood film examination is performed routinely if the automated blood count is significantly abnormal or if a specific clinic indication is stated on the request form. **If a film examination is required please state the reason clearly.**

6.4.3. **ESR**

The ESR is performed on an EDTA blood sample and is most accurate if it is carried out within 2 hours of venepuncture. Samples for ESR can be accepted for up to 24 h providing they have been stored at 2-8ºC.

6.4.4. **Screening for Sickle Haemoglobin**

Patients with sickle cell trait or disease may present with medical or surgical problems, and it is important to consider the presence of sickle cell disease in any individual of non-Northern European origin. Some patients may be previously undiagnosed and therefore unaware of their condition. The screening test for sickle haemoglobin cannot distinguish between the disease and the carrier state. Any positive screening test results should be assumed to represent sickle cell disease until the haemoglobin phenotype is confirmed by electrophoresis. This cannot be done as an emergency. Positive results for
screening tests should be discussed with a Clinical Haematologist before embarking on surgical procedures, particularly if general anaesthesia is required.

### 6.4.5. Routine Coagulation

A prothrombin time, activated partial thromboplastin time, fibrinogen level and D-dimer assay are performed in the routine laboratory. The ratio of citrate anticoagulant to blood in the coagulation test tubes is critical and therefore these tubes must not be under-filled. It is important to ensure that the anticoagulant is mixed adequately with the blood as inadequate mixing may result in a degree of coagulation activation which will result in abnormal laboratory results. It is also important that blood samples for coagulation tests are transported to the laboratory without delay as some coagulation factors are labile at room temperature and therefore delays in testing will result in erroneous laboratory results. If tests are required on patients taking anticoagulant therapy, the anticoagulant should be stated clearly on the request form. Blood should not be taken for coagulation studies via a line or indwelling catheter which has contained heparin. Even a trace of residual heparin will interfere with coagulation test results. All coagulation tests are most accurate if carried out within 4hrs of venepuncture.

### 6.4.6. Bone Marrow Aspiration/Trephine

If a bone marrow examination is required then please consult with one of the Clinical Haematologists contactable via switchboard. If sufficient notice is given, trephine biopsies can be arranged to coincide with general anaesthesia for surgery.

### 6.4.7. HbA1c

An EDTA whole blood sample is used for HbA1c measurement. Although no special patient or specimen preparation is required, it is important that the venepuncture is clean and that the sample is well mixed immediately after venepuncture. HbA1c is not available on patients with known haemoglobinopathies or if the patient has had a transfusion in the last 3 months.

### 6.5. Add-on Tests

- QEHB inpatients and outpatients: Please send a request form with the patient’s details and tests required, clearly stating it is an add-on request.
- Moseley Hall Hospital, St Mary's Hospice, Royal Orthopaedic Hospital and GP surgeries: Please telephone extension 15986 to request additional tests.

Please note that add-on tests will not be dealt with urgently. Due to sample storage procedures within the department, it may not be possible to access a sample quickly. If an add-on result is required urgently, it may be more appropriate to re-bleed the patient.

Please be aware that due to varying sample stability, it may not be possible to add-on further tests.

Please call extension 15986 to discuss if required.
### 6.6. Repertoire of Routine Haematology Tests

#### 6.6.1. General Screening

All combination of these tests can be performed from 1 full Purple top tube (4 mL).

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Blood Count (FBC) &amp; 5 part differential***</td>
<td></td>
<td></td>
<td>Purple/EDTA 4 mL</td>
</tr>
<tr>
<td>Haemoglobin (HGB)</td>
<td>135 – 180 g/L (male)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red Cell Count (RBC)</td>
<td>115 – 165 g/L (female)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.2-5.7 x 10¹²/L (male)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.8-5.1 x 10¹²/L (female)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematocrit (HCT)</td>
<td>0.40 – 0.54 (male)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 – 0.47 (female)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Cell Volume (MCV)</td>
<td>80 – 99fL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Cell Haemoglobin (MCH)</td>
<td>27 – 33pg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Cell Haemoglobin Concentration (MCHC)</td>
<td>315-365g/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet Count (PLT)</td>
<td>150 – 450 x 10⁹/L</td>
<td>24hrs*</td>
<td></td>
</tr>
<tr>
<td>White Blood Cell Count (WBC)</td>
<td>4.0 – 11.0 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutrophils</td>
<td>2.0 – 7.5 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>1.0 – 4.0 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monocytes</td>
<td>0.2 – 0.8 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eosinophils</td>
<td>0.0 – 0.4 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basophils</td>
<td>0.0 – 0.2 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reticulocyte Count</td>
<td>20 – 80 x 10⁹/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythrocyte Sedimentation Rate (ESR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17-50 years</td>
<td>1 – 10</td>
<td>1 – 12</td>
</tr>
<tr>
<td></td>
<td>50-60 years</td>
<td>1 – 12</td>
<td>1 – 19</td>
</tr>
<tr>
<td></td>
<td>&gt;60</td>
<td>1 – 19</td>
<td>1 – 22</td>
</tr>
<tr>
<td>Manual Blood Film</td>
<td></td>
<td></td>
<td>48 Hours**</td>
</tr>
<tr>
<td>Malaria Parasite Screen (Blood Film / Antigen test)</td>
<td></td>
<td></td>
<td>24 Hours*</td>
</tr>
<tr>
<td>Infectious Mononucleosis (Glandular Fever - Slide Test)</td>
<td></td>
<td></td>
<td>24 hours*</td>
</tr>
<tr>
<td>Haemoglobin S detection (HbS) (Sickle Screen)</td>
<td></td>
<td></td>
<td>2 h from receipt if urgent</td>
</tr>
<tr>
<td>HbA1c Not available on patients with known haemoglobinopathies ****</td>
<td></td>
<td></td>
<td>20-42 mmol/mol</td>
</tr>
</tbody>
</table>

** Unless a blood film is required for confirmation of a diagnosis when it will be examined within 2hrs

*** Reference range for the FBC is Adapted from B Bain Blood Cells – A Practical Guide 5th Ed and J.V
6.6.2. Routine Coagulation Screen

**Full Screen requires 1 full Blue top tube.**

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prothrombin Time ratio (PT)</td>
<td>0.8 - 1.2</td>
<td></td>
<td>Blue Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>Activated Partial Thromboplastin Time ratio (APTT)</td>
<td>0.9 - 1.1</td>
<td>24 Hours *</td>
<td></td>
</tr>
<tr>
<td>Thrombin Time ratio</td>
<td>0.8 - 1.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>1.5 – 4.0g/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-dimer</td>
<td>&lt;250ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR</td>
<td>Dependent upon therapeutic requirement</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.7. Urgent Samples

Should you require any urgent full blood count or coagulation specimens to be analysed in the laboratory during core hours at QEH, you must telephone the routine laboratory prior to dispatch of the sample to obtain a specimen reference number (ext.0121 371 5986). This ‘urgent specimen’ number must be written on the request form as must the **correct location** of the patient. This will facilitate its processing and ensure that the results are returned directly to the requesting source. It is important to do this in order that we identify urgent specimens and provide easy identification for the laboratory staff on arrival within the department.

The following tests are available out-of-hours:
- Full blood count
- PT, APTT (+ fibrinogen and D-dimer if appropriate)
- Sickle cell solubility screening test
- Malarial parasites
- Blood film for diagnostic purposes

The following locations are already prioritised.

<table>
<thead>
<tr>
<th>Location</th>
<th>Turnaround time (from receipt of specimen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED, CDU, WACT, WACB, WACE, WAST W620 QCHEMO</td>
<td>1 hour</td>
</tr>
<tr>
<td>WCCA, WCCB, WCCC, WCCD, WADM, WAMB, Oncology, W622, QCCU, QSSU, St Mary’s Hospice and GP samples marked urgent.</td>
<td>1 hour</td>
</tr>
<tr>
<td>All Trust inpatients</td>
<td>4 Hours</td>
</tr>
</tbody>
</table>

All Turnaround times for inpatients are monitored for FBC APTT PT and DDIMER.

Please note that at times of high demand or if there are instrument malfunctions we may
not be able to achieve this turnaround times.

6.8. **Specialist Investigations & Factors Affecting Analysis**

The following tests are performed by the Special Assay department. Sample tubes need to be filled to the correct mark as under-filled or over-filled samples alter the anticoagulant: blood ratio which may lead to erroneous results. Samples should be sent to the laboratory as soon as possible after venepuncture to ensure protein stability. All coagulation tests are most accurate if carried out within 4 h of venepuncture. Haemolysed and lipaemic samples may also affect the validity of results making clinical interpretation difficult.

Please note that samples will be stored in the department for one month after the date of reporting of results. After this time requests for “add-on” test analysis will not be possible and fresh samples will need to be sent to the laboratory.

### 6.8.1. Thrombophilia Screen

*These tests require Blue top tubes. For a full thrombophilia screen please send at least 4 tubes*

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lupus anticoagulant screen</td>
<td>Please see report</td>
<td>21 days*</td>
<td>Blue</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>Antithrombin function (AT)</td>
<td>83-127 u/dL</td>
<td>21 days*</td>
<td></td>
</tr>
<tr>
<td>Protein C function</td>
<td>65-171 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein S Antigen (Free Protein S)</td>
<td>Male 75-139 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female 55-125 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor V Leiden mutation by PCR</td>
<td>Please see report</td>
<td>21 days*</td>
<td></td>
</tr>
<tr>
<td>Prothrombin gene 20210A mutation by PCR</td>
<td>Please see report</td>
<td>21 days*</td>
<td></td>
</tr>
</tbody>
</table>

These tests are complex to perform and batching is necessary, please send to the Special Assay laboratory: **0121 371 5988**

### 6.8.2. von Willebrand Factor Screen

*These assays are to be requested through the Haematology Consultant*

*These tests require 3x Blue top tubes*

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVIII:C</td>
<td>57-158 u/dL</td>
<td>21 days*</td>
<td>Blue</td>
</tr>
<tr>
<td>von Willebrand Factor Antigen (VWF:Ag)</td>
<td>48-175 u/dL</td>
<td></td>
<td>Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>von Willebrand Factor Activity (VWF:RCo, RICO)</td>
<td>47-154 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>von Willebrand Factor Collagen Binding activity (vWF:CBA)</td>
<td>42-259 u/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.8.3. Factor Assays

These assays are to be requested through the Haematology Consultant

**These tests require 2 Blue top tubes**

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>FII (Factor 2)</td>
<td>87-129 u/dL</td>
<td></td>
<td>Blue Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>FV (Factor 5)</td>
<td>66-135 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FVII (Factor 7)</td>
<td>66-170 u/dL</td>
<td>21 days*</td>
<td></td>
</tr>
<tr>
<td>FX (Factor 10)</td>
<td>76-171 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIX (Factor 9)</td>
<td>82-166 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FXI (Factor 11)</td>
<td>70-164 u/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FXII (Factor 12)</td>
<td>64-183 u/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.8.4. Haemoglobinopathy Diagnosis

**These tests require Purple top tubes.**

Please note these tests are referred and performed at Heart of England NHS Foundation Trust

<table>
<thead>
<tr>
<th>Test</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin separation by High Pressure Liquid Chromatography (HPLC) ***</td>
<td>5 Days*</td>
<td>Purple EDTA 4 mL</td>
</tr>
<tr>
<td>Haemoglobin F and haemoglobin A2 estimation ***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemoglobin S estimation ***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose-6-phosphate dehydrogenase screen (G6PD) ***</td>
<td>7 Days</td>
<td></td>
</tr>
</tbody>
</table>

If a diagnosis of Thalassaemia is suspected it is essential to exclude iron deficiency, please send a sample for serum ferritin (yellow/Ochre top).

6.8.5. Haematinics

**These tests require one (yellow/Ochre top) for serum B<sub>12</sub> & folate.**

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum vitamin B&lt;sub&gt;12&lt;/sub&gt;</td>
<td>&lt;105 ng/L, B&lt;sub&gt;12&lt;/sub&gt; deficiency highly likely 105-200 ng/L, B&lt;sub&gt;12&lt;/sub&gt; deficiency possible (review haematological/clinical findings to confirm) &gt;200 B&lt;sub&gt;12&lt;/sub&gt; deficiency unlikely</td>
<td>24 Hours</td>
<td>Yellow 4 mL</td>
</tr>
<tr>
<td>Serum folate</td>
<td>2.7-18.6 μg/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ferritin</td>
<td>10-320 μg/L female</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18-360 μg/L male</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NB. Haematinics assays are now undertaken at the Clinical Biochemistry Dept.
### 6.8.6. Other Specialist Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference interval</th>
<th>Target Turnaround</th>
<th>Specimen Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet aggregation test – <strong>must</strong> liaise with Haematology Consultant. ***</td>
<td>Please see report</td>
<td>24 hrs</td>
<td>Blue Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>Urinary Haemosiderin ** ***</td>
<td></td>
<td></td>
<td>10mL of urine in a plain container</td>
</tr>
<tr>
<td>Heparin Induced Thrombocytopenia Screen (HIT)</td>
<td>&gt;0.4-1.0 weak positive</td>
<td>21 days*</td>
<td>Red 6ml</td>
</tr>
<tr>
<td></td>
<td>&gt;1.0 Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADAMTS13 activity</td>
<td>38-110%</td>
<td>21 days*</td>
<td>Blue Trisodium Citrate 3.5 mL</td>
</tr>
<tr>
<td>ADAMTS13 inhibitor (IgG)</td>
<td>Neg &lt;12 U/mL</td>
<td>21 days*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Borderline 12-15 U/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive &gt;15 U/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti Xa assay</td>
<td>Dose dependent please see report</td>
<td>21 days*</td>
<td></td>
</tr>
<tr>
<td>Bethesda Assay</td>
<td>Please see report</td>
<td>21 days*</td>
<td></td>
</tr>
</tbody>
</table>

**KEY**

* Unless urgent by prior arrangement with laboratory.

** Unless a blood film is required for confirmation of a diagnosis when it will be examined within 2hrs.

*** Please note that this assay is not currently included in our ISO15189:2012 accreditation scope.

**** Note clinical advice is provided by Biochemistry.
7. Blood Bank

7.1. Introduction

Blood Transfusion carries risk and good clinical practice requires that blood components should be prescribed only when the benefit to the patient is likely to outweigh the risks. Prescription of these components shall be in conjunction with the Maximum Surgical Blood Ordering Schedule (MSBOS) and Trust Transfusion Policy all of which can be found on the Trust Intranet.

The requirement for transfusion of blood or blood components shall be recorded in the notes prior to completing a request form. The patient should be asked if they wish to have a transfusion and given the appropriate information leaflets if circumstances allow. These should available in all clinical areas. The component type and quantity required should be requested in conjunction with the above guidance, to request further information leaflets contact the Transfusion Practitioners on ext. 15966.

A comprehensive guide to UHB Transfusion Services, Guidelines, Sample Requirements and Indications for Blood Use can be found in the Blood Transfusion Policy and its linked Procedures 1-8 available on the Trust Intranet

The guidelines have been drawn up in line with nationally agreed indication codes and recommendations

Laboratory hours and telephone numbers are as listed under Laboratory Haematology Contact QEHB Blood Bank on ext. 13297/8 or bleep 1376, there is a member of staff on duty 24/7.

7.2. Blood Bank Repertoire, Samples & Factors Affecting Analysis

- Blood group and antibody screen  
  *EDTA blood sample (Purple Top):*
- Cross-match  
  *EDTA blood sample (Purple Top):*
- Direct antiglobulin test (Coomb’s test)  
  *EDTA blood sample (Purple Top):*
- Suspected warm/cold antibodies (please discuss with Blood Bank first – may require several EDTA blood samples and a clotted sample)
- Transfusion Reaction
  - Post-transfusion specimen (including at least one EDTA specimen and red top clotted sample, all hand written)
  - Remainder of bag (or empty bag) with which the complication occurred, if available
  - Administration tubing, if available
  - Samples to haematology for FBC and PT/PTT
  - Samples to biochemistry for profile
- Platelet antibodies, leukocyte antibodies, HLA typing (these tests can be arranged by prior arrangement with the Tissue Typing Laboratory at the Blood Transfusion Centre.
  *Clotted Sample (Red Top x2 & EDTA x2)*

Rejection Criteria

All samples must be hand written with registration no, DOB, forename, surname, time and date taken and signed. Under-filled samples will be rejected.
Clinical Laboratory Services Queen Elizabeth Hospital

Samples for complex red cell, platelet and granulocyte antibody tests, will be referred to the NHSBT. It is recommended that if patients require these investigations it should be discussed with a Clinical Haematologist.

7.3. Request Procedure

All requests for blood or blood components (red cells, plasma, platelets and cryoprecipitate) must be made on the transfusion request form. Transfusion request forms can be either hand-written or an addressograph label for patient details can be used on the request form but all other details must be completed by hand. If an addressograph label is used for patient details then initials should be put on the label. Patient details on the sample must be hand written using a ball-point pen, signed and dated. It is important that the person performing the phlebotomy completes ‘Sample taken by’ box on the request form and signs the blood tube and request form.

Blood transfusion errors are most often those of patient identification. Full details on patient identification can be found on the Blood Transfusion Policy Procedure 2. Patients identity must be confirmed by asking the patient to state their

- First and Surname
- Date of Birth
- Check this information and the hospital registration number against the wrist band and request form.

Information on the request form and the blood tube should be double-checked against the wristband to ensure that it is both complete and correct. Patient information on the blood tube must be taken from the patient not the form.

There is zero tolerance regarding sample labelling and requesting in blood bank. Only samples that meet the following criteria will be accepted:

- All samples must be hand written onto the bottle label, sticky labels of any kind are not acceptable.
- The details on the sample and request card must match.
- Pre-printed addressographs are acceptable on the request form but should be initialled.
- On the sample and the form there must be;
  - Registration number.
  - Surname.
  - Forename.
  - Date of Birth.
  - Gender.

In addition to this the form must also have:-

- Consultant details.
- A contact number.
- Reason for the request.
- Location of patient.
- Phlebotomist’s name.
- Signature of the requestor.
- Date and time when sample drawn.
- Type of Request i.e. G&S, Crossmatch and number of units if required.
Clinical Laboratory Services Queen Elizabeth Hospital

- Special Instructions - The laboratory must be informed if these are required e.g. Irradiated, CMV negative, HLA selected, sickle negative etc.

In an emergency, the registration number, gender and phonetic trauma name will be acceptable.

7.4. Timing of Requests

7.4.1. Planned Transfusion
At least 24 hours’ notice of blood requirement must be given before the blood is required. Blood will be issued after the ABO and Rhesus (D) groups have been checked and the blood has been screened for atypical antibodies. If there are atypical antibodies, suitable blood may then have to be obtained from the NHSBT. This may take up to 48 hours.

7.4.2. Urgent Transfusion
When a transfusion is urgently required, it is very important that Blood Bank is clearly informed to state that an emergency specimen is on the way and how soon blood is required as the choice of emergency procedure depends directly on this information. The ward or operating theatre will be telephoned when blood is ready. Please allow for the time taken for the specimen to arrive in the laboratory.

7.4.3. Immediate Transfusion
(For massive and rapid blood loss – please refer to: Blood Transfusion: Procedure 5: Massive Blood Loss & Urgent Transfusion available on the Trust Intranet)
Immediate transfusion request may be required for massive and rapid blood loss please send an EDTA blood sample to the Blood Bank as soon as possible. If blood is required urgently, group specific blood will be issued in the absence of a completed antibody screen. The decision to transfuse uncross matched blood is a medical decision, please see procedure 5.
If the need for transfusion is so great that there is no time to wait for ABO grouped blood, then emergency O negative blood can be found in the following locations

<table>
<thead>
<tr>
<th>Location of Blood Fridge</th>
<th>Door Number</th>
<th>Number of bags of emergency O negative blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Bank Issue room</td>
<td>A/-1/CLS/C5a</td>
<td>4</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>A/1/AE/7</td>
<td>10</td>
</tr>
<tr>
<td>Main Theatres</td>
<td>A/2/STR/20A</td>
<td>4</td>
</tr>
<tr>
<td>Ambulatory Care</td>
<td>A/0/AC/130</td>
<td>2</td>
</tr>
<tr>
<td>Welcome Theatre</td>
<td>Floor 2 – across the link bridge. ID badges will only work on staff with Welcome Theatre access privileges</td>
<td>3</td>
</tr>
<tr>
<td>Royal Orthopaedic Hospital</td>
<td>Theatres</td>
<td>6</td>
</tr>
</tbody>
</table>

O Rh (D) negative is compatible with all blood groups but may cause a reaction in patients who have antibodies. It is most important that a blood specimen for blood group and
antibody screen is obtained from the patient at the earliest opportunity so that group specific blood can be supplied.

**N.B:** *When blood is removed from the Blood Bank before full compatibility can be established, the responsibility for the safety of the transfusion rests solely with the medical officer prescribing the blood.*

When removing emergency O Negative blood, log the blood components out of the Satellite blood fridge log and complete the patient details in the blood register. This **MUST** include the time and date the units are removed, who they are for (name and Reg. No.), where the patient is and who took the units. Emergency blood that is taken to wards where PICS is available, the transfusion must be both prescribed and recorded on PICS.

If the blood is transfused the card attached to each unit **MUST** be completed and placed in the basket in the fridge from which the unit(s) were removed.

If blood is returned unused the date/time returned **MUST** be written on the register. It is vital that blood bank staff know how long the blood is out of the fridge.

### 7.5. Patients with Allo-antibodies

Blood for transfusion is routinely typed for ABO and Rhesus (D) groups only. If a patient has produced an allo-antibody stimulated either by a previous transfusion or by pregnancy, it will be necessary to search for blood negative for the antigen. Some patients carry an antibody identification card, or such information is displayed in their notes. This information **MUST** be written on all cross-match request forms. Please try to give at least 24 hours’ notice of transfusion or expect a delay otherwise. When a new antibody is identified in a patient, Blood Bank will request a further 4 x EDTA of blood for investigation by the National Blood Service who will confirm the antibody and issue an antibody identification card which the patient must carry at all times.

### 7.6. Repeat Transfusions (sample interval)

One of the complications of blood transfusion is that the patient may develop a new red cell antibody. Red cell antibodies may cause a serious transfusion reaction if incompatible blood is given to the patient. If there is a gap between transfusions then a new sample is required to check whether a new antibody has developed.

For repeat transfusions the following applies:

#### 7.6.1. Patients Transfused Within the Last 3 Months

Samples collected no more than 72 hours prior to the actual transfusion when the patient has been transfused or pregnant within the preceding 3 months.

#### 7.6.2. ROH, QEHB and Pre Assessment Clinics

The samples from patients attending QEHB and ROH pre-op assessment clinic are stored for 4 weeks. It is important that pre-operative assessment clinic nursing staff inform patients that a condition of keeping the transfusion sample for 4 weeks is that patients must inform the ward upon admission that they have had a transfusion elsewhere or are or have been pregnant. In these cases, a new transfusion sample must be taken. Samples which contain antibodies require a FRESH sample for crossmatch.
7.6.3. Renal
If a patient attending the dialysis unit as an out-patient has a sample taken during the visit, providing no transfusion was given at the same visit, this sample can be used. If a transfusion was given then a fresh sample MUST be taken no more than 72 hours before the next transfusion episode.

7.6.4. Cardiac Clinic
The samples from patients attending cardiac pre-op assessment clinic are stored for 4 weeks during which time some patients may have received top up transfusions pre–op. As a precaution when the cardiac list arrives check each transfusion history.

7.6.5. Haematology Day Unit
The requests for cross-match from patients attending Haematology Clinics are for in-patient treatment during the next few days and providing the patient has not been transfused for 3 months prior the sample being taken then this sample is safe to use. If the patient has been transfused during the last 3 months then a fresh sample MUST be taken no more than 72 hours before the next transfusion episode unless the consultant concerned authorises the use of the sample.

7.6.6. Liver
Liver samples are kept for seven days in the specimen fridge. Treat as a routine group and save sample.

IF IN DOUBT IT IS SAFER TO REQUEST A FRESH SAMPLE

7.7. Massive Transfusion
During massive transfusion, i.e. a patient receiving 10 or more red cell bags within 24 hours, the patient’s total circulation is replaced with donor blood. Note that subsequent serum samples will contain very little of the patient’s original blood serological profile. Stored blood contains minimal plasma/platelets, shock also disturbs blood coagulation.

(note: all patients born after 1 January 1996 must be identified as they must be issued with non UK sourced plasma. This is a DOH directive.)

7.8. Non-Red Cell Components (General)
Components do not require a cross-match but the blood group of the patient must be known before compatible components can be issued. These always require a fresh blood administration set. If a blood group has not been performed then a transfusion sample must be sent. A request form is required. In emergency situations a telephone order can be made giving all the details required and a request form must be sent as soon as possible. Specific details of each blood components can be found in the Trust Blood Transfusion Policy. Blood Bank provides red cells, platelets, fresh frozen plasma (including virucidally inactivated) and cryoprecipitate.

NB – Octaplas is obtained from blood from Blood Bank at QEHB after consultation with Haematology consultants.
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7.9. Blood Products

7.9.1. Prothrombin complex concentrate (Beriplex)
See Guidelines on trust intranet for the use of Prothrombin Complex Concentrate (Beriplex) in life-threatening haemorrhage in patients on warfarin or acquired deficiency of vitamin K dependant clotting factors. Available from the emergency pharmacy fridges, emergency department and Level 4 at QEH.

7.9.2. Albumin
Obtained from Pharmacy

7.9.3. Activated factor VII - rFVIIa (Novoseven)
Available from emergency pharmacy fridges, emergency department and Level 4 at QEH. Guidelines for use are on the hospital intranet for the use of recombinant activated factor VII (NOVOSEVEN) in life-threatening uncontrolled haemorrhage.

7.9.4. Anti D
Obtained from the Women’s Unit after consultation with Haematology Medical staff
If unsure discuss the use of these products with Blood Bank or Haematology medical staff.

7.10. Blood Collection
Blood issue areas are situated at:

<table>
<thead>
<tr>
<th>Location/Department</th>
<th>Door number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood bank</td>
<td>A/-1/CLS/C5a</td>
</tr>
<tr>
<td>WCCA</td>
<td>A/2/CC/160</td>
</tr>
<tr>
<td>Theatre 3</td>
<td>A/2/TH/158</td>
</tr>
<tr>
<td>Main Theatres</td>
<td>A/2/STR/20A</td>
</tr>
<tr>
<td>Welcome Theatres</td>
<td>Wellcome Building – across the link bridge</td>
</tr>
<tr>
<td>Ward 621</td>
<td>A/6/W621/11</td>
</tr>
<tr>
<td>W625</td>
<td>A/6/W625/33</td>
</tr>
<tr>
<td>Ambulatory Care</td>
<td>A/0/AC/130</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>A/1/AE/7</td>
</tr>
<tr>
<td>WCCD</td>
<td>A/2/CC/43</td>
</tr>
</tbody>
</table>

Queen Elizabeth Hospital
The main issue area in the QEHB is secure at all times and will require a Trust identity card for access.
7.10.1. Collection of Blood or Components
This procedure of collection of platelets and FFP is the same as blood. The only difference is the storage and transport temperature. The full procedure is discussed in the Transfusion Policy (available on the Trust Intranet). Only those trained and assessed as competent in the procedure can collect blood and blood components. The procedure is also prominently displayed in the blood bank issue areas. Only one unit of blood can be collected at a time. Exceptions are generally associated with emergencies in theatres, Critical Care Units or Accident and Emergency. When components of different types are collected at the same time they should be carried in separately.

7.11. Return of Blood and Blood Components
All unused blood/components must be returned to Blood Bank with the form Authority For Return of Unused Blood/ Blood Components. Please complete all patient details on the form. Return Blood/FFP to drawer marked ‘returned blood’ in Issue Blood Bank fridge. If cryoprecipitate or platelets are to be returned, contact Blood Bank. If blood/FFP was not stored at 4º (+/- 2º) for longer than 30 minutes, the Blood Bank on 13297 or bleep 1376, must be contacted.

7.12. Reservation Period

7.12.1. Blood for Surgery
Cross-matched blood for patients undergoing surgery will be automatically de-reserved between 08.00 and 09.00 two days following the stated date required and the blood returned to bank stock. If the operation is delayed, or if you wish to transfuse after this time, then you must telephone the Blood Bank so that the blood will continue to be reserved for your patient. Platelets, Fresh Frozen Plasma and Cryoprecipitate will be automatically de-reserved between 08.00 and 09.00 on the day following the date required.

7.12.2. Blood for Anaemia
Cross-matched blood will be held for a maximum of 48 hours after the stated time required or first unit transfused. The patient may have formed antibodies during this time and it is therefore unsafe to transfuse the remainder of the cross-matched blood. If further transfusion is required, please send a fresh blood sample and transfusion request.

7.13. Serious Adverse Reactions and Events - SHOT and SABRE
It is mandatory that serious transfusion hazards and incidents must be recognised, managed and reported to either SHOT (Serious Hazards of Transfusion); and/or SABRE (Serious Adverse Blood Reactions and Events). All blood transfusion related incidents, including serious transfusion reactions, must be reported using the Trust Clinical Incident process. In addition Blood Bank must be notified immediately by telephone so that appropriate investigation can be undertaken which may include the immediate withdrawal of issued components. The Hospital Transfusion Team will generate a report for SHOT and SABRE, and the matter will be reported to the Hospital Transfusion Committee. All transfusion reactions will be investigated by the laboratory.
7.14. **Traceability**

By law blood bank is required to document evidence of the fate of every blood component received by the Trust. If blood or blood components are administered to a patient, it is the clinical areas responsibility to record this evidence in PICS or the area’s blood registers/transfusion record. All blood components that are not transfused must be returned to blood bank as soon as possible with appropriate documentation (form WNP 0606; authority to collect/return blood or blood components). The law requires 100% traceability and Blood Bank audits, reports and monitors compliance on a continuous basis. Issues of non-compliance are reported to the Trust’s Hospital Transfusion Committee on a quarterly basis and to the MHRA in an annual return.
8. Clinical Microbiology

8.1. Introduction

This guide gives information on how to use the Clinical Microbiology Department, a separate guide is provided on the rational use of Antimicrobials available on the Intranet. See Trust Guidelines for Antimicrobial Prescribing

Advice on the microbiological investigation of patients with infection, and their treatment, can be obtained from the Clinical Microbiologists who provide a 24 hour service.

<table>
<thead>
<tr>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Microbiologists</td>
<td></td>
</tr>
<tr>
<td>Dr Ira Das</td>
<td></td>
</tr>
<tr>
<td>Dr Miruna David, (Clinical Service Lead)</td>
<td></td>
</tr>
<tr>
<td>Dr Martin Gill</td>
<td></td>
</tr>
<tr>
<td>Dr Elisabeth Holden</td>
<td>Ext. 16516 or external 0121 371 6516</td>
</tr>
<tr>
<td>Dr Sima Jog</td>
<td></td>
</tr>
<tr>
<td>Dr Debbie Mortiboy</td>
<td></td>
</tr>
<tr>
<td>Dr Nim Wickramasinghe</td>
<td></td>
</tr>
<tr>
<td>Specialist Registrars</td>
<td></td>
</tr>
<tr>
<td>Virologists</td>
<td></td>
</tr>
<tr>
<td>Dr H Osman or Dr Erasmus Smit</td>
<td>Ext. 16518 / 16516 or mobile telephone via hospital switchboard</td>
</tr>
<tr>
<td>Out-of-hours</td>
<td></td>
</tr>
<tr>
<td>On-call Medical Microbiologist, Virologist or Biomedical Scientist:</td>
<td>Mobile telephone via hospital switchboard (a rota operates for this service)</td>
</tr>
<tr>
<td>(This service is provided by staff from home)</td>
<td></td>
</tr>
<tr>
<td>Infection Control Nursing Team</td>
<td>Ext. 13785 (out of hours contact the On-call Clinical Microbiologist)</td>
</tr>
<tr>
<td>Community Infection Control Nurses</td>
<td>0121 466 6304 (Birmingham Community Healthcare)</td>
</tr>
<tr>
<td>Decontamination Advisor</td>
<td>Ext. 13852 or mobile telephone through switchboard</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Ext. 15977 or external 0121 371 5977</td>
</tr>
<tr>
<td>Mr Paul Arrowsmith</td>
<td></td>
</tr>
<tr>
<td>Laboratory Operational Managers</td>
<td>Ext. 16532 or external 0121 371 6532</td>
</tr>
<tr>
<td>Miss Catherine Swann</td>
<td>Ext. 16532 or external 0121 371 6532</td>
</tr>
<tr>
<td>Miss Katie Dedicoat</td>
<td>Ext. 16530 or external 0121 371 6530</td>
</tr>
<tr>
<td>Hospital Infection Research (HIRL)</td>
<td>Ext. 16070 or external 0121 371 6070</td>
</tr>
<tr>
<td>Ms Christina Bradley</td>
<td></td>
</tr>
<tr>
<td>Specimen Reception</td>
<td>Ext. 13306 or external 0121 371 3306</td>
</tr>
<tr>
<td>Departmental Direct line</td>
<td>0121 371 6516</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:Lorraine.day@uhb.nhs.uk">Lorraine.day@uhb.nhs.uk</a></td>
</tr>
</tbody>
</table>
8.2. Use of the Clinical Microbiology Department

The services available in the Department of Clinical Microbiology are outlined below. It is important that all medical and nursing staff familiarise themselves with these guidelines, to optimise use of these services.

8.2.1. Access to Services

<table>
<thead>
<tr>
<th>Core Hours</th>
<th>Out of hours (On Call)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday – Friday 09.00 - 19.00</td>
<td>Monday – Friday 19.00 - 08.00</td>
</tr>
<tr>
<td>Weekend 08.00 -16.00</td>
<td>Weekend 16.00 - 08.00</td>
</tr>
<tr>
<td>Bank Holidays – As for weekends</td>
<td>Bank Holidays – As for weekends</td>
</tr>
</tbody>
</table>

8.2.2. Out-of-hours

The out-of-hours service is provided by on-call Biomedical Scientists from home.

Emergency specimens outside laboratory hours should be arranged directly with the on-call Biomedical Scientist (contact via the hospital switchboard). In general, the results of any specimens which are required to be analysed on-call should influence the patient's immediate management.

Tests available on the emergency service for Clinical Microbiology include the examination of:

- Cerebrospinal fluid.
- Peritoneal Dialysis fluid.
- Ascitic taps.
- Synovial fluid.
- Aspirates from deep-seated infections.
- Pericardial fluids.
- Bronchial lavage.
- Multi organ transplant serology.
- Intra-operative specimens that cannot be repeated.

Blood cultures that are taken out of hours should be sent to the laboratory immediately. There is no need to notify the on-call technician or Clinical Microbiologist.

If urgent examination of a specimen not listed above is felt necessary, please contact the on-call Medical Microbiologist via the hospital switchboard.

8.2.3. Specimen Containers

Specimens should only be sent to the laboratory in sterile containers or the appropriate blood tubes/collection kits.
Details of tests performed and collection containers required are shown in:

[PUB_221 Guide to Specimen Containers for Pathology Requests]

and on the intranet as web pages


8.2.4. Request Forms

A separate Clinical Microbiology request form is required for each specimen with the patient's minimum data set and the requesting doctor's bleep number to facilitate communication of urgent or important results. Microbiology uses three types of request form, see Appendix 9. Correct selection is essential for prompt processing.


The background colour of each test corresponds to the print colour of the appropriate request form. Use of the correct request form will facilitates the sorting and onward processing of samples. Relevant clinical details must be given, including duration of illness and current antibiotic therapy to facilitate relevant clinical guidance.

Please do not include tests that are performed by other laboratory disciplines, e.g. CSF Protein or Cytology investigations on a Microbiology request form as this delays processing of requests.

8.3. Turnaround Times

These figures are from the time of receipt in the laboratory to issue of the report for specimens received during normal working hours and are quoted as ‘working’ days.

The table below gives guidance on turnaround times, however, some organisms require extended incubation. In some instances, special analyses may be required which may increase turnaround times. More detail is contained in the relevant sections that follow.
Investigations / Tests | Expected Turnaround Time
--- | ---
**Routine Bacteriology, (M,C&S)** |  
Negative Report | 2 to 4 days  
Positive Report | 3 to 5 days*  
TB Culture | Up to 10 weeks  
Fungal Culture | Up to 4 weeks  
Detection of C. difficile | Within 30 hours  

**Serology / Virology** |  
Routine - assays performed on-site | 3 to 7 days  
Exception – Hepatitis D | Up to 28 days  
Referred Serology | 7 to 28 days  

**Molecular Microbiology** |  
Hepatitis B and C viral loads | Up to 14 days  
HIV viral load | Up to 7 days  
CMV viral load | Up to 3 days  
EBV viral load | Up to 7 days  
*N. gonorrhoeae / C. trachomatis (NAAT)* | Up to 7 days  
Rapid Flu A, Flu B and RSV | 24 hours  
TB PCR | Up to 72 hours  
Norovirus PCR | 24 hours  

*Please note: Some organisms require extended incubation.

Urgent virology tests are available following needle-stick injury or other incidents. Please telephone Clinical Biochemistry to obtain an “urgent laboratory number”, (see Section 5.3).

8.4. **High Risk Specimens**

It is the responsibility of both the staff who request laboratory investigations and those who collect the sample to ensure that there is no infection hazard to those who transport or subsequently analyse the sample.

All specimens are potentially hazardous and must be collected, transported, examined and disposed of with care but some may be known to constitute a "high risk". All specimens (including blood, serum, urine, faeces, CSF, other aspirated fluids, biopsies) from certain patients are particularly hazardous to staff who handle them, for example patients with Hepatitis B, HIV, CJD and TSE.

**DO NOT** send high risk samples via the Specimen Delivery System, (SDS).  
Please use the portering service.

Certain infections constitute an even greater risk (Hazard Group pathogens, as listed...
below), if such infections are suspected, the advice of the Clinical Microbiologist should be sought immediately.

Trust infection control procedures MUST be strictly adhered to when collecting samples from patients.

8.4.1. Hazard Group 3 Pathogens

All specimens from suspected or confirmed infections with Hazard group 3 pathogens include the following:

- All patients who have fever within 21 days of return from Africa (potential risk of infection with Hazard Group 4 pathogens).
- Rabies.
- All specimens and other material that may contain tubercle bacilli even if examination for them is not requested.
- Stools from patients with possible enteric infection, including tapeworm and Echinococcus granulosum.
- Liver or Hydatid cysts and associated aspirates.
- Other samples as directed by the Infection Control Team.
- The following infections (suspected or confirmed):
  - Bacillus anthracis (Anthrax).
  - Brucella spp. (Brucellosis).
  - Chlamydia psittaci (Psittacosis).
  - Clostridium botulinum (Botulism).
  - Corynebacterium diphtheria.
  - Escherichia coli 0157 and other verotoxin producing strains.
  - Francisella tularensis (Tularaemia).
  - Burkholderia mallei (Glanders).
  - Burkholderia pseudomallei (Melioidosis).
  - Salmonella paratyphi A (Paratyphoid A).
  - Salmonella typhi (Typhoid).
  - Shigella dysenteriae Type 1.
  - Yersinia pestis (Plague).
  - Blastomycosis.
  - Coccidiomycosis.
  - Histoplasmosis.
  - Paracoccidiomycosis.
  - Q fever and other rickettsial infections.
  - Arbovirus infections (except Semliki Forest).
  - Uganda S. Yellow Fever, Herpes Virus B.

8.5. Creutzfeldt Jacob Disease/TSE

Samples of brain tissue and/or spinal cord material from patients with Creutzfeldt-Jakob disease/TSE must be clearly labelled as possible or confirmed CJD.

A protocol for dealing with patients and samples is available in the Trust Infection Prevention & Control Policy.

N.B. Safety Note. If suspicion of new variant CJD or TSE exists, all specimens must be processed according to Trust Policy. If in doubt contact the Consultant Virologist or Microbiologist.  [http://uhbpolicies/assets/TseIncCjdProcedure.pdf](http://uhbpolicies/assets/TseIncCjdProcedure.pdf)
8.5.1 Hazard Group 4 Pathogens

Organisms, viruses and materials that are extremely hazardous and which may cause serious epidemic disease require the most stringent conditions for their containment. If these diseases are suspected then specimens should not be sent to the laboratory without prior consultation with the Infection Control Doctor.

Hazard Group 4 infections include:
- Ebola virus.
- Lassa fever virus.
- Guaranito.
- Junin.
- Machupo.
- Nipah.
- Sabia.
- Herpes virus simiae (B virus).
- Hendra (formerly equine morbillivirus).
- Marburg virus.
- Omsk.
- Russian spring summer encephalitis.
- Whitepox virus.
- Crimea (Congo) haemorrhagic fever (CCHF) virus.
- Venezuelan equine encephalitis virus.

8.6. Test Repertoire

8.6.1. General Bacteriology, (M, C&S)

The laboratory will perform culture on a range of clinical specimens for pathogenic microorganisms. Where appropriate; microscopic investigations will be performed, e.g. Gram’s stain. If investigations for TB are required this must be clearly indicated.

Significant isolates will be identified using a combination of mass spectrometry, (Maldi-TOF) and biochemical tests as required. Antimicrobial susceptibility testing is carried out in accordance with EUCAST guidelines.

Organisms with unusual identity and/or susceptibility patterns may require confirmation by specialist referral centres.

8.6.2. Urine

Midstream urine (MSU) specimens are only of diagnostic value if adequate preparation has been made to clean the peri-urethral area (NOT with an antibacterial substance) before obtaining the urine.

The bladder should be partly emptied before obtaining a MSU.

Samples of urine should be stored in a refrigerator at 4°C until transport is available.

At least 4 mL of urine should be collected into a plain universal container.

Boric acid containers (Sarstedt tubes) should be to the line indicated on the tube. Do not over fill the containers.

Catheter samples and samples from indwelling devices are also suitable for culture. Please state the site from which the urine specimen has been collected on the request form, e.g. CSU, nephrostomy, supra-pubic aspirate etc.
Microscopic analysis for the presence of ova or casts may be performed if specifically requested, these samples must be received in a sterile universal container.

If examination for *Mycobacterium tuberculosis* is required, this must be clearly indicated on the request form. Please obtain an **EMU sample** using a sterile universal container. Samples should be collected on 3 consecutive days and sent to the laboratory on the day of collection.

Urine samples may also be processed for detection of Legionella antigen. Please use a sterile universal container.

### 8.6.3. Pus and Exudates

Wherever possible, a sample of pus is preferable to a swab. The site from which the pus was obtained must be clearly stated. Pus should be sent in a sterile universal container.

When pathogens such as *Actinomyces* or tubercle bacilli are suspected, it should be clearly stated on the request form, as routine methods will not reveal these organisms.

### 8.6.4. Swabs

Material on swabs dries out rapidly and organisms will lose viability. Transport media is provided within the swab container, but rapid transit to the laboratory is essential.

Charcoal swabs are not suitable for virology investigations.

The site from which the swab has been taken must be clearly indicated on both the request form and swab container. Please provide relevant clinical details.

Conjunctival swabs should always be obtained before antibiotic creams or drops are applied. Investigations for chlamydial disease require a special collection set available from Specimen Reception, (extension 13306).

IUCD are also suitable for culture and must be sent to the laboratory in a sterile universal container. Cultures from IUCD samples are incubated for up to 10 days.

If *Acanthamoeba* infection is suspected, consult a Medical Microbiologist before taking any samples. This investigation is not performed in this laboratory and must be referred.

### 8.6.5. MRSA Screening Swabs

A full MRSA screen requires a combined swab taken from the nose (both anterior nares), and groin (both sides) along with a separate throat swab. The swabs should be moistened in sterile saline before applying to the site and placed in the charcoal transport medium to maintain viability during transit to the laboratory.

Please note: MRSA must be requested on the form, (not M, C+S).

### 8.6.6. Cerebrospinal Fluid (CSF)

In suspected cases of meningitis or where urgent analysis is required, CSF should be sent immediately to the laboratory in a sterile universal container.

**CSF samples must not be sent via the Sample Delivery System, (SDS).**

Notify the laboratory using extension number 16520 during normal working hours or via switchboard at other times.
A cell count and Gram film will be carried out and reported to the requesting clinician as a priority. If TB, viral or parasitic investigations are required, this should be clearly stated on the request form.

If subarachnoid haemorrhage is suspected, the first and third samples should be sent, (examination for Xanthachromia is performed by Biochemistry, see Section 5.8).

Samples that are heavily blood stained or clotted will not be counted.

For routine CSF samples, microscopy results will be released to PICS as soon as analysis has been completed. Final culture reports are issued within 5 working days.

Please discuss with the Clinical Microbiologist or Virologist if further test required

8.6.7. Other Sterile Fluids

The laboratory will examine samples of ascites, peritoneal dialysis fluid and synovial / bursa fluids. If urgent processing is required notify the laboratory using extension number 16520 during normal working hours or via switchboard at other times.

Samples must be received in a sterile universal container. If TB, viral or parasitic investigations are required, this should be clearly stated on the request form.

A cell count is performed on ascites and peritoneal dialysis fluids. To avoid samples clotting in transit, an additional EDTA tube may be sent with the universal container.

Samples that are heavily blood stained or clotted will not be counted.

Synovial/bursa fluids are examined for the presence of birefringent crystals.

All samples will have a Gram film.

Please Note: Samples received in an EDTA tube only cannot be Gram stained or cultured.

Sterile fluids may also be sent in blood culture bottles. It is not possible to perform cell counts or direct Gram’s stain on these samples. Please send an additional universal container and/or EDTA tube if these analyses are required.

8.6.8. Blood Cultures

An automated blood culture system is in use. Three bottle types are available:

1. Aerobic (blue top).
2. Anaerobic (purple top).
3. Mycobacteria (red top).

To avoid contamination - ensure the bottle tops are cleaned and disinfected with an isopropyl alcohol swab (steret) before inoculation with blood.

Do not cover or remove the bottle bar code.

A “set” is one aerobic and one anaerobic bottle. A minimum of 10 mL is required for each blood culture bottle. Whenever possible, two blood culture sets should be taken, about 30 minutes apart, prior to the initiation of antibiotic therapy.
Clinical Laboratory Services Queen Elizabeth Hospital

If bacterial endocarditis is suspected, 3 separate blood cultures should be taken over a 48 hour period if the clinical condition allows treatment to be delayed.

Blood cultures are incubated for up to 5 days.

Positive blood cultures will be reported to the requesting clinician directly by a Clinical Microbiologist as appropriate.

Negative blood cultures will be reported at 48 hours and again on completion of the 5 day incubation time.

In cases of suspected Brucellosis, blood cultures are incubated for 14 days. Thus, it is important to record on the request form the patient's suspected diagnosis.

If Mycobacterial infection is suspected specific blood culture bottles should be used as detailed above. These are available on request from the laboratory, (extension 16534) and must be transported in the white protective pod as supplied. These samples must not be sent via the Sample Delivery System, (SDS), please request a porter to deliver samples to the laboratory. These bottles will require extended incubation.

8.6.9. Fluids and Joint Aspirates Received in Blood Culture Bottles

The blood culture system outlined above may also be used for the incubation of other sterile fluids, including ascites, peritoneal dialysis fluid, pleural fluid, synovial fluid and joint aspirates. Samples are incubated as detailed above.

Results will be communicated to the requesting clinician via the Clinical Microbiologist.

Please Note: It is not possible to perform cell counts or direct Gram’s stain on these samples. Please send an additional universal container and/or EDTA tube if these analyses are required, (see Section 8.6.7).

8.6.10. Intra-operative Tissue Samples.

All tissue/curetting samples should be sent to the laboratory in a sterile universal container as soon as possible. If there is a risk of desiccation, the specimen may be placed in a small amount of sterile saline.

DO NOT use formalin containers.

All tissue samples receive extended enrichment cultures for the isolation of fastidious micro-organisms.

Results will be communicated to the requesting clinician via the Clinical Microbiologist.

8.6.11. Faeces

Specimens of faeces should be sent in universal faecal containers (blue cap), a minimum of 2 g, (approximately the size of a large pea), is required for routine culture.

The faeces will be cultured routinely for Salmonella species, Shigella species, Campylobacter species and E. coli 0157.

It is essential that clinical information is given in all cases. Additional culture media are used in cases where infection with cholera, Yersinia is possible. It is therefore important that relevant clinical information is included on the request form (particularly regarding foreign travel).
Please Note: Faecal samples are unsuitable for Helicobacter pylori testing – please send a separate orange request form with a clotted, (red top) blood sample. Requests for Calprotectin and Lactose intolerance should be sent to Biochemistry. Parasitology investigations must be requested separately. The request form must detail any relevant clinical information in particular regarding foreign travel. A minimum of 10g, (approximately the size of a walnut), is required for these investigations. Other samples, such as liver aspirates, hydatid cysts and CSF must also clearly indicate if parasite investigations are required.

8.6.12. Clostridium Difficile
Testing for Clostridium difficile, (C.diff), is performed once daily, 7 days a week. Samples must arrive in the laboratory by 11 am to be included in the run. Samples received after this time are not guaranteed to be processed the same day. At least 2ml of loose or liquid stool is required. Formed samples are unsuitable for testing.

- Samples are NOT tested for *C. difficile* if they have been positive within the last 14 days.
- Samples are NOT tested for *C. difficile* if they have been negative within the last 3 days

Results are communicated electronically to Bed Management Teams and Infection Control

8.6.13. Norovirus
Testing for Norovirus is only performed on samples that are suspected of being part of an outbreak, or following advice from QEHB Microbiology Consultants. The test may be performed on loose/liquid stool or vomit samples. Samples must be collected in a sterile universal container.

Results are communicated electronically to Bed Management Teams and Infection Control

8.6.14. Sputum and Respiratory Samples
*Samples dispatched to the laboratory in sputum traps which have not been sealed with a screw cap are unsafe for portering and laboratory staff!*
Salivary samples are unsuitable for testing. Sputum samples received in the laboratory for culture are not routinely examined for *Mycobacterium tuberculosis*. When tuberculosis is suspected, it is essential to indicate this on the request form so that staining, culture (and PCR where relevant) for *Mycobacterium tuberculosis* can be carried out. Quantiferon for latent TB infection is performed by immunology. Broncho-alveolar lavages, (BAL) and pleural fluids may be sent in sterile universal containers. If urgent processing is required notify the laboratory using extension number 16534 during normal working hours or via switchboard at other times.
Clinical Laboratory Services Queen Elizabeth Hospital

8.6.15. Rapid Influenza A, Influenza B and RSV testing
Throat swabs or nasopharyngeal aspirates for Influenza A, Influenza B, RSV test must be received in 3ml Cepheid viral transport media.

Please Note: If a comprehensive respiratory virus screen is required, e.g. for immuno-compromised patients, samples must be collected in a different tube.

If you are unsure; contact the laboratory using extension number 16534 during normal working hours or via switchboard at other times.

Results are communicated electronically to Bed Management Teams and Infection Control.

8.6.16. Mycology
Samples of skin, hair and nails are examined for the presence of dermatophytes. Samples should be collected in to a specimen envelope available from the laboratory, (extension 16522). Samples are examined microscopically for the presence of fungal elements and an interim report issued. Samples are incubated for at least 2 weeks. Extended incubation may be necessary.

Other fungal investigations, (yeasts and invasive fungi), may be requested on various samples, please discuss with the Clinical Microbiologists before sending samples to the laboratory. Extended incubation of up to 4 weeks may be required.

Serological tests for evidence of fungal infection may also be requested (Section 8.6.20).

8.6.17. Pregnancy Testing
Pregnancy testing is undertaken on urine samples collected into a plain sterile universal container only.

8.6.18. Antibiotic Assays
Gentamicin, vancomycin, amikacin & tobramycin assays are available routinely. Other antibiotics may occasionally require monitoring – this should be discussed with the Clinical Microbiologist.

This test is performed by Clinical Biochemistry.

A GREEN request form must be completed to avoid delays in testing

The results for these assays are available on the Browser immediately after testing. Results are usually available within 24 hours of receipt.

Clinical advice is available via extension 16516 or 16537 during normal working hours or via switchboard at other times.

Information on antibiotic treatment (all the prescribed antibiotics, dosing regimens and sampling times) and the age of the patient must be supplied on the request form; otherwise interpretation of results will be difficult.

Full information on the appropriate monitoring of antibiotics can be found on the UHB Trust website, (link below). Alternatively, a guide is available through the Help menu in PICS.

http://uhbpolicies/assets/AntimicrobialPrescribingGuidelines.pdf

For users outside the UHB Trust please refer to your local guidelines.
8.6.19.  Virology
A comprehensive range of common Viral Serology tests is provided by the department. Other Viral Serology, Viral Culture and PCR investigations are referred to the PHE Birmingham Heartlands Hospital or specialist centres as appropriate. Some investigations require a sample to be collected in to specific transport media, e.g. for Influenza or Herpes Simplex Virus. If you are unsure which sample type is needed, contact the laboratory on extension 16539 during normal working hours or via switchboard at other times.

8.6.20.  Serology (including antigen detection)
Please state clearly the serological tests required and provide relevant clinical information. If unsure, contact Clinical Microbiologist or Virologist for advice.

When adequate information is not provided, serum will be stored and a report requesting more details issued. Serum will be discarded after 2 weeks if this additional information is not received.

Many serological tests require both acute and convalescent sera (10-14 days following onset); the PHE laboratory will not perform assays on acute phase serum until a follow up convalescent sample is provided. Serological assays which require a follow up sample will be stored in the Queen Elizabeth Hospital Microbiology laboratory and a report issued requesting a convalescent sample. The serum will be discarded after one month if convalescent serum is not provided. When patients present late in the clinical course of an infection and only convalescent serum is available, please state this information clearly on the request form to ensure the assay will be performed.

As a general rule, serological assays require a red top (clotted) sample. PCR tests require a purple top (EDTA) sample.

If a number of different tests are required, it may be necessary to send additional tubes to ensure there is sufficient serum or plasma available for testing.

Please use the correct request form – see Appendix 9
If you are unsure which tube or request form to use contact the laboratory on Extension 16539 during normal working hours or via switchboard at other times.

Samples received in incorrect containers will not be processed.

The following tests are available.
## Viruses
- CMV antibody (IgG)
- CMV antibody (IgM*)
- Hepatitis A antibody (total and IgM)
- Hepatitis B surface antigen and antibody
- Hepatitis B anti-core antibody (total & IgM)
- Hepatitis B e antigen and antibody
- Hepatitis C antibody
- Hepatitis D serology
- Hepatitis D viral load*
- Hepatitis E Serology, IgG & IgM*
- Hepatitis E PCR*
- Herpes simplex Serology* EBV antibodies*
- Herpes simplex PCR*
- Varicella zoster PCR*
- HIV (1 and 2)
- HTLV antibodies
- Influenza antibodies*
- Measles Serology
- Mumps Serology, (IgG & IgM)*
- Parvovirus antibody, (IgG&IgM)*
- Rubella antibodies (IgG)
- Rubella antibodies (IgM)*
- Varicella zoster IgG

## Bacteria
- Anti-staphylococcal antibodies*
- Antistreptolysin titres, (ASOT)*
- *Bordetella pertussis* serology*
- Brucella antibodies*
- Clostridium difficile toxin A/B
- Chlamydia psittaci*
- Coxiella burnetti (Q-fever)*
- Helicobacter pylori IgG
- Legionella pneumophila*
- Leptospirosis*
- Lyme disease serology*
- Meningococcal PCR (combined with Pneumococcal) and antibodies*
- Mycoplasma pneumoniae PCR*
- Mycobacterial investigations* (requests for Gamma Interferon must be sent to Clinical Immunology)
- Syphilis serology

## Fungi & Parasites
- Cryptococcal antigen
- Pneumocystis carinii (P.jirovei) PCR – in blood or respiratory samples*
- Fungal precipitins *
- Galactomannan– serum or BAL *
- β-glucan, (blood)
- Hydatid and amoebic antibodies*
- *Toxoplasma gondii* antibodies (IgM + IgG) + PCR as appropriate*
- Schistosoma Antibodies*
- Strongyloides Antibodies*
- Filarial Antibodies*
- Microscopy for parasites other than blood film for malaria

* Tests referred to specialist laboratories

Please request EBV and/or CMV serology (IgG and IgM) to exclude acute infection
Many of these tests are routinely available in the Clinical Microbiology Department.
However, if a rapid result is required please telephone and discuss.
Other serological tests may be arranged on request. Results are available 3 to 7 days following receipt. Please contact the laboratory if you require more information regarding a request.
8.6.21. Transplantation Serology

QEHB will process blood samples from potential organ donors at any time 7 days a week. Results are available within 6 hours of receipt of the sample. Any delays in processing will be communicated to the Transplant Co-ordinator, (SNOD) making the request. The laboratory requires 2 plain red top (clotted without gel) samples for testing. Additional EDTA tubes must be sent for Hepatitis E PCR, Malaria and T. cruzi.

8.6.22. Molecular Microbiology

Hepatitis B and C & HIV viral loads, along with Epstein-Barr and Cytomegalovirus PCR testing are available at QEHB. These tests must only be requested on patients that have had positive serology results. The relevant specimens required can be found in the Guide to Specimen Containers for Pathology Requests PUB_221.

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen Requirements</th>
<th>Results Generated / Assay Range</th>
<th>Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hep B DNA</td>
<td>EDTA x 2</td>
<td>10 - 1,000,000,000 IU/mL</td>
<td>14 days</td>
</tr>
<tr>
<td>Hep C RNA</td>
<td>EDTA x 2</td>
<td>12 - 100,000,000 IU/mL</td>
<td>14 days</td>
</tr>
<tr>
<td>HIV Viral Load</td>
<td>EDTA x 2</td>
<td>40 - 10,000,000 copies/mL</td>
<td>7 days</td>
</tr>
<tr>
<td>CMV PCR</td>
<td>EDTA x 1</td>
<td>200 - 100,000,000 copies/mL</td>
<td>3 days</td>
</tr>
<tr>
<td>EBV PCR</td>
<td>EDTA x 1</td>
<td>150 – 200,000,000 IU/mL</td>
<td>7 days</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae / Chlamydia trachomatis</td>
<td>Aptima Tube*</td>
<td>Detected / Not Detected / Invalid / Equivocal</td>
<td>7 days</td>
</tr>
</tbody>
</table>

*Self-taken vaginal swab (orange), urine, (yellow), all other sites, (purple)

8.6.23. Chlamydia Investigations

Screening for Chlamydial infections (and in tandem - N. gonorrhoea) is performed using a molecular technique, (NAAT). Specific Endocervical and male urethral transport swabs are required for this test. These swabs are available on request from the laboratory. Urine samples are preferred; collection kits for urine are also available.

8.7. Add on Tests

Microbiology will endeavour to perform additional tests on specimens (except Serology) at the request of medical staff and if we are contacted within 48 hours of receipt. Serology specimens are processed, in most cases, by Biochemistry and so are an exception unless from an out-patient where the test would affect their management. See Section 5.5.3

The feasibility of performing extra tests on a specimen is reliant on there being sufficient material, that the specimen is appropriate for the test and that it is still available. Consideration should be given to resubmitting specimens that can easily be obtained unless, in the interim, antibiotics have been administered.
8.8. Procedure for the Notification of Infectious Diseases by Clinicians

Please follow the Trust procedure for the Notification of Infectious Diseases.

http://uhbpolicies/assets/InfectiousDiseasesNotificationProcedure.pdf

All cases should be notified by the clinician caring for the case to the Consultant in Communicable Disease Control (CCDC).

*It is important that the clinical team caring for the patient also informs the patient’s general practitioner at an early stage, as notification directly from the laboratory to the CCDC can result in the immediate follow-up of the patient’s family by the CCDC.*

<table>
<thead>
<tr>
<th>Hours</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day, 9.00am – 5.00pm Health Protection Unit</td>
<td>0844 225 3560</td>
</tr>
<tr>
<td>Out-of-Hours</td>
<td>West Midlands Ambulance Service 01384 679031</td>
</tr>
</tbody>
</table>

8.9. Useful Telephone Numbers

<table>
<thead>
<tr>
<th>Designation</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Infection Control Officers</em></td>
<td></td>
</tr>
<tr>
<td>Department of Microbiology, Queen Elizabeth Hospital Birmingham</td>
<td>0121 371 3785 (Direct line) Out of hours, via UHB switchboard</td>
</tr>
<tr>
<td>Birmingham Community Healthcare NHS Trust, including Dental, West Heath and Moseley Hall Hospitals</td>
<td>0121 466 6304 Out of hours, via UHB switchboard</td>
</tr>
<tr>
<td>The Royal Orthopaedic Hospital</td>
<td>0121 685 4354 Out of hours, via UHB switchboard</td>
</tr>
<tr>
<td>Occupational Health Personnel</td>
<td>0121 627 8285/6 (Ext. 51488)</td>
</tr>
</tbody>
</table>
9. Cellular Pathology

9.1. Service Background
The Department of Cellular Pathology provides a diagnostic histopathology, cytopathology, muscle biopsy, electron microscopy, post mortem and mortuary service to internal users (other Trust departments e.g. surgery) as well as external users (GPs, dental and private practices). The Department also incorporates the Tissue services for the Trust; this department is responsible for managing and ensuring compliance of the licensable activities which falls under the HTA Human Application Sector, this includes procurement, testing, storage, traceability, disposal and distribution of human tissue and cells for therapeutic use.

Cellular Pathology department operates within the Quality Management System of the Clinical Laboratory Services and is working towards ISO 15189:2012. The department is led by both a consultant medical Clinical Service Lead and a technical Service Manager. Cellular Pathology participates fully in UK NEQAS External Quality Assurance where appropriate.

Cellular pathology processes over 32,000 Histopathological 4,500 Cytopathological and up to 100 post mortem cases/year, 140 muscle and nerve biopsies and 800 electron microscopy requests.

The Cellular Pathology department provides a comprehensive pathology service to the Trust, South Birmingham Community and Mental Health Trusts, Private Hospitals, General Practitioners and General Dental Practitioners. A specialist/expert referral service is also provided to hospitals in the West Midlands, nationally and to international clients.

As part of our contingency plans and to maintain quality and turnaround times it may be necessary to send patient material to other centres for processing/ and or reporting occasionally. The quality of these services would be established prior to material being sent out and if specimens were reported off site this would be recorded on the final report.

9.2. Service Hours
Different sections in Cellular Pathology are open at slightly different times during the working day (Monday – Friday). In general terms the core opening hours are as follows:

<table>
<thead>
<tr>
<th>Service</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histopathology</td>
<td>07:00 to 17:00 weekdays.</td>
</tr>
<tr>
<td></td>
<td>07:00 to 11:00 Sundays</td>
</tr>
<tr>
<td>Cytopathology</td>
<td>09:00 to 17:30 weekdays.</td>
</tr>
<tr>
<td>Electron Microscopy</td>
<td>08:00 to 17:30 weekdays.</td>
</tr>
<tr>
<td>Muscle Biopsy Service</td>
<td>08:00 to 17:30 weekdays.</td>
</tr>
<tr>
<td>Mortuary</td>
<td>08:00 to 16:00 weekdays.</td>
</tr>
</tbody>
</table>

9.2.1. Out of Hours
There is currently no out of core hour service in Cellular Pathology.

In the mortuary, there is an out of core hour viewing and release of bodies service
Clinical Laboratory Services Queen Elizabeth Hospital

supported by the Trust 24/7 clinical team.

9.2.2. Urgent Histopathology Biopsy Requests

Urgent histopathology biopsy requests e.g. renal transplant / renal biopsy / cardiac biopsy MUST BE AT THE CELLULAR PATHOLOGY SPECIMEN RECEPTION NO LATER THAN 13:30. Requests received after this time may not be processed until the next routine run and a result will NOT be available on the same day.

9.3. Laboratory Management

Several key personnel are involved with the management of the Department of Cellular Pathology at QEHB. These are as follows:

<table>
<thead>
<tr>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Service Lead</strong></td>
<td></td>
</tr>
<tr>
<td>Dr Shalini Chaudhri (Consultant Pathologist)</td>
<td>0121 371 3347 (DDI: 13347) or via <a href="mailto:shalini.chaudhri@uhb.nhs.uk">shalini.chaudhri@uhb.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Clinical Governance Leads</strong></td>
<td></td>
</tr>
<tr>
<td>Dr Shalini Chaudhri</td>
<td></td>
</tr>
<tr>
<td><strong>Human Tissue Authority</strong></td>
<td></td>
</tr>
<tr>
<td>Designated Individual</td>
<td></td>
</tr>
<tr>
<td>Dr Rachel Brown (Post Mortem Licence)</td>
<td>0121 371 3339 (DDI: 13339) or via <a href="mailto:rachel.brown@uhb.uk">rachel.brown@uhb.uk</a></td>
</tr>
<tr>
<td>Dr Shalini Chaudhri (Human Application)</td>
<td>0121 371 3347 (DDI: 13347) or via <a href="mailto:shalini.chaudhri@uhb.nhs.uk">shalini.chaudhri@uhb.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Cellular Pathology Manager</strong></td>
<td></td>
</tr>
<tr>
<td>Martin Collard</td>
<td>0121 371 5960</td>
</tr>
<tr>
<td><strong>Histopathology Manager</strong></td>
<td></td>
</tr>
<tr>
<td>Daniel Kearns</td>
<td>0121 371 3352 (DDI: 13352) or via <a href="mailto:Daniel.kearns@uhb.nhs.uk">Daniel.kearns@uhb.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Cytopathology Manager</strong></td>
<td></td>
</tr>
<tr>
<td>Becci Taylor</td>
<td>0121 371 3336 (DDI: 13336) or via <a href="mailto:Rebecca.Taylor@uhb.nhs.uk">Rebecca.Taylor@uhb.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Electron Microscopy</strong></td>
<td></td>
</tr>
<tr>
<td>Dr Liz Curtis Clinical Scientist</td>
<td>0121 371 5721 / 5720 (DDI: 15721 / 15720) or via <a href="mailto:elizabeth.curtis@uhb.nhs.uk">elizabeth.curtis@uhb.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Muscle Service</strong></td>
<td></td>
</tr>
<tr>
<td>Dr Liz Curtis Clinical Scientist</td>
<td>0121 371 5721 / 5720 (DDI: 15721 / 15720) or via <a href="mailto:elizabeth.curtis@uhb.nhs.uk">elizabeth.curtis@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Ferhana Maqsood</td>
<td>0121 371 5720 (DDI: 15720)</td>
</tr>
<tr>
<td><strong>Mortuary Manager</strong></td>
<td></td>
</tr>
<tr>
<td>Robert Hawkesford.</td>
<td>0121 371 2520 (DDI: 12520) or via <a href="mailto:robert.hawkesford@uhb.nhs.uk">robert.hawkesford@uhb.nhs.uk</a></td>
</tr>
</tbody>
</table>
### Tissue Services

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Julie Dulson</td>
<td>0121 371 6838 (DDI:16838) or via <a href="mailto:julie.dulson@uhb.nhs.uk">julie.dulson@uhb.nhs.uk</a></td>
</tr>
</tbody>
</table>

### Quality Lead

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helen Stokes</td>
<td>0121 371 3344 (DDI: 13344) or via <a href="mailto:helen.stokes@uhb.nhs.uk">helen.stokes@uhb.nhs.uk</a></td>
</tr>
</tbody>
</table>

### Health and Safety

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee Robertson</td>
<td>0121 371 3314 (DDI: 13314) or via <a href="mailto:lee.robertson@uhb.nhs.uk">lee.robertson@uhb.nhs.uk</a></td>
</tr>
</tbody>
</table>

### Training Lead

Vacant

### Specimen Reception

Ext. or external 0121 371 3314

### Departmental Direct line

0121 371 6516

### E-Mail

9.4. **Consultant Pathologists**

Cellular Pathology currently employs 18 consultant pathologists who cover a broad spectrum of clinical specialities and are available to offer clinical advice and interpretation of results if required.

<table>
<thead>
<tr>
<th>Title</th>
<th>Clinical Specialities</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Shalini Chaudhri (Consultant Pathologist)</td>
<td>Breast and Urological Pathology</td>
<td>0121 371 3347 (DDI: 13347) or via <a href="mailto:shalini.chaudhri@uhb.nhs.uk">shalini.chaudhri@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Rahul Hejmadi</td>
<td>GI and Dermatopathology</td>
<td>0121 371 3341 (DDI: 13341) or via <a href="mailto:rahul.hejmadi@uhb.nhs.uk">rahul.hejmadi@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Rachel Brown</td>
<td>Hepatobiliary and Head and Neck Pathology</td>
<td>0121 371 3339 (DDI:13339) or via <a href="mailto:rachel.brown@uhb.uk">rachel.brown@uhb.uk</a></td>
</tr>
<tr>
<td>Dr Rasoul Amel-Kashipaz</td>
<td>Hematolymphoid and ENT pathology. Neuropathology, morbid anatomy (post mortem) and cardiac transplant pathology.</td>
<td>0121 371 3355 (DDI: 13355) or via <a href="mailto:rasoul.amel-kashipaz@uhb.nhs.uk">rasoul.amel-kashipaz@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Martyn Carey</td>
<td>Sarcoma and soft tissue tumours, GI and Urological pathology.</td>
<td>0121 371 3346 (DDI: 13346) or via <a href="mailto:martyn.carey@uhb.nhs.uk">martyn.carey@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Nayneeta Deshmukh</td>
<td></td>
<td>0121 371 2080 (DDI: 13340) or via <a href="mailto:nayneeta.deshmukh@uhb.nhs.uk">nayneeta.deshmukh@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Isabelle Hero</td>
<td>Breast and Pulmonary pathology</td>
<td>0121 371 3304 (DDI: 13304) or via <a href="mailto:isabelle.hero@uhb.nhs.uk">isabelle.hero@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Professor Stefan Hubscher (consultant Histopathologist and the Leith Professor of Pathology)</td>
<td>Hepatobiliary and Pancreatic pathology.</td>
<td>0121 371 3345 (DDI: 13345) or via <a href="mailto:stefan.hubscher@uhb.nhs.uk">stefan.hubscher@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Santhosh Nagaraju</td>
<td>Neuropathology, Cardiac transplant pathology and Morbid Anatomy (post mortem) pathology.</td>
<td>0121 371 3302 (DDI: 13302) or via <a href="mailto:santhosh.nagaraju@uhb.nhs.uk">santhosh.nagaraju@uhb.nhs.uk</a>.</td>
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<tr>
<td>Dr Desley Neil</td>
<td>Transplant and Cardiovascular pathology.</td>
<td>0121 371 3349 (DDI: 13349) or via <a href="mailto:desley.neil@uhb.nhs.uk">desley.neil@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Claudia Roberts</td>
<td>Dermatopathology, Lymphoma and Lymphoreticular pathology.</td>
<td>0121 371 3357 (DDI: 13357) or via <a href="mailto:claudia.roberts@uhb.nhs.uk">claudia.roberts@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Kassiani Skordillis</td>
<td>Renal, GI and Urological pathology. Clinical Service Lead for Molecular Pathology and a consultant Histopathologist with an interest in gastro-intestinal tract, lymphoma, sarcoma, hepatobiliary and molecular pathology.</td>
<td>0121 371 3354 (DDI: 13354) or via <a href="mailto:kassiani.skordillis@uhb.nhs.uk">kassiani.skordillis@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Philippe Taniere</td>
<td></td>
<td>0121 371 3350 (DDI: 13350) or via <a href="mailto:phillipe.taniere@uhb.nhs.uk">phillipe.taniere@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr BinduVyedianath</td>
<td>Renal, and Lymphoreticular pathology.</td>
<td>0121 371 3342 (DDI: 13342) or via <a href="mailto:bindu.vyedianath@uhb.nhs.uk">bindu.vyedianath@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Adrian Warfield</td>
<td>Head and Neck, Thoracic and Morbid Anatomy (post mortem) pathology.</td>
<td>0121 371 3348 (DDI: 13348) or via <a href="mailto:adrian.warfield@uhb.nhs.uk">adrian.warfield@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Mona Elshafie</td>
<td>Skin and GI pathology.</td>
<td>0121 371 3358 (DDI: 13358) or via <a href="mailto:Mona.Elshafie@uhb.nhs.uk">Mona.Elshafie@uhb.nhs.uk</a>.</td>
</tr>
<tr>
<td>Dr Timothy Bates</td>
<td>Oral and Maxillofacial Histopathology</td>
<td>0121 371 5723 (DDI:15723) or via <a href="mailto:Timothy.Bates@uhb.nhs.uk">Timothy.Bates@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Abeer Shaaban</td>
<td>Breast pathology</td>
<td>0121 371 3356 (DDI:13356) or via <a href="mailto:Abeer.Shaaban@uhb.nhs.uk">Abeer.Shaaban@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Davide Zardo</td>
<td>Skin and GI pathology.</td>
<td>0121 371 3480 (DDI:13356) or via <a href="mailto:Davide.zardo@uhb.nhs.uk">Davide.zardo@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Ute Pohl</td>
<td>Neuropathology, morbid anatomy (post mortem) and Muscle pathology.</td>
<td>0121 371 3346 (DDI:13356) or via <a href="mailto:Ute.pohl@uhb.nhs.uk">Ute.pohl@uhb.nhs.uk</a>.</td>
</tr>
</tbody>
</table>

### 9.5. Request Form Completion

In order to process specimens it is essential that request forms are fully completed in a clear and legible format. The use of patient ID stickers is permitted however please ensure you use the full patient sticker **NOT** the smaller blood tube sticker. All specimens received into Cellular Pathology must meet the agreed laboratory minimum dataset; any specimens not meeting the criteria will be returned to the requesting department.
Minimum Dataset required (See Appendix 14.7)
Please ensure that any important information (e.g. clinical history, bleep number etc.) is clearly indicated on the form and ensure that any priority or urgent cases are marked as such.
  o Trust cases can be requested via a theatre book or by completing an internal histopathology / cytopathology request form. See Appendix 9 Hospital Request Forms
  o GP and dental practices should complete the external request form which can be found at http://www.uhb.nhs.uk/laboratory-request-forms.htm

9.6. Specimen Labelling and Multi-Part Cases
If more than one specimen from the same patient attributed to a case is sent they should be clearly indicated as part 1, 2, 3 etc. with an note on the request form as to what each part is and where it has come from (anatomically) e.g. 1. Transverse Colon, 2. Splenic Flexure, 3. Descending Colon etc.

9.7. Hazardous Specimens
Specimens arising from patients with known or suspected transmissible diseases (e.g. tuberculosis, viral hepatitis, HIV) must be clearly labelled as such to prevent unnecessary risk to laboratory staff.

9.8. Specimen Containers supplied to the users
Due to the wide range of cellular pathology specimens several key container types exist as follows :

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small specimens</td>
<td>Biopsies and small resection e.g. skin ellipses, appendicies.</td>
</tr>
<tr>
<td>Large specimens</td>
<td>Suitable for larger specimens e.g. gall bladders, larger skin resections femoral heads These pots are also suitable for biopsy specimens where the tissue is adhered to glass microscope slides</td>
</tr>
<tr>
<td>Large resection specimen’s</td>
<td>e.g. bowel, heart, breast tissue.</td>
</tr>
<tr>
<td>&quot;Mega&quot; Specimen Buckets</td>
<td>Large anatomical or specimen resections e.g. large sarcomas.</td>
</tr>
<tr>
<td>Dry Samples (Within Lab hours only)</td>
<td>Dry samples sent to the lab e.g. 100k Genomic Project, frozen sections; MOHS samples: lymph nodes; Research projects</td>
</tr>
</tbody>
</table>

**Cytopathology Specimens**

| Urine | Whole volume urines | Jerry can +/- cytospin collection fluid or a universal container. |
| Smears kits | | Microscope slides; slide carriers; spray fix and cytorich red needle wash containers. |
| Serous Fluids/ Sputum/ respiratory fluids | | Universal Containers |

Adequate fixation of tissue and appropriate processing are imperative to get the best possible diagnostic sections from tissue. The process from receipt to slides being available for diagnosis can take anywhere from several hours (in the case of small fragments of rapidly processed tissue e.g. renal biopsies) to several days (for larger specimens which take longer for the fixative to penetrate or for hard tissues which require decalcification prior to processing). For this reason specimen turnaround times are hugely variable and the specimen type and size should always be kept in mind if a report is not immediately available.
9.8.1. Requesting Specimen Containers

<table>
<thead>
<tr>
<th>Location</th>
<th>Sample containers</th>
<th>Stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theatres</td>
<td>Yellow top 60 mL Pots White 350 mL pots Specimen buckets</td>
<td>Main theatre</td>
</tr>
<tr>
<td>Outpatients</td>
<td>Yellow top 60 mL Pots White 350 mL pots Specimen buckets Cytopathology Urine containers Smears preparation kits (Slides; transport containers; cytorich red</td>
<td>Telephone Cellular Pathology reception (DDI 13314)</td>
</tr>
<tr>
<td>Wards</td>
<td>Universal Containers Cytopathology Urine containers</td>
<td>Ward normal stock</td>
</tr>
<tr>
<td>GP’s</td>
<td>All Sample types</td>
<td>Telephone Cellular Pathology reception (DDI 13314)</td>
</tr>
<tr>
<td>Dental Practitioners</td>
<td>Dental Kits (Universal Container and yellow 60 mL pots)</td>
<td>Telephone Cellular Pathology reception (DDI 13314)</td>
</tr>
</tbody>
</table>

When requesting stock a member of staff from the Cellular Pathology department will inform the requestor when they will be ready for collection by the portering staff. Consumables provided by the lab should be transported via the porters so please allow time for preparation and transport.

9.9. Transportation of Specimens

Specimens are collected at regular intervals from theatres and all relevant departments via portering services. **Urgent and unfixed (dry/not in formalin)** specimens should **NOT** be left until the next routine collection – telephone portering services and arrange for a member of staff to bring the sample(s) to the laboratory without delay.

9.10. Urgent Reporting

Occasionally it may be necessary for a requesting clinician to highlight a specimen as clinically urgent. If an urgent report is required it should be clearly identified or indicated on the request form. Urgent requests should be sent to Cellular Pathology via the porters without delay.

To ensure that cases are not delayed within the laboratories please make sure that the request form is correctly completed and all sections are filled in properly. Once received
urgent cases will be highlighted by the specimen reception and prioritised appropriately in the departmental workload

9.11. Histopathology Test Repertoire

9.11.1. Intra-operative Frozen Sections
The department provides a rapid diagnostic service for intra-operative tissue specimens. Requests for frozen section should be telephoned to the histopathology laboratory (DDI: 13314) in advance of the procedure being undertaken, preferably on the day prior to surgery. Where this is not possible, e.g. an incidental finding during surgery, the request should still be telephoned to the laboratory prior to the sample leaving theatre. When calling the laboratory please ensure that you have the following information available as it will be asked for by the person receiving the call:

- Patient's full name.
- Registration number.
- Date of birth.
- Contact number or bleep number.
- Patient's consultant.
- Tissue type / nature of specimen.
- Expected date and time of delivery to the Lab.

Tissue taken for frozen section should be placed into a suitably sized container without any form of fixative (i.e. dry) and sent to Cellular Pathology without delay.

The process from specimen receipt in the laboratory to verbal report issued takes no longer than 15 minutes however this time may be shortened or lengthened slightly based on the nature of the sample received.

High risk biohazardous tissues are not suitable for frozen sectioning unless absolutely clinically required. Examples of these include tuberculous lesions, specimens from patients with viral hepatitis and specimens from patients who are HIV positive. If there is any doubt as to whether the specimen is suitable or not please contact the laboratory and ask for the advice of the Laboratory Manager or a Consultant Pathologist.

9.11.2. MOHS
Mohs, is microscopically controlled surgery used to treat common types of skin cancer. During the surgery, after each removal of tissue and while the patient waits, the fresh tissue is snap frozen and sectioned for microscopic examination. The examination informs the decision for additional tissue removal.

The process from specimen receipt in the laboratory to verbal report issued takes no longer than 15 minutes per sample block however specimens with multiple samples will take additional time.

NOTE: Mohs clinics are booked with the department to ensure that there are clinical and technical staff available to complete the test.
Clinical Laboratory Services Queen Elizabeth Hospital

9.11.3. Neuropathological Smears
The department provides a rapid diagnostic service for intra-operative brain tissue specimens. Requests for neuro smears should be telephoned to the laboratory in advance as per intra-operative frozen sections.

Tissue taken for neuropathological smears should be placed into a sterile universal container (UC) without any form of fixative (i.e. dry) and sent to Cellular Pathology without delay. These specimens are often tiny and so any delay in receipt may lead to artefactual damage which can be detrimental to any further laboratory processing.

The process from specimen receipt in the laboratory to verbal report issued takes no longer than 15 minutes however this time may be shortened or lengthened slightly based on the nature of the sample received.

9.11.4. Small Biopsy Specimens
The department provides both a routine and urgent diagnostic service for small biopsy specimens.

Specimens should be placed into 60 mL pre-filled containers of neutral buffered formalin.

- Wherever possible small or endoscopic biopsies should be placed into mini biopsy or microcassettes cassettes (small yellow cassettes) before being placed into the neutral buffered formalin pots. Supplies of cellsafe cassettes can be sourced from the Cellular Pathology Specimen Reception.
- Breast or other fine cores may be placed onto white cards before being placed into neutral buffered formalin pots. Please ensure the cores are stretched out linearly prior to fixation as knotted cores are not easy to separate out in the laboratory.

Please note that biopsies are delicate and should be handled with care, avoid the use of forceps wherever possible to prevent trauma artefact to the tissue.

9.11.5. Urgent Biopsy Specimens (Rapid Paraffin Service)
The department provides a rapid paraffin service for clinically urgent biopsy specimens; a report can be issued on the same day that the specimen arrives in the department. It should be noted however that not all specimens are suitable for rapid processing. In general terms only liver, renal and cardiac biopsies are processed in this way. Other specimens may be suitable however advice should be sought from the Histopathology Manager (DDI: 13352) or a trimming room senior Biomedical Scientist (BMS 2 or above) (DDI: 13314) prior to sending other tissue types.

Tissues for the rapid paraffin service must be received by the department no later than 13:30. Please ensure that the name and bleep number of the requesting clinician is clearly indicated on the request form to allow for the verbal report to be issued.

Specimens received after 13:30 will NOT be processed urgently and will be placed onto the “normal” biopsy run later in the day thus same day reporting will not be possible.

9.11.6. Resection Specimens
The department provides a routine and urgent diagnostic histopathology service for larger surgical resection specimens. Tissue should be placed into appropriately sized containers
which will allow for the specimen and at least ten times its volume in fixative (i.e. neutral buffered formalin) to be contained.

**DO NOT** use containers which are too small to allow for this volume of fixative to be used or squash specimens into small pots. Specimens should be free-floating in fixative not pressed up against the sides of the container as this leads to distortion of the tissue and may make further processing unnecessarily difficult.

### 9.11.7. MIHRO Cases

The Midlands Integrated Reporting for Haemato-Oncology (or MIRHO) Service is a joint venture between the Haematology Service based at University Hospitals Birmingham NHS Foundation Trust, the West Midlands Regional Genetics Service housed at Birmingham Women’s Hospital, the Department of Cellular Pathology at University Hospital Birmingham NHS Foundation Trust and the Clinical Immunology Service based at the University of Birmingham. The service takes clinical data from the combined processes within each of these specialised laboratory services to produce one fully integrated pathology report to direct patient management through the clinical service users i.e. clinicians and physicians. Samples are booked into a bespoke data management system called Haemato-Oncology Diagnostic Service (or HODS).

MIHRO samples are taken in clinic by the medical, nursing or phlebotomy teams. Samples may be whole blood, or bone marrow trephine (BMT) tissue samples bone marrow aspirates, skin biopsies and CSF.

Samples that will be sent to Immunology will generally be Blood EDTA, Bone Marrow EDTA, Unstained slides and CSF’s.

Samples that will be sent to Genetics will be Blood EDTA, Blood Lithium Heparin, Bone Marrow EDTA and Bone Marrow Lithium Heparin.

Samples processed in Histopathology/ Cytology (University Hospital Birmingham : Bone marrow trephine (BMT) biopsies; Skin biopsies / small excisions; Lymph nodes.

### 9.12. Cytopathology

The department provides the diagnostic cytopathology services for the Trust including fine needle aspirations, endoscopic brushings and washings, EUS-FNAs, serous fluids urines and CSF.

#### 9.12.1. Senior Staff and Useful Telephone Numbers

- Rebecca Taylor (Head of Cytopathology) 13336
- Secretarial office (report enquiries) 13326
- Specimen reception 13314

#### 9.12.2. Receipt of Specimens

Routine specimens should reach the laboratory before 16:30 so that they can be processed within normal working hours. Specimens collected out of laboratory hours should be stored refrigerated until the next morning on which the laboratory is open.

Cytology sample that do not meet the minimum data requirements on request form or sample, are processed, to ensure that sample integrate is maintained. Details of missing data are added to the report.
9.12.3. Request for Consumables and Request Forms
Sample containers for use in cytology and request forms can be order by contacting the Cytology Department; they can be collected from the Cellular Pathology reception or the main pathology Reception CLS level-1 QEHB. Cytology samples which do not meet the MDS will not be returned. They will be processed in order to preserve the diagnostic material while attempts are made to contact the sender. These samples will not be reported until adequate labelling of specimen and request form has been undertaken.

9.12.4. Transport of Specimens
Minimal delay between collection and receipt by the laboratory is necessary in order to prevent degeneration of cellular components and consequent loss of diagnostic value. All cytological specimens are potentially biohazardous and must be transported in leak proof containers enclosed in sealed bags. Specimens sent to the laboratory via the SDS should be placed in specimen bags and lids on the all containers should be securely closed.

9.12.5. Urgent Samples
Urgent Cytology for Cyclo and Tacs should be available for reporting within 24 hours in line with KPI.

Specimens from patients with known or suspected tuberculosis, HIV, viral hepatitis or other transmissible disease should be labelled clearly.

Cytology DO NOT except or handle any specimens that are ?prion disease or CJD.

9.12.6. Cytopathology Test Repertoire
Specimens should be received as either pre-prepared slides, fresh unfixed samples in white- topped universal containers, or suspended in CRR. Equipment used to collect the specimen such as brushes or drains are inappropriate.

9.12.6.1. Sputum
A series of three early morning ‘deep cough’ specimens should be collected on three consecutive days for maximum sensitivity. Post physiotherapy and post bronchoscopy specimens are suitable but should be clearly identified as such.

9.12.6.2. Serous Fluids
50mls or the whole volume if less is aspirated should be sent in sterile universal containers. Include any tissue fragments or clots. Do not add fixative of anticoagulant. Drain bags are not suitable for transporting specimens and should NOT be sent.

9.12.6.3. Cerebrospinal Fluid (CSF)
Rapid processing is essential to preserve cells in CSF. These specimens should be sent to the laboratory within one hour.

ALL CSF SPECIMENS SHOULD REACH THE LABORATORY BY 16:30 AT THE
9.12.6.4. Urine
A representative aliquot of a maximum of 25ml of urine is sufficient for cytology processing. Ensure that this is not the first sample of the day.
Catheter urine and bladder washings are also acceptable but please mention this on the request form. Mid-stream urine samples are not suitable for cytology because they contain few cells.

9.12.6.5. Endoscopic Brushings
Immediate fixation is important and all slides must be labelled with PENCIL with the patient’s name and hospital number before the smears are made.

9.12.6.6. Fine needle aspiration
Unless the clinician is experienced in this procedure, including making good quality smears, it is recommended that they contact the laboratory for advice before beginning the procedure. Smears should be made and the needle rinsed out in cytorich red fluid. For ENT specimens in particular it is important that smears are sent as well as needle washings. Only prepared smears and needle washings are accepted. The sending of needles sheathed or otherwise is strictly forbidden.

9.12.6.7. EUS-FNAs
Please send all the specimen in cytorich red fluid.

Cervical smears are NOT accepted in nor prepared by cytopathology at QEHB. Please send any cervical smear specimens to the Cytopathology Laboratory at Birmingham Women’s Hospital (BWH).

9.12.7. Reporting
Once specimens are reported and authorised by the laboratory they can be accessed on the intranet by appropriate staff. In addition a typed copy will be sent to the destination specified on the request form (FOR EXTERNAL USERS ONLY). If the specimen is needed for a particular MDT or clinic, then please state this on the request form. Urgent reports can be issued verbally if necessary to a suitable member of medical staff. Please put a mobile telephone number or a bleep number (that will be answered immediately) on the request form. Telephone reports will only be issued on request via telephone.

The Electron Microscope Unit is used routinely at magnifications of between 1500 and 70,000 times to examine the ultrastructure of cells and their surroundings. The EM unit receives approx. 800 samples a year, the majority of which are renal, but about 100 muscle and 30 nerve biopsies are also collected. Other specimens include cardiac biopsies, occasional skin biopsies and tumour samples.
9.13.1. Specimen Requests

Specimens from outside the department requiring EM should be sent in a small sample container (e.g. bijou or Eppendorf tube) containing at least 2 mL of an EM fixative. A glutaraldehyde based fixative such as 2.5% glutaraldehyde in phosphate buffer is ideal but 10% buffered formalin is also acceptable.

In larger tissue samples individual pieces should be no larger than 3 mm cubed and should be completely submerged in fixative.


Renal biopsies from QEHB are delivered to the Cellular Pathology Specimen Reception and EM samples are taken in the EM Lab. External users package specimens for EM in firmly closed leak proof containers, together with sufficient absorbent material to contain any liquid, in sealed bags. The sealed bags are placed securely in a small padded envelope with the address label as given above under key information.

The EM unit makes use of the Histology request form for both internal and external users. A copy of the light microscopy report is also required.

Clinical advice can be obtained from Dr Liz Curtis on 0121 371 5720
Elizabeth.curtis@uhb.nhs.uk


Muscle biopsies are performed as part of the investigation of a clinically suspected neuromuscular disorder when other less invasive tests have not provided a firm diagnosis. The Muscle Biopsy Service receives muscle and nerve samples from the whole of the West Midlands region and occasionally from elsewhere in the UK.

This department offers the following investigative techniques:

- Muscle Histochemistry methods on frozen sections
- Muscle immunocytochemistry on frozen sections.
- Electron Microscopy.
- Histology and immunocytochemistry on paraffin wax sections.
- Arrangements can be made to send tissue away for DNA analysis.

If required samples can be referred to specialist centres for further investigation

- Metabolic tests.
- Mitochondrial Assays and MtDNA.
- Protein analysis for adult Limb Girdle Muscular Dystrophies.
- Rare paediatric dystrophies.

9.14.1. Transport of specimens at QEHB

If a member of the muscle biopsy team is required to collect a nerve or muscle biopsy from QEHB theatres there should be a delay of no longer than 30 minutes between the biopsy being taken and the sample are being placed into fixative for electron microscopy.

Please call the lab to request collection as soon as possible once the specimen is
available. Prior to collection muscle should be kept in a dry universal container on water ice (ice can be supplied by the Muscle Lab) and the nerve should be kept in a dry universal container at room temperature. A copy of the Muscle Biopsy request form noting the time the biopsy was taken should be completed by the requesting clinician.

9.14.2. Transport from External sources

Medical or secretarial staff from the requesting centre liaises directly with the Muscle Lab to book a biopsy.

A Senior Biomedical Scientist will travel to the hospital to collect the biopsy which is received fresh. Clinical details are preferably received in advance of the biopsy from the requesting medical staff but relevant information may be transcribed from the patient’s notes onto the Muscle Biopsy Request Form by the Scientist collecting the biopsy. The Scientist decides which tests will be required on the basis of this information. The biopsy is cut up and fixed for certain tests on site, the rest of the specimen is brought back to the lab on ice and some is frozen in liquid nitrogen and the remainder allocated for further tests.

9.15. Mortuary Services

9.15.1. Confirmation of Death

See Trust Bereavement Care policy.

9.15.2. Deaths to be Reported to Her Majesty's Coroner

See Trust Bereavement Care policy.

9.15.3. Requesting an Autopsy (Post Mortem Examination)

See Trust Bereavement Care policy.

The reasons for requesting post-mortem can be discussed with the family by the clinical team and the relatives can be offered an information leaflet ‘information about post mortem examination for relatives’. A consent discussion is then held with the family. It is a requirement of the HTA that persons seeking consent for post-mortem are trained to do so. Arrangements will then be made within pathology for performing the post-mortem and the report sent in due course to the consultant and also to the deceased’s general practitioner.

- Request for a post-mortem examination should be made on form PM2, available on wards and in the Bereavement Care Office.
- An abstract of the clinical history should be given together with specific questions to be answered by the pathologist at post-mortem.
- Consent for a Post-mortem must be obtained by an approved qualified staff from appropriate personal.

Before obtaining consent from relatives it is recommended that all medical staff are familiar with the UHB NHS Trust booklet “Information about post-mortem examination for relatives”. Relatives should be talked through the revised PM consent form (PM1) and fully informed consent should be obtained.

Medical staff may contact the consultant pathologist for advice on post-mortem protocols.
9.15.4. **An Autopsy (post-mortem)**

Usually an autopsy will be performed that day if the Post Mortem Declaration Form reaches the Mortuary before 11:00, otherwise it will be the next working day. The pathologist will usually demonstrate the findings at noon in the Mortuary, where there is a viewing gallery. The medical staff and medical students should try to attend the demonstration. In special circumstances autopsies may be done at short notice, if the body has to be removed from the Mortuary quickly.

9.15.5. **Post Mortem Pathology**

In cases where a death certificate can be issued, but outstanding questions remain about the death, a ‘hospital’ or consented post-mortem may be requested. Any cases where the cause of death is unknown, or in specific circumstances, for example following an accident or within 24 hours of an invasive procedure, cases need to be referred to HM Coroner.

9.15.6. **The Death Certificate**

See Trust Bereavement Care policy.

9.15.7. **Cremation Form**

See Trust Bereavement Care policy.

9.15.8. **Out of core hours Viewings and release of bodies**

Outside of core hours (Mon-Fri 8:00-16:00) all viewing and releases of bodies to Funeral directors, SOCO, HM Coroner or appropriate personnel; are undertaken by the Trust 24/7 Clinical Team / Clinical Site manager. Please contact the on call manager for to arrange a viewing for family members or release of a body.

9.16. **Tissue Services**

Tissue Services is responsible for the management of all activities involving human tissue (not organ) intended for patient use at University Hospitals Birmingham NHS Foundation Trust (UHB NHS FT) that requires licensing by the HTA. The Department also incorporates the Tissue services for the Trust; this department is responsible for the procurement, storage and distribution of Tissue, skin, vessels and the procurement or peripheral blood stem cells.

9.16.1. **Donor Selection**

Donor selection is carried out by the Consultant’s responsible for patient treatment.
Clinical Laboratory Services Queen Elizabeth Hospital

The majority of donors are for autologous treatment. The donor selection process for allogeneic tissues supplied by NHSBT is carried out by NHSBT. The donor selection for liver vessels occurs as part of the Liver Transplant programme.

The donor selection for PBSC donation is primarily for autologous treatment; allogeneic donor selection is carried out under the direction of the Haematology Consultants.

9.16.2. Tissue Receipt

Tissue Services staff inspect the packaging of the sample to ensure it complies with the procedure and will either accept or reject the tissue accordingly. Stored skin is not inspected by Tissue Services staff but is the responsibility of the surgeon who packed the material (in theatre at the time of taking the sample).

9.16.3. Tissue Storage

Any problems with skin tissue requested for autologous cells or Liver Vessel Storage would be reported to the Tissue Service Operations Manager who would inform the requesting Burns Consultant; liver consultant or Clinical Service Lead (CSL for Burns). All tissue storage occurs according to written procedures and follows either supplier instructions or in house procedures, which represent many years of clinical practice.

9.17. Turnaround Times

The department monitors its turnaround times on a regular basis. In addition, the department actively monitors outstanding cases, notifying reporting pathologists that cases are still unreported. In general terms, the average expected turnaround times (from arrival in specimen reception to a report, either verbal or written, is issued) for Cellular Pathology are as outlined below.

Histopathology:
- Intra-operative histopathology specimens (frozen sections) **fifteen minutes**.
- Neuropathological smears **fifteen minutes**.
- Routine histopathology biopsy specimens **ten calendar days**.
- Urgent histopathology biopsy specimens (rapid processing) **by the end of the same working day**.
- Routine histopathology resection specimens **ten calendar days**.

NB: All histopathology specimens are subject to monitoring via the DoH Census to ensure all cases are reported within six working weeks.

Cytopathology:
- Routine cytopathology specimens **ten calendar days**.
- Urgent cytopathology specimens; **one calendar day** (where the case does not require further testing e.g. IHC).

Muscle Biopsy Service:
- Histochemistry results is **five to seven working days**.
- The current turnaround time for cases referred to specialist centres is 2-3 months depending on tests requested.

Electron Microscopy:
- Renal and cardiac turnaround times are approx. 10 to 14 days.
- Muscle and nerve biopsies approx. 10 to 14 weeks.
10. Molecular Pathology

The discipline of Molecular Pathology encompasses those investigations which determine the diagnostic, prognostic and predictive profile of pathology specimens through the analysis of alterations to DNA, RNA or—in certain cases—Proteins. This can include small mutations or large chromosomal aberrations, DNA methylation, and changes to RNA transcription and protein expression levels.

10.1. Service Background

The department of Molecular Pathology is part of the clinical Laboratory services. The department provides a service to internal users within the Trust, external users regional; national and International. The department processed over 15,000 molecular pathology tests per year.

Molecular pathology department operates within the Quality Management System of the Clinical Laboratory Services and is led by both a consultant medical Clinical Service Lead and a technical Service Manager.

This is a new service working toward accreditation to ISO 15189:2012, has a recommendation for accreditation. Molecular Pathology participates fully in External Quality Assurance where appropriate. For further information please contact the laboratory manager or clinical service lead.

10.2. Service Hours

Molecular Pathology : 09:00 to 17:00 weekdays.

There is no out of hours service

10.3. Laboratory Management

Several key personnel are involved with the management of the Department at QEHB. These are as follows :

<table>
<thead>
<tr>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Service Lead</td>
<td>0121 371 3350 (DDI: 13350) or via <a href="mailto:phillipe.taniere@uhb.nhs.uk">phillipe.taniere@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Philippe Taniere</td>
<td></td>
</tr>
<tr>
<td>Clinical Scientist</td>
<td>0121 371 3312 (DD:13312) or via <a href="mailto:Matthew.Smith@uhb.nhs.uk">Matthew.Smith@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Matthew Smith</td>
<td></td>
</tr>
<tr>
<td>Cellular Pathology Manager</td>
<td>0121 371 5960</td>
</tr>
<tr>
<td>Martin Collard</td>
<td><a href="mailto:Martin.collard@uhb.nhs.uk">Martin.collard@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Molecular Operation Manager</td>
<td>0121 371 3351 (DDI: 13351) or via brendan.o’<a href="mailto:sullivan@uhb.nhs.uk">sullivan@uhb.nhs.uk</a></td>
</tr>
<tr>
<td>Brendan O’Sullivan</td>
<td></td>
</tr>
</tbody>
</table>
10.4. Molecular Test Repertoire

10.4.1.1. Breast Cancers
The section offers a comprehensive HER2 analysis service for breast cancers. Immunohistochemistry, with the Roche/Ventana 4B5 antibody, is used to screen patients for expression levels of the HER2 protein and identify those “over-expressers” who are most likely to benefit from treatment with Trastuzumab (Herceptin). Where expression levels are equivocal, FISH is used to determine amplification at the gene level. Service users may access the full service, or submit cases for FISH analysis only if performing their own IHC.

10.4.1.2. Gastric Cancers
As with breast cancers, HER2 analysis is performed in Gastric cancers to assist in predicting which therapies patients will benefit from. As well as this standard-of-care testing, mismatch-repair analysis and ISH for EBV are also available on demand.

10.4.1.3. Colorectal Cancers
RAS (KRAS and NRAS) mutations confer resistance to anti-EGFR monoclonal antibodies, and act as a negative predictive marker for these therapies. . . The National Institute for Clinical Excellence (NICE) has approved the use of Cetuximab and Panitumumab for the treatment of metastatic colorectal cancer in patients who carry normal, “wild-type” RAS genes. RAS testing is mandatory prior to their prescription.

BRAF gene mutation analysis is provided on demand for colorectal cancer patients. This can be used to inform patient management or, in combination with mismatch repair expression (see below), to help establish the presence of the inherited cancer syndrome HNPCC (Lynch syndrome).

We are a reference centre for Mismatch repair (MMR) protein expression analysis in patients suspected to have Lynch syndrome; we test over 700 cases a year. Immunohistochemical testing allows identification of patients without normal DNA repair processes, who are therefore more likely to have Lynch syndrome. Mismatch repair protein expression is also requested increasingly to help inform patient chemotherapy decisions, as patients lacking MMR expression appear to have reduced sensitivity to certain cytotoxic treatments. BRAF p.Val600Glu (“V600E”) specific immunohistochemistry (IHC) is available on demand.
10.4.1.4. Lung Cancers

EGFR mutations correlate with the effectiveness of certain Tyrosine Kinase Inhibitors (TKIs) such as Gefitinib, Erlotinib, Afatinib, and Osimertinib against some Non-Small Cell Lung Cancers (NSCLCs). Activating mutations are reported to correlate with significant responses to such treatment, whilst certain other mutations correlate with resistance to first- and second-generation TKIs, but predict response to newer agents. EGFR mutation status is therefore vital in deciding the most appropriate treatment regime. In 2016, the service began offering EGFR analysis on plasma circulating-cell-free (ccf)DNA. Of particular use in testing patients for acquired, targetable secondary mutations when they begin to progress whilst on treatment targeting their primary EGFR mutation, it may also function as a surrogate where clinical circumstances make obtaining a more representative tissue specimen for initial diagnostic testing difficult or impossible. The service can provide specialised collection for users wishing to submit samples.

Anaplastic lymphoma kinase (ALK) gene fusions can be targeted with specific inhibitors, and translocation analysis using immunohistochemistry or Fluorescence In-Situ Hybridisation (FISH) is now standard alongside EGFR mutation analysis to determine 1st line treatment for lung NSCLC. In addition to ALK analysis, the service provides FISH and IHC testing for ROS fusions in lung cancer on demand as an adjunct to therapeutic decision making.

PD-L1 expression analysis has joined EGFR and ALK testing in informing first (and second) line anti PD-1 / anti-PD-L1 monoclonal antibody treatment for lung NSCLC. A relatively recent addition to the testing landscape, in 2016, immunohistochemical analysis using companion-diagnostic antibodies specific to the relevant treatments gives a quantitative expression result.

10.4.1.5. Gastrointestinal Stromal Tumours (GIST)

Up to 90% of all malignant GISTs harbour gain-of-function mutations in the KIT / PDGFRA genes. Primary mutations have been described in exons 9, 11, 13 & 17 of KIT, and exons 12, 14 & 18 of PDGFRA. Secondary (acquired or treatment associated) mutations have also been described. Selective TKIs have a high response rate in patients with advanced GISTs, which are largely radiotherapy and chemotherapy resistant. Evidence suggests that the type and location of KIT or PDGFRA mutations in GISTs predicts the response to TKI treatment.

10.4.1.6. Melanomas

The BRAF gene is frequently mutated in human melanomas, with mutations seen in 35-50% of cases. Mutations lead to constitutive activation and aberrant signalling, and subsequent malignant behaviour. Drugs that treat those cancers by inhibiting BRAF are now licensed for use in metastatic disease.

The NRAS gene is also frequently mutated in melanoma; between 10-20% of tumours show an NRAS mutation, and these are thought to be mutually exclusive with alterations in BRAF. NRAS testing is offered as a supporting aid in selecting patients for access to novel therapeutic interventions or clinical trials targeting the pathway activated by mutant NRAS.

Mutations in the KIT gene are seen in Acral and mucosal melanomas and represent potential therapeutic targets.

PD-1 and PD-L1 inhibition, particularly in combination with anti-CTLA4 therapies, has shown profound and sustained effects against metastatic melanoma. Whilst PD-L1 expression analysis is not mandatory for prescription, as it is with some lung NSCLC
therapies, it has been shown to be helpful in informing decisions on whether to use mono- or combination-therapy.

10.4.1.7. Brain Tumours
The revision of the WHO classification of CNS tumours in 2016 has expanded the range of essential and desirable molecular analyses performed. Epigenetic silencing of the MGMT (O6-methylguanine–DNA methyltransferase) gene by promoter methylation is associated with longer overall survival in patients with glioblastoma who, in addition to radiotherapy, received alkylating chemotherapy with temozolomide. High levels of MGMT activity in cancer cells create a resistant phenotype by hindering the therapeutic effect of alkylating agents and may be an important determinant of treatment failure.

Combined loss of chromosome arms 1p and 19q (denoted as 1p-/19q−) is a powerful predictor of chemotherapeutic response and survival in oligodendrogliomas. A FISH based analysis of these loci is available as a tool to assist patient management. More recently it has been employed diagnostically in the differentiation of ATRX-positive Oligodendrogliomas and Astrocytomas.

Mutation analysis of the IDH1 and IDH2 genes is used as a supplement to immunohistochemistry. Whilst the IDH1 R132H-specific antibody detects the majority of IDH mutated tumours, mutation analysis for rarer R132 variants along with IDH R100 and IDH2 R172 mutations is used in particular relevant clinical scenarios.

10.5. Sample Types

<table>
<thead>
<tr>
<th>Test</th>
<th>Sample type</th>
<th>Specific requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast / Gastric cancer</td>
<td>Sample of tumour</td>
<td>Paraffin block from biopsy, resection or cell block; or unstained mounted sections at 3-4μm on coated/charged slides</td>
</tr>
<tr>
<td>IHC</td>
<td>confirmatory/supplementary FISH testing only</td>
<td>A labelled reference slide highlighting desired area for analysis, as appropriate.</td>
</tr>
<tr>
<td>FISH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal Cancer Mutation Testing</td>
<td>Sample of tumour</td>
<td>Paraffin block from biopsy, resection or cell block; or unstained mounted sections of the tumour cut at 4μm</td>
</tr>
<tr>
<td>IHC testing</td>
<td>Sample of tumour</td>
<td>Paraffin block from biopsy, resection or cell block; or unstained mounted sections at 3μm on coated/charged slides</td>
</tr>
<tr>
<td>Lung cancer Mutation Testing</td>
<td>Sample of tumour</td>
<td>Paraffin block from biopsy, resection or cell block; or unstained mounted sections of the tumour cut at 4μm</td>
</tr>
<tr>
<td>IHC testing</td>
<td>Sample of tumour</td>
<td>Paraffin block from biopsy, resection or cell block; or unstained mounted sections at 3μm on coated/charged slides</td>
</tr>
<tr>
<td>FISH</td>
<td>confirmatory/supplementary FISH testing only</td>
<td>A labelled reference slide highlighting desired area for analysis, as appropriate.</td>
</tr>
<tr>
<td>EGFR1 Mutation on circulating Tumour DNA</td>
<td>Blood</td>
<td>8-10ml blood in PAXgene ccfDNA</td>
</tr>
<tr>
<td></td>
<td>Sample must be received within 2-3 days of sample collection</td>
<td>Tubes available on request. Please contact the laboratory. If utilising the provided PAXgene ccfDNA tubes, please invert gently 8-10 times immediately</td>
</tr>
</tbody>
</table>
10.6. Request Forms

All request forms can be obtained by contacting the Molecular department. All areas within the request form must be completed and a copy of the original pathology report attached with each request.

10.7. Transport of Specimens

Samples for all tests provided may come from local, regional, national and international users.

For samples sent by post: Copies of representative tissue blocks and (where applicable) original histology/cytology reports along with the appropriate request form are sent in the appropriate manner to either Dr Philippe Taniere or Mr Brendan O’Sullivan at the Department of Cellular Pathology, UHB NHSFT. Cytology fluids and ccfDNA samples may also be sent in this manner.

Samples sent by internal transport / portering / external Trust vehicles: Samples may be directly brought by vehicular transport from local / regional users as appropriate.

Internal (Trust) referral: Oncology / Pathology staff from within the Trust may directly access testing by emailing the Molecular Pathology staff with relevant requests at the address MOLLab@uhb.nhs.uk.

10.8. Acceptance and Rejection of Samples

Acceptance of samples for testing is reliant on the minimum data set being met (Appendix 4)
10.8.1. Factors affecting interpretation of results
Blood sample must be stored at room temperature and received in the lab within 2-3 days of collection. Any variation in storage or delays in the sample reaching the lab, will potential result in the sample being rejected for processing.

10.9. Clinical Advice
Clinical advice can be obtain from the lab by contacting

**Clinical Service Lead**  Dr Philippe Taniere  0121 371 3350 (DDI: 13350)
philipe.taniere@uhb.nhs.uk

**Clinical Scientist**  Dr Matthew Smith  0121 371 3312 (DD: 13312)
Matthew.Smith@uhb.nhs.uk

**Operation Manager**  Brendan O’Sullivan  0121 371 3351 (DDI: 13351)
brendan.o’sullivan@uhb.nhs.uk
10.10. Turnaround Times

The department monitors its turnaround times on a regular basis. In addition the department actively monitors outstanding cases, notifying reporting pathologists that cases are still unreported. In general terms the average expected turnaround times (from arrival in specimen reception to a report, either verbal or written, is issued) for Molecular Pathology are as outlined below.

<table>
<thead>
<tr>
<th>Test</th>
<th>Quoted Turnaround time (working days)</th>
<th>Assays currently included in our application for ISO15189:2012 accreditation scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK translocation testing by FISH</td>
<td>&gt;90% in 7-10 days</td>
<td>Yes</td>
</tr>
<tr>
<td>ALK translocation testing by IHC</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>EGFR/ALK by Real Time PCR/IHC</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>BRAF Testing by Real Time PCR</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>EGFR tissue mutation testing by Real Time PCR</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>EGFR plasma mutation testing by Real Time PCR</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>Her-2 Testing (IHC)</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>HER-2 Testing (FISH)</td>
<td>&gt;90% in 7-12 days</td>
<td>Yes</td>
</tr>
<tr>
<td>Kit / PDGFRa Testing (1-2 exons) by Sanger Sequencing</td>
<td>&gt;90% in 7-15 days</td>
<td>No</td>
</tr>
<tr>
<td>Kit / PDGFRA Testing (3+exons) by Sanger Sequencing</td>
<td>&gt;90% in 15-30 days</td>
<td>No</td>
</tr>
<tr>
<td>KRAS Testing by Pyrosequencing</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>MGMT Testing by Pyrosequencing</td>
<td>&gt;90% in 7-10 days</td>
<td>Yes</td>
</tr>
<tr>
<td>MMR Testing by IHC</td>
<td>&gt;90% in 7-10 days</td>
<td>No</td>
</tr>
<tr>
<td>N/KRAS Testing by Pyrosequencing</td>
<td>&gt;90% in 7-10 days</td>
<td>Yes</td>
</tr>
<tr>
<td>NRAS Testing by Pyrosequencing</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>ROS Testing (IHC)</td>
<td>&gt;90% in 5-7 days</td>
<td>Yes</td>
</tr>
<tr>
<td>ROS Testing (FISH)</td>
<td>&gt;90% in 7-10 days</td>
<td>No</td>
</tr>
<tr>
<td>PDL-1</td>
<td>&gt;90% in 5-7 days</td>
<td>No</td>
</tr>
<tr>
<td>Next Generation Sequencing</td>
<td>&gt;90% in 7-10 days</td>
<td>Yes</td>
</tr>
</tbody>
</table>

All effort is made to obtain a diagnostic results, this may require the test to be repeated and may delay the report. Please contact the lab if you have any concerns.
11. Appendix 1 – Clinical Specimens, General

Most hospital patients require a clinical laboratory analysis derived from a clinical specimen at some time during their stay. The main products of any clinical laboratory are the analytical data and/or clinical advice reported for the specimens analysed or examined (the ‘report’). The laboratory maintains a Quality Management System to assure that chemical and biological measurements or physical examinations are made properly, interpreted correctly, and reported appropriately. The Clinical Laboratory is subject to accreditation by an external agency – United Kingdom Accreditation Service, abbreviated to ‘UKAS’. With the exception of some POCT and some Transfusion matters (see Trust Transfusion Policy http://uhbpolicies/assets/BloodTransfusionPolicy.pdf ) it is the responsibility of the laboratory (and therefore its accreditation) generally starts with the receipt and acceptance of a valid specimen and ends with the effective issuing of a report.

The life-cycle of a laboratory analysis from specimen collection to clinical decision based on a laboratory report is summarised by 3 phases:

- pre-analytical (the requesting of a test by a responsible practitioner, the collection and delivery of a specimen to, and receipt by, the laboratory);
- analytical (the laboratory testing process);
- post-analytical (the reporting of a result by the laboratory and the receipt of that result by the responsible practitioner).

The quality of the laboratory report is crucially affected by the pre-analytical phase and the quality of the specimen that is received in the laboratory. This quality is influenced by the following factors:

- Quality of sampling;
- Handling of the specimen;
- Storage of the specimen;
- Transport of the specimen to the laboratory;
- Time taken to reach the laboratory
- Legible and complete labelling to allow unambiguous identification of the patient;
- Adequate clinical details to allow the interpretation of the result.

These appendices are intended as a general guide to requesting, collecting and handling of clinical specimens for laboratory analysis. They describe the best practice requirements (or where to find information about this) for the pre-analytical phase of a request for laboratory analysis, within the Trust before delivery to the laboratory reception area.

This compliments the advice and information given in the Guide to Specimen Containers for Pathology Requests.
12. Appendix 2 – Clinical Specimens, Quick Reference

*Proper preparation of the patient, good specimen collection and correct handling of a clinical specimen are essential for the production of valid results by the laboratory.*

<table>
<thead>
<tr>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance on the specimen containers required for individual tests in Biochemistry, Haematology is available as PUB_003. For Microbiology see PUB_221. Also see; <a href="http://www.uhb.nhs.uk/gp-specimen-container-guide.htm">www.uhb.nhs.uk/gp-specimen-container-guide.htm</a>.</td>
</tr>
<tr>
<td>available in the Clinical Laboratory Services section of the Trust Intranet and Internet.</td>
</tr>
<tr>
<td>Patient identification, sample labelling, and sample quality relating blood transfusion requests can be found at <a href="http://uhbpolicies/assets/BloodTransfusionProcedure2.pdf">http://uhbpolicies/assets/BloodTransfusionProcedure2.pdf</a></td>
</tr>
<tr>
<td>Information on Infection Control at the bedside, including Standard Precautions, cleanliness and decontamination and waste disposal is available in the Trust Infection Prevention &amp; Control Policy available under the Policies and Guidelines section of the Trust Intranet. This document also contains some guidance on labelling, handling and transportation of clinical specimens and the management of inoculation incidents etc.</td>
</tr>
</tbody>
</table>

**Quick Reference Guide (this information is expanded in the appendices following)**

<table>
<thead>
<tr>
<th>Task</th>
<th>Extra Information</th>
</tr>
</thead>
</table>
| Completing a Request Form | ▪ Enter all details on the Request Form. If you append a patient specific printed label make sure you add any necessary subsidiary information (e.g. clinical details)  
▪ See the following (available on the Trust Internet and Intranet): [www.uhb.nhs.uk/gp-specimen-container-guide.htm](http://www.uhb.nhs.uk/gp-specimen-container-guide.htm)  
▪ A poorly made out request form which does not conform to the Minimum Data Set (including relevant clinical details) may lead to the rejection of the clinical specimen and the potential need to collect another sample! |
| Check the patient is appropriately prepared | ▪ Inform the patient of the specimen collection procedure and prepare them for the process.  
▪ Certain laboratory investigations require the patient to be especially prepared, e.g. fasted. Information on laboratory investigations requiring special patient preparation can be obtained by contacting the laboratory. |
| Confirm the identity of the patient | ▪ Identify the patient by checking the request form against the patient’s wrist band.  
▪ Do not rely on the label at the bedside, this can be out of date if a patient has just been moved etc. |
| Taking a Blood Sample | ▪ Positively identify the patient:  
  ▪ **UHB Patients.** The identity of the patient must be confirmed by checking the patient’s wrist band. Do not rely on other information around the bedside. **All hospital specimens must be labelled AFTER checking the PATIENT’S WRISTBAND wherever possible.**  
  ▪ **Direct Access/OPD Patients.** The identity of the patient must be confirmed by asking them to confirm their full name and date of birth. ‘Calling names’ or ‘preferred names’ are not acceptable. Labels must be stuck on the sides of specimen
| **Minimise the risk of poor sampling** | Prevent dilution of the sample by avoiding sites above or near an I.V. infusion. |
| **Minimise the risk of mixed up samples and sub samples.** | Samples and request forms from a patient must be collected, labelled and packaged **one at a time, and where possible, in the presence of the patient, after confirming their identity.**  
It is essential that samples are not collected and taken to a central point for labelling and packaging. This is to avoid the risk of mixing up samples from other patients.  
**Poorly labelled specimens which do not conform to the Minimum Data Set or mismatched specimens and requests will be rejected.** |
| **Label the Specimen Container** | Label the specimen container yourself at the bedside immediately after collection and double check this against the request.  
**Poorly labelled specimens which do not conform to the Minimum Data Set will be rejected.** |
| **Ensure that environmental and storage conditions are fulfilled to protect specimens from deterioration.** | Specimens should be transported to the laboratory as soon as possible after collection. Delay may result in deterioration of the specimen and invalidate the results of any investigations carried out.  
If a delay in specimen transportation is likely and you are unsure what to do, contact the laboratory to seek advice on the most appropriate way to store the specimen. |
| **Ensure the safe disposal of all materials used in specimen collection.** | Used needles should always be discarded directly into an approved sharps container, without being re-sheathed. All other non-sharp disposables should be placed in a clinical waste bag. |
| **Ensure that high risk specimens are identified and processed correctly.** | The Laboratory treats all specimens received as potentially hazardous and applies ‘standard precautions’. **However, if a specimen is suspected or known to present an infectious hazard, the person requesting the specimen has the responsibility to ensure that the form and containers are appropriately labelled.** In particular:  
i. Blood tests likely to be performed in a reference laboratory. Although likely it cannot be assumed that they use ‘standard precautions’.  
ii. If the specimen is blood culture and the patient is suspected to be infected with a Hazard group 3 organism e.g. Brucellosis; Typhoid; Anthrax; Plague.  
iii. If the patient is suspected of having CJD and the specimens are brain, CNS tissue, CSF.  
iv. Any specimens from patients suspected of being infected with a Hazard group 4 organism e.g. Lassa Fever; Marburg; Ebola; Yellow Fever. |
| **Ensure that all spillages and breakages are dealt with correctly.** | In the laboratory see:  
o. **Laboratory H&S Manual (AHS_P001).**  
In the event of a spillage it is essential to ensure that staff do not become infected by leaking or broken specimens, by culture spillage or contaminated by spilled chemicals.  
Refer to the procedures in your location for dealing with spillages and breakages or seek advice from a senior member of staff in your area.  
If necessary contact the laboratory for advice on any aspect of dealing with spillages and breakages of pathology specimens. |
| Minimise the risk to the specimen collector, carrier, the general public and the receiving laboratory. | ▪ Training courses in Venepuncture for nursing staff etc. are provided by the Trust.  
▪ For consignment out of the Trust or between Trust sites ensure that all H&S responsibilities and legal requirements are met, e.g. ADR transport of dangerous goods regulation, postal regulations etc. all apply to diagnostic specimen transport. |
13. Appendix 3 - Health, Safety, Infection Control and Security

*It is important to be aware of the safety and security implications of the collection, storage and transport process for clinical specimens.*

In the laboratory see the **Laboratory H&S Manual (AHS_P001)**.

There are safety and security implications at all stages of the collection process and the storage and transport of clinical specimens. In particular, all biological specimens should be handled as if their infectivity status is unknown so protect yourself and others even though the specimen may be contained in a specimen container. Take care to follow your local **Health, Safety & Welfare Policy and Infection Prevention and Control Policy**

http://uhbpolicies/assets/InfectionPreventionAndControlPolicy.pdf

In particular:

- **Standard precautions** must be adhered to when harvesting any clinical material, with particular emphasis on hand hygiene and prevention of cross-contamination.
- Guard against the potential for transmission of infection by the accepted routes of transmission (Ingestion, Inhalation, Inoculation and Eyes).
- Needle-stick injuries are avoidable and can be prevented, understand the risk and responsibilities of using 'sharps' and their disposal.
- Never use sharp points (scissors or blades) near blood bags.
- Take care when wearing gloves to avoid the inadvertent cross-contamination of telephones, door handles etc.
- Work to your local manual handling policy

The following document is available for visitors to the laboratory:

**Guidance for Laboratory Visitors (PUB_006)**

The following documents are available for Porters, Transport drivers and couriers:

**Guidance for the Carriage of Laboratory Specimens (PUB_005)**

**Guidelines on the Transportation of Clinical Specimens by Road (PUB 048)**

Rules and Regulations relating to road transport of diagnostic specimens are noted below, and Trust transport drivers carry an approved ‘Safe Systems of Work’ document. If you are contracting a third party for delivery or collection of diagnostic material please ensure that all parties are aware of, and conform to, the requirements of relevant transport regulations. Incidents and ‘near-misses’ that relate to specimen collection, storage and transport should be recorded via the Trust Incident Reporting System.

13.1. Security

Security of a collected specimen should be a priority. Having to take a repeat specimen is an unnecessary invasive clinical procedure for the patient and some specimens cannot be repeated. Also the request card and container contain private patient information.

Each ward and clinical department producing clinical specimens should have specimen collection boxes held in a secure location (e.g. by the nurses station). Specimens which
are particularly **urgent** should be identified separately. Do not situate a collection boxes in an unmanned area, particularly where there is easy access by the public or other patients. Note the timing of porter/driver rounds for your clinical area to avoid specimens remaining uncollected or left for extent periods as biological deterioration may affect the result.
14. Appendix 4 - Requesting a Test or Examination

The steps in the chain of events from specimen request and collection to a receipt and analysis at the laboratory is a multi-stage chain of events, and there should be responsibility and accountability at each stage.

The procedure should not be undertaken lightly and care should be taken that the clinical intervention required and the actual analysis requested will yield clinically useful information.

14.1. Responsibility & Accountability

At each stage of the chain of requesting an analysis, procuring a specimen and delivering this to the laboratory there is a hand-off (or hand-over) to another party (e.g. from phlebotomist, to ward, to porter etc.) which carries a risk of error arising from misunderstanding, misinformation or inappropriate delay. The participants in each stage have ownership of that stage and should take responsibility to ensure the reduction of the risk associated with their hand-off. Don’t assume that everyone knows a specimen is urgent unless there is a clear notification at each hand-over.

14.2. Medico-legal Examinations

There are procedures for 2 special cases that may arise where clinical specimens may also be relevant to a legal or criminal investigation:

- Seizure of Clinical Material or Data/Documentation by a Law Enforcement Agency
- Medicolegal Specimens and Maintaining the ‘Chain of Evidence’

These are noted in the laboratory document - Control of Clinical Material and Data Manual (QAA_P007)

14.3. Requesting Procedure

The requesting of a clinical analysis to aid in diagnosis should only be undertaken by an authorised practitioner (a competent and clinically trained individual). The procedure should not be undertaken lightly and care should be taken that the clinical intervention required and the actual analysis requested will yield clinically useful information.

Special arrangements and precautions relating to request for Blood and Blood Products can be found in the Trust Transfusion Policy

http://uhbpolicies/assets/BloodTransfusionPolicy.pdf

and associated procedures.

A minimum data-set required by the laboratory is noted below, and in line with legal requirements for the procurement of blood and blood products the blood bank and pathology reception operates a zero tolerance policy with regards to the minimum data set requirement for requests forms and sample labelling. All requests should be made on an approved form only.
14.4. Request Form & Specimen Label

Separate, colour coded, request forms are available for each laboratory, and please ensure that the correct request form is completed to a high standard. Non-approved forms with data in different locations are difficult to read and transcribe and constitute a clinical risk, the laboratory reserves the right to reject these. Images of some of the current request cards in use are shown at the end of this manual.

<table>
<thead>
<tr>
<th>Request Form Colour Codes (Trust only)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Green/White</td>
<td>Clinical Biochemistry + Viral Serology/Antibiotic Assays</td>
</tr>
<tr>
<td>Red/White</td>
<td>Haematology</td>
</tr>
<tr>
<td>Black/Pink</td>
<td>Blood Transfusion</td>
</tr>
<tr>
<td>Blue/White</td>
<td>Clinical Microbiology</td>
</tr>
<tr>
<td>Orange/White</td>
<td>Virology</td>
</tr>
<tr>
<td>Yellow Strip</td>
<td>Immunology</td>
</tr>
<tr>
<td>Black/White</td>
<td>Histopathology</td>
</tr>
<tr>
<td>Black/White</td>
<td>Neuropathology</td>
</tr>
<tr>
<td>Black/Yellow</td>
<td>Cytopathology (Non gynae)</td>
</tr>
</tbody>
</table>

14.5. The Request Form – General Principles

Ensure that the request form is legible and completed as fully as possible. The correct request form must be completed and must accompany any specimen to the correct laboratory. Both the specimen label and the request form must contain the appropriate minimum data set.

There must be:

- Unequivocal identification of the patient and matched to the specimen to the request - bear in mind the regional and cultural predominance of certain common names;
- Sufficient information to allow the specimen collector to make the correct choice of timing, specimen to collect (specimen type) and container to use;
- Sufficient information to identify the exact site of sampling (e.g. for biopsies, some culture swabs, etc.). Where different sample sites are included on one request form the site of each specimen must be unequivocally noted on the specimen label also;
- Sufficient information to aid the audit trail of a specimen from request to laboratory;
- Sufficient clinical details to allow laboratory interpretation of the result an analysis, including any current condition or therapy that might interfere with analyses;
- Time of sample collection – for some assays the time a specimen has been in transit can greatly affect the quality of the result.

All details on the request card should be completed including details of current therapy. Please include the NHS number if known on both the request card and specimen bottle. If printed labels are available please double check you are using the correct one: the large label with the bar code should be applied to the request card and the small labels attached to the specimen containers. You must ensure that the correct location is entered on the request card. Failure to record this will mean that a report cannot reach the patient’s notes. This is particularly important if the patient has moved and labels from the previous location are used, you must ensure that the correct current location is entered on the label. Where a two-part form is used please ensure that information is legible on both parts of the form.
NB: it is not acceptable to use a pre-printed label on a specimen for transfusion purposes, this must be handwritten, legibly and unambiguously. Poorly labelled or mismatched specimens may not be analysed for medical legal reasons.

It is a requirement of the Blood Safety and Quality Regulations that the blood bank and pathology reception operate zero tolerance with regards to the minimum data set requirement for blood transfusion product requests forms and sample labelling.

All Immunology requests received by the Trust will be collated for onward transfer to the Medical School.

14.6. Specimen Tracking

A specimen tracking audit trail is crucial (for quality assurance, clinical governance clinical governance and medical-legal reasons).

There must be a traceable history and "chain-of-custody" which should include:
- the identification and location of the responsible clinician ordering the test;
- the analytical tests/examinations required;
- the patient, location and medical specialty (i.e. the original source of the specimen unambiguously identified);
- the person collecting the specimen with the date and time collected;
- the nature of the specimen collected (and if appropriate, anatomical site of origin);
- the analytical tests required;
- the laboratory undertaking the analysis;
- identification of priority status;
- where the results should be sent (if different from above);
- the resulting analytical data relating to that specimen (and sub-samples thereof);
- the reported result.

14.7. Minimum Data-set

Data on the request form and the specimen must be compatible. All specimens must carry a minimum, legible and compatible data-set on both the request form and the specimen label.

<table>
<thead>
<tr>
<th>Patient Data Item</th>
<th>Request Form</th>
<th>Specimen Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Forename (not just initials)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Hospital ID &amp;/or NHS number</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Report Destination</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Requesting Practitioner</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Consultant (if different from above)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Clinical Details</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Date of Collection</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Time of Collection</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Specimen type (&amp; site if appropriate)</td>
<td>√</td>
<td>√ (for Histology)</td>
</tr>
<tr>
<td>Investigations required</td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>

Certain specimens labels may have insufficient room to physically allow a full data set in this case include as many key identifiers as possible.

Additional information may also be required such as notification of known or suspected biohazard of the specimen, priority of the result (or date required if for Cellular Pathology), or to aid the reconciliation of the patient with a record on ‘Lorenzo’ or in the patient’s notes.
Time of collection is crucial in several circumstances, including:

1) To assess the suitability of a sample for tests where cellular degradation over time (e.g. K⁺ leakage) may interfere or give an incorrect result.
2) For tests that are part of a timed series (Dynamic Function Tests, e.g. Glucose Tolerance Tests, Endocrine Function Tests etc.),
3) To allow the laboratory to properly audit specimen turnaround times.

*If sufficient clinical details are not provided then the laboratory will not be in a position to offer an interpretation of the result of the test or examination,* in this case the laboratory will note this on the report.

If patient anonymity is important a properly coded identifier may be used but this has to be part of a documented system which properly and unambiguously identifies the patient.

Computer software systems may be in use within the Trust (e.g. PICS) which are capable of generating patient specific printed labels. The use of computer generated patient identification (PID) labels for the request form and specimen introduces a risk of misidentification under certain circumstances. Always double check that the correct label has been affixed to the correct request and is accompanied by the correct specimen.

**NB:** it is not acceptable to use a pre-printed label on a specimen tube for **transfusion purposes**, this *must* be handwritten, legibly and unambiguously.

If and when barcodes might be used to identify a request and specimen or sample, these *do not* replace the requirement for adequate labelling, but in addition the barcode on the specimen and the request form *must* be identical.

In exceptional circumstances where the minimum dataset is impossible to collect, such as an unidentified patient attending casualty, the laboratory may process the request but will make it clear on the report supplied that necessary data is missing for the unambiguous reconciliation of the patient with the sample received.
15. Appendix 5 – Specimen Collection

Improper collection and/or handling of specimens can lead to a variety of problems, for example haematoma in a phlebotomised patient or haemolysis in a blood specimen. Care should therefore be taken at every step to ensure the quality of the procedure and the specimen collected and sent for analysis.

15.1. Training

Each type of specimen collection has its own principles, procedures and risks. It is essential to be trained in and understand these risks before embarking on such collection. Training and competency should be documented. This is particularly so where the use of medical devices is concerned (Medicines and Healthcare products Regulatory Agency, NHS Litigation Authority, Healthcare Commission etc.). In this context Medical Devices include needles, diagnostic and therapeutic equipment, etc. Wards and departments should ensure the fully documented competency of the practitioner before they are permitted to undertake the procedure.

Nursing and non-laboratory staff requiring training in phlebotomy should contact their Clinical Skills Training Team.

15.2. Non-Laboratory Testing

In the case of Point-of-care testing (POCT), where the laboratory may not be directly involved all general principles of quality assurance, patient care, training, audit trail and specimen integrity apply. All POCT within the Trust should involve the formal participation of the relevant clinical laboratory in line with Trust policy.

15.3. Collecting a Specimen

The collection of a specimen may involve phlebotomy, the collection of a variety of other bodily fluids (CSF, urine, faeces, semen etc.) or the harvesting of a biopsy or body part each has its own principles, procedures and risks which should be understood.

Always confirm that the correct patient is being approached for the procedure required. Where the patient is conscious and competent ask the patient to confirm the spelling of their name and check the details against the patient ID bracelet and the request form. If the patient is not competent for any reason then check the details with ward/department/surgery staff, the ID bracelet and the request form.

15.4. ‘Order of Draw’

For a guide to which specimens to collect for the different analytes and examinations which might be requested, please refer to the Guide to Specimen Containers for Pathology Requests [http://www.uhb.nhs.uk/gp-specimen-container-guide.htm](http://www.uhb.nhs.uk/gp-specimen-container-guide.htm)
or the vacuette guide. [http://www.uhb.nhs.uk/Downloads/pdf/LaboratoryVacuetteSelectionChart.pdf](http://www.uhb.nhs.uk/Downloads/pdf/LaboratoryVacuetteSelectionChart.pdf)

When taking blood samples, please observe the ‘order of draw’ to avoid cross-contamination of tube contents. As a matter of principle this order when using a multi-sample technique will be Blood Culture bottles first followed by Citrate, then Serum tubes,
followed by other ‘additive’ tubes (Heparin before EDTA). Always mix gently but thoroughly.

15.5. **Specimen Container Colour Key**

**NB:** This key refers to the Greiner Vacuette® system used by the Trust. Other systems in use by other trusts may not match this so please take care to check the tube type required.

### Blood Culture

<table>
<thead>
<tr>
<th>Colour top</th>
<th>Nominal Volume (mL)</th>
<th>Description</th>
<th>Mix by Inverting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>8-10</td>
<td>Aerobic</td>
<td>6-8x</td>
</tr>
<tr>
<td>Purple</td>
<td>8-10</td>
<td>Anaerobic</td>
<td>6-8x</td>
</tr>
</tbody>
</table>

Volumes shown are for tubes supplied by this Trust, tubes from other sources may be of different volumes.

<table>
<thead>
<tr>
<th>Colour top</th>
<th>Nominal Volume (mL)</th>
<th>Description</th>
<th>Mix by Inverting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue</td>
<td>2.7</td>
<td>Citrate</td>
<td>6-8x</td>
</tr>
<tr>
<td>Red</td>
<td>6</td>
<td>No additive</td>
<td>6-8x</td>
</tr>
<tr>
<td>Yellow/Gold</td>
<td>3.5</td>
<td>SST (gel)</td>
<td>6-8x</td>
</tr>
<tr>
<td>Light Green</td>
<td>3</td>
<td>Heparin (gel)</td>
<td>6-8x</td>
</tr>
<tr>
<td>Dark Green</td>
<td>6</td>
<td>Heparin</td>
<td>6-8x</td>
</tr>
<tr>
<td>Purple</td>
<td>4</td>
<td>EDTA</td>
<td>6-8x</td>
</tr>
<tr>
<td>Grey</td>
<td>2</td>
<td>Fluoride/Oxalate</td>
<td>6-8x</td>
</tr>
<tr>
<td>Dark Blue</td>
<td>6</td>
<td>No additive</td>
<td>6-8x</td>
</tr>
</tbody>
</table>

SST® = Serum Separator Tube, contains a polymer gel + clot activator  
EDTA = Ethylenediamine Tetraacetic Acid  
* For Aluminium investigation only  
** For Trace Element investigation (except Aluminium), glass only

15.6. **Request Forms and Other Supplies**

Request forms must be ordered via the print room. Users of blood collection tubes who are not on the EDC top up system should obtain any blood collection tubes from logistics with the weekly order. Areas not on the top up system should continue to request and receive their blood tube supplies via the Portering team.

15.7. **Request Forms and Other Supplies for GPs**

A combined GP request form is available for Clinical Biochemistry and Haematology (for use by GPs only, not for use within the UHB Trust). Separate request forms are required for Microbiology and Cellular Pathology. Electronic forms approved by the PCT are also accepted.
Request forms and blood collection tubes for Biochemistry, Haematology and Microbiology as well as faeces pots, urine bottles and Microbiology specimen containers and swabs may be requested using a single requisition form available from Clinical Laboratory Services. Tel: (0121) 371 15990

Please state the exact requirements, especially for urine containers, as it may be necessary to add special preservatives to some collection bottles.
16. Appendix 6 – Specimen Rejection

Poorly labelled specimens and incomplete request forms are a clinical governance issue and may constitute a serious clinical risk.

Poorly completed or mismatched requests may not be analysed for medical legal reasons. The laboratory has the authority to refuse a request that does not carry a minimum dataset to allow the unambiguous identification of the patient and requesting practitioner and to unambiguously match the specimen with the request form (see above).

The laboratory does not have the authority to amend details on a specimen or request form if incorrectly given. ‘Unrepeatable’ but insufficiently identified specimens may sometimes be accepted but only when the requesting doctor formally accepts responsibility for confirming their authenticity. In normal circumstances within the Trust this will involve attending the laboratory to label the specimen. Changes to the request or specimen must be amended and signed by the requesting practitioner. In exceptional circumstances only, the laboratory may undertake to examine or test an inappropriately labelled specimen but the attendant risk to the patient will be noted on the report.

Any specimens that are rejected will be recorded by the laboratory.

Please help us to help you by supplying as much information as possible including date/time of sample was taken, name of requesting physician and relevant clinical details every time you request an investigation.

16.1. Specimen Rejection

In general the following conditions will lead to the rejection of a specimen and request form by Specimen Reception:

- Specimen label or Request form that does not meet the MDS declared by the laboratory.
- Specimen label and Request form with mismatched details.
- Illegible details that cannot be deciphered after seeking a second opinion from appropriate qualified staff.

16.1.1. Exception(s) to the Rejection Process

For patients were there is a valid reason for not knowing the true identity (e.g. unconscious in ED) then ‘Unknown’ or similar indication when printed as the name is acceptable to allow the processing of the sample, but see Exceptions – Reporting below.
Clinical Laboratory Services Queen Elizabeth Hospital

Where there is uncertainty in the identification of the primary sample or instability of the analytes in the primary sample and the primary sample may be considered unrepeatable or critical the Specimen Reception will refer the problem to the appropriate laboratory (e.g. Duty Biochemist or similar).

The laboratory may choose to process the sample but the result would not normally be released until the requesting physician or appropriate delegated responsible person takes responsibility for identification and acceptance of the primary sample and provision of the proper information or a senior authority within the laboratory accepts the specimen for clinically valid reasons. The signature of the person taking such responsibility should be recorded on, or traceable to, the request form (e.g. noted in the Notepad facility of TelePath).

16.1.2. Exceptions - Reporting

If for any reason a sample compromised in this way is to be analysed and reported without documented acceptance by the requesting physician (or delegate), then there must be identification of a senior authority from within the laboratory for this action (e.g. signed on the request form with reasons noted for a single exception, or clear controlled documentation of instructions for a recognised block or class of specimens).

In the case of doubt over the identity or other details relevant to the care of the patient the report must indicate this with appropriate caveats to apply to the interpretation of the result or clear notification of any doubt about the identification of the patient.

16.1.3. Handling Rejected Specimens and Requests

Specimens and request forms are still to be assigned a laboratory number in the usual way. A distinct TelePath code should be used which will generate text similar to the following example text on the report output:

“Minimum acceptable data criteria have not been met; therefore sample has not been processed.”
17. Appendix 7 – Specimen Carriage

Specimen transportation systems need to ensure the timely arrival of specimens at the correct destination at minimum risk to both laboratory and non-laboratory personnel and in accordance with current regulations.

It is the responsibility of the user/sender (consignor) to collect and package specimens according to these guidelines and the relevant legislation in force. The laboratory reserves the right to refuse acceptance of patients’ specimens, not packaged in accordance with current regulations which pose a risk or hazard.

The laboratories receive clinical specimens from wards, departments and clinics at UHB, GP practices in the Birmingham Community Healthcare Trust and some others, community hospitals, community practitioners (e.g. district nurses), Kidney Dialysis Units, patients or relatives of patients, and (occasionally) undertakers.

This section refers to the movement of these specimens from the locations listed above to the Laboratory.

Modes of Transport include:

- Personal transport by patients or relatives.
- Individual transport by Trust, PCT employees (e.g. porters, nurses and doctors, midwives and community nurses).
- Hospital transport (e.g. vans).
- Outside agencies (e.g. Royal mail, independent couriers).
- Specimen Delivery System.

For advice on any aspect of transporting specimens to the laboratory, please contact the laboratory.

Whilst Clinical Laboratory Services works closely with the Trust Transport and Porting Managers of Division to ensure that strategies and schedules accord with laboratory working arrangements, the laboratories do not manage these services and are not responsible for the collection and delivery of specimens.

For GP users transport may be provided by arrangement with the Trust for specimen collection and delivery of reports and supplies. If specimens are submitted through the post it is a legal requirement that postal regulations must be observed.

When contracting a Courier to transport specimens to the Laboratory it is important that the following is documented:

- The courier company and staff are aware of the nature of the goods being transported.
- The courier company has provided appropriate training for their staff in the transportation of such goods and health and safety requirements in line with ADR and other H&S regulations.
- The courier company complies with national regulations and legislation regarding the transportation of biological materials.

General taxi firms do not follow the above guidelines and are therefore inappropriate.
Clinical Laboratory Services Queen Elizabeth Hospital

17.1. Handling & Storage
Clinical specimens should be handled and stored in a manner that best preserves the integrity of the element(s) to be analysed or examined within the likely timeframe before delivery to the laboratory, and that ensures the security of the specimen (including data protection responsibilities to the patient).

Pathology specimens sent by road or other transport should be transported in UN3373 compliant carriers/containers.

17.1.1. Specimen Degradation
It is important to understand the stability of the material to be measured, cultured or examined and to ensure that the specimen is received in the laboratory within good time to avoid anomalous results which might arise from specimen degradation. At the extreme some analyses require the specimen to be kept at a specific temperature and to arrive within tens of minutes, whilst some analyses might tolerate storage and transport at room temperature over several hours.

In general the following considerations should be taken into account when determining the delay permissible within the transit process from patient to laboratory:

- Transit time (from specimen collection, including collection and storage time)
- Storage temperature
- Transit temperature

This handbook contains contact details for the laboratory sections and personnel, and where appropriate, basic advice regarding the appropriate storage conditions and transit times for commonly requested specimens.

If there is any doubt always contact the laboratory for advice.

17.1.2. Collection, Storage & Transit Times
Specimens should be transported to the laboratory as soon as possible after collection. Delay could result in deterioration in the specimen and invalidate the results of any investigations carried out. The specimen delivery system can be used for the majority of specimens.

If a delay in transporting pathology specimens to the laboratory is unavoidable ensure the correct storage of specimens to prevent them from deterioration (room temperature, refrigerated or frozen as appropriate to the specimen type). If necessary seek advice on the most appropriate way to store the specimen.

It is important to keep the total time from specimen collection to arrival at the laboratory to a minimum taking into account the normal scheduled routines of transport and portering arrangements. Storage and Transit Conditions

Some specimens require, or are aided by, storage and transport under cool conditions (fridge storage, transport on ice etc.), others tolerate or require room temperature and occasionally storage and urgent transport at approximately body temperature is required.
Clinical Laboratory Services Queen Elizabeth Hospital

Always be sure of the ideal conditions required for the specimen you are collecting and try to meet these conditions. Whatever these may be the following should be observed:

- All specimens should be sent in a specially designed container and usually a sealed bag.
- The request form must be physically separated from the specimen to prevent contamination if leakage should occur.
- The container used to transport specimens must prevent contamination of the vehicle or person conveying the specimens if leakage should occur.
- Specimens must never be carried or transported directly in the hand or in a coat pocket.

Specimens to be transported on the public highway are classified as Goods Dangerous for Carriage and subject to regulation (see below).

17.1.3. Urgent Specimens
Urgent specimens should be directed to the correct testing laboratory without delay. Analysis will be prioritised.

17.1.4. Routine Specimens
Every effort should be made to get routine specimens generated from within the Trust to the testing laboratory within 2 hours of collection.

17.2. Porters
There are limited collections by portering staff. Ad hoc porters can be called to take urgent specimens to the laboratory specimen reception. Transport should be contacted directly if the specimen cannot wait. Tests requiring urgent analysis should be brought to the attention of the laboratory staff by a prior telephone call.

Do not forget to inform the laboratory to expect an urgent sample (this is a requirement for the Biochemistry & Haematology laboratories that operate an emergency number allocation).

Muscle biopsies are by arrangement only and must be booked in advance (at least 48 hours).

17.3. Specimen Delivery System

The SDS is a pneumatic tube system that transports carriers between clinical areas and Clinical Laboratory services. This system must only be used for the transport of specimens across the Trust.

It is important to make sure when sending specimens using the SDS that the Carrier lid is closed correctly prior to dispatch to the laboratory.

The following should not be received via the SDS:

1. Anything that can’t comfortably fit into the carrier, is greater than 2.5kg and presents a health and safety risk.
2. Any specimen that is not in a sealed specimen container and in a sealed specimen transport bag.
3. Transfusion blood and blood components.
4. Clinical waste including empty blood bags.
5. Specimens for blood gas analysis.
6. Specimens on ice.
7. Specimens of Cerebral Spinal Fluid (CSF).
8. Specimens that carry a high risk of infection:
   - Hazard Group 4 organisms; Includes Haemorrhagic fevers e.g.: Ebola, Marburg and Lassa fever.
   - Specimens from patients who have potentially been exposed to biological warfare organisms; anthrax, smallpox, botulism, tularaemia.
9. Any form of CJD or vCJD.
10. Any specimens for the Cellular Pathology Department whether fresh, frozen or in formalin except cytology specimens.
11. Any sample that is considered unrepeatable.

17.4. Transport Between Hospitals

There is a regular scheduled service of vans running from the Trust to GPs and other Trusts and key sites around Birmingham by day to ensure delivery of specimens to the appropriate laboratory.

17.5. Transport Regulations

UK Carriage regulations refer to the European Directives (ADR – road, RID – rail) which are updated every 2 years, for example ‘European Agreement concerning the International Carriage of Dangerous Goods by Road 2009’ (ADR 2009). Air Transport of dangerous goods is covered by the International Civil Aviation Organisation (ICAO) ‘Technical Instructions for the Safe Transport of Dangerous Goods by Air’. These are essentially similar but there are some minor differences.

For the purposes of transport by road, air or postal service, specimens of material (blood, tissue, excreta, secreta etc.) collected from humans or animals are counted as infectious material, that is, they are known, or reasonably expected to contain pathogens.

Under these regulations specimens must be:

- classified;
- packaged;
- labelled;
- and transported

according to strict codes defined in the EU legislation. These are subject to change and anyone sending or transporting specimens must ensure that transport by road air or post (including transport arrangements contracted out to a third party) conforms to the current legislation.

Departments that engage in the transfer of diagnostic specimens should also ensure that there are auditable records of the relevant training of staff involved, including training on relevant local policies and any legal requirements governing the carriage of such goods appropriate to their duties and responsibilities.

A synopsis of some of the information under ADR 2007 that is likely to be relevant to
transport of diagnostic specimens is given in the following sections, but always check for the most up-to-date guidance before proceeding.

17.5.1. Classification

Biological agents, or materials that may contain them, are allocated to UN Division 6.2 - Infectious Substances. Division 6.2 includes biological products, cultures, genetically modified micro-organisms (GMMs) and genetically modified organisms (GMOs) and medical/clinical waste.

Infectious substances are divided into the following categories:

- **Category A**: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. This includes cultures of highly infectious agents. Most substances in this category are assigned to UN2814.

- **Category B**: Any infectious substance that does not meet the criteria for inclusion in Category A. Diagnostic specimens are considered as a minimum to fall into this category. Substances in this category are assigned to UN3373 (except cultures which are UN2814 or UN2900)

NB: The Royal Mail will not carry Category A material.

Blood or blood components for transfusion or transplant or tissues or organs for transplant are not subject to these regulations.

17.5.2. Packaging

For Category A substances please seek informed advice and ensure that you check the material against the ‘Approved List of Biological Agents’ (available on-line from HSE) and ascertain the correct packaging requirements.

Substances assigned to UN3373 (i.e. most diagnostic specimens) should be packaged in accordance with PI 650.

Packaging which should be of good quality and strong enough to withstand the shocks and loadings encountered under normal conditions, including minimum dimensions for the outer packaging and the capability to survive a drop-test. Check the regulations for details of these requirements if you are unfamiliar with them.

The packaging should consist of 3 components:

- **A primary receptacle.** A primary watertight leak-proof receptacle containing the specimen. The receptacle must be packaged with enough absorbent material to absorb all fluid in case of breakage.

- **A secondary receptacle.** A second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage.

- **Outer packaging.** Secondary packaging is placed in outer shipping packaging with suitable cushioning material. Outer packaging protects their contents from outside influences, such as physical damage, while in transit. The smallest overall external dimension shall be 10 x 10 cm.

Each completed package is normally required to be correctly marked, labelled and accompanied with appropriate shipping documents (as applicable).

**The completed package shall be capable of successfully passing a drop test as set out in the regulations (height not less than 1.2 m).**
17.5.3. Labelling of Packaging

Packaged according to PI 620, labelling required for category A substances includes:
- The proper shipping name (i.e. infectious substance affecting humans).
- The appropriate UN number (UN 2814).
- The appropriate warning label.
- Consignor and consignee.

Packaged according to PI 650, labelling for category B substances includes:
- The proper shipping name (e.g. Diagnostic Specimens).
- The approved diamond shaped symbol of the correct dimensions.
- The appropriate UN number (UN3373).
- The consignor and consignee.

17.5.4. Bodies and Limbs

- Bodies must be transported to the mortuary using the approved trolley.
- A body bag should always be used in line with Trust guidance.
- Limbs for disposal must be securely contained and ethically packaged using an approved waste container.
- Unfixed tissue or body parts for pathological investigation must be transported in accordance with good practice.

17.5.5. Transport Beyond the Trust

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations apply to the carriage of dangerous goods by road & rail. It places special duties on everyone with a role in the carriage of dangerous goods, and specific duties on those in the transport chain. It is essential that these roles and responsibilities are understood and that the legal requirements are met.

Always check that your chosen carrier conforms to the requirements of the legislation. This may be discussed with the Trust Transport Manager and his staff.

17.5.6. Vehicle Contamination/Decontamination

It is a requirement of ADR 2009 that if an infectious substance has leaked or been spilt in a vehicle or container, that vehicle or container may not be re-used until it has been thoroughly cleaned, and, if necessary disinfected or decontaminated. Any other articles carried in the vehicle may need to be examined for possible contamination.

17.5.7. Postal Regulations

With regard to sending specimens through the post, advice is given below, but if you still unsure then the Clinical Microbiology laboratory can advise on current requirements or an arrangement can be made with them to correctly package and send the material via their courier.

17.6. Dispatch of Specimens to the Laboratory

Core laboratory opening times for laboratories can be found in the relevant sections of this Laboratory Handbook. Outside of these times, arrangements should be made with the on-call staff via switchboard, to ensure receipt of specimens is possible, and that specimens are stored in the correct manner. Please ensure compliance with ADR regulations for transport by road.
Clinical Laboratory Services Queen Elizabeth Hospital

17.6.1. Dispatch of Urgent Specimens

Definition of urgent specimens:
- Telephoned request to the laboratory for a specimen to be treated as urgent.
- Histology frozen sections (previously arranged with the laboratory).
- CSF samples are treated as urgent by Microbiology.

The user must inform the laboratory if an urgent specimen is being dispatched to the laboratory. For Biochemistry and Haematology specimens, telephoned urgent requests are recorded and given an ‘urgent’ number.

Urgent specimens from GP practices must include a contact number to telephone results back to the clinician or deputising locum. Detailed guidance is available from the Royal College of Pathologists
http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/g025_outofhoursreporting_nov10.pdf
“Out-of-hours reporting of markedly abnormal laboratory test results to primary care: Advice to pathologists and those that work in laboratory medicine.”

17.6.2. Dispatch of Routine Specimens

UHB Locations
Specimens are collected by Trust porters and drivers, from UHB wards, clinics and departments and some local and Community Hospitals according to published schedules. Information on correct transportation, packaging, labelling guidelines and laboratory opening times, must be observed.

GP Practice Locations
Specimens are collected by Trust drivers from GP practices at scheduled times throughout the day, Monday to Friday. Outside of these times, users must make their own arrangements for specimens to be delivered to the laboratory if results are required urgently. Information on correct transportation, packaging, labelling guidelines and laboratory opening times, must be observed.

Alternatively, the user should contact the laboratory for information on storing specimens correctly to ensure they do not deteriorate prior to the next scheduled delivery.

Other Locations
- Individual practitioners (doctors, nurses etc.).
- Community practitioners (community nurses, nursing home practitioners).
- Kidney Dialysis Units etc.

These may transport specimens directly, or by courier to the laboratory or to the nearest GP practice or community hospital for those specimens to be included in the next scheduled collection from that location. Information on correct transportation, packaging, labelling guidelines and laboratory opening times, must be observed.

Outside of normal hours, laboratory staff must be informed of a delivery of specimens to ensure receipt of specimens is possible, and that specimens are stored in the correct manner upon receipt.
18. Appendix 8 - Laboratory Results
For general enquiries, consultant advice and interpretation of results please see the Contact Telephone Numbers section for each discipline.

Reference ranges quoted in this handbook are for general guidance only and correct at the time of publication, please check your hard copy report for the current ranges relevant to the patient details you supply.

18.1. Laboratory Reports
Clinical Laboratory Services has computer systems which are networked into the Trust Intranet, enabling electronic transmission of reports.

18.1.1. Electronic Reporting to wards.
Reports from Laboratory Haematology, Cellular Pathology, Clinical Microbiology and Clinical Biochemistry can be viewed on the wards via the following systems:

- Results Browser,
- PAS Viewer,
- PICS,
- EPRO and some other systems.

You should use these systems to view reports rather than telephoning the laboratories for results. Excessive telephone enquiries slow down the work of the laboratory and lengthens turnaround times. Results Browser and PAS Viewer are accessed via the Intranet and only require a network password. Permission may have to be set by the Trust’s Help Desk (ext. 2199). Access via PICS and the other systems are inherent in their logons.

NB: Results on these systems are dependent on correct demographic data including current location AND registration number.

18.1.2. Electronic Results for GPs
Reports for GPs can be transmitted electronically by arrangement with the laboratory and are transmitted several times a day (02:00, 06:00, 10:00, 14:00, 18:00, and 22:00).

18.1.3. Printing Reports
Currently hard copy reports are printed for locations that still require them. For QEHB there is a results tracker project to be implemented in 2015 which will eventually negate the need for printing of hard copy reports in the vast majority of cases. When this is implemented hard copy reporting will be discontinued wherever possible.
18.2. **GP Enquiries for Results**

A direct line (**GPs only**) has been created for all results enquiries relating to **Biochemistry, Haematology and Microbiology** investigations:

(0121) 371 5999/5990

for general **Cellular Pathology** enquiries, telephone:

(0121) 371 3326

For other general enquiries, consultant advice and interpretation of results please see the Contact Telephone Numbers section for each discipline.

18.3. **Referral of Specimens to Third Party Laboratories**

Each laboratory will have their own procedure for handling and dispatching referred specimens, see *Related Documentation* on the cover pages for cross reference to relevant laboratory procedures and work instructions.

Addresses of all referral laboratories are available on the Trusts Intranet and Internet, see:

[PUB_050 Addresses of Referral Laboratories]

Where samples have been sent to a third party laboratory for testing or clinical referral this will be made clear on the final report.
19. Appendix 9 – Laboratory Request Form Images

Examples of some of the request forms used by the laboratory.

19.1. Hospital Request Forms

Biochemistry Form
Page 1 Front

Biochemistry Form
Page 2 Front

Biochemistry Forms
Page 2 Rear
**Histology Request Form**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Details</td>
<td>complete ALL fields</td>
</tr>
<tr>
<td>Surname</td>
<td></td>
</tr>
<tr>
<td>Forename</td>
<td></td>
</tr>
<tr>
<td>Reg. No / NHS No</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>M/F/U</td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Postcode</td>
<td></td>
</tr>
<tr>
<td>Patient Category</td>
<td>NHS / Private Patient</td>
</tr>
<tr>
<td>Frozen / Urgent specimens</td>
<td>Contact number</td>
</tr>
</tbody>
</table>

**Nature and Site of Specimen:**

**Clinical History:**

(History, clinical findings, relevant investigations and previous treatment, previous histology/cytology results, presumptive clinical diagnosis)

**Requesting RMO:**

GMC / GDC No. _______ Name _______ Signature _______

**Laboratory Use Only:**

Trimmed By: _______ / _______ Date Trimmed: _______ / _______ Photographed: Yes / No X-Ray: Yes / No Details: Yes / No Fresh Tissue Taken: Yes / No

**Macroscopic Description:**

**Additional copies can be downloaded from www.uhb.nhs.uk/laboratory-request-forms.htm**
# Muscle Biopsy Request Form

## Muscle Biopsy Service Cellular Pathology

## Queen Elizabeth Hospital Birmingham

### Field Descriptions:

- **Surname**
- **Other Names**
- **Date of Birth**
- **Hospital**
- **Registration No.**
- **Muscle Biopsy Number**

### Clinical Summary

1. **Symptoms and Findings on Examination** (muscle pain, weakness, cramps, hypertrophy, myotonia, fasciculation, sensory symptoms, rash) and distribution (localized, diffuse, distal, proximal).

2. **Temporal Profile** What has been the duration and progression of symptoms?

3. **Additional relevant information** (Toxins or drug exposure (e.g., steroids), alcohol consumption, paraneoplastic conditions, collagen vascular or endocrine disease), test results (nerve conduction and EMG studies, ischaemic exercise test, serum and cat lactate, ESR, TFT and serum CK), ethnic origin.

### Muscle to be Biopsied (State Left or Right)

### Current Clinical Diagnosis? (especially important if a mitochondrial or metabolic disorder is suspected)

### Specimen Collection Details

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Theatre</th>
<th>Surgeon</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
</table>

### Consultant

Ultimately responsible for patient care and Address for reports.

---

Please return to:

Muscle Biopsy Service, Department of Cellular Pathology Level -1, Queen Elizabeth Hospital Birmingham

Mineshaw Way, B15 2WB  [0121 371 5721]  Fax [0121 371 3333]

University Hospital Birmingham NHS Foundation Trust

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**Document Code:** PUB_002  
**Version Number:** 8.6  
**Date of Issue:** 07/08/18  
**Approved By:** H Peat Compliance Manager  
**Page:** 124 of 127
19.2. GP Request Forms

GP Request Form
Microbiology & Virology

GP Request Form
Haematology & Biochemistry

GP Electronic Request
Haematology & Biochemistry

When creating electronic formats can all users create their templates from the previous GP requests shown.
Biochemistry must be created on a separate request to Haematology.
20. APPENDIX 10 User Information

20.1. How should a patient collect and store a faeces (stool) sample

You should:

- collect your stool (faeces) sample in a clean container
- store the container in a fridge in a sealed plastic bag if you can't hand it in straight away

Collecting a stool sample

Your GP or another healthcare professional, such as a nurse, should explain how to collect the stool sample. It should be collected in a clean, dry screw-top container.

Your doctor or a member of staff at the hospital will give you a plastic (specimen) container to use, although you can use any clean container as long as you can seal it.

Try not to collect urine or water from the toilet with the stool sample, but don't worry if you do. If you need to urinate, do this first before collecting the stool sample.

To collect a stool sample:

- label the container with your name, date of birth and the date
- place something in the toilet to catch the stool, such as a potty or an empty plastic food container, or spread clean newspaper or plastic wrap over the rim of the toilet
- make sure the sample doesn't touch the inside of the toilet
- use the spoon or spatula that comes with the container to place the sample in a clean screw-top container and screw the lid shut
- if you've been given a container, aim to fill around a third of it – that's about the size of a walnut if you're using your own container
- put anything you used to collect the sample in a plastic bag, tie it up and put it the bin
- wash your hands thoroughly with soap and warm running water

Follow any other instructions your doctor gives you.

Storing a stool sample

Stool samples should be handed in as soon as possible, as some can't be analysed if they've been refrigerated – your doctor will tell you if this is the case.

If you can't hand the stool sample in immediately, you should store it in a fridge, but for no longer than 24 hours. Place the container in a sealed plastic bag first.

Stool samples must be fresh – if they aren't, the bacteria in them can multiply. This means the levels of bacteria in the stool sample won't be the same as the levels of bacteria in your digestive system. If the levels of bacteria don't match, the test results may not be accurate.

If you can't hand your stool sample in immediately, find out how long it can be kept in the fridge. Your GP or the healthcare professional who requested the test will be able to tell you.

What are stool samples used for?

Your GP or another healthcare professional may ask you for a stool sample to help them diagnose or rule out a particular health condition.

Stools contain bacteria and other substances that are present in the digestive system. By testing the levels of these substances and bacteria in your stools, it's possible to work out what's happening in your digestive system.
20.1.1. How should a patient collect and store a midstream urine (MSU) sample?

N.B. These instructions are not relevant to the collection of 24 hour urine samples. For guidance on the collection of 24 hour urine samples please speak to your requesting clinician.

You should:

- collect your urine sample in a completely clean (sterile) container
- store it in a fridge in a sealed plastic bag if you can’t hand it in straight away

Collecting a urine sample

Your doctor or another healthcare professional should give you a container and explain how you should collect the urine sample.

You can collect a urine sample at any time of day, unless your GP or practice nurse advises you otherwise.

The types of urine sample you might be asked for include a random specimen, first morning specimen or timed collection.

To collect a clean urine sample:

- label the container with your first name, surname, date of birth and the date
- wash your hands
- start to urinate and collect a sample of urine "mid-stream" in a sterile screw-top container
- screw the lid of the container shut
- wipe clean the outside of the pot and wash your hands thoroughly
- make a final check to see that your details are clear and correct on the pot

Follow any other instructions your doctor gives you.

What’s a mid-stream urine sample?

A mid-stream urine sample means you don’t collect the first or last part of urine that comes out. This reduces the risk of the sample being contaminated with bacteria from:

- your hands
- the skin around the urethra, the tube that carries urine out of the body

Storing a urine sample until you hand it in

If you can’t hand your urine sample in within an hour, you should keep it in the fridge at around 4C (39F) for no longer than 24 hours. Put the container of urine in a sealed plastic bag first. The bacteria in the urine sample can multiply if it isn’t kept in a fridge. If this happens, it could affect the test results.