Approved by: Deputy Service Manager - Alan Dearden
Date of Ratification: EQMS Version 6  29/10/14
Originator / Author: Gillian Southwart
Last reviewed by: Gillian Southwart
Review dates can be viewed on EQMS
Always check on EQMS that this is the most up to date version of this document

SPECIAL
HAEMATOLOGY
LABORATORY
&
HAEMATOLOGICAL
MALIGNANCY
DIAGNOSTIC LINKS
Service (HMDL)

USER HANDBOOK
CONTENTS

- Introduction 4
- Location of Laboratory 4
- Contact Details 4
- Hours of Business 5
- Key Staff 5
- Quality & Governance 6
- Transport of Specimens 6
- Request Form 8
- Completion of Request Form 8
- General Acceptance / Rejection Criteria 10
- Measurement of Uncertainty 10

Information for patients and users 10

Haemostasis & Thrombosis Laboratory 11
- Contact Details 11
- Request Forms 12
- Specimen Requirements 12
- Available Tests 13
- Key Factors 14
- Referred samples 15
- Clinical Advice & Guidelines 16

Haemoglobinopathy Laboratory 17
- Contact Details 17
- Hours of Business 18
- Request Forms 18
- Specimen Requirements 18
- Available Tests 19
- Key Factors 19
- Additional Testing 19
- Referred Samples 20
- Clinical Advice & Guidelines 20

Haematological Malignancy Diagnostic Links service 21
- Contact Details 21
- Hours of Business 21
- Available Tests 21
- Sample Labelling Requirements 23
- Timing of Samples 23
- Transportation of Samples 24
- Key Factors 24
- Additional Testing 25
- Request forms 25
- Sample Processing 26
• Urgent Requests 28
• Referred Samples 28
• Clinical Advice & Guidelines 29

**Molecular Diagnostic Laboratory** 29
• Contact Details 29
• Hours of Business 29
• Request Form 30
• Specimen Requirement 30
• Available Tests 30
• Key Factors 31
• Time Limitation for Requesting Additional Testing 31
• Clinical Advice 31

Appendix 1 Special Haematology Request Form 32
Appendix 2 Haemostasis & Thrombosis Request Form 32
Appendix 3 Antenatal Haemoglobinopathy Request Form 33
Appendix 4 HMDL Request Form 34

**Version 5 changes:**

• Document approver changed from Laboratory Manager to Alan Dearden Deputy Service Manager.
• Addition of contact details for Alan Dearden.
• Change of Haemostasis and Thrombosis Senior Biomedical Scientist from Chris Watson to Barbara Hopkins.
• Clinical Lead for Haemostasis and Thrombosis changed from Dr S Pavord to Dr R Gooding.
• Addition of Sharepoint ID numbers to referenced inSite documents
• Removal of PFA-100 test from Haemostasis and Thrombosis available laboratory tests.
• Additional information included in the Haemoglobinopathy introduction.

**Version 6 Changes:**

• Available laboratory areas changed from three to four sections
• Update of contact details for Clinical Leads
• Inclusion of electronic test (Sunquest Ice) requesting for GP surgeries
• Use of Blood Sciences Combined Request form for GP surgeries
• Inclusion of Quality & Governance
• Inclusion of Specimen Transport and removal of the use of the air tube transport system
• Change of wording for request form used for HIT screens
• Review and update of sample labelling
• Out of hours monitoring of LMWH/UFH and new oral anticoagulants changed to Anti Xa assay
• Inclusion of the availability of the S Test during the Out of Hours period
• Change in reference ranges for all Factor Assay; Ristocetin Co factor; von Willebrand Antigen
• Inclusion of the Chromogenic VIII assay
• Reference made to the guidelines for the new oral anticoagulant
• Change in reference range for HbA₂
• Change of referral laboratory for the Red Cell Membrane (EMA) analysis.
• Amendment of transport provision for Haemostasis genetic referral samples

**Introduction**

The Special Haematology & HMDL User Handbook is intended to serve as a quick user guide to the services available from the University Hospital of Leicester (UHL) Special Haematology & HMDL Department. The services provided are available to all three hospitals within the UHL as well as the Leicestershire PCTs. The department comprises of four sections; each area has its own Clinical Lead:

Head of Service          Dr L Barton
Haemostasis & Thrombosis Dr R Gooding
Haemoglobinopathy        Dr C Chapman
Haematological Malignancy Diagnostic Links (HMDL) Service Dr L Barton
Molecular                Dr L Barton

**Location of Department:**

The Special Haematology and HMDL Department is based at the Leicester Royal Infirmary, located on the second floor of the Sandringham building.

**Contact Details:**

Haemostasis Laboratory - 0116 258 6619

Haemoglobinopathy Laboratory - 0116 258 7531

HMDL Laboratory – 0116 258 6518

Molecular Laboratory - 0116 258 7531
Hours of Business:

Routine Laboratory Service
Monday – Friday 8:00 – 20:00

Out of Hours Service
This is a limited service which is only available after discussion with the on call Haematology Consultant. Please contact the Consultant via the UHL switchboard.

Key Staff:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bud Dziombak</td>
<td>Service Manager Special Haematology and HMDL</td>
<td>Ext 6501</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:bud.dziombak@uhl-tr.nhs.uk">bud.dziombak@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Alan Dearden</td>
<td>Deputy Service Manager Special Haematology and HMDL</td>
<td>Ext 7531</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:Alan.Dearden@uhl-tr.nhs.uk">Alan.Dearden@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Keith Chambers</td>
<td>Haemoglobinopathy Senior Biomedical Scientist</td>
<td>Ext 7531</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:keith.chambers@uhl-tr.nhs.uk">keith.chambers@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Barbara Hopkins</td>
<td>Haemostasis Senior Biomedical Scientist</td>
<td>Ext 6619</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:Barbara.hopkins@uhl-tr.nhs.uk">Barbara.hopkins@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Gillian Southwart</td>
<td>Quality</td>
<td>Ext 7531</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:gillian.southwart@uhl-tr.nhs.uk">gillian.southwart@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Ben Metcalfe</td>
<td>HMDL Co-ordinator</td>
<td>Ext 6518</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[<a href="mailto:benjamin.metcalfe@uhl-tr.nhs.uk">benjamin.metcalfe@uhl-tr.nhs.uk</a>]</td>
</tr>
<tr>
<td>Dr L Barton</td>
<td>Consultant Haematologist &amp; Head of Service for Special Haematology and HMDL</td>
<td>Ext 6614</td>
</tr>
<tr>
<td>Dr C Chapman</td>
<td>Consultant Haematologist</td>
<td>Ext 6614</td>
</tr>
<tr>
<td>Dr R Gooding</td>
<td>Consultant Haematologist</td>
<td>Ext 6602</td>
</tr>
</tbody>
</table>
Quality & Governance

The Special Haematology & HMDL Laboratory participates in a full range of National Quality Assurance Schemes. It is accredited by the Clinical Pathology Accreditation (CPA) scheme http://www.cpa-uk.co.uk/ with reference number 0197.

a) Complaints procedure
A complaint may be made via any normal means of communication. To the NHS Trust – normally via the Patient Advice and Liaison Service (PALS), who will direct relevant aspects of any complaint to the laboratory. To the laboratory directly – normally to the Clinical Services Director, the Head of Operations, or to the above through the Governance manager.

b) Confidentiality
The laboratory is committed to maintaining patient confidentiality and practices Caldecott principles. At times this will mean that electronic communications (phone, fax, email) to and from the laboratory may be constrained by protocols intended to preserve patient confidentiality. These controls will be in accordance with professional and regulatory guidance.

Transport of Specimens to the Laboratory

NOTE: for transport of specimens for the following HMDL and Haemostasis & Thrombosis please refer to the relevant sections within this handbook

General information

Specimens are delivered periodically throughout the day to Specimen Reception on Level 2 in the Sandringham building. Staff from the laboratory collect samples regularly throughout the day from Specimen Reception.

The transport of samples must be carried out in a way that minimises the risk of infection to those persons who may come in contact with them e.g. clinical distributors, Pathology drivers, taxi drivers, laboratory staff.

Please ensure that the container is appropriate for purpose that the lid is properly closed and sealed and it is not contaminated on the outside.

Specimens must be placed in a grip-seal bag. This bag must then be sealed. In order to avoid accidental contamination please do not place request forms in the same bag as the specimen. Refer to appropriate section for specific transport requirements.

Portering Service

Samples from the ward, theatre, clinics requiring processing by the Haemoglobinopathy Laboratory and the Molecular Diagnostic Service may be
transported using the routine portering service. Collection is by the Clinical Distributors at regular intervals during the day.

The collection of urgent / out of hour’s samples must be organised at ward / theatre level by contacting the porter on duty.

- All specimens should be carried in individual sealed leak proof bags.
- Under no circumstances should anyone transport specimen containers in their hands or pockets.
- All specimens should be transported on / in an appropriate trolley and tray or receptacle that will contain leaks and spills. It is recommended that all trolleys used for conveyance of specimens have available spill kits, including an approved disinfectant and absorbent mopping up material
- Specimens should be transported in such a way to maintain patient confidentiality.
- All specimens to be taken directly from source to the laboratory should be delivered in a timely manner.

**Pathology Transport Service**

All Biological specimens transported to and from the Pathology Laboratories are considered to be Cat B status or below

All diagnostic specimens must be enclosed in the appropriately labelled bags and transport boxes - these must not be opened unnecessarily by the driver. The laboratory follows UN 3373 (P650 packaging instruction) as European Agreement Carriage of Dangerous Goods by Road (ADR) as regulated by Carriage of Dangerous Goods Regulations 2007.

**Taxi Service**

Specimens sent to the laboratory must be packaged correctly according to guidelines for sending of samples through the normal post. Alternatively, special transport boxes may be used.

- Transport boxes must by made of impervious material e.g. plastic which can be cleaned and disinfected as required and have a secure lid,
- The box must be able to contain liquid in the event of a leaking specimen.

**Transport of referral Samples**

Samples sent by the laboratory must be packaged correctly according to guidelines for sending of samples through the normal post. Alternatively
special transport boxes may be required if the samples needs to be transported in a controlled environment. Please contact the laboratory for further advice.

Request Form:

This department uses five different request forms:

Special Haematology request form – available in all outpatient departments and GP surgeries for requesting any Haemostasis/Thrombotic test, non-antenatal Haemoglobinopathy screening or Molecular diagnostic test - Appendix 1.

Haemostasis and Thrombosis request form – for use by the Haemostasis & Thrombosis Unit and the Haematology Obstetrics service- Appendix 2.

Combined Antenatal Haemoglobinopathy Screening and Family Origin Questionnaire request form – this form MUST be used when requesting haemoglobinopathy screening for antenatal patients- Appendix 3.

HMDL Specimen request form – for investigation by the HMDL laboratory – Appendix 4

Electronically produced request form – ward based requests MUST be electronically generated apart from HMDL requests and Antenatal Haemoglobinopathy screening which remain paper based. GP surgeries that use Sunquest Ice electronic requesting facility should use this method for test requesting.

NOTE: If GP surgeries do not have electronic test requesting and the Special Haematology request form is not available it is acceptable to use the Blood Science Combined request form, clearly stating the test required

Completion of Request Form:

Ensure that all areas of the request form are fully completed. Incomplete request forms can lead to delays in processing the request.

The request form must contain the following information:

- Surname and forename – initials not accepted.
- Date of Birth.
- Gender of patient
- Hospital number and/or NHS number.
- Patient location.
- Consultant/GP or person legally authorized to request examination.
Special Haematology and HMDL

- Contact phone number or bleep number.
- Type of primary sample and, where relevant, the anatomic site of origin
- Date and, where relevant, time of primary specimen collection.
- Test requested.
- Relevant clinical information about the patient and the request.
- Any relevant drug therapy must be documented on the request form.
- When requesting Haemostasis/Thrombotic tests.
- Signature of Doctor or Midwife.

Specimen Labelling

Ensure the specimens are correctly labelled. Inadequately labelled samples can lead to delays in processing the request.

The specimen must contain the following information:
- Surname and forename – initials not accepted.
- Date of Birth
- Samples from UHL patients must contain the unique hospital number
- Samples from GP /community patients should where known contain the NHS number
- Date and time of sample
- Location of patient.

If request forms and/or specimens are received unlabelled or inadequately labelled the laboratory reserves the right to discard the specimen for medico-legal reasons.

High Risk Specimens

Samples from High Risk (danger of infection) patients should be appropriately marked in line with Trust Policy.

The high risk box MUST be ticked or a yellow “high risk” sticker attached to all request forms for patients known or suspected of having a blood-borne infection (i.e. HIV, hepatitis B, hepatitis C, salmonella septicaemia, etc). All such samples MUST be contained in a biohazard bag.

Associated Pathology Directorate procedure documents available on INsite documents (Sharepoint):

- Notification of Hazard Group 4 Pathogen Specimens within Pathology :- Sharepoint ID 2324513063
- Notification to Wards of Incorrectly Identified Hazardous Samples :- Sharepoint ID 6206612832
General Acceptance / Rejection of Samples Criteria

Acceptance criteria
- Request form correctly completed – refer to Completion of Request Form
- Samples labelled correctly – refer to sample labelling
- Receipt of correct specimen container
- Adequate sample volume

Rejection criteria
- Incorrect sample
- Unsuitable anticoagulant
- Insufficient sample volume
- Underfilled or overfilled container rendering the anticoagulant / blood ratio unsuitable (Haemostasis & Thrombosis samples)
- Leaking sample
- Sample too old
- Contaminated sample
- Inappropriately clotted
- Haemolysis
- Lipaemia
- Jaundice
- Inappropriate timing
- Inappropriate test requesting
- Insufficient or incorrect labelling of sample or request form
- Use of an inappropriate request form

For specific test related acceptance / rejection criteria please contact the relevant laboratory.

Measurement of Uncertainty.

Within any laboratory analytical process or procedure there will always be a degree of variability. This will vary with specimen type and test. Measurement Uncertainty is available on request.

Information for Patients and Users

The following information for patients and users is made available via the relevant Clinicians, Nurse Specialist and Specialist Counsellors. Such information includes:
- Explanation of the clinical procedure to be performed enabling informed consent
- Interpretation of results and the importance to patient and family members
Haemostasis and Thrombosis Laboratory

The unit at Leicester Royal Infirmary is comprised of the Special Haematology and HMDL Laboratory and The Haemostasis and Thrombosis Unit which includes a Comprehensive Care Centre for Haemophilia. The Clinical and Laboratory staff can provide a full haemostatic/thrombotic diagnostic service including follow up, counselling, registration and family studies as appropriate.

The Haemostasis Laboratory provides a comprehensive service for the investigation of both thrombotic and bleeding disorders. This includes:

1. Specialist assays to investigate abnormal routine screening test results.
2. Investigation of patients with bleeding disorders within UHL using specialist techniques to diagnose, classify and monitor Haemophilia, von Willebrand’s Disease, platelet disorders and other coagulation factor deficiencies.
3. Investigation of patients with thrombotic disorders within UHL using specialist techniques to diagnose inherited and acquired thrombotic defects including Antithrombin, Protein C, Protein S deficiency and Lupus anticoagulant antibodies.
4. Monitoring of Heparin therapy using Anti-Xa assays and other newer anticoagulants such as the Direct Thrombin Inhibitors.
5. An out of hour’s service for urgent tests.
6. Specialist support and advice to other laboratories and clinical staff throughout UHL.

Contact Details:

Haemostasis Laboratory, Special Haematology, Room 215/216, Level 2 Sandringham Building, Leicester Royal Infirmary.
Tel No. 0116 258 6619

Opening Hours:

Monday to Friday 08.00 to20:00.

For advice or testing outside these hours please contact the On Call Haematology Registrar who will advice on suitability of tests. Out of hours testing will only be performed after authorisation from Haematology medical staff.

Available tests out of hours:

Factor Assays
Anti Xa assays for monitoring therapy using Low molecular weight heparin, Unfractionated Heparin and other newer anticoagulants
Inhibitor Assay
Ristocetin co factor assay
Any other tests must be discussed with a Haemostasis and Thrombotic consultant

Request Forms:

- The Haemostasis Centre and related clinics use Haemostasis and Thrombosis Request forms - Appendix 2.
- All general clinics use the green Special Haematology request forms - Appendix 1.
- All ward based requests should be electronically requested if the appropriate test code is available. Please contact the relevant laboratory if advice is required.

Sample Requirements:

- For any sample queries or advice please contact the Haemostasis Laboratory 0116 2586619.
- Specific sample requirements are listed in the following table.
- For ‘Timing of Samples’ please refer to the Haemostasis and Thrombosis guidelines located on Insite.
- Please contact laboratory for advice on sample requirements for paediatric requests. Paediatric 1.2ml sample tubes are available. Babies may have to be bled on successive days to obtain sufficient sample for full investigation.
- Samples must be taken during normal working hours and before 16.30 as the plasma preparation is lengthy. There is rarely justification for testing out of hours. If exceptional circumstances arise out of hours please discuss with Haematology Registrar and make arrangements with laboratory on-call staff otherwise samples may be lost.
- Sample collection must be taken into green citrated venous samples, taken with a minimum of stasis, without vacuum, using a 21 gauge needle and transported immediately by hand, to Special Haematology laboratory, Level 2, Sandringham Building to arrive within two hours of phlebotomy. **Do not send samples through the air tube or via the routine clinical distribution service.**
- Please state date and time of sample collection on the request form and sample.
- The request form must be completed with all patients’, ward/clinic details and any relevant clinical information.
- The sample must be labelled with full name – initial not accepted, DOB, gender of patient, hospital number, date and time of sample.
- All samples must be received within a sealed specimen bag. High Risk samples MUST be labelled appropriately.
- Underfilled, overfilled, haemolysed, old or clotted samples are unsuitable for testing and will be discarded, as will unlabelled samples.
- Please send green Special Haematology request form with clinical details and history fully recorded and name of medic with whom discussed as this
Special Haematology and HMDL

will help us to ensure relevant tests are performed and correctly interpreted. At the LGH and GGH sites request forms are available from the respective laboratories (LGH – Ext. 4566, GGH – Ext. 3575).

- At LGH and GGH, samples must be transported to the respective Haematology laboratory where the plasma will be stored for subsequent transport to LRI.

Available tests:

<table>
<thead>
<tr>
<th>TEST</th>
<th>SAMPLE REQUIREMENTS</th>
<th>TURNAROUND TIMES$</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Clotting Screen¹</strong></td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Prothrombin Time</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>INR</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Factor Sensitive APTT</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>Batch specific- refer to report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Lupus sensitive APTT</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>Batch specific- refer to report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>2.0 - 4.0g/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Thrombin Time</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>15 – 18 secs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td><strong>Thrombophilia Screen²</strong></td>
<td>Four 4.3ml citrate samples</td>
<td>2 weeks</td>
<td></td>
</tr>
<tr>
<td>Lupus Screen</td>
<td>Two 4.3ml citrate samples</td>
<td>2 weeks</td>
<td>Batch specific- refer to report</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antithrombin</td>
<td>Two 4.3ml citrate samples</td>
<td>2 weeks</td>
<td>90 - 120%</td>
</tr>
<tr>
<td>Protein C</td>
<td>Two 4.3ml citrate samples</td>
<td>2 weeks</td>
<td>69 - 128%</td>
</tr>
<tr>
<td>Protein S</td>
<td>Two 4.3ml citrate samples</td>
<td>2 weeks</td>
<td>53 - 128% (F) 71 - 165% (M)</td>
</tr>
<tr>
<td><strong>von Willebrand Screen³</strong></td>
<td>Four 4.3ml citrate samples</td>
<td>4 weeks</td>
<td></td>
</tr>
<tr>
<td>Ristocetin Co-factor</td>
<td>Two 4.3ml citrate samples</td>
<td>4 weeks</td>
<td>44.6- 138.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2hrs on request)</td>
<td></td>
</tr>
<tr>
<td>Collagen Binding Assay</td>
<td>Two 4.3ml citrate samples</td>
<td>4 weeks</td>
<td>50 - 200%</td>
</tr>
<tr>
<td>von Willebrand Antigen</td>
<td>Two 4.3ml citrate samples</td>
<td>4 weeks</td>
<td>51.9 – 154.3%</td>
</tr>
<tr>
<td>Ristocetin Induced Plt Agg</td>
<td>Two 4.3ml citrate samples</td>
<td>4 weeks</td>
<td>1.0 - 1.25mg/ml</td>
</tr>
<tr>
<td>Platelet Function Studies</td>
<td>Sample bottles only available from Haemostasis Clinic</td>
<td>4 weeks</td>
<td>Please Discuss with Laboratory</td>
</tr>
<tr>
<td>Factor VIII</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>59.6 – 177.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
<tr>
<td>Chromogenic VIII assay</td>
<td>One 4.3ml citrate sample</td>
<td>2 weeks</td>
<td>41 – 179%</td>
</tr>
<tr>
<td>Factor IX</td>
<td>One 4.3ml citrate sample</td>
<td>Same day</td>
<td>72 - 154%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1hr on request)</td>
<td></td>
</tr>
</tbody>
</table>
### Special Haematology and HMDL

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Sample Type</th>
<th>Turnaround Time</th>
<th>% Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor XI</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>74-152%</td>
</tr>
<tr>
<td>Factor XII</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>35-147%</td>
</tr>
<tr>
<td>Factor II</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>78.7 – 115.5%</td>
</tr>
<tr>
<td>Factor V</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>53.8 – 127.7%</td>
</tr>
<tr>
<td>Factor VII</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>47.4 – 143.4%</td>
</tr>
<tr>
<td>Factor X</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (1hr on request)</td>
<td>73.1-132.7%</td>
</tr>
<tr>
<td>Factor XIII</td>
<td>One 4.3ml citrate sample</td>
<td>2 weeks</td>
<td>Please Discuss with Laboratory</td>
</tr>
<tr>
<td>Inhibitor Screen</td>
<td>One 4.3ml citrate sample</td>
<td>2 weeks (4hrs on request)</td>
<td>Please Discuss with Laboratory</td>
</tr>
<tr>
<td>Inhibitor Assay</td>
<td>Two 4.3ml citrate samples</td>
<td>2 weeks</td>
<td>Please Discuss with Laboratory</td>
</tr>
<tr>
<td>Anti Xa assay for Heparins or oral direct Xa inhibitors</td>
<td>One 4.3ml citrate sample</td>
<td>Same day (2hrs on request)</td>
<td>See UHL Guidelines for Heparin. See guidelines for Newer Oral Anticoagulant</td>
</tr>
<tr>
<td>Heparin Induced Thrombocytopenia (HIT)</td>
<td>One 4.3ml gel sample</td>
<td>Same day</td>
<td>See UHL Guidelines for Heparin Induced Thrombocytopenia (HIT)</td>
</tr>
</tbody>
</table>

$^*Turn round times is defined as the time taken for 95% of samples to be tested and reported*

1. **Special Clotting Screen** - Includes Prothrombin Time, Factor Sensitive APTT, Lupus sensitive APTT, Fibrinogen, Thombin Time
2. **Thrombophilia Screen** - Includes Lupus Screen, Antithrombin, Protein C, Protein S
3. **von Willebrand Screen** - Includes Ristocetin Co-factor, Collagen Binding Assay, von Willebrand Antigen

Haemostasis & Thrombosis reference ranges may vary due to changes in reagent batches. Please check iLab for the most up to date information.

**Key factors known to affect the performance of the test or interpretation of the results:**

Refer to Haemostasis and Thrombosis Guidelines; these documents are available on the UHL Document Management System and can be located using the search facility on Insite.

**For additional testing please contact the Haemostasis Laboratory for availability of samples.**
Referred samples

- Contact Haemostasis Laboratory for specific instruction regarding arrangement of referral samples.

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen requirements</th>
<th>Transport method</th>
<th>Referral Laboratory</th>
<th>*Turnaround time</th>
</tr>
</thead>
<tbody>
<tr>
<td>von Willebrand Multimers</td>
<td>1ml citrated plasma</td>
<td>Courier (Roadrunner)</td>
<td>Haemophilia Laboratory, Royal Free Hospital, Hampstead, London</td>
<td>1 month</td>
</tr>
<tr>
<td>Paediatric thrombophilia tests</td>
<td>Citrated plasma (frozen)</td>
<td>Courier (Roadrunner)</td>
<td>Haemostasis Department, Great Ormond Street Hospital, London</td>
<td>1 month</td>
</tr>
<tr>
<td>Alpha 2 Antiplasmin</td>
<td>1 ml citrated plasma (frozen)</td>
<td>Courier (Roadrunner)</td>
<td>Haemostasis Research Unit, University College, London, London</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Plasminogen</td>
<td>1 ml citrated plasma (frozen)</td>
<td>Courier (Roadrunner)</td>
<td>Haemostasis Research Unit, University College, London, London</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Factor XIII assay</td>
<td>1ml citrated plasma (frozen)</td>
<td>Courier (Roadrunner)</td>
<td>Haemostasis Research Unit, University College, London, London</td>
<td>3 weeks</td>
</tr>
<tr>
<td>ADAMTS 13</td>
<td>2ml citrated plasma + 1 ml serum(frozen)</td>
<td>Courier (Roadrunner)</td>
<td>Coagulation Department, Royal Hallamshire Hospital, Sheffield</td>
<td>7-10 days</td>
</tr>
<tr>
<td>VIII Binding assay</td>
<td>Frozen citrated plasma</td>
<td>Courier (Roadrunner)</td>
<td>Coagulation Department, Royal Hallamshire Hospital, Sheffield</td>
<td>6 weeks</td>
</tr>
<tr>
<td>2 stage FVIII assay</td>
<td>Frozen citrated plasma</td>
<td>Courier (Roadrunner)</td>
<td>Vitamin K Diagnostic Laboratory, St Thomas' Hospital, Sheffield</td>
<td>1 week - Urgent on request</td>
</tr>
<tr>
<td>Warfarin assay</td>
<td>4-5ml serum or EDTA plasma. Spun and separated</td>
<td>First Class Post</td>
<td>Hospital, London Vitamin K Diagnostic Laboratory, St Thomas' Hospital, Sheffield</td>
<td>10 days</td>
</tr>
<tr>
<td>Vitamin K assay</td>
<td>4-5ml serum or EDTA plasma. Spun and separated</td>
<td>First Class Post</td>
<td>Hospital, London Vitamin K Diagnostic Laboratory, St Thomas' Hospital, Sheffield</td>
<td>10 days</td>
</tr>
<tr>
<td>Test</td>
<td>Sample Requirement</td>
<td>Turnaround Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PIVKA II</td>
<td>1-2 ml serum. Spun and separated.</td>
<td>First Class Post 10 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilia A Genetics</td>
<td>5ml EDTA</td>
<td>Next Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilia B Genetics</td>
<td>5ml EDTA</td>
<td>Next Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilia A/B Carrier Genetics</td>
<td>5ml EDTA + sample from Index case</td>
<td>Next Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor XI Genetics</td>
<td>5ml EDTA</td>
<td>LPS Nottingham transport</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor VII Genetics</td>
<td>5ml EDTA</td>
<td>LPS Nottingham transport</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor X Genetics</td>
<td>5ml EDTA</td>
<td>LPS Nottingham transport</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen Genetics</td>
<td>5ml EDTA</td>
<td>LPS Nottingham transport</td>
<td></td>
<td></td>
</tr>
<tr>
<td>von Willebrand Genetics</td>
<td>5ml EDTA</td>
<td>LPS Nottingham transport</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Turn around time is that stated for the completion of the assay from time of receipt of sample at the referral laboratory. Extra time must be allowed for delivery of sample and return of report.

**Clinical Advice and Interpretation:**
- For clinical advice please contact Haemostasis Clinic on Ext.6500 or contact on call Haematology Registrar.

**Guidelines:**
Haemostasis and Thrombosis Guideline.
Haemoglobinopathy Laboratory Service

The Haemoglobinopathy Service at UHL comprises Specialist clinical services for patients with major Haemoglobin Disorders, the laboratory diagnostic services and a community based counselling, screening and support service. The clinical and laboratory staff can provide a full haemoglobinopathy diagnostic service, including counselling, registration, family studies and support for the neonatal and antenatal screening programmes.

This laboratory will screen blood samples to identify patients who have or are carriers of inherited disorders of red cells. Most of the work is to identify abnormalities of haemoglobin production (known as haemoglobinopathies or haemoglobin disorders). Tests for enzyme disorders (e.g. G6PD deficiency) and some specialised tests of red cell function are also available.

Haemoglobinopathies

These conditions consist of haemoglobin variants (structural abnormalities of haemoglobin) such as sickle cell disorders, or thalassaemias (reduced globin chain synthesis)

Universal antenatal screening programme

All pregnant women must be offered screening for haemoglobinopathy at the first point of contact with the GP or midwife, and samples will be processed in accordance with NHS Sickle Cell & Thalassaemia Screening Programme and British Committee for Standards in Haematology guidelines.

The Newborn blood spot test

This screening programme is coordinated regionally, but abnormal results will also be forwarded to the community based Sickle Cell and Thalassaemia Service for action.

Opportunistic testing

Extended family screening, preoperative screening and investigation of microcytosis, screening of new patients with specific family origin are all indications for opportunistic testing for haemoglobin disorders.

Results of haemoglobinopathy screening will be reported, with interpretation in the light of red cell indices. Where carriers of major haemoglobinopathies are detected, patient details will automatically be forwarded to the community based Sickle Cell and Thalassaemia Centre, and counselling and information on the condition will be offered.

Contact Details:
Haemoglobinopathy Laboratory, Special Haematology, Room 215/216, Level 2 Sandringham Building, Leicester Royal Infirmary
0116 258 7531
Opening Hours:  
Monday to Friday 08.00 to 20:00  
For advice or testing outside these hours please contact On Call Haematology Registrar who will advise on suitability of tests. Out of hours testing will only be performed after authorisation from Haematology medical staff.

Available tests out of hours.  
- Sickle cell test  
- Haemoglobin S %

Request Forms:  
- Antenatal clinics and the community midwifery service must use the new combined Antenatal Haemoglobinopathy Screening Family Origin Questionnaire request form – appendix 3. or where available the electronic version of this request form  
- All ward requests must be made via iCM  
- Out Patient departments and GPs should make the request using the Special Haematology request form – appendix 1

Specimen Requirements:  
- For any sample queries or advice please contact Haemoglobinopathy Laboratory.  
- Specific sample requirements are listed in the following table.  
- Samples may be transported to the laboratory from the wards/clinic via the Clinical Distribution Service, or the Pathology Transport Service. Urgent samples must be brought directly to the Haemoglobinopathy Laboratory.  
- Inform the laboratory when sending Urgent requests.  
- Samples must be labelled with full name – initials not accepted DOB hospital/NHS number and the date taken.  
- The request form must be completed with all patients’ identification, ward/clinic/GP details, gender of patient and any relevant clinical information.  
- Patients that have recently received a blood transfusion should be tested at least 4 months post transfusion.  
- All samples must be received within a sealed specimen bag.  
- High Risk samples MUST be labelled appropriately.
Available test

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen requirements</th>
<th>$^*$Turnaround time</th>
<th>Reference range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobinopathy screen</td>
<td>One 2.7ml EDTA (purple top) send a separate 4.9ml EDTA and request form to Haematology for a FBC</td>
<td>3 working days</td>
<td>Hb A₂ 2.2 - 3.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hb F 0 - 1.0%</td>
</tr>
<tr>
<td>Sickle Cell screen</td>
<td>One 2.7ml EDTA (purple top) send a separate 4.9ml EDTA and request form to Haematology for a FBC</td>
<td>3 working days or 1 hour on Urgent request</td>
<td></td>
</tr>
<tr>
<td>G6PD screen</td>
<td>One 2.7ml EDTA (purple top)</td>
<td>1 working day</td>
<td></td>
</tr>
<tr>
<td>G6PD assay</td>
<td>One 2.7ml EDTA (purple top)</td>
<td>2 working day</td>
<td>5.0-10.4U/gHb</td>
</tr>
<tr>
<td>Iso-electric focusing</td>
<td>Performed as confirmatory test for abnormal haemoglobins detected in the initial haemoglobinopathy screen</td>
<td>7 working days</td>
<td></td>
</tr>
</tbody>
</table>

$^*$Turn round times is defined as the time taken for 95% of samples to be tested and reported.

**Key factors:**
Results are invalid if the sample has been taken within four months of a previous blood transfusion.
- Reference range values for HbA₂ and HbF will not be reached until 1 year of age (and in some individuals it may take longer).
- Iron deficiency can affect the red cell indices and in severe iron deficiency it may reduce the HbA₂%.
- Anti retroviral drug therapy can affect both red cell indices and HbA₂. Please request a haemoglobinopathy screen before commencing retroviral therapy.
- The haemoglobinopathy screen should be performed as soon as possible after the sample has been taken, ideally within 24 hours.

**Time limit for requesting additional examination:**
Haemoglobinopathy screen – 5 days from date sample is taken
G6PD screen/assay – 5 days from date sample is taken.
The G6PD assay should by performed as soon as possible as the method used measures the G6PD activity.
*These time limits are valid only if the sample has been stored at 4°C in the interim.*
Referred samples:
- Contact the Haemoglobinopathy laboratory for specific instruction regarding arrangement of referral samples.

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen requirements</th>
<th>Transport method</th>
<th>Referral Laboratory</th>
<th>*$Turnaround time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Cell Membrane Defects (EMA)</td>
<td>4.9ml EDTA</td>
<td>LPS Nottingham transport</td>
<td>Nottingham University Hospital Queens Medical Centre</td>
<td>1-24 days depending on complexity of request</td>
</tr>
<tr>
<td>Pyruvate Kinase</td>
<td>Minimum 1ml EDTA, a copy of the FBC and Retic count is required</td>
<td>Next day delivery</td>
<td>Red Cell Laboratory, Kings College Hospital</td>
<td>10 working days</td>
</tr>
<tr>
<td>DNA analysis for Thalassaemia &amp; abnormal haemoglobins</td>
<td>Two 2.7 EDTA</td>
<td>Courier (Roadrunner)</td>
<td>National Haemoglobinopathy Reference Service John Radcliffe Hospital, Oxford</td>
<td>3-40 days depending on urgency and complexity of request</td>
</tr>
<tr>
<td>Oxygen Dissociation Curve</td>
<td>4.9ml EDTA, normal control is required.</td>
<td>Courier (Roadrunner)</td>
<td>Haematology Department, City Hospital, Birmingham</td>
<td>2 days</td>
</tr>
</tbody>
</table>

*Turn around time is that stated for the completion of the assay from time of receipt of sample at the referral laboratory. Extra time must be allowed for delivery of sample and return of report.

$Turn round times is defined as the time taken for 95% of samples to be tested and reported.

Clinical advice:
For clinical advice contact the on call Haematology Specialist Registrar.
A community based counselling service is available from the Sickle Cell and Thalassaemia Centre 0116 2943057.

Guidelines:
NHS Sickle Cell and Thalassaemia Screening Programme
www.sct.screening.nhs.uk
Haematological Malignancy Diagnostic Links Laboratory (HMDL)

The Department co-ordinates the testing of bone marrow, CSF and other liquid samples (e.g. pleural fluid) when a haematological malignancy is suspected. A number of tests are performed within the central laboratory with additional tests requested from other allied laboratories. These are mainly within UHL but some samples are sent to specialist laboratories elsewhere for testing. *All samples must be sent to the central laboratory for initial screening.*

**Useful Contact Numbers**
HMDL Laboratory 0116 258 6518

Email the team
UHO-tr.LNRHMDL1@nhs.net

This email is for GENERAL ENQUIRES ONLY.

For enquiries about specific patients please discuss with the On Call Haematology Registrar

**Hours of Business**
Routine service
- Monday-Friday 08:00-17:00

Out of Hours
- Please contact the on-call Haematology SpR via switchboard

**Location of HMDL Central Laboratory**
Level 2 Sandringham Building, accessed through the Morphology Laboratory

**Available tests**

**Bone marrow**
Bone marrow examinations can only be ordered by Haematology Registrars, Consultants and other specially trained staff. Please contact the On Call Haematology Registrar if you feel a patient may need a bone marrow.

Bone marrows are performed on the Haematology Day ward (level 2, Osborne Building).
CSF/Pleural aspirates
If CSF/Pleural aspirate etc requires investigation, please discuss with the HMDL Laboratory or Haematology Registrar prior to taking the sample. This will ensure the correct samples are taken into the correct medium and that the clinical staff is aware of urgent cases. The samples must be hand delivered to the HMDL laboratory urgently. In most cases these specimens are processed and reported in Histopathology however if the patient is known to have a Haematological Malignancy or there is a high suspicion of such the please discuss with the Haematology Registrar

Peripheral Blood
Can be used for molecular analysis or in patients with CLL, for Cytogenetics/FISH.

The following tests can be performed on specimens:
- Bone marrow aspirates /CSF/pleural fluid etc samples are stained and examined morphologically
- Morphological screening is used to assess which additional tests are required
- If a diagnosis is possible from the aspirate alone the sample will be reported
- If additional tests are required these are organised and a final integrated report is generated including the results of all tests performed on the sample

Tests sent to allied laboratories within UHL
- Flow cytometry - processed in the Department of Immunology
- Trephine biopsy - processed and stained in the Department of Histopathology prior to reporting in HMDL central Laboratory
- Cytogenetics/FISH - processed in the Department of Cytogenetics
- Immunohistochemistry - processed and reported in the Department of Histopathology
- Molecular analysis-for B and T cell gene rearrangement studies are performed in Histopathology.

Sample Requirements, Sample Labelling, Timing of Samples and Transportation of Samples to Laboratory:

Bone marrow samples
Morphology/Immunophenotype
Blood Film (essential for urgent specimens)
BMA slides x 4
Or 5ml EDTA
Trephine 10% formalin
(wheré required)

Cytogenetics/FISH
Bone marrow 5ml heparinised tissue culture medium  
Peripheral blood 10ml Li Heparin  

**Molecular:**  
Bone marrow 2-5ml EDTA  
Peripheral blood 5-10ml EDTA  

**Tissue samples**  
**LN or tissue**  
Fresh (UHL)  
*(send urgently and inform lab immediately)*  
Fixed 10% formalin  

**Other**  
CSF  
1. For morphology/molecular send sample in plain universal  
2. For flow cytometry send samples in Transfix medium  

PNH 4.9ml EDTA  

**Sample labelling requirements**  
The Department reserve the right to reject any samples that are incorrectly labelled;  

- NEVER pre-label sample bottles.  
- NEVER use addressograph labels on the sample tubes  
- Ensure the patient is positively identified, especially with the unconscious patient.  
- Ensure that 3 points of identification are placed on the sample bottles / glass slides:  
  1. Full Name including surname and forename (middle names should not be used as this may lead to duplication of records).  
  2. Date of Birth.  
  3. Hospital/NHS Number.  
- Date and Time of marrow collection must be recorded on the request form.  
- Tubes must be in date and filled to correct volume.  

**Timing of samples**  
**Bone marrow**  
In order that samples can be screened and processed appropriately, bone marrow samples should arrive in the laboratory before 2.30 pm  

In urgent situations if you feel a bone marrow is required but the samples will arrive after 2.30 pm this MUST be discussed with the HMDL laboratory as...
soon as possible. The allied laboratories can then be warned about the arrival of late samples.

Non-urgent cases arriving in the HMDL laboratory after this time may be processed the following day.

**CSF samples**

CSF samples must be transferred to the laboratory as soon as possible and except in urgent cases, should arrive in the laboratory by 3.30pm.

Cytospins must be performed as soon as possible to preserve the integrity of cells in the sample. Please discuss with the HMDL laboratory or the Haematology On Call Registrar if you feel a sample needs to be taken outside of the normal Haematology Lumbar Puncture lists (Paed: Tue and Thur am; Adult: Thur am). This will include all samples taken for non-Haematology based patients. This is critical as it may require arranging for specialist laboratory staff to process the samples and examine the film out of hours.

**Transportation of Samples to the Laboratory**

For all samples except peripheral blood for flow cytometry then:

**UHL**

Please ensure all samples are delivered directly to the Special Haematology/HMDL Laboratory and not left in Pathology Specimen Reception.

**LGH/GGH**

Please liaise with the Haematology laboratory on site to transfer the samples to Special Haematology/HMDL.

**Other Hospitals**

Samples are transferred using the daily pick-up service or courier as per local agreements.

**Key factors known to affect the performance of the test or interpretation of the results:**

- Wherever possible please ensure that particles can be seen on aspirate slides, if not please attempt another sample otherwise the sample may be inadequate for analysis.
- It is suggested that trephine samples should be a minimum of 16mm in size, certainly if less than 10mm please attempt another sample as an inadequate sample may result in the patient having to undergo another procedure.
- CSF samples must be processed immediately and so should be transported directly to the laboratory without delay as cell viability
declines rapidly with time. Out of hours cases should be discussed with the on call Haematology Registrar prior to the sample being taken

- Similarly CSF samples for flow cytometry should be taken into Transfix medium
- RNA rapidly degrades and so for molecular studies involving RNA, samples must be sent to testing laboratories as soon as possible and taking samples on a Thursday/Friday should be avoided where possible

Time limit for requesting addition examination
- Bone marrow aspirate/trephine: no limit
- Cytospin: samples are kept for 48hours but cell viability is such that meaningful results may only be obtained if additional tests are requested within 24hours; CSF samples taken directly into transfix medium have a viability of 72 hours
- Cytogenetic/FISH: 48 hours for samples received in Heparinised medium

Request Forms
A specific HMDL request form is available – see Appendix 4
A single HMDL request form is required for bone marrow samples/CSF/other fluid samples (even if sample for flow cytometry and histopathology are taken) except in cases where cytogenetics is required under which circumstances the cytogenetics request form should ALSO be completed.

Completion of Request Forms:
It is important that request forms are fully completed; we wouldn’t ask for information if we didn’t need it. Incomplete forms can lead to delays or errors in interpretation of results.

Ensure that the sample forms are fully completed and that all information is provided.

The form must contain the following information:

- Surname and first name.
- Date of birth.
- Gender.
- Hospital number and NHS number.
- Patient location and current Consultant.
- Details of requesting doctor.
- Indication for sample (provide sufficient information to allow appropriate evaluation in ALL/lymphoma please indicate if T or B cell of origin).
- Recent FBC.
- Whether the patient is anticoagulated.
- Samples and tests required.
- If the patient has had previous samples analysed through HMDL and details of transplantation where appropriate.
- Signature of the doctor.
• Date and time of specimen collection.

**Patient Identity and Demographic Information is Vital**

Clinical details are important to assist in defining the correct testing strategy, the interpretation of results and to produce a useful and meaningful report. Please include the reason for requesting the investigation.

The name of requesting clinician (with bleep number) and the name of the Consultant/GP (if different from above) must be included on the request form. The person requesting the investigation must sign the request form.

Please include the address for the report i.e. ward, consultant.

If request forms and/or specimen containers are received unlabelled or inadequately labelled, the laboratory reserves the right to discard the specimen for medico-legal reasons.

**Sample Processing Times and Urgent Requests**

**Time Taken to Report Samples**

Anticipated turn round times are given below.

For urgent requests it is important to discuss the case with the HMDL Laboratory to ensure the samples are dealt with as efficiently as possible.

**INTEGRATED REPORT:**

*For cases requiring aspirate/trephine report and flow cytometry only*

Cases in which immunohistochemistry/ genetic/molecular results are needed to confirm the diagnosis will have longer turn round times dependent on the extent of testing required. Individual turn round times for each test modality are stated. However provisional reports may be issued in these cases.

<table>
<thead>
<tr>
<th>Test</th>
<th>*Target (Working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent cases e.g. new acute leukaemia; burkitt lymphoma</td>
<td>Initial/preliminary report within 24 hours (preliminary verbal report/electronic notification will be given the same day if received by 1pm)</td>
</tr>
<tr>
<td>MDS, MPD</td>
<td>95% within 10 days</td>
</tr>
<tr>
<td>CML (may not include trephine)</td>
<td>95% within 3 days</td>
</tr>
<tr>
<td>CLL</td>
<td>95% within 10 days</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>95% within 10 days</td>
</tr>
<tr>
<td>Myeloma/MGUS</td>
<td>Initial report within 24 hours for new myeloma (verbal report/electronic notification may be given the same day in new myeloma &gt;15% plasma cells); All other cases: 95% within 10 days</td>
</tr>
</tbody>
</table>
IMMUNOHISTOCHEMISTRY
95% in 3 working days from the point of request

FISH

<table>
<thead>
<tr>
<th>Urgent FISH</th>
<th>Majority of cases will be available within 24 hours but overall 90% in 2 days (3 days if sample arrives on Friday)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PML myc for suspected BL</td>
<td></td>
</tr>
<tr>
<td>Other FISH</td>
<td>Verbal report within 5 working days if abnormal, 95% complete within 10 working days (majority will be &lt;=10 days)</td>
</tr>
<tr>
<td>ALL Specific AML subtypes</td>
<td></td>
</tr>
</tbody>
</table>

CYTOGENETICS

ACC (Association of Clinical Cytogenetics) best practice guidelines state urgent cytogenetics for cases of AML, CML and ALL should be available within 14 calendar days (10 working days). Other non-urgent cases within 21 calendar days (15 working days); however we are aiming for the following with a hope to revise this further after one year.

<table>
<thead>
<tr>
<th>Cytogenetics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute leukaemia</td>
<td>95% within 10 wd (but majority quicker)</td>
</tr>
<tr>
<td>CML-BCR-abl</td>
<td>95% within 3 wd (verbal report may be given prior to this)</td>
</tr>
<tr>
<td>MDS</td>
<td>95% within 15 wd</td>
</tr>
<tr>
<td>MPD (Jak 2 negative only)</td>
<td>95% within 15 wd</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>95% within 15wd (aiming for 3d for urgent diagnostic cases)</td>
</tr>
<tr>
<td>CLL</td>
<td>95% within 15 wd</td>
</tr>
<tr>
<td>Myeloma</td>
<td>95% within 15 wd</td>
</tr>
</tbody>
</table>

Timing relates to when cytogenetic/FISH is requested e.g. lymphoma cases will have undergone prior morphological and immunohistochemical analysis before FISH is requested.
HISTOLOGY

<table>
<thead>
<tr>
<th>Test</th>
<th>Sample Requirement</th>
<th>Referral Laboratory</th>
<th>Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>B/T cell receptor gene rearrangement</td>
<td>Bone Marrow/Blood in EDTA Trephine Sample</td>
<td>Histology Department, Level 3, Sandringham Building, UHL</td>
<td>10 Working days</td>
</tr>
</tbody>
</table>

Urgent Samples

*It is essential to contact the laboratory if you are sending an urgent request.* If we do not know a sample is urgent it is likely to be processed with routine samples. Urgent requests should be communicated by telephoning the HMDL laboratory or discussing with the Haematology Registrar (page via switchboard). This will allow appropriate prioritisation of urgent requests.

High Risk Specimens

Samples from High Risk (danger of infection) patients should be appropriately marked in line with Trust Policy. The high risk box MUST be ticked or a yellow “high risk” sticker attached to all request forms for patients known or suspected of having a blood-borne infection (i.e. HIV, hepatitis B, hepatitis C, salmonella septicaemia, etc).

All such samples MUST be contained in a biohazard bag

Referred Samples

*Trial samples should be co-ordinated through the relevant trial co-ordinator.*

For enquiries regarding trials contact the Clinical Research Unit (0116 356 5998) or NCRN trials office (0116 258 6078).

<table>
<thead>
<tr>
<th>Molecular Studies</th>
<th>Specimen requirements</th>
<th>Transport method</th>
<th>Referral Laboratory</th>
<th>*Turnaround time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLL MRD</td>
<td>10ml peripheral blood in EDTA</td>
<td>Next Day delivery</td>
<td>HMDS Leeds</td>
<td>10 working days</td>
</tr>
<tr>
<td>CML: BCR-abl quantitation/MRD</td>
<td>20ml peripheral blood in Heparin or EDTA or 2-5ml of bone marrow</td>
<td>Next Day delivery</td>
<td>Hammersmith Hospital, London</td>
<td>10 working days</td>
</tr>
<tr>
<td>CML: BCR-abl diagnostic</td>
<td>10ml peripheral blood in EDTA</td>
<td>LPS Nottingham transport</td>
<td>Nottingham City Hospital</td>
<td>10 working days</td>
</tr>
<tr>
<td>VNTR/STR transplanted before April 2011</td>
<td>2-5ml Bone marrow or 10ml peripheral blood in EDTA</td>
<td>Next Day delivery</td>
<td>Manchester Royal Infirmary Transplant Laboratory</td>
<td>10 working days</td>
</tr>
<tr>
<td>VNTR/STR transplanted after April 2011</td>
<td>2-5ml Bone marrow or 10ml peripheral blood in EDTA</td>
<td>LPS Nottingham transport</td>
<td>Nottingham City Hospital</td>
<td>10 working days</td>
</tr>
<tr>
<td>VNTR (post transplant) Aplastic Anaemia</td>
<td>2-5ml Bone marrow or 10ml peripheral blood in EDTA</td>
<td>Next Day delivery</td>
<td>West Midlands Regional Genetics Lab.</td>
<td>3 weeks</td>
</tr>
<tr>
<td></td>
<td>Sample Type</td>
<td>Delivery Time</td>
<td>Referral Location</td>
<td>Turnaround Time</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------------</td>
<td>---------------------</td>
<td>------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>APML (diagnostic</td>
<td>2-5ml Bone marrow in EDTA</td>
<td>Next Day delivery</td>
<td>Molecular Diagnostic Unit, Guy’s Hospital, London</td>
<td>Within 2 weeks</td>
</tr>
<tr>
<td>samples and MRD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRD other than APML</td>
<td>2-5ml Bone marrow in EDTA</td>
<td>Next Day delivery</td>
<td>Manchester Royal Infirmary</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Children with APML</td>
<td>2-5ml Bone marrow in EDTA</td>
<td>Next Day delivery</td>
<td>Sheffield Children’s Hospital</td>
<td>14 days</td>
</tr>
<tr>
<td>Adults with ALL</td>
<td>2-5ml Bone marrow in EDTA / 10ml peripheral blood in EDTA</td>
<td>Next Day delivery</td>
<td>University College Hospital, London</td>
<td>14 days</td>
</tr>
<tr>
<td>Paediatric / TYA with ALL</td>
<td>2-5ml Bone marrow in EDTA / 10ml peripheral blood in EDTA</td>
<td>Next Day delivery</td>
<td>Sheffield Hallamshire Hospital</td>
<td>14 days</td>
</tr>
</tbody>
</table>

*Turn around time is that stated for the completion of the assay from time of receipt of sample at the referral laboratory. Extra time must be allowed for delivery of sample and return of report.

Clinical Advice
For clinical advice please contact the Haematology On Call Registrar.

Guidelines:

SPECIAL HAEMATOLOGY MOLECULAR DIAGNOSTIC LABORATORY

The Special Haematology Molecular Diagnostic Laboratory provides additional support to both the Haemostasis and Thrombosis clinic and the HMDL service. The majority of requests are generated from within the UHL but some samples are received from other laboratories as well as GP surgeries.

Contact Details
Special Haematology Laboratory, Room 215/216, Level 2 Sandringham Building, Leicester Royal Infirmary
0116 258 7531

Open hours
Monday – Friday 8:00-20:00
Request Form

Requests for Factor V Leiden Gene Mutation and Prothrombin Gene Mutation should be made using the Special Haematology Request form – appendix 1. Requests for JAK-2 analysis should be made using the HMDL Request form – appendix 4

Specimen Requirements:
• For any sample queries or advice please contact Special Haematology Laboratory
• Specific sample requirements are listed in the following table.
• Samples may be transported to the laboratory from the wards/clinic via the Clinical Distribution Service, the air tube system or the Pathology Transport Service.
• Urgent samples must be brought directly to the Special Haematology Laboratory. Inform the laboratory when sending Urgent requests.
• Samples must be labelled with full name, DOB hospital/NHS/Unit number and the date taken.
• The request form must be completed with all patients’ identification, ward/clinic/GP details, gender of patient and any relevant clinical information.
• Patients that have recently received a blood transfusion should be tested at least 4 months post transfusion.
• All samples must be received within a sealed specimen bag.
• High Risk samples MUST be labelled appropriately.

Available Tests:

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen Requirement</th>
<th>*$Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAK-2</td>
<td>4.9ml EDTA</td>
<td>14 working days</td>
</tr>
<tr>
<td>Factor V Leiden gene mutation</td>
<td>4.9ml EDTA</td>
<td>14 working days</td>
</tr>
<tr>
<td>Prothrombin gene Mutation</td>
<td>4.9ml EDTA</td>
<td>14 working days</td>
</tr>
</tbody>
</table>

*Turn around time is that stated for the completion of the assay from time of receipt of sample at the referral laboratory to the issuing of the authorised report. Extra time must be allowed for delivery of sample and return of report.

$Turn round times is defined as the time taken for 95% of samples to be tested and reported
Key factors:
Results are invalid if the sample has been taken within four months of a previous blood transfusion.

Time Limit for requesting additional examination

- unlimited provided sufficient DNA/RNA stored

Clinical Advice:
For clinical advice please contact the Haematology On Call Registrar
Appendix 1

Appendix 2

Haemostasis & Thrombosis Request Form

<table>
<thead>
<tr>
<th>Patient Details</th>
<th>DATE &amp; TIME RECEIVED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNIT No.</td>
<td>Hospital:</td>
</tr>
<tr>
<td>SURNAME:</td>
<td>Department:</td>
</tr>
<tr>
<td>FORENAME:</td>
<td>Consultant:</td>
</tr>
<tr>
<td>ADDRESS:</td>
<td>Requesting Medic:</td>
</tr>
<tr>
<td>D.O.B.</td>
<td>State if urgent or if results required by specific Date/Time:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anticoagulant Therapy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td></td>
</tr>
<tr>
<td>Heparin Dog</td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td></td>
</tr>
<tr>
<td>Time Last Injection</td>
<td></td>
</tr>
<tr>
<td>HMW Heparin</td>
<td></td>
</tr>
<tr>
<td>Heparin Assay</td>
<td></td>
</tr>
<tr>
<td>LMW Heparin</td>
<td>Target Range</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bleeding Disorders</th>
<th>Thrombotic Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR</td>
<td>Protein S Free</td>
</tr>
<tr>
<td>F IX</td>
<td>Protein C</td>
</tr>
<tr>
<td>APTT FS</td>
<td>APCR V</td>
</tr>
<tr>
<td>Warfarin</td>
<td></td>
</tr>
<tr>
<td>F XII</td>
<td></td>
</tr>
<tr>
<td>APTT FS 50/50</td>
<td></td>
</tr>
<tr>
<td>F VII</td>
<td></td>
</tr>
<tr>
<td>APTT LA</td>
<td></td>
</tr>
<tr>
<td>F II</td>
<td></td>
</tr>
<tr>
<td>APTT LA 50/50</td>
<td></td>
</tr>
<tr>
<td>F V</td>
<td></td>
</tr>
<tr>
<td>ICT</td>
<td></td>
</tr>
<tr>
<td>F X</td>
<td></td>
</tr>
<tr>
<td>Fibrogen</td>
<td></td>
</tr>
<tr>
<td>D-Dimer</td>
<td></td>
</tr>
<tr>
<td>Platelet Function</td>
<td></td>
</tr>
<tr>
<td>F VIII</td>
<td></td>
</tr>
<tr>
<td>vWF Antigen</td>
<td></td>
</tr>
<tr>
<td>F XIII</td>
<td></td>
</tr>
<tr>
<td>vWF CEA</td>
<td></td>
</tr>
<tr>
<td>inhibitor Screen</td>
<td></td>
</tr>
<tr>
<td>vWF Ref</td>
<td></td>
</tr>
<tr>
<td>inhibitor Assay</td>
<td></td>
</tr>
</tbody>
</table>

Misc./Comment

Appendix 3
**Special Haematology and HMDL**

### Family Origin Questionnaire

Please tick ALL sections that apply to the woman and the baby's father.

**A. AFRICAN-CARIBBEAN (BLACK)**
- Caribbean islands
- Africa (excluding North Africa)
  - Any other African or African-Caribbean family origins (please write in...)

**B. SOUTH ASIAN (ASIAN)**
- India or Indian-African
- Pakistan
- Bangladesh

**C. SOUTH EAST ASIAN (ASIAN)**
- China including Hong Kong, Taiwan, Singapore
- Thailand, Indonesia, Burma
- Malaysia, Vietnam, Philippines, Cambodia, Laos
  - Any other Asian family origins (please write in... (e.g. Caribbean-Asian)

**D. OTHER NON-EUROPEAN (OTHER)**
- North Africa, South America etc
- Middle East (Saudi Arabia, Iran etc)
  - Any other Non-European family origins (please write in...)

**E. SOUTHERN & OTHER EUROPEAN (WHITE)**
- Sardinia
- Greece, Turkey, Cyprus
- Italy, Portugal, Spain
  - Any other Mediterranean country
- Albania, Czech Republic, Poland, Romania, Russia etc

**F. UNITED KINGDOM (WHITE)**
- England, Scotland, N Ireland, Wales

**G. NORTHERN EUROPEAN (WHITE) refer to chart**
- Austria, Belgium, Ireland, France, Germany, Netherlands
- Scandinavia, Switzerland etc
  - Any other European family origins, refer to chart
    - (Please write in... (e.g. Australia, N America, South Africa)
      - # Higher risk for alpha zero thalassaemia

**H. DON'T KNOW** (incl. pregnancies with donor egg/sperm)

**I. DECLINED TO ANSWER**

**SCREENING TEST DECLINED** Do you want a reason why declined?
- Yes
- No

---

**Appendix 4**

SPUS001 Page 33 of 34 Version 6 29/10/14
### HMDL Specimen Request Form

**Addressograph Label**
- Hospital: [Field]
- Location: [Field]
- Consultant: [Field]
- Requested by: [Field]
- Date requested: [Field]

**Clinical Details:** (Including suspected diagnosis, recent chemotherapy or GCSF etc.)
- [ ] Yes
- [ ] No

**Infection risk?:**
- [ ] Yes
- [ ] No

**Is the patient anticoagulated?:**
- [ ] Yes
- [ ] No

**FBC**
- Normal
- [ ] Neut
- [ ] Lymph
- [ ] Hb
- [ ] MCV
- [ ] WCC
- [ ] Eosin
- [ ] Pt
- [ ] Blasts

**Lymphoma staging marrow?:**
- [ ] Yes
- [ ] No

**Tests and Samples (tick or specify number of samples where needed):**

<table>
<thead>
<tr>
<th>Test</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Blood Film</td>
<td>[ ]</td>
</tr>
<tr>
<td>BMA slides</td>
<td>[ ]</td>
</tr>
<tr>
<td>Trephine</td>
<td>[ ]</td>
</tr>
<tr>
<td>CSF (Plain)</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flow cytometry:</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral blood EDTA</td>
<td>[ ]</td>
</tr>
<tr>
<td>BM EDTA</td>
<td>[ ]</td>
</tr>
<tr>
<td>CSF (Transfix)</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial samples?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify trial:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cytogenetics:</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture medium (bone marrow)</td>
<td>[ ]</td>
</tr>
<tr>
<td>Lithium Heparin (Peripheral blood)</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Molecular:**
- PB EDTA
- BM EDTA
- ACD

<table>
<thead>
<tr>
<th>Specify test(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify Laboratory (number(s) from overleaf)</td>
</tr>
</tbody>
</table>

**Other sample/test (specify):**

**Sample taken by:**
- [ ] [Field]

**Date / Time taken:**
- [ ] [Field]

**Anatomical site RPI:**
- [ ] [Field]
- [ ] / other

**LAB USE ONLY**
- Screened as: [Field]
- [ ] [Field]
- [ ] [Field]

**Date / Time received:**
- [ ] [Field]

**Version 6**
- [ ] [Field]
- 20/10/14