



9305

## Laboratory User Guide

HMDS provides an integrated diagnostic service covering all aspects of the diagnosis monitoring of haematological malignancies and related conditions. The laboratory has facilities for flow cytometry, immunohistology and a wide range of molecular investigation. Metaphase cytogenetic studies are carried out by the Department of Clinical Genetics and results integrated into the HMDS report. Further details of the service can be found at [www.hmds.info](http://www.hmds.info).

All staff take part in regular, mandatory training for Information Governance and are made aware of the Data Protection Act.

Staff fully respect the need for patient confidentiality at all times.

HMDS achieved accreditation to ISO 15189:2012 standards in March 2017 following assessment by UKAS (United Kingdom Accreditation Services).

### Contacting HMDS:

The full postal address of the laboratory is:

HMDS  
St James's Institute of Oncology  
Level 3 Bexley Wing  
St James's University Hospital  
Leeds LS9 7TF

Telephone for General Enquiries: 01132067851  
Fax: 01132067883

Email addresses of individual staff members can be obtained through the nhs.net contact directory

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## **Opening times and arrangements for urgent samples**

Staff are working in the laboratory between 8.30am and 8pm Monday to Friday and from 9am to 1pm on Saturday.

To ensure safe arrival of samples sent late in the day please call the laboratory if you expect a sample to arrive after 5pm (except for routine late deliveries)

An on call service is available, which includes bank holidays, for clinically urgent requests. This is where there is an immediate need to commence treatment. This service is accessed by contacting the consultant on call through the St James's switchboard, on 0113 243 3144. This should be done before the sample is taken. The laboratory is open on Good Fridays, but with reduced staffing levels, please notify the laboratory prior to sending a sample.

Where an urgent case is a bone marrow aspirate and trephine biopsy, please note that the processing of the trephine biopsy will result in delay to the final typed report, in these instances a telephoned report can be issued.

## **Clinical Advice and Interpretation.**

HMDS has senior staff experienced in all aspects of the diagnosis of haematological malignancies. If you are unsure who to contact please call 01132067851 and ask to speak to any of the consultants or clinical scientists who will be able to direct your enquiry appropriately.

Any unexpected results will be telephoned through to the referring consultant - as per urgent cases.

Should an examination (undertaken by HMDS) be delayed, which would compromise patient care the referring consultant / department will be notified in-person or through the HILIS messaging system.

MDT meetings across the region are attended by HMDS consultant/clinical scientist staff. HMDS is a core member of these MDT meetings.

## **Requesting Investigations:**

Please complete the request form fully. In particular three points of patient identification are required and this should include the NHS number.

The blank HMDS request form can be obtained from the laboratory or downloaded from [www.hmnds.info](http://www.hmnds.info) or HILIS. However, it is recommended that the electronic request form is used, this form is completed online, printed out and sent with the sample.

This is available on the HILIS homepage (<https://nww.hmnds.leedsth.nhs.uk/hilis4>), a HILIS login is not required.

Use of this system could greatly reduce the potential for errors, from both the referral source and internally within HMDS, so please consider introducing this into your practice. For patients previously investigated by HMDS, a significant proportion of the request form can be auto-filled based on the NHS number, making the process much faster.

All specimen containers should be fully labelled. Secure packaging is important. Please ensure that bone marrow smears are not exposed to formalin when a trephine and aspirate sample are being sent together. Blood count data should be entered especially when a specimen of bone marrow is being sent.

If there are changes in the patient's condition or relevant new information emerges after the specimen is sent, please contact the laboratory so that additional investigations may be initiated if required. For flow cytometric

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investigation or where extraction of RNA is required this must be within 24 hours. Investigations on tissue blocks and stored DNA can generally be carried out on archived material without time limit.

## **Sample Requirements and Transport**

**It is recommended that centres referring cases to HMDS send through a fax (or email) notification, so we are aware of the samples being sent and can follow these up should they not arrive within the expected timeframe.**

### Peripheral Blood;

Send in EDTA tube 10ml required

Courier or hospital transport or by first class mail\*\*

### Cerebro-spinal fluid

Sterile container - minimum volume 0.5mls. The specimen must arrive within 24hours and should be sent by the fastest available route.

### Bone Marrow

Fresh marrow smears and marrow sample in EDTA tube.

Trephine biopsy should be fixed in 10% Formalin

Courier or hospital transport or by first class mail\*\*

### Needle core biopsies

Should be fixed in 10% formalin

Sent by fastest practical route usually taxi or express courier

### Endoscopic Biopsies for ? coeliac disease

Endoscopic biopsies should be sent both fixed in 10% formalin and fresh (and be kept moist by including a dampened gauze swab in the container)

Sent by fastest practical route usually taxi or express courier

### Unfixed Tissue Excision Biopsy (non- needle cores)

Where possible a portion of the sample should be sent fresh (and be kept moist by including a dampened gauze swab in the container) and a piece placed in 10% formalin.

Sent by fastest practical route usually taxi or express courier

### Fixed Tissue Block

Secure package

Transport according to degree of urgency.

**\*\* Please note: HMDS does not have a postal delivery on Saturday. This means that any sample posted on Friday does not reach us until Monday morning and this can result in samples being inadequate for processing, (we comment on the adequacy of the sample in the report, giving an explanation if it is inadequate), particularly for those cases which require flow cytometry or RNA extraction.**

**Clinically non-urgent samples which will be sent via the postal service to HMDS fresh, i.e. BM, PB, unfixed tissue, SHOULD NOT be taken on Fridays. If there are situations where this is considered unavoidable HMDS should be contacted by telephone (0113 2067851) BEFORE THE SPECIMEN IS TAKEN for advice on how best to proceed.**

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**Notes:**

1. All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations, particularly those involving flow cytometry or RNA extraction. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay please keep samples in the following conditions before transportation.
  - a. Peripheral blood and bone marrow samples- keep refrigerated between 2-8°C
  - b. Unfixed tissue samples- keep biopsy moist by including a saline dampened gauze swab in the container and keep refrigerated between 2-8°C.
  - c. Fixed tissue samples in formalin- keep at room temperature.
  - d. CSF samples should be kept refrigerated between 2-8°C.
  - e. Samples that require DNA and/or RNA extraction- please ring the lab if there is going to be a delay greater than 24 hours to discuss the storage of these samples, as some tests may not be performed if the storage is incorrect or the delay is considerably longer.
  - f. Needle core biopsies sent fresh undergo significant autolytic changes, this affects both morphology and immunophenotyping, we therefore recommend these are sent fixed in 10% formalin.
2. Cytogenetic samples require a separate sample in a Li Heparin container and should be sent direct to the Regional Genetics Laboratory in Ashley Wing, SJUH or per local arrangements.
3. Samples from within LTH should be sent by the airtube system where possible or by internal transport. The HMDS airtube station is 502.
4. When sending samples by post a secure container should be used to conform to current postal regulations. (P650) applicable and UN 3373 and labelled according to the guidelines.
5. It is essential that appropriate labels are attached to request forms and container where a sample is suspected as being 'High Risk'. Flow cytometry cannot be carried out routinely on these samples.
6. Samples should be sent direct to HMDS and **NOT** to Pathology Reception - otherwise samples maybe delayed.
7. Samples may be sent via Hays DX (our exchange number is Leeds 92LS), please fax details of specimen sent, this allows us to follow up if cases do not arrive on time.

If there is any doubt about how to send a sample please contact the laboratory.

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## External Quality Assurance

The department participates in the following EQA schemes

<b>EQA Provider</b>	<b>Modules registered</b>
UK NEQAS for Cellular Pathology Technique	General & bone marrow trephine (pilot scheme)
UK NEQAS for Immunocytochemistry	Lymphoma
Shandon Tissue Processors Quality Reporting System (QRS)	Excelsior Processor
UK NEQAS for General Haematology	Full blood count
UK NEQAS for Leucocyte Immunophenotyping	<ul style="list-style-type: none"> <li>• Leukaemia diagnostic interpretation – parts 1 and 2</li> <li>• PNH - Screening</li> <li>• PNH - High resolution</li> <li>• MRD flow cytometry - ALL</li> <li>• MRD flow cytometry - B CLL</li> <li>• Molecular diagnosis of haematological malignancies:- <ul style="list-style-type: none"> <li>Jak-2 V617F mutation status</li> <li>BCR-ABL quantitation</li> <li>BCR-ABL and AML translocations</li> <li>Post SCT chimerism monitoring</li> <li>IgH /TCR clonality status</li> <li>NPM1 mutation status (pilot scheme)</li> <li>FLT-3 mutation status (pilot scheme)</li> <li>BCR-ABL1 kinase domain mutations</li> <li>C-KIT D816V</li> <li>BRAF V600E mutation for hairy cell leukaemia</li> <li>Paediatric acute leukaemia translocations</li> </ul> </li> </ul>
UK NEQAS for Cytochemistry	Haemosiderin (Perls stain)
Euroclonality Quality Control Group	IgH/TCR Clonality - Bioment-2
UKNEQAS Edinburgh for Molecular Genetics	DNA extraction for fresh and FFPE material
CEQAS (Cytogenetic External Quality Assessment Scheme)	Mature B & T-cell neoplasms (FISH only for CLL and Lymphoma) plus pilot Lymphoma (FFPE), Myeloma (sample plus on-line) Acquired microarray (CLL) - <i>Pilot scheme</i>
Bournemouth IgHVH sequencing EQA scheme	IgHVH sequencing - Dr Zandie Davis
British Lymphoma Pathology Group (BLPG)	All haematopathologists within HMDS participating

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## Turnaround times

For HILIS users turnaround times can be viewed on the “resources” page, both average turnaround times and (95 percentile) times are listed by specimen type (these turnaround times are constantly updated)

The turnaround time is from receipt of sample to authorised report being available on HILIS.

For users of the service without HILIS access, the following turnaround times are accurate at the time of publication. The turnaround time is from receipt of sample to authorised report being available on HILIS.

<b>Sample Type / investigation</b>	<b>Average turnaround times (95 percentile) - in working days</b>
Peripheral blood / immunophenotyping	4.0 (7.0)
Peripheral blood / PNH	4.0 (9.0)
Peripheral blood / molecular investigation	8.0 (14.0)
Bone marrow aspirate / immunophenotyping	2.0 (5.0)
Bone marrow aspirate with trephine / immunophenotyping	4.0 (7.0)
Trephine biopsy / immunophenotyping	5.0 (11.0)
CSF	2.0 (3.0)
Effusion / immunophenotyping	3.0 (6.0)
Fresh and fixed histological tissues / immunophenotyping	4.0 (7.0)
Fresh spleen / immunophenotyping	6.0 (7.0)
Histological blocks / immunophenotyping	3.0 (7.0)
Chimerism	7.0 (13.0)
Community monitoring samples	13.0 (19.0)

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## Referral of investigations from HMDS

1. Tissue biopsies with non haematological malignancies are referred back to the histopathology department in the hospital where the biopsy was taken.
2. Histology cases originating from the Leeds Teaching Hospitals which show granulomatous inflammation have material sent to the Molecular Microbiology Laboratory, Microbiology Department [CPA ref: 61], Leeds General Infirmary for TB PCR investigations .
3. Bone marrow aspirate samples from patients with acute promyelocytic leukaemia have a sample of cDNA sent to Department of Haematology [CPA ref: 0799], Guy's and St. Thomas's Hospital, London. This is the national reference centre for these investigations.
4. Genomic DNA and cDNA from patients with atypical myeloproliferative disorders are referred to Prof. Nick Cross at the Wessex Regional Genetics Laboratory [CPA ref: 1175], Salisbury. This is the national reference centre for these investigations.

Further information regarding the service can be found on the HMDS website

## General Enquires

Head of Department: Cathy Burton  
01132067963  
[cathy.burton1@nhs.net](mailto:cathy.burton1@nhs.net)

Service manager: David Blythe  
01132067851  
[dblythe@nhs.net](mailto:dblythe@nhs.net)

If there are problems or complaints about the service please call us. We aim to resolve most problems immediately and informally. If this cannot be done please write to Cathy Burton in the first instance.

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