



# HMDS

Haematological Malignancy Diagnostic Service

## Laboratory User Guide

Version: 4.4



9305



## Scope of User Guide

This user guide is designed to give an overview of the Haematological Malignancy Diagnostic Service (HMDS), including the availability of clinical advice, as well as the scope and limitations of the service. It is intended as a quick reference guide for all users, both within the Leeds Teaching Hospitals NHS Trust (LTHT), and primary and other secondary care health providers who use the service.

## Introduction by Dr Catherine Cargo & Dr Ruth de Tute

HMDS is a Specialist Integrated HMDS (SIHMDS) medical laboratory that provides a diagnostic service for haematological malignancies, which includes leukaemia, lymphoma and myeloma. The laboratory provides a comprehensive diagnostic service to the Yorkshire Cancer Network and The Yorkshire Coast and the Humber Cancer Network as well as receiving referrals from across the UK. HMDS also acts as a diagnostic reference centre for many national and international clinical trials.

HMDS was established in 1992 to bring together all of the laboratory techniques used to diagnose haematological malignancies. HMDS utilises techniques of flow cytometry, histology and immunohistochemistry, and a wide range of molecular based techniques in the diagnosis of haematological malignancy.

**Flow Cytometry:** is a highly effective method of identifying both normal and malignant populations according to the pattern of protein expression within liquid samples with individual cells free in suspension. The technique utilises fluorescent labelled monoclonal antibodies to detect the presence of a specific protein or other molecule on the cell surface or in the cytoplasm or nucleus.

**Histology and Immunohistochemistry:** microscopic examination of tissue sections plays an important role in the diagnosis of haematological malignancy. Changes in the interaction between malignant and normal cells are a fundamental property of all types of haematological malignancy. This can be observed microscopically by identifying changes in the relative proportions of different types of cell, the breakdown of the internal structure of tissue, and the detection of cells in locations where they would not normally be found. The application of immunohistochemistry allows the immunophenotype of cells to be determined using antibodies targeted to tissue bound antigens.

**Molecular Based Techniques:** these techniques are based on the analysis of RNA and DNA, and involve techniques such as PCR, Sangar Sequencing, Next Generation Sequencing, Fluorescent In Situ Hybridisation, Single Nucleotide Polymorphism, to determine molecular abnormalities. Molecular abnormalities of specific genes are a feature of many types of haematological malignancy. These may be characteristic of a particular subtype, or be a factor in determining prognosis and treatment.

The analysis and interpretation of results across the techniques are the basis for the WHO framework for haematological oncology diagnostics and classifications. It has been widely recognised that integrating results from such techniques and technologies into a single report is the most effective way to ensure diagnostic accuracy, and ultimately allow optimal treatment of patients. This is made possible at HMDS through the use of a bespoke laboratory information management system (LIMS), HILIS.

Over the years HMDS approach in the diagnosis of haematological malignancy has been strengthened by the rapid development of diagnostic technology, and is now regarded as the national standard of care. HMDS remains at the forefront of applying new diagnostic techniques for the benefit of patients.



## HMDS North East and Yorkshire Genomic Laboratory Hub Service Commitments

Leeds Teaching Hospital, Sheffield Children's NHS Foundation Trust, and Newcastle Upon Tyne Hospitals NHS Trusts, have formed a partnership to deliver the North East and Yorkshire Genomic Laboratory Hub service (NEY GLH). NEY GLH is the designated Genomic Laboratory Hub for the North East, North Cumbria, Yorkshire and Humber region, providing core genetic testing in both rare disease and cancer across the region, and also a defined list of specialised services nationally. For referrers within England, all tests on the National Genomic Test Directory are centrally commissioned by NHSE and therefore costs for these tests will not be invoiced by HMDS. Further information can be found at, <http://www.ney-genomics.org.uk>.

### Dr Catherine Cargo HMDS Clinical Lead



Dr Catherine Cargo is a Consultant Haematologist and Clinical Lead in HMDS. She graduated from Queens University, Belfast and completed post graduate training in the Belfast City Hospital completing an MSc in Haematopathology through the University of York. Her specific interest is in the diagnosis and management of myeloid malignancies and has completed a PhD exploring the use of new molecular diagnostic technologies in this area. She is also the joint Clinical Lead for Haematolo-Oncology within the North East and Yorkshire Genomics Laboratory Hub.

### Dr Ruth de Tute HMDS Scientific Lead



Dr Ruth de Tute is a Consultant Clinical Scientist and the Scientific Lead at HMDS. Having trained in a local general haematology laboratory, Ruth joined the flow department at HMDS in 2004, completing a PhD in flow immunophenotyping of mature B-cell lymphoproliferative disorders. With a particular focus on detection of low levels of disease, Ruth is involved in many UK myeloma and lymphoma trials. She is also Scientific and Deputy Lead for the Oncology theme of the NIHR Leeds In Vitro Diagnostics Co-operative.

***Our aim is to ensure all service users receive a high quality, appropriate and clinically relevant service.***

***Leading the way in integrated diagnostics for haematological malignancies.***

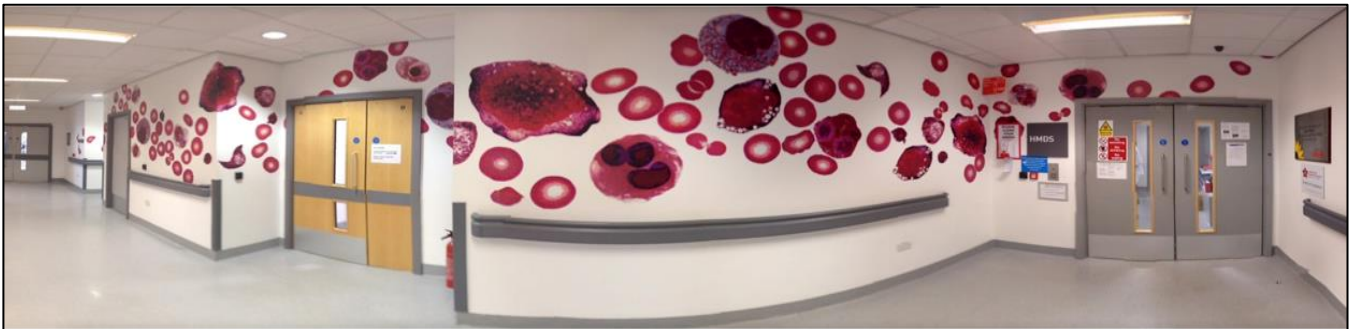
# Contents

|  |           |
|--|-----------|
| <b>1.0 Contact Us</b> .....  | <b>5</b>  |
| <b>2.0 Opening Hours</b> .....                                       | <b>6</b>  |
| <b>3.0 Governance</b> .....  | <b>7</b>  |
| 3.1 Information Governance.....                                      | 7         |
| 3.2 Clinical Governance .....  | 7         |
| 3.3 Raising a Complaint .....  | 7         |
| <b>4.0 Requesting HMDS Investigations</b> .....                      | <b>8</b>  |
| 4.1 Patient Consent .....  | 8         |
| 4.2 Request Acceptance and Rejection Criteria.....                   | 9         |
| 4.3 Labelling Samples Acceptance and Rejection Criteria .....        | 9         |
| 4.4 Labelling Danger of Infection (DOI) Samples .....                | 9         |
| 4.4.1 What is a “high risk” DOI Specimen? .....                      | 10        |
| <b>5.0 Urgent Clinical Requests &amp; Out of Hours Service</b> ..... | <b>11</b> |
| 5.1 Urgent Requests within Routine Service Hours .....               | 11        |
| 5.2 Urgent Requests Out of Hours.....                                | 11        |
| <b>6.0 Sample Requirements &amp; Transport</b> .....                 | <b>12</b> |
| 6.1 Sample requirements .....  | 12        |
| 6.3.1 Peripheral Bloods .....  | 12        |
| 6.3.2 Bone Marrow Aspirates.....                                     | 12        |
| 6.3.3 Bone Marrow Trepines.....                                      | 12        |
| 6.3.4 Bed Side Smears .....  | 12        |
| 6.3.5 Fine Needle Aspirates (FNA).....                               | 13        |
| 6.3.6 Cerebro-Spinal Fluids (CSF) .....                              | 13        |
| 6.3.7 Vitreous Biopsies / Washings .....                             | 13        |
| 6.3.8 Pleural Effusions .....  | 13        |
| 6.3.9 Surgical Tissue Excisions .....                                | 13        |
| 6.3.10 Surgical Tissue Needle Core Biopsies .....                    | 13        |
| 6.3.11 Skin Biopsies .....   | 14        |
| 6.3.12 Gastric Endoscopic Biopsies .....                             | 14        |
| 6.3.13 FFPE Blocks & Slides .....                                    | 14        |
| 6.4 Sample Transport.....  | 15        |
| <b>7.0 HMDS Reports &amp; Results</b> .....                          | <b>16</b> |
| 7.1 Clinical advise & Interpretation .....                           | 16        |
| <b>8.0 Turnaround Times (TATs)</b> .....                             | <b>17</b> |
| <b>9.0 Referred Tests within HMDS Reports</b> .....                  | <b>18</b> |



## 1.0 Contact Us

HMDS is located on level 3 at Bexley Wing, St James Hospital, and can be accessed via the blue lifts located on level 0 by the main entrance desk. Once on level 3 turn right along the corridor, right again, and the department is sign posted HMDS and has blood cell images on the wall (see image below).



## HMDS



**Postal Address:**

HMDS  
Level 3,  
Bexley Wing,  
St. James University Hospital,  
Beckett Street,  
Leeds,  
LS9 7TF

**General Enquiries**

0113 2067851

[hmds.lth@nhs.net](mailto:hmds.lth@nhs.net)

**Specimen Reception Enquiries**

0113 2068328

**Flow Cytometry Enquiries**

0113 2068344

**Histology Enquiries**

0113 2068646

**Molecular Enquiries**

0113 2068168

**Clinical Lead** (Dr Catherine Cargo)

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[rdetute@nhs.net](mailto:rdetute@nhs.net)

**Laboratory Manager** (Dharmesh Mistry)

0113 2068120

[dharmesh.mistry2@nhs.net](mailto:dharmesh.mistry2@nhs.net)



**HMDS Website:** [www.hmds.info](http://www.hmds.info)

|                                 |
|---------------------------------|
| <b>Routine Service Hours</b>    |
| Monday - Friday: 09:00 – 17:00  |
| <b>Specimen Reception Hours</b> |
| Monday - Friday: 09:00 – 20:00  |

**Please Note:** Staff may be available in the department between Monday to Friday 08:00-20:00, and Saturday 09:00 to 13:00. Provision can be made for urgent samples (see section 5.0 Urgent Clinical Requests & Out of Hours Service).

**Weekends and bank holidays are not routinely staffed, and the service is limited to a range of tests.**



## 3.0 Governance

HMDS is part of the Leeds Teaching Hospitals NHS Trust (LTHT). LTHT is the entity that is held legally responsible for all of HMDS activities. It was established as a legal entity in 1998, and the order of establishment was amended in 2004. The Trust is also registered with the Care Quality Commission (CQC). HMDS sits within the Oncology Clinical Service Unit (CSU) at LTHT.

HMDS is a UKAS accredited medical laboratory No: 9305. HMDS has chosen not to display the UKAS accreditation symbol within HMDS reports. This is due to the limitation of the HMDS's laboratory information management system (HILIS). The HMDS website (<http://hmds.info/ukas>) provides a hyperlink to the certificate of UKAS accreditation, UKAS accreditation schedule, UKAS accredited definitive test lists, and a table of tests not UKAS accredited. HMDS has established departmental policies and procedures to meet the requirements of BS EN ISO 15189, 'Medical laboratories- Requirements for quality and competence'.

HMDS participate in Proficiency Testing (PT) programmes to demonstrate technical and interpretive competencies, whilst providing an objective measure of the accuracy of the testing we provide to our users. The HMDS PT programme register can be provided upon request via the Quality Manger.

### 3.1 Information Governance

HMDS adheres to LTHT policies on General Data Protection Regulation (GDPR) and Information Governance. Contractually, HMDS employees must ensure the confidentiality of personal information. Furthermore, HMDS employees participate in Information Governance mandatory training annually, and compliance is reviewed.

### 3.2 Clinical Governance

All operating procedures within HMDS are based around the principle of producing an integrated final report in accordance with the recommendation of the National Institute of Health and Clinical Excellence Improving Outcome Guidance for Haematological Oncology and the Cancer Reform Strategy. The rationale for this approach is based on the cross validation of independently produced test results at the final reporting stage.

The diagnostic criteria used within HMDS are taken from the WHO classification of tumours of the haematopoietic and lymphoid tissues (Swerdlow, S. H. et al. International Agency for Research on Cancer & World Health Organization. WHO classification of tumours of haematopoietic and lymphoid tissues. (International Agency for Research on Cancer, 2017, 4th edition revised). This is the internationally accepted standard in haematological malignancy diagnosis.

### 3.3 Raising a Complaint

**HMDS Complaint:** All formal complaints of the HMDS service should be raised in writing to the Clinical Lead and Scientific Lead. Following the receipt of a complaint, HMDS will acknowledge the receipt of the complaint to the complainant. All complaints received will be addressed in a timely manner and reviewed by the HMDS Quality Group to ensure that they are investigated impartially, with the progress if applicable, and the outcomes being communicated back to the complainant.

**Patient Complaint:** Information regarding making a complaint is available on The Leeds Teaching Hospitals NHS Trust website (<http://www.leedsth.nhs.uk>) on the [Patient Advice and Liaison Service \(PALS\) and Complaints](#) page. This is designed to deal with complaints from patients or their legal representatives. For a complaint received through LTHT PALS, the findings and actions are reported back to PALS as well as the complainant.





## 4.0 Requesting HMDS Investigations

All HMDS investigations **MUST** be requested via an approved HMDS request form. An approved HMDS request form can be downloaded from <http://hmds.info/hmds-request-form>.



Alternatively, users who have access to the HMDS HILIS Data Systems **SHOULD** request HMDS investigations via our online request form. The HMDS online request form can be accessed from <http://hmds.leedsth.nhs.uk/hilis4>



Supporting referral letters and reports can also be sent with the request, but **ONLY** in conjunction with an approved HMDS request form.

### 4.1 Patient Consent

Patient consent is inferred by HMDS on the grounds that the patient has willingly submitted to the sample collection procedure.



## 4.2 Request Acceptance and Rejection Criteria

It is the responsibility of the person completing the request to ensure that the patient details and clinical information supplied to HMDS is correct and relevant to the request. Three points of patient identification are required as a minimum to ensure the positive identification of the patient and should include the NHS number. Inadequate or inappropriate HMDS requests may lead to delays, incorrect diagnosis, inappropriate treatment, morbidity or mortality. As such, HMDS has the right to refuse inadequate or inappropriate requests.

## 4.3 Labelling Samples Acceptance and Rejection Criteria

All samples sent **MUST** be labelled with the patient details as on the HMDS request form.

The minimum acceptable information, on sample container should include all of the following:

- Surname
- Forename
- NHS number or unit number or date of birth
- Date and time of collection

Other labels on the sample **MUST** not mask the patient identification information.



HMDS has the right to refuse unlabelled, inadequately labelled or mislabelled samples.

## 4.4 Labelling Danger of Infection (DOI) Samples

In some circumstances, it may be necessary to send samples from patients that are positive or potentially positive for high infection risk organisms, which may present a risk to HMDS personnel.

Samples from high infection risk patients **MUST** be labelled with a DOI label on the HMDS request form and sample to alert HMDS personnel of the risks, and sufficient clinical details to enable the HMDS personnel to know what special precautions are necessary to process the sample. Writing "Danger of Infection" is not adequate and can easily be missed.



**Please Note: All fresh surgical tissues that are suspected or known DOI should be sent fixed in 10% formalin.**



#### 4.4.1 What is a “high risk” DOI Specimen?

Clinical judgment must be used to label samples correctly, and the onus for this is on the requestor. Samples from the following **MUST** have a “Danger of Infection” label:

- patients with proven infection with a Hazard Group 3 (HG3) pathogen e.g. hepatitis B and C, HIV, tuberculosis and other mycobacteria, typhoid, brucella and anthrax
- A patient who is part of an on-going outbreak caused by a HG3 pathogen.
- Patients suspected of having a HG3 pathogen (information from clinical history and examination)

If there is doubt as to whether a specimen is “high risk”, please contact HMDS (**0113 2068328**). 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 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.

**Please Note: HMDS will not routinely process liquid CJD samples. A morphology assessment maybe provided. Please call HMDS (0113 2067851) if there is a clinical need for such a request.**

**HMDS will NOT accept samples from patients suspected of having any pathogen in Hazard Group 4, e.g. viral haemorrhagic fever (Lassa, Marburg, Ebola and Congo Crimean), or Hendra or Nipah viruses.**



## 5.0 Urgent Clinical Requests & Out of Hours Service

### 5.1 Urgent Requests within Routine Service Hours

Referrers **MUST** call HMDS (0113 2067851) for a request that requires an urgent result.

### 5.2 Urgent Requests Out of Hours

HMDS has a dedicated out of hours service for urgent clinical requests where there is an immediate need to commence treatment.

The HMDS out of hours service can **ONLY** be accessed by contacting the HMDS on-call consultant via the St James's switchboard (0113 2433144) **PRIOR** to taking the sample. The time and location of delivery of the sample should be agreed before it is sent to HMDS.

#### Examples of requests that will be considered for urgent processing out of hours will include:

Flow cytometry and morphological assessment for suspected acute leukaemia

Investigations for suspected Burkitt lymphoma

PML stain to confirm/exclude APML

**Please Note: This service should only be reserved for request where there is a definite clinical need.**

## 6.0 Sample Requirements & Transport

### 6.1 Sample requirements

All sample containers should be sourced locally. HMDS **ONLY** provide sample containers for collection of fine needle aspirate.

| Sample Type                        | HMDS Sample Requirements   | Transport to HMDS | Storage precautions before transporting to HMDS |        |
|------------------------------------|--|-------------------|---|--------|
| <b>6.3.1 Peripheral Bloods</b>     | Investigations for new diagnosis of leukaemia/lymphoma<br><br>Lymphocytosis<br><br>Investigation of possible MPN<br><br>PNH<br><br>B-cell subsets for patients on rituximab (e.g. RA, SLE)   | 1 x 4ml EDTA      | Within 24 Hours                                 | 2-8 °C |
|                                    | MRD monitoring   | 2 x 4ml EDTA      |   |        |
|                                    | BCR-ABL molecular monitoring   | 3 x 4ml EDTA      |   |        |
|                                    | Chimerism studies  | 3 x 6ml EDTA      |   |        |
|                                    |  |                   |   |        |
| <b>6.3.2 Bone Marrow Aspirates</b> | EDTA tube, accompanied by a bedside smears (max of x5 slides only), and a peripheral blood sample in an EDTA tube.<br><br><b>Please indicate on the tube which sample is the first pull.</b><br><br><b>Peripheral blood counts should be sent when a bone marrow sample is sent.</b> | Within 24 Hours   | 2-8 °C  |        |
| <b>6.3.3 Bone Marrow Trepines</b>  | Send fixed in 10% Neutral Buffered Formalin (min volume of fixative 60ml).   | Within 24 Hours   | Room Temperature                                |        |
| <b>6.3.4 Bed Side Smears</b>       | Send a max of x5 slides only.<br><br><b>Any additional slides will be discarded and not processed by HMDS.</b><br><br><b>Please ensure smears are not exposed to formalin.</b>   | Within 24 Hours   | Room Temperature                                |        |

|   |   |                              |  |
|---|---|------------------------------|--|
| <p><b>6.3.5 Fine Needle Aspirates (FNA)</b></p>           | <p>Paediatric EDTA with a small volume of saline buffer are supplied by HMDS for transport of cells obtained by fine needle aspiration.</p>   | <p>Within 24 Hours</p>       | <p>2-8 °C</p>  |
| <p><b>6.3.6 Cerebro-Spinal Fluids (CSF)</b></p>           | <p>CSF should be sent in a sterile universal container. A min of 0.5ml is recommended.</p> <p><b>Please do not send in additives/fixatives as it can render the sample unsuitable for flow cytometry. If further guidance is required, please contact the HMDS Flow Cytometry Section (0113 2068344).</b></p>   | <p><b>Within 4 Hours</b></p> | <p>2-8 °C</p>  |
| <p><b>6.3.7 Vitreous Biopsies / Washings</b></p>          | <p>Vitreous biopsies should be sent in the syringe.</p> <p><b>Please make sure the lid is adequately tightened as they can leak.</b></p> <p>Vitreous washings can also be referred in the collection bag.</p>   | <p><b>Within 4 Hours</b></p> | <p>2-8 °C</p>  |
| <p><b>6.3.8 Pleural Effusions</b></p>                     | <p>Pleural effusions should be sent in a sterile universal container. A min volume of 5ml is recommended.</p>   | <p><b>Within 4 Hours</b></p> | <p>2-8 °C</p>  |
| <p><b>6.3.9 Surgical Tissue Excisions</b></p>             | <p>When possible and if there is no DOI risk, the complete excision or a portion of the excision should be sent fresh, and kept moist by including a dampened gauze swab in the container.</p> <p><b>Please avoid complete submersion in saline.</b></p> <p>If there is sufficient sample available, a portion should also be sent fixed in 10% formalin.</p> <p><b>If further guidance is required, please contact the HMDS Histology Section (0113 2068646).</b></p> <p><b>Prior to sending fresh spleen resections or any large resections, please also contact the HMDS Histology Section (0113 2068646).</b></p> | <p>Within 24 Hours</p>       | <p>Fresh Tissue: 2-8 °C<br/>Fixed Tissue: Room Temperature</p> |
| <p><b>6.3.10 Surgical Tissue Needle Core Biopsies</b></p> | <p>Send fixed in 10% Neutral Buffered Formalin (min volume of fixative 60ml)</p>  | <p>Within 24 Hours</p>       | <p>Room Temperature</p>  |



## 6.4 Sample Transport

It is recommended that centres referring samples to HMDS send through an email notification ([hmds.lth@nhs.net](mailto:hmds.lth@nhs.net)), so we are aware of the samples being sent and can follow these up should they not arrive within the expected timeframe. All samples **MUST** be tightly sealed and sent securely packaged via the most direct and quickest route.

**Please Note: HMDS recommend all samples to be sent directly to the HMDS Specimen Reception and within the HMDS Specimen Reception opening hours (see 2.0 Opening Hours).**

**Samples could be refused if not sent directly to and within HMDS Specimen Reception opening hours.**

To ensure the safe arrival of samples sent late in the day, please call **Specimen Reception (0113 2068328)** if you expect a sample to arrive after 17:00 (excluding routine late deliveries).

Samples can also be sent via Hays DX (our exchange number is Leeds 92LS), please email the details of the samples sent ([hmds.lth@nhs.net](mailto:hmds.lth@nhs.net)).

If sending samples via the post a secure container should be used to conform to current postal regulations. (P650) applicable and UN 3373 and labelled according to the guidelines.

**Please don't post fresh samples (e.g. PB, BMA, unfixed surgical tissues) to HMDS on Fridays. HMDS does not have a postal delivery on Saturday. This means that any fresh samples posted on Friday won't reach us until Monday, which can render samples inadequate for processing. If you do need to send a fresh sample to HMDS on a Friday, alternative transport should be arranged (e.g. courier service, taxi, shuttle service), and specimen reception notified.**





## 7.0 HMDS Reports & Results

HMDS reports are generated by compliance to operating procedures within HMDS based on the principles of producing an integrated final report in accordance with the recommendation of the National Institute of Health and Clinical Excellence Improving Outcome Guidance for Haematological Oncology and the Cancer Reform Strategy. The rationale for this approach is based on the cross validation of independently produced test results at the final reporting stage. HMDS reports undergo a double reporting process before authorised HMDS reports are issued. Reports will be emailed to the email address provided on the HMDS requested form, which **SHOULD** be nhs.net email accounts. Registered HILIS users can also view authorised reports within HILIS (HMDS LIMS).

Any result deemed clinically urgent by HMDS will be telephoned through to the referring consultant. Should an examination (undertaken by HMDS) be delayed, which would compromise patient care the referring consultant / department will be notified directly via email or phone, or through the HILIS messaging system.

In the event of a clinical urgency, defined as the necessity for immediate treatment, an interim report may be discussed verbally between an authorised HMDS reporter and an authorised referring clinician who is responsible for the care of the patient.

**Please note: In such circumstances, the requesting clinician should understand that the diagnosis is based on incomplete data, and there is a risk of subsequent changes following completion of the investigations.**

### 7.1 Clinical advise & Interpretation

HMDS has personnel experienced in all aspects of the diagnosis of haematological malignancies. If you are unsure whom to contact please call HMDS (**0113 2067851**), and ask to speak to any of the HMDS Consultants or Clinical Scientists who will be able to direct your enquiry appropriately.

HMDS Consultants and the Clinical Scientists attend MDT meetings across the region and HMDS is a core member of these MDT meetings.

## 8.0 Turnaround Times (TATs)

TATs are monitored as part of the HMDS Key Performance Indicators (KPI). There are no national guidelines for TATs for SIHMDS so the service produces target turnaround times based on the clinical need and the data generated within HILIS. HMDS will aim to process requests within the target TATs documented in the table below.

**Please note: Compliance to the target TATs are subject to the complexity of the case.**

| Sample Type / investigation                                     | Target turnaround times (working days) |
|---|--|
| <b>Diagnostic TAT Targets</b>                                   |  |
| BMA (Flow cytometry &/or morphology)                            | 4                                      |
| PB (Flow cytometry &/or morphology)                             | 4                                      |
| PNH (Flow cytometry)  | 2                                      |
| Bone marrow aspirate with trephine (Flow cytometry & Histology) | 5                                      |
| Fresh and fixed Surgical tissues (Histology)                    | 7                                      |
| Referred FFPE Blocks & Slides (Histology)                       | 5                                      |
| <b>Molecular TAT Targets</b>                                    |  |
| FLT3/NPM1   | 3                                      |
| Urgent FISH (BCR/ABL, MYC/IGH)                                  | 3                                      |
| Routine FISH/ASO-PCR/MLPA/Clonality/Chimerism                   | 14                                     |
| Myeloid/lymphoid NGS  | 21                                     |

For HILIS users, these can be viewed on the “resources” page and this is updated in real time. The TAT is from receipt of sample to authorised report or molecular result being available on HILIS.

## 9.0 Referred Tests within HMDS Reports

| Department   | Referred Tests   |
|--|--|
| <p><b>Cellular Pathology</b>, St James's University Hospital, Beckett Street, Leeds, LS9 7TF</p> <p>UKAS accredited medical laboratory No: 8924</p>  | <p>Specials stains that are not the scope of UKAS accreditation at HMDS.</p> <p>Immunohistochemistry markers that are not the scope of UKAS accreditation at HMDS.</p> |
| <p><b>North East and Yorkshire Genomic Laboratory Hub (NEY GLH)</b>, Central Lab, Ashley Wing, St James's University Hospital, Leeds, LS9 7TF</p> <p>UKAS accredited medical laboratory No: 8096</p> | <p>Cytogenetics: requested by LTHT clinician and sample forwarded on by HMDS.</p>  |
| <p><b>Wessex Regional Genetics Laboratory</b>, Salisbury District Hospital, Odstock Road, Salisbury, SP2 8BJ</p> <p>UKAS accredited medical laboratory No: 9005</p>                                  | <p>FIP1L1-PDGFRB RQ-PCR<br/>ETV6-PDGFRB RQ-PCR</p> <p>The tests above are not UKAS accredited, however it is the national reference centre for these tests.</p>        |
| <p><b>The Christie Pathology Partnership LLP</b>, Christie Hospital, Manchester, M20 4BX</p> <p>UKAS accredited medical laboratory No: 9028</p>  | <p>Cytogenetics: requested by referring clinician and sample sent directly to Christie.</p>  |