The Royal Marsden Hospital

The Royal Marsden Hospital’s Specialist Integrated Haematological Malignancies Diagnostic Service (RMH SIHMDS)

This document describes the services provided by the constituent laboratories of the RMH SIHMDS. These are:

1. Immunophenotyping by Flow Cytometry (pages 7-11)
2. Cytogenetics (pages 12-15)
3. Molecular Diagnostics (pages 17-21)
4. Haematopathology (pages 22-25)

Key contacts for the service:

Queries relating clinical management should be directed to the clinical service lead: Dr David Taussig: david.taussig@rmh.nhs.uk  Tel: 020 8915 6578
Operational issues should be directed to the managerial service lead: Alison Morilla: alison.morilla@icr.ac.uk  Tel: 020 8915 6516/6517

The laboratories are situated in the Centre for Molecular Pathology and the McElwain Laboratories both located on the west side of the Royal Marsden Hospital (RMH) on its Sutton site.

UKAS accreditation
The laboratories are fully UKAS accredited with the following reference numbers:

Cytogenetics: UKAS 8444
Molecular Diagnostics and Immunophenotyping: UKAS 9839
Histology: UKAS 9929

Hours of service:

Centralised specimen reception operates from 09:00 to 17:30pm Monday to Friday.
All laboratories operate between 09:00 and 17:30pm Monday to Friday.
Out of hours service:

The Immunophenotyping laboratory offer an out of hours service for clinically urgent cases which covers Friday evening, Saturday, Sunday and Bank Holidays, this can be accessed by either phoning the laboratory during working hours or via the RMH switchboard (020 8642 6011) out of working hours. Please contact these laboratories as soon as possible so that resources can be allocated to deal with out of hours samples. Out of hours samples should be enclosed in packaging that is clearly marked “Urgent” and “The laboratory’s name”.

The Cytogenetics laboratory: Samples are cultured out of hours and some processing is done. However, the Cytogenetics Laboratory does not operate a routine out of hours analysis and reporting service. It may be possible to undertake analysis for exceptionally urgent clinical referrals but only if sufficient notice has been given so that arrangements can be made for suitable staff to attend, as the laboratory does not have an on-call provision. For urgent samples likely to arrive outside of the normal working hours, please notify the laboratory in advance. Such samples should be sent by courier to the RMH switchboard and enclosed in packaging that is clearly marked “Urgent” and “Please contact Cytogenetics”.

Clinical advice is available out of normal working hours via the RMH switchboard (020 8642 6011)

Complaints procedure

Any complaints concerning the performance of the service should be directed to the SIHMDS Managerial lead in the first instance. Any complaints which affect patient care will be dealt with according to the Royal Marsden NHS foundation Trust’s internal incident reporting procedure

SIHMDS Request Form:

Requests for studies by any or all of these laboratories should be made using the integrated HMDS request form. Internal users of the service can find this request form on the RMH intranet under Clinical services/ Pathology/service guides and forms. External users can email the HMDS manager, Alison Morilla at alison.morilla@icr.ac.uk or phone the Business Administrators on 020 8915 6513 or 6520 to request a RMH SIHMDS request form.

Urgent requests:

Samples which are identified as being clinically urgent by referrers should be clearly labelled on the request form as urgent. Referrers should indicate the clinical importance of a fast turnaround of results. Each laboratory will use their own urgent pathways to fast track such samples.

Verbal requests:

Following sample receipt additional tests can be requested by referrers via telephone but should be followed by faxing a completed request form or sending a confirmatory email indicating the additional tests for audit purposes.

Time limits for requesting additional tests within RMH SIHMDS:

Flow cytometry tests:  72 - 96 hours
Karyotype studies:     48 hours
FISH studies:         48 hours
DNA testing:          7 days from receipt of sample (for a fresh sample) or indefinite if the sample has already been stored as a DNA sample.
Minimum data sets:

The RMH SIHMDS requires the referrer to provide the following:

Patient demographics:
Patient forename, surname, Date of Birth, Gender, Hospital number and/or NHS number.

It is the referring organisation’s responsibility to ensure the correct identity of the patient and that it corresponds to the information on the request form at the time the sample is taken.

Clinical details:
Diagnosis: Minimum: Presentation features, Hb, WBC, Platelets
Plus
According to the suspected diagnosis: WBC differential, organomegaly, stage, LDH, B12/folate status, paraprotein type and levels

Treatment response/MRD:
Details of treatment including type and duration
Relapse:
Prior treatment and response

User contact details:

A contact telephone number for someone who can help with problems concerning the sample or the requests made, must be included on the request form.

Acceptance/rejection policy:

Samples will be rejected according to the individual laboratory’s acceptance criteria described in the individual sections below.
Wherever possible and especially if the sample referred has arisen from an invasive procedure such as bone marrow or cerebrospinal fluid the laboratories will accept samples without a fully complete data set but will add a caveat to any report relating to the sample. The report will indicate that the sample was unlabelled/incorrectly labelled and state that the decision to act on the report resides with the referring clinician. Unlabelled samples will be rejected by the RMH HMDS laboratories.

Confidentiality policy:

All patient data will be handled according the Trust’s confidentiality policy. Annual Information governance training is mandatory for all Staff working within the Trust.

Transportation:

All samples should be sent to the RMH HMDS Centralised Specimen reception for booking in and sample distribution. Samples can be sent by first class post; by courier or via inter hospital transportation. Transportation and packaging of samples should be performed according to the sender’s policy for safe transport of pathological specimens.
See HSE guidance on http://www.hse.gov.uk/biosafety/biologagents.pdf

Postal Address:

RMH SIHMDS Laboratories
The Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust
Cotswold Road
Sutton
Surrey SM2 5NG
Courier deliveries:
The laboratories are situated in the Centre for Molecular Pathology; a large cream and green building located on the west side of the Royal Marsden Hospital (RMH) on its Sutton site. Access is made via the Cotswold Road entrance to the site.

Sample requirements:
It is assumed that appropriate patient consent has been obtained by the referral centre.

**Peripheral Blood (PB):**
Peripheral blood in Heparin or EDTA according to the test requested plus a stained or unstained PB film

**Bone marrow (BM):**
BM aspirate in Heparin or EDTA according to the test requested
BM trephine in fixative (or saline for processing by flow cytometry or cytogenetics)

**Plus a stained or unstained BM aspirate film of good quality and a PB film – if a good quality film is not included this will affect the quality of the integrated diagnosis**

**Lymph nodes/other tissue:**
Fresh tissue in saline (to arrive within 24 hours)
Tissue in fixative
Paraffin embedded tissue blocks, slides scrolls as appropriate

**Body fluids:**
Cerebrospinal fluid (CSF), Ascitic Fluid (AF), Pleural Fluid (PF) should all be sent fresh and arrive in the laboratory within 24 hours as the cells in these fluids are labile.

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<thead>
<tr>
<th>Sample Storage</th>
<th>Sample</th>
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<tbody>
<tr>
<td><strong>Histopathology</strong></td>
<td>Fixed or fresh tissue (see below)</td>
</tr>
<tr>
<td><strong>Immunophenotyping/Flow cytometry</strong></td>
<td>Bone marrow or blood in either EDTA or heparin. Body fluids: ascites, pleural effusion, fine needle aspirate, BM trephines and solid tissue in saline.</td>
</tr>
<tr>
<td><strong>Molecular Diagnostics</strong></td>
<td>Bone marrow or blood in EDTA Fresh or fixed tissue.</td>
</tr>
<tr>
<td><strong>Karyotype (chromosomes)</strong></td>
<td>Fresh tissue* in heparin. *Usually bone marrow aspirate; other tissues are suitable in some circumstances.</td>
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<tr>
<td><strong>FISH</strong></td>
<td>Fresh or fixed tissue (BM/PB/other).</td>
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Sample storage prior to sending to RMH SIHMDS:
Please see instructions in the individual laboratory sections below.
**Issues relating to sample integrity:**

The referring organisation will be informed as soon as possible if a sample has leaked in transit so that they can send another sample if appropriate. If sample quality is poor for example a haemodilute bone marrow or a peripheral blood which contains clots, the laboratory will use their individual policies to decide whether to reject or accept the sample. If the sample is processed a caveat will be added to the report describing the issue and how it may affect the results.
**RMH SIHMDS: staff list**

**Clinical Head:** Dr David Taussig 020 8915 6578

**Service Manager:** Alison Morilla 020 8915 6516/6518

**Medical:**

- Dr Sunil Iyengar, Consultant Haematologist 020 8915 6647
- Dr Kevin Boyd, Consultant Haematologist 020 8915 6647
- Dr Dima El-Sharkawi, Consultant Haematologist 020 8661 6647
- Dr S Easdale, Consultant Haematologist
- Dr C De Lord, Consultant Haematologist
- Dr R Dowse, Consultant Paediatric Haematologist
- Dr S Tewari, Consultant Paediatric Haematologist
- Dr Andy Wotherspoon, Consultant Histopathologist 020 8915 6559
- Dr Ayoma Attygale, Consultant Histopathologist 020 8915 6559
- Dr Simon O’Connor, Consultant Histopathologist 020 8915 6559
- Dr Katherine Vroobel, Consultant Histopathologist 020 8915 6559

**Laboratory Leads:**

- Mr Alan Dunlop, Immunophenotyping /Flow Cytometry
- Dr Lisa Thompson, Molecular Diagnostics (Clinical Genomics)
- Ms Julie Howard-Reeves, Cytogenetics (Clinical Genomics)
- Ms Natalie Peters, Histology/Haematopathology

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<thead>
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<tr>
<td><a href="mailto:Immunophenotyping@icr.ac.uk">Immunophenotyping@icr.ac.uk</a></td>
<td>020 8915 6517 / 6518</td>
</tr>
<tr>
<td><a href="mailto:Molecular@icr.ac.uk">Molecular@icr.ac.uk</a></td>
<td>020 8915 6554 / 6536</td>
</tr>
<tr>
<td><a href="mailto:Cytogenetics@icr.ac.uk">Cytogenetics@icr.ac.uk</a></td>
<td>020 8722 4232</td>
</tr>
<tr>
<td><a href="mailto:MedSec.Haematopathology@rmh.nhs.uk">MedSec.Haematopathology@rmh.nhs.uk</a></td>
<td>020 8915 6576 / 6549</td>
</tr>
</tbody>
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**Abbreviations used in this document:**

- **RMH:** The Royal Marsden NHS Foundation Trust
- **ICR:** The Institute of Cancer Research.
- **PCR:** Polymerase chain reaction.
- **MRD:** Minimal residual disease.
- **FISH:** Fluorescence in-situ hybridisation
- **FFPE:** Formalin-fixed, paraffin-embedded
Immunophenotyping (by Flow Cytometry) Laboratory

a) Key Flow Cytometry laboratory staff:
Mr. Alan Dunlop Head of Immunophenotyping
alan.dunlop@nhs.net 020 8915 6512/ 6518

Miss Lynnsay Fuller Laboratory Manager
lynnsay.fuller@rmh.nhs.uk 020 8915 6516/6 518

Results/general enquiries: 0208 915 6517/6518
Fax: 0208 915 6756
Group Email: rmh-tr.immunophenotyping@nhs.net

b) Location of Laboratory
The laboratory is located on the ground floor (west side) of the Centre of Molecular Pathology which is adjacent to the main site of the Royal Marsden Hospital, Sutton.

c) Services offered:
The laboratory offers:

- Multiparametric flow cytometry immunophenotyping for diagnosis and disease monitoring of leukaemias, lymphomas and plasma cell dyscrasias;
- Detection of Paroxysmal Nocturnal Haemoglobinuria (PNH)
- CD34 enumeration for Stem cell transplantation

Types of samples processed:
The laboratory primarily processes bone marrow or peripheral blood specimens but can also process other samples such as:
- Cerebrospinal fluid
- Pleural effusion
- Ascitic fluid
- Solid tissues, such as lymph nodes, spleen and liver pieces (please transport in saline NOT fixative).
- Fine needle aspirates
- BM trephines (please transport in saline NOT fixative).

Important: It is essential that all specimens other than PB and BM are processed within 24 hours of being taken.

Laboratory repertoire:
Diagnosis:
- Acute leukaemia / CML in blast crisis panels
- Chronic lymphoproliferative disorders panels (B- and T-cell)
- Multiple Myeloma and plasma cell disorders panel

Sample requirements: 2-5ml PB or BM in heparin or EDTA; any body fluid in saline; any tissue in saline NOT fixative
Minimal residual disease (MRD):
Following treatment samples can be assessed for minimal residual disease in both acute and chronic leukaemias

- Acute leukaemia
- Mature B- and T-cell disorders
- Chronic lymphocytic leukaemia:
- Plasma cell dyscrasias:

Sample requirements: 2- 5ml BM in heparin or EDTA


Sample requirements: 2- 5ml PB in EDTA NOT BM

CD34 enumeration:
The laboratory offers this service in support of the Royal Marsden transplant team. The service includes:
- Quantification of CD34 positive stem cells in both mobilised PB and in stem cell harvests.
- Quantification of CD3 positive lymphocytes for donor lymphocyte infusions (DLIs).
- Viability of CD34 positive stem cells at the point of harvest collection (pre-freezing) and at the point of infusion (post-thawing).
- Viability of CD3 positive lymphocytes at the point of DLI

Sample requirements: 2- 5ml PB in EDTA, 1-2ml stem cell product

d) Hours of Service:
The laboratory operates from 8.00 hrs to 17.30 hrs Mondays to Fridays.

e) Out of hours service
On call service is available for Friday evenings, weekends and bank holidays. Out of hours the Royal Marsden switchboard (020 8642 6011) can contact the person on-call. Please ensure that you notify the laboratory staff concerning any samples being sent late on Friday afternoon.

f) Request form
Please fill all the relevant fields with the relevant information, please note that the minimum data we require for the sample to be accepted for processing, is: Name, Date of Birth and/or Hospital Number, the minimum clinical information to direct the choice of antibody panels to be tested and the type of sample. However please note that it is important to provide as much relevant clinical information as possible in order to reach an accurate diagnosis. Please tick the request test to be performed and if you select ‘other’ please specify the test you require.

We require a contact name and telephone number in the case of any queries concerning the sample.
Request forms are available from the SIHMDS service manager: email: Alison.morilla@icr.ac.uk
g) **Sample transportation**

**Internal samples**

Samples may be taken to the Pathology suite (2nd floor, RMH Sutton) and left in the tray outside the microbiology laboratory. Pathology secretaries will inform us that a sample is waiting and this will be collected as required by our centralised specimen receptionist. Alternatively samples may be brought directly to the Specimen reception in the CMP. Samples may be sent from the Chelsea site via internal transport from the reception desk or taken to the Haematology laboratory at the Chelsea site (see below for the mailing address)

**Transport/packaging and collection of samples should follow the** Pathology Service Policy and Procedures for the Receipt and Handling of Specimens (Path Man 4)

**External samples**

Samples may be sent by first class post or by courier. Transportation and packaging of samples should be performed according to the sender’s policy for safe transport of pathological specimens.

**Please address specimens to:**

**RMH SIHMDS Laboratories**
Immunophenotyping Laboratory
The Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust
Cotswold Road
Sutton
Surrey SM2 5NG

**Note:** PB and BM samples awaiting transportation can be kept at ambient temperature. If there is a delay, samples can be stored in a temperature-monitored laboratory fridge. There must be no risk of the sample being frozen.

**Out of hours urgent samples:**

These should be addressed as above but marked as ‘Urgent’ and labelled with ‘Immunophenotyping Laboratory’ The courier should be instructed to take the sample to switchboard in the Royal Marsden hospital as this is the only place manned 24 hours a day. Switchboard will then inform the person on-call.

h) **Clinical advice and interpretation:**

For immunophenotyping / flow cytometry interpretation/advice please contact the laboratory.

For clinical management and advice on morphology assessment in addition to immunophenotyping; please contact. Dr David Taussig (Acute leukaemias, Myeloproliferative disorders), Dr Sunil Iyengar & Dr Dima El-Sharkawi (Chronic Lymphoproliferative disorders) or Dr Kevin Boyd (plasma cell dyscrasias)

i) **Specimen minimum requirements:** (see above for specific test requirements)

Please send 2 to 5mls of blood or 2 to 5 mls of bone marrow in EDTA or preservative free heparin. The sample should be labelled with the name and Date of Birth and/or Hospital for cross reference with the request form and to meet our sample acceptance criteria.

**This should be accompanied by a film (stained or unstained) of the same type as the sample sent.**

Information, including consultant’s name, clinical details and suspected diagnosis, must be provided on the Haem-Onc request form.

Samples received in the laboratory 72 hours after being taken may not be processed as the immunophenotyping results obtained could be unreliable. If the sample is processed a caveat will be added to the report to indicate the age of the sample and how this may affect the results.
j) Further studies:
If, according to our professional judgement, we feel that further tests may be required in order to obtain a correct diagnosis, it is our policy to pass the sample to another laboratory within the haematology-oncology facility. For example, this may include passing the sample to our molecular diagnostics team to test for TCR to confirm the clonality of a T cell population or to request FISH for t(11;14) in the case of a clonal CD5 positive B-cell population with a low CLL score.

We feel that this is in the interest of patient care in facilitating a quick diagnosis, negating the need for further samples being taken and extra consultant appointments.

k) External quality control / NEQAS participation:
The laboratory participates in ten external quality assurance schemes for flow cytometry:

- UK Neqas for Leukaemia Immunophenotyping (Part 1)
- UK Neqas Leukaemia Diagnosis Interpretation (Part2)
- UK Neqas Paroxysmal Nocturnal Haemoglobinuria,
- UK Neqas Minimal Residual Disease programme for ALL by flow cytometry,
- UK Neqas CD34+ Stem Cell Enumeration.
- UK Neqas Cerebrospinal Fluid CSF Immunophenotyping (not accredited),
- UK Neqas Minimal Residual Disease programme for B-CLL by Flow Cytometry (not accredited),
- UK Neqas Minimal Residual Disease programme for Plasma cell Myeloma by Flow Cytometry (not accredited),
- UK Neqas Minimal Residual Disease for AML by Flow Cytometry (not accredited)
- UK Neqas Haematological Malignancy Bone marrow Aspirate Assessment (not accredited).

Consultant haematologists participate in the South Thames morphology EQA scheme, which sends out slides for morphological review three times a year.

l) Reports:
Flow cytometry reports: these will be inputted and authorised by a senior HPC registered staff member onto the RMH HIS system in a timely manner in accordance with our stated turnaround times.

Final consultant authorised reports: these include morphological review and a final diagnosis, will be generated by a Consultant Haematologist.

Telephone reports: a provisional flow cytometry report can be given to an appropriate member of the user’s medical team or by a senior HCPC registered member of the team only. A record of who was spoken to and the results given will be recorded in the appropriate way, following RMH policy.

Faxed reports: provisional flow cytometry or completed reports can be faxed to an appropriate member of the user’s medical team to a fax machine located in a secure position which will ensure the confidentiality of the results sent, according to RMH policy.

NB. The clinician requesting the results will be asked for the patient’s date of birth or hospital number in addition to the patient’s name to cross reference the identity of the patient.

Electronic Reports: pdf reports can be sent via nhs mail only.

Printed reports: Completed reports are sent by first class post to the referring Hospital Consultant and to any other relevant parties, as requested.

m) Turnaround times

Leukaemia immunophenotyping:

Urgent samples: Provisional / flow cytometry reports are faxed or telephoned within 4 hours of receipt in the laboratory, if the specimen was received before 1pm or otherwise within 24 hours of receipt.

Non-urgent samples: Flow cytometry/provisional reports authorised by senior HPC registered staff
are available within 3 working days. Completed reports including morphological review and final diagnosis by a Consultant Haematologist will be posted/available within 5 working days.

**CD34 enumeration:**

Mobilised PB samples: **60 minutes** from sample receipt in 80% of cases  
Stem cell harvests: **80 minutes** from sample receipt in 90% of cases

**n) Factors affecting reliability of results**

1. Poor quality samples eg. haemodilute bone marrows or samples containing clots will affect the quality of the results obtained  
2. Samples which are more than 72 hours old will contain a proportion of dead and dying cells which may lead to misleading results. Also some antigens are more labile than others which may lead to false negativity for some cell markers  
3. Samples which are sent with insufficient clinical information may result in inappropriate tests being carried out and uninformed interpretation being made  
4. Samples sent without an accompanying smear for morphological review may result in inappropriate tests being carried out and uninformed interpretation being made

**l) Time limits for requesting additional tests within SIHMDS**

Flow cytometry tests: 72 -96 hours  
Karyotype studies 48 hours  
FISH studies: 48 hours  
DNA testing: 7 days from receipt of sample
The Clinical Cytogenetics Laboratory

Introduction:

The Clinical Cytogenetics Laboratory provides a Regional diagnostic Cytogenetic service for acquired (oncology) chromosome abnormalities for haematological malignancy, sarcoma and solid tumour referrals. This document refers principally to the haemat-o- oncology (HMDS) service.

a) Key Staff and contact details:

Head of Laboratory: Julie Howard-Reeves, BSc, FRCPath. julie.howard-reeves@icr.ac.uk
Head of Haem-Onc Section: Tracy Thornton, BSc tracy.thornton@icr.ac.uk

Telephone: 020 8722 4232/ 4213 Central Laboratory and Fax
Group email: cytogenetics@icr.ac.uk

b) Location of Laboratory:

The laboratory is located in the McElwain Building, which is adjacent to the Royal Marsden Hospital, on its Sutton site.

c) Service offered:

The laboratory provides two main types of assay: karyotype (chromosome analysis) and FISH (Fluorescence in-situ hybridisation).

d) Hours:

The laboratory’s formal hours are 9am to 5.30pm, Monday to Friday. However, it is generally occupied from 8am to 6pm.

e) Out of hours service:

Samples are cultured out of hours and some processing is done. However, the Cytogenetics Laboratory does not operate a routine out of hours analysis and reporting service. It may be possible to undertake analysis for exceptionally urgent clinical referrals but only if sufficient notice has been given so that arrangements can be made for suitable staff to attend, as the laboratory does not have an on-call provision.

For urgent samples likely to arrive outside of the normal working hours, please notify the laboratory in advance. Such samples should be sent by courier to the RMH switchboard and enclosed in packaging that is clearly marked “Urgent” and “Please contact Cytogenetics”.

f) Specimen Request Form:

Samples must be accompanied by a completed request form, preferably the integrated SIHMDS request form that is also used for immunophenotyping histology and molecular diagnostics. Local forms are acceptable so long as they provide the minimum information:
The patient’s name, date of birth, and the NHS and/or Hospital number;
The type of sample;
If unfixed, the date the sample was taken;
The required test clearly indicated;
A named contact in case of enquiry.

The sample must have at least two forms of ID that match the ID on the request form.

g) Sample transportation:

Samples for cytogenetic studies should be sent directly to the laboratory:

RMH SIHMDS Laboratories
Clinical Cytogenetics Laboratory
The Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust
Cotswold Road
Sutton, Surrey SM2 5PT

Samples awaiting transportation can be kept at ambient temperature. If there is a delay, fresh samples for
Cytogenetics can be stored in a temperature-monitored laboratory fridge. There must be no risk of the sample being
frozen.

Samples for karyotype study are best sent by courier; most samples that are received within 24 hours will be
successful but the failure rate increases with delay and particularly when the cell count is high. First class post is usually
adequate for samples needing only a FISH study.

Transport and packaging of samples should be done following the sender’s policy for safe transport of pathological

Most samples will survive if sent in heparin only, e.g. in a vacutainer tube, as long as there is no delay in them reaching
the laboratory. If the cell count is high, then the cells will quickly exhaust the oxygen and will die, so it is particularly
important that such samples reach the laboratory quickly. The addition of culture medium will help; if none is available
locally, the laboratory can supply transport tubes with culture medium already added.

h) Advice and interpretation of results:

Reports normally contain an interpretation of the result. If further advice or interpretation is required, please
contact one of the senior staff in the laboratory on 020 8722 4232. For clinical advice, please contact the appropriate
consultant via RMH switchboard.

i) Referral elsewhere:

The laboratory does not routinely refer samples elsewhere

j) Laboratory repertoire:

The laboratory usually undertakes tests in accordance with the SIHMDS Diagnostic Pathway, summarised
below. It may also amend or discontinue tests if the results from the other SIHMDS laboratories indicate that it is
appropriate to do so.

1. The laboratory usually undertakes a karyotype (chromosome) study in the following circumstances:

   o All acute leukaemias at diagnosis.
   o CML at presentation, at acceleration or blast crisis, and at six-monthly intervals if on treatment with a
     TKI (e.g. Imatinib / Dasatinib) until a complete cytogenetic response is achieved; thereafter, an
     annual karyotype study for Ph-negative clones.
   o Myelodysplastic syndrome and aplastic anaemia at diagnosis.
Primary myelofibrosis and other myeloproliferative neoplasms if no driver mutations have been identified by molecular studies.

T-Prolymphocytic leukaemia

Burkitt lymphoma

2. The laboratory keeps stocks of the commercially-available, commonly-required DNA probes for haemato-oncology FISH studies. FISH studies are usually undertaken in the following circumstances:

- As an adjunct to karyotype studies, as appropriate.
- According to Trial requirements.
- CLL: Using two probes for deletion of ATM (at 11q22) and TP53 (at 17p13). If the immunophenotype study reports CD5 positivity with a low CLL score, then FISH is done with probes for IGH-CCND1 to check for a t(11;14)(q13;q32).
- Abnormal eosinophilia, with probes for PDGFRα, PDGFRβ and FGFR1.
- Lymphomas: Not all lymphomas are routinely studied, but the laboratory stocks probes relevant to some lymphoma types (including ALCL, Burkitt, mantle cell, DLBCL, follicular, MALT) which can be applied on request.
- Myelomas: Samples normally undergo CD138+ve cell selection; FISH studies are done with the current appropriate panel of probes which provide prognostic information.
- Follow-up samples when a suitable cytogenetic abnormality has already been identified and if a more sensitive result cannot be provided by immunophenotyping or molecular diagnostics.
- Studies of samples that have not provided metaphase divisions for karyotype analysis, where a specific chromosome abnormality is anticipated from the diagnosis.
- Studies of previously-fixed samples supplied for specific tests. This includes cytopsins and paraffin-embedded sections.
- Upon specific request by the referring clinician.

k) Exclusions:

The laboratory does not provide a service for routine follow-up assessment if this can be done better by the molecular or immunophenotyping laboratories, unless specifically requested to do so.

In certain cases, if the immunophenotype finding indicates that the disease suspected is not present then the Cytogenetic analysis may be discontinued, but fixed cells are stored in case cytogenetic analysis is still required.

l) Specimen requirements:

The preferred tissue in most cases is a good-quality bone marrow aspirate. If the sample is scanty, please send blood as well. The sample should be collected in heparin. (EDTA is not suitable for a chromosome study and is suboptimal for FISH studies.)

Studies of ascites and pleural effusions are usually successful if enough cells are present; a chromosome study can distinguish between malignant and reactive effusions. These samples should be collected into sterile containers.

For diagnosis of lymphoma, a fresh sample of the primary tissue is preferred rather than secondary tissues such as bone marrow. A karyotype study is not an efficient way of excluding BM infiltration.

CSF is not suitable for a karyotype study but a FISH study for a previously-identified abnormality is usually possible.
m) **Criteria for accepting/rejecting samples:**

The laboratory reserves the right to reject all unlabelled samples. In view of the difficulty of replacing some samples, they may be processed and an analysis attempted. The report will indicate that the sample was unlabelled / incorrectly labelled and will state that the decision to act on the report resides with the referring clinician.

n) **Reporting times:**

Karyotype studies: Cells have to be cultured for at least 17 hours to collect suitable divisions, and up to five days for some diagnoses. The processing and slide preparation can take a further 1-2 days. In difficult cases, preparation of extra slides can add further delays.

- FISH studies: the initial processing takes two days (most tissues) or three days (sections). In a case of suspected APML a *PML-RARA* FISH study may be processed, analysed and reported sometimes within the same day if received early enough. For all studies, the analysis time is variable.

Professional guidelines state that 95% of high-priority samples should be reported within 14 calendar days, and 95% of standard-priority samples within 21 days. In practice, most samples are reported well within these times, depending on the cultures and tests required. Some very urgent results can be obtained in less than 24 hours. In some cases, such as myelomas, analysis is usually done on a sequential basis depending on initial findings, which is more cost-effective than undertaking all possible FISH tests at once but does take longer.

If a result is needed for a particular date, please notify this date in advance to the laboratory and every effort will be made to meet it.

o) **Factors affecting success rate/results:**

The most common causes for failing to obtain a karyotype result are –

- Delay in receiving sample
- Clotted sample
- Inadequate sample
- Inappropriate sample
- Wrong sample container (EDTA instead of heparin).
- High cell count

Note also that clonal cells may be at a very low level in, or absent from, the dividing cell population, and so may not be represented in the cells analysed. In addition, some abnormalities are cryptic and cannot be seen in a karyotype study.

See also the comments in section g, above.

p) **Quality assurance:**

The laboratory participates in all the relevant UK Quality Assessment Schemes for cytogenetics, and Performance Certificates are available upon request. It is accredited to UKAS standard ISO15189.

q) **Time limits for further tests:**

Requests for additional tests or a change to the tests on the request form can be accommodated in cases where the appropriate cultures were originally initiated. If different cultures are needed, and a chromosome study is wanted, then the request has to be made well within 72 hours of the sample being taken.

Any remaining fixed material is stored for at least one year in case further diagnostic studies are required. Note: This material is not available for research unless all the appropriate written consents and ethical clearances have been obtained.

r) **Other studies: Solid tumours**

The laboratory provides a FISH service for diagnostic studies of sarcomas and selected other solid tumours, and can supply a specific request form for these investigations that describes the type of material needed. The probes currently stocked include:

- ALK at 2p23
- DDIT3 (CHOP) at 12q13
EWSR1 at 22q12
ETV6 at 12p13
FOXI1 (FKHR) at 13q14
FUS at 16q11
MDM2 at 12q15
SS18 (SYT) at 18q11
**ROS at 6q22**
RET at 10q11
USP6 at 17q13.2
Clinical Genomics Department
Molecular Diagnostics Laboratory

This document describes the service provided by the Molecular Diagnostics Laboratory. The laboratory is accredited by UKAS standard ISO15189 (Lab no: 9839)

a) Staff and contact numbers:

For enquiries please contact the laboratory on the telephone numbers below:

Main office enquiries: 020 8915 6565
Dr Lisa Thompson, Head of Clinical Genomics (Diagnostics)
Dr Michael Hubank, Head of Clinical Genomics (Translational Research)
Dr Sandra Hanks, Laboratory Manager-
Ms Dorte Wren, Consultant Clinical Scientist, (Acting lead for HMDS – Molecular)
Dr Suzanne MacMahon, Senior Clinical Scientist, Solid tumours-
Ms Dee Collins/ Ms Marion Sullivan; Team Administrator-
Fax: 020 8915 6566
We can also be contacted by email:
rmh-tr.moleculardiagnostics@nhs.net

b) Location:

Clinical Genomics Department
Molecular Diagnostics
The Centre for Molecular Pathology
The Royal Marsden Hospital NHS Foundation Trust
15 Cotswold Road, Sutton, Surrey, SM2 5NG

c) Service provided:

The laboratory provides rapid and accurate molecular profiling of solid tumour and haematological malignancies. Working together with immunophenotyping, cytogenetics and histology services, Molecular Diagnostics forms part of the integrated Haematological Malignancies Diagnostic Service, which operates in compliance with NICE Improving Outcomes Guidance. Working closely with our Translational Research team we are able to rapidly translate novel techniques into the diagnostic setting, contributing to the development of new cancer diagnosis tools for precision medicine.

d) Hours of service:

9.00am to 5.00pm, Monday to Friday.
e) **Out of hours service:**
Currently no out of hours service is provided. Samples received after 5.00pm will be processed the following working day.

f) **Instructions for completion of the request form:**
Please fill **ALL** the fields provided with the relevant demographic/clinical information. For patient’s details, stickers with the patients information can be used. Similarly, stickers can be used for the Consultant and referring hospital information.

If some information is unknown or not applicable please fill the field in with “UNKNOWN” and “N/A”, respectively, rather that leaving it blank. Samples with attached request forms that do not contain all the relevant information can be rejected by the lab or put “on hold” until a new and completely filled request form has been received.

Please tick which investigations are to be performed. If in doubt please contact us on the numbers given above.

g) **Sample acceptance / rejection**
Samples e.g. peripheral blood, bone marrow, must be labelled with the patient first name and surname, D.O.B., hospital number and the date and time the sample was taken. In the case of FFPE sections and blocks, the histopathology number must be clearly displayed. The details on the sample must correspond to those on the request form. Unlabelled samples will **NOT** be accepted.

h) **Transportation of samples:**
Internal samples - will be sent -together with the request form- to Clinical Pathology (RMH, Sutton, 1st floor), as per Trust policy, as soon as possible after taking the sample. In the case of samples sent from the Chelsea site, they will be transported in the pathology containers on the RMH inter-site coach, to be delivered to Clinical Pathology. Samples will be then collected from Clinical Pathology by Laboratory staff and taken to The Centre for Molecular Pathology. See HSE guidance on [http://www.hse.gov.uk/biosafety/biologagents.pdf](http://www.hse.gov.uk/biosafety/biologagents.pdf)

External samples - please package samples according to the HSE guidance and address specimens to:

RMH SIHMDS Laboratories  
Clinical Genomics Department  
Molecular Diagnostics Laboratory  
The Centre for Molecular Pathology  
The Royal Marsden Hospital NHS Foundation Trust  
15 Cotswold Road  
Sutton  
Surrey, SM2 5NG

i) **Availability of Clinical advice and interpretation:**
Please contact us on the numbers provided above if you need help with the interpretation and/or clinical significance of the results issued by our laboratory. For clinical advice, however, please contact any of the Haematology Consultants in the Haemato-Oncology clinical Unit at the RMH via Switchboard on **020 8642 6011**

j) **Specimens required, laboratory repertoire, turnaround times and performance issues:**
We can process peripheral blood/bone marrow in EDTA; Formalin-fixed paraffin embedded (FFPE) sections and blocks or fresh frozen tissue.
We prefer samples collected in EDTA since heparin can inhibit the PCR reaction. However, we can process heparin samples if needed. Samples should be sent on the day of collection and at ambient temperature. Clotted samples are unsuitable for molecular analysis, in these situations please obtain a new sample if possible.

Samples for MRD monitoring should ideally be received 24-48hrs after collection to ensure a reliable result can be obtained.

**Peripheral blood (PB) in EDTA** - please send 3-10 mL of PB except in the case of MRD and Chimerism studies where 10-20 mL of blood is recommended.

**Bone Marrow (BM) in EDTA** – please send at least 1 mL of BM unless this is not feasible (e.g. paediatric samples).

**Body fluids** can also be processed if the cell count is at least $10^5$.

**FFPE blocks** – please send a representative tissue block with a return address.

**FFPE sections** - please send one H&E section and three 10 µm mounted sections. Plain (uncharged) slides

For more information on how to process these samples and for request forms please contact us by phone or email.

**Investigations performed:**

We provide both qualitative and quantitative PCR analyses, depending on the type of test required. Quantitative PCR by Real-Time PCR is performed for Minimal Residual Disease (MRD) monitoring, whilst semi-quantitative PCR/allele-specific PCR and fragment analysis is performed for Chimerism, certain mutation analysis and clonality analysis. NGS panels are used for most mutation analysis.

The percentage conformance turnaround time is provided for each test type and is dependent on the sample quality, percentage tumour infiltration and additional testing requirements e.g. sequence confirmation.

### Molecular Diagnostics

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Cell Clonality</td>
</tr>
<tr>
<td>TCell Clonality</td>
</tr>
<tr>
<td>IGHV Mutational Status</td>
</tr>
<tr>
<td>Chimerism</td>
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<tr>
<td>BCR-ABL</td>
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<tr>
<td>Acute leukaemia mutation panel (NGS)</td>
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<tr>
<td>Includes FLT3*, NPM1, IDH1, IDH2, RUNX, TP53, CEBPa, KIT</td>
</tr>
</tbody>
</table>

1. **Mutation detection**

We perform mutation detection using a bespoke pan-cancer targeted Next Generation Sequencing DNA panels encompassing frequently mutated genes. A laboratory defined virtual panel specific to the tumour type (see table below) will be applied and reported in line with the NHSE National Genomic Test Directory for Cancer. The panel can detect single nucleotide variants and small insertion/deletions. Supplementary methods e.g. fragment analysis, direct Sanger sequencing and ARMS/ASO-PCR will be employed for complex mutations, confirmation of low level variants, large insertion/deletions or in cases of low quantity/quality DNA obtained from the sample.
NGS and Fragment analysis performed

*IDH1 and IDH2 mutation detection in AML* is supported by Celgene Ltd.

*TP53 mutation detection in CML* is supported by Janssen-Cilag Ltd.

Please contact the laboratory for further information and request forms for the services provided above.

### Turn Around Times Percentage conformance (NGS panel)

- >90% of results expected within 21 calendar days

### Turn Around Times Percentage conformance (mutation specific)

- >90% of results expected within 14 calendar days

2. **Clonality assessment**: clonality tests for B-cell receptor (*IGH* and *IGK* genes) and T-cell receptor (*TCRB* and *TCRG*) are performed by fluorescent PCR amplification using the BIOMED2 protocols, followed by GeneScan analysis. For **B-cell clonality**, we analyse at least 5 of the following targets: FR1, FR2, FR3 and DJ for the *IGH* genes, and VJK and KDE for the *IGK* genes. **T-cell clonality** analyses are performed using 5 different targets: 2 PCRs for the *TCRB* VDJ rearrangements, 1 for *TCRB* DJ rearrangements and 2 PCRs for *TCRG* VJ rearrangements. By combining the different targets the sensitivity of the analysis is >95%.

### Percentage conformance

- >90% of results expected within 14 calendar days

3. **Mutational status of the Ig Variable regions**: the mutational status of *IGHV* in CLL is routinely analysed for prognostic purposes if requested.

### Percentage conformance

- >90% of results expected within 21 calendar days

4. **The analysis of fusion genes in acute leukaemias** is performed quantitatively by Real-Time PCR on RNA samples from AML, ALL and CML patients. We currently have one panel of fusion genes for AML (*PML-RARA, RUNXI-RUNXI1, CBFB-MYH11* and *BCR-ABL1*) and another one for ALL (*BCR-ABL1, ETV6-RUNXI, TCF3-PBX1, KMT2-AFF1* and *STIL-TAL1*—only for T-cell leukaemias). *BCR-ABL1* is also analysed in suspected CML. We perform MRD analysis of acute leukaemias (or CML) only if we know that one of the markers was present at diagnosis.

### Percentage conformance

- >90% of results expected within 14 calendar days

In the case of urgent haemato-oncology RT-PCR >90% of results expected within 5 calendar days

5. **Chimerism analysis**: For this analysis we require a donor sample and a sample from the patient prior to transplantation. We perform lineage-specific Chimerism analysis (CD3 v CD15) ONLY in peripheral blood samples unless otherwise stated.

### Percentage conformance

- >90% of results expected within 14 calendar days

### Performance issues:

| **TP53 gene targeted NGS (CLL)** |
| **BRAF gene targeted NGS (HCL)** |
| **Translocation panel AML/ALL (RT-PCR)** |
| **MPN NGS panel (JAK2Exon 12 & 14/CAL-R & c-MPL)** |
| **JAK2 Exon 12 & 14** |

Extended NGS panels (please contact the laboratory for further information)
Fresh liquid samples **MUST** be kept at ambient temperature and reach our lab within 24-48 hours from venepuncture to allow for successful DNA/RNA extraction (except frozen samples, FFPE tissue samples or PB/BM films, where there is no limit). Occasionally, samples older than 48 hours will be analysed (i.e. samples collected over the weekend/bank holiday periods), although in these cases the chances of a successful report are significantly diminished.

Other factors affecting the reliability of results include:

Clotted samples
Inadequate samples
Leaking samples
Inappropriate sample
Incorrect collection tube used i.e. anticoagulant
Inadequate sample labelling
Inadequate request data quality

**k) Time limit for requesting additional examinations:**

All DNA and RNA samples are stored indefinitely for all examinations. FFPE blocks will be returned to the referrer once testing is complete.

Please note that we only store DNA or RNA, depending on the investigation originally requested, and therefore we will not be able to perform a DNA-based investigation on a sample where we only stored RNA and vice versa.

**l) Organisational and departmental approach to protection of personal information**

The Trust and all laboratories operate in conformance with the Data Protection Act 1998 and Computer Misuse Act 1990 applied by the Confidentiality and Data Protection Act Policy. All staff must undertake annual mandatory training in Information Governance.

**m) Complaints procedure**

The Trust has a formal Concerns and Complaints Policy and Procedure: all concerns and complaints are taken seriously and fully investigated with responses provided to the persons raising these. Pathology also has a policy and procedure for dealing with complaints addressed directly to the laboratories.
Haematopathology Laboratory

Introduction
This guide deals briefly with the Histopathology available services available to the Royal Marsden NHS Foundation Trust. It is intended to enable the users of the Department to make the best use of the Laboratory service. The information provided includes the type of specimens required and the range of tests routinely performed. In order to provide you with the most efficient service, it is essential that a fully completed form accompanies a correctly labelled sample. This ensures that there is no possibility of assigning samples to the incorrect patient request. A copy of the referring hospitals report is also required with all outside review cases.

a) Staff and contact details

Key Histopathology Staff, CMP Sutton

<table>
<thead>
<tr>
<th>Staff</th>
<th>Title</th>
<th>Contact No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr A Wotherspoon</td>
<td>Head of Department and Consultant Histopathologist</td>
<td>6559</td>
</tr>
<tr>
<td>Dr A Attygalle</td>
<td>Consultant Histopathologist</td>
<td>6559</td>
</tr>
<tr>
<td>Dr S O'Connor</td>
<td>Consultant Histopathologist</td>
<td>6559</td>
</tr>
<tr>
<td>Dr Katherine Vroobel</td>
<td>Consultant Histopathologist</td>
<td>6559</td>
</tr>
<tr>
<td>Ms N Peters</td>
<td>Laboratory Manager</td>
<td>6549</td>
</tr>
<tr>
<td>Ms C Shipley</td>
<td>Senior Biomedical Scientist</td>
<td>6576</td>
</tr>
<tr>
<td>Mr D Asa</td>
<td>Senior Biomedical Scientist</td>
<td>6576</td>
</tr>
<tr>
<td></td>
<td>Specimen Reception</td>
<td>6572</td>
</tr>
<tr>
<td></td>
<td>Medical PA</td>
<td>6559</td>
</tr>
</tbody>
</table>

b) Location of Laboratory

The Histopathology department is located on the ground floor of the Centre for Molecular Pathology. Access to the department is controlled via electronic locks which are opened by authorized ID badges only. Please contact Natalie Peters if legitimate access is required.
c) Services offered

The laboratory offers:

- a wide panel of tinctorial and immunohistochemical techniques for the diagnosis and disease monitoring of haematology-oncology malignancies
- processing formalin fixed tissue to paraffin wax blocks

A full list of techniques is available on request.

d) Hours

Laboratory opening:

- Weekdays: 8.00-17.00
- Fresh samples are accepted up to 16.30

Medical PA 08.30 – 17.00

e) Out of hours service:

The Laboratory does not currently offer an out of hours service.

f) Specimen request form:

Samples must be accompanied by the integrated SIHMDS request form. Please ensure that all the relevant fields are completed. The minimum data required for accepting a sample is: Name, Date of Birth and hospital number/ NHS number, for pre-processed tissue a histopathology report from the original institution is also required. It is the responsibility of the medical officer to ensure that the request forms and specimens carry all of the correct information. If the material has come from an external institution a copy of their report must also be included to ensure the material is processed.

Request forms that are incorrectly filled in, mislabelled or missing the external report may incur a delay.
A contact name and telephone number must be provided in case of queries regarding the sample.

g) Sample transportation:

Within the hospital, samples must be sent to the laboratory in a sealed (mini grip) bag with the request form (and any other relevant additional information) in the open envelope on the side of the bag.

Specimens being transported from Sutton to Fulham Road, and vice versa, in a green pathology transport bag which complies with UN3373 regulations. Specimens are put into mini grip bags with the forms in the separate envelope section. Larger specimens are put in white bags, which are tied into a knot.

External samples for Haematopathology should be sent directly to the laboratory via courier or post to the following address:

RMH SIHMDS Laboratories
Histopathology Department
Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust Hospital
Downs Road
Sutton
Surrey
SM2 5NG
Transport and packing of samples should be done in line with the sender’s policy for the safe transport of pathological specimens.

**h) Referral elsewhere**

The laboratory does not routinely refer haematopathology samples elsewhere.

**i) Laboratory repertoire:**

We offer both immunohistochemistry and tinctorial demonstration techniques for the diagnosis of Haematopathology samples. The department has >100 routine immunohistochemistry antibodies.

1. Individual specialist immunohistochemistry antibodies for clinical diagnosis include:
   - CD27
   - CD13
   - CD33
   - Fascin
   - FOXP1
   - Perforin
   - SOX11

2. Diagnostic immunohistochemistry antibody panels for diagnosis of haematopathology conditions including:
   - T cell follicular helper cell markers comprising of PD1, ICOS and CXCL13
   - Hairy Cell Leukaemia Diagnosis IHC markers including Annexin A1, CD25, TRAP, CD11c, CD123

**j) Specimen requirements:**

Samples sent to the Histopathology Laboratory should be:

- Wet tissue in 10% neutral buffered formalin
- Formalin fixed paraffin embedded tissue
- Stained slides with accompanying representative block of tumour, and/ or twenty 1µm unstained slides on positively charged slides

**k) Reporting and turnaround times**

1. **Results and Enquires**

   For all enquiries regarding results please contact the Histopathology medical PA on 6559.

   For booking in enquiries please contact Ext 6570 or 6571.

2. **Results on HIS/EPR**

   The results of all cases dealt with by the Department are entered on the Hospital computer when they have been fully signed off. These are accessible to the users of the Hospital system under ‘Electronic Patient Records’.

   Samples may have been booked under either the patient’s 10 digit NHS Number or a temporary E-Number rather than the 6 digit RMH Number, if the patient was not registered at the time of booking. Users should therefore search using
patient name and/or date of birth if no record exists under the RMH number. It must be stressed that under the Department’s policies results will not be given over the telephone.

3. Result Validation

Once reports have been signed results are available on the HIS System via the EPR. Please note that results will not be given out over the telephone. Queries should be directed to the relevant consultant, please contact medical PA on ext 6559.

The laboratory participates in NEQAS assessment programs for routine cellular pathology techniques and immunohistochemistry, interlaboratory comparisons have been established for techniques not within the remit of external EQA assessment programmes. This ensures that the high quality of work within the department is maintained. All consultant pathologists participate in national EQA schemes.

4. Issuing of reports

Histopathology results are available on the hospital computer system, as soon as they are signed off by Consultants, via EPR. Samples may have been booked under the patients 10 digit NHS number or a temporary E-number rather than the 6 digit RMH number if the patient was not registered at the time of booking. Users should therefore search using the patient name and/or date of birth if no record exists under the RMH number.

Copies of the signed reports are filed and the original requests are stored in chronological order prior to electronic archiving. Copies of signed reports and request forms are available on request from the appropriate medical PA. Results for samples processed and reported within the laboratory will be sent electronically using NHS.net or faxed to an appropriate member of the user’s medical team to a secure fax machine, to ensure patient confidentiality, as per the RMH and local department policy.

Reports for users signed up to the Trust ‘order and view’ system will automatically be sent to the portal on release of either the histopathology report (for cases where an integrated report is not required) or on release of the integrated report.

5. Turnaround times (TAT)

Histopathology

- Biopsies, Bone Marrow Trephines: TATs 8 working days in 85% of cases. Does not include additional testing such as reflex testing/additional clinical genomics testing.

Urgent Samples

- Please make sure that a request for a sample to be done urgently is only made when it is essential for the patient’s wellbeing and not for convenience. Unnecessary urgent requests delay other patient results as they are placed ahead in the work schedule. Indicating the date of the patient’s next appointment on the histopathology request form will enable prioritization of samples.

Referral cases

- On receipt of all relevant material: TAT 8 working days in 85% of cases. Does not include additional testing such as reflex testing/additional clinical genomics testing.

1) Sample storage and disposal

1. Formalin fixed tissue
Wet tissue specimens are retained for at least a period of four weeks after the final report has been issued, as recommended by the Royal College of Pathologists ‘Retention and storage of pathological records and specimens (5th Edition April 2015)’ report. Tissue is then disposed of.

2. Paraffin wax blocks and microscope slides
Blocks and slides are kept indefinitely. This conforms to the recommendations by the Royal College of Pathologists ‘Retention and Storage of pathological specimens (5th Edition, April 2015).

m) Clinical Advice and Interpretation

All Consultant Pathologists in the department are available to give clinical advice and interpretation pertaining to their reports, and all seek to ensure that the diagnostic repertoire is clinically relevant. All Consultants attend the MDT’s relevant to their clinical specialty.

Laboratory Scientific staff are available to offer advice and information on procedures undertaken within the department, including factors which might affect the performance of a test or the interpretation of results.