

Department of Paediatric Laboratory Medicine

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Haematology

Handbook for External Users

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**Welcome to the Department of Haematology at Great Ormond Street Hospital for Children NHS FoundationTrust**

The Department of Haematology is committed to providing a service of the highest quality and shall be aware of and take into consideration the needs and requirements of its users. As an external user, we are delighted to be able to offer a comprehensive service of some of the most specialised tests in paediatrics.

This hand book gives details of the tests we offer to external users, how to request these tests, sample requirements as well as the clinical advice available.

Results are available via the GOSH portal, please contact the laboratory manager of the relevant section for details of how to access the results portal.

The Haematology department is a UKAS accredited medical laboratory, No. 8623. Unless otherwise stated, all the tests we offer are UKAS accredited. The department transitioned over from CPA in 2017 and have continued throughout this time to maintain the high standards demanded of UKAS. Please log on [www.ukas.com](http://www.ukas.com) for the most recent reports on our accreditation status.

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A price list for the tests offered is also available, please contact the laboratory manager for further details. Invoices are sent once the results have been authorised

The department also offers a full range of routine tests and are always willing to assist other laboratory providers in times of need. Please contact the laboratory manager for further information.

**Contact us**

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| Main hospital switchboard | **020 7405 9200** | |
|  | **Telephone** | **Bleep / direct line** |
| Out of hours service 20:00 - 08:00 Monday to Friday and all weekend and bank holidays | | |
| Haematology and Coagulation | Switchboard and ext 5390 |  |
| Blood Transfusion | 0207 813 8527 | bleep 0590 |
| Routine working hours Monday to Friday 08:00 – 17:30 |  |  |
| Laboratories |  |  |
| Haematology and Coagulation specimen reception | 5388 |  |
| Haematology Laboratory | 5390 |  |
| Coagulation Laboratory | 5387 |  |
| Blood Transfusion Laboratory | 8527 | direct line 0207 813 8527 |
| Blood Transfusion emergency line | 8158 | bleep 0590 |
| SIHMDS – Flow Cytometry | 7901 / 1481 | direct line 0207 829 7901 |
| SIHMDS – Molecular BMT / Immune Reconstitution | 5400 |  |
| SIHMDS – Molecular MRD | 5400 | direct line 0207 829 7901 |

**Who’s Who**

|  |  |  |  |
| --- | --- | --- | --- |
| Senior laboratory staff | | | |
| Lead Laboratory Manager | Christine Morris | 8664 | Direct Line 0207 829 8664 |
| Haematology and Coagulation Laboratory Manager | Kiran Sagoo | 7883 | Direct Line 0207 829 7883 |
| Blood Transfusion Laboratory Manager | Penny Eyton-Jones | 8467 | Direct Line 0207 813 8467 |
| Quality Lead | Kelly Cripps | 5515 |  |
| Transfusion Practitioner | Rachel Moss | 5396 | bleep 0189 |
| SIHMDS Flow Cytometry Lead Healthcare Scientist | Rebecca Thomas | 7901 | Direct Line 0207 829 7901 |
| SIHMDS Molecular BMT / Immune reconstitution Lead Healthcare Scientist | Susanne Kricke | 5400 / 5762 | Direct Line 0207 829 5400 |
| Clinical advice | | | |
| Haematology Specialist Registrars - Laboratory |  | 5394 / 0235 | bleep 0006  OOH via switchboard 0207 405 9200 |
| Haematology Specialist Registrars - Haemophilia |  | 5394 / 0235 | bleep 0381  OOH via switchboard 0207 405 9200 |
| Haematology Consultants, CNS and the BMT team |  |  | Contact the relevant Haem SpR in the first instance |

# Advisory Services

**Clinical advice**

The laboratory specialist registrars and consultants are contactable for clinical advice from 09:00 – 17:30 Monday to Friday

At all other times a Specialist Registrar and Consultant are on call and contactable via the switchboard.

The laboratory Specialist Registrars and Consultants are contactable for clinical advice including;

* clinical indications and choice of appropriate tests
* advice on individual clinical cases
* professional judgement on the interpretation of the results of examinations

**Technical and Scientific advice**

Please contact the laboratory before collecting samples if you require any advice around the service or testing.

# Sample Labelling

### All samples must be taken and labelled in accordance with National Guidelines at the patient bedside for patient identification. Please refer to individual tests for specific sample requirements.

All samples must be accompanied by a request form, which are available on the website. For Blood Transfusion samples, the name and signature of the venesector is also required.

In instances where a sample fails to meet laboratory acceptance criteria, the requesting ward or doctor will be contacted and a statement to that effect documented in the report.

**Request Forms**

Please complete an appropriate request form to accompany the sample. Specific request forms the following tests can be downloaded from our website:

<https://www.gosh.nhs.uk/wards-and-departments/departments/laboratory-medicine/>

Please discuss request for blood film/ bone marrow film morphology with the Haematology Specialist Registrar covering the laboratory before sending the sample.

The request form must also contain the address for the invoice. The cost of each test is available on request.

**Sending us a Sample**

Please send samples to the following addresses:

|  |  |
| --- | --- |
| **Haematology, Coagulation and Blood Transfusion**  (including slides for the haematology registrars) | **Specialist Intergrated Haematological and Molecular Diagnostic Service (SIHMDS)**  (Flow cytometry, molecular BMT/ immune reconstitution, molecular MRD) |
| Haematology Department  Level1  Camelia Botnar Laboratories  Great Ormond Street Hospital  Great Ormond Street  London  WC1N 3JH | SIHMDS  Level 2  Camelia Botnar Laboratories  Great Ormond Street Hospital  Great Ormond Street  London  WC1N 3JH |

**Accessing your Results**

Results are available from the results portal on our website. The Turnaround time for each test is given in the test section.

In order to gain access to the results portal, please complete the [nQuire application form](http://www.labs.gosh.nhs.uk/media/762011/nQuire%20access%20request%20form.pdf)on the web page. Alternatively, please telephone the laboratory for results.

Grossly abnormal or unexpected abnormal results are automatically telephoned to the requesting ward or doctor.

### Requesting additional investigations

If additional investigations are required after the specimen has been dispatched or processed by the laboratory, please telephone as soon as possible.

There is a practical time limit for requesting additional investigations, as the laboratory stores specimens for variable time periods before disposal.

Please note that some specimens deteriorate in storage rendering them unsuitable for further investigation.

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| **Laboratory Investigations** | | | | | |
| Haematology | | | | | |
| **Test** | **Sample requirements** | **Turnaround time** | **Additional information** | **Contact the laboratory to arrange the test in advance** | **Form to use** |
| Blood Film Report, including bone marrow slides | 0.3ml venous or capillary blood, EDTA | 72 hours | Unstained films or stained with May-Grünwald / Giemsa. Clearly state the patient's forename, surname, hospital number and date of collection on each slide.  Please state the reason for request. | Discuss with the Haem SpR before sending | Blood Film request form |
| FBC | 0.5ml venous or capillary blood, EDTA | 2 hours | Must arrive within 6 hours of collection | Not required | FBC request form |
| Glucose-6-Phosphate Dehydrogenase (G6PD) | 5ml venous or capillary blood, EDTA or lithium heparin | 8 days | Please state the reason for the request.  Please send a control sample from a normal caucasian female bled at the same time as the patient. | Please contact the laboratory when sending urgent samples. | Red cell enzyme request form |
| Methotrexate Level | 1ml venous or capillary blood, EDTA or serum | 24 hours | State number of hours post start of methotrexate infusion. Samples must arrive by 14:00 Mon-Fri and by 11:00 at weekends and bank holidays.  This assay is unsuitable for patient’s who are on glucarpidase rescue treatment. | Please contact the laboratory to arrange the test in advance, if sending out of hours or at weekends. Samples must be booked with the laboratory on Friday if required at the weekend or during a bank holidays. External requests must use the Great Ormond Street methotrexate request form.  If the patient is on glucarpidase rescue treatment. Please contact the laboratory before taking the sample. | Methotrexate request form  Sample from patients on glucarpidase rescue treatment sent to:  Biochemistry Department  University College Hospital  60 Whitfield Street  W1T 4EU |
| Red Cell Folate | 0.5ml venous or capillary blood, EDTA | 48 hours | Sample processed for FBC to provide a haematocrit. | Not required | External requests must use the Great Ormond Street red cell folate request form. |

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| **Laboratory Investigations** | | | | | |
| Coagulation | | | | | |
| **Test** | **Sample requirements** | **Turnaround time** | **Additional information** | **Contact the laboratory to arrange the test in advance** | **Form to use** |
| Anti-Xa Assay | 1.4ml venous blood, citrate (0.5ml neonatal coagulation bottles are unsuitable for this test) | 12 hours | Fill exactly to the line indicated on the bottle. Sample must arrive within I hour of collection.  0.5ml neonatal coagulation bottles are unsuitable for this test.  Capillary samples are unsuitable for coagulation tests.  If the sample is not taken by a peripheral route, it is essential to avoid heparin contamination.  Samples must be taken 4-6 hours post last dose of low molecular weight heparin. | Please contact the laboratory prior to sending samples | External requests must use the Great Ormond Street  anti-Xa request form. |
| Factor Assays (APTT Based)  VIII IX XI XII | 2 x 1.4ml venous blood, citrate | 10 days | Fill exactly to the line on the bottle. Must arrive within 2 hours of collection. Capillary samples are unsuitable for coagulation tests. 2.8ml will be sufficient for all tests and a coagulation screen. Factors VIII, IX, XI and XII will be performed. | Please contact the laboratory prior to sending samples |  |
| Factor Assays (PT Based)  II V VI X | 2 x 1.4ml venous blood, citrate | 10 days | Fill exactly to the line on the bottle. Must arrive within 2 hours of collection. Capillary samples are unsuitable for coagulation tests. 2.8ml will be sufficient for all tests and a coagulation screen. Factors II, V, VII and X will be performed. | Please contact the laboratory prior to sending samples |  |
| Factor VIII Chromogenic | 1.4ml venous blood, citrate | 10 days | Fill exactly to the line on the bottle. Must arrive within 2 hours of collection. Capillary samples are unsuitable for coagulation tests. If performed with other factor assays, 2.8ml will be sufficient for all tests and a coagulation screen. | Please contact the laboratory prior to sending samples |  |
| Inhibitor Assays | 3 x 1.4ml venous blood, citrate | 10 days | Fill exactly to the line on the bottle. Must arrive within 2 hours of collection. Capillary samples are unsuitable for coagulation tests. | Not required |  |
| Factor VIII : Vwf Antigen Ratio | None | 30 days | This test is a ratio of factor VIII to vWF antigen. No sample is required for the ratio itself. | Not required |  |
| Fibrinogen Antigen | 1.4ml venous blood, citrate | 90 days | Fill exactly to the line indicated on the bottle. Sample must arrive within 2 hours of collection. Capillary samples are unsuitable for coagulation tests. | Not required |  |

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| **Laboratory Investigations** | | | | | |
| Blood Transfusion | | | | | |
| **Test** | **Sample requirements** | **Turnaround time** | **Additional information** | **Contact the laboratory to arrange the test in advance** | **Form to use** |
| Blood Group and Antibody Screen | 2ml venous blood, EDTA (Blood Transfusion bottle only) | Up to 48 hours | Handwritten and signed by the person who identified and bled the patient. Sample must be labelled at the patient bedside in accordance to BSH Guidelines | Please contact the laboratory if the sample is urgent. | Complete external form, venesector name must be included on the form |
| Direct Antiglobulin Test | 1ml venous blood, EDTA (Blood Transfusion bottle only) | Up to 24 hours | Handwritten and signed by the person who identified and bled the patient. Sample must be labelled at the patient bedside in accordance to BSH Guidelines | Not required | Complete external form, venesector name must be included on the form |
| Isohaemagglutinin Titres  IgM and Total Isohaems (IgG + IgM) | 2ml venous blood, EDTA (Blood Transfusion bottle only) | Up to 7 days | Handwritten and signed by the person who identified and bled the patient. Sample must be labelled at the patient bedside in accordance to BSH Guidelines | Please contact the laboratory when sending urgent samples. | Complete external form, venesector name must be included on the form |

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|  | **Laboratory Investigations** | | | | | | | | | |
|  | Specialist Intergrated Haematological and Molecular Diagnostic Service | | | | | | | | | |
|  | SIHMDS samples: discuss with laboratory as volume required is influenced by total cell count specifically immunophenotyping, MRD and engraftment analysis | | | | | | | | | |
|  | Flow Cytometry | | | | | | | | | |
| **Test** | | **Sample requirements** | **Turnaround time** | **Additional information** | | | | **Contact the laboratory to arrange the test in advance** | | **Form to use** |
| B-cell maturation panel | | ACD-A 9ml bottle, of BM aspirate | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Bone marrow/blood characterisation  (haematological) | | ACD-A 9ml bottle, Venous or BM aspirate  Note: Pancytopaenic patient may require larger volume | 5 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Bone Marrow film report | | bone marrow film or 0.3ml bone marrow, EDTA | 7 days | Clearly record the patient's surname, forename, hospital number and date of collection on each slide. | | | | Not required | | External referrals must use the Great Ormond Street blood film request form |
| CD66abce expression on leukaemic cells | | ACD-A 9 ml bottle, Venous or BM aspirate | 4 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| EMA binding (HS) | | EDTA Venous  Small volume required 200uls | 7 days | EMA can be performed on FBC sample | | | | Contact ext 1481 | |  |
| Erythroid Immunophenotyping | | ACD-A 9ml bottle, Venous or BM aspirate | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Flow MRD  (ALL, AML, Post BMT and CAR-T monitoring) | | ACD-A 9ml bottle, Venous or BM aspirate  Note: Pancytopaenic patient may require larger volume | 5 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping /Molecular MRD requests | | | | Not required | |  |
| Intra cellular markers  (MPO, cCD79a, cCD3) | | ACD-A 9ml bottle, Venous or BM aspirate | 4 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| iron stain | | bone marrow slide | 10 days |  | | | | Not required | |  |
| Lymphoid immunophenotyping | | ACD-A 9ml bottle, Venous or BM aspirate  Tissue Biopsy  (discuss with lab)  CSF, Pleural Fluid, Perrineal Fluid, Other Fluid – Put into sterile universal | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests  Optimally same day analysis is required | | | | Contact ext 1481 | |  |
| Lymphoma immunophenotyping | | ACD-A 9ml bottle, Venous or BM aspirate  Tissue Biopsy (discuss with Lab) | 3days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests  Discuss with lab size of sample required | | | | Contact ext 1481 | |  |
| MLL associated NG2 expression on leukaemia cells | | ACD-A 9ml bottle, Venous or BM aspirate | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Myelodysplastic/myeloproliferative disorders (diagnostic and follow up) | | ACD-A 9ml bottle, Venous or BM aspirate  Note: Pancytopaenic patient may require larger volume | 5 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Myeloid  immunophenotyping | | ACD-A 9ml bottle, Venous or BM aspirate | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests | | | | Contact ext 1481 | |  |
| Neuroblastoma solid tumour markers (diagnostic and follow up) | | ACD-A 9ml bottle, Venous or BM aspirate  Tissue Biopsy (discuss with Lab) | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping requests  Discuss with lab size of sample required | | | | Contact ext 1481 | |  |
| Platelet glycoproteins | | 1.4ml EDTA, Venous | 24hrs | To arrive in lab <3hrs post sampling  Hand deliver (do not put in chute system) | | | | Contact ext 1481 | |  |
| PNH | | 1.4ml EDTA, Venous | 4 days |  | | | | Contact ext 1481 | |  |
| Pre CAR-T Assessment and leukaemic cell quantification of:  -CD19  -CD22  -CD52  -CD7 | | ACD-A 9ml bottle, Venous or BM aspirate  Note: Pancytopaenic patient may require larger volume | 3 days | This analysis can be performed on an ACD-A sample that has been sent for other immunophenotyping/Molecular MRD requests | | | | Contact x1481 | | Form available at request |
|  | Molecular and Immune Reconstitution | | | | | | | | | |
| Test | | Sample requirements | TAT | | Additional information | | Contact the laboratory to arrange the test in advance | | External referrals | |
| ADA Mutation | | 1ml venous blood, EDTA | Up to 60 Days | | ISO 15189 accredited | | Not required | |  | |
| BMT engraftment studies | | 1ml venous blood, EDTA  Or  1ml bone marrow, EDTA | 10 days | | For whole blood chimerism or whole bone marrow chimerism only.  Please note that there is also a separate test for cell lineage chimerism analysis (listed in this table)  ISO 15189 accredited | | Not required | | The laboratory requires a pre-BMT and a donor sample to process this request. In case this is a first-time request, and these samples are not available, please contact the lab on 0207 405 9200 x5400. | |
| Cell lineage chimerism analysis | | 5ml venous blood, EDTA | 10 days | | ISO 15189 accredited | | Not required | | The laboratory routinely processes CD3+ T cells, CD15+ granulocytes and/or CD19+ B cells. Other cell lineages are available upon request. Please contact the lab on 0207 405 9200 x5400 for further information.  The laboratory requires a pre-BMT and a donor sample to process this request. In case this is a first-time request, and these samples are not available, please contact the lab on 0207 405 9200 x5400 | |
| Recipient Pre-BMT sample | | 1ml venous blood, EDTA  **Or** 10ng extracted DNA  **Or** buccal swab (sterile, no transport medium) | 30 days | | ISO 15189 accredited | | Not required | | This is a non-reportable test. A pre-BMT sample is required to interpret subsequent samples for engraftment/chimerism studies. | |
| Donor sample | | 1ml venous blood, EDTA  Or 10ng extracted DNA  Or buccal swab (sterile, no transport medium) | 30 days | | ISO 15189 accredited | | Not required | | This is a non-reportable test. A donor sample is required to interpret subsequent samples for engraftment/chimerism studies. | |
| Cell fractionation | | 5ml venous blood, EDTA | 7 days | | ISO 15189 accredited | | Not required | |  | |
| Spectratyping | | 5ml venous blood, EDTA | 28 days | | If requesting this test alongside the TRECS test, a total of 5ml is sufficient for both tests  ISO 15189 accredited | | Not required | |  | |
| TRECS analysis | | 5ml venous blood, EDTA | 28 days | | Also, if requesting this test alongside the Spectratyping test, a total of 5ml is sufficient for both tests  ISO 15189 accredited | | Not required | |  | |
| TRECs screening on Dried Blood Spots (Guthrie card) | | 1 dried blood spot | 28 days | | Not ISO 15189 accredited | | Contact laboratory on 0207 405 9200 x5400 | | Only available by prior arrangement.  For retrospective investigation of immune deficiencies only. | |
| Kymriah CART cell persistence by VCN | | 5ml venous blood, EDTA | 21 days | | ISO 15189 accredited | | Not required | |  | |
| **Dispatch/ Handling**  **Instructions for all Molecular and Immune Reconstitution samples** | | Transport to laboratory at room temperature.  Do not refrigerate samples.  Should be received within 72 hours of collection | | | | | | | | |
| **Request forms for external requests** | | Requests forms are available to users by emailing gos-tr.molhaem@nhs.net. | | | | | | | | |
|  | Molecular Minimal Residual Disease (molecular MRD) - including ALLTogether (A2G) Trial | | | | | | | | | |
|  | **1 Criteria for Accepting or Rejecting Samples** | | | | | | | | | |
|  | * All recommendations in this Handbook, for molecular MRD analysis of ALL samples, are taken from the A2G Trial 2019 Protocol for UKMRD Network. A copy of the handbook is available upon request by e-mailing [gos-tr.sihmdsmolecularmrd@nhs.net](mailto:gos-tr.sihmdsmolecularmrd@nhs.net). * If a sample does not fit any of the scenarios outlined in the six paragraphs below, the next course of action shall be discussed with a Haematology Consultant. | | | | | | | | | |
|  | 1. **Preparation of Patient** | | | | | | | | | |
|  | * No special requirements. | | | | | | | | | |
|  | **3 Consent** | | | | | | | | | |
|  | * Informed Consent, if given, by patient/ guardian is managed by the clinical team and signed evidence is sent to the GOSH Data Management Team. Data   Management Team informs laboratory staff via LIMS (EPIC) when any patient consents to A2G Trial.   * Molecular MRD samples are tested in exactly the same manner whether the patient is on Trial or not. * For GOSH patients who consent to the Trial, laboratory staff send some patient cells to the UK Biocentre at Stockport, UK and forward anonymised patient results to CRCTU (Cancer Research UK Clinical Trials Unit). | | | | | | | | | |
|  | 1. **Request Form** | | | | | | | | | |
|  | * All requests for molecular MRD analysis should be on an A2G 2019 MRD Request Form, whether the patient/ guardian has consented to the trial or not. If the   patient has consented to Trial, or for new diagnosis patients please also complete and send a Cell Bank sample information sheet. Please fill in all blank fields on forms.   * These forms are available to users by e-mailing gos-tr.sihmdsmolecularmrd@nhs.net | | | | | | | | | |
|  | 1. **Suitable Sample Type and Anticoagulant** | | | | | | | | | |
|  | **Sample Type** | | | | | **Minimum Amount** | | | | |
|  | Bone Marrow Aspirate | | | | | Diagnosis: 10 x106 mononuclear cells | | | | |
|  | All other timepoints: 5x106 mononuclear cells | | | | |
|  | Peripheral Blood – is only acceptable if the sample is a diagnostic sample from a patient who cannot provide a bone marrow aspirate.  Peripheral blood can only be used if the blast count is >20%.  Peripheral blood will not be accepted for relapse samples or for any other timepoints. | | | | | Diagnosis: 10 x106 mononuclear cells | | | | |
|  | All other timepoints: 5 x106 mononuclear cells | | | | |
|  | Bone Marrow Trephine – UNFIXED Trephine (in saline-soaked gauze) is only acceptable for diagnostic ALL samples with cell-poor, or no, accompanying bone marrow aspirate. | | | | | * In such cases an accompanying histopathology/flow cytometry report for the sample specimen is required to proceed with molecular MRD using a trephine sample. * If the sample is inadequate for both histology and molecular MRD, allow a Haematology or Histology Consultant decide which information will be of most use and process the sample accordingly. * If trephine is received in saline for a condition other than ALL, or with an accompanying aspirate sample that has adequate cell count for both immunophenotyping and molecular MRD – laboratory staff will take the sample without delay to Histology staff on Camelia Botnar Laboratories Level 3 to add formalin to the trephine before the tissue deteriorates further. | | | | |
|  | Bone Marrow Aspirate Slides | | | | | * FIXED or UNFIXED slides are only accepted when no other diagnostic material is available and only after discussion with laboratory staff or Haematology Consultant. | | | | |
|  | **Anticoagulant** | | | | | | | | | |
|  | * Bone marrow aspirate or peripheral blood samples should be taken in ACD tubes. * EDTA may be used only if ACD is unavailable. * Requests for molecular MRD analysis of EDTA samples is at the discretion of the requesting Consultant and interpretation of that result must be made with this in mind. | | | | | | | | | |
|  | 1. **Transportation of Samples** | | | | | | | | | |
|  | Temperature | | | | | * Transport to the laboratory at room temperature.   Samples are not to be refrigerated overnight or for longer periods as this will negatively affect mononuclear cell isolation | | | | |
|  | Timing | | | | | * For optimum results, sample processing must begin as soon as possible and no later than 6 hours post collection.   Samples received outside of this timeframe will still be tested but interpretation of that result must be made with this in mind and is the responsibility of the clinician. Date and time sample received is printed on each report. | | | | |
|  | Delivery route | | | | | * GOSH samples may be delivered to the laboratory (CBL Level 2 P2.012) directly from theatre/ ward by any GOSH staff member, between 09:00 and 17:15, Mon-Fri. Outside these times the sample must be delivered to the Haematology Scientist On-Duty (CBL Level1 P1.012). * External samples are sent to the laboratory via Mail or Courier and received by the SIHMDS Haematology Laboratory (CBL Level 2 P2.012). Such packages will normally be addressed to Stuart Adams, Camelia Botnar Laboratories, Great Ormond Street Hospital, WC1N 3JH.   Patients/ guardians are never required to deliver such samples personally to the laboratory. | | | | |

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| **6. Suitable Timepoints and Listed Turnaround Times for molecular MRD Analysis** | | | | |
| Patient | Timepoint | | | Turnaround Time |
| 1st diagnosis ALL patient | Diagnosis | | 29 Days | |
| Day 29 (timepoint 1) | | 5 Days | |
| Patients who were molecular MRD risk at Day 29 (TP1) | Day 71/Day 78 (timepoint 2) | | 5 Days | |
| Every relapse ALL patient | Re-screening for Diagnostic markers | | 29 Days | |
| Off trial timepoints | | 5 Days | |
|  | |  | |
| Any Other Timepoint\*\* | | | 5 days | |
| \*\* Molecular MRD testing will not be performed on: Day 15 induction/reinduction, or End of treatment (EOT) samples unless contacted by clinician via email and/or phone call. (gos-tr.sihmdsmolecularmrd@nhs.net) | | |  | |
| 7 Time frame for Storage of Sample and Documents Post Analysis | | | | |
| Samples | | 2 months | | |
| Paperwork | | Indefinite (digitally); 2 years (physically) | | |
| 1. External Quality Assurance (EQA) | | | | |
| The molecular MRD laboratory at GOSH is a member of the UKALL molecular MRD Virtual Laboratory Network and of the international group Euro-MRD, a branch of ESHLO. We participate in two EQA exercises per year, both run by Euro-MRD/ ESHLO. Our membership status can be seen on ESHLO.eu.  Our EQA performance can be seen by external users by e-mailing [gos-tr.sihmdsmolecularmrd@nhs.net](mailto:gos-tr.sihmdsmolecularmrd@nhs.net).  The molecular MRD laboratory, NGS Screen and qPCR follow up testing is ISO 15189 accredited. | | | | |

**Invoices and Payments**

Invoices for each test are sent on a monthly basis, following the release of the results. There is a charge for handling samples which arrive and are not suitable for analysis.

**Laboratory Policy on Protection of Personal Information**

The laboratory adheres to the Trust’s Policy on Information Governance to ensure compliance with the key principles of Information Governance. The Trust wishes to ensure all patients and service users to have confidence that their records will be maintained securely and will not be disclosed or shared inappropriately.

The laboratory has a procedure for the management of data and protection of personal information that is controlled and maintained by the Pathology System Manager and the Data Manager.

These procedures cover:

* Security - data is accessible only to authorised users via a valid and current password.
* Individual user access to functions and facilities  - this is restricted to ensure no user has inappropriately high access levels.
* Confidentiality and data protection - the security and access features ensure confidentiality is maintained to authorised and appropriate parties.
* All staff within the laboratory complete mandatory information governance training, are aware of the requirements to maintain confidentiality and the restrictions imposed by the laboratory with regard to information dissemination.

The Trust Data Protection Officer and ICT Department advise the laboratory regarding requirements to comply with current and future legislation for Data Protection.

If you have any further query please contact the laboratory.

**Laboratory Complaints Procedure**

The medical and senior management staff in the Department of Paediatric Laboratory Medicine work very closely with users both within the Hospital Trust and with external referring clinicians. In order to provide the best service to its users, the department encourages both positive and negative feedback

To make a complaint about the service, please write/email the Lead Laboratory Manager in the first instance. Investigation of the complaint and resolution will be made within 20 working days.