Accredited Laboratory
Reference No: 03-GB-009.991

NHS
Manchester University
NHS Foundation Trust

A Guide to the Histocompatibility and Immunogenetics Services Provided to Support Haematopoietic Progenitor Stem Cell Transplantation

This guide outlines the Histocompatibility and Immunogenetics (H&I) services provided by the Transplantation Laboratory, Manchester Royal Infirmary in support of Haematopoietic Progenitor Stem cell transplant (HPCT) programmes. The guide is of use to clinical and support staff in bone marrow transplant units.

Revised by Alison Logan, Natalia Diaz Burlinson, Dr Helena Lee, Dr Anna Barker, Julie Johnson, Karen Wood, Jennifer Lord, Stephine Whiteside, Dr Paul Wright & Professor Kay Poulton.

Valid until Dec 2025

Contents

1. Introduction

The Transplantation Laboratory is a regional specialty pathology service and as such offers a wide range of high quality, efficient and cost-effective services using state of the art technologies to Manchester University NHS Foundation Trust, other regional Trusts, and healthcare providers. The main services provided by the Transplantation Laboratory are described below:

a) Haematopoietic Progenitor Stem Cell Transplantation

The Transplantation Laboratory provides Histocompatibility & Immunogenetics (H&I) support for the haematopoietic progenitor stem cell transplantation programmes at Manchester University NHS Foundation Trust (MRI and RMCH) and other regional trusts. The laboratory utilises state of the art molecular HLA typing technologies for patients and their potential donors who may need a stem cell or bone marrow transplant. The laboratory is one of the leading laboratories in the country in the application of chimaerism monitoring using short tandem repeats post progenitor stem cell transplantation. The laboratory provides additional KIR typing and interpretation of results for haploidentical stem cell transplants.

The laboratory offers a rapid and professional Graft Information and Advisory Service (GIAS) to undertake donor selection. This service is delivered by highly qualified and experienced HCPC registered staff and is led by an RCPath qualified H&I Consultant Clinical Scientist.

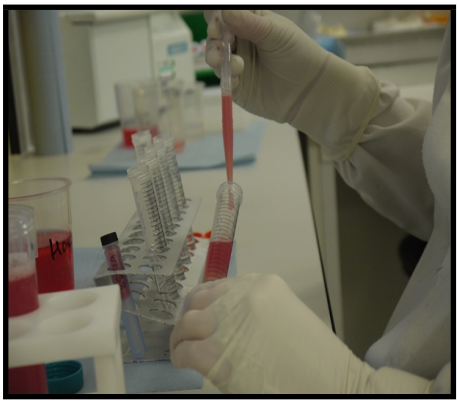
b) Solid Organ Transplantation

In addition to supporting the HPCT services, the laboratory provides H&I support for:

- Kidney, kidney and pancreas, pancreas and islet cell transplantation programmes at Manchester Royal Infirmary.
- Cardiothoracic organ transplantation at Wythenshawe Hospital.
- There is a 24 hour on-call service for kidney / kidney and pancreas / pancreas only / islet transplantation and all thoracic organ transplants.

c) Immunogenetics testing

The Transplantation Laboratory provides testing to support disease diagnosis and management for the Manchester University NHS Foundation Trust, Primary Care Centres and hospitals. A range of tests are provided, including HLA-B*27 and HLA-B*57:01 determination and HLA typing to support the diagnosis of Actinic Prurigo, Uveitis, Birdshot Retinopathy, Narcolepsy and Coeliac Disease. On request the laboratory can perform additional HLA typing to aid disease diagnosis and drug hypersensitivity investigations for tests in addition to those outlined.



d) Research and Innovation

The Transplantation Laboratory participates in research and innovation relevant to the clinical services provided to ensure that we continually improve our service provision in line with the current clinical evidence base. Projects are closely tailored to local clinical practice to ensure the most appropriate services are provided for the patients.

The Transplantation Laboratory is part of a cross-directorate network, known as the Manchester Institute of Nephrology and Transplantation (MINT). MINT is a multi-professional body of physicians, surgeons, nursing staff, scientists, other professions allied to medicine and managers. Its aim is to improve and develop the research and educational activities of the transplantation, nephrology and dialysis services to achieve the best possible care for transplant patients.

e) Audit

The Transplantation Laboratory is actively involved in audit related to laboratory activities as well as clinical audit in conjunction with the services we support. The process of clinical audit directly relates to the Trust's Clinical Effectiveness Strategy that aims to improve the quality and outcome of patient care. The laboratory also has an internal audit cycle against ISO 15189:2012 and European Federation for Immunogenetics standards to ensure continual compliance and continual improvement in transplant outcome.

f) Quality Assurance

The Transplantation Laboratory is a UKAS accredited medical laboratory No.7878 and has European Federation of Immunogenetics accreditation (EFI No: 03-GB-009.991).

The laboratory has a well-established quality management system in operation, which allows the laboratory to be focused on continual improvement in line with needs and requirements of our users. The QMS provides a structured framework for the laboratory and is monitored and maintained by the Laboratory Operations and Quality Manager. The Quality Policy which is reviewed annually describes the aims of the services.

Any test performed in the laboratory is subject to a variety of factors that may influence the outcome of the result. Some of these factors include the quality of the sample itself, the test method, reagents used and different operators carrying out the same process. Variations can also be caused by procedures that involve the measurement of analytes and reagents whereby environmental factors such as temperature and humidity may affect results. Any equipment used in the process will further introduce the opportunity for variation. To provide a measure of confidence in results produced it is necessary to identify all factors which may contribute to variation in a process and assess their potential to influence uncertainty. Once identified these factors must be reduced or controlled to an acceptable level and a value for the range of acceptable uncertainty assigned where possible.

The Transplantation Laboratory has chosen, where possible, to utilise internal quality control material and data to establish Uncertainty of Measurement where applicable. Upon request the laboratory shall make its estimates of measurement of uncertainty (MoU) available to laboratory users.

Participation in external quality assurance programmes such as UK NEQAS and UCLA schemes, together with continual internal quality assessment monitoring of our tests, ensures that the laboratory's high quality standards are maintained.

UK NEQAS schemes conform to high standards of professionalism, impartiality, clinical relevance and strict financial accountability across all disciplines and specialities, so that all concerned with the quality of laboratory investigations may have confidence in the service provided.

A highly experienced consultant team offers support to clinicians and service users 24 hours a day, seven days a week. The team provides information related to using the service, interpretation of test results and clinical advice. Reviews and changes to the service provision will be in consultation with our users and will be clearly defined in revised Service Level Agreements (SLAs), where applicable.

The Transplantation Laboratory actively supports and encourages staff training and continual professional development. It is recognised by the Royal College of Pathologists, the National School of Healthcare Scientists and the British Society for Histocompatibility and Immunogenetics as a training laboratory in Histocompatibility and Immunogenetics. Where appropriate, staff members are registered with the Health and Care Professions Council (HCPC).

Details of our accreditation, including current certificates and performance data, are available upon request from the Laboratory Operations and Quality Manager (julie.johnson2@mft.nhs.uk).

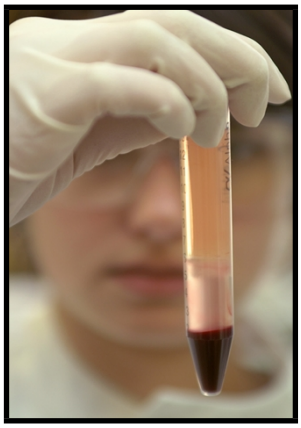
In order to help us improve our service, you may be asked to complete a questionnaire. We greatly appreciate and value your input and would like to thank you for your assistance and suggestions.

g) Complaint Procedure

The Transplantation Laboratory is continually aware of, and takes into consideration the requirements of its users and staff, whilst striving to create the best standards of professional care. According to Trust policy, any complainants are referred to the Patient Advice and Liaison Service (PALS) who can support staff and patients to achieve speedy solutions. Also, complaints can be directed to the Laboratory Director, a Consultant Clinical Scientist or any Transplantation Laboratory representatives at multidisciplinary team meetings. Please make any concerns you have about the quality of the service known to us as soon as possible; we take your complaints seriously.

Any suggestions from users regarding any aspect of our service provision, or indeed how the User Guide could be improved, are very welcome. Please forward any suggestions to the Laboratory Operations & Quality Manager (julie.johnson2@mft.nhs.uk).

h) Clinical Liaison and Advice



A Consultant Clinical Scientist or deputy will always be available to attend multi-disciplinary team meetings as required in order to ensure optimum communication between the laboratory and clinical teams and provide advice relating to the Haematopoietic Progenitor Stem Cell Service.

An experienced consultant team offers support to clinicians and service users 24 hours a day, 7 days a week. The team provides interpretation of test results and clinical advice.
A 24-hour, 365-day on-call service is provided for deceased donor HLA typing and crossmatching, and an FRCPath qualified Clinical Advice Scientist is always available for the provision of advice.

I) Confidentiality and Personal Information

The Transplantation Laboratory adheres to Manchester University NHS Foundation Trust's policies on data protection and disclosure.

2. General Information

2.1 Postal Address

Transplantation Laboratory
2nd Floor, Purple Zone
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL

Tel: 0161 276 6397
Fax: 0161 276 6148 (secure)

2.2 Business Hours

Opening Hours for routine work: 08.30 – 17.00 hrs

Out of hours, weekends and Bank holidays: On call staff & Clinical Advice Scientist can be paged via MFT switch
Tel: 0161 276 1234

2.3 Laboratory Key Personnel

Laboratory Director

Professor Kay Poulton PhD, FRCPath
Consultant Clinical Scientist
Tel: 0161 276 6397
Email: kay.poulton@mft.nhs.uk

Consultant Clinical Scientists

Mr Stephen Sheldon, FRCPath
Tel: 0161 276 6397
Email: stephen.sheldon@mft.nhs.uk

Ms Natalia Diaz Burlinson, FRCPath
Tel: 0161 276 6397
Email: Natalia.DiazBurlinson@mft.nhs.uk

Dr Helena Lee PhD, FRCPath
Tel: 0161 276 6323
Email: helena.lee@mft.nhs.uk

HPCT Support Services Enquires

Alison Logan MPhil
Principal Clinical Scientist
Tel: 0161 276 6661
Email: alison.logan@mft.nhs.uk

Dr Anna Barker PhD, FRCPath
Principal Clinical Scientist
Tel: 0161 276 6632
Email: anna.barker@mft.nhs.uk

Laboratory Operations and Quality Manager

Julie Johnson MSc. HCPC
Principal Clinical Scientist
Tel: 0161 276 6424
Email: julie.johnson2@mft.nhs.uk

General Enquiries

Business and Administration Manager
Judith Spencer
Tel: 0161 276 6397
Fax: 0161 276 6148
Email: judith.spencer@mft.nhs.uk

2.4 Essential Telephone Numbers

Specimen Reception:	0161 276 6471
Admin office:	0161 276 6397
HPCT support service and GIAS enquiries:	0161 276 6661/6662/6514
Chimaerism monitoring enquiries:	0161 276 6662/6661
Immunogenetics team – General Enquiries:	0161 276 6661/6662

2.5 Essential Email Addresses

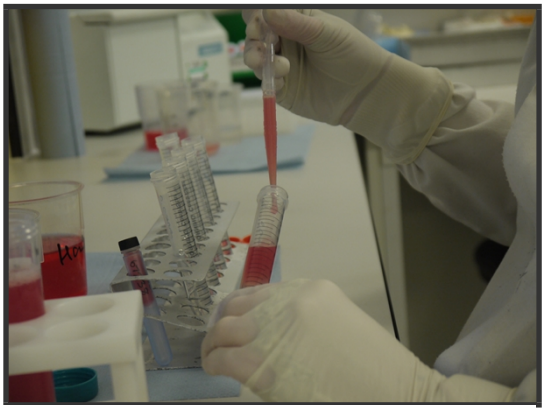
HPCT Enquiries: **mft.TransplantationLabHSCT@nhs.net**
TransplantationLaboratory.HSCT@mft.nhs.uk
Solid Organ Enquiries: **mft.Histocompatibility@nhs.net**

2.6 Internet page

https://mft.nhs.uk/mri/services/transplantation-laboratory

3. Use of the Laboratory

3.1 Service Availability



The laboratory is open for receipt of routine specimens from 08:30 to 17:00 between Monday to Friday. Internal on site samples may be sent directly to the laboratory using the pneumatic pod system (Transplantation Pod No 805).

There is an on-call service provision available outside of normal working hours provided by an on call team consisting of a HCPC registered Clinical Scientist, a technologist and a Clinical Advice Scientist. This service is generally restricted to the solid organ transplant programme and the laboratory on call team are contactable by pager via the hospital switchboard (0161-276 1234).

3.2 Labelling of sample containers

The Transplantation Laboratory will make every effort to ensure requests are processed in a safe and timely manner, but it is essential that request forms and samples are labelled appropriately and legibly. The minimum acceptance criteria for requests are normally **3 key identifiers** that should include at least:

- Patient's name (forename and surname)
- Date of birth
- Hospital number and or MRI District number
- NHS number
- Home address of the patient

These are all identifiers specific to the patient which help us to confirm identity and are essential.

It is also important to clearly identify the investigations required when completing the request card, please only select the test required and send only the appropriate sample tube.

If you have any concerns regarding this please ring 0161 276 6471 / 6397 for further advice.

Specimens will not be accepted for analysis if:

- There are insufficient unique identifiers for the patient as specified
- Incorrect sample type or tube
- Incorrect transportation conditions mean that the sample is not viable for testing
- Sample is received in a hazardous condition e.g. leaking or sharps attached
- Mismatch of details between the form and sample(s)
- The information provided is illegible

Samples that fail to meet the described criteria will be discarded as unsuitable for analysis, and the sender will be informed. The only exception to this is for patients whose identity is anonymous and they have their own unique identifier, for example potential stem cell donors. In other circumstances samples may be accepted without the 3 key identifiers at the discretion of the laboratory.

3.3 Transportation of routine samples to the laboratory

All users are advised to refer to P650 Packaging Instruction which applies to UN No. 3373 (Diagnostic Specimens) for information on the correct procedures for packaging and transporting samples. When sending samples to the laboratory it is important to follow the correct courier and postal procedures and ensure the specimens are appropriately packaged (**See appendix 8.1**).

All specimens should be transported at room temperature **(22^{o}C - 25^{o}C)**, unless otherwise instructed, avoiding where possible prolonged over exposure to heat. The samples should be transported directly to the laboratory as quickly as possible after collection to maintain the integrity of the sample and avoid compromising the results.

Internal on site specimens may be transported directly to the Transplantation Laboratory via the porter's rounds during the normal working day or by pneumatic pod system to Pod No 805. Samples should be placed in a specimen bag with the request for transportation around the trust.

Please contact the laboratory on 0161 276 6471 / 6397 if there are specific questions regarding transportation of specimens.

3.4 Urgent samples

If a result is required urgently and the sample will arrive during working hours the laboratory MUST be notified by telephone so that we can prioritise your request.

All samples should be packaged and transported as above. If you need to submit a sample out of normal working hours for testing on-call, please contact the Clinical Scientist on-call via the hospital switchboard (0161 276 1234).

3.5 Acceptance time limit after sample drawing

Time limits and storage temperature requirements are imposed to maintain the integrity of the sample, to ensure accuracy and reliability of the testing and reduce the need for repeat samples. For all tests complete the request card or an ICE request for users within MFT. See **Appendix 8.2** for a full list of tests and samples required.

Engraftment Monitoring

Whole Blood - minimum 3ml EDTA blood **No time limit**

Bone Marrow - minimum 1ml marrow **No time limit**

Single/Multiple Lineage Analysis -

A minimum sample of **3ml EDTA blood per cell lineage** and the patient's current WBC (if possible) is required for this test. Samples can be received in the laboratory Monday-Thursday 09:00 – 17:00 and Friday 09:00 -13:00, **and *must* be received within 24 hours of the sample being taken.**

In some circumstances a buccal swab may be requested as reference material. Please follow the manufacturer's instructions sent with the kit. Blood spots should be taken according to the manufacturer's instructions that accompany the kit used.

HLA and KIR genotyping

Whole blood – minimum 3ml EDTA blood **No time limit**

Buccal swab **No time limit**

Dried Blood Spot **No time limit**

HLA antibody screening

5ml Clotted blood (no anticoagulant) **Up to 48 hours**

Storage conditions prior to sending

Clotted samples can be kept overnight at 4^{o}C but sent immediately the next morning to the laboratory for testing.

EDTA blood samples should be kept at room temperature whilst waiting and during transport to the laboratory, avoiding any excessive heat exposure.

Request cards can be obtained from the Business and Administration Manager, please call on 0161 276 6397 or email *judith.spencer@mft.nhs.uk*. These request cards are also available in electronic format upon request.

4. General Information regarding services available

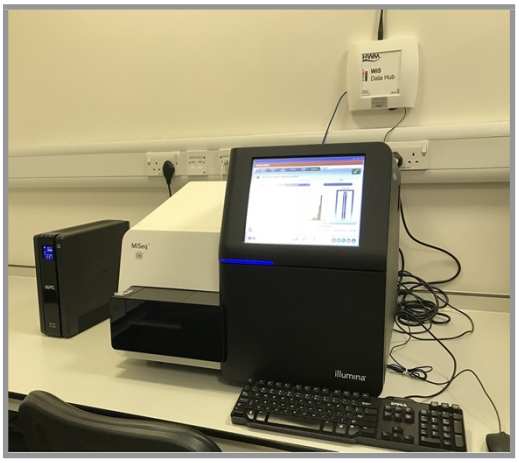
4.1 Descriptions of standard tests

What is HLA typing (Tissue Typing)?
HLA typing is performed predominantly to match a donor and recipient for solid organ or haemopoietic progenitor stem cell transplantation (HPCT). Minimising the number of HLA mismatches between donor and recipient maximises the opportunity for optimal transplant survival.

HLA molecules are crucial to normal immune processes by enabling the cells involved in immune responses to recognise foreign organisms and react against them. Following transplantation the recipient's immune cells can recognise donor HLA molecules as foreign and react against them causing rejection.

For HPCT it is essential to have minimal HLA mismatching to reduce the risk of graft versus host disease (GvHD) and mortality. GvHD is mainly caused by immunocompetent T cells transferred with the graft that recognise recipient cells as foreign and mount an immune mediated reaction.

HLA typing refers to the series of laboratory tests whereby the HLA molecules expressed on the surface of an individual's body cells are identified. HLA molecules are on the surface of all nucleated cells (i.e in humans, all cells apart from red blood cells) but lymphocytes are routinely used for tests because they can easily be isolated from anti-coagulated peripheral blood.



The technique used for testing varies according to the clinical requirement. For example, a rapid, but intermediate resolution technique (LinkSēq™) may be used to HLA type a potential donor in a solid organ transplant setting.

LABType® SSO offers intermediate level resolution and facilitates rapid batch testing of samples for routine testing. A patient requiring HPCT will require extensive next generation sequencing (NGS) based typing analysis to provide a high resolution HLA type. This is to ensure that the recipient and donor are matched as closely as possible. The Transplantation Laboratory employs state of the art NGS HLA typing technology to identify the best matched donor for a patient.

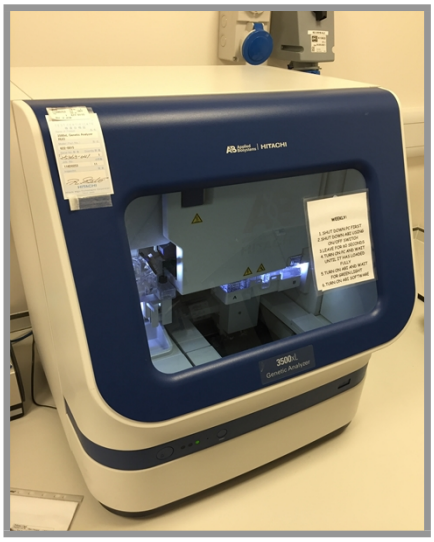
An individual's HLA type defines the combination of HLA molecules on the surface of their body cells. These are determined genetically. The HLA genes are unique in the human genome because of their considerable variability, which results in many different HLA types. The HLA genes are identified by letters (e.g. HLA-A) and the different gene products (specificities) by numbers (e.g. HLA-A2). Each individual inherits one set of HLA molecules from each parent thus they have two HLA-A, two HLA-B types and so on. For the purpose of matching for HPCT we consider matching HLA-A*, B*, C*, DRB1* and DQB1* alleles to be of importance. Whenever possible, donors and recipients are matched for HLA DPB1*.

In unrelated HPCT other factors such as donor CMV status, age, gender, and permissive DPB1* algorithms are considered when selecting the optimal donor. Additional factors such as blood group may be taken into consideration when there are two donors of equivalent HLA match for a patient to rank the donors in priority order.

What is Chimaerism Monitoring?

The Transplantation Laboratory is one of the leading centres in the UK in the field of Chimaerism monitoring.

In the post-transplant period, engraftment can be monitored by analysis of “short tandem repeat” (STR) markers in the patient’s peripheral blood or bone marrow aspirate. This post-transplant engraftment monitoring is referred to as Chimaerism monitoring. STR markers are variable DNA sequences, which differ in length by multiples of repeated units. The variability of these markers means that in most cases, the donor and recipient will not share the same sized STR marker. By monitoring these size differences in the post-transplant sample, we can measure the success of the engraftment by calculating the percentage of donor derived cells in the recipient’s sample.



In some scenarios post HPCT it is of clinical value to assess donor engraftment in more than one cell lineage in the post-transplant period. Several options exist and the assay can be tailored to a specific patient.

What is Antibody Screening?

Individuals can produce antibodies directed against HLA specificities that they do not possess. This can happen following exposure to non-self HLA during pregnancy, blood transfusion or transplantation. These antibodies are detected in serum and can potentially react with a donor organ or graft and cause transplant rejection.

Sometimes it is not possible to identify a fully HLA matched donor or the patient is to undergo a haploidentical HPCT from a partially matched relative. In these scenarios it is important that the patient is screened for the presence of antibodies and that the specificities of the antibodies are defined. If a patient has HLA specific antibodies, it is best to avoid these specificities in a potential donor, as the antibodies would combine with the infused donation and reduce the cell dose available for the transplant. Not all donor directed antibodies are a veto to transplantation, and a risk assessment following antibody definition would be required. This is particularly important in HPCT using umbilical cord donations due to the limited material available.

Samples for HLA antibody screening should be sent to the laboratory on initial referral prior to donor selection, and as close as possible to the time of transplant. HLA specific antibodies are detected and defined by microbead array techniques, which are highly sensitive and specific. They are referred to as Luminex assays and are semi quantitative.

What is KIR Genotyping?
The KIR genes profile (KIR genotype) of the recipient and their donor are thought to be important in HPCT outcome. It may be of clinical value in some cases to perform testing for KIR genes for example if a haploidentical donor is to be considered or there are multiple HLA matched donors for a patient. KIR genotyping is available upon request from the laboratory.

Graft Information and Advisory Service (GIAS)
The laboratory offers a rapid and professional Graft Information and Advisory Service (GIAS) to undertake donor selection. This is to ensure that the optimal HPC donor is selected for each patient. The team has vast expertise in the selection of adult unrelated donors, cord blood units and family members for haploidentical transplantation. This service is delivered by a highly qualified and experienced HCPC registered team of staff and directed by an RCPath qualified H&I Consultant Clinical Scientist who is involved in HPCT donor selection policy making within the H&I community at a national and international level.

During working hours the generic email address for the HPCT team in the laboratory and the telephone lines ensure a fully qualified member of staff is always available to the transplant clinicians and coordinators to answer any enquiries.

The procedures followed by the Transplantation Laboratory for the selection of related and matched unrelated donors are illustrated in appendices 8.3 and 8.4.

- At initial referral to laboratory (**1st set of bloods**) send 5ml EDTA blood for HLA typing, a buccal swab and 5ml clotted blood for antibody screening (if required).

- At second referral send 5ml EDTA blood for **verification typing.** A further 5ml clotted blood for antibody screening if requested by the team for patient's who are undergoing an HLA mismatched transplant. It is an essential accreditation requirement to confirm the patient and donor HLA type on a second sample.

Recipient samples should be received within the timeframe detailed in 3.5 by the laboratory and by midday on Friday, to allow adequate time for processing, except by prior arrangement. They can be sent by 1st class post in appropriate packaging (see Appendix 8.1).

5. Requesting Tests/Samples Required

The Transplantation Laboratory has its own distinctive request cards which can be obtained from the departmental business and administration manager (judith.spencer@mft.nhs.uk). Internal on-site requests should be made using the ICE system using the Transplantation Laboratory tab following the MFT standard operating procedure. All other requests should be made using the request cards shown below following the procedure described below for the test required.

5.1 HLA Typing (Tissue Typing of Patient)

As a minimum requirement, include patient surname, forename, date of birth, hospital number/MFT district number, referring hospital, consultant, person requesting the test and the date sample taken. It is essential that the patient is clearly identified on the card and on the specimen. Please tick the relevant test required box or state clearly what test is required. For HLA typing of a related potential donor, include relative name and patient name.

5.2 Current HPCT Request card

TRANSPLANTATION LABORATORY,
MANCHESTER ROYAL INFIRMARY

TEL: 0161 276 6397 FAX: 0161 276 6148 (Secure)
transplantationlaboratory.hsct@mft.nhs.uk
mft.transplantationlabhsct@nhs.net
mft.nhs.uk/mri/services/transplantation-laboratory/

NHS
Manchester University
NHS Foundation Trust

*Essential information required in order to process request

SURNAME* (BLOCK CAPITALS)	FORENAMES*	DATE OF BIRTH*	SEX	HOSPITAL*

DISTRICT NUMBER	HOSPITAL NUMBER	NHS NUMBER	SAMPLE DATE*

DIAGNOSIS	ETHNIC ORIGIN	CMV SEROSTATUS	ABO / Rh	CONSULTANT*

For more information regarding how to complete a sample request, please refer to our website (listed in header)

TEST REQUEST

HLA TYPING: ☐ 3ml EDTA Blood ☐ Buccal Swab ☐ Blood Spot
HLA-SPECIFIC ANTIBODY SCREENING: ☐ 5ml Clotted Blood Sample
DONOR CHIMERISM ANALYSIS: ☐ Peripheral Blood (3ml EDTA Blood) ☐ 1ml Bone Marrow
SPLIT CELL POPULATIONS (EDTA Blood – 3ml per lineage): ☐ CD3+ ☐ CD15+ ☐ CD19+ Other: _____
Split cell population samples are time sensitive. Please send to the laboratory as urgent.

Donor ID: _____ Date of Transplant: _____

FOR LABORATORY USE ONLY

Date	BMT Lab No.	DNA No.	Serum No.	Patient No.
BMT Reg No.:				
			BMT / BMR / MUD / CBD	

Samples booked in by: _____

☐ **HLA TYPING** **Reviewed by:** _____

☐ A ☐ B ☐ C ☐ DRB1 ☐ DRB3/4/5 ☐ DQB1 ☐ DPB1

Requested on HLA Typing Database by: _____

Chimerism Analysis: ☐ Whole Blood ☐ CD3+ ☐ CD15+ ☐ CD19+ ☐ Bone Marrow Other: _____

Entered onto BMT Sample / BMT Outcome Database by: _____

☐ **Antibody Screening** [CI / CII] specificity definition required if Pos ☐ Consult Pt. Services

Requested by: _____

HPCT REQUEST CARD

6. Reporting of Results

To maintain patient confidentiality and comply with General Data Protection Regulations (GDPR) and other legal requirements, all results are reported via encrypted email or in writing only to an authorised individual. They are signed by a Consultant Clinical Scientist or named deputy. Other results are only reported by telephone after agreement by a Consultant Clinical Scientist. Provision of non-urgent results by fax is available on request during office hours, and advice from a Clinical Advice Scientist is available on a 24hr basis. The Measurement of Uncertainty (MoU) shall be considered for all examinations which include a measurement step where it has influence on the reported result. Estimates of the MoU will be made available to users upon request.

Turnaround Time (TAT)
All times are quoted as working days from the receipt of the sample in the Transplantation Laboratory.

Intermediate level HLA typing of HPCT patients and potential donors:	**5 days**
Single locus screening of related donors:	**3 days**
High resolution typing of patients and donors:	**10 days**
Urgent HLA antibody screening for HPCT patients:	**2 days**
Routine HLA antibody screening for HPCT patients:	**15 days**
KIR typing:	**5 days**
Post-Transplant Engraftment Chimaerism monitoring routine: (refers to calendar days)	**3 days**
Urgent Chimaerism Engraftment monitoring:	**24 hours***

*Samples received after 13:00 on a Friday will be processed and reported on the following Monday

Over 90% of the results are reported within **the specified working days** from receipt of samples. Special arrangements requiring a shorter turnaround may be established on a user-specific basis, by arrangement with the Consultant Clinical Scientist and subject to the technical limitations of the assays. The turnaround times quoted are supported by audit data. Some stages of our search for donors are dependent upon external agencies (national and international donor registries) and may introduce delays in the process which are outside the laboratory's control.

7. Standards

All aspects of the HPCT service are compliant with the relevant standards for HPCT.

Standards for Histocompatibility Testing Version 8.0 European Federation for Immunogenetics (EFI). January 2018.

UK NEQAS Chimaerism monitoring guidelines (2014).

BSHI Guidelines: HLA matching and donor selection for haematopoietic progenitor cell transplantation. 2021 edition.

8. Appendix

8.1 Requirements for sending specimens by post

In order to comply with UN code number UN3373 there should be three layers of packaging:

1. The primary container containing the specimen

2. Secondary packaging e.g. a sealable plastic bag that contains enough absorbent material to contain the entire contents of the primary container without leakage occurring

3. Outer packaging, to be labelled with the destination address, the name of the sending department and address, and be clearly marked “Diagnostic Specimen”

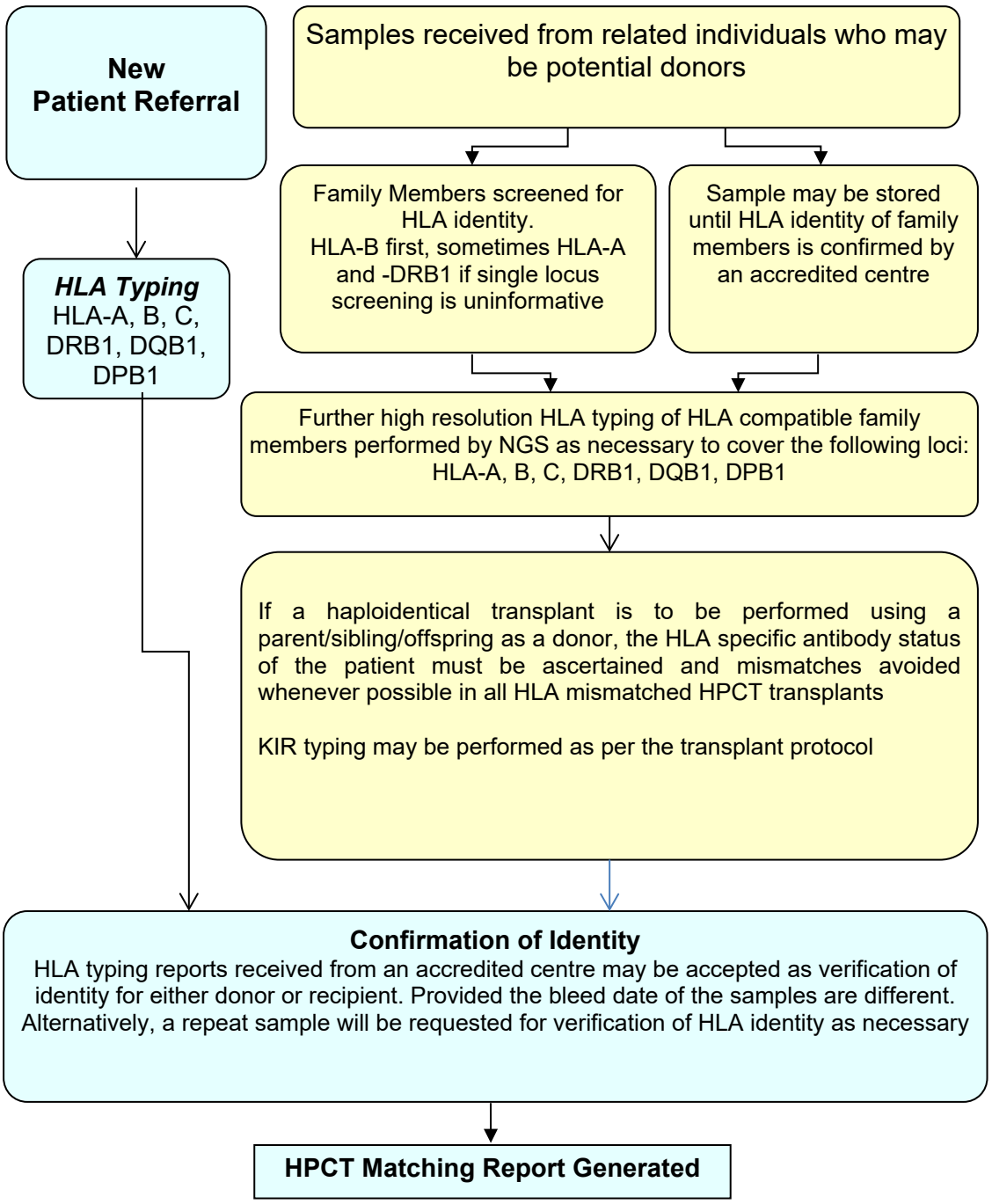
Appropriate packaging is available from suppliers including the Royal Mail, Royal Mail Safebox, FREEPOST, SWC1 143, Ross–on-Wye, HR9 7ZB.

8.2 List of Tests and Samples Required

Test	Sample Required
Recipient HLA Typing (Initial HLA type)	5ml EDTA plus a buccal swab and 5ml clotted blood
Recipient HLA Typing (Verification HLA type)	5ml EDTA
Recipient HLA-Specific Antibody Screen/definition	5ml clotted blood
Chimaerism Analysis Whole Blood	3ml EDTA
Chimaerism Analysis Bone Marrow Aspirate	Minimum 1ml
Lineage specific Chimaerism Analysis	3ml EDTA **per lineage**
KIR genotyping	5ml EDTA

* The samples used for HLA typing tests are 5ml EDTA blood (if WBC>$4.0x10^6$/l). If the WBC<$4.0x10^6$/l, please send 20ml EDTA blood.

8.3 HPCT Donor selection procedure- Related Transplantation



8.4 HPCT Donor selection procedure- Unrelated Transplantation