Manchester University
NHS Foundation Trust

UKAS MEDICAL
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A Guide to the Histocompatibility and Immunogenetics Services Provided to Support Kidney, Pancreas and Islet Cell Transplantation

This guide outlines the Histocompatibility and Immunogenetics (H&I) services provided by the Transplantation Laboratory, Manchester Royal Infirmary in support of renal, pancreas and islet cell transplant programmes. The guide is of use to clinical and support staff in renal dialysis units, diabetes centre and renal transplant units.

Revised by Dr Judith Worthington,
Prof Kay Poulton & Dr Julie Johnson.

Contents

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 service is delivered by highly qualified and experienced HCPC registered staff and is led by a team of FRCPath qualified H&I Consultant Clinical Scientist.

The main services provided by the Transplantation Laboratory are described below:

a) Solid Organ Transplantation

The laboratory provides Histocompatibility & Immunogenetics (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.

b) Haematopoietic Progenitor Stem Cell Transplantation

The Transplantation Laboratory provides (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 FRCPath qualified H&I Consultant Clinical Scientists.

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 is 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 network, which is cross-directorate and is 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 15189:2022 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 and has European Federation of Immunogenetics accreditation (EFI No: 03-GB-009.991).

The Transplantation laboratory operates within the bounds of a combination of both a UKAS fixed and flexible scope of practice which is clearly defined within the published schedule of accreditation on the UKAS website. Any requests for changes to the laboratory scope are impartially and independently reviewed by the laboratory Director and CCS and fully validated. Where any modifications to the scopes are made, these will be amended to the UKAS Master list and communicated directly to the users describing the use and impact to service as appropriate. The UKAS Master list is available upon request. Any technical aspect of the laboratory that operates within the flexible scope of accreditation with be clearly identifiable on any report signifying that any outcome from the technique falls within the bounds of the flexible scope of accreditation.

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 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 enforced a systematic approach to identifying and managing risk which is an inherent part of the day to day working practice and a fundamental part of the clinical effectiveness philosophy. Each member of the team is encouraged to manage risks by internal auditing and report incidents, near misses and hazardous situations. By reporting and investigating the root causes of these incidents and outcomes of internal audits, practices can be altered to improve the way services are delivered. All such potential risks are assessed and mitigated as much as possible and where any residual risks remain this shall be communicated as appropriate via email or MDT meetings.

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 uncertainty 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 both the Royal College of Pathologists, the National School for 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).

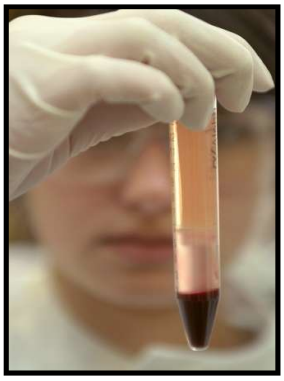
In order to help us improve our service, you may be asked to complete a questionnaire. We greatly appreciate and value your input and would like to thank you for your assistance and suggestions.

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 Service provision.

A 24-hour, 365-day on-call service is provided for deceased donor HLA typing and crossmatching. The Clinical Advice Scientist (CAS) on call rota is staffed by experienced Clinical Scientists who hold FRCPath and who have been trained to offer clinical advice out of hours in support of transplantation.

i) Confidentiality and Personal Information

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

j) Patient consent

The Transplantation Laboratory adheres to Manchester University NHS Foundation Trust's policy on informed consent. Patient consent is obtained at the point of contact via the patients' consultant team whose responsibility it is to ensure the patient is informed, has capacity and that it is voluntary.

k) Educational facilities for users

The Transplantation Laboratory is proud to be able to facilitate training as required for our users by training HCPC Clinical scientists. If you have any educational needs, please contact the laboratory via general enquires.

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

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 Critico (see 3.1) or MFT switch Tel: 0161 276 1234

2.3 Laboratory Key Personnel

Laboratory Director

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

Consultant Clinical Scientists

Dr Helena Lee PhD, FRCPath
Tel: 0161 276 6397
Email: Helena.Lee@mft.nhs.uk

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

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

Kidney Pancreas Support Services Enquires

Dr Judith Worthington PhD, FRCPath
Principal Clinical Scientist
0161 276 7988
Email: judith.worthington@mft.nhs.uk

Patrick Flynn MSc, DipRCPath
Principal Clinical Scientist
0161 276 6651
Email: Patrick. Flynn @mft.nhs.uk

Mrs Marie Hampson, DipRCPath
Senior Clinical Scientist
0161 276 7919
Email: marie.hampson@mft.nhs.uk

Dr Steven Jervis, PhD DipRCPath
Senior Clinical Scientist
0161 276 6656
Email: steven.jervis@mft.nhs.uk

Laboratory Operations and Quality Manager

Dr Julie Johnson, DProf
Principal Clinical Scientist
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
Histocompatibility Team – General Enquiries	0161 276 7988 / 7919 / 6651 / 6656

2.5 Essential Email Addresses

Transplantation Laboratory (general enquiries) : TransplantLab@mft.nhs.uk
Cardiothoracic Patient Listings : OnCall.TLab@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 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.

The on-call team can be contacted through the paging service provided by Critico or directly via the MRI Switchboard (0161 276 1234).

Using the Critico paging service
There are a number of ways to send messages via Critico.

Web-Send

- Go to www.criticogroup/web-send
- Enter the pager number of the person you are trying to contact in the "Number" field.
- Enter the telephone number that you wish to be contacted on, in the "Message" field.
- Click the "Send" button.

Email

- Send an email to *PagerNumber*.pageone@p1c.net
- Replace *PagerNumber* with the pager number of the person you are trying to contact.
- Make sure there is no signature in the body of the email and click "Send".

Via SMS Text Message

- Send a text to either 07860023039 or 07860023040.
- In the message, first type the pager number of the person you are trying to contact, then a space, then the number that you wish to be contacted on.

DDI (numeric) or Call-Centre (message)

- Dial the pager number of the person you are trying to contact.
- Follow the voice prompt to either:
- Enter a numeric message via your telephone keypad (the number you wish to be contacted on).
- Wait for the operator to answer and dictate your message when asked. The operator should confirm that your message has been sent.

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 request are normally **3 key identifiers** that should include at least:

- Patient's name (forename and surname)
- Date of birth
- Hospital number and or MFT 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 above 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 patient samples from Genitourinary Medical Centres or 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 2**)

All specimens should be transported at room temperature **(approximately 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 or via the paging service provided by Critico (see 3.1 Service Availability for instructions) or 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 HIVE request for users within MFT. See **Appendix 3** for a full list of tests and samples required.

HLA genotyping

Whole blood – minimum 3 ml EDTA blood	**No time limit**
Buccal swab	**No time limit**
Dried Blood Spot	**No time limit**

HLA antibody/ donor specific antibody (DSA) testing

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

Crossmatching

EDTA/ Heparinised blood for crossmatching	**Up to 24 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 Transplantation Laboratory, please call on 0161 276 6397 or email *TransplantLab@mft.nhs.uk* . These request cards are also available in electronic format upon request.

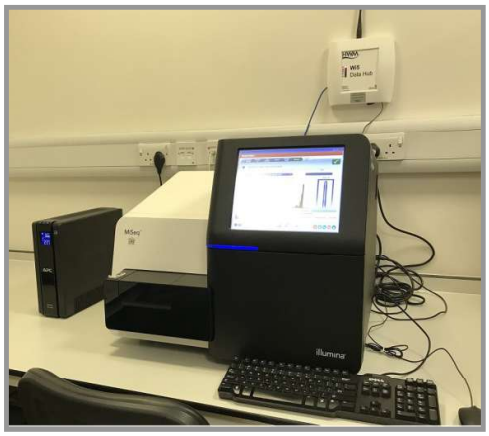
4. General Information regarding services available

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.



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.

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.

The technique used for testing varies according to the clinical requirement. All patients receive extensive next generation sequence (NGS) based typing analysis to provide a high-resolution HLA verification type.

The Transplantation Laboratory employs state of the art NGS HLA typing technology to assist in interpretation of HLA antibodies and thus permit suitable donor identification.

A rapid, but intermediate resolution technique (LinkSēq™ or QType) is also used to HLA type a potential donor in a solid organ transplant setting. These Rapid techniques may also be used in certain situations that require a rapid HLA typing result, or where supplementary testing is required to resolve an ambiguous HLA type or verify an HLA typing result produced from an alternative HLA typing methodology. Where this has been used and it may have a significant impact for the users they will be informed directly.

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.

It is important that patients are screened for the presence of HLA antibodies and that the specificities of any antibodies detected are defined prior to transplantation. **Samples for antibody screening should be sent to the laboratory every 8-10 weeks from patients on the transplant list and approximately two weeks after a known sensitising events (e.g. blood transfusions).** When a patient is known to have antibodies against a particular HLA specificity, that specificity is listed as an unacceptable donor antigen.

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.

For sensitised parous female patients being listed for transplantation, it is our policy to HLA type the father of the children or the children themselves in order to fully define pregnancy-related sensitisation where possible.

Some patients have non graft damaging “autoantibodies” that can cause false positive donor crossmatches, the laboratory will request samples to specifically test for these as necessary.

What is Crossmatching?

Crossmatching is a pre-transplant test in which donor lymphocytes are tested against serum samples from the potential recipient(s) to ascertain whether any donor–reactive antibodies are present that would cause transplant rejection. Donor-reactive antibodies that cause a positive crossmatch test are normally a contraindication to transplantation.

- The *cytotoxic crossmatch* is a cell killing test.
- The *flow cytometry crossmatch is* a more sensitive test that uses fluorescence to detect antibody binding to donor cells.
- A “*virtual crossmatch*” assessment is performed pre-transplant for solid organ patients, whereby the donor HLA type is reviewed against the patient’s HLA antibody profile (antibodies are listed as unacceptable antigens) to determine whether the patient has any donor-directed antibodies that could cause a positive crossmatch test result. In cases where all unacceptable antigens have been clearly defined, sensitised patients can be transplanted without the need for a prospective crossmatch as long as all

unacceptable antigens are absent from the donor HLA type. This is the basis of the current solid organ allocation process in the UK and the low frequency of unexpected positive crossmatches for patients suggests that patients who have been rigorously assessed and defined as negative for donor-directed antibodies can safely proceed to transplant before the crossmatch test result is available. The purpose of this approach is to reduce the cold ischaemia time without compromising the safety of transplantation.

Potential recipients will be assessed for their suitability for a “virtual crossmatch” against a particular donor and a “virtual crossmatch negative” report issued if appropriate. The transplant unit must be able to confirm that no potential sensitisation events have occurred since the date of the last patient serum sample tested for HLA antibodies.

Risk Assessment Crossmatching

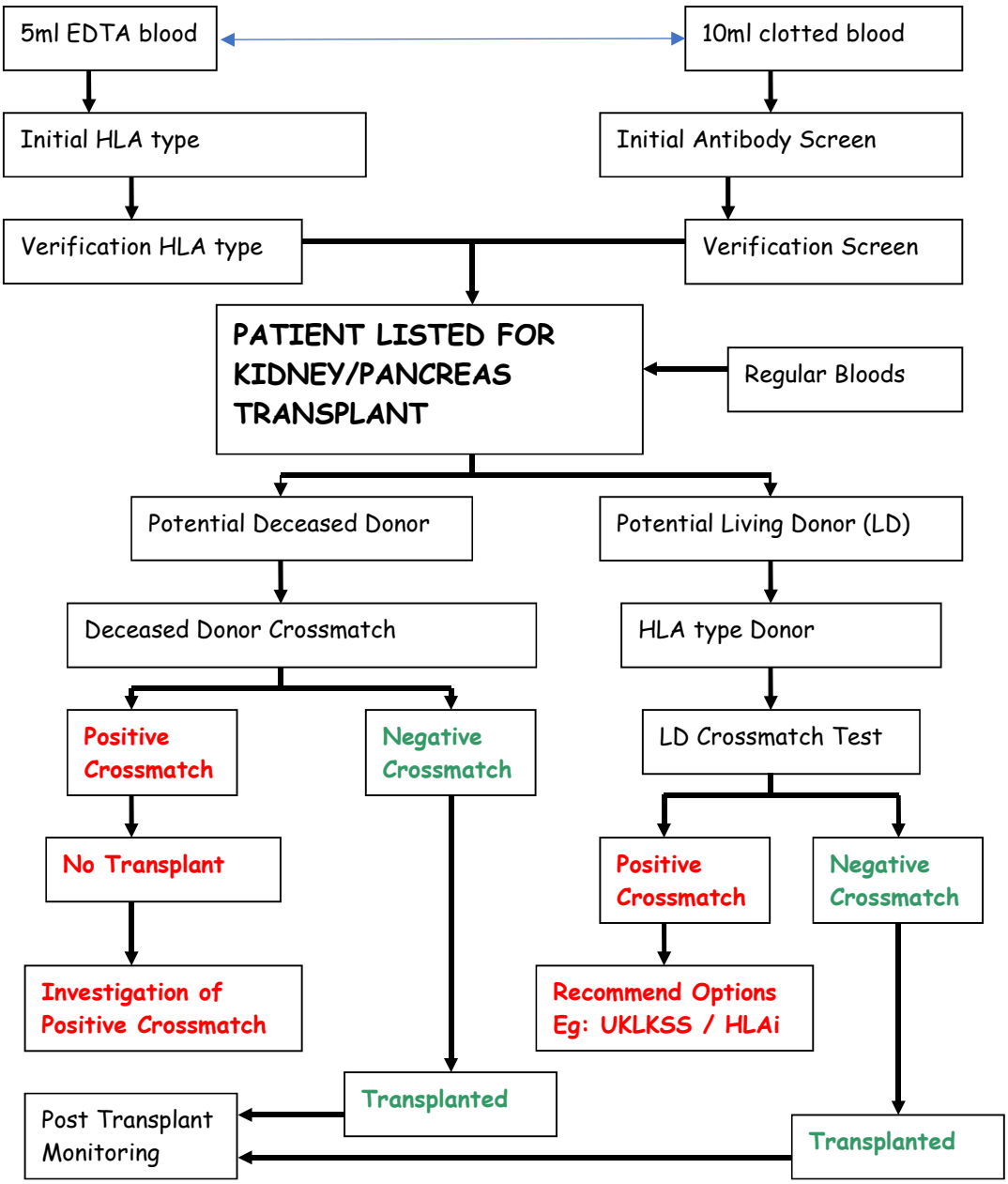
For patients with donor-directed antibodies, a pre-transplant “*risk assessment crossmatch*” can be performed on request. In a “risk assessment crossmatch” the level of immunological risk associated with proceeding to transplant with a particular donor is determined by performing a cytotoxic and flow cytometry crossmatch using both current and historic serum samples for the recipient. Immunological risk is then assigned based on the BSHI/BTS guidelines for Detection and Characterisation of Clinically Relevant Antibodies in Allotransplantation.

It must be noted that the validity of virtual and risk assessment crossmatch results for antibody positive patients is dependent on the donor HLA type being correct. In 2025, nationally, discrepancies were detected in 0.05% of donor HLA types after the organs had been allocated.

Post-transplant Donor Specific Antibody (DSA) testing

Post-transplant recipients can produce specific antibodies associated with transplant rejection. A post-transplant antibody monitoring service is available, including testing for donor-directed antibodies. Post-transplant samples for DSA testing to support the diagnosis of rejection should be sent when clinically indicated to support the diagnosis of antibody-mediated rejection.

Overview of Kidney / Pancreas Support Service for Patients with Chronic Renal Failure



5. Requesting Tests/Samples Required

The Transplantation Laboratory has its own distinctive request cards which can be obtained from the Transplantation Laboratory (TransplantLab@mft.nhs.uk). Internal on-site requests should be made using the HIVE 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 for the test required.

Appendix 3 includes a list of laboratory tests and sample requirements

NHS
Manchester University
NHS Foundation Trust

THE TRANSPLANTATION LABORATORY, MANCHESTER ROYAL INFIRMARY
TEL: 0161 276 6397 FAX: 0161 276 6148

SURNAME*	FORENAME*	DATE OF BIRTH*	SEX	HOSPITAL*

HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ____ Rh ____	Date ____ No. Units ____		

DIAGNOSIS* DONOR OTHER
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I ☐ ☐

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

RELATIONSHIP OF DONOR TO RECIPIENT_____
RECIPIENT_____

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____

DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

CM7817. 04/18 REV 3

KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

5.1 HLA (Tissue) Typing (Recipient)

Complete the request card as follows -It is essential that the patient is clearly identified on the card and on the specimen.

As a minimum requirement include –

1. patient surname, forename, date of birth, hospital number, referring hospital, consultant, person requesting the test and the date sample taken.
2. Select the relevant diagnosis.
3. Select the test required –
   a) at initial referral to laboratory (**1st set of bloods**) send both a 5ml EDTA blood for HLA typing and 10ml clotted blood for antibody screening.
   b) at surgical referral send both a 5ml EDTA blood for **verification typing** and 10ml clotted blood for antibody screening.

Recipient samples should be received within 24 hours by the laboratory and by <u>midday on Friday,</u> to allow adequate time for processing, except by prior arrangement.

<u>Send 5ml EDTA blood and 10ml clotted blood</u>

NHS
Manchester University
NHS Foundation Trust

THE TRANSPLANTATION LABORATORY, MANCHESTER ROYAL INFIRMARY
TEL: 0161 276 6397 FAX: 0161 276 6148

1

SURNAME*	FORENAME*	DATE OF BIRTH*	SEX	HOSPITAL*

HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

2

DIAGNOSIS*
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I DONOR ☐ OTHER ☐

3

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____ RELATIONSHIP OF DONOR TO RECIPIENT_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA

RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____
☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1
Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN
CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

CM7817: 04/18 REV 3

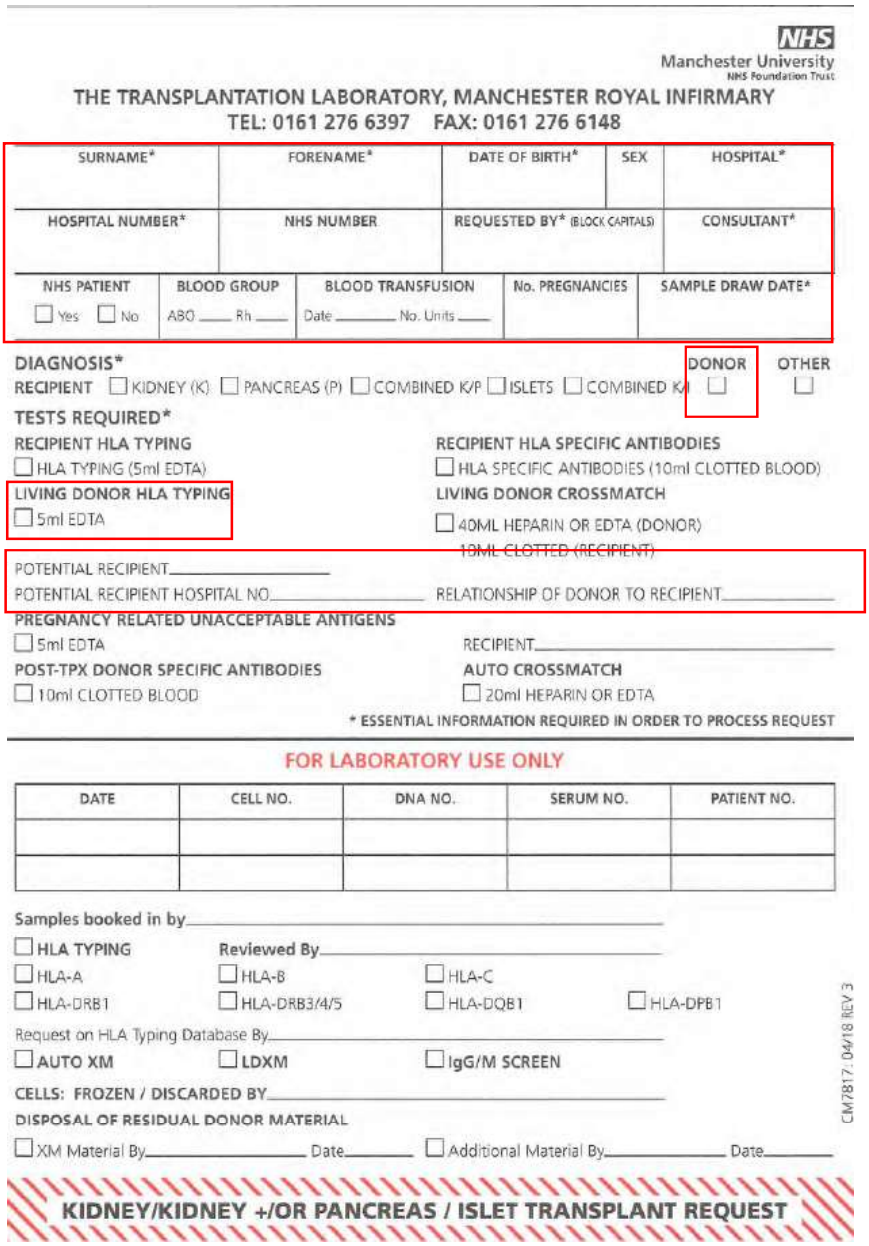
KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

5.2 HLA (Tissue) Typing (Potential Living Donor)

Complete the request card as follows -It is essential that the patient is clearly identified on the card and on the specimen.

As a minimum requirement include –

1. Potential donor surname, forename, date of birth, hospital number, referring hospital, consultant, person requesting the test and the date sample taken Wherever possible attach a copy of the potential donor's ABO report to the request card.
2. Select the relevant diagnosis.
3. Select the test requested and include the name of potential recipient plus relationship.



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1

SURNAME*	FORENAME*	DATE OF BIRTH*	SEX	HOSPITAL*

HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

2

DIAGNOSIS*
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I ☐ DONOR ☐ OTHER

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

3

LIVING DONOR HLA TYPING
☐ 5ml EDTA

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
~~10ML CLOTTED (RECIPIENT)~~

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____ RELATIONSHIP OF DONOR TO RECIPIENT_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA
RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

CM7817. 04/18 REV 3

KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

5.3 HLA (Tissue) Typing Pregnancy Related Bloods

Complete the request card as follows -It is essential that the patient is clearly identified on the card and on the specimen.
As a minimum requirement include –

1. surname, forename, date of birth, hospital number, referring hospital, consultant, person requesting the test and the date sample taken and name of potential recipient plus relationship.
2. Select the relevant diagnosis.
3. Select test required – Pregnancy related unacceptable antigens including the recipient's name.

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SURNAME*	FORENAME*	DATE OF BIRTH*	SEX	HOSPITAL*

HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

2

DIAGNOSIS* DONOR OTHER
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I ☐ ☐

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO._____ RELATIONSHIP OF DONOR TO RECIPIENT_____

3

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

CM/7817. 04/18 REV 3

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5.4 HLA (Tissue) Typing (Deceased Donor)

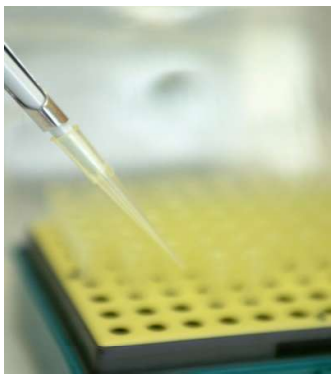
The on-call Clinical Scientist should be notified by the Specialist Nurse for Organ Donation (SN-OD) as soon as a potential donor has been identified. Samples must be accompanied by an NHSBT HLA Typing Request form (FRM4279/7.2) and should be delivered to Central Specimen Reception (CSR) at MRI.

Instructions on how to contact the laboratory on-call staff are printed on the specimen box lid. The on-call Clinical Scientist should immediately be notified of their arrival by the reception staff in CSR via switchboard so that collection and delivery to the laboratory can be arranged.

These will only be tested once consent has been given.

Send 10ml EDTA blood

5.5 HLA Antibody Screening



Routine bi-monthly samples from patients on the transplant list or post-transplant need not be accompanied by a request card although tubes must be clearly labelled with patient name, date of birth, hospital number and date of sample collection.

Samples can be received within 48 hours Monday to Friday and sent by 1st class post in appropriate packaging. (See Appendix 2)

<u>Send 10ml clotted blood</u>

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HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

DIAGNOSIS* DONOR ☐ OTHER ☐
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____ RELATIONSHIP OF DONOR TO RECIPIENT_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA

RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

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KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

5.6 Crossmatching (Deceased Donor)

Deceased organ donor samples

Donor spleen and lymph node specimens should be taken by the organ retrieval team and despatched to the Transplant Unit (MRI Ward 45). The on-call Clinical Scientist must be immediately notified of their arrival by the ward staff so that collection and delivery to the laboratory can be arranged.

Recipient samples

If a sample is requested by the laboratory for crossmatching against a potential kidney donor, send 10ml clotted blood as a matter of urgency.

For patients proceeding to transplant on the basis of a Virtual Crossmatch a “Day of Transplant” sample (10ml clotted blood) should always be sent to the laboratory for retrospective testing.

The Tissue Typer on call can be contacted through the paging service provided by Critico (See section 3.1) or directly via MRI Switchboard (0161 276 1234). Alternatively, it may be necessary to contact via the On Call mobile phones.

5.7 Crossmatching (Living Donor)

These tests must be pre-arranged with the laboratory, are time sensitive and must be accompanied by a request card – see an example below.

From the recipient **send 10ml clotted blood.**

From the donor **send 50ml EDTA blood**

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HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

DIAGNOSIS*
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I

DONOR ☐ OTHER ☐

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____ RELATIONSHIP OF DONOR TO RECIPIENT_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA

RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

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KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

5.8 Donor Specific Antibodies

Post-transplant samples for donor specific antibody testing to support the diagnosis of antibody-mediated rejection must be accompanied by a request card. See example below. Guidelines for the frequency of testing are shown in Appendix 7.

Send 10ml clotted blood.

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HOSPITAL NUMBER*	NHS NUMBER	REQUESTED BY* (BLOCK CAPITALS)	CONSULTANT*

NHS PATIENT	BLOOD GROUP	BLOOD TRANSFUSION	No. PREGNANCIES	SAMPLE DRAW DATE*
☐ Yes ☐ No	ABO ___ Rh ___	Date ___ No. Units ___		

DIAGNOSIS*
RECIPIENT ☐ KIDNEY (K) ☐ PANCREAS (P) ☐ COMBINED K/P ☐ ISLETS ☐ COMBINED K/I DONOR ☐ OTHER ☐

TESTS REQUIRED*

RECIPIENT HLA TYPING
☐ HLA TYPING (5ml EDTA)

RECIPIENT HLA SPECIFIC ANTIBODIES
☐ HLA SPECIFIC ANTIBODIES (10ml CLOTTED BLOOD)

LIVING DONOR HLA TYPING
☐ 5ml EDTA

LIVING DONOR CROSSMATCH
☐ 40ML HEPARIN OR EDTA (DONOR)
10ML CLOTTED (RECIPIENT)

POTENTIAL RECIPIENT_____
POTENTIAL RECIPIENT HOSPITAL NO_____ RELATIONSHIP OF DONOR TO RECIPIENT_____

PREGNANCY RELATED UNACCEPTABLE ANTIGENS
☐ 5ml EDTA

RECIPIENT_____

POST-TPX DONOR SPECIFIC ANTIBODIES
☐ 10ml CLOTTED BLOOD

AUTO CROSSMATCH
☐ 20ml HEPARIN OR EDTA

* ESSENTIAL INFORMATION REQUIRED IN ORDER TO PROCESS REQUEST

FOR LABORATORY USE ONLY

DATE	CELL NO.	DNA NO.	SERUM NO.	PATIENT NO.

Samples booked in by_____

☐ HLA TYPING Reviewed By_____
☐ HLA-A ☐ HLA-B ☐ HLA-C
☐ HLA-DRB1 ☐ HLA-DRB3/4/5 ☐ HLA-DQB1 ☐ HLA-DPB1

Request on HLA Typing Database By_____
☐ AUTO XM ☐ LDXM ☐ IgG/M SCREEN

CELLS: FROZEN / DISCARDED BY_____
DISPOSAL OF RESIDUAL DONOR MATERIAL
☐ XM Material By_____ Date_____ ☐ Additional Material By_____ Date_____

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KIDNEY/KIDNEY +/OR PANCREAS / ISLET TRANSPLANT REQUEST

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 email is available on request during office hours and Clinical Advice Scientist is available on a 24hr basis. The Measurement uncertainty (MU) shall be considered for all examinations which include a measurement step where it has influence on the reported result. Estimates of the MU will be made available to users upon request. Users shall be informed of deviations from agreement that may impact on results.

All times are quoted as working days from the receipt of the sample in the Transplantation Laboratory

For **HLA typing results** from renal patients, 90% will be issued **within 10 working days** of correct specimen receipt.

HLA typing results for deceased donors will be reported by email to NHSBT-OTDT, **within 4 hours of specimen receipt**.

HLA antibody screening results for new patients will be reported when the patient is listed for transplantation, unless specifically requested. For patients on the transplant list data on current antibody status is included on the circulated monthly transplant list. When there is a change in the antibody profile of a listed patient that would change their predicted wait time a *Renal Patient Antibody Profile* will be issued.

Potential Living Donor Compatibility Summary will be issued when all essential information and samples have been received by the laboratory usually **within 15 days of receipt**.

Deceased Donor / Recipient Crossmatch results are reported to the transplant team, **within 5 hours of receipt of crossmatch specimens**.

Immediate pre-transplant Living Donor / Recipient Crossmatch. A report will be issued by the day preceding the transplant date.

Donor Specific Antibodies results will be reported **within 15 working days of receipt**. Copy reports are available to view via HIVE.

Turnaround Time (TAT)

Over 90% of the results are reported within **the specified timescale** 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.

7. Patient Registration on the Kidney/Pancreas Transplant List

Essential Tests -

- **All patients**
  - ABO blood group report
  - HLA type (tested on two separate occasions)
  - HLA antibody screen
- **IgM alloantibody positive patients**
  - Autoantibody test

Recommended Tests -

- **Parous female patients**
  - HLA type of partner/father(s) of their children, or
  - HLA type of each child

Listing Process -

Refer patients to Transplant Surgeons. The referral letter **must** be accompanied by a completed listing proforma signed by the referring physician, plus a copy of the ABO blood group report. When the patient has been assessed and / or discussed at MDT, the form will then be countersigned by a Consultant Transplant Surgeon and then sent to the Transplantation Laboratory.

The Transplantation Laboratory will acknowledge receipt of the listing proforma and request any outstanding samples. When all necessary testing is complete the patient will be registered on the local and national (NHSBT-OTDT) lists.

Each month the laboratory will issue a report to each referring centre to show which patients are pending entry to the list and the outstanding specimens/data/tests.

As soon as the patient is registered on the transplant list a “Notification of Entry to the List” will be issued to the referring physician stating the patient’s antibody status, transplant category, organ required and an individualised review of factors that might affect wait time to transplant.

In addition, a letter is sent to the patient to notify them that they have been registered with NHSBT OTDT and whether they are currently “Active” on the list or “Temporarily Suspended”.

8. Maintenance on the Transplant List

Laboratory Tests

10ml clotted blood samples from each patient on the transplant waiting list must be sent to the Transplantation Laboratory every 8-10 weeks for HLA antibody screening and use in crossmatching.

10ml clotted samples must be sent two weeks post blood transfusion accompanied by a request card which includes transfusion information.

Any other tests will be specifically requested in writing by the laboratory as necessary.

Administration

A copy of the transplant list will be circulated monthly to each referring centre, the transplant unit and other individuals as agreed.

A monthly list will be circulated of all patients from whom clotted samples have not been received within the previous three months. A sample from each patient on the list should be urgently sent to the laboratory.

Requests to amend a patient's status on the transplant list must be notified to the recipient co-ordinators via email TransplantWaitingList@mft.nhs.uk, as soon as patient's suitability for transplantation changes. Local and national lists will be amended Monday to Friday.

Multi-disciplinary team meetings / Clinical Liaison / Patient Information

Representatives from the laboratory regularly meet with the clinical teams at the referring dialysis centres. These meetings facilitate the review of current transplant lists and patients in work up for transplant listing. They also include comprehensive reviews of patients with complex immunological profiles and provide advice on Transplant Options for these patients.

In addition, the laboratory contributes to patient education events including a monthly meeting organised at Manchester Royal for newly registered patients. The laboratory also offers the opportunity for patients to be referred to joint Nephrology / Immunology clinics. These clinics provide the patient with the opportunity meet with members of the transplant team (representatives from the laboratory and nephrology) to discuss their chance of a transplant offer and strategies to improve their chance of an offer.

9. Transfer of Patients to Other UK Transplant Units

NHSBT-OTDT issued guidelines in April 2006 designed to prevent patients being disadvantaged when transferring from one unit to another in terms of their registration on the national list.

As part of the maintenance of the transplant list the Transplantation Laboratory will notify NHSBT-OTDT when a patient is transferring to another transplant centre. In order to do this the referring dialysis centre must supply in writing to the Transplantation Laboratory the name of the patient transferring, the unit to which the patient is transferring and if possible, the name of the clinician who will assume responsibility at the receiving unit. In all cases a date from which the transfer is to be effective must be included.

Until the transfer process is completed the patient remains on the referring unit's transplant list. This is to ensure that the patient does not lose any accrued wait time points on the national list.

10. Deceased Donor Crossmatching and Transplantation

Potential recipients for a kidney/pancreas/islets from a deceased donor are identified by NHSBT-OTDT under the National Allocation Schemes.

Crossmatching

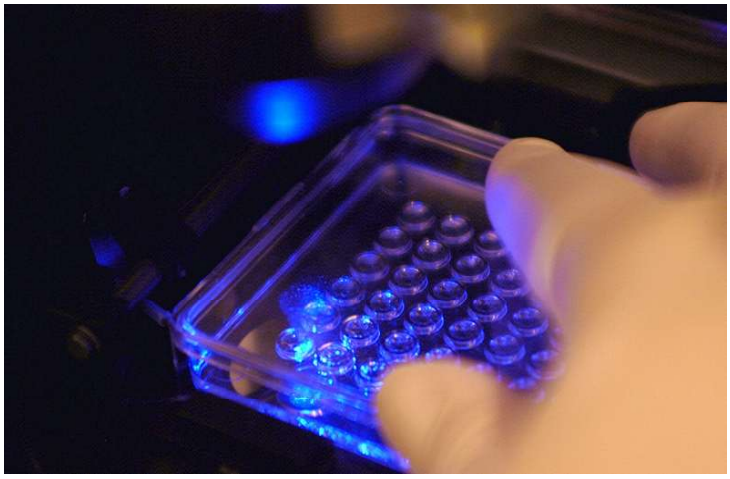
This is an essential pre-transplant procedure which must be carried out to ensure that the recipient has no donor-directed antibodies that would result in early transplant failure.

Potential recipients will be assessed for their suitability for “virtual crossmatching” and a “Virtual Crossmatch Negative” report issued when appropriate. For patient proceeding to transplant on the basis of a Virtual Crossmatch a “Day of Transplant” sample must be taken for retrospective testing.

Where a patient is NOT eligible for a Virtual Crossmatch the crossmatching requirements for that donor / recipient pair will be assessed and samples requested as appropriate via the recipient co-ordinators. All testing will be performed in parallel where possible to avoid delays which may lead to prolonged cold ischaemia time.

If a current recipient sample is requested by the laboratory for crossmatching against a potential donor, a 10ml clotted blood sample should be sent *to the laboratory as a matter of urgency*.

All crossmatch results are reported to the transplant team verbally, in writing by email and reports uploaded to HIVE.



11. Living Donor Programme

Initial donor selection

Laboratory tests: patients

ABO blood group – Copy results must be sent to the Transplantation Laboratory
HLA type
HLA specific antibody test
For parous female patients - HLA type father(s) of children or HLA type of each child.

Laboratory tests: donor

ABO blood group – Copy results must be sent to the Transplantation Laboratory
HLA Type

Compatibility Summary

Potential donors will be typed for HLA-A, -B, -Cw, -DR, -DQ and -DP. A Living Donor Compatibility Summary will be issued within three weeks of specimen receipt. The Living Donor Compatibility Summary will indicate the risk factors associated with each potential donor and their potential transplant options

Crossmatching

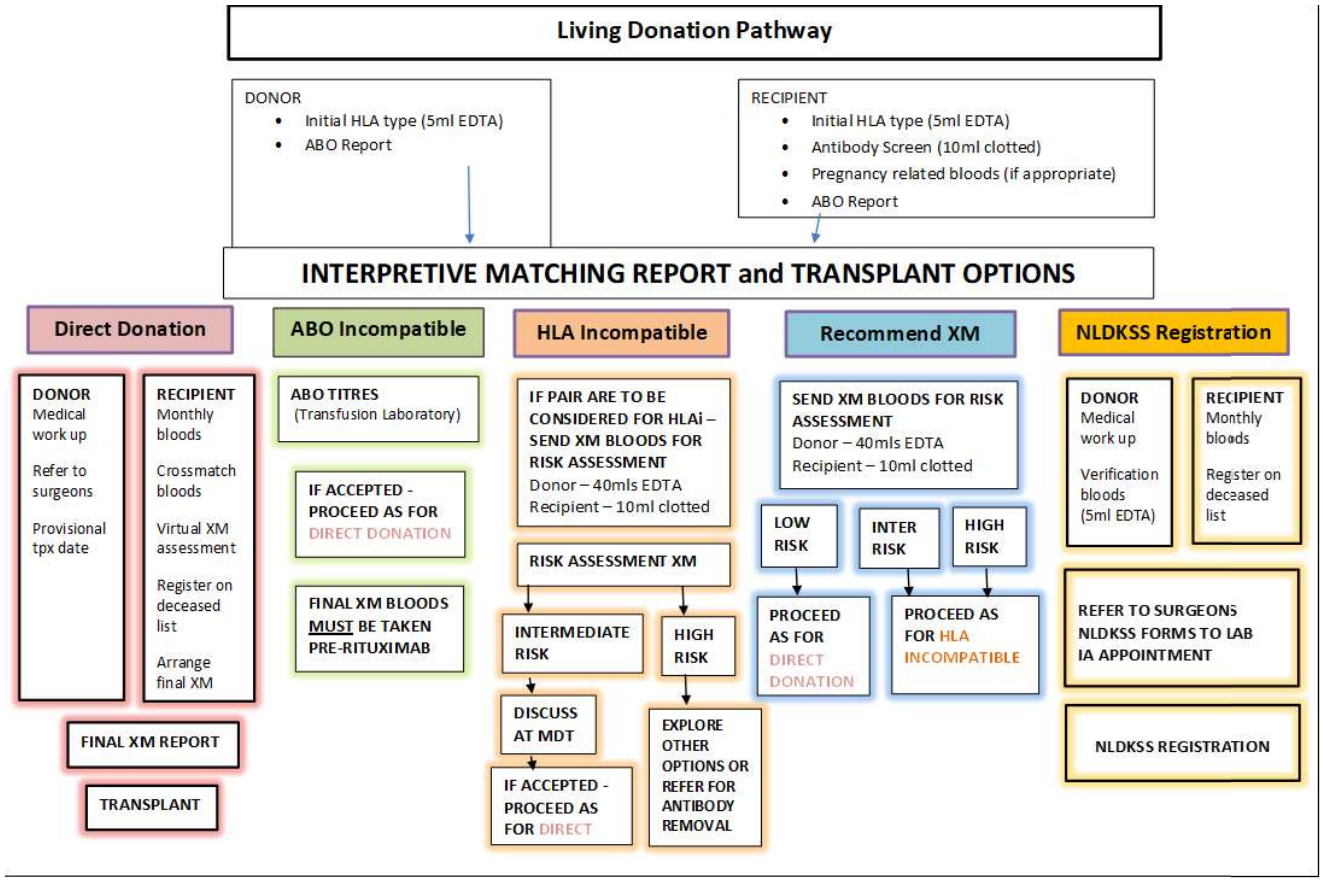
HLA antibody positive patients: Samples for crossmatching may be requested to assess the clinical significance of donor directed antibodies. They will be crossmatched by flow cytometry and cytotoxicity if indicated.
If the crossmatch is negative, then work up can proceed, an immediate pre-transplant crossmatch and antibody screen is also performed.
If the crossmatch is positive, a positive crossmatch report will be issued, and the pair may be referred for paired/pooled registration or HLA antibody reduction.
HLA antibody negative patients or patients with fully defined antibody profiles:
If patients fulfil the criteria for a "virtual crossmatch" as described previously, then a Virtual Crossmatch Report will be issued when the preliminary crossmatch test is requested. For patients who do not fulfil the criteria a flow cytometry crossmatch and antibody screen will be carried out. A final flow cytometry crossmatch test will be carried out in the week preceding the transplant.

United Kingdom Living Kidney Sharing Scheme (UKLKSS) Registration Process

ABO incompatible and / or HLA incompatible donor / recipient pairs can be registered with NHSBT-OTDT for Paired / Pooled donation. Compatible donor-recipient pairs who may seek a better HLA or age match may also be registered in the scheme.
The pairs are registered electronically by living donor co-ordinators via Living Path (livingpath.nhsbt.nhs.uk). The co-ordinators notify the laboratory once the pairs are available for the addition of H&I information by the laboratory.

Essential tests and information for donor registration

- Donor HLA type (tested on 2 separate occasions)
- Donor ABO blood group
- Surgical review of donor and recipient
- Recipient registration with NHSBT-OTDT on deceased donor list


Living Donation Pathway
DONOR
Initial HLA type (5ml EDTA)
ABO Report
RECIPIENT
Initial HLA type (5ml EDTA)
Antibody Screen (10ml clotted)
Pregnancy related bloods (if appropriate)
ABO Report
INTERPRETIVE MATCHING REPORT and TRANSPLANT OPTIONS
Direct Donation
ABO Incompatible
HLA Incompatible
Recommend XM
NLDKSS Registration
DONOR Medical work up
Refer to surgeons
Provisional tpx date
RECIPIENT Monthly bloods
Crossmatch bloods
Virtual XM assessment
Register on deceased list
Arrange final XM
FINAL XM REPORT
TRANSPLANT
ABO TITRES (Transfusion Laboratory)
IF ACCEPTED - PROCEED AS FOR DIRECT DONATION
FINAL XM BLOODS MUST BE TAKEN PRE-RITUXIMAB
IF PAIR ARE TO BE CONSIDERED FOR HLAi – SEND XM BLOODS FOR RISK ASSESSMENT
Donor – 40mls EDTA
Recipient – 10ml clotted
RISK ASSESSMENT XM
INTERMEDIATE RISK
HIGH RISK
DISCUSS AT MDT
IF ACCEPTED - PROCEED AS FOR DIRECT
EXPLORE OTHER OPTIONS OR REFER FOR ANTIBODY REMOVAL
SEND XM BLOODS FOR RISK ASSESSMENT
Donor – 40mls EDTA
Recipient – 10ml clotted
LOW RISK
INTER RISK
HIGH RISK
PROCEED AS FOR DIRECT DONATION
PROCEED AS FOR HLA INCOMPATIBLE
DONOR Medical work up
Verification bloods (5ml EDTA)
RECIPIENT Monthly bloods
Regster on deceased list
REFER TO SURGEONS NLDKSS FORMS TO LAB IA APPOINTMENT
NLDKSS REGISTRATION

12. Post-Transplant Follow-up

Transplant recipients may produce HLA specific antibodies associated with transplant rejection.

10ml clotted blood samples should be sent from kidney/pancreas transplant recipients to the Transplantation Laboratory **weekly** while the patient is on the Transplant Unit and then **when a transplant patient attends their initial follow-up clinic****. Following the initial visit monthly bloods should be taken for the first year and annually thereafter. Antibody production can then be monitored to identify humoral rejection. Also, a comprehensive immunological profile will be established should the patient require repeat transplantation.

If clinically indicated a Donor Specific Antibody test should be sent to the laboratory.

***** *10ml clotted blood samples accompanied by a request card must also be sent to the Transplantation Laboratory whenever a diagnostic transplant biopsy is performed.*

Islet cell transplant recipients receive Basiliximab as part of the immunosuppressive protocol. Serum samples should be sent to the Laboratory 48hours, 7-, 14- and 28-days post first infusion.

13. Standards

All aspects of the services provided for the renal / pancreas transplant programme are compliant with the relevant standards/guidelines.

BSHI BTS: Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation.

Standards for Histocompatibility Testing Version 8.0 European Federation for Immunogenetics (EFI). January 2020

ISO 15189:2022(en) *Medical laboratories — Requirements for quality and competence*

14. Appendix

Appendix 1:

Effect of Rituximab on Laboratory Assays

As you will be aware, Rituximab is an IgG monoclonal antibody directed against CD20 which is expressed on B lymphocytes. It is therefore an anti-B cell agent and one of the main routes of action is thought to be by complement activation.

In the cytotoxic crossmatch test, donor lymphocytes are incubated with recipient serum. If donor directed HLA specific antibodies are present, then the donor cells are killed, and this positive result is a contraindication to transplantation.

If a patient is treated with Rituximab, then that will be present in their serum and will also cause cell killing in the crossmatch test. That false positive result will deny a patient a transplant that might actually have been compatible. This situation arose recently when a patient's current serum sample was unexpectedly crossmatch positive. In the absence of information to identify this as a false result, transplantation had to be denied pending further investigation. It transpired that there were no HLA specific antibodies in that sample, but the patient had been treated with Rituximab four months previously.

With this in mind, please notify the Transplantation Laboratory when a patient is treated with Rituximab. The solid phase HLA antibody detection and definition tests we employ are not affected by Rituximab. It is possible to increase the frequency of these tests and to use the results alongside information on the patient's treatment in the interpretation of a crossmatch result. In that way, patients will not be denied a compatible transplant.

Many thanks for your support,

Kay Poulton

Consultant Clinical Scientist

Appendix 2

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.

Appendix 3

List of Tests and Samples Required

Test	Sample Required
Recipient HLA Typing (Initial HLA type)	5ml EDTA and 10ml clotted blood
Recipient HLA Typing (Verification HLA type)	5 ml EDTA and 10ml clotted blood
Recipient HLA-Specific Antibody Screen	10ml clotted blood
Recipient Autoantibody test	20ml EDTA and 10ml clotted blood
Potential Living Donor HLA Typing	5ml EDTA blood
Deceased Donor HLA Typing	10ml EDTA blood
Crossmatching (Deceased Donor)	**Donor:** 50 ml EDTA blood and/or spleen and lymph node samples **Recipient:** 10ml clotted blood
Crossmatching (Living Donor)	**Donor**: 40ml EDTA blood **Recipient**: 10ml clotted blood
Recipient Post-Transplant Monitoring	10ml clotted blood

Appendix 4

Tools available for transplant chance calculation and estimated wait times

NHS BT OTDT have built an on-line calculator called NHSBT Kidney Risk Communication Tool (Kidney-RCT). It was designed to aid discussions between patients and clinicians. The calculator asks for some details about the patient and presents the results in the form of graphs and bar charts based on these details.

Currently the results presented for kidney patients are: waiting time (from point of listing) and chance of getting a transplant whilst acknowledging the risk of death on the list or removal from the list. To create the results presented, data about patients in the past were used to build statistical models and extract results based on what happened to people “like this”.

The Kidney-RCT has been designed to be used by clinicians with patients. It is a communication tool and should not be used by itself to make decisions. The Kidney-RCT can be found on the NHS BT OTDT clinical website (https://otdt.nhs.uk/transplantation/tools-policies-and-guidance).

Appendix 5

Crossmatching for Deceased Donor Renal Transplantation

The purpose of the crossmatch test is to determine whether a patient has antibodies which indicate sensitisation against the specific donor. The cytotoxic crossmatch test has long been established as the definitive pre-transplantation test to prevent hyperacute rejection.

Cytotoxic crossmatching

Patient serum samples are added to donor lymphocytes and incubated. If the serum contains donor-specific HLA antibodies these bind to the donor lymphocytes and cause cell death. This can be visualised using a microscope.

Flow cytometry crossmatching

Flow cytometry crossmatching is a more sensitive method of crossmatching and is used as an additional test for patients deemed to be at "higher risk" e.g.: those with complex HLA specific antibody profiles.

A flow cytometer detects antibody binding to donor lymphocytes using fluorescence. Software is used to calculate whether the result is positive or negative. This test, when required, is **conducted in parallel** with the cytotoxic crossmatch test.

Patient serum samples are chosen carefully to represent the patient's screening history.

These tests take on average **3 hours** from receipt of donor material or, if required, a clotted sample from the recipient.

Virtual crossmatching

A virtual crossmatch report may be issued ***before crossmatch testing takes place*** for some eligible patients. This is followed up by a retrospective cytotoxic crossmatch test which is subsequently also reported.

Patients eligible for a virtual crossmatch are those who have been rigorously assessed and defined as **having no donor-directed sensitisation.**

In some instances, HLA antibody positive patients may be considered as suitable for virtual crossmatch. However, these patients are assessed on a case-by-case basis and may require HLA antibody specificity definition testing prior to a report being issued.

The virtual crossmatch report states that it is essential that the patient has experienced no sensitising events (e.g. transfusion of blood products, infection or pregnancy) since the date of the most recent HLA antibody test result. It is also noted that in 2025, nationally, discrepancies were detected in 0.05% of donor HLA types after organs had been allocated. This poses a risk for sensitised patients progressing to transplant on the basis of a negative virtual crossmatch.

Samples required for deceased donation crossmatching

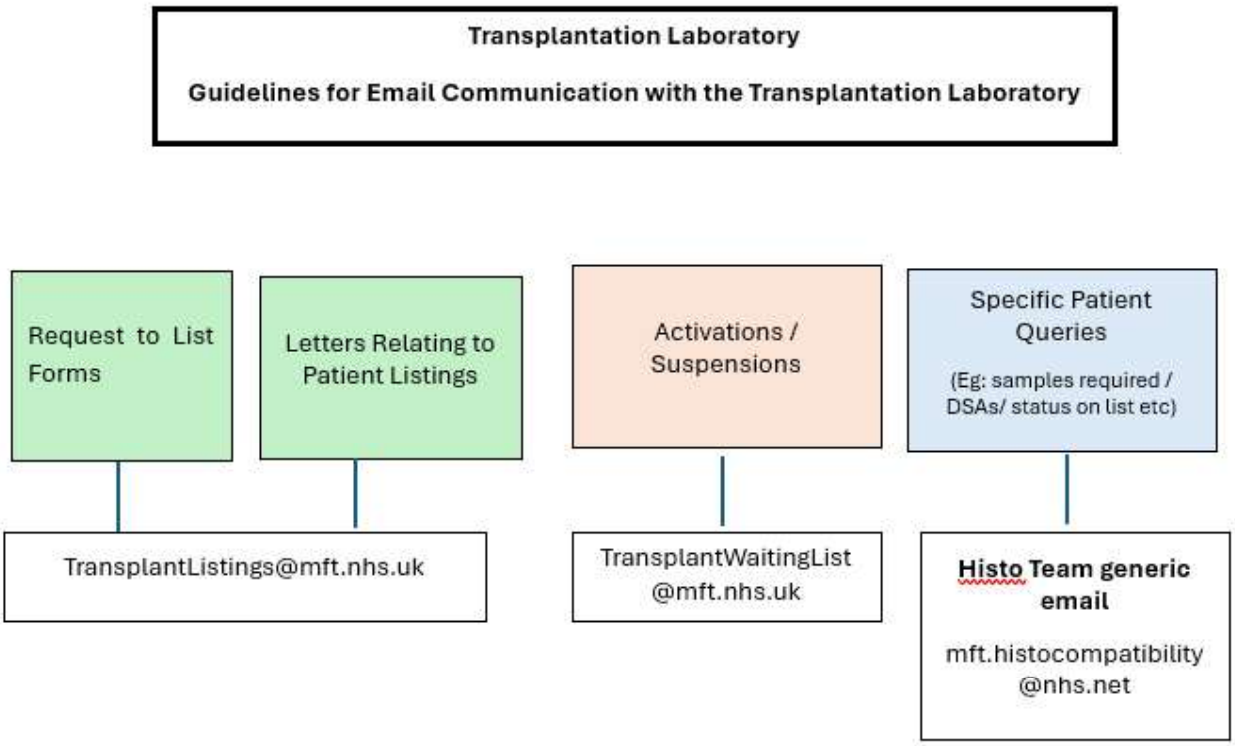
Recipient

Serum samples stored by the laboratory are used for crossmatching. A **clotted blood** sample taken from the recipient taken on the day of transplant is required for the crossmatch test.

Deceased Donors

Peripheral blood (50ml EDTA and/ or Spleen (or lymph node) for crossmatch and confirmatory HLA type.

Appendix 6



Appendix 7

Guidelines for DSA testing

Background
Donor-Specific HLA-Antibodies (DSA) are associated with allograft rejection and graft failure of transplanted organs. By systematic post-transplant monitoring in kidney, or simultaneous pancreas and kidney transplant recipients, it is possible not only to identify patients at highest risk of immune-mediated graft loss, but also to initiate early intervention strategies to prevent this. In this policy, we aim to provide guidelines for monitoring all recipients post-transplant for the presence of DSA, with recommended additional measures should the clinical post-transplant profile indicate that the patient is at high risk of graft loss. These recommendations have been adapted from Tait et al, 2013 *Transplantation Volume 95, Number 1, January 15, 2013, and BSHI BTS: Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation*

1. **During the First 12 months**
   a. **Standard Risk Patients (No pre-transplant donor directed antibody)**
   Screen for the presence of DSA under the following circumstances:

   12 months after transplantation, unless there is cause for concern. e.g.
      1. Whenever a significant change in immunosuppression is considered (e.g. reduction/withdrawal/conversion)
      2. Suspected non-compliance
      3. Graft dysfunction
      4. Before transfer of care to another transplant centre.

   b. **Standard Risk Patients (Pre-transplant donor directed antibody detectable by Luminex only)**

   Monitor for DSA at one month, unless there is cause for concern. e.g.
      1. Whenever a significant change in immunosuppression is considered (e.g. reduction/withdrawal/conversion)
      2. Suspected non-compliance
      3. Graft dysfunction
      4. Before transfer of care to another transplant centre.

   c. **Intermediate risk Patients (Pre-transplant donor directed antibody detectable by flow cytometry crossmatch)**
   Monitor DSA on day 4, 7, 14 and weekly thereafter for first month. If there is additional cause for concern:
      Send samples to the Transplant Laboratory daily during period of concern for accurate monitoring of DSA fluctuations. All samples will be stored, and testing will be performed as appropriate after discussion with the laboratory and clinical teams to assess appropriate frequency of testing.

   Monitor monthly if all is well until Month 6

   d. **High Risk Patients (Pre-transplant donor directed antibody detectable by complement dependent cytotoxicity)**
   These patients are recognised to be at very high risk of early clinical rejection and AMR in the first three months.

      i. Monitor DSA on day 4, 7, 10, 14 and weekly thereafter for first month.
      ii. If there is additional cause for concern:
      Send samples to the Transplant Laboratory daily during period of concern for accurate monitoring of DSA fluctuations. All samples will be stored, and testing will be performed

as appropriate after discussion with the laboratory and clinical teams to assess appropriate frequency of testing.

iii. Monitor monthly if all is well until Month 6
iv. Monitor every 3 months

2. After 12 months

Monitor annually upon the anniversary of the transplant, unless there is cause for concern as outlined above.