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USER MANUAL

**REGIONAL HISTOCOMPATIBILITY & IMMUNOGENETICS
LABORATORY**

Additional Information & Cross References	
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1.0 Contact Details

Regional Histocompatibility & Immunogenetics Laboratory
 First Floor, Northern Ireland Blood Transfusion Building
 Belfast City Hospital
 Lisburn Road
 Belfast, BT9 7TS

Telephone: 028 950 43240 (internally 43240)
 Analogue contingency line: 028 961 57427
 Fax contingency line: 028 961 57428 (please call this number prior to sending a fax)

General enquiries (Admin only): TissueTypingGenEnq@belfasttrust.hscni.net
 Laboratory test enquiries: TissueTyping-SM@belfasttrust.hscni.net

On call scientist: 028 9032 9241 and ask for Tissue Typing on call

Table 1: Laboratory Contact Details

Position	Name	Telephone (028)	Email
Clinical Lead	Position vacant		
Laboratory Service Manager	Miss Elaine Boyle	950 44529	elaine.boyle@belfasttrust.hscni.net
Senior Clinical Scientist	Miss Bernadette Magee	950 43702	bernie.magee@belfasttrust.hscni.net
Senior Clinical Scientist	Dr Brian McIlhatton	961 55774	brian.mcilhatton@belfasttrust.hscni.net
Principal Biomedical Scientist	Mr Miceal Cole	950 42894	miceal.cole@belfasttrust.hscni.net
Antibody Section	Mr Ashley Meenagh	950 42894	ashley.meenagh@belfasttrust.hscni.net
Serology Section	Mr Miceal Cole	as above	as above
Molecular Section	Dr Jessica McCappin	950 42893	Jessica.mccappin@belfasttrust.hscni.net
Information & Admin Manager	Ms Elaine McNamara	950 43735	Elaine.mcnamara@belfasttrust.hscni.net
Information Systems manager	Mr Gerry Lennon	950 46090	gerry.lennon@belfasttrust.hscni.net
Quality Officer	Dr Fionnuala Williams	950 48750	fionnuala.williams@belfasttrust.hscni.net

ODT & Transplant Co-Ordinators contact	TissueTyping-SM@belfasttrust.hscni.net
Urgent DSA requests	HLAantibodies@belfasttrust.hscni.net

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1.1. General Information

The regional Histocompatibility & Immunogenetics (H&I) Laboratory is a speciality laboratory which provides a range of complex molecular, serological and cellular testing to support kidney transplantation, haematopoietic stem cell transplantation, blood transfusion services and diagnosis of HLA-associated diseases.

It is located within the Belfast Health and Social Care Trust, on the Belfast City Hospital (BCH) site in the Northern Ireland Blood Transfusion (NIBTS) building.

The laboratory is currently accredited by the United Kingdom Accreditation Service (UKAS) under the standards defined for Medical laboratories – requirements for quality and competence (ISO 15189:2012). The scope of the laboratory accreditation with UKAS is as outlined in the following link;

[9811 Medical Single \(ukas.com\)](https://www.ukas.com/9811/medical-single)

The laboratory has recently moved to a bespoke Manzen LIMS system (August 2019), for logging all samples received and for reporting of results. This system will soon be linked to the Electronic Care Record (ECR) system to enable users to access results and reports electronically. In the interim reports are issued to the relevant clinicians via the postal system or via email as agreed with the clinical teams. If any users have any difficulties in obtaining reports or information, please contact the H&I admin team or main laboratory.

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1.2. Laboratory services

a) Kidney transplantation

The laboratory supports kidney transplantation by:

1. determining the HLA type of potential donors and recipients
2. defining HLA antibodies in recipient serum
3. liaising with ODT to ensure compatible kidneys are offered for patients
4. assessing compatibility between donor and recipient pairs (cross matching)
5. stratifying risk associated with HLA antibodies
6. communicating with clinicians to facilitate personalised decision making
7. testing for the development of post-transplant HLA donor specific antibodies

b) Haematopoietic stem cell transplantation

The laboratory supports haematopoietic stem cell transplantation by:

1. determining the HLA type of potential donors and recipients
2. assigning haplotypes within families
3. advising on compatible donor options for recipients
4. coordinating high resolution HLA typing

c) Blood transfusion services

The laboratory supports blood transfusion services by:

1. defining HLA antibodies in patients with platelet refractoriness
2. determining class I HLA type for patients with platelet refractoriness
3. providing search results for HLA matched platelets and packed red cells
4. determining the HLA type of volunteer platelet and stem cell donors (service level agreement)

d) Diagnosis of HLA-associated disease

The laboratory supports the diagnosis of disease by testing for the associated risk HLA alleles for:

1. Ankylosing spondylitis/anterior uveitis
2. Behcet's disease
3. Birdshot's chorioretinopathy
4. Coeliac disease

HLA testing for other HLA associated genetic diseases is available upon agreement with the laboratory.

The H&I laboratory does not offer any patient facilities.

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1.3. Opening hours

Normal working hours

9.00 am to 5.00 pm Monday to Friday, excluding bank holidays.

On call service

24 hours, 365 days a year out-of-hours on call service for kidney transplantation. Enquiries to the duty on-call scientist and clinical on-call scientist are made via the Belfast Trust switchboard.

1.4. Clinical advice

When advice on the clinical relevance of laboratory results is required please contact the H&I laboratory during working hours. At other times, please contact the on-call duty clinical scientist or consultant/head of laboratory via the BHSCT switchboard. Consultant advice is available 24 hours a day, 365 days a year.

If you have difficulty in collecting a blood sample from a patient for an H&I test, please contact the laboratory for further assistance. In some instances it may be appropriate to collect a buccal swab sample, but please be aware that the result time will be extended by 2 days. This is to permit Covid screening prior to HLA testing.

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1.5. Sample documentation

Request forms:

(available by contacting 028 950 43240 or TissueTypingGenEnq@belfasttrust.hscni.net)

1. patient's full name*
2. date of birth*
3. gender
4. Health & Care Number and / or Hospital Number*
5. date of sample acquisition*
6. test request*
7. clinical details
8. name and contact details of requesting clinician*
9. signature of clinician, nurse or phlebotomist who has taken the sample*¹

¹ indicates the exception for disease association request forms.

Specimen:

(available by contacting 028 950 43240 or TissueTypingGenEnq@belfasttrust.hscni.net)

1. patient's full name*
2. date of birth*
3. Health & Care Number and / or Hospital Number*
4. date of sample acquisition*
5. signature of clinician, nurse or phlebotomist who has taken the sample*

Please note that;

* indicates mandatory information. Samples may be rejected if these fields are not completed. Users will be informed of request rejection by letter, which will state the reason for rejection.

Additional testing requests on existing samples

There may be occasions when a clinician wishes to retrospectively request additional testing to be performed on a sample already received by the laboratory. Please contact the laboratory for advice regarding the suitability of the request.

1.6. Frequency of testing

The H&I laboratory adheres to the British Society of Histocompatibility and Immunogenetics (BSHI) guidelines for the frequency of testing.

Each renal unit is issued with a collection schedule for HLA specific antibody testing for patients on the transplant waiting list and for post-transplant monitoring.

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1.7. Sample requirements




Please see appendix 1 for details on sample requirements.

The laboratory must be informed if a patient has received monoclonal or polyclonal antibody therapies or chemotherapy agents as these may interfere with testing. This includes, but is not limited to, anti-thymocyte globulin (ATG), Rituximab, Bortezomib, IV immunoglobulin and cyclophosphamide.

1.8. Sample storage

If samples are to be left in a clinical area after the last collection the samples need to be stored as outlined below. If samples are to be stored in the fridge overnight then ensure that the samples are removed from the fridge the next working day and left at the designated sample collection point.

Table 2: Storage conditions for samples left in the clinical areas overnight

Sample Type	Sample Container	Storage conditions - overnight only
Clotted sample		2-8°C fridge
EDTA sample		2-8°C fridge
Citrated sample		All samples must be delivered to the H&I laboratory during normal working hours During the out-of-hours period, samples should be stored horizontally at room temperature and forwarded to the laboratory as soon as possible the next working day.

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1.9. Sample packaging and transport

Users should refer to the Trust policy document titled 'Transport of specimens to the Laboratory'. This policy is available in the Belfast Trust Laboratories User Manual which is accessible on the home page of the intranet or via the internet at:

[Laboratory Services | Belfast Health & Social Care Trust \(hscni.net\)](#)

Urgent samples

The laboratory must be telephoned to arrange all urgent samples before the specimen is sent to the laboratory. It is not sufficient to mark the request form as urgent. The requesting clinician is responsible for arranging transport of urgent samples to the laboratory. Samples should not be left in the clinical areas over weekends and bank holiday periods.

Deceased donor samples

Laboratory staff must be contacted to arrange testing.

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1.10. Data Protection

The legal requirement for the Trust and its staff to treat personal information confidentially and hold it securely is set out in the Data Protection Act 1998, Data Protection Act 2018 and the GDPR regulations 2016. The Belfast Health & Social Care Trust has the following document in place and it is available via the BHSC Intranet site or from the laboratory on request: Policy On the Data Protection and Protection of Personal Information 2018 (reference TP026/08).

1.11. Consent and confidentiality

To comply with the Human Tissue Act legislation (Human Tissue Act, 2004), it is the responsibility of the requester to ensure that any patient or donor has been informed of and has consented to the tests being requested.

The H&I laboratory may ask the requester to provide a copy of this information. Patients/donors should be informed that any residual material of a sample may be stored as part of required archiving protocols or to enable further investigation for the benefit of the individual. They also must be informed that excess surplus material may be used anonymously for quality control purposes, service development or education, and / or ethics committee approved research projects.

Where patient or donor consent is required it is the responsibility of the requester to ensure the subjects of any tests have given informed consent. Unless written notice is received to the contrary, consent for investigations and the use of any surplus sample in scheduled purposes (quality control, staff development or ethics committee approved research) will be assumed.

The H&I laboratory will seek patient consent prior to disclosing clinical information and family history to healthcare professionals that are not directly involved with the care pathway of the initial referral.

All donor and patient details are handled according to local and national regulations with reference to patient confidentiality.

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1.12. Communication of Results

The H&I laboratory does not directly report results to patients, parents or carers. All relevant reports are printed, signed by authorised staff and sent to the requesting clinician.

Verbal reports

Urgent/critical and amended results may be telephoned or emailed to relevant users e.g. the crossmatch results from deceased and living donor crossmatches will be communicated verbally or by email followed by a hard copy report.

Emailing reports

The Belfast City Renal Unit also has access to TissueTyping-SM@belfasttrust.hscni.net in regard to communication relating to deceased donor crossmatching results.

Renal Patient Antibody Results

Pre-transplant HLA antibody testing results are not routinely reported with agreement of the clinical team. Reports are issued on request.

Antibody profiles for renal transplant patients, on the deceased donor waiting list, are reported electronically to NHSBT-ODT.

1.13. Cessation of Testing

If for any reason an examination has to be stopped, e.g. due to an identified quality issue, reports may need to be withheld until the non-conformity etc. has been resolved. The H&I laboratory will alert all users of any delay in the reporting of results if it impacts the patient care pathway or treatment and will also inform the user when testing has resumed.

1.14. Referral Tests

High resolution HLA molecular typing is outsourced to NHSBT Filton. The H&I laboratory reviews the suitability of all referral laboratories and holds documentation to substantiate their suitability. Further details are available upon request.

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1.15. Measurement Uncertainty

Measurement Uncertainty uses the principles of metrology to provide a measure of the dispersion of values within which the true result is likely to lie. The H&I laboratory implements the BSHI guidelines regarding Measurement Uncertainty. Please contact the H&I laboratory if you require further details.

1.16. External Quality Assurance

All laboratory tests performed are externally quality assured; test performance can be obtained upon request.

1.17. Point of Care Testing

The H&I laboratory does not provide point of care testing.

1.18. User Satisfaction and Complaints

The H&I laboratory is committed to continuously improving the quality and range of services provided and welcomes any comments or suggestions from the service users. A User Satisfaction Survey is conducted biennially by the H&I laboratory and forms part of the Management Review (MR). Current users of the H&I laboratory are invited to participate in this survey and responses are discussed, included in the MR and feedback given to users. A summarised version of the MR report will be made available to users of the service upon request to the laboratory manager.

The H&I laboratory is committed to fully investigating failures in service delivery to reduce the risk of recurrence, improve the service and ensure compliance with the Trust clinical governance policies. Please contact the H&I Laboratory Service Manager if there are concerns or complaints. All complaints are recorded, reviewed and acted upon.

However, if you are unhappy with the handling or resolution of your complaint, then please contact the Trust Complaints Department.

Complaints Department

BHSCT Complaints Department
Musgrave Park Hospital
McKinney House
Stockman's Lane
Belfast
BT9 7J





Tel: 028(95) 048000

Fax: 028(90) 903018

[Email:complaints@belfasttrust.hscni.net](mailto:complaints@belfasttrust.hscni.net)




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Appendix 1: Tests and sample requirements

Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
HLA Specific Antibody Screening (<i>routine</i>) (Luminex)	Blood (clotted)		9 ml	Routine HLA specific antibody screening to be performed every 3 months as per BSHI guidelines. This pertains to all patients active and suspended on the waiting list, and from all patients identified as suitable for transplantation.	Pos/Neg - detailed in report	Ideally received within 24hrs Refer to Interfering therapeutic agents*	Renal - up to 15 working days Liver – up to 10 working days **(99.9% compliance)
HLA Specific Antibody Screening & Identification (<i>urgent</i>) (Luminex)	Blood (clotted)		9 ml	To be arranged in collaboration with the H&I laboratory.	Pos/Neg - detailed in report	Ideally received within 24hrs Refer to Interfering therapeutic agents*	1 - 2 working days **(100% compliance)
Routine Post-transplant collection of samples (Luminex)	Blood (clotted)		9 ml	Year 1 Post-Transplant Collected every 2 weeks for the initial 2 months period, then at 6 months and 1 year. Year 2+ Post-Transplant 1 sample collected annually on the approx. transplant anniversary.	For storage until re-graft is required	Ideally received within 24hrs Refer to Interfering therapeutic agents*	N/A
HLA Specific Antibody Screening Renal Recipients - Post Transfusion (Luminex)	Blood (clotted)		9 ml	Samples must be taken on 2 occasions after a blood transfusion - ideally at 14 & 28 days post-transfusion. This applies to all patients already on the waiting list and to those identified as suitable for transplantation but not yet listed with NHSBT.	Pos/Neg - detailed in report	Ideally received within 24hrs Refer to Interfering therapeutic agents*	Up to 15 working days **(99.9% compliance)







*List of Interfering therapeutic agents: ATG, Bortezomab, Campath/Alemtuzmab, Cyclo-Phosphamide, IVIG/Plasmaphoresis, MMF, Rituximab, Tamoxifen, etc.

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Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
1 st Living Donor Crossmatching <i>(flow cytometry/CDC)</i>							
Recipient	Blood (clotted)		9 ml	To be organised via Living Donor Transplant Co-ordinators BCH#48293/49437	Pos/Neg - detailed in report	Ideally taken from the peripheral vein and received within 24hrs of venesection. Sent to the laboratory first thing on day of crossmatch.	Report within 10 working days (verbal, email or hard copy results if necessitated)
Donor	Blood (sodium citrate)		60 ml	If storing citrate samples overnight before forwarding to the laboratory please ensure they are stored horizontally at room temperature.		Cell viability - sample should be ideally tested within 24hrs of venesection. Poor cell viability may affect assay validity. Refer to Interfering therapeutic agents *	
Final Living Donor Virtual Crossmatch (VXM) <i>(luminex SAB)</i>	Blood (clotted)		9 ml	To be supplied within 14 days of the Transplant date.	Pos/Neg for DSA - detailed in report	Ideally received within 24hrs of venesection Refer to Interfering therapeutic agents *	2-3 working days of testing





*List of Interfering therapeutic agents: ATG, Bortezomab, Campath/Alemtuzmab, Cyclo-Phosphamide, IVIG/Plasmaphoresis, MMF, Rituximab, Tamoxifen, etc.

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Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
HLA Autoantibody Cross-matching (flow cytometry/CDC)	Blood (sodium citrate)		20 ml	Samples are organised in collaboration with the renal recipient transplant co-ordinator and laboratory staff.	Pos/Neg - Qualitative report	Cell viability - Sample should be tested within 24hrs Refer to Interfering therapeutic agents*	N/A (Results held locally)
	Blood (sodium citrate)		40 ml	If storing citrate samples overnight before forwarding to the laboratory please ensure they are stored horizontally at room temperature.			
HLA Typing for Local Deceased Donors (RT-PCR/ CDC)	Blood (sodium citrate)		20 ml	Must be arranged through the Specialist Nurses for Organ Donation (SNOD).	Qualitative-detailed in report	Poor cell viability may affect serological HLA typing.	Within 4 hours **(87.7% compliance)
	Blood (EDTA)		4 x 2ml or 3 x 4ml				
Deceased Donor Crossmatching (CDC)	Spleen/ Lymph node		N/A	N/A	Qualitative-detailed in report	Poor cell viability may affect serological HLA typing.	Up to 8 hours depending on complexity (numbers too small for statistical accuracy for compliance evaluation)
	Blood (sodium citrate)		Up to 100mls				

*List of Interfering therapeutic agents: ATG, Bortezomab, Campath/Alemtuzmab, Cyclo-Phosphamide, IVIG/Plasmapheresis, MMF, Rituximab, Tamoxifen, etc.






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Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
HLA Molecular Typing for Renal Recipient & Living Donor <i>(PCR-SSO Luminex)</i>	Blood (EDTA)		4 ml	N/A	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 12 working days <i>(92.1% compliance)</i> N.B.Buccal requests will require an extra 2 days.
	Buccal/ Cytology brush		N/A				
HLA Molecular Typing for Haematopoietic Stem Cell Transplantation (HSCT) Recipient and Potential Donors <i>(PCR-SSO Luminex)</i>	Blood (EDTA)		4 ml	All HLA-typing of families within N. Ireland must be pre-booked and organised through the Bone Marrow Transplant Co-ordinator (via BCH switchboard – Bleep No. 1675).	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture. Leucopenia or Leucocytosis: WCC <math><1.0 \times 10^9/L</math>, or >math>20.0 \times 10^9/L</math>. The presence of blast cells	Up to 12 working days <i>(85.5% compliance)</i> N.B.Buccal requests will require an extra 2 days.
	Buccal/ Cytology brush		N/A				
High resolution HLA molecular typing for Haematopoietic Stem Cell <i>(Referral test – Sequencing NGS)</i>	DNA	N/A	20µl of DNA (standardised to 50ng/µl)	N/A	Qualitative-detailed in report	DNA quantity - minimum 3µg.	An extra 7 days is required in addition to the routine 12 working days. <i>(98.1% compliance)</i>

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Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
Partially HLA Matched <u>Blood</u> for Renal Recipients (RT-PCR/ PCR-SSO Luminex)	Blood (EDTA) and (clotted)	 	4 ml 9 ml	This service is provided Monday-Friday (excluding bank holidays) in conjunction with Northern Ireland Blood Transfusion Service (NIBTS)). The patients' consultant must contact an NIBTS consultant to discuss the patient's requirements (Tel: 028 90321414 ext.4678 or 4788). It is the responsibility of NIBTS to liaise with the H&I laboratory. If storing samples overnight before forwarding to the laboratory please ensure they are stored horizontally at room temperature	Qualitative-detailed in report	Leucopenia or Leucocytosis: WCC <1.0 x10 ⁹ /L, or >20.0 x10 ⁹ /L.	Up to 3 working days ** (100% compliance)
Partially HLA Matched <u>Platelets</u> (RT-PCR/ PCR-SSO Luminex)	Blood (EDTA) and (clotted)	 	4 ml 9 ml	This service is provided Monday-Friday (excluding bank holidays) in conjunction with Northern Ireland Blood Transfusion Service (NIBTS)). The patients' consultant must contact an NIBTS consultant to discuss the patient's requirements (Tel: 028 90321414 ext.4678 or 4788). It is the responsibility of NIBTS to liaise with the H&I laboratory. If storing samples overnight before forwarding to the laboratory please ensure they are stored horizontally at room temperature	Qualitative-detailed in report	Leucopenia or Leucocytosis: WCC <1.0 x10 ⁹ /L, or >20.0 x10 ⁹ /L. The presence of blast cells.	Up to 3 working days ** (100% compliance)

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Test	Sample	Container	Volume	Precautions	Reference Range	Test Limitations/ Interpretations	Turnaround Times
HLA Typing for Bone Marrow & Platelet Registers <i>(PCR-SSO Luminex)</i>	Blood (EDTA)		6 ml	Samples are taken from potential donors at NIBTS blood donation sessions, and should arrive in the laboratory within 24 hours.	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 3 months to report to NIBTS ** (85.0% compliance)
HLA-B*27 Testing <i>(PCR-SSP / RT-PCR)</i>	Blood (EDTA)		4 ml	N/A	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 12 working days ** (96.8% compliance)
HLA-DQ testing for Coeliac disease <i>(PCR-SSO Luminex)</i>	Blood (EDTA)		4 ml	N/A	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 12 working days ** (93.3% compliance)
HLA-B*57:01 testing for Drug Hypersensitivity <i>(PCR-SSO Luminex/ RT-PCR)</i>	Blood (EDTA)		4ml	N/A	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 12 working days (new test compliance data not available)
Other HLA – Disease Association Requests <i>(PCR-SSO Luminex)</i>	Blood (EDTA)		4 ml	N/A	Qualitative-detailed in report	Sample should be received and DNA isolated within 7 days of venepuncture.	Up to 12 working days ** (93.3% compliance)

****N.B.** Turnaround time compliance is based on requests received April 2021 – March 2022.

Any H&I requests not mentioned above must be discussed with the Head of Laboratory/Discipline Specific Manager before sending the sample.