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Laboratory enquiries / Secretary
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On Call Scientist
Tel: 0141 211 3000 and ask for on-call tissue-typist
Introduction

This user manual is intended as a guide for users of the services provided by the Greater Glasgow and Clyde (GGC) Histocompatibility and Immunogenetics (H&I) Service.

a) Laboratory scope and location

The H&I laboratory is located on Level 1 of the Laboratory Medicine Building at Gartnavel General Hospital (GGH), Glasgow. It offers a comprehensive range of molecular, serological and cellular tests which support solid organ transplantation (kidney and heart), haematopoietic progenitor cell (HPC) transplantation, disease association testing and pharmacogenetic testing. Tests performed in support of these services are detailed in Appendix 1.

The laboratory is currently accredited by the United Kingdom Accreditation Service (UKAS, https://www.ukas.com/browse-accredited-organisations/?org_cat=847&parent=Medical%20Laboratories&type_id=7&cpage=1) and by the European Federation for Immunogenetics (EFI).

The H&I laboratory is committed to providing the highest quality and standard of service. In order to accomplish this, the laboratory:

• operates a Quality Management System
• upholds professional codes and values
• implements and complies with standards set out by local, national and international regulatory bodies
• reports examination results in a manner that is timely, confidential, accurate and clinically useful
• undertakes approved research and development projects in collaboration with other specialities
• performs duties as would befit a centre of excellence in H&I
• complies with local, national and international standards on confidentiality and data protection

b) Opening hours

Normal working hours
Monday - Friday 8.00 – 16.30

24 hour transplant on-call service
An on call service is provided to facilitate kidney and heart transplantation. Contact can be made via the GGH switchboard. Please ask for the on-call tissue typist.

A one in four on-call Consultant / Principal Clinical Scientist rota is shared with the H&I service in Edinburgh. Scientists are contacted directly for virtual crossmatch queries, and indirectly via the on-call tissue-typist.
c) Deliveries and visitors

Deliveries
Routine samples are delivered to the H&I laboratory. Out of hours, urgent samples must be delivered to the sample drop box located at the front door to 21 Shelley Road when agreed in advance with the on call scientist.

Entrance to the building for deliveries is obtained via intercom. Small goods may be delivered via the side entrance. If lift access is required, this must be requested via the laboratory.

Parking
Parking is accessible in the nearby NHS car park (maximum 4 hours) or at a charged parking facility at the hotel situated directly across from the laboratory entrance.

Visitors
Visitors are seen by appointment only.

d) Sample documentation

Sample labelling and completion of request forms
Please note: * indicates mandatory information – the sample may be rejected if these fields are not completed.

Specimen
*Name
*CHI number (for samples originating in Scotland)
*Date of sample acquisition.

Request form (yellow H&I form)
*Name
*Date of birth
*CHI number (for samples originating in Scotland)
*Hospital and ward
*Consultant/requester to whom the report is to be issued
*Clinical details
*Date of sample acquisition (see above N.B)

Additional Paperwork
Renal patient for activation
*Fully completed activation form

HPC transplant patient for volunteer unrelated donor search
* Completed VUD referral form
Please note that as soon as a patient presents with a condition that may require HPC transplant, an EDTA (buccal or saliva may be sent from patients with low cell counts, or
circulating blast cells) and clotted sample should be forwarded to the laboratory. This will prevent unnecessary delay at a later date.

**Local deceased donors**
* Copy of blood group report
* HLA Typing Request Form (FRM4279/2) completed by donor coordinator.

**e) Sample requirements**

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen Requirement</th>
<th>Minimum Volume /ml</th>
<th>Target Turnaround Time from sample receipt to test result authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease association testing</td>
<td>EDTA⁵</td>
<td>4</td>
<td>21 days except B*57:01 (7 days)</td>
</tr>
<tr>
<td>HLA typing (recipient)</td>
<td>EDTA⁵</td>
<td>8</td>
<td>21 days</td>
</tr>
<tr>
<td>HLA typing (potential living donor)</td>
<td>EDTA⁵</td>
<td>8</td>
<td>21 days</td>
</tr>
<tr>
<td>HLA typing (local deceased donor)</td>
<td>EDTA</td>
<td>50</td>
<td>4 hours⁴ from receipt of sample 8 hours³ from sample bleed time</td>
</tr>
<tr>
<td>HLA antibody testing Unsensitised patient</td>
<td>Clot</td>
<td>6</td>
<td>14 days</td>
</tr>
<tr>
<td>HLA antibody testing sensitised patient</td>
<td>Clot</td>
<td>6</td>
<td>28 days</td>
</tr>
<tr>
<td>URGENT HLA antibody testing¹</td>
<td>Clot</td>
<td>6</td>
<td>4 hours</td>
</tr>
<tr>
<td>Living donor crossmatches²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(i) vXM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ii) Flow +/- CDC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deceased donor crossmatches CDC +/- Flow³</td>
<td></td>
<td></td>
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</table>

¹Urgent HLA antibody testing is available in exceptional circumstances and this requires agreement between the requester and senior laboratory staff.

²All living donor CDC and Flow crossmatches must be pre-arranged with the laboratory.

³All deceased donor typing must be pre-arranged with the on-call scientist. Target TAT is 80% within 8 hours of sample bleed time and within 4 hours of time sample received in laboratory.
Assuming donor and recipient HLA type is known and recipient HLA antibody testing is up-to-date

Buccal or saliva samples may also be received

Notes

- The laboratory must be informed if patients have a low lymphocyte count
- Please inform the laboratory if patients are receiving therapeutic antibody treatment e.g. rituximab, ATG

f) Sample packaging and transportation

HLA typing (EDTA) and antibody analysis (clotted) samples
These samples are stable at ambient (22°C) temperature for 4 days.

Crossmatching samples
These must not be refrigerated and should be received within 24 hours of venesection. All crossmatches must be booked in the lab diary in advance by contacting the laboratory.

Urgent deceased donor samples
Samples (EDTA, peripheral blood, spleen, lymph node) from deceased donors must be sent directly to the laboratory. The laboratory/on-call scientist must be notified in advance of the expected arrival time.
Delivery notification forms to attach to the packaging are made available to transplant coordinators and the transplant unit.

Packaging of samples
All samples must be packaged in containers compliant with UN packaging instruction P650 (http://www.un3373.com/p650-packaging/) and labelled as shown below. Information with regard to high risk specimens must be clearly displayed on both sample and request form.

Transport of samples
Samples should be transported in the sealable bag attached to the yellow H&I request form.
Specimens from the GGH site are delivered via local arrangements. All other specimens must be transported by van, courier or taxi or sent by post (observing postal regulations). Arrangements should be confirmed within your local organisation.
g) Reporting of results

Reports are computer generated from the laboratory patient management system. Reports generated from this system are valid without a signature for electronic transmission and in this format will be sent to the requester by secure email. If the patient has been registered on Clinical Portal (CP) the report will be uploaded to CP. If a secure email address is unavailable, reports are printed, signed by authorised staff and dispatched by internal hospital mail. Measurement uncertainties have been assessed for our examination procedures and these are available to users upon request.

Verbal reports

In order to prevent sensitive or incorrect information being released to inappropriate individuals, verbal reporting is actively discouraged. A verbal report may be issued in an emergency by a senior member of staff to a suitably qualified person. A hard copy report will follow as soon as possible.

Faxing reports

Faxing of reports that include patient name and personal information has been prohibited by The Scottish Government.

Emailing reports

Reports will only be sent between secure email addresses as per NHS GGC Email Usage policy.

Clinical advice

Senior laboratory staff may be contacted during working hours (contact details on Page 2). Out with normal hours, there is an on call Consultant / Principal Clinical Scientist available for advice who can be contacted via the on call tissue typist. The on-call Consultant / Principal Clinical Scientist rota is served by CCS from SNBTS Edinburgh (UKAS and EFI accredited laboratory) and NHS GG&C. An annual review of CPD to ensure competency is maintained is undertaken.

(h) Referral of samples for additional testing

HPC transplant patient and donor serum samples are referred for CMV testing to The West of Scotland Specialist Virology Centre (WoSSVC) based at Glasgow Royal Infirmary. This laboratory is UKAS accredited (UKAS Ref No: 9319).

The WoSSVC's ongoing accreditation status and performance in external proficiency testing is reviewed biannually,

Professional opinion on the results generated by the WoSSVC, will be sought from the
Consultant in Charge

(i) Confidentiality
All patient and donor details, including test results, will be handled according to local and national regulations as described within the H&I laboratory Quality Manual available to users upon request.

J) Service Agreements
Service agreements detailing responsibilities of the H&I laboratory and the transplant service users have been issued. These agreements are reviewed every two years by the H&I laboratory director and the director of the transplant service (adult cardiac, adult renal, adult HPC, paediatric renal and paediatric HPC).

(k) Complaints procedure
The H&I laboratory endeavours to provide the best service possible to its users. If there has been a shortfall in expectations or an identified problem with the service, please contact the Quality Manager. Formal complaints must be made in writing. All complaints are recorded, reviewed and acted upon to improve the overall service.
Appendix 1: Laboratory services

1. Renal transplantation

The H&I laboratory supports the renal transplant programme in Glasgow which serves adults in the West of Scotland and all children nationally.

(i) Recipient work up for transplant listing

Prior to registration on the national transplant list, the following H&I testing is performed:

- HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing at intermediate resolution. HLA antibody screening on two independent serum samples
- HLA type is verified on a second independently drawn blood sample

The H&I laboratory collates this data and other relevant clinical information before activating the patient on the UK transplant list.

(ii) Patients listed for renal transplantation

For listed patients, the H&I laboratory:

- undertakes HLA antibody screening and identification on serum samples acquired minimally at 3 monthly intervals
- stores serum samples
- suspends and reactivates patients as necessary

(iii) Transplantation with a deceased donor kidney

The H&I laboratory will:

- provide a 24 hour, 365 day on call service
- HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing at low/intermediate resolution for deceased donors.
- perform a prospective or retrospective (in the case of virtual crossmatch) crossmatch for recipients receiving a transplant
- crossmatch historic and current recipient serum samples against donor T and B-cells using the complement dependent cytotoxic crossmatch (CDC) method and / or flow cytometry crossmatch.
- report results to the transplant surgeon with Consultant Clinical Scientist advice as required

(iv) Post-transplant HLA antibody testing

The H&I laboratory will provide this service annually as routine and at any time it is clinically indicated.
(v) **Potential live donor work up**

This will not commence until the recipient has completed work up (section i). The H&I laboratory will:

- undertake HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1 and DQB1 typing at intermediate resolution. Additional HLA loci may be defined as required.
- perform a virtual crossmatch
- crossmatch, a selection of patient serum samples against donor T and B-cells by CDC and/or flow cytometry.
- report results to the live donor transplant coordinator and the requesting clinician
- perform verification HLA typing on selected living donors

(vi) **Local deceased donors**

The H&I laboratory:

- undertake HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing at low resolution meeting the minimum requirements for deceased donor typing
- reports HLA types to NHSBT within 4 hours of receipt of donor material

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### 2. Cardiac transplantation

The H&I laboratory supports the national cardiac transplantation programme based at the Golden Jubilee National Hospital, Clydebank.

(i) **Recipient work up**

Prior to registration on the national transplant list, the following H&I testing is performed:

- HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1 and DQB1 typing at intermediate resolution. HLA-DPA1 and DPB1 are tested if indicated.
- HLA antibody screening on two independent serum samples
- HLA type is verified on a second independently drawn blood sample

The results are reported to the cardiac transplant coordinator for listing on the national cardiac transplant list.

(ii) **Patients listed for cardiac transplantation**

For listed patients, the H&I laboratory:

- undertakes HLA antibody screening and identification on serum samples acquired at 3 monthly intervals (minimally)
- store serum samples
(iii) Transplantation

The H&I laboratory will:

- provide a 24 hour, 365 day on call service
- HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing at low/intermediate resolution for deceased donors.
- perform a prospective or retrospective (in the case of virtual crossmatch) crossmatch for recipients receiving a transplant
- crossmatch historic and current recipient serum samples against donor T and B-cells using CDC and/or flow cytometry crossmatch.
- report results to the transplant surgeon with Consultant Clinical Scientist advice as required

3. Haematopoietic Progenitor Cell transplantation

The H&I laboratory supports the national HPC transplant units at the Queen Elizabeth University Hospital (QEUH), Glasgow and the Royal Hospital for Children, Glasgow.

(i) Recipient work up

The H&I laboratory:

- performs high resolution HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing.
- performs verification HLA typing on an independent blood sample
- tests recipient sera for HLA specific alloantibodies
- requests and records CMV testing results
- reports results to the transplant centre

(ii) Potential related donor work up

The H&I laboratory:

- undertakes intermediate resolution HLA-A, B and DRB1 typing for all potential related donors
- undertakes high resolution HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing for selected potential related donors
- requests CMV testing results
- performs verification HLA typing on an independent blood sample from the selected donor
- reports results to the clinical apheresis unit (adults) and the transplant unit

(iii) Unrelated adult donor search

The H&I laboratory:

- initiates a search of the UK and international unrelated adult donor registries upon receipt of a volunteer unrelated donor (VUD) form.
• selects and requests blood samples from potential matching donors
• performs high resolution HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 typing on shortlisted donors
• requests and collates CMV testing results
• confirms the absence of HLA mismatches between donor and recipient
• performs verification HLA typing on blood received from the donor at the time of medical examination
• informs the transplant centre on the search and donor identification process
• provides written reports of HLA results and compatibility

(iv) Cord blood search
The H&I Laboratory:
• initiates a search of cord blood banks when appropriate
• prepares a shortlist of cords according to pre-defined criteria
• requests unit reports for shortlisted cords
• requests verification HLA typing for shortlisted cords
• acquires a DNA sample from selected cords and performs high resolution verification HLA typing
• performs verification HLA typing on DNA extracted from the infused product
• informs the transplant centre on the search and cord blood unit identification process
• provides written reports of HLA results and compatibility

4. Disease association testing and pharmacogenetics
The H&I laboratory:
• provides HLA typing to assist in the diagnosis of ankylosing spondylitis, Behçet’s disease, Birdshot chorioretinopathy, coeliac disease and narcolepsy
• tests for HLA-B*57:01 to identify individuals at risk of hypersensitivity to abacavir
• will perform other HLA typing tests when requested as agreed with the consultant clinical scientist where there is clinical evidence to support HLA typing as a useful tool in diagnosis and/or patient management

5. Research studies
The H&I laboratory will undertake histocompatibility and Immunogenetics testing to support appropriately funded and ethically approved research studies. Agreement must be made with the laboratory prior to the commencement of testing.