

# TISSUE TYPING (H&I) USER GUIDE

## CONTENTS

<b>A</b>	<b>Introduction.....</b>	<b>1</b>
<b>B</b>	<b>Location of and contact details for the laboratory .....</b>	<b>2</b>
<b>C</b>	<b>Opening hours of the laboratory .....</b>	<b>2</b>
<b>D</b>	<b>Clinical services offered by the laboratory .....</b>	<b>2</b>
<b>E</b>	<b>Examinations offered by the laboratory .....</b>	<b>3</b>
<b>F</b>	<b>Instructions for completion of the request form .....</b>	<b>4</b>
<b>G</b>	<b>Instructions for preparation of the patient .....</b>	<b>4</b>
<b>H</b>	<b>Instructions for patient-collected samples .....</b>	<b>5</b>
<b>I</b>	<b>Instructions for transportation of samples.....</b>	<b>5</b>
<b>J</b>	<b>Requirements for patient consent .....</b>	<b>5</b>
<b>K</b>	<b>Criteria for accepting and rejecting samples .....</b>	<b>6</b>
<b>L</b>	<b>Factors affecting results .....</b>	<b>6</b>
<b>M</b>	<b>Availability of clinical advice.....</b>	<b>6</b>
<b>N</b>	<b>Policy on protection of personal information.....</b>	<b>6</b>
<b>O</b>	<b>Complaint procedure .....</b>	<b>6</b>

## **A** Introduction

The ISO 15189:2012 standards (section 5.4.2) require the laboratory to have information for patients and users. This document provides this information.

## TISSUE TYPING (H&I) USER GUIDE

### **B** Location of and contact details for the laboratory

Tissue Typing Laboratory  
Box 209  
Addenbrookes Treatment Centre (ATC) Level 6  
Cambridge University Hospitals NHS Foundation Trust  
Hills Road  
Cambridge  
CB2 0QQ

**Tel:** 01223 217739

**Email:** [tissue.typing@nhs.net](mailto:tissue.typing@nhs.net)

#### **Clinical Director of Tissue Typing (Histocompatibility & Immunogenetics):**

Sarah Peacock MSc, FRCPath  
**Tel:** 01223 217741 (internal 217741)  
[sarah.peacock22@nhs.net](mailto:sarah.peacock22@nhs.net)

#### **Head of Laboratory & Consultant Clinical Scientist:**

Sarah Maxfield, MSc, FRCPath  
**Tel:** 01223 217739 (internal 217739)  
[sarah.maxfield3@nhs.net](mailto:sarah.maxfield3@nhs.net)

### **C** Opening hours of the laboratory

The laboratory is open **09:00** to **17:00** Monday to Friday. For contact details see [section B](#).

An on-call service for HLA typing and crossmatching for deceased donor transplantation only is available out of hours. To access this service contact the on-call tissue typist via Addenbrooke's Hospital contact centre (01223 245151/80500).

### **D** Clinical services offered by the laboratory

The H&I (Tissue Typing) laboratory provides a specialist service, offering a comprehensive range of molecular and serological techniques to inform selection of HLA compatible donor and recipient pairs in support of:

- solid organ transplantation for the renal, pancreas, liver, small intestine, multi-visceral and cardio-thoracic programmes
- allogeneic stem cell transplantation for haematological disorders such as aplastic anaemia, acute lymphoblastoid leukaemia and chronic myeloid leukaemia.

Immunogenic testing also aids clinical diagnosis of disease, selection of strategies for drug hypersensitivity reactions and facilitates an understanding of the causes (aetiology) and mechanisms of the disease.

The laboratory supports the East of England, including Cambridgeshire, Norfolk, Suffolk and areas of Bedfordshire, Hertfordshire and Essex, working closely with clinical staff in Departments of Transplant, Renal Medicine and Haematology, as well as local GPs.

## TISSUE TYPING (H&I) USER GUIDE

### E Examinations offered by the laboratory

Test		Primary sample volume	Methodology	Turnaround times (TAT)
HLA Class I & II typing (second field) (A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB1)	EDTA	9ml *	Next Generation Sequencing (NGS)	85% within 21 calendar days
HLA Class I & II typing (first field) (A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB1)	EDTA	9ml ***	RT-PCR	90% within 4 hours (deceased donor typing) 85% within 21 calendar days (all else)
HLA-B27 (Ankylosing spondylitis)	EDTA	2.6ml	RT-PCR	90% within 14 calendar days
HLA-B*57:01 (Abacavir hypersensitivity)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA-B51 (Behcet's disease)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA-DQB1*02/DQA1*05, DQ8 (Coeliac disease)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA-A29 (Birdshot retinopathy)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA-DR15/DQ6 (Narcolepsy)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA-B58 (Allopurinol induced adverse drug reaction)	EDTA	9ml *	Next Generation Sequencing	85% within 21 calendar days
HLA specific antibody screen	Serum	9ml *	Luminex (LabScreen Mixed)	98% within 14 days 85% within 7 days
HLA specific antibody characterisation	Serum	9ml *	Luminex (Single Antigen Bead)	98% within 14 days 85% within 7 days
Living and deceased donor crossmatch	EDTA	36ml	Lymphocytotoxicity	Not reported

\* Any combination of sample tubes can be sent up to ~9ml.  
Lower sample volumes can be used for paediatric patients – contact the laboratory for information.

\*\* Nationally agreed volumes to be sent for deceased donor HLA typing are:

- 6ml EDTA for adults
- 3ml EDTA for paediatric

#### Special precautions:

- The EDTA sample requirements for HLA typing assume the patient has a white blood cell count in the range 4.2-10.8x10<sup>9</sup>/L. If the white blood cell count is lower please send a buccal swab (see Section H or contact the laboratory for advice).

## TISSUE TYPING (H&I) USER GUIDE

### Biological reference intervals

ISO 15189:2012 defines this as “a specified interval of the distribution of values taken from a biological reference population.” A biological reference population is defined as “any group of individuals in a well-defined state of health or disease.” Due to the nature of the assays undertaken by the H&I laboratory the laboratory considers it is not appropriate to have a biological reference interval defined.

### Clinical decision values

ISO 15189:2012 does not define a clinical decision value, however it could be viewed to be synonymous with a clinical decision limit – a value above or below which a clinical decision might be made. For all laboratory assays these values are described in the individual SOPs which are available to users upon request.

## F Instructions for completion of the request form

The laboratory receives both electronic and paper based requests. Samples must be accompanied by a FULLY completed request form or electronic request form. The requester’s name and contact details must be legible. The report will be returned to the originating consultant and clinic/ward unless otherwise specified.

If a request form is required please see: <https://www.cuh.nhs.uk/our-services/tissue-typing/> or email the laboratory to request one.

### All patient samples must be labelled with:

- first name
- surname
- date of birth
- NHS number / hospital number
- sample date

Please note that failure to meet requirements for sample labelling, appropriate blood specimen container and sample packaging may result in rejection of the sample.

## G Instructions for preparation of the patient

It is important to ensure that the correct sample and volume is taken for the test required otherwise it may not be possible for a result to be issued. Contact the laboratory for any other factors which may affect the sample for the test being requested or the result being issued.

Please refer to:

- [Peripheral venous cannula \(PVC\) insertion and management \(adult\) and venepuncture procedure](#) (link for on-site Trust staff only)

along with any local policies that are relevant.

## TISSUE TYPING (H&I) USER GUIDE

### H Instructions for patient-collected samples

The only patient collected samples would be those taken from buccal swabs. Please contact the laboratory to request that a kit is sent out to you.

These are commercial kits which include instructions for use which should be followed. Buccal swab samples are stable at ambient temperature (15-25°C) for one year. Samples should be stored at ambient temperature and should arrive in the laboratory in a timely manner for the test to be performed. Any samples not meeting these criteria will not be accepted by the laboratory.

### I Instructions for transportation of samples

#### **Packaging:**

Specimen container must be placed in an individual clear, plastic, marsupial transport bag properly sealed to contain potential leakage. It is the sender's responsibility to ensure that the outer packaging for specimens transported by postal services must be conform to the relevant postal/transport legislation and marked with diamond shaped mark UN 3373 and Biological substances, Category B.

[Guidance on regulations for the transport of infectious substances](#)

**For local delivery of samples NOT transported by Royal Mail:**

- **Transport to Addenbrooke's hospital:**

Tissue Typing laboratory  
Box 209  
ATC Level 6  
Addenbrooke's Hospital  
Hills Road  
Cambridge  
CB2 0QQ

- **Transport within Addenbrooke's Hospital:**

Pneumatic tube (hospital POD) / Destination code (POD number): **308**

### J Requirements for patient consent

It is the responsibility of the requester to ensure that any samples sent to the laboratory have been taken with full informed consent for the tests being requested.

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 must also 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.

To aid with this a patient information leaflet is available: <https://www.cuh.nhs.uk/patient-information/human-tissue-act-tissue-typing-patient-information-and-consent/>.

## TISSUE TYPING (H&I) USER GUIDE

### **K** Criteria for accepting and rejecting samples

If the sample cannot be sent directly to the laboratory it must be refrigerated and the Laboratory notified for advice. **NOTE: Do not freeze samples.**

Serum samples should be delivered to arrive in the Tissue Typing laboratory within 48 hours of being taken. Any samples that arrive after this time point will be accepted or rejected at the discretion of the receiving scientist. This decision will be based on the test requested, sample appearance, patient history and whether the sample has been centrifuged and/or refrigerated during this time.

EDTA samples for DNA extraction may be processed up to 1 week after being taken, results for older samples cannot be guaranteed.

EDTA samples for crossmatch tests must be received by the Laboratory within 24 hrs and no later than 10:00am the day after they are taken.

### **L** Factors affecting results

For all laboratory assays a list of factors known to significantly affect the performance of the examination or the interpretation of the results are described in the individual SOPs which are available to users upon request.

### **M** Availability of clinical advice

Clinical staff can be contacted using the information given in [section B](#) above for clinical advice on ordering of examinations and on interpretation of examination results.

### **N** Policy on protection of personal information

The laboratory complies with the relevant data protection guidelines as prescribed by the Trust.

### **O** Complaint procedure

If you are unhappy with any aspect of the service you receive from us in the first instance you should speak to a member of staff in the laboratory as soon as possible using the information given in [section B](#) above.

If you feel unable to speak directly to staff or the issue is not dealt with satisfactorily, then please contact the [Patient Advice and Liaison Service \(PALS\)](#) <https://www.cuh.nhs.uk/have-your-say/patient-advice-and-liaison-service-pals> who will be able to assist you.