

# UK NEQAS

International Quality Expertise



## Histocompatibility & Immunogenetics

### PARTICIPANT MANUAL

2018

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## 1. Introduction

UK NEQAS for Histocompatibility and Immunogenetics has provided a comprehensive range of EQA Schemes for laboratories operating clinical Histocompatibility and Immunogenetics (H&I) services since 1975.

The Scheme's host organisation is Velindre NHS Trust and it operates from dedicated facilities in South Wales at the Welsh Blood Service - within the Welsh Transplantation and Immunogenetics Laboratory.

H&I laboratory support is required for:

- (i) Solid organ transplantation
- (ii) Haematopoietic stem cell transplant programmes
- (iii) HLA typing as an aid to disease diagnosis, e.g. HLA-B27 and the spondyloarthropathies
- (iv) Unrelated haematopoietic stem cell donor panels
- (v) The provision of HLA/HPA matched blood products.

The primary laboratory investigations are:

- (vi) determination of HLA/HPA type
- (vii) the detection and specification of antibodies directed towards HLA or HPA specificities
- (viii) crossmatching of patients' sera against donors' lymphocytes.

Consideration is also given to Schemes that cover other aspects of clinical work performed in an H&I laboratory and not currently covered by other EQA Schemes.

All aspects of the Scheme are under continuous review in collaboration with the UK NEQAS for H&I Steering Committee and suggestions for enhancements to the existing schemes or development of new schemes are always welcome (see section 4, contact details).

UK NEQAS for H&I is a member of the UK NEQAS Charity and operates in accordance with the UK NEQAS code of practice (available from the UK NEQAS website [www.ukneas.org.uk](http://www.ukneas.org.uk))

## Accreditation

UK NEQAS for H&I is accredited by United Kingdom Accreditation Service (UKAS) to ISO 17043:2010 (UK NEQAS for H&I is operated by Velindre NHS Trust, a UKAS proficiency testing provider No 8351). Full details of accredited schemes can be found in our Schedule of Accreditation available from the UKAS website [www.ukas.com](http://www.ukas.com). A copy of the Accreditation Certificate is available from the UK NEQAS for H&I website [www.ukneqashandi.org.uk](http://www.ukneqashandi.org.uk).

For developing and pilot schemes, once the viability of the scheme has been established a scoring system will be developed to monitor performance and accreditation will be sought.

## 2. AIMS OF AND PARTICIPATION IN THE SCHEME

UK NEQAS for H&I is a not-for-profit organisation aiming to:

- Provide professionally-led and scientifically-based EQA schemes with a primarily educational objective
- Help the laboratory appraise its performance and monitor improvements externally through continuous operation, regular distributions of samples and performance feedback
- Produce reports which are designed to be clear, informative and structured to assist interpretation
- Assess technical, analytical and interpretative performance of a laboratory.

EQA forms an essential part of quality assurance within a laboratory and provides evidence of individual laboratory performance. However, it gives only a snapshot of a laboratory's performance at any given time and the information reported back is inevitably a retrospective view of the quality of results. It should be undertaken in addition to, not in place of, other quality assurance measures.

Participation in an appropriate, accredited EQA Scheme is a requirement of accreditation to ISO15189 standards.

### 3. Participant Manual

This Manual provides the information necessary for effective participation in the UK NEQAS for H&I Schemes. It is revised and issued on a yearly basis. Minor updates are occasionally made during the year. Notification will be provided of any major additions or amendments during the year.

**Please take the time to study all sections in this document and to familiarise all of the staff in your laboratory with the contents of the manual.**

### 4. Contact Details

#### Scheme Staff

Contact Address:	UK NEQAS for H&I Welsh Blood Service Ely Valley Road Talbot Green Pontyclun CF72 9WB Wales United Kingdom	Director:	Dr Tracey Rees
Telephone:	+44 (0) 1443 622185	Manager:	Deborah Pritchard
FAX:	+44 (0) 1443 622 001	Deputy Manager:	Melanie Bartley
		HCS Practitioner:	Geraint Clarke
		QA Officer:	Luke Gardner

Email: [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk)

Website: [www.uknegashandi.org.uk](http://www.uknegashandi.org.uk)

### 5. Contact with UK NEQAS for H&I

The office is open between the hours of 09:00 and 17:00 Monday to Friday with an answering machine to pick up all messages outside these times. Participants are requested to give their Laboratory Code Number when contacting the Centre.

For queries relating to routine operations, e.g. participation fees, day-to-day organisation of UK NEQAS for H&I Schemes, participants' contact changes, additional material/reagents, assessment clarification, assessment anomalies, copies of reports, please contact the office.

To discuss any aspect of UK NEQAS for H&I please contact the Schemes' Director, Manager or any other member of the Steering Committee who will be pleased to help. A list of contact names and numbers is given in Section 28.

If you wish your views to be discussed by the Steering Committee please send your comments in writing to Deborah Pritchard. Correspondence will normally be circulated only to the Steering Committee and the BSHI Representative to UK NQAAP for Immunology and will normally be anonymised before distribution.

For details of other UK National External Quality Assessment Services, please contact Julie Gelder (UK NEQAS Executive Manager/Company Secretary) or see: <http://www.ukneqas.org.uk/> .

Participant correspondence and the actions taken are logged.

## 6. Complaints

UK NEQAS for H&I has a policy in place to deal with complaints from participants. Complaints will only be treated as such if the participant states clearly that they are making an official complaint. Other issues will be dealt with as assessment appeals (section 10.9) or correspondence. Complaints should be in the form of a fax, email or letter.

All complaints will receive written acknowledgement within 2 working days and receive a prompt and thorough investigation, to identify the root cause of the problem. All formal complaints will be discussed with the Steering Committee.

Complaints aim to be resolved with a final written response within 30 days. However, if this is not possible, an estimated close out date will be supplied and regular communication sent with updates to the progress of the complaint. Any unresolved complaints can be directed to the Chair of the Steering Committee, the Chair of the National Quality Assurance Advisory Panel for Immunology (NQAAP) or the Royal College of Pathologists' Joint Working Group for Quality Assessment in Pathology (JWG).

At all times during the complaints procedure, participant confidentiality will be maintained.

**Complaints about UK NEQAS for H&I should be made in writing to: Deborah Pritchard, Schemes' Manager, UK NEQAS for H&I, Welsh Blood Service, Ely Valley Road, Talbot Green, Pontyclun CF72 9WB. Tel: 01443 622185; Fax: 01443 622001; e-mail: ukneqashandi@wales.nhs.uk.**

## 7. Confidentiality

Data from participants is treated with strict confidentiality. Each laboratory is registered under a unique laboratory number, which is only known to the Schemes' Manager and UK NEQAS for H&I staff. Laboratory identifiers and performance information are confidential and will not be released to a third party without the written permission of the Head of the participating laboratory. Participants are free to release information concerning their own individual performance to whoever they wish.

For UK laboratories, confidentiality guidelines issued by the Joint Working Group (JWG) for Quality Assurance apply (see section 29). The performance details of any UK laboratories may be shared with the relevant UK National Quality Assurance Advisory Panels (NQAAP) or JWG if they request it. Unsatisfactory performance will be notified to the NQAAP. UK laboratories identified to NQAAP regarding Scheme 5A will also be identified to the UK NQAAP for Clinical Cytogenetics and Molecular Genetics.

Contact information supplied by participants will only be used for contacting participants about matters relating to the operations of UK NEQAS, related questionnaires and the annual meeting. The Scheme will not pass on contact details to other registered participants for the purposes of sharing information relating to the use of techniques or equipment without acquiring consent to do so. All reports and the data they contain are copyrighted and may not be published in any form without permission of the Scheme Director.

## 8. Participation

### 8.1. Registration

All Schemes are open to UK NHS and Private Sector clinical laboratories, research institutions, relevant manufacturers, and laboratories worldwide.

Participation in the UK NEQAS for H&I Scheme(s) may begin at any time during the year with pro rata charges being made. Participation will commence following the return of completed registration documents and the receipt of an official purchase order number. Participation will commence with the next scheduled distribution provided that documents are received at least one week prior to the date of the next distribution.

Registration forms are available from the UK NEQAS for H&I website, [www.ukneqashandi.org.uk](http://www.ukneqashandi.org.uk) or on request. A completed registration form **MUST be completed and returned** either by email or FAX.

Participation is for a period of one year (February 2018 – January 2019). Annual re-registration takes place each year, with registration forms provided to all existing participants before commencement of the new distribution year. It is the laboratory's responsibility to ensure that all contact details, including the billing contact, are correct. If re-registration forms are not completed this will be taken as an indication that registration should continue on the same basis as the previous year, unless a request to de-register is received in writing. Any material sent in the meantime will be charged for. Failure to supply signed registration forms will result in suspension of reports.

By signing the registration forms participants agree to abide by the conditions for participation (section 8.8) and all other expectations as stated in this participant manual. UK laboratories also agree to abide by the JWG Conditions of EQA Scheme Participation Guidelines (Section 29).

### 8.2. Subscription Fees

UK NEQAS for H&I is a not-for-profit organisation. Fees are subject to annual review based on the full costs of operating the Schemes. Refunds of EQA charges are only payable under exceptional circumstances and at the Scheme Director's discretion.

The annual subscription fees are listed on the current registration form or available from the UK NEQAS for H&I office. If a participant joins part way through the annual period, a reduced fee is payable reflecting the number of samples to be supplied for that part year. Please note that all invoices must be paid in **UK STERLING (GBP) AND FREE OF ALL BANK CHARGES.**

During registration participants are requested to provide details of the financial invoice address along with a purchase order number. Velindre NHS Trust will invoice participants for the annual subscription fees which are due within 30 days of invoice receipt. Within the UK, invoices cannot be raised without an order number. Heads of department are asked to ensure prompt payment of subscriptions as part of participation in UK NEQAS for H&I Schemes. Participants will be charged for all Schemes they receive samples for, regardless of whether they submitted results. UK NEQAS for H&I reserve the right to charge administration fees for re-issue of invoices due to incorrect completion of financial information by participants (e.g. VAT liability) or due to accounts not being cleared due to non-payment in GBP or excess bank charges.

**Late payment or failure to pay the subscription charge will result in suspension from participation in UK NEQAS for H&I schemes.**

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### 8.3. Cancellation Of Participation

Please notify us in writing if you wish to cancel your participation in any scheme. Any withdrawals not communicated to the Scheme Office or made after sample distribution will be invoiced for the samples received. Please note that registration and payment is for a distribution year, and cancellations part way through a distribution year will not be subject to refunds.

### 8.4. Laboratory Reference Number

At registration, each participant is assigned a unique laboratory number that is used on performance reports and for internal data handling, in order to preserve confidentiality. This number is unique to an individual laboratory. Please quote your laboratory reference number on all result submissions and communications, including telephone enquiries to enable us to respond to queries as quickly and efficiently as possible.

### 8.5. EQA Timetable

A full timetable is published in the Participant Manual and on the UK NEQAS for H&I website before the start of distributions each year. It is the responsibility of the participant to be aware of the start and closing dates of all Schemes they are currently enrolled for. These can be found on the website or in section 30. Participants will be charged for all Schemes they receive samples for, regardless of whether they submit results.

### 8.6. Sample Delivery

Subscription charges include 1<sup>st</sup> class Royal Mail delivery within the UK and Airmail overseas, although additional carriage services can be selected during registration at an additional cost.

Courier delivery is recommended for non-UK destinations, and is essential for schemes that require viable lymphocytes for testing (e.g. Scheme 1A, 2A, 2B).

Several UK NEQAS for H&I schemes are distributed on the same date to minimise delivery costs to participants (refer to the distribution timetable in section 31 for details). Only one delivery charge is made for all samples distributed on the same date.

### 8.7. Certificate Of Participation

UK NEQAS for H&I are able to issue a Certificate of Registration to laboratories on request.

## 8.8. Conditions For Participation

1. EQA samples must be tested and interpreted in an identical manner to a laboratory's routine clinical samples
2. Participants must inform UK NEQAS for H&I:
  - i. If the expected samples do not arrive
  - ii. Reason(s) for failure to test EQA samples
3. Participants must return signed registration documents, provide a purchase order number and ensure UK NEQAS for H&I are informed of any changes in contact information
4. Failure to pay subscription fees on presentation of an invoice will result in suspension from participation
5. Participants will be charged for all Schemes they receive samples for, regardless of whether they submitted results
6. Cancellation of participation must be in writing to the scheme
7. All reports and the data they contain are copyright and may not be published in any form without the permission of the Director
8. Collusion between laboratories is not allowed. If a laboratory was suspected of collusion, UK NEQAS for H&I would review the laboratory's participation in its schemes
9. UK laboratories agree to abide by the JWG Conditions of EQA Scheme Participation

## 8.9. Our commitment to UK NEQAS for H&I Participants

### UK NEQAS for H&I will:

- Respect your confidentiality
- Despatch samples and report according to the published timetable
- Accurately maintain our contact database
- Not give participant information to anyone (except as detailed in this Participant Manual)
- Provide you with all the information for you to fully participate in our schemes
- Provide schemes 'at cost' and will not make a profit
- Rectify assessment errors in a timely fashion
- Resolve disputes in an impartial and professional manner
- Willingly provide advice on all scheme issues
- Endeavour to comply with EFI EPT Standards for Providers



## 9. Samples

### 9.1. Types of Samples

UK NEQAS for H&I distributes several samples for EQA testing:

- CPD-A1 blood donations +/- RPMI 1640 tissue culture medium containing *tri*-Sodium citrate.
- Isolated lymphocyte preparations (non-UK participants only) in Park/Terasaki medium
- DNA
- Serum

### 9.2. Source of Samples

Blood, lymphocyte and DNA samples are obtained from established blood donors at the Welsh Blood Service. Donors are typically of north-western European extraction. Samples may be random (Schemes 1A, 2A, 2B, 4A1, 4A2 and 4B) or selected (Scheme 8 and Educational Scheme) or a mixture of random and selected (Schemes 1B, 5A and 7).

Serum samples obtained from parous women or transplant patients are used as a source of HLA/HPA antibodies.

**Not all distributed EQA material is tested for disease markers. As with all biological material, samples should be considered as potentially hazardous. Handle with caution and apply accepted standards of Good Laboratory Practice.**

### 9.3. Preparation of Samples

UK NEQAS for H&I apply stringent procedures for sample preparation to ensure homogeneity and that high quality samples are distributed to participants. This includes checking the lymphocyte content and viability (for schemes that require viable lymphocytes for testing) of samples before they are distributed.

Blood samples required for mononuclear cell preparations are diluted with RPMI 1640 tissue culture medium containing *tri*-Sodium citrate.

Isolated lymphocyte preparations can be distributed to non-UK participants with extended shipping times. Lymphocyte preparations are isolated from whole blood samples by density gradient media separation, with the resultant lymphocytes suspended in Park/Terasaki medium for transport.

All sera distributed contain sodium azide.

DNA extracts are issued with their DNA concentrations indicated.

Some aspects of the EQA scheme activities are subcontracted e.g. supply of EQA material, reference result typing and homogeneity testing. All subcontractors are regularly reviewed to ensure the standard of the Scheme is not compromised. UK NEQAS for H&I is responsible for this work.

## 9.4. Distribution and Packaging

Samples are sent to named individuals in each participating laboratory in accordance with the published timetable (see section 31). Once samples are sent all participating laboratories are emailed informing them of the distribution. If samples do not arrive then it is the participant's responsibility to inform UK NEQAS for H&I.

EQA samples have a minimal likelihood that pathogens are present and are therefore sent as 'exempt human specimens'. Packaging conforms to IATA Packing Instruction 650. However, as with all biological material samples should be considered as potentially hazardous. Handle with caution and apply accepted standards of Good Laboratory Practice.

All samples are transported at ambient temperature and should be processed as soon as possible on receipt. Samples for schemes that require viable lymphocytes for testing are not stable and will deteriorate with increased storage time and exposure to extremes of temperatures. Participants must assess the quality of the samples on receipt to ensure they are suitable for testing.

## 9.5. Sample Handling

The majority of samples used for EQA are from low-risk routine blood donors who have been tested for the following disease markers: HIV, HBsAg, HCV and syphilis. HIV Ag-Ab, HBsAg and HCV Ag-Ab are tested for on the Bio-Rad Elite™ system; antibodies to *Treponema pallidum* (syphilis) are tested by TPHA on the PK™ Blood Grouping system.

Some EQA samples may be obtained from healthy volunteers, patients (with consent) or residual material from other laboratories, which may not have been tested for disease markers.

**As with all biological material, samples should be considered as potentially hazardous. Handle with caution and apply accepted standards of Good Laboratory Practice.**

## 9.6. Storage

All samples should be tested as soon as possible after delivery. Samples for schemes that require viable lymphocytes for testing are not stable and will deteriorate with increased storage time. If storage is necessary, EQA samples should be treated and stored as clinical samples.

## 9.7. Sample Testing

Samples must be tested in the same way as clinical material to ensure that the Scheme and assessments are a reliable measure of the quality of laboratory patient testing. UK NEQAS for H&I Schemes are intended to be educational in nature, so if problems are identified this will allow improvements in the quality of patient testing.

The materials distributed are provided as specimens for the sole purpose of enabling external quality assessment at the recipient's laboratory during the current distribution. No claim is made that they may be suitable for any other purpose or at any other point in time, although it is accepted that residual material may be retained by the participant and used for method evaluation.

Materials issued by UK NEQAS for H&I are designed to replicate patient samples as closely as possible and as such can be tested by routine methods used by participants. Schemes are generally analyte driven and different methods should give comparable qualitative results (e.g. Scheme 1B, participants can test using flow cytometry or molecular methods), therefore the method is not considered during assessment. Where H&I testing methods are known to not give comparable results (e.g. due to differences in test sensitivity) schemes have developed to accommodate this (e.g. Scheme 2A and 2B CDC and flow cytometry crossmatching).

Samples for schemes that require viable lymphocytes for testing are not stable and will deteriorate with increased storage time and exposure to extremes of temperatures. Participants must assess the samples on receipt to ensure they are suitable for testing.

If any participant believes that the EQA samples have been affected by conditions during transportation, have issues with sample labelling or any other factor which may have an impact on the ability to obtain a result then the laboratory MUST contact the Scheme as soon as possible (before the result deadline) with the reasons why they are unable to test samples, using [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk). Participants that do not return results or specify why samples could not be tested before the result deadline are assessed as unacceptable.

It is important to ensure sample uniformity by carefully mixing each EQA sample prior to testing using the procedure applied to clinical samples. Isolated lymphocyte suspensions are prepared under sterile conditions and transported in Park Terasaki medium. Prior to testing, the samples should be washed and re-suspended to give an appropriate cell count.

If a result is unable to be determined for EQA material and routine laboratory policy is to send the sample to another laboratory for confirmatory testing, this must not be performed for UK NEQAS for H&I samples. Instead, the result should be reported as 'equivocal' with the reasons for the undetermined result stated. Participants are not penalised during assessment in these situations.

## 9.8. Repeat Samples

For the majority of UK NEQAS for H&I Schemes all material is distributed to participants, therefore repeat samples are not available.

A limited supply of serum and DNA samples are retained by UK NEQAS for H&I, which may be available to participants upon request.

## 10. Results, Assessment and Unacceptable Performance

### 10.1. Submission of results

Results should be submitted on the official UK NEQAS for H&I result forms. Forms can be downloaded from the UK NEQAS for H&I website [www.uknegashandi.org.uk](http://www.uknegashandi.org.uk).

Please note that the result form version in use may change slightly throughout the year, so please check that the most up to date report form for each distribution of samples is used. Participants submitting results on incorrect forms will be asked to resubmit results on the latest version of the result forms.

Participants that have been unable to test samples MUST return report forms stating the reason for not testing. Technical issues and invalid results (e.g control failures, replicate issues, sample quality issues) should be reported as 'Not Tested' with the reason stated. 'Not tested' reports will not be assessed. Equivocal results are only accepted for certain schemes – please see the relevant scheme section for full information.

Detailed method information will be collected on separate forms to the scheme results forms. Ordinarily this information will only need to be completed once each year (with the first set of samples), unless changes to the technique/methods being used are made.

UK NEQAS for H&I encourage submission of results via e-mail to allow immediate acknowledgement of receipt to [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk). However, results can also be submitted via post or fax.

All participants are expected to return results promptly within the specified reporting period. A timetable of result deadlines for each distribution of samples is available on the UK NEQAS for H&I website or in section 30 of the Participant Manual. Participants who fail to return results or return results after the distribution closing date may not be assessed. Participants are expected to return 100% of results. Where a laboratory is unable to return a set of results, an explanation must be provided in writing to [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk).

The majority of UK NEQAS for H&I schemes are assessed on a consensus basis, therefore samples are distributed with the assigned value not being determined. Where a reference result is used, this testing is performed alongside or after the close of the EQA scheme. For these reason UK NEQAS for H&I is unable to disclose results early.

## 10.2. Online Data Entry

UK NEQAS for H&I offers online data entry using 'Google Forms' software. Online data entry forms can be accessed from the UK NEQAS for H&I website [www.uknegashandi.org.uk](http://www.uknegashandi.org.uk). Note that result forms may not be available for each scheme, and standard result forms should be used if online forms are unavailable. Data entry forms are password protected, please contact the UK NEQAS for H&I Office for the current password.

The software functionality for online data entry is currently limited, and participants are unable to save or view submitted results. Participants are therefore requested to carefully check entered data and print a copy of each completed page before pressing submit. Full instructions are provided on the online data entry pages.

Data entry errors submitted using the online forms are considered part of the assessment. Any participants that are uncomfortable with the limited functionality of the current software should continue to complete the standard result forms and submit via e-mail (see section 10.1). A full bespoke EQA computer package with extended functionality is being developed and expected to be in place during 2018/2019.

## 10.3. Acceptance of Results

Participants should make every effort to return their results on or before the deadline date indicated for a particular Scheme. Please ensure that handwritten submissions are clear and legible. Participants may be asked to resubmit forms that are unclear or incorrectly completed.

Late results may be accepted if assessment and reports have not been completed. Results will not be accepted for assessment or performance review once schemes' results are published on the UK NEQAS for H&I website. Requests for extensions to report deadlines should be made to the Scheme Manager.

Amended results will be accepted if they are transmitted prior to the deadline and if they are clearly marked 'amended results'.

## 10.4. Performance Reports

Individual laboratory performance reports are sent to named individuals in line with the published report timetable (section 30). Participants will also receive performance tables detailing the assessment of all participants for a particular distribution, along with performance of all participants over the past year.

Detailed results summaries including details of methodology and individual participant reported results also form part of the reports and may be downloaded from the website: <http://www.uknegashandi.org.uk>

Excel spreadsheets of Scheme 3 results are available on request from: [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk)

At the end of each distribution year, an annual performance certificate will be sent to each participant, detailing their overall performance for each Scheme they participated in.

## 10.5. Performance Criteria

This information should be read in conjunction with the specific assessment criteria detailed for each Scheme in the 'Schemes' section of the Participants' Manual.

In general, performance assessment for UK NEQAS for H&I Schemes is based on establishing a consensus result for HLA/ABO/HFE/HPA/KIR specificities/alleles, antibody presence/absence, antibody specificities, cell/serum crossmatch test positive/negative, for all test samples.

To establish the consensus result, 75% or more of participant's results must be in agreement. If there is less than 75% agreement, consensus is not established and that result is not assessed. Scheme 3 - HLA Antibody Specificity Analysis - also uses a 95% consensus level for the absence of an HLA specificity.

For genotyping schemes (1B, 4A1, , 4A2, 5A, 7, 9, 10) a reference result will be used for assessment in the event that a consensus result is not achieved. For Scheme 8, and Scheme 4A1 (HLA-DPB1 typing) a reference result for assessment will always be used.

Reference typing, will be subcontracted to an EFI and ISO15189 accredited laboratory. In most instances this will be the Welsh Transplantation and Immunogenetics Laboratory, UK NEQAS for H&I's host laboratory. A laboratory of a Steering Committee member may also be used for a reference result if alternative/additional testing is required.

Scheme 5B - Interpretative: HFE Genotype and Hereditary Haemochromatosis uses a penalty points system. The Educational and Pilot Schemes are not assessed.

Satisfactory performance is generally based on achieving a specified number of results in agreement with consensus/reference assignments in a year. These are set according to those established by EFI (minimum performance standards) or greater.

Participants that have informed UK NEQAS for H&I of a valid reason for not testing EQA sample(s) are marked as 'Not Tested' and are not assessed. In these instances, the total number of samples tested on the report is reduced.

Participants that do not submit results without notification are assessed as 'Unacceptable'. Where a choice of categories for assessment is provided at registration (e.g. HLA loci for HLA Typing or PBL/T-cell/B-cell for crossmatching) all categories must be reported. Failure to report a registered assessment category will result in unacceptable performance.

Scheme assessment and satisfactory performance criteria are reviewed by the Steering Committee each year and take into account current 'EFI EPT Standards for Providers' established by the EFI EPT Committee. Proposed changes in Schemes' assessment and/or the determination of satisfactory performance are brought to the NQAAP for ratification.

The method used to test the samples is generally not considered during scheme assessment. Schemes are generally analyte driven and different methods should give comparable qualitative results (e.g. Scheme 1B, participants can test using flow cytometry or molecular methods). Where H&I testing methods are known to not give comparable results (e.g. due to differences in test sensitivity) schemes have developed to accommodate this (e.g. Scheme 2A and 2B CDC and flow cytometry crossmatching).

## 10.6. Unsatisfactory Performance

Laboratories not meeting the 'Satisfactory Performance' criteria will receive written notification of their 'Unsatisfactory Performance' status, as soon as it occurs, offering advice and assistance.

A Corrective and Preventative Action (CAPA) form MUST be completed by the participant with a summary of the investigation into the reasons for their unacceptable performance together with any corrective actions. The form is available to complete online or download on the UK NEQAS for H&I website (unsatisfactory performance) <http://www.ukneqashandi.org.uk>

The CAPA must be returned to UK NEQAS for H&I within 20 working days of the date of the 'Unsatisfactory Performance' notification. Corrective action taken as a result of unsatisfactory performance can lead to an improvement in proficiency within an individual laboratory, and allows UK NEQAS for H&I to offer guidance and assistance to laboratories.

Note: this does not apply to Interpretative Schemes, e.g. Scheme 5B.

## 10.7. UK Laboratory Unacceptable Performance

The National Quality Assurance Advisory Panels (NQAAPs) are responsible to the pathology professions for monitoring the maintenance of satisfactory standards of diagnostic work in clinical laboratories in the United Kingdom, whether in the public or private sector. They are accountable to the professions through the RCPATH JWG and their relationship with participants is strictly professional and confidential. Members of the NQAAPs are nominated by the appropriate professional bodies and approved by the JWG. The NQAAPs provide help, support and education to participants in UK NEQAS and other EQA programmes in a confidential setting.

The UK NEQAS for H&I schemes come under the UK NQAAP for Immunology for the monitoring and maintenance of satisfactory performance standards. The Director/Manager reports to UK NQAAP by written report prior to each UK NQAAP meeting (usually three times per year) and by attendance at each meeting.

All UK laboratories receiving 'Unsatisfactory Performance' notification are reported to UK NQAAP for Immunology. Failure to reply within 20 working days of the date of an 'Unsatisfactory Performance' notification or replies deemed unsatisfactory will be specifically reported to UK NQAAP for Immunology who may take further action.

The H&I professional representative on the UK NQAAP for Immunology is proposed by the British Society for Histocompatibility and Immunogenetics. This representative also sits, as an observer, on the Schemes' Steering Committee.

In registering for participation in the UK NEQAS for H&I Scheme(s), UK participant laboratories agree to abide by/uphold the conditions of scheme participation of the JWG on EQA. These can be found in section 29 or at: [http://www.rcpath.org/Resources/RCPATH/Migratedresources/Documents/J/Joint\\_Working\\_Group\\_Conditions\\_of\\_Participation\\_August10.pdf](http://www.rcpath.org/Resources/RCPATH/Migratedresources/Documents/J/Joint_Working_Group_Conditions_of_Participation_August10.pdf)

## **10.8. Non-Analytical Errors**

Non-analytical errors, e.g. clerical or reporting mistakes, are considered as part of the assessment procedure. Normally no allowance is made for these on appeal.

## **10.9. Assessment Appeals**

An appeal against an assessment, including any relevant laboratory evidence, should be made in writing to [uknegashandi@wales.nhs.uk](mailto:uknegashandi@wales.nhs.uk). Any errors made by UK NEQAS in assigning your results will be rectified and an amended report issued. Appeals will be acknowledged in writing within 2 working days.

Appeals are reviewed on an individual basis by the Director and Manager in the first instance. If an appeal cannot be easily approved, the Director or Manager will present the appeal at the next Steering Committee meeting for a decision. The participant laboratory will be informed of the outcome of the Committee's decision as soon as possible (and usually within ten working days) of the Steering Committee meeting. The Committee's decision is final.

## **10.10. Policy On Testing Returned Scheme's Material**

UK NEQAS for H&I has occasionally been asked to test Scheme's material returned by a Participant. In the past, this request has usually come from a laboratory that has been penalised and is questioning the validity of their findings or is questioning the proper labelling of Scheme's samples.

UK NEQAS for H&I apply stringent procedures, fully detailed in Standard Operating Procedures, for the handling of all test material. UK NEQAS for H&I's practices for the collection, processing, aliquotting, labelling, packing and disposal of any remaining material and labels are such that it is extremely unlikely for samples to be mixed-up, disordered or incorrectly labelled.

The UK NEQAS for H&I Steering Committee, unanimously agree that UK NEQAS for H&I should not normally retest returned Scheme's material. The Committee pointed out that returned material, whether in the primary container or not, may not be that originally dispatched and/or may have become 'contaminated'. It also highlighted that Scheme's samples are tested by multiple laboratories and that their unanimously reported findings always provided the basis of sample assessment.

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## 11. General Information

### 11.1. Participant Meeting

An annual participant meeting is arranged each year. Every participating laboratory is encouraged to send at least one representative.

The focus of the meeting is to allow participant laboratories to discuss matters of current interest relating to the Schemes. This usually includes

- (i) a report on each Scheme
- (ii) educational scientific presentations
- (iii) formal opportunities for a full participant discussion of each Scheme and UK NEQAS for H&I in general.

### 11.2. Endorsement by UK NEQAS for H&I

UK NEQAS for H&I does not endorse any equipment, reagents, calibrants, test kits or any manufacturers or suppliers.

### 11.3. Scheme Review and Pilot Schemes

The Schemes are reviewed annually by the Steering Committee and fully discussed at the Annual Participants' Meeting. The Steering Committee consider comments from, for example, their members, participants, professional organisations and members of the discipline, regarding the nature and operation of Schemes and the establishment of new Schemes. Feedback and suggestions from participants are always welcome. Participant Satisfaction Surveys are regularly distributed. Other questionnaires may also be sent which are more scheme specific. Feedback is analysed and changes are made wherever possible to improve the service.

### 11.4. Bespoke Schemes

UK NEQAS for H&I is able to provide specific EQA schemes for certain HLA, HPA and HFE alleles. Bespoke schemes will use selected stored DNA/blood from samples previously tested in UK NEQAS for H&I's Schemes. Consequently, these samples are considered as well-documented reference material.

Due to the nature of Scheme 2A - Cytotoxic Crossmatching and Scheme 2B - Crossmatching by Flow Cytometry, UK NEQAS for H&I are normally unable to supply additional sera/blood samples for these Schemes.

Requests for a bespoke scheme, giving full details of requirements, should be made to: Deborah Pritchard Schemes' Manager [ukneqashandi@wales.nhs.uk](mailto:ukneqashandi@wales.nhs.uk)



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## 11.5. EFI Accreditation

### **UK NEQAS for H&I and External Proficiency Testing (EPT) Requirements for European Federation For Immunogenetics (EFI) Accreditation**

EFI have formally stated that our Schemes are acceptable as appropriate external quality assessment/external proficiency testing schemes for laboratories applying for or renewing EFI Accreditation. Accordingly, UK NEQAS for H&I is included in the EFI “Register of EPT Providers” (available to download from <http://www.efiweb.eu/efi-committees/ept-committee.html>).

UK NEQAS for H&I will continue to work to ensure it complies with EFI Accreditation requirements for EPT.

## 11.6. HLA Nomenclature

Nomenclature for HLA specificities and HLA alleles is complex and is continuously being reviewed and updated. The latest Nomenclature Report, HLA Dictionary and HLA Nomenclature Updates can be found at <http://hla.alleles.org/>

Participants are requested to report their findings using the correct nomenclature relevant to the methodology used. The IMGT/HLA database update (<http://www.ebi.ac.uk/ipd/imgt/hla/docs/release.html>) from the January two years prior to start of the Scheme will be taken as the ‘reference’ allele baseline for the entire year and participants will be expected to report their findings in accordance with this report as a minimum. (e.g in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

## 12. SCHEME 1A – HLA PHENOTYPING

Scheme 1A is aimed at laboratories undertaking HLA-A, B, C, DR, DQ typing or any combination of these, using serological techniques.

The Steering Committee acknowledges that few laboratories use serological HLA typing in isolation, and many use DNA-based supplementary techniques to aid in the definition and refinement of the HLA specificities detected by serology. Therefore, in line with previous years' results, there will ordinarily be an expectation that Scheme 1A results are reported by participants at the split specificity level - based on a combination of serological and molecular typing results.

Participants are requested to report Scheme 1A results using the correct HLA specificity nomenclature <http://hla.alleles.org/> and see section 11.6.

### PURPOSE

To assess participants' ability to use serological and supplementary methods to correctly identify HLA specificities.

### SAMPLES

A total of ten blood samples will be sent each year as five distributions of two blood samples.

### REPORTING

Depending on their typing strategies participants may register for HLA- A, B, C, DR, DQ assessment

Participants must only register to be assessed on those loci tested using serological methods. Participants must make a report for each HLA locus for which they have registered.

It is acknowledged that many laboratories use supplementary techniques to confirm serological HLA specificity assignment. The report should detail the HLA phenotype using official WHO HLA specificity nomenclature.

Reports should be made at the split specificity level, where appropriate, using the results of the serological typing and any typing performed using supplementary techniques.

Participants must only use the reporting forms provided on the UK NEQAS for H&I website and are required to make their report within 10 days.

### ASSESSMENT

Participants will be assessed on the HLA loci for which they are registered.

The consensus complete HLA phenotype for assessment is determined by at least 75% of laboratories agreeing each specificity. Specificities failing to reach the 75% consensus level will not be assessed.

A "blank" forms part of the assessment if at least 75% of laboratories report a single specificity at a locus.

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**Assessment Procedure**

Each complete HLA phenotype in agreement with the consensus phenotype	Acceptable
Each complete HLA phenotype not in agreement with the consensus phenotype	Unacceptable
Each sample/registered loci not reported - with valid reason	Not Assessed
Each sample/registered loci not reported / late submission of results	Unacceptable

**SATISFACTORY PERFORMANCE**

Satisfactory performance is obtaining nine or more complete HLA phenotypes in agreement with the consensus phenotypes in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Summary sheets of all reported specificities and supplementary information.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

### 13. SCHEME 1B - HLA-B27 TESTING

HLA testing can be performed as an aid to disease diagnosis, one of the most commonly tested being HLA-B27 which is associated with, e.g. ankylosing spondylitis.

#### PURPOSE

To assess participants' ability to correctly determine the HLA-B27/B2708/B\*27 status as positive or negative. Participants should use technology routinely employed by their laboratory to determine the B27 status (e.g. flow cytometry, molecular methods).

#### SAMPLES

A total of ten blood samples will be sent each year as five distributions of two blood samples.

#### REPORTING

Participants are required to report on HLA-B27/B2708/B\*27 status as "positive" or "negative". An "equivocal" report is accepted for laboratories that are unable to determine a positive or negative result (i.e. by flow cytometry) and their normal clinical procedure would be to refer the sample to another laboratory. Technical failures and other issues should be reported as 'not tested'.

Participants must only use the reporting forms provided on the UK NEQAS for H&I website and make their report within 14 days.

#### ASSESSMENT

The "HLA-B27" status of each sample is determined by at least 75% of laboratories agreeing on the presence or absence of "HLA-B27". A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

#### Assessment Procedure

Each sample report in agreement with the consensus/reference "HLA-B27" status	Acceptable
Each sample report not in agreement with the consensus/reference "HLA-B27" status	Unacceptable
Each sample not reported - with valid reason, or equivocal result	Not Assessed
Each sample not reported / late submission of results	Unacceptable

#### SATISFACTORY PERFORMANCE

Satisfactory performance is making ten sample reports in agreement with the consensus/reference "HLA-B27" status in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

#### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- The HLA type of the donor samples (for indication only).
- Summary sheets of all reported "HLA-B27" results.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

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## 14. SCHEME 2A - CYTOTOXIC CROSSMATCHING

If present at a high concentration, patient antibodies corresponding to donor mismatched HLA antigens can cause immediate and irreversible rejection of a transplanted organ. Performing a prospective complement dependant cytotoxicity (CDC) crossmatch between donor and recipient can prevent hyperacute rejection. Participants may register to test peripheral blood lymphocytes (PBL) and/or T-cells and/or B-cells, with and/or without dithiothreitol (DTT) treatment of sera, according to their local method and practice.

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### New for 2018

Equivocal reports are not accepted for Scheme 2A. Technical issues and invalid results (e.g control failures, replicate issues, sample quality issues) should be reported as 'Not Tested' with the reason stated. The Steering Committee feel that there are no circumstances where a result is undetermined or equivocal for cytotoxic crossmatching, and these reports will no longer be accepted for Scheme 2A.

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#### PURPOSE

To assess participants' ability to correctly determine cell/serum cytotoxic crossmatch status. Note that the scheme is a technical assessment of cytotoxic crossmatching, and results should not be 'interpreted' before reporting.

The Steering Committee acknowledges that this crossmatching scheme will only partially emulate current crossmatching practice.

#### SAMPLES

A total of ten blood samples and forty serum samples will be sent each year as five distributions. Each distribution will comprise of two blood samples and their two corresponding sets of four selected sera (approximately 150µl each). A serum set may include test serum replicates.

Each set of four sera must be tested against its corresponding blood sample.

#### REPORTING

At registration participants may opt for assessment of the following cell/DTT combinations according to their local practice;

Peripheral Blood Lymphocytes with DTT  
T-Cell with DTT  
B-Cells with DTT

Peripheral Blood Lymphocytes without DTT  
T-Cell without DTT  
B-Cells without DTT

Test results should be reported as positive or negative using established local criteria. Participants must make a report for each cell/DTT category for which they have registered.

Tests reported as weakly positive will be interpreted as positive for assessment purposes.

Participants are requested to report reaction strength, using their own scoring system, to enable comparison between laboratories.

Technical issues and invalid results (e.g control failures, replicate issues, sample quality issues) should be reported as 'Not Tested' with the reason stated. Equivocal reports are not accepted for Scheme 2A.

Participants must only use the reporting forms provided on the UK NEQAS for H&I website. Participants are required to make their report within 10 days.

## **ASSESSMENT**

The crossmatch status of each sample is determined by at least 75% of laboratories agreeing on the positivity or negativity of each cell/DTT combination. Crossmatching tests failing to reach the 75% consensus level will not be assessed. All PBL, T-cell, B-cell results with/without DTT treatment of sera are considered independently.

### **Assessment Procedure**

A result in agreement with the consensus findings	Acceptable
A result not in agreement with the consensus findings	Unacceptable
Each sample/registered category not reported - with valid reason,	Not Assessed
Each sample/registered category not reported / late submission of results	Unacceptable

## **SATISFACTORY PERFORMANCE**

Satisfactory performance is making 85% of reports in agreement with the consensus findings in a year for each cell/DTT combination registered for.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

## **INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- The HLA phenotype of the donor and CDC detected specificities of the sera (for indication only).
- A summary sheet of all crossmatching results.
- Performance information on the current and previous year's samples.
- Performance information (non-assessed) on hidden replicate sera.

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## 15. SCHEME 2B - CROSSMATCHING BY FLOW CYTOMETRY

If present before transplantation patient antibodies corresponding to donor mismatched HLA antigens can cause rejection of a donor organ. Flow cytometry crossmatching between donor and recipient is a more sensitive crossmatch technique than the complement dependent cytotoxicity test for detecting donor specific antibodies.

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### New for 2018

Equivocal reports will now contribute to the consensus result and be assessed for Scheme 2B.

I.e. if 75% or more of participants agree on the positivity or negativity of a result, any laboratories reporting 'equivocal' will be assessed as 'unacceptable'. Likewise, if 75% of participants report equivocal, any laboratories reporting positive or negative will be assessed as 'unacceptable'. If the 75% consensus result is not reached when including the equivocal reports, the sample will not be assessed.

The Steering Committee acknowledge that not all laboratories have an 'equivocal' region and only those that would report 'equivocal' clinically should report this way. Technical issues and invalid results (e.g control failures, replicate issues, sample quality issues) should be reported as 'Not Tested' with the reason stated. 'Not tested' reports will continue to be not assessed.

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### PURPOSE

To assess participants' ability to correctly determine cell/serum flow cytometry crossmatch status. Note that the scheme is a technical assessment of flow cytometry crossmatching, and results should not be 'interpreted' before reporting.

The Steering Committee acknowledges that this crossmatching scheme will only partially emulate current crossmatching practice.

### SAMPLES

A total of ten blood samples and forty serum samples will be sent each year as five distributions. Each distribution will comprise of two blood samples and their two corresponding sets of four selected sera (approximately 300µl each). A serum set may include test serum replicates.

Each set of four sera must be tested against its corresponding blood sample for IgG antibody binding.

### REPORTING

At registration participants may opt for T-cell and/or B-cell crossmatch assessment. Participants must make a report for each cell type for which they have registered.

Test results should be reported as positive or negative **compared to the local negative control**. Equivocal reports will be accepted if the local criteria for a positive or negative result are not met, and equivocal is the result that would be reported clinically.

Technical issues and invalid results (e.g control failures, replicate issues, sample quality issues) should be reported as 'Not Tested' with the reason stated.

Tests reported as weakly positive will be interpreted as positive for assessment purposes.

Participants must only use the reporting forms provided and are required to make their report within 10 days.

---

## ASSESSMENT

The crossmatch status of each sample is determined by at least 75% of laboratories agreeing on a positive, negative or equivocal result for each test. Crossmatching tests failing to reach the 75% consensus level will not be assessed.

### Assessment Procedure

A result in agreement with the consensus findings	Acceptable
A result not in agreement with the consensus findings	Unacceptable
Each sample not reported - with valid reason,	Not Assessed
Each sample not reported / late submission of results	Unacceptable

## SATISFACTORY PERFORMANCE

Satisfactory performance is making 85% of reports in agreement with the consensus findings in a year for each cell type registered for.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

## INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- The HLA phenotype of the donor and CDC detected specificities of the sera (for indication only)
- A summary sheet of all reported crossmatching results.
- Performance information on the current and previous year's samples for all laboratories.
- Performance information (non-assessed) on hidden replicate sera.



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## 16. SCHEME 3 - HLA ANTIBODY SPECIFICITY ANALYSIS

Most H & I laboratories provide a service for testing of patients' sera for the presence of antibodies directed towards HLA-class I (A, B, C) or class I and class II (DR, DQ, DP) specificities. This may be within the context of solid organ or haematopoietic stem cell transplantation, provision of blood products or the investigation of a clinical condition, e.g. thrombocytopenia.

Many laboratories undertake this service using a two-tier system. The first stage – antibody detection (Scheme 6) determines which sera should be selected for the comprehensive second stage – antibody specificity assignment. Both stages are equally important since failure to detect the presence of antibodies during “screening” will obviously deny that serum the benefit of the often more comprehensive testing associated with antibody specification. Where numerous patients' sera are tested an effective two-stage system can significantly reduce laboratory workload thus allowing more resources to be applied to the important antibody specificity assignment stage.

For Scheme 3 (HLA Specificity Analysis) sera are provided that are known to contain antibodies directed towards HLA-class I and/or class II specificities.

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### New for 2018

DPB antibodies will be assessed as part of Class II registration. Laboratories must report any DPB antibodies detected in the samples. DQA, DPA antibodies may be reported but will not be assessed.

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#### PURPOSE

The purpose of this Scheme is to assess the laboratory's ability to determine the component HLA specificity or specificities in the antisera using all methods the laboratory employs for clinical samples. Note that the scheme is a technical assessment of antibody definition and the Steering Committee acknowledges that it will only partially emulate current clinical practice.

#### SAMPLES

A total of ten serum samples will be sent each year as two distributions of five samples. Volumes of approximately 1ml of serum will be distributed.

#### REPORTING

At registration participants may opt for Class I only (A, B, Cw) or Class I and Class II (A, B, Cw, DRB, DQB, DPB) antibody assessment.

Only those specificities detailed on the reporting forms will be assessed, e.g. reports of anti-A9, Bw4 and Bw6 will not be assessed.

Participants may report other antibody findings, e.g. DPA, DQA, MICA, allele specific antibodies and results of Luminex based complement binding assays (e.g. C1q, C3d etc). These are not currently assessed.

Participants are also invited to report the specificities they would consider as unacceptable for a standard risk patient waiting for deceased donor kidney transplant based on the test results. For this interpretation of results, participants are asked to assume the antibody identification results are reproducible and the sensitising events are unknown.

Participants must only use the reporting forms provided and are required to report antibody specificities within a period of 6 weeks.

## **ASSESSMENT**

Class I and Class II IgG specificities will be assessed independently.

Consensus presence of a specificity is determined by at least 75% of laboratories agreeing the specificity.

Consensus absence of a specificity is determined by at least 95% of laboratories agreeing the absence of the specificity.

Results failing to reach the consensus levels above will not be assessed.

### **Assessment Procedure**

Assigning a consensus specificity	Acceptable
Missing a consensus specificity	Unacceptable
Assigning a specificity where the consensus is negative	Unacceptable
Each sample not reported - with valid reason,	Not Assessed
Results not submitted/ late submission of results	Unacceptable

## **SATISFACTORY PERFORMANCE**

Satisfactory performance is testing ten serum samples and getting at least 75% of specificities in agreement with the consensus findings in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

## **INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Where known, the HLA phenotypes of the serum donors (for indication only).
- Summary sheets of all reported antibody findings.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

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## 17. SCHEME 4A1 – HLA TYPING AT 1<sup>ST</sup> FIELD RESOLUTION

Scheme 4A1 is for laboratories that undertake DNA HLA based typing at the 1<sup>st</sup> field level (formerly known as low resolution or 2-digit typing). Participants are requested to report results using the correct nomenclature <http://hla.alleles.org/>. The IMGT/HLA database update (<http://www.ebi.ac.uk/ipd/imgt/hla/>) from the January two years prior to start of the Scheme will be taken as the 'reference' allele baseline for the entire year and participants will be expected to report their findings in accord with this report as a minimum (e.g. in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

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### New for 2018

Participants are able to register for assessment of DPB1 alleles. This is for laboratories that type clinically at a low-intermediate resolution e.g. PCR SSP or SSO results for solid organ transplant antibody analysis, where the results may not meet the minimum typing requirements of Scheme 4A2 – 2<sup>nd</sup> field resolution typing (i.e. unable to resolve all ambiguities resulting from polymorphisms located within exon 2). Scheme 4A1 DPB1 results will be assessed against a reference DPB1 type.

There are no minimum typing requirements for DPB1 in Scheme 4A1, so laboratories are able to report the DPB1 results at the resolution that is applicable to their clinical need. This includes reporting strings of DPB1 alleles that differ at the first field. Assessment is performed by comparing the participant DPB1 result to the reference DPB1 type; acceptable results will include the reference allele in the report. Laboratories performing 'high resolution' DPB1 typing would still be expected to participate in Scheme 4A2.

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### PURPOSE

To assess participants' ability to correctly determine HLA alleles at the 1<sup>st</sup> field level.

### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

### REPORTING

Participants may register for any of the following: HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, and DPA1 for 1<sup>st</sup> field assessment, or 'presence of' assessment for DRB3, DRB4 and, DRB5. DPA1 results will be assessed if sufficient results are received.

Participants may register for DPB1 low-intermediate resolution assessment.

Participants must only use the reporting forms provided and return results within 2 weeks.

### ASSESSMENT

Participating laboratories will be assessed on the loci they designate at registration.

The consensus full HLA genotype is determined by at least 75% of laboratories agreeing each allele. A "blank" forms part of the assessment if at least 75% of laboratories report a single allele at a locus.

A reference result will be used for DPB1 assessment and for other results failing to reach the 75% consensus level (see section 10.5).

Participants will only be assessed on those alleles that appear in the IMGT/HLA database update from the January two years prior to start of the Scheme (e.g. in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

### Assessment Procedure

Each full HLA genotype in agreement with the consensus/reference type	Acceptable
Each full HLA genotype not in agreement with the consensus/reference type	Unacceptable
Each sample not reported - with valid reason	Not Assessed
Each sample not reported / late submission	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is obtaining nine or more full HLA genotypes in agreement with the consensus/reference genotypes in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- Summary sheets of all reported alleles.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.
- Summary of 'interpreted' serological specificities.

## 17.1. SCHEME 4A1i – INTERPRETIVE HLA GENOTYPE

UK NEQAS for H&I are aware that many H&I laboratories use DNA techniques only for HLA typing, but that results often have to be 'interpreted' to the appropriate specificity (e.g. DQB1\*03:01 group 'interpreted' as DQ7) during routine laboratory work.

This may be required for;

- Donor specific antibody analysis
- Deceased donor HLA typing reports for National Organ Allocation
- HLA associated disease reports
- Identification of potential unrelated haematopoietic stem cell donors in registry databases which may have been typed using serology

Participants are requested to report results using the correct nomenclature <http://hla.alleles.org/>.

See also: R. Holdsworth, C.K. Hurley, S.G.E. Marsh, M. Lau, H.J. Noreen, J.H. Kempenich, M. Setterholm, M. Maier. A summary of HLA-A, -B, -C, -DRB1/3/4/5 and -DQB1 alleles and their association with serologically defined HLA-A, -B, -C, -DR and -DQ antigens Tissue Antigens. 2009 **73**:95-170

### PURPOSE

To assess participants' ability to correctly interpret their Scheme 4A1 DNA based typing results to the 'split' HLA specificity level. Note that Scheme 4A1i is only available to participants registered for Scheme 4A1.

### SAMPLES

Results from participants' HLA typing at the first field level for Scheme 4A1 will be used as the basis for interpretation.

### REPORTING

Participants may register for interpreted specificity assessment for any of the following: HLA-A, B, Cw, DRB1, DQB1 or 'presence of' assessment for Bw4/6 and DR51/52/53.

Participants must only use the reporting forms provided and return results within 2 weeks.

Participants are requested to report 'interpreted' results to the split specificity level where appropriate (e.g. B\*40:01 allele group as B60, DQB1\*03:01 group as DQ7, C\*03:03 allele group as Cw9) using the correct nomenclature <http://hla.alleles.org/>.

The Steering Committee acknowledge that there are HLA alleles/allele groups with no specificity equivalent and these may be reported as e.g. B15, B40. The Steering Committee also acknowledge that HLA-C alleles above C\*10 do not have a recognised specificity, but these should still be reported as the HLA phenotype e.g. Cw16. Null alleles should be reported using the suffix 'N' e.g. Cw4N if a definitive definition of a null allele has been made.

Do not report Bw4 for associated A specificities

### ASSESSMENT

Participating laboratories will be assessed on the loci they designate at registration.

The consensus full HLA type is determined by at least 75% of laboratories agreeing each specificity. A "blank" forms part of the assessment if at least 75% of laboratories report a single specificity at a locus. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

Scheme 4A1 results form the basis for Scheme 4A1i interpretation. Therefore samples with results that are deemed 'unacceptable' for Scheme 4A1 will not be assessed in Scheme 4A1i.

### Assessment Procedure

Each full HLA type in agreement with the consensus/reference HLA type	Acceptable
Each full HLA type not in agreement with the consensus/reference HLA type	Unacceptable
Each sample/registered loci not reported - with valid reason	Not Assessed
Each sample assessed as 'unacceptable' in Scheme 4A1	Not Assessed
Each sample /registered loci not reported / late submission	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is obtaining nine or more full HLA types in agreement with the consensus/reference HLA types in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- Summary sheets of all reported specificities.
- Performance information on the current and previous year's samples for all laboratories.

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## 18. SCHEME 4A2 – HLA TYPING TO 2<sup>ND</sup> OR 3<sup>RD</sup> FIELD RESOLUTION

Scheme 4A2 is for laboratories that undertake DNA HLA based typing at the 2<sup>nd</sup> or 3<sup>rd</sup> field level (i.e. high resolution typing or next generation sequence typing).

Participants can choose at registration whether to be assessed at the 2<sup>nd</sup> field or 3<sup>rd</sup> field level.

Participants are requested to report Scheme 4A2 results using the correct nomenclature. The IMGT/HLA database update (<http://www.ebi.ac.uk/ipd/imgt/hla/>) from the January two years prior to start of the Scheme will be taken as the 'reference' allele baseline for the entire year and participants will be expected to report their findings in accord with this report as a minimum (e.g. in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

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### NEW FOR 2018

Participants can register for assessment of results at the 3<sup>rd</sup> field resolution. Participants must be able to distinguish all nucleotide substitutions within the coding sequence for 3<sup>rd</sup> field assessment.

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#### PURPOSE

To assess participants' ability to correctly determine HLA alleles to the 2<sup>nd</sup> or 3<sup>rd</sup> field level

#### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

#### REPORTING

Participants may register for any of the following: HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1, for 2<sup>nd</sup> or 3<sup>rd</sup> field assessment.

Participants must only use the reporting forms provided and return results within 3 weeks

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**For typing to the 2<sup>nd</sup> field**, HLA alleles should be assigned on the basis of differences in exons 2 and 3 for class I and exon 2 for class II, **as a minimum requirement**. Alleles with identical sequences over these exons which have not been excluded due to testing other areas of the gene should be reported.

Participants registered for 2<sup>nd</sup> field assessment should define all ambiguities that encompass a null allele wherever the polymorphism is located (see statement on EFI Standard below).

HLA alleles must be identified at the level of resolution which defines the first and second fields by at least resolving all ambiguities resulting from polymorphisms located within exons 2 and 3 for HLA class I loci, and exon 2 for HLA class II loci, as a minimum. Alleles with identical sequences over these exons which have not been excluded due to testing other areas of the gene should be reported in the same group e.g. allele x / allele y, where "/" means "or", e.g. DRB1\*01:01/01:02/01:04 means DRB1\*01:01 or DRB1\*01:02 or DRB1\*01:04. Ambiguous typing combinations (heterozygous positions identified by sequencing, e.g. cis/trans ambiguities) that have not been excluded should also be reported.

Information on identical allele sequences and ambiguous allele combinations over exons 2 and 3 for HLA class I loci, and exon 2 for HLA class II loci are taken from the latest IMGT/HLA ambiguous allele combinations file release (<http://www.ebi.ac.uk/ipd/imgt/hla/ambig.html>).

Please report alleles fully, e.g. DRB4\*01:02-01:03 and not as DRB4\*01:02-03 which may be interpreted as DRB4\*01:02-01:03 or as DRB4\*01:02-03:01.

**The European Federation for Immunogenetics (EFI) 'STANDARDS FOR HISTOCOMPATIBILITY & IMMUNOGENETICS TESTING version 7.0, standards state:**

- F1.1.4.1** HLA alleles must be identified at the level of resolution which defines the first and second fields according to WHO nomenclature by at least resolving all ambiguities:
  - F.1.1.4.1.1** resulting from polymorphisms located within exons 2 and 3 for HLA class I loci, and exon 2 for HLA class II loci.
  - F.1.1.4.1.2** that encompass a null allele, wherever the polymorphism is located, unless it can be demonstrated that an expressed antigen is present on the cells.

It is expected that EFI accredited laboratories that register for HLA typing to the 2<sup>nd</sup> field will have developed a strategy to comply with this Standard for the recognition of null alleles

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**For typing to the 3<sup>rd</sup> field**, HLA alleles should be assigned on the basis of any differences in the coding region as a minimum requirement. Alleles that differ in non-coding regions (i.e. 4<sup>th</sup> field results) may be reported for comparison with other laboratories, but the 4<sup>th</sup> field will not be assessed

**ASSESSMENT**

Participating laboratories will be assessed on the loci they designate at registration.

The consensus full HLA genotype is determined by at least 75% of laboratories agreeing each allele. A "blank" forms part of the assessment if at least 75% of laboratories report a single allele at a locus. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

Participants will only be assessed on those alleles that appear in the IMGT/HLA database update from the January two years prior to start of the Scheme (e.g. in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

**For typing to the 2<sup>nd</sup> field**, reports containing groups of alleles are considered acceptable if all alleles within the group have identical sequences over exons 2 and 3 for class I and exon 2 for class II. Alleles that differ within these exons are considered 'unacceptable'.

Reports containing ambiguous allele typing combinations (e.g. cis/trans ambiguities) defined over exons 2 and 3 for class I and exon 2 for class II are considered acceptable.

For alleles reported above the 2<sup>nd</sup> field resolution, (e.g. 3<sup>rd</sup> or 4<sup>th</sup> field) the report up to the 2<sup>nd</sup> field will be used for assessment, unless registered for 3<sup>rd</sup> field assessment (see below).

**For typing to the 3<sup>rd</sup> field**, reports containing groups of alleles are considered acceptable if all alleles within the group have identical sequences over the coding region. Alleles that differ within the coding region are considered 'unacceptable'.

For alleles reported above the 3<sup>rd</sup> field resolution, (e.g. 4<sup>th</sup> field) the report up to the 3<sup>rd</sup> field will be used for assessment.



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### Assessment Procedure

Each full HLA genotype in agreement with the consensus/reference type	Acceptable
Each full HLA genotype not in agreement with the consensus/reference type	Unacceptable
Each sample/registered loci not reported - with valid reason	Not Assessed
Each sample/registered loci not reported / late submission of results	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is obtaining nine or more full HLA genotypes in agreement with the consensus/reference genotypes in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- Summary sheets of all reported alleles.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.
- Sheets detailing i) the sequences that are identical over exons 2 and 3 for class I and exon 2 for class II and ii) ambiguous typing combinations (heterozygous positions identified by sequencing) defined over these exons.
- Participants reporting strings of alleles containing 'null' alleles will be notified.

## 19. SCHEME 5A – HFE TYPING

The HFE gene is associated with hereditary haemochromatosis. Two mis-sense mutations in the HFE gene, a cysteine282tyrosine (C282Y) (rs1800562, NG\_008720.2:g.10633G>A; NM\_000410.3:c.845G>A; NP\_000401.1:p.Cys282Tyr) and a histidine63aspartic acid (H63D) (rs1799945, NG\_008720.2:g.8671C>G; NM\_000410.3:c.187C>G; NP\_000401.1:p.His63Asp), have both been shown to be associated with the development of disease. Other HFE mutations have also been associated with haemochromatosis.

### PURPOSE

To assess participants' ability to correctly determine HFE mutations.

### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

### REPORTING

Participants may register to have the H63D (Hist63Asp) mutation, C282Y (Cys282Tyr) mutation and S65C (Ser65Cys) mutation of the HFE gene assessed.

Participants are requested to report any other HFE gene mutations that they detect for participant information purposes.

Participants must only use the reporting forms provided and are required to return results within 2 weeks.

### ASSESSMENT

The consensus HFE mutations for assessment are determined by at least 75% of laboratories agreeing the mutations. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

#### Assessment Procedure

Each sample report in agreement with the consensus/reference H63D and C282Y and S65C genotype	Acceptable
Each sample report not in agreement with the consensus/reference H63D and C282Y and S65C genotype	Unacceptable
Each sample/registered genotype not reported - with valid reason	Not Assessed
Each sample/ registered genotype not reported / late submission	Unacceptable

### **SATISFACTORY PERFORMANCE**

Satisfactory performance is making ten sample reports in full agreement with the consensus/reference H63D and C282Y and S65C genotypes (if applicable) in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### **INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- A summary sheet of all reported HFE genotypes.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

## 20. SCHEME 5B - INTERPRETATIVE: HFE GENOTYPE AND HEREDITARY HAEMOCHROMATOSIS

### PURPOSE

To assess participants' ability to make an accurate, clear and concise clinical report, appropriate for the range of clinical staff involved in a patient's care and treatment, given HFE genotype and other relevant clinical information.

Participants are requested to note the EMQN best practice guidelines for the molecular genetic diagnosis of hereditary haemochromatosis (HH), published in 2015 when making their reports. (<http://www.nature.com/ejhg/journal/vaop/ncurrent/full/ejhg2015128a.html>).

### CLINICAL SCENARIOS

HFE genotype will be provided, together with various pieces of clinical information, on two patients twice a year.

Note that the Scheme 5B clinical scenarios will be distributed by e-mail.

### REPORTING

Participants are expected to make a report on each of the patient scenarios.

Reports must be written in English and **must be identical in format to that used for routine clinical reporting.**

Participants are required to return their reports within 4 weeks.

### ASSESSMENT

For each of the patient scenarios several interpretative criteria expected to be covered by the report, will be identified and agreed by the Expert Advisors. Full or half penalty points may be awarded for interpretative criterion not covered by the report.

Scoring Procedure	Penalty points
Each feature in agreement with an identified criterion	0
A principal agreed interpretative criterion not covered by the report	up to 3
Other agreed interpretative criterion not covered by the report	½ or 1
Significant erroneous patient identifiers or other information errors in the report (each error)	½ or 1

**NOTE: The Expert Advisors determine the 'principal' and 'other' interpretative criteria.**

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**Assessment Procedure**

Each scenario where 50% or less of the possible penalty points is allocated	Acceptable
Each scenario where more than 50% of the possible penalty points is allocated	Unacceptable
Each scenario not reported - with valid reason	Not Assessed
Each scenario not reported / late submission	Unacceptable

**SATISFACTORY PERFORMANCE**

Satisfactory performance is obtaining 4 'Acceptable' classifications in a year.

**NOTE: Unsatisfactory Performance Notifications (see section 10.6) are NOT sent to participants of Interpretative Schemes.**

**INFORMATION / ANALYSIS PROVIDED TO PARTICIPANTS**

- Each laboratory will receive an itemisation of interpretative points applicable to each clinical scenario indicating how their report coincided with the criteria identified.
- A summary of all participants' scores.
- General comments from the Expert Advisors on each scenario.

## 21. SCHEME 6 – HLA ANTIBODY DETECTION

Most H & I laboratories provide a service for testing of patients' sera for the presence of antibodies directed towards HLA-class I (A, B, C) or class I and class II (DR, DQ, DP) specificities. This may be within the context of solid organ or haematopoietic stem cell transplantation, provision of blood products or the investigation of a clinical condition, e.g. thrombocytopenia.

Many laboratories undertake this service using a two-tier system. The first stage – antibody detection determines which sera should be selected for the comprehensive second stage – antibody specificity assignment (see Scheme 3). Both stages are equally important since failure to detect the presence of antibodies during “screening” will obviously deny that serum the benefit of the often more comprehensive testing associated with antibody specification. Where numerous patients' sera are tested an effective two-stage system can significantly reduce laboratory workload thus allowing more resources to be applied to the important antibody specificity assignment stage.

The test sera supplied in Scheme 6 may or may not contain HLA antibodies directed towards HLA-class I and/or class II specificities. Accordingly, this Scheme assesses the laboratory's ability to undertake the initial “screening” process which places individual patients' sera into the “no HLA antibodies detected” category or “HLA antibodies probably present – requires further analysis” category.

### **PURPOSE**

To assess participants' ability to correctly determine the presence of HLA antibodies using all 'screening' methods the laboratory employs for clinical samples.

### **SAMPLES**

A total of twelve serum samples will be sent each year as two distributions of six serum samples. Volumes of approximately 1ml of serum will be distributed.

### **REPORTING**

At registration participants may opt for Class I only or Class I and Class II antibody assessment.

Participants are required to report the presence or absence of HLA Class I or HLA-Class I and Class II antibodies.

Participants must only use the reporting forms provided and are required to return their results within 3 weeks.

### **ASSESSMENT**

Participating laboratories will be assessed on the antibody class or classes they designate at registration.

The consensus findings for Class I and Class II antibodies are determined separately.

Consensus positivity or negativity of each sample is determined by at least 75% of laboratories agreeing on the presence or absence of Class I or Class II antibody.

Samples failing to reach the 75% consensus level will not be assessed.

The reports of participants registered for Class I and II assessment must be in agreement with the consensus Class I and Class II findings on a serum to achieve an 'Acceptable' classification.

### Assessment Procedure

Each report in agreement with the consensus presence/absence of Class I or both Class I and Class II antibody	Acceptable
Each report not in agreement with the consensus presence/absence of Class I or both Class I and Class II antibody	Unacceptable
Each sample/registered class not reported - with valid reason, or equivocal	Not Assessed
Each sample/registered class not reported / late submission of results	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is making 80% of reports on all sera in agreement with the consensus Class I or **both** the consensus Class I and Class II antibody findings in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- Summary sheets of all reported antibody findings.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

## 22. SCHEME 7 – HLA-B\*57:01 TYPING FOR DRUG HYPERSENSITIVITY

Pharmacogenetics, generally accepted as the study, or clinical testing, of genetic variation that gives rise to differing responses to drugs, is increasingly being applied to the prospective testing of patients for HLA-B\*57:01 who are to be treated with the antiretroviral drug abacavir. Thus, a strong association exists between HLA-B\*57:01 and the development of drug hypersensitivity reactions to abacavir. Accordingly, this scheme tests participants' ability to define HLA-B\*57:01 using the method(s) they employ for routine clinical service HLA-B\*57:01 testing.

### PURPOSE

To assess participants' ability to correctly determine HLA-B\*57:01 status.

### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

### REPORTING

Participants are required to report on the HLA-B\*57:01 status as positive or negative.

Participants are encouraged to report a B\*57 - non-B\*57:01 - allele for information purposes.

Participants must only use the reporting forms provided and are required to return results within 10 days.

### ASSESSMENT

The consensus HLA-B\*57:01 status of each sample is determined by at least 75% of laboratories agreeing on the presence or absence of HLA-B\*57:01. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

#### Assessment Procedure

Each report in agreement with the consensus/reference HLA-B*57:01 status	Acceptable
Each report not in agreement with the consensus/reference HLA-B*57:01 status	Unacceptable
Each sample not reported - with valid reason, or equivocal	Not Assessed
Each sample not reported / late submission of results	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is making ten sample reports in agreement with the consensus/reference HLA-B\*57:01 status in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.



**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Summary sheets of all reported HLA-B\*57 results.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

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## 23. SCHEME 8 – HLA GENOTYPING FOR COELIAC AND OTHER HLA ASSOCIATED DISEASES

This scheme is aimed at laboratories that provide a service as an aid to the diagnosis of Class I and Class II HLA associated diseases, e.g. coeliac disease, birdshot retinopathy, actinic prurigo and narcolepsy (excluding HLA-B27 testing which is covered in Scheme 1B). Participants of Scheme 8 are mainly laboratories that perform partial HLA typing or use a commercial kit(s) to detect the presence of specific disease-associated HLA alleles.

As participants have different clinical requirements for the diseases they test for in terms of loci and resolution (1<sup>st</sup> or 2<sup>nd</sup> field), Scheme 8 uses a reference typing result for assessment. This means that laboratories participating in Scheme 8 are able to report the relevant HLA associated diseases at the resolution that is applicable to the needs of their clinical users. Assessment is performed by comparing the participant results to the reference type (at the 1<sup>st</sup> or 2<sup>nd</sup> field level).

Laboratories may also report interpretative comments as would appear on clinical reports, these will not be assessed in 2018.

Laboratories are not penalised for reporting 'strings' of HLA alleles e.g. DQB1\*03:02/03:03 if this is the resolution they report for clinical samples.

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### New for 2018

Scheme 8 now includes all Class I and Class II HLA associated diseases (excluding HLA-B27). Sample material will be whole blood and assessment based on a reference typing result. The reporting format has changed and includes interpretative comments (not assessed).

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#### PURPOSE

To assess participants' ability to correctly determine disease associated HLA allele families/alleles.

#### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

#### REPORTING

At registration participants must designate the HLA associated diseases they wish to be assessed for.

Participants are required to report their HLA genotyping findings relevant to each disease registered for. Participants should report the loci and at the resolution they test and report clinically. Each disease must have its own report form completed. Interpretative comments for the disease risk the genotype confers, as reported clinically may also be reported (not assessed).

Participants are requested to report results using the correct nomenclature <http://hla.alleles.org/>.

Participants must only use the reporting forms provided and are required to return results within 3 weeks.

## ASSESSMENT

Participating laboratories will be assessed on the alleles reported for each sample and disease.

Assessment will be at the 1<sup>st</sup> or 2<sup>nd</sup> field level appropriate to the individual participant's results for each locus.

A reference result will be used for assessment. Reports of groups of alleles must include the reference allele.

Participants will only be assessed on those alleles that appear in the IMGT/HLA database update (<http://www.ebi.ac.uk/ipd/imgt/hla/>) from the January two years prior to the start of the Scheme (e.g in 2018 the IMGT/HLA release version 3.23.0 01-2016 will be used throughout 2018).

### Assessment Procedure

Each HLA genotype in agreement with the 1 <sup>st</sup> or 2 <sup>nd</sup> field reference type	Acceptable
Each HLA genotype not in agreement with 1 <sup>st</sup> or 2 <sup>nd</sup> field reference type	Unacceptable
Each sample/disease not reported - with valid reason, or equivocal	Not Assessed
Each sample not reported / late submission	Unacceptable

## SATISFACTORY PERFORMANCE

Satisfactory performance is obtaining ten samples in agreement with the reference genotype in a year for each disease registered for.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

## INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- Summary sheets of all reported results and the reference HLA type.
- Information on methodology.
- Performance information on the current year's samples for all laboratories.

## 24. Scheme 9 – KIR GENOTYPING SCHEME

Killer-cell immunoglobulin-like receptor (KIR) molecules play an important role in immune function and have important interactions with HLA Class I molecules. Two kinds of KIR haplotype have been described based upon gene content, and are designated A and B. KIR genes are highly polymorphic and different genotypes have been associated with outcome after haematopoietic stem cell transplantation, especially in the haploidentical transplant setting.

### PURPOSE

To assess participants' ability to correctly determine the presence or absence of specific KIR genes

### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

### REPORTING

Participants can register for assessment for the presence/absence of: KIR2DL1, KIR2DL2, KIR2DL3, KIR2DL4, KIR2DL5, KIR3DL1, KIR3DL2, KIR3DL3, KIR3DS1, KIR2DS1, KIR2DS2, KIR2DS3, KIR2DS4, KIR2DS5, KIR2DP1, KIR3DP1.

Participants can report any other KIR polymorphisms they detect or subtypes for information. Subtypes for 2DS4 and 3DP1 may be reported as FULL or DEL.

Participants can also report an 'A' or 'B' haplotype for each sample based on the gene content of the sample. This information will not be assessed.

Participants must only use the reporting forms provided and return results within 2 weeks.

### ASSESSMENT

Participating laboratories will be assessed on the loci they designate at registration.

The consensus KIR genotype is determined by at least 75% of laboratories agreeing the presence/absence of each gene. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

#### Assessment Procedure

Each full KIR genotype in agreement with the consensus/reference genotype	Acceptable
Each full KIR genotype not in agreement with the consensus/reference genotype	Unacceptable
Each sample not reported - with valid reason	Not Assessed
Each sample not reported/late submission	Unacceptable

### **SATISFACTORY PERFORMANCE**

Satisfactory performance is obtaining nine or more full KIR genotypes in agreement with the consensus/reference genotypes in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### **INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Summary sheets of all reported findings.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

## 25. SCHEME 10 -HPA GENOTYPING SCHEME

Human Platelet Antigen's (HPA) are polymorphic and can stimulate the production of HPA specific antibodies. HPA genotyping is therefore used to aid investigations in several clinical situations, including neonatal alloimmune thrombocytopenia (NAIT), post-transfusion purpura (PTP) and cases of platelet transfusion refractoriness.

### PURPOSE

To assess participants' ability to correctly determine HPA polymorphisms

### SAMPLES

A total of ten blood samples will be sent each year as two distributions of five blood samples.

### REPORTING

Participants can register for assessment for any combination of the following: HPA-1, HPA-2, HPA-3, HPA-4, HPA-5, HPA-6, HPA-15.

Participants can report any other HPA polymorphisms they detect for information.

Participants must only use the reporting forms provided and return results within 2 weeks.

### ASSESSMENT

Participating laboratories will be assessed on the loci they designate at registration.

The consensus HPA genotype is determined by at least 75% of laboratories agreeing the presence/absence of each allele. A reference result will be used for assessment for samples failing to reach the 75% consensus level (see section 10.5).

#### Assessment Procedure

Each full HPA genotype in agreement with the consensus/reference genotype	Acceptable
Each full HPA genotype not in agreement with the consensus/reference genotype	Unacceptable
Each sample/registered loci not reported - with valid reason	Not Assessed
Each sample/registered loci not reported / late submission	Unacceptable

### **SATISFACTORY PERFORMANCE**

Satisfactory performance is obtaining nine or more full HPA genotypes in agreement with the consensus/reference genotypes in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.

### **INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Summary sheets of all reported findings.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

## 26. SCHEME 11 – HPA ANTIBODY DETECTION/SPECIFICATION

Human Platelet Antigen's (HPA) are polymorphic and can stimulate the production of HPA specific antibodies. HPA antibody detection/specification is important in several clinical situations, including neonatal alloimmune thrombocytopenia (NAIT), post-transfusion purpura (PTP) and cases of platelet transfusion refractoriness.

### PURPOSE

To assess participants' ability to correctly detect the presence of and determine the specificity of HPA antibodies

### SAMPLES

A total of eight serum/plasma samples will be sent each year as two distributions of four samples.

### REPORTING

Participants are required to report the presence or absence of HPA antibodies in each sample. Participants are also required to report the HPA antibody specificities in samples designated as 'positive'.

HLA antibody presence/absence results may also be reported.

Participants must only use the reporting forms provided and are required to return results within 4 weeks.

### ASSESSMENT

Consensus presence of a specificity is determined by at least 75% of laboratories agreeing the presence of the specificity. Consensus absence of a specificity is determined by at least 95% of laboratories agreeing the absence of the specificity. Specificities failing to reach the consensus levels will not be assessed. The percent consensus for each specificity is calculated independently from other reported specificities.

### Assessment Procedure

Assigning a consensus specificity	Acceptable
Missing a consensus specificity	Unacceptable
Assigning a specificity where the consensus is negative	Unacceptable
Each sample not reported - with valid reason	Not Assessed
Each sample not reported / late submission of results	Unacceptable

### SATISFACTORY PERFORMANCE

Satisfactory performance is testing ten eight samples and getting at least 75% of specificities in agreement with the consensus findings in a year.

Laboratories with unsatisfactory performance will receive written notification of their status and will be expected to reply to UK NEQAS for H&I detailing their corrective actions (see section 10.6). For UK laboratories, unsatisfactory performance will be reported to UK NQAAP for Immunology. For UK laboratories, failure to reply or replies deemed unsatisfactory are likely to be further actioned by UK NQAAP for Immunology.



**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Where known, the HPA types of the serum/plasma donors (for indication only).
- Summary sheets of all reported antibody findings.
- Information on methodology.
- Performance information on the current and previous year's samples for all laboratories.

## 27. EDUCATIONAL SCHEME

### PURPOSE

To provide participants with a variety of interesting samples/scenarios to test that offer a beneficial educational element.

Laboratories can register to receive the educational HLA typing (see section 27.1) and/or clinical scenarios (section 27.2) and/or crossmatching (see section 27.3).

### REPORTING

Participants must only use the reporting forms provided and are required to report their findings within the deadline stated.

### ASSESSMENT

The educational scheme samples and scenarios are not assessed.

### SATISFACTORY PERFORMANCE

Not applicable.

### INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS

- For samples, summary sheets of all reported findings and information on methodology will be issued after each distribution.
- Relevant references will be supplied whenever possible.
- For scenarios, a summary of all returns and a summary of the most frequent responses will be issued after each distribution.

## 27.1. EDUCATIONAL HLA TYPING SCHEME

A total of four samples for HLA typing will be sent each year as two distributions of two samples. The samples may be sent as blood samples or DNA extracts. The HLA typing samples are available free of charge to laboratories that participate in Scheme 1A or 4A1 or 4A2.

## 27.2. INTERPRETATIVE EDUCATIONAL SCENARIOS (iED)

A total of three clinical scenarios will be distributed throughout the year, covering haematopoietic stem cell transplantation, solid organ transplantation and platelet/transfusion immunology.

Laboratories can register to receive some or all of the scenarios. The educational clinical scenarios will be distributed to participants by e-mail and are provided free of charge to participants of other UK NEQAS for H&I Schemes.

Participants are encouraged to discuss the scenarios in laboratory meetings or distribute to relevant staff to get the maximum benefit to the laboratory. Even if the laboratory does not undertake the particular test mentioned in the scenario or offer the service (e.g. platelet support or cord blood transplantation), participants are encouraged to respond based on H&I knowledge, published evidence and relevant guidelines (where applicable).

### **27.3. EDUCATIONAL CROSSMATCH SCHEME (EDXM)**

Participants can register to receive samples to perform combined crossmatching, HLA typing and antibody detection/specification to mimic testing performed for solid organ transplantation. Participants are expected to report the results of all the individual test components as performed in their laboratory, and also provide an interpretation of the results if they were obtained in a clinical kidney transplant setting. Full instructions and details are provided at the time of sample distribution.

One blood sample and up to three serum samples will be distributed each year for the combined crossmatching, HLA typing and antibody detection/specification scheme. These samples are available free of charge to laboratories that participate in Scheme 2A or 2B or 3.

## 28. STEERING GROUP

The Schemes' Director is advised by a Steering Committee, current members, the category of their membership and their contact details are listed below.

The Steering Committee's constitution, including accountability, remit, composition, membership and finance are essentially as laid down in the UK NEQAS Executive's document "Steering Committees" latest revision, October 2004 (available from UK NEQAS).

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## 29. JOINT WORKING GROUP FOR QUALITY ASSURANCE (JWG) GUIDELINES FOR UK PARTICIPANTS

In registering for participation in the UK NEQAS for H&I Scheme(s), UK participant laboratories agree to abide by/uphold the conditions of scheme participation of the JWG on EQA. These are reproduced below.

### **Royal College of Pathologists' Joint Working Group for Quality Assurance: Conditions of EQA Scheme Participation. Published August 2010.**

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and UKAS.

1. The Head of a Laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.
2. The Laboratory should be registered with available EQA schemes to cover all the tests that the Laboratory performs as a clinical service.
3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.
4. Changes in the test methodology of the Laboratory should be notified in writing to the appropriate scheme organiser and should be reflected in the EQA schemes with which the laboratory is registered.
5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see below) will be sent directly to the Head of the Laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.
6. The EQA code number and name of the Laboratory and the assessment of individual Laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of Laboratory and Head of Department) and the tests and EQA schemes for which that Laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.
7. A NQAAP may, with the written permission of the Head of a Laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the Laboratory from maintaining a satisfactory standard.
8. Laboratories' EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.

9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 2 weeks of a laboratory being identified as a persistent poor performer (red), the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The identity of a persistently poor performing laboratory (red) will be made available to members of the NQAAP and JWG. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out; if appropriate, this letter will be copied to accreditation/regulatory bodies such as UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the Laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert may be arranged.

10. If persistent poor performance remains unresolved (black), the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues, the laboratory will be referred to the Care Quality Commission for further action.

11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

Joint Working Group for Quality Assurance in Pathology, August 2010.

### 30.UK NEQAS for H&I Dates for 2018

	Distribution	Result deadline	Scheme report (week beginning)	Meetings (unconfirmed)
February	27th 2B 01+02/18			
March	06th 1B 01+02/18 06th 8 01-05/18 13th 5B 01+02/18 13th iED Scenario 1/18 13th 10 01-05/18 13th 11 01-04/18 20th 1A 01+02/18 20th 2A 01+02/18	09th 2B 01+02/18 20th 1B 01+02/18 27th 8 01-05/18 27th 10 01-05/18 30th 1A 01+02/18 30th 2A 01+02/18	26th 2B01+02/18	
April	17th 3 01-05/18 17th 4A1 01-05/18 24th 7 01-05/18 24th 9 01-05/18	10th 5B 01+02/18 10th iED Scenario 1/18 10th 11 01-04/18	09th 1B 01+02/18 16th 1A 01+02/18 16th 2A 01+02/18 23rd 8 01-05/18	
May	01st 2B 03+04/18 15th 1B 03+04/18 22nd 5A 01-05/18 22nd ED 01+02/18 22nd EDXM 01/18	01st 4A1 01-05/18 04th 7 01-05/18 08th 9 01-05/18 11th 2B 03+04/18 29th 1B 03+04/18 29th 3 01-05/18	07th 10 01-05/18 07th iED Scenario 1/18 21st 11 01-04/18 21st 7 01-05/18 28th 2B 03+04/18	Steering Committee
June	05th 1A 03+04/18 05th 2A 03+04/18 19th 4A2 01-05/18 19th 6 01-06/18 26th iED Scenario 2/18	05th 5A 01-05/18 05th ED 01+02/18 15th 1A 03+04/18 15th 2A 03+04/18	04th 5B 01+02/18 04th 9 01-05/18 18th 1B 03+04/18 18th 4A1 01-05/18 25th 5A 01-05/18 25th ED 01+02/18	
July	10th 2B 05+06/18 24th 1B 05+06/18	03rd EDXM 01/18 10th 4A2 01-05/18 10th 6 01-06/18 20th 2B 05+06/18 24th iED Scenario 2/18	02nd 1A 03+04/18 02nd 2A 03+04/18 30th 3 01-05/18	
August		07th 1B 05+06/18	06th 2B 05+06/18 13th 6 01-06/18 20th iED Scenario 2/18 27th 1B 05+06/18 27th 4A2 01-05/18	
September	11th 1A 05+06/18 11th 2A 05+06/18 18th 5B 03+04/18 25th 10 06-10/18 25th 11 05-08/18	21st 1A 05+06/18 21st 2A 05+06/18	10th EDXM 01/18	



**UK NEQAS for H&I dates for 2018 (Continued)**

October	02nd 2B 07+08/18	09th 10 06-10/18	08th 1A 05+06/18	Steering Committee
	09th iED Scenario 3/18	12th 2B 07+08/18	08th 2A 05+06/18	
	16th 1B 07+08/18	16th 5B 03+04/18	29th 2B 07+08/18	
	16th 8 06-10/18	23rd 11 05-08/18		
	30th 7 06-10/18	30th 1B 07+08/18		
	30th 9 06-10/18			
November	06th 5A 06-10/18	06th 8 06-10/18	19th 10 06-10/18	
	06th ED 03+04/18	06th iED Scenario 3/18	19th 1B 07+08/18	
	13th 3 06-10/18	09th 7 06-10/18	26th 7 06-10/18	
	13th 4A1 06-10/18	13th 906-10/18	26th 11 05-08/18	
	20th 1A 07+08/18	20th ED 03+04/18		
	20th 2A 07+08/18	20th 5A 06-10/18		
		27th 4A1 06-10/18		
		30th 1A 07+08/18		
		30th 2A 07+08/18		
	December	04th 4A2 06-10/18	21st 2B 09+10/18	03rd 8 06-10/18
04th 6 07-12/18		27th 3 06-10/18	03rd 5A 06-10/18	
11th 2B 09+10/18		27th 4A2 06-10/18	10th 9 06-10/18	
		27th 6 07-12/18	10th 5B 03+04/18	
			17th 1A 07+08/18	
		17th 2A 07+08/18		
January 2019	15th 1B 09+10/18	29th 1B 09+10/18	14th 2B 09+10/18	Steering Committee
	22nd 1A 09+10/18		14th ED 03+04/18	
	22nd 2A 09+10/18		21st iED Scenario 3/18	
			21st 4A1 06-10/18	
			28th 6 07-12/18	
February		01st 1A 09+10/18	11th 4A2 06-10/18	
		01st 2A 09+10/18	18th 1B 09+10/18	
			18th 1A 09+10/18	
			18th 2A 09+10/18	
			25th 3 06-10/18	

### 31. DISTRIBUTION TIMETABLE 2018

Scheme 1A Scheme 2A	Scheme 1B Scheme 8 *	Scheme 2B	Scheme 4A1/4A1i Scheme 3	Scheme 4A2 Scheme 6	Scheme 5A Educational Samples EDXM*	Scheme 7 Scheme 9	Scheme 10 Scheme 11	iED	5B
20 March	06 March*	27 February					13 March	13 March	13 March
	15 May	01 May	17 April		22 May*	24 April			
05 June	24 July	10 July		19 June				26 June	
11 September	16 October*	02 October					25 September		18 September
20 November		11 December	13 November	04 December	06 November	30 October		09 October	
22 January	15 January								

\*Scheme 8 sent in 2 distributions

\* EDXM one distribution

Scheme 1A – HLA Phenotyping

Scheme 1B – HLA-B\*27 Testing

Scheme 2A – Cytotoxic Crossmatching

Scheme 2B – Crossmatching by Flow Cytometry

Scheme 3 – HLA Antibody Specificity Analysis

Scheme 4A1 – HLA Typing at 1<sup>st</sup> Field Resolution

Scheme 4A1i – Interpretive HLA Genotype

Scheme 4A2 – HLA Typing to 2<sup>nd</sup> or 3<sup>rd</sup> Field Resolution

Scheme 5A – HFE Typing

Scheme 5B – Interpretive: HFE Genotype and HH

Scheme 6 – HLA Antibody Detection

Scheme 7 – HLA-B\*57:01 Typing for Drug Hypersensitivity

Scheme 8 – HLA Genotyping for Coeliac and other HLA associated diseases

Scheme 9 – KIR Genotyping

Scheme 10 – HPA Genotyping

Scheme 11 – HPA Antibody Detection/Specification

ED - Educational Scheme samples

iED – Interpretive Clinical Scenarios

EDXM – Educational Combined Crossmatch/HLA Type/Antibody analysis