# UK NEQAS

Education | Quality | Global


## Histocompatibility & Immunogenetics

# PARTICIPANT MANUAL

## 2026-27

## CONTENTS

## 1. Introduction

The United Kingdom based National External Quality Assessment Service for Histocompatibility and Immunogenetics (UK NEQAS for H&I) 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 University NHS Trust and it operates from dedicated facilities in South Wales at the Welsh Blood Service located 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.ukneqas.org.uk).

### Accreditation

Velindre University NHS Trust, a United Kingdom Accreditation Service (UKAS) accredited proficiency testing provider, No 8351, operates UK NEQAS for Histocompatibility and Immunogenetics (H&I).

Full details of accredited schemes can be found in our Schedule of Accreditation available from the UKAS website www.ukas.com. A copy of the Accreditation Certificate is available from the UK NEQAS for H&I website 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 interpretive 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 ISO:15189 standards.

## 3. Participant Manual

This Manual, covering the 2026-27 distribution year, 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

| | |
|---|---|
| Contact Address: | UK NEQAS for H&I<br>Welsh Blood Service<br>Ely Valley Road<br>Talbot Green<br>Pontyclun<br>CF72 9WB<br>Wales<br>United Kingdom |
| Telephone: | +44 (0) 1443 622185 |
| Email: | ukneqashandi@wales.nhs.uk |
| Website: | www.ukneqashandi.org.uk |
| Participant's Portal: | https://ukneqas-vunhst.wales.nhs.uk/ |

## Scheme Staff

| | |
|---|---|
| Director: | Deborah Pritchard |
| Manager: | Amy De'Ath |
| Deputy Manager: | Melanie Bartley |
| HCS Practitioner: | Geraint Clarke |
| QA Officer: | Jack Jefferies |
| MLA: | Sue Davies |

## 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 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 at ukneqashandi@wales.nhs.uk.

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 Amy De'Ath at ukneqashandi@wales.nhs.uk. Correspondence will normally be circulated only to the Steering Committee and will be anonymised before distribution.

For details of other UK National External Quality Assessment Services, please contact the NEQAS Central Office at centraloffice@ukneqas.org or see http://www.ukneqas.org.uk/.

Relevant participant correspondence and the actions taken are logged for monitoring purposes.

## 6. Complaints or Concerns

Although we are committed to providing our customers with an excellent service there may be times when we fail to fully meet your requirements. We firmly believe that every concern or complaint is to be valued as an opportunity to discuss with our customers how the service can be improved.

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 concerns, assessment appeals (section 10.9) or general correspondence. Complaints should be in the form of an 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. On completion of the investigation, the complainant will be notified in writing of the result of the investigation and any corrective actions that have been instigated. Formal complaints may 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.

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: Amy De'Ath, Manager, UK NEQAS for H&I, Welsh Blood Service, Ely Valley Road, Talbot Green, Pontyclun, CF72 9WB. Tel: 01443 622185; e-mail: ukneqashandi@wales.nhs.uk.**

## 7. Confidentiality and Impartiality

UK NEQAS for H&I has a commitment to impartiality. We ensure impartiality in our processes and operations to maintain the integrity and reliability of our schemes. We identify and manage any potential conflicts of interest and ensure that all activities are conducted without bias.

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.

Anonymised results, method information and outcomes of sample assessment (Acceptable/Unacceptable classification) are available for all participants of a scheme to view in the Participant Portal. This allows maximum

educational benefit of the schemes, by enabling participants to fully compare results and methods with other participating laboratories, and assist with the investigation of 'unacceptable' results.

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.

To view the UK NEQAS for H&I Privacy Disclaimer please visit https://ukneqashandi.org.uk/disclaimer/.

The performance details of any UK laboratories may be shared with the relevant bodies such as MHRA, UKAS or the CQC (see section 31).

Other interested parties requesting information may be provided with summary reports, at the discretion of the UK NEQAS for H&I Manager, which give an overview of results but do not reveal identifiable data from any laboratory.

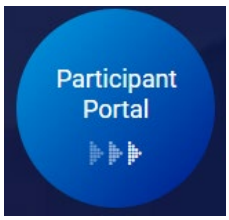
All UK NEQAS for H&I reports and the data they contain are copyrighted and may not be published or used for publicity and promotion in any form without permission of the Scheme Director, though performance data and reports may be shared with relevant service users and accreditation bodies as required.

# 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 can be completed via the Participant's Portal link on the UK NEQAS for H&I website, www.ukneqashandi.org.uk, or by typing https://ukneqas-vunhst.wales.nhs.uk/ into your internet browser.

Participation is for a period of one year (April 2026 – March 2027). Annual re-registration takes place each year, with a notice to re-register via the Participant's Portal issued 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 is not completed, your laboratory will not be able to submit results for inclusion in assessment and therefore no reports will be issued. If your laboratory does not wish to continue participation a request to withdraw should be received in writing or submitted via the Participant's Portal. Any material sent in the meantime will be charged for.

By completing the registration process participants agree to abide by the conditions for participation (section 8.8) and all other expectations as stated in this participant manual.

## 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 in the registration process in the Participant's Portal 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.**

## 8.3. Cancellation Of Participation

Please notify us in writing or withdraw via the Participant's Portal if you wish to cancel your participation in any scheme. Any withdrawals not communicated to the UK NEQAS 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 (which operates on a financial year from April 2026 to March 2027). 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

All domestic (UK) and international shipments are sent via courier to ensure a swift service with traceability of parcels. UK based laboratories can opt to select 9am/12pm next day delivery during registration at an additional cost. Expedited services such as express medical delivery may be available to international shipments at an additional cost. Please contact ukneqashandi@wales.nhs.uk to discuss your requirements.

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

Your laboratory can view a Certificate of Registration on request via the Participant's Portal.

## 8.8. Conditions For Participation

1. Data provided to UK NEQAS for H&I by participants will be used solely for dealing with your UK NEQAS participation. A Privacy Policy is available from our website. Your data will be stored in accordance with this policy.

2. Membership of the Scheme starts on 1st April each year and continues until 31st March in the next year. If a participant joins part way through the annual period, a reduced fee may be payable reflecting the proportion of the annual service to be supplied for that part year. Participants will be charged for all Schemes they receive samples for, regardless of whether they submitted results.

3. In the event of a participant failing to pay subscription fees by the due date the Scheme reserves the right to suspend, without notice, the membership of that participant without prejudice to any claim for payment for services already provided.

4. Samples distributed as part of the Scheme should be treated, handled and disposed of as if they were clinical specimens. Participants must ensure that their laboratory facilities and expertise are adequate to ensure the safe handling of these specimens during their participation in the Scheme.

5. UK NEQAS H&I may amend the design of Schemes during the year. Participants will be informed of changes to scheme design or operation by email. This would also be reflected in the Participant Manual.

6. The Scheme will despatch the exercise material on the date published in the annual schedule, unless unforeseen circumstances require a change to the date; in this case, participants will be notified by email and/or by a message posted on the website.

7. Participants must inform UK NEQAS for H&I:

   If the expected samples do not arrive

   Reason(s) for failure to test EQA samples

8. Participants must complete annual registration information on the Participant's Portal, provide a purchase order number and ensure any changes to staff or contact information are updated. It is the participant's responsibility to maintain accurate contact detail on the UK NEQAS H&I Portal. Enrolment in the scheme is not evidence that a laboratory is correctly performing relevant recognised national or international standards.

9. A participant may withdraw from the Scheme at any time, but no refund will be given of fees paid. Cancellation of participation must be made in writing to the scheme office or via the Participant's Portal.

10. Collusion between laboratories or falsification of results is not permitted. If a laboratory was suspected of collusion, UK NEQAS for H&I would review the laboratory's participation in its schemes and potential suspend participation. Laboratories based in the UK will have their identity disclosed to the appropriate bodies who may take further action.

11. All reports, and the data they contain, issued by the Scheme are Copyright and may not be distributed, published or used for promotion in any form without permission of the Scheme Director.

12. Information provided to UK NEQAS for H&I are confidential. However, anonymised results, method information and outcomes of sample assessment (Acceptable/Unacceptable classification) are available for all participants of a scheme to view in the Participant Portal. See the 'Confidentiality' section of the Participant Manual for full details. Performance is confidential to the participant and will not be released by the Scheme Organiser to third parties other than under any agreed and defined mechanism for providing counselling to 'poor performers'. However, in instances relating to persistent poor performance or lack of participation where patient care may be compromised the Scheme Organiser is free to pass relevant information to third parties.

13. UK laboratories who provide a clinical service agree to abide by section 31.0 of the Participant Manual additional quality assurance monitoring.

14. Participants in the Scheme have entire responsibility for all samples distributed to them under the Scheme and all activities carried out by them or any third party in relation to the samples from the time of their receipt. UK NEQAS does not take any responsibility for delays or losses due to the postal service.

15. The legal entity and the Scheme warrant that all work carried out by it in relation to the Scheme will be carried out using all reasonable care and skill. All conditions, terms and warranties implied by common law, statute or otherwise are, to the extent permitted by law, hereby excluded.

16. The legal entity and the Scheme shall not be liable in any circumstances for indirect or consequential loss howsoever caused, including, without limitation, loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims.

17. The liability of the Scheme and legal entity to the participant in any annual period resulting from or in connection with the provision of the Scheme to the participant shall under no circumstances exceed the amount of the annual fee paid by the participant in respect of that annual period.

18. These conditions shall be governed by and construed in accordance with UK law, and UK NEQAS for H&I and the participant submit to the exclusive jurisdiction of the UK Courts.

19. The remit of UK NEQAS for H&I is to provide laboratories with information on their performance against criteria outlined in the Schemes section of the Participant Manual. It is the remit of laboratories to take appropriate action on any issues that EQA testing may highlight.

20. Performance in EQA should not be used to endorse the use of certain methods of testing or commercial product use.

## 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
- 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
- Act impartially

# 9. Samples

## 9.1. Types of Samples

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

- CPD-A1 blood donations (either fresh or frozen e.g. scheme 7 and 8) +/- RPMI 1640 tissue culture medium containing *tri*-Sodium citrate
- Isolated lymphocyte preparations (non-UK participants only) in Park/Terasaki medium
- DNA
- Serum
- Plasma
- Commercial products such as National Institute for Biological Standards and Controls International Standards

## 9.2. Source of Samples

Blood, lymphocyte and DNA samples are typically obtained from established blood donors at the Welsh Blood Service. Donors are typically of north-western European extraction.

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

On occasion samples may be obtained from external sources such as the National Institute for Biological Standards and Controls or NHS Blood and Transplant.

**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.

In certain schemes 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 comprised. 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 notified 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, HCV Ab and Syphilis are tested for on the Abbott Alinity ™ 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 manner as routine clinical material in regards to storage, processing and disposal 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 respectively).

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 Office or register the result as not tested on the Participant Portal as soon as possible (before the result deadline) with the reasons why they are unable to test samples, using ukneqashandi@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 ‘not tested’ 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 always 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. Please contact ukneqashandi@wales.nhs.uk to discuss requirements.

## 10. Results, Assessment and Unacceptable Performance

### 10.1. Submission of results

UK NEQAS for H&I use a bespoke EQA computer package. The online Participant's Portal can be accessed from the UK NEQAS for H&I website www.ukneqashandi.org.uk or by linking directly to https://ukneqas-vunhst.wales.nhs.uk/. Results should be submitted via the Participant's Portal.

Participants that have been unable to test samples MUST state on their result report forms 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 also be collected as part of the result entry process on the Participant's Portal. 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.

Results must be submitted via the Participant's Portal. 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 the comments section of the result submission form on the Participant's Portal or in writing to ukneqashandi@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

The Participant's Portal has been designed to allow results to be entered and submitted by one or multiple users, depending how your laboratory wishes to submit EQA results. We recommend that a user enters the results, then another user verifies the results before submitting them. Results can be entered and submitted by the same user (either immediately or at a later date). In this instance, we would recommend entered results are printed prior to submission and checked by a second person. Data entry errors submitted using the online system are considered part of the assessment.

If a sample could not be tested due to sample quality issues or technical failure you must still complete and submit the result form on the Participant's Portal detailing the reason for non-submission.

Results can be edited and re-submitted on the Participant's Portal at any point up until the result deadline.

### 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.

Late results may be accepted at the discretion of the Manager. Results will not be accepted for assessment or performance review once schemes' results are published on the UK NEQAS for H&I Participant's Portal. Requests for extensions to report deadlines should be made to the Operations Manager.

## 10.4. Performance Reports

Individual laboratory performance reports will be available to view on the Participant's Portal in line with the published report timetable (section 30). Participants will also be able to view performance tables detailing the assessment of all participants for a particular distribution, along with performance of all participants over the past year. Detailed summaries of methodology used in each Scheme will also be available to view.

At the end of each distribution year, an annual performance certificate will be available on the Participant's Portal for each laboratory, detailing your overall performance for each Scheme you 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/HFE/HPA/KIR specificities/alleles, antibody presence/absence, antibody specificities or 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, Scheme 11 - HPA Antibody Detection/Specification and Scheme 13 – HNA Antibody Detection/Specification also uses a 95% consensus level for the absence of an HLA specificity.

For genotyping schemes (1B, 4A1, 4A2, 5A, 9, 10, 12) a reference result may be used for assessment in the event that a consensus result is not achieved. For Scheme 7 and 8 a reference result for assessment will always be used.

Reference typing, will be subcontracted to an EFI and ISO:15189 accredited laboratory. In most instances this will be the Transplantation Services Laboratory at the Welsh Blood Service, 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 or if the Welsh Blood Service does not provide that service.

Scheme 5B - Interpretive: HFE Genotype and Hereditary Haemochromatosis uses a penalty points system.

The Educational and any Pilot Schemes in operation 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: https://efi-web.org/committees/standards-committee

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: https://efi-web.org/committees/ept-committee. Proposed changes in Schemes' assessment and/or the determination of satisfactory performance are brought to the Steering Committee 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 on the Participant's Portal with a summary of the investigation into the reasons for their unacceptable performance together with any corrective actions. Further guidance on completing the form is available on the UK NEQAS for H&I website ukneqashandi.org.uk/capa-guidance/.

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 Interpretive Schemes, e.g. Scheme 5B.

Participants will be classified as a Persistent Poor Performer (PPP) if they are classed as poor performers within a scheme for two annual rounds of EQA within the last 3 years (either consecutive or non-consecutive). The classification of being a PPP will be at the discretion of the NEQAS Director who will take into account if the error(s) are due to EQA specific reporting errors, for example.

## 10.7. UK Laboratory Unacceptable Performance

For UK laboratories, see section 31.0 on additional performance monitoring.

A representative from the British Society for Histocompatibility and Immunogenetics sits, as an observer, on the Schemes' Steering Committee.

## 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 ukneqashandi@wales.nhs.uk **within four weeks** of results being issued. 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 will be reviewed impartially 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 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, aliquoting, 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.

## 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 acts independently and impartially and does not endorse any equipment, reagents, calibrants, test kits or any manufacturers or suppliers.

### 11.3. Scheme Review and Pilot Schemes

The Schemes are continually reviewed 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, HNA 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: ukneqashandi@wales.nhs.uk

## 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 (https://www.ebi.ac.uk/ipd/imgt/hla/release/) from the April 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. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

## 12. SCHEME 1A – HLA PHENOTYPING

Scheme 1A is aimed at laboratories undertaking HLA-A, B, Cw, 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, Cw, 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 within the UK NEQAS for H&I Participant's Portal 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 reference HLA type may be used for the assessment of HLA-Cw.

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

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

## 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 or not tested" 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 within the UK NEQAS for H&I Participant's Portal 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

## 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.

**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.

*NEQAS recommend retaining residual material for further testing in the event of poor performance to facilitate root cause analysis.*

**REPORTING**

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

| | |
|---|---|
| Peripheral Blood Lymphocytes with DTT | Peripheral Blood Lymphocytes without DTT |
| T-Cell with DTT | T-Cell without DTT |
| B-Cells with 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.

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.

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 within the UK NEQAS for H&I Participant's Portal 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 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.

UK NEQAS for H&I reserve the right to not assess a result if non-viability related performance is deemed to be an issue.

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

- The HLA phenotype of the donor samples and CDC detected specificities of the sera (provided on request, for indication only).

## 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 dependant cytotoxicity test for detecting donor specific antibodies.

**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.

*NEQAS recommend retaining residual material for further testing in the event of poor performance to facilitate root cause analysis.*

**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.

Equivocal reports will continue to 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.

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal 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.

UK NEQAS for H&I reserve the right to not assess a result if non-viability related performance is deemed to be an issue.

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.
- The HLA phenotype of the donor samples and CDC detected specificities of the sera (provided on request, for indication only).

## 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 is for 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.

Participants can choose to report antibodies to HLA-DQA and -DPA. These antibodies will not be formally assessed.

**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 blood samples will be sent each year as three distributions. Participants will receive three blood samples in the first shipment, four samples the second shipment and three samples in the final shipment.
Volumes of approximately 1ml of serum will be distributed.

*NEQAS recommend retaining residual material for further testing in the event of poor performance to facilitate root cause analysis.*

**REPORTING**

At registration participants may opt for Class I only (A, B, Cw) and/or Class II (A, B, Cw, DRB, DQB, DPB) antibody assessment. DQA, DPA antibodies may be reported but will not be assessed.

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. 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 within the UK NEQAS for H&I Participant's Portal 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Where known, the HLA phenotypes of the serum donors (for indication only).
- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

## 17. SCHEME 4A1 – HLA TYPING AT 1ST FIELD RESOLUTION

Scheme 4A1 is for laboratories that undertake DNA HLA based typing at the 1st 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 April 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. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

**PURPOSE**

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

**SAMPLES**

A total of ten blood samples will be sent each year as three distributions. Participants will receive three blood samples in the first shipment, four samples the second shipment and three samples in the final shipment.

**REPORTING**

Participants may register for any of the following: HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1 for 1st field assessment, or 'presence of' assessment for DRB3, DRB4 and, DRB5.

Participants may register for DPB1 or DPA1 low-intermediate resolution assessment. 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 – 2nd field resolution typing (i.e. unable to resolve all ambiguities resulting from polymorphisms located within exon 2). Scheme 4A1 DPB1/DPA1 results may be assessed against a reference genotype if consensus is not determined.

There are no minimum typing requirements for DPB1 or DPA1 in Scheme 4A1, so laboratories are able to report the DPB1/DPA1 results at the resolution that is applicable to their clinical need. This includes reporting strings of DPB1/DPA1 alleles that differ at the first field. Assessment is performed by comparing the participant DPB1/DPA1 result to the reference DPB1/DPA1 type if consensus is not met; acceptable results will include the consensus/reference allele in the report. Laboratories performing 'high resolution' DPB1/DPA1 typing would still be expected to participate in Scheme 4A2.

Classification of null alleles is not required in this scheme but participants are encouraged to note the presence of null alleles when submitting results or by reporting 'N' e.g. DRB4*01N.

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal 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 may be used for DPB1/DPA1 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 April two years prior to start of the Scheme (e.g. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 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. Maiers. 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 within the UK NEQAS for H&I Participant's Portal 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.

Please note that participants have the option of reporting Bw4 for associated HLA-A specificities should they wish. Those that do not report will not be penalised.

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

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

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

Participants can choose at registration whether to be assessed at the 2nd field or 3rd 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 April 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. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

Participants who register for assessment of results at the 3rd field resolution must be able to distinguish all nucleotide substitutions within the coding sequence for 3rd field assessment. All ambiguities must be resolved.

**PURPOSE**

To assess participants' ability to correctly determine HLA alleles to the 2nd or 3rd field level.

**SAMPLES**

A total of ten blood samples will be sent each year as three distributions. Participants will receive three blood samples in the first shipment, four samples the second shipment and three samples in the final shipment.

**REPORTING**

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

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal and return results within 4 weeks

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## HLA TYPING TO 2ND FIELD RESOLUTION

For typing to the 2nd 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 2nd 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 8.1, standards state:**

| | |
|---|---|
| **F1.1.4** | High resolution typing is defined as the identification of HLA alleles that encode the same protein sequence within the antigen binding site |
| **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: |
| **F1.1.4.1.1** | Resulting from polymorphisms located within exons 2 and 3 for HLA class I loci, and exon 2 for HLA class II loci |
| **F1.1.4.1.2** | 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 2nd field will have developed a strategy to comply with this Standard for the recognition of null alleles.

**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 April two years prior to start of the Scheme (e.g. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

For typing to the 2nd 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 2nd field resolution, (e.g. 3rd or 4th field) the results up to the 2nd field will be used for assessment, unless registered for 3rd field assessment (see below). Participant's that report at 3rd or 4th field resolution and want to compare their results with other centres will need to do so manually using the results summary table.

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## HLA TYPING TO 3RD FIELD RESOLUTION

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

**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 April two years prior to start of the Scheme(e.g. the IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

For typing to the 3rd field, participants must report to 3rd field resolution with no ambiguities permitted. Laboratories reporting cis/trans ambiguities will be penalised. Participants must sequence all the relevant exons to produce an unambiguous 3rd field HLA type. For example, DRB1*07:01:01/07:79 would be deemed 'unacceptable'. Likewise, DQB1*03:02:01/03:02:26 would also be deemed 'unacceptable' as ambiguities in the exon 4 have not be resolved in both cases.

For alleles reported above the 3nd field resolution, (e.g. 4th field) the results up to the 3nd field will be used for assessment. Participant's that report at 4th field resolution and want to compare their results with other centres will need to do so manually using the results summary table.

---

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

- Information 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 are available on request.

## 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 three distributions. Participants will receive three blood samples in the first shipment, four samples the second shipment and three samples in the final shipment.

**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 within the UK NEQAS for H&I Participant's Portal and are required to return results within 42 days.

**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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 20. SCHEME 5B - INTERPRETIVE: 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. (https://www.nature.com/articles/ejhg2015128).

**CLINICAL SCENARIOS**

HFE genotype may 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 electronically.

**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 interpretive 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 interpretive criterion not covered by the report.

| **Scoring Procedure** | **Penalty points** |
|---|---|
| Each feature in agreement with an identified criterion | 0 |
| A principal agreed interpretive criterion not covered by the report | up to 3 |
| Other agreed interpretive 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' interpretive criteria.**

**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 Interpretive Schemes as per the RCPath Principles and guidance for interpretive external quality assessment schemes in laboratory medicine** https://www.rcpath.org/uploads/assets/146c22f7-dbc1-47ef-99d6bd6356a327e6/Principles-and-guidance-for-interpretive-external-quality-assessment-schemes-in-laboratory-medicine.pdf.

**INFORMATION / ANALYSIS PROVIDED TO PARTICIPANTS**

- Each laboratory will receive an itemisation of interpretive 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. thrombocytopaenia.

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. Any method of antibody detection can be used but the technique must reflect clinical practice for antibody detection in your laboratory.

**PURPOSE**

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

**SAMPLES**

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

*NEQAS recommend retaining residual material for further testing in the event of poor performance to facilitate root cause analysis.*

**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 within the UK NEQAS for H&I Participant's Portal 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 22. SCHEME 7 – HLA-RELATED PHARMACOGENETICS
### (formerly known as 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 a variety of drugs where a hypersensitivity reactivity is noted in association with a specific HLA type. For example, the prospective testing of patients for HLA-B*57:01 who are to be treated with the antiretroviral drug abacavir. This scheme tests participants' ability to define relevant HLA types using the method(s) they employ for routine clinical service testing for hypersensitivity or drug suitability.

In addition to Abacavir, participants can choose to be assessed for HLA genotypes associated with other hypersensitivity reactions including Allopurinol, Carbamazepine, Oxcarbazepine, Lamotrigine, Flucloxacillin, Phenytoin as well as Tebentafusp suitability.

**PURPOSE**

To assess participants' ability to correctly determine relevant HLA type for the drug specified:

- Abacavir Hypersensitivity - B*57:01
- Allopurinol Hypersensitivity - B*58:01
- Carbamazepine Hypersensitivity - A*31:01, B*15:02
- Oxcarbazepine Hypersensitivity - B*15:02
- Lamotrigine Hypersensitivity - B*15:02
- Flucloxacillin Hypersensitivity - HLA-B*57:01
- Phenytoin Hypersensitivity - B*15:02
- Tebentafusp Suitability - A*02:01

**SAMPLES**

A total of ten blood samples will be sent each year as three distributions. Participants will receive three blood samples (previously frozen) in the first shipment, four samples the second shipment and three samples in the final shipment.
There is also an option to receive pre-prepared DNA samples instead of whole blood samples. There will be a charge for this service.

**REPORTING**

At registration participants must designate the drug they wish to be assessed for. Participants are required to report their HLA genotyping findings relevant to each drug registered for.

Participants are required to report on the relevant HLA allele status as positive or negative.

Participants can report other alleles for information purposes but these will not be assessed.
Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal and are required to return results within 10 days.

**ASSESSMENT**

The consensus HLA status of each sample is determined by at least 75% of laboratories agreeing on the presence or absence of a relevant HLA allele for each drug. 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 type | Acceptable |
| Each report not in agreement with the consensus/reference HLA type | 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 type in a year per drug that they have 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

## 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, psoriasis 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 (1st or 2nd 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 1st or 2nd field level).

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.

### Continuing in 2026-27: Pilot Assessment of Interpretative Comments for Coeliac Disease

Currently laboratories may report interpretive comments as they would appear on clinical reports for interest only. In 2026-27, interpretative comments will continue to not be formally assessed but laboratories are encouraged to submit their comments. These comments will be reviewed against guidelines and a summary report issued to participants to highlight potential areas for improvement.

Pritchard D, Anand A, De'Ath A, Lee H, Rees MT. UK NEQAS and BSHI guideline: Laboratory testing and clinical interpretation of HLA genotyping results supporting the diagnosis of coeliac disease. Int J Immunogenet. 2024 Jan;51 Suppl 1:3-20. doi: 10.1111/iji.12649. Epub 2023 Dec 28. PMID: 38153308.

**PURPOSE**

To assess participants' ability to correctly determine disease associated HLA allele families/alleles for Coeliac Disease, Narcolepsy, Actinic Prurigo, Birdshot Retinopathy, Behcet's Disease, Rheumatoid Arthritis, Diabetes and Psoriasis.

**SAMPLES**

A total of ten blood samples will be sent each year as three distributions. Participants will receive three blood samples (previously frozen) in the first shipment, four samples the second shipment and three samples in the final shipment.
There is also an option to receive pre-prepared DNA samples instead of whole blood samples. There will be a charge for this service.

**REPORTING**

At registration participants must designate the HLA associated diseases they wish to be assessed for. Scheme 8 now includes all Class I and Class II HLA associated diseases (excluding HLA-B27, see Scheme 1B).

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. Interpretive 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 within the UK NEQAS for H&I Participant's Portal 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 1st or 2nd 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.

Interpretive comments can be included although these will not be assessed.

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 April two years prior to the start of the Scheme (e.g. IMGT/HLA release version 3.56 (2024-04) will be used throughout 2026-27).

**Assessment Procedure**

| | |
|---|---|
| Each HLA genotype in agreement with the 1st or 2nd field reference type | Acceptable |
| Each HLA genotype not in agreement with 1st or 2nd 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 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 opt to report an 'A' or 'B' haplotype for each sample based on the gene content. This information will not be included in formal assessment.

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 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-9 and HPA-15.

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

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal 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**

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

| | |
|---|---|
| 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

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

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.

*NEQAS recommend retaining residual material for further testing in the event of poor performance to facilitate root cause analysis.*

**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 within the UK NEQAS for H&I Participant's Portal and are required to return results within 4 weeks.

Participants can opt to register for assessment at any combination of HPA antibodies e.g. HPA-1, 3 and 5 only, to align with their detection capabilities.

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

| | |
|---|---|
| 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 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Where known, the HPA types of the serum/plasma donors (for indication only) as available on request.
- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

## 27. SCHEME 12 – HNA GENOTYPING

Human Neutrophil Antigens (HNA) are polymorphic glycoproteins found on the surface of neutrophils. These antigens play a crucial role in the immune system. They are important in transplantation and transfusion for several reasons: transfusion reactions such as febrile reactions, transfusion-related acute lung injury (TRALI), transplant rejection and neutropenia. HNA genotyping is used as an aid to investigate and diagnose these clinical conditions.

**PURPOSE**

To assess participants' ability to correctly determine HNA 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: genotyping at HNA-1,2,3,4 and/or 5.

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

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal and return results within 2 weeks.

**ASSESSMENT**

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

The consensus HNA 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).

**Indicative Assessment Procedure**

| | |
|---|---|
| Each full HNA genotype in agreement with the consensus/reference genotype | Acceptable |
| Each full HNA 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 HNA 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.

- End of year summary of participant performance.

## 28. SCHEME 13 – HNA ANTIBODY DETECTION/SPECIFICIATION

Human Neutrophil Antigens (HNA) are polymorphic glycoproteins found on the surface of neutrophils that can stimulate the production of HNA antibodies. HNA antibody detection/specification is important in several clinical situations, including: transfusion reactions such as febrile reactions, transfusion-related acute lung injury (TRALI), transplant rejection and neutropenia. HNA genotyping is used as an aid to investigate and diagnose these clinical conditions.

**PURPOSE**

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

**SAMPLES**

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

**REPORTING**

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

HLA antibody presence/absence results may also be reported.

Participants must only use the reporting forms provided within the UK NEQAS for H&I Participant's Portal and are required to return results within 4 weeks.

Participants can opt to register for assessment at any combination of HNA antibodies e.g. HNA-1,2,3,4 and/or 5, to align with their detection capabilities.

**ASSESSMENT**

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

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.

**Indicative 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 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, see section 31.0 on additional performance monitoring.

**INFORMATION/ANALYSIS PROVIDED FOR PARTICIPANTS**

- Where known, the HNA types of the serum/plasma donors (for indication only) as available on request.
- Anonymised summary table of all participant results, comments and methodology. Including sample assessment result (acceptable/unacceptable classification) for each participant.
- End of year summary of participant performance.

# 29.EDUCATIONAL SCHEMES

**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, anonymised summary table of all participant results, comments and methodology.
- For samples, an analysis of the identification of the HLA allele of interest will be provided. Relevant references will be supplied whenever possible.
- For scenarios, an anonymised summary of all returns and an analysis of responses will be issued after each distribution

## 29.1. 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 will be sent as DNA extracts. The HLA typing samples are available free of charge to laboratories that participate in Scheme 1A or 4A1 or 4A2.

## 29.2. INTERPRETIVE 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).

## 29.3. 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 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.

## 30. STEERING COMMITTEE

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 "Role & Remit of Steering Committees and Specialist Advisory Groups" (ref: GUINEQ002).

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## 31. Quality Assurance Oversight for UK Participants

In registering for participation in UK NEQAS for H&I scheme(s), UK participant laboratories agree to abide by/uphold the following conditions of scheme participation:

The Head of a Laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme(s). The Laboratory should be registered with available EQA schemes to cover all the tests that the Laboratory performs as a clinical service.

Laboratories' EQA performance will be graded using a traffic light system:

- green indicates no concerns
- amber indicates poor performance
- red indicates persistent poor performance
- black indicates cases that cannot be resolved by UK NEQAS for H&I or its Steering Committee

The criteria for poor performance is detailed in the relevant scheme section of the Participant Manual (sections 10.5, 12-28). Persistent poor performance is defined in section 10.6 of the Participant Manual.

When a laboratory shows poor (amber) performance the Organiser will make contact with the participant in accordance with section 10.5 through issuing performance reports and reviewing corrective and preventative actions.

Once a laboratory has been identified as a persistent poor performer (red), UK NEQAS for H&I will review the case internally and decide whether the performance issues are EQA-specific (e.g. Portal-specific data entry errors) or could cause wider impact on patient safety. If this is the case then UK NEQAS for H&I will notify the Head of the Laboratory in writing to seek remedial action, the timescale and responsibility for carrying this out. Advice and support may be offered to the Head of the Laboratory in writing by UK NEQAS for H&I or its Steering Committee. If appropriate, this notice will be copied to accreditation/regulatory bodies such as UKAS who may arrange an urgent visit to the laboratory. The identity of the PPP laboratory will be disclosed to these organisations as deemed necessary by UK NEQAS for H&I.

If persistent poor performance remains unresolved (black) then the laboratory will be referred to additional relevant bodies such as MHRA, UKAS or CQC. The identity of the PPP laboratory will be disclosed to these organisations as deemed necessary by UK NEQAS for H&I.

## 32.UK NEQAS for H&I Dates for 2026-27

| | Distribution Date | | Results Deadline<br>Subject to change if extensions granted | | Scheme reports issued by<br>(on or before) | |
|---|---|---|---|---|---|---|
| **April** | **1B 01-02/2026** | 28 April 2026 | | | | |
| **May** | **5B 01-02/2026** | 05 May 2026 | **1B 01-02/2026** | 12 May 2026 | **1B 01-02/2026** | 26 May 2026 |
| | **3 01-03/2026** | 19 May 2026 | | | | |
| | **4A1 01-03/2026** | 19 May 2026 | | | | |
| | **iED 01/2026** | 26 May 2026 | | | | |
| **June** | **2B 01-02/2026** | 02 June 2026 | **5B 01-02/2026** | 02 June 2026 | | |
| | **1A 01-02/2026** | 09 June 2026 | **4A1 01-03/2026** | 02 June 2026 | | |
| | **2A 01-02/2026** | 09 June 2026 | **2B 01-02/2026** | 12-Jun-2026 | | |
| | **4A2 01-03/2026** | 16 June 2026 | **1A 01-02/2026** | 19-Jun-2026 | | |
| | **6 01-04/2026** | 16 June 2026 | **2A 01-02/2026** | 19-Jun-2026 | | |
| | **5A 01-03/2026** | 30 June 2026 | **iED 01/2026** | 23 June 2026 | | |
| | **7 01-03/2026** | 30 June 2026 | **3 01-03/2026** | 30 June 2026 | | |
| | **8 01-03/2026** | 30 June 2026 | | | | |
| **July** | **1B 03-04/2026** | 07 July 2026 | | 07 July 2026 | **2B 01-02/2026** | 03 July 2026 |
| | **3 04-07/2026** | 14 July 2026 | **7 01-03/2026** | 10 July 2026 | **1A 01-02/2026** | 03 July 2026 |
| | **4A1 04-07/2026** | 14 July 2026 | **4A2 01-03/2026** | 14 July 2026 | **2A 01-02/2026** | 10 July 2026 |
| | **2B 03-04/2026** | 21 July 2026 | **8 01-03/2026** | 21 July 2026 | **iED 01/2026** | 21 July 2026 |
| | **9 01-05/2026** | 28 July 2026 | **1B 03-04/2026** | 21 July 2026 | **7 01-03/2026** | 24 July 2026 |
| | **10 01-05/2026** | 28 July 2026 | **4A1 04-07/2026** | 28 July 2026 | **5B 01-02/2026** | 28 July 2026 |
| | **11 01-04/2026** | 28 July 2026 | **2B 03-04/2026** | 31 July 2026 | **3 01-03/2026** | 28 July 2026 |
| | **12 01-02/2026** | 28 July 2026 | | | **4A1 01-03/2026** | 30 July 2026 |
| | **13 01-02/2026** | 28 July 2026 | | | | |
| **August** | **1A 03-04/2026** | 04 August 2026 | **5A 01-03/2026** | 11 August 2026 | **6 01-04/2026** | 04 August 2026 |
| | **2A 03-04/2026** | 04 August 2026 | **9 01-05/2026** | 11 August 2026 | **1B 03-04/2026** | 04 August 2026 |
| | **iED 02/2026** | 25 August 2026 | **10 01-05/2026** | 11 August 2026 | **4A2 01-03/2026** | 18 August 2026 |
| | **5B 03-04/2026** | 01 September 2026 | **12 01-02/2026** | 11 August 2026 | **8 01-03/2026** | 18 August 2026 |
| | | | **1A 03-04/2026** | 14 August 2026 | **2B 03-04/2026** | 21 August 2026 |
| | | | **2A 03-04/2026** | 14 August 2026 | **9 01-05/2026** | 25 August 2026 |
| | | | **3 04-07/2026** | 25 August 2026 | **10 01-05/2026** | 25 August 2026 |
| | | | **11 01-04/2026** | 25 August 2026 | **12 01-02/2026** | 25 August 2026 |
| | | | **13 01-02/2026** | 25 August 2026 | **5A 01-03/2026** | 25 August 2026 |
| | | | | | **4A1 04-07/2025** | 25 August 2026 |
| | | | | | **1A 03-04/2026** | 28 August 2026 |
| **September** | **ED 01-02/2026** | 08 September 2026 | **iED 02/2026** | 22 September 2026 | **2A 03-04/2026** | 04 September 2026 |
| | **EDXM 01/2026** | 08 September 2026 | **ED 01-02/2026** | 22 September 2026 | **3 04-07/2026** | 22 September 2026 |
| | **4A2 04-07/2026** | 15 September 2026 | **5B 03-04/2026** | 29 September 2026 | **11 01-04/2026** | 22 September 2026 |
| | **6 05-08/2026** | 15 September 2026 | | | **13 01-02/2026** | 22 September 2026 |
| | **2B 05-06/2026** | 22 September 2026 | | | | |
| **October** | **1A 05-06/2026** | 06 October 2026 | **2B 05-06/2026** | 02 October 2026 | **ED 01-02/2026** | 20 October 2026 |
| | **2A 05-06/2026** | 06 October 2026 | **6 05-08/2026** | 06 October 2026 | **iED 02/2026** | 20 October 2026 |
| | **1B 05-06/2026** | 13 October 2026 | **4A2 04-07/2026** | 13 October 2026 | **2B 05-06/2026** | 23 October 2026 |
| | **5A 04-07/2026** | 20 October 2026 | **1A 05-06/2026** | 16 October 2026 | **1A 05-06/2026** | 30 October 2026 |
| | **7 04-07/2026** | 20 October 2026 | **2A 05-06/2026** | 16 October 2026 | | |
| | **8 04-07/2026** | 20 October 2026 | **EDXM 01/2026** | 20 October 2026 | | |
| | **3 08-10/2026** | 27 October 2026 | **1B 05-06/2026** | 27 October 2026 | | |
| | **4A1 08-10/2026** | 27 October 2026 | **7 04-07/2026** | 30 October 2026 | | |
| **November** | **2B 07-08/2026** | 10 November 2026 | **8 04-07/2026** | 10 November 2026 | **6 05-08/2026** | 03 November 2026 |
| | **1A 07-08/2026** | 17 November 2026 | **4A1 08-10/2026** | 10 November 2026 | **2A 05-06/2026** | 06 November 2026 |
| | **2A 07-08/2026** | 17 November 2026 | **2B 07-08/2026** | 20 November 2026 | **1B 05-06/2026** | 10 November 2026 |
| | **1B 07-08/2026** | 24 November 2026 | **1A 07-08/2026** | 27 November 2026 | **7 04-07/2026** | 13 November 2026 |
| | **ED 03-04/2026** | 24 November 2026 | **2A 07-08/2026** | 27 November 2026 | **EDXM 01/2026** | 17 November 2026 |
| | | | | | **4A2 04-07/2026** | 17 November 2026 |
| | | | | | **5B 03-04/2026** | 24 November 2026 |
| **December** | **iED 03/2026** | 08 December 2026 | **5A 04-07/2026** | 01 December 2026 | **8 04-07/2026** | 08 December 2026 |
| | **4A2 08-10/2026** | 15 December 2026 | **1B 07-08/2026** | 08 December 2026 | **4A1 08-10/2026** | 08 December 2026 |
| | **6 09-12/2026** | 15 December 2026 | **ED 03-04/2026** | 08 December 2026 | **2B 07-08/2026** | 11 December 2026 |
| | | | **3 08-10/2026** | 08 December 2026 | **1A 07-08/2026** | 11 December 2026 |
| | | | | | **5A 04-07/2026** | 15 December 2026 |
| | | | | | **2A 07-08/2026** | 18 December 2026 |
| | | | | | **1B 07-08/2026** | 22 December 2026 |

## UK NEQAS for H&I dates for 2026-27 (Continued)

| | Distribution Date | | Results Deadline<br>Subject to change if extensions granted | | Scheme reports issued by<br>(on or before) | |
|---|---|---|---|---|---|---|
| **January** | **9 06-10/2026** | 12 January 2027 | **iED 03/2026** | 05 January 2027 | **ED 03-04/2026** | 05 January 2027 |
| | **10 06-10/2026** | 12 January 2027 | **6 09-12/2026** | 05 January 2027 | **3 08-10/2026** | 05 January 2027 |
| | **11 05-08/2026** | 12 January 2027 | **4A2 08-10/2026** | 12 January 2027 | | |
| | **12 03-04/2026** | 12 January 2027 | **9 06-10/2026** | 26 January 2027 | | |
| | **13 03-04/2026** | 12 January 2027 | **10 06-10/2026** | 26 January 2027 | | |
| | **5A 08-10/2026** | 19 January 2027 | **12 03-04/2026** | 26 January 2027 | | |
| | **7 08-10/2026** | 19 January 2027 | **7 08-10/2026** | 29 January 2027 | | |
| | **8 08-10/2026** | 19 January 2027 | | | | |
| | **2B 09-10/2026** | 26 January 2027 | | | | |
| **Februrary** | **1A 09-10/2026** | 02 February 2027 | **2B 09-10/2026** | 05 February 2027 | **iED 03/2026** | 02 February 2027 |
| | **2A 09-10/2026** | 02 February 2027 | **11 05-08/2026** | 09 February 2027 | **6 09-12/2026** | 02 February 2027 |
| | **1B 09-10/2026** | 09 February 2027 | **13 03-04/2026** | 09 February 2027 | **9 06-10/2026** | 09 February 2027 |
| | | | **8 08-10/2026** | 09 February 2027 | **10 06-10/2026** | 09 February 2027 |
| | | | **1A 09-10/2026** | 12 February 2027 | **12 03-04/2026** | 09 February 2027 |
| | | | **2A 09-10/2026** | 12 February 2027 | **7 08-10/2026** | 12 February 2027 |
| | | | **1B 09-10/2026** | 23 February 2027 | **4A2 08-10/2026** | 16 February 2027 |
| | | | | | **2B 09-10/2026** | 26 February 2027 |
| | | | | | **1A 09-10/2026** | 26 February 2027 |
| **March** | | | **5A 08-10/2026** | 02 March 2027 | **2A 09-10/2026** | 05 March 2027 |
| | | | | | **11 05-08/2026** | 09 March 2027 |
| | | | | | **13 03-04/2026** | 09 March 2027 |
| | | | | | **8 08-10/2026** | 09 March 2027 |
| | | | | | **1B 09-10/2026** | 09 March 2027 |
| | | | | | **5A 08-10/2026** | 16 March 2027 |

This information is also available to download on our website: https://ukneqashandi.org.uk/calendar/

## 33. DISTRIBUTION TIMETABLE 2026-27

| | | Scheme 1A<br>Scheme 2A | Scheme 1B** | Scheme 2B | Scheme 3<br>Scheme 4A1/4A1i | Scheme 4A2<br>Scheme 6 | Scheme 5A<br>Scheme 7<br>Scheme 8 | Scheme 9<br>Scheme 10 / 11<br>Scheme 12 / 13 | Educational Samples**<br>EDXM* | iED | 5B |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2026 | April | | 28th April | | | | | | | | |
| | May | | | | 19th May | | | | | 26th May | 5th May |
| | June | 9th June | | 2nd June | | 16th June | 30th June | | | | |
| | July | | 7th July | 21st July | 14th July | | | 28th July | | | |
| | August | 4th August | | | | | | | | 25th August | |
| | September | | | 22nd September | | 15th September | | | 8th September* | | 1st September |
| | October | 6th October | 13th October | | 27th October | | 20th October | | | | |
| | November | 17th November | 24th November** | 10th November | | | | | 24th November** | | |
| | December | | | | | 15th December | | | | 8th December | |
| 2027 | January | | | 26th January | | | 19th January | 12th January | | | |
| | February | 2nd February | 9th February | | | | | | | | |
| | March | | | | | | | | | | |

** ED & 1B Shipped Together

* EDXM one distribution

** ED & 1B Shipped Together

**Scheme 1A - HLA Phenotyping**
**Scheme 1B - HLA-B27 Testing**
**Scheme 2A - Cytotoxic Crossmatching**
**Scheme 2B - Crossmatching by Flow Cytometry**
**Scheme 3 - HLA Antibody Specificity Analysis**
**Scheme 4A1 - HLA Typing at 1st Field Resolution**
**Scheme 4A1i - Interpretive HLA Genotype**
**Scheme 4A2 - HLA Typing to 2nd or 3rd Field Resolution**
**Scheme 5A - HFE Typing**
**Scheme 5B - Interpretive: HFE Genotype and HH**
**Scheme 6 - HLA Antibody Detection**
**Scheme 7 - HLA-related Pharmacogenetics**
**Scheme 8 - HLA Genotyping for Coeliac Disease and Other HLA-associated Diseases**
**Scheme 9 - KIR Genotyping**
**Scheme 10 - HPA Genotyping**
**Scheme 11 - HPA Antibody Detection/Specification**
**Scheme 12 - HNA Genotyping (New Scheme)**
**Scheme 13 - HNA Antibody Detection/Specification (New Scheme)**
**Scheme ED - Educational HLA Typing**
**Scheme iED - Interpretive Clincial Scenarios**
**Scheme EDXM - Educational Combined Crossmatch/HLA Typing/Antibody Analysis**