UK NEQAS for Leucocyte Immunophenotyping (LI) Terms and Conditions of Participation for UK-based centres

1. Registration and Fees

- Registration with the UK NEQAS LI programme is on an annual basis.
- Participants agree to pay a fee for services provided by the programme. Invoices will be raised by Sheffield Teaching Hospitals NHS Trust and will be payable within 30 days of issue. VAT will be charged if applicable.
- Participants must provide accurate invoicing address details as invoices which need to be credited and reissued will incur administration fees.
- Participants must provide a purchase order where this is required by the financial organisation responsible for payment of the invoice. Failure to provide a purchase order will result in suspension from the programme until such time as a valid purchase order is received.
- Purchase orders must be raised to Sheffield Teaching Hospitals NHS Foundation Trust.
- The financial year is from 1st April to 31st March. Participants registering in the programme or re-registering for the year will be charged in full and no refunds will be given for registrations cancelled during the year. If a participant wishes to withdraw from UK NEQAS LI services, they need to email admin@ukneqasli.co.uk directly. Registration fees will be pro rata if programmes are registered mid-year.
- Failure to pay the invoice will result in suspension from the programme until the invoice is paid in full.

2. Contact Information

- Participants are asked to provide contact details for
    - Head of Department (Default contact)
    - Primary contact for receipt of samples and reports
    - Contact details for the finance department responsible for paying invoices
    - Additional email address contacts can also be added

3. Data Protection and Privacy

- All contact details provided to UK NEQAS LI will be used for the purposes of providing EQA Services. UK NEQAS LI have the right to keep contact names in our secure databases for medical legal purposes. The right to erasure does not apply to health and social care information; this needs to be retained for care and medico-legal purposes. Any request to erasure or to be forgotten will be assessed on a case-by-case basis, along with relevant case law. If you wish to know what data we hold or to make a data deletion request please go to https://www.ukneqasli.co.uk/contact-us/. We will contact participants with respect to UK NEQAS LI-related information, including distribution of samples, closing date reminders, report availability and EQA performance, changes to programmes, surveys and new programmes. Your details will also be shared with other members of the UK NEQAS consortium for the purposes of marketing.
- If you wish to opt-out of non-standard emails (those not relating to distribution release/ report availability) and data share with other UK NEQAS Centres it will be the responsibility of the individual to contact UK NEQAS LI to confirm this. Please note if you do not choose to opt out then you will miss out on information and updates regarding the UK NEQAS consortium.
- The UK NEQAS LI Privacy Policy can be found at the following link: https://sheffield-ukneqas.ipassportqms.com/document_download/NjRlNTgxYzctMTI4ZS00MTg4LWI2ZDMtZDdkYzJhMTFlZTg3
- Participant details, their results and their performance data remain confidential unless we are required by law to share this information. Where required by law or authorised by contractual arrangements to release confidential information, UK NEQAS LI will notify those concerned of the information released, unless prohibited by law. For UK participants, the relevant National Quality Assessment Advisory Panel overseen by the Royal College of Pathologists Quality Assurance in Pathology committee (see https://www.rcpath.org/profession/committees/qapc.html and NHSE (where labs are testing NHS patient samples) are informed when a UK participant is identified as having performance issues.
- All participant data is managed through validated information systems with appropriate security measures to prevent unauthorised access, tampering, or loss.

4. Programme Design

UK NEQAS LI will:

- Ensure EQA/PT programmes are fit for purpose, clinically relevant, and representative of real-world samples, as far as practicable.

- Use statistically sound methods for performance evaluation.
- Clearly explain how performance is assessed and scored.
- Update participants with scheme design changes or method modifications.

5. Communication

UK NEQAS LI will:

- UK NEQAS LI will communicate key dates (e.g. distribution schedules, result deadlines).
- Notify participants of changes to the scheme, use of subcontractors, or any issue affecting validity.
- Provide timely distribution of samples, performance reports, and certificates (where applicable).
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6. Participation and Performance

- Where certificates of registration are issued, it should be noted this does not confirm participation in any distribution and programme by the registered centre.
- If results are not received, this will be recorded as a non-return, and in the absence of a valid reason received in a timely manner, for the non-return, will be a critical result for that distribution.
- If a participant fails to return results for multiple distributions, with no reasonable explanation, their registration for that programme may be removed.
- Performance assessment is carried out according to the statistical methods described for each programme. The assessments are a statistical measure, designed to assist participants in evaluating the performance of their tests/assays. It is important for participants to use their own professional judgement in evaluating the clinical relevance of any differences between their results and the target results.
- Laboratories shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the submission date. Participants should treat EQA samples like patient samples and refer testing on for additional testing if this reflects local practice. If this conflicts with other local or national guidelines please contact UK NEQAS LI. Where evidence of collusion is found, participant performance will be scored as a critical for that round.
- Participants will be contacted by the Scheme if performance in one or more EQA rounds is deemed of concern. If performance continues to be of concern, this may be referred anonymously to the UK NEQAS LI Steering Committee/Specialist Advisory Group for advice. If there is still no resolution to performance issues, the laboratory may be referred to the NQAAP, which may require laboratory contact details to be forwarded.
- Participants are expended to thoroughly investigate performance issues and complete root cause analysis forms provided by UK NEQAS LI.
- Repeat samples are standardly available for all programmes. Please contact admin@ukneqasli.co.uk for further information in timely manner.
- Artificial Intelligence (AI) systems should not be used in the UK NEQAS LI programmes without UK NEQAS LI's explicit knowledge.

7. Transparency & Feedback

UK NEQAS LI will provide participants with access to:

- Individualised reports including their performance
- Group-level comparison data, where appropriate.
- A clear explanation of poor performance outcomes
- Allow participants to appeal or query performance scores through a defined, fair process.

8. Responsiveness to Performance Issues

UK NEQAS LI will:

- Identify and act upon critical participant performance.
- Offer guidance or escalate through advisory or regulatory bodies when necessary.
- Engage constructively with participants to resolve concerns.

9. Governance and Impartiality

- UK NEQAS LI maintains impartiality in all EQA/PT activities and has procedures to identify and manage any threats to this impartiality. Participants should report any perceived conflicts of interest.
- When external providers are used for EQA/PT activities, participants will be notified on the UK NEQAS LI website and on the appropriate trial reports where this affects the validity of the PT scheme. Core activities including scheme design, performance evaluation, and report authorisation remain under direct UK NEQAS LI control.

10. Complaints and Appeals

- Participants may submit complaints about EQA/PT activities through the UK NEQAS LI website [https://www.ukneqasli.co.uk/contact-us/appeals-and-complaints/]. A formal appeals process is available for performance evaluations on the link above.

11. Continuous Improvement

- UK NEQAS LI will regularly review and improve EQA/PT processes and statistical methods and will solicit participant feedback to enhance service quality.

12. Trial Schedules and Sample Availability

- Trial schedules (https://www.ukneqasli.co.uk/eqa-pt-programmes/trial-schedules/) are a guide only as we are reliant on the availability of clinical samples. UK NEQAS for Leucocyte Immunophenotyping reserves the right to cancel or vary the number of shipments. Please note that your participation entitles you to the service and not the number of shipments.

Quality Assurance in Pathology Committee (QAPC): Conditions of EQA Scheme Participation

The Quality Assurance in Pathology Committee is a multidisciplinary group accountable to the College for the oversight of performance in external quality assurance (EQA) schemes and monitoring of the EQA performance of clinical laboratories in the UK. This is achieved via discipline specific National Quality Assurance Advisory Panels (NQAAP) which report to the committee. In turn, the Quality Assurance in Pathology Committee will work with laboratories with unsatisfactory performance but is also bound to report persistent performance issues to the Care Quality Commission (CQC).

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.

2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.

3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.

4. Changes in the test methodology of the laboratory should be reflected in the online portal of the EQA schemes with which the laboratory is registered.

5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see below) will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and/or the QAPC. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

6. A NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.

7. Laboratories' EQA performance will be graded using a traffic light system. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.

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

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

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