Member of UK NEQAS consortium

GenQA Terms and Conditions

Purpose and Scope

This document outlines the Terms and Conditions applicable to membership of and participation in GenQA services.

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Contents

1. INTRODUCTION

GenQA is operated by Oxford University Hospitals NHS Foundation Trust and accredited to ISO17043:2010 **[UKAS 7872]**. GenQA is located on two sites, Oxford and Edinburgh.

For contact details please see the GenQA website Contact.

This document outlines the Terms and Conditions for participation in GenQA services. Participants are required to agree to and abide by these Terms and Conditions at the beginning of every EQA year.

2. GOVERNANCE

GenQA Management is supported by international Expert Advisors acting as EQA assessors and Scientific Advisory Groups (SAGs) for each EQA discipline as well as a Scientific Advisory Board comprising of all SAG chairs and invited experts.

3. CONDITIONS OF PARTICIPATION

GenQA services are designed for public and private sector clinical laboratories/centres serving clinicians or patients. We welcome:

- Clinical laboratories/centres,
- Laboratories with research or industrial roles,
- Individuals subscribing to GENie (Online Genomic Individual Education platform)
- Manufacturers* of diagnostic instruments and reagents

**Manufacturers participate on a 'technical and analytical/genotyping' only basis, i.e. receiving samples and returning results with no clinical interpretation provided.*

GenQA operates in accordance with the RCPath Joint Working Group (JWG) Conditions of Participation by UK Clinical Laboratories in External Quality Assessment Schemes .

4. TERMINATION OF PARTICIPATION

Participants can request for their account to be de-activated at any time. Please send an email request for de-activation to info@genqa.org giving the reasons for the request. GenQA will deactivate the account and related registered staff.
Participants must ensure that they have saved all relevant historical EQA information (Individual Laboratory Reports, Summary Reports, Performance Certificates etc.) as they will no longer have access once the registered staff has been disassociated from the account.

4.1 Non-Payment of invoices

GenQA reserves the right to suspend participants and withhold EQA participation for non-payment of outstanding invoices.

4.2 Disqualification

If GenQA detects any incidence of EQA result sharing prior to EQA report submission or any other form of collusion, the GenQA Director shall investigate. If collusion is suspected, the participant will be withdrawn from the EQA assessment. Their Individual/Laboratory/Centre Report(s) will state that the participant has been found colluding with another participant, and no

participation certificate will be issued. GenQA reserves the right to disqualify any participant from future EQAs if there is evidence of falsification or collusion with another participant.

5. CONFIDENTIALITY AND DATA PROTECTION

All participant and case data is held on password-protected computers on networks operated and maintained by Oxford University Hospitals NHS Foundation Trust, NHS Lothian and University of Edinburgh as well as on a server operated and maintained by Certus Technology, all of which are securely maintained and backed-up by the relevant IT Departments. All data is held in accordance with the Data Protection Act 2018.

Participating laboratories/centres are identified by the GenQA unique identifier (G******) assigned at the point of registration and the corresponding laboratory and staff identities are known only to GenQA staff. Participants may, in certain circumstances, waive their right to confidentiality but agreement to must be given in advance in writing. If disclosure of identity is requested by an interested party or regulatory authority, reasons for the request must be communicated in advance and agreement confirmed in writing.

Individuals subscribing to GENie will not receive a GenQA unique identifier but will be identified through their login details.

5.1 Disclosure of laboratory identity

Performance scores (and some other relevant raw data) may be shared with the relevant national regulatory body where applicable -Centre Suisse de Contrôle de Qualité (CSCQ) in Switzerland, National Quality Assurance Advisory Panel (NQAAP) for Genetics in the UK- under defined circumstances as part of the routine reporting of persistent poor performance. When a laboratory is referred to NQAAP the identity of the laboratory will be disclosed to the panel.

The standard of performance of all NHS England funded laboratories within the Genomic Medicine Service will be disclosed to the Genomics Unit, NHS England by GenQA, in accordance with the contract between the laboratory and NHS England.

The identity and poor performance status of any English Neonatal Screening laboratory participating in the molecular newborn screening EQAs falling below the standards of acceptable performance will be disclosed by the Director to the UK National Screening Committee.

In order to maintain performance monitoring for EQAs offered jointly with other EQA providers (e.g. EMQN) and to prevent laboratories from alternately registering with either of these providers (Scheme Hopping/EQA Provider Hopping), the identity of laboratories with poor performance and persistent poor performance may be shared between the Scheme Directors if applicable.

By registering to participate in GenQA EQAs participating laboratories agree to the disclosures outlined in this section.

5.2 Disclosure of anonymised EQA participation and performance scores

Performance scores may be shared with local management, accrediting bodies and suppliers of equipment and reagents where appropriate and necessary, but only with the participant's explicit written permission.

Participation information on whether a laboratory participates in GenQA or a specific EQA will be disclosed to Orphanet for inclusion in their database and other EQA related bodies. This does NOT include the GenQA Participant identifier, raw data or information on EQA performance. Participants can specifically request that the participation information is not disclosed to Orphanet; this request has to be made to the GenQA Director in writing.

6. FEES AND INVOICING

GenQA is a Not-for-Profit Organisation and ensures the. EQA charges are kept to a minimum.. EQA charges include the postage/courier costs to deliver samples where appropriate.

Participants will be charged for all EQAs in which they are enrolled, regardless of whether they submit results for the EQA or not. Refunds are only payable in exceptional circumstances. For more details, please see our EQA Withdrawal Policy

All invoices are raised in Pound Sterling and include payment instructions and bank details. Terms of Payment are 30 days from date of invoice.

Individuals subscribing to GENie (arther than those enrolled through a laboratory/centre) will be required to pay via Paypal for each chargeable module they enrol in (see www.genqa.org/genie).

7. EQA Process

All EQA services are listed in the annual catalogue available on the website. Registered participants are informed by email once the new catalogue is available.

Any changes to the planned EQAs will be communicated to participants by GenQA as soon as possible.

7.1 Import documentation

It is the participating laboratory's responsibility to ensure that it holds all relevant import licenses for the EQA samples. Any special requirements must be communicated to GenQA at the point of enrolment or at least a month before the EQA in question opens. For more information please see the GenQA Handbook.

7.2 EQA material:

- Is designed to represent the relevant clinical material routinely tested in the participating laboratories, such as DNA, cells, blood, blood spots, plasma or tissue sections as well as tumour, chromosome and FISH images or data files.
- Is provided as specimens for the sole purpose of enabling external quality assessment at the recipient's laboratory during the current distribution and must not be tested for any other disease/genes/variants than that which is requested by GenQA.
- Is derived from human origin and, with the exception of Fresh Frozen Tissue (Category B), is of a non-infectious, non-toxic and non-hazardous nature.
- Does not constitute *in vitro* medical diagnostic devices (IVDs), and no claim is made that they may be suitable for any other purpose or at any other point in time
- Should be tested using your standard laboratory procedures for clinical samples
- May not be used for any purpose other than education and training

7.3 Repeat samples

It is the participant's responsibility to inform GenQA on info@genqa.org. if samples do not arrive by the date given in the EQA open email or EQA Distribution Letter, repeat samples, if available, and documentation will be sent as soon as possible.
Sufficient EQA material is usually supplied to perform all necessary analyses plus a modest number of repeat analyses.
Repeat samples can be requested using the Repeat Sample Request Form. GenQA are unable to guarantee that additional material will be available.

7.4 EQA Withdrawal

Any participant wishing to withdraw from an EQA must complete a GenQA EQA Withdrawal Request Form and send it to info@genqa.org prior to the starting date of the EQA. For more information, please see the GenQA Withdrawal Policy.

8. PERFORMANCE

All GenQA EQAs, with the exception of Pilot EQAs, are marked, scored and performance designations are awarded.

8.1 Performance Designations

There are two performance designations (see Performance Monitoring for more information): Satisfactory or Poor.

8.2 Performance Criteria

Performance Criteria exist for all Disciplines covered by GenQA EQA. All Performance Criteria are ratified by NQAAP for Genetics and are regularly reviewed. All Performance Criteria are available on https://www.genqa.org/monitoring

8.3 Performance Monitoring

The performance criteria for poor performance and persistent poor performance are agreed by the appropriate GenQA Specialist Advisory Group and ratified by the UK National Quality Assessment Advisory Panel (NQAAP) for Genetics. The Performance Criteria for the different specialties are available on the website under Performance Monitoring.

8.4 GENie

The GENie (Online Genomic Individual Education) platform is for educational purposes only and there is no performance monitoring. Outcomes and feedback, where appropriate will be provided through the platform.

9. COMMUNICATION

GenQA uses the email addresses given at registration or account creation to communicate with participants regarding specific EQAs and EQA related matters. GenQA accepts no responsibility for the delivery of emails. **It is the responsibility of the participant to ensure that all contact details are correct at all times**.

For more information about the emails being sent regularly please see the GenQA Members Handbook.

GenQA welcomes feedback from participants. All general communication and feedback should be directed to info@genqa.org and should include the GenQA unique identifier (G******) or username if related to GENie.

9.1 Appeals

Participants are given 15 working days from the release of the Pre-Appeals Individual Laboratory Report (ILR) to appeal their EQA results. For information on how to submit appeals please see the Participant Website User Guide.

9.2 Complaints

Formal complaints need to be made in writing (email or letter) to the Director or Deputy Director If outside bodies need to be involved in resolving the complaint, the complainant will be informed of the delay and will be kept informed of the progress. If appropriate, the formal written complaint is discussed with the relevant Specialist Advisory Group (SAG) or the Scientific Advisory Board. All complainants will receive a concluding letter from the GenQA Director outlining any findings and consequent improvements if appropriate.

All complaints are logged, and the action taken is recorded and audited annually by GenQA.

10 COPYRIGHT

The GenQA logo as well as all images, EQA cases, reports and documents are copyright.
A tailored logo is available for participants wishing to advertise their participation in GenQA EQAs. Please see the GenQA Handbook for more details