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Member of UK NEQAS consortium

GenQA
Performance Criteria

Purpose and Scope

This management procedure document details the processes involved in determining the performance standard of laboratories participating in GenQA EQAs.

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1. Performance Criteria

This document details the general process involved in determining the performance standard of laboratories/centers (herein after referred to as 'participant') taking part in GenQA External Quality Assessments.

GenQA distributes validated test materials/case scenarios to externally assess a participant's analytical/genotyping and interpretive performance.

1.1 Outline of marking system

The general marking system covers:

- Analytical/Genotyping accuracy
- Interpretation of results
- Clerical accuracy

The total score for each category is 2.0 points. The measurement of performance will take the form of deductions which reflect the scale of error or omission according to pre-determined marking criteria agreed by a panel of experts (assessors) in the relevant field. GenQA staff will ensure consistency of marking criteria between and within the respective EQA rounds, and across all GenQA EQAs. Individual scores and EQA means will be calculated to two decimal places. Note that all categories may not apply to all EQAs, e.g., Interpretation only EQAs will not assess the Analytical/Genotyping accuracy category.

Categories may be modified in line with the EQA being delivered e.g., the DNA extraction and DNA quantification EQAs. See Section 2.1.4 for further details. In summary, the marking system for the Sample Handling EQAs covers:

- Mass of DNA and/or Scored quality metrics – DNA extraction EQAs
- Accuracy of DNA concentration measurement – DNA Quantification.

The Sample handling EQAs use cumulative scoring for quality/quality scoring of DNA or measurement accuracy. Each category for each case is scored out of 2.0 points

1.2 Data Monitoring

Performance data of each participant are stored on the GenQA website. Participants can access their EQA reports and performance data via their own password protected account. Participants can only access their own EQA data.

Clinical Genetics EQAs assess clinical staff as opposed to a structured laboratory and in most European countries there is no requirement from the registration body for clinical staff to take part in EQA. Therefore, there is not official follow up of Poor Performance.

Performance data are monitored by GenQA. The results submitted by each participant and the subsequent assigned scores for all EQAs are stored on the GenQA website which is password protected to ensure only relevant GenQA staff have access to the data. It is the responsibility of GenQA to take appropriate action in the event of poor performance or persistent poor performance.

A comparison of performance data between EQA rounds as well as a year-on-year comparison is performed by GenQA staff. This includes performance in the same disease/disorder EQA and between disease/disorder EQAs. This ensures that any poor performance or persistent poor performance trends are identified promptly and action can be taken by the Deputy

Directors and the relevant GenQA Specialist Advisory Group (SAG) or the GenQA Scientific Advisory Board if deemed appropriate and approved by the Director.

2. Performance classification and definition

Following Royal College of Pathologists UK Joint Working Group for Quality Assurance (JWG) recommendations (October 2010) the subsequent categories (as defined in this document) will be applied:

- Laboratories operating at an **acceptable level of performance** are classed as "**green**".
- Laboratories deemed to be **poor performing laboratories** are classed as "**amber**".
- Laboratories deemed to be **persistent poor performing laboratories** are classed as "**red**".
- Persistent poor performing laboratories not responding appropriately to NQAAP/ JWG action as defined by the JWG are classed as "**black**" (UK laboratories only).

2.1 Definition of poor performance (Amber status)

There are only two categories of performance for any GenQA EQA: "**satisfactory**" and "**poor**". A specific set of marking criteria, based on the specifics of each individual EQA case, are applied.

Poor performance (amber status) is defined as follows:

- **Analytical/Genotyping: Scoring a 'zero' score in any case within an EQA for a genotype (= Critical analysis/genotyping error).**
- **Interpretation: Scoring a 'zero' score in any case within an EQA for interpretation (= Critical interpretation error).**
- **Sample handling EQAs: Overall EQA score below the acceptable threshold based on marking criteria (See Section 2.1.4).**

The performance criteria are designed to identify errors or omissions that are defined as "**critical**" or "**non-critical**".

2.1.1 Critical error

A "**critical error**" is an error made when:

- There is an incorrect analysis/genotype reported;
- The analytical/genotyping or interpretive category within an EQA case that may lead to serious clinical consequences or implies a significant lack of diagnostic skill or scientific knowledge on the part of the participant;
- A report contains advice which is considered by the assessors to be dangerously erroneous, or when a report does not contain advice considered by the assessors to be essential. This will be sufficient to constitute Poor Performance, irrespective of the scores achieved in the categories above;
- There is a failure to interpret the significance of the genetic result in EQAs where interpretation is assessed.

All **critical errors** are given a 2.0 point deduction (i.e. a 'zero' score) and laboratories are categorised as "poor performance (amber status)". **A critical error in the analytical/genotyping category will result in the remaining categories being unmarked.**

A critical error in the interpretation category will result in the clerical accuracy category being unmarked.

2.1.2 Non-critical error

A "**non-critical**" error would not be expected to have serious clinical consequences but would still be consistent with a lack of diagnostic skill, communicative ability or scientific knowledge. Non-critical errors will lead to point deductions but will not result in a poor performance categorisation. The scoring of the Clerical Accuracy category does not lead to poor performance.

2.1.3 Non-participation

If a participant enrols for an EQA but fails submit results by the EQA submission deadline without either formerly withdrawing from the EQA or informing GenQA of their reason for non-participation, they will be deemed a poor performer due to non-submission.

2.1.4 Defining performance threshold for sample handling EQAs

Scores for each category (quality and yield, or measurement accuracy) are set on either previously defined values based on the volume/sample type provided, or by EQA consensus. Performance criteria thresholds are set based on the overall score for all samples for all categories.

The marking criteria performance threshold is set for the DNA extraction EQAs based on if laboratories have extracted DNA of sufficient quality and yield based on the sample type/ volume of sample provided.

The marking criteria is set for the DNA quantification EQA based on whether laboratories have accurately measured the concentration of DNA compared to other participating laboratories for a sufficient number of samples within the EQA.

In both instances, laboratories would receive poor performance if the scores reflect that the measurement accuracy, or quality and/or yield of DNA extracted would have serious consequences for downstream clinical testing.

2.1.5 Action following poor performance identification (Amber status)

All scores for the EQA assigned by the assessors are reviewed by senior GenQA staff meeting. Following completion of the appeals process, all critical errors are reviewed by GenQA and performance criteria applied to identify poor performing participants.

If a participant has fallen below the acceptable performance standard described in this document for analysis/genotyping and/or interpretation GenQA will inform the participant of their poor performance/amber status and ask them to complete an online EQA Performance Investigation form. The participant is given a defined period (determined as reasonable by the GenQA, a minimum of 20 working days), in which to complete and return this form to GenQA. Senior GenQA staff will provide feedback to the participant relating to the error investigation outlined in the form.

The participant remains a poor performer (amber status) until the participant performs satisfactorily in the next round of EQA. At that point their status as a current poor performer

(amber status) is removed. The poor performance remains on record for four years (see section 2.2a and 2.2b).

2.2 Definition of Persistent Poor Performance (Red status)

Persistent poor performance (red status) is defined as follows:

(a) Those participants who perform poorly in two out of any three consecutive EQA rounds.

(b) A poor performance within one year following a previous persistent poor performance designation.

Participants meeting the above criteria will be classed as "red" whilst their persistent poor performance status stands.

Performing poorly on analysis/genotyping in one EQA and interpretation in the subsequent EQA will have the same consequences as performing poorly on analysis/genotyping for two subsequent EQAs.

A participant who has performed poorly across different EQAs may, at the discretion of the GenQA Director, be classed as a persistent poor performer and ratified by the GenQA Scientific Advisory Board, even if they have not met the criteria for Persistent Poor Performance in any individual EQA.

2.2.1 Action following identification of a persistent poor performing laboratory where there is no National assurance body

Once a participant meets the criteria for persistent poor performance as described in section 2.2, and this has been ratified by the GenQA Scientific Advisory Board, the GenQA Director will write to the participant informing them of their persistent poor performance status and offer help and advice in order to improve the service provided by the laboratory. The GenQA Director will not reveal the identity of the participant to any outside parties providing such assistance unless the participant has specifically given permission to do so.

The participant is given a defined period (appropriate to the situation) in which to respond to the GenQA Director. If no satisfactory response is obtained within the given time period, the GenQA Director will resend the letter by email and post (requiring a signature upon delivery) with a further 20 working day period for a response. If the participant continues to fail to provide a satisfactory response, then the GenQA Director will telephone the participant to seek the required information. If contact is not successful, the GenQA Director will discuss the situation and suitable action with the GenQA Scientific Advisory Board by email. The identity of the laboratory will not be disclosed to the GenQA Scientific Advisory Board.

2.2.2 Action following identification of a persistent poor performing (Red status) laboratory with intervention by a National Assurance Body (FOPH, NQAAP)

GenQA is obliged to notify FOPH (Switzerland) or NQAAP for Genetics (UK) respectively of any persistent poor performance as described in section 2.2. Prior to notifying the national bodies, GenQA will obtain ratification of the persistent poor performance from the GenQA Scientific Advisory Board.

The GenQA Director, in consultation with FOPH or NQAAP for Genetics, will decide when the active persistent poor performance (red status) of the participant can be removed. The persistent poor performance will remain on record.

- **Federal Office of Public Health (FOPH) referral (for Swiss laboratories)**

In the case of persistent poor performance (red status) the GenQA Director will inform the participant of their referral to the Chairman of FOPH, and that their identity will be revealed to the FOPH. The participant's identity will remain confidential within the FOPH at all times. FOPH will assess each referral, taking into account the magnitude of the problem, the participant's previous record, response to the contact by the GenQA Director and other considerations. FOPH will make a response directly to the head of the referred participant. The FOPH 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 SAS (Swiss Accreditation Service) who may arrange an urgent visit to the participant.

The Chairman of FOPH will notify the GenQA Director when the active persistent poor performance (red status) of the laboratory can be removed. The persistent poor performance will remain on record.

- **NQAAP referral (for UK laboratories)**

In the case of persistent poor performance (red status) the GenQA Director will inform the participant of their referral to Chairman of NQAAP (Genetics) with details of their performance. and that their identity will be revealed to the NQAAP panel and, subsequently, the Joint Working Group for Quality Assurance (JWG). The identity of the laboratory will remain confidential within the panel.

The NQAAP panel will assess each referral, taking into account the magnitude of the problem, the participant's previous record, response to the contact by the GenQA Director, and other considerations. The panel will consider the best approach to improve the situation and the Chair will contact the participant directly, requesting a response by a specific date. 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 who may arrange an urgent visit to the participant. Advice is offered to the participant in writing or, if appropriate, a visit to the participant from a NQAAP member or appropriate agreed expert(s) may be arranged.

The Chairman of NQAAP for Genetics will notify the GenQA Director when the active persistent poor performance (red status) of the laboratory can be removed. The persistent poor performance will remain on record.

2.3 Definition of Unresolved Persistent Poor Performance (Black status): UK laboratories only

If a persistent poor performance of a UK participant remains unresolved, the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the

appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the participant's Head of Department concerned. If such supportive action fails to resolve the problem and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer (or nearest equivalent within the organisation) of the Trust or Institution hosting the participant of the problem, the steps which have been taken to rectify it and, the cause of the problem, where identified. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues; the laboratory will be referred to the Care Quality Commission for further action.

The Chairman of NQAPP for Genetics will notify the GenQA Director when the active persistent poor performance/red status of the laboratory can be removed. The persistent poor performance will remain on record.

3. Ratification of Criteria

The criteria in this document were approved by the:

- GenQA Scientific Advisory Board on 19th November 2024, and
- UK National Quality Assurance Advisory Panel for Genetics on 20th November 2024.

Abbreviations:

EQA:	External Quality Assessment
FOPH:	Federal Office of Public Health
JWG:	Joint working group
ISO:	International Organisation for Standardisation
NQAAP:	National Quality Assurance Advisory Panel
UKAS:	United Kingdom Accreditation Service
UK NEQAS:	UK National External Quality Assessment Service