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ISO 17043 Accredited EQA Schemes

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Poor Performance Criteria for the Molecular Rapid Aneuploidy (MRA) External Quality Assessment (EQA) scheme

1. Performance Criteria

This document details the process involved in determining the performance standard of laboratories participating in the MRA EQA scheme.

It is the responsibility of the Cytogenetics Scheme Director to monitor the performance of all CEQAS participants and to take appropriate action in the event of poor performance or persistent poor performance.

It is the responsibility of the Molecular Genetics Scheme Director to monitor the performance of all UK NEQAS Molecular Genetics participants and to take appropriate action in the event of poor performance or persistent poor performance.

1.1 Outline of marking system

The marking system covers:

- Analytical/Genotyping accuracy,
- Interpretation of the results,
- Clerical accuracy.

The total score for each category is 2.0 points. The measurement of performance will typically take the form of deductions, *e.g.* -0.5, -1.0 or -2.0, which reflect the scale of error or omission and accordingly to peer ratified criteria. The CEQAS and UK NEQAS for Molecular Genetics Scheme Directors will ensure consistency of scoring criteria between the MRA rounds. Individual participants' scores and scheme means will be calculated to two decimal places.

Clerical Accuracy will not contribute towards poor performance.

2. Performance classification and definition

As a consequence of the UK Joint Working Group for Quality Assurance (JWG) recommendations the following categories will be applied:

- Laboratories operating at an acceptable level of performance are classed as “green”.
- Laboratories deemed to be poor performing laboratories, as defined in this document, are classed as “amber”.
- Laboratories deemed to be persistent poor performing laboratories, as defined in this document, are classed as “red”.
- Persistent poor performing laboratories not responding appropriately to NQAAP/ JWG action as defined by the JWG are classed as “black”.

2.1 Definition of poor performance (Amber status)

There are only two categories of performance for any EQA: “**satisfactory**” and “**poor**”. A specific set of performance criteria (marking criteria) are designed for each EQA case and ratified by experts, based on the problems posed by the particular circumstances of that case.

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 in either the analytical/genotyping or interpretive category within an EQA case that could lead to serious clinical consequences or imply a significant lack of diagnostic skill or scientific knowledge on the part of the participating laboratory. Where 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.

All **critical errors** are given 2.0 point deduction (i.e. a zero score) and laboratories are categorised as “poor performance (amber status)”. **A critical error in one category may result in the remaining categories being left unmarked.**

Poor performance (amber status) is defined as follows:

Genotyping: Scoring a 0 score in any case within an EQA round for a genotype/analysis.
Interpretation: Scoring a 0 score in any case within an EQA round for interpretation.

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 not result in zero scores or a poor performance categorisation either individually or by accrual.

2.1.3 Non-participation

If a laboratory (UK and non-UK) registers for an EQA scheme but fails to participate without informing the Scheme Director of a suitable reason for non-participation, then it will be deemed a poor performer due to non-participation.
Registration by UK laboratories in each round of EQA for all referral categories/diseases offered as a clinical service is a requirement both of the Molecular Genetics EQA Scheme and the Cytogenetics EQA scheme. EQA participation is also a requirement of ISO15189 Medical Laboratory accreditation.

Laboratories will not be expected to continue participation for any disease no longer offered as a clinical service but should inform the EQA Scheme Director in writing when this occurs. The Scheme Director will follow up any non-registration of previous participants.

2.1.4 Action following poor performing laboratory (Amber status)

Once the scores for the EQA round have been finalised by all the Scheme Assessors, then the appropriate Scheme Director reviews the scores for each participating laboratory. If any participant has fallen below the acceptable performance standard described in this document for genotyping and/or interpretation then the Scheme Director will contact the participant informing them of their error, their laboratory's poor performance/amber status and request that a root cause analysis is undertaken. The laboratory is given a defined period (determined as reasonable by the Scheme Director, a minimum of 15 working days) in which to respond to the Scheme Director with the cause of the error.

No extra rounds of EQA are provided for laboratories in the MRA scheme.

The laboratory remains a poor performing laboratory (amber laboratory) until the laboratory performs satisfactorily in the next round of EQA when their active poor performance/amber status is removed. The poor performance remains on record.

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.

These laboratories will be classed as "red" whilst the persistent poor performance status stands.

Performing poorly on genotyping in one round of EQA and interpretation in the next round will have the same consequences as performing poorly on genotyping for two rounds of EQA. A comparison of performance data between EQA rounds, as well as a year-on-year comparison is performed by the Scheme Director. A participant who has performed poorly for more than one disease/tissue in more than one EQA round may, at the discretion of the Scheme Director, be referred for Persistent Poor Performance even if they have not met the criteria for Persistent Poor Performance in any individual EQA. This ensures that any poor performance trends are identified promptly and action can be taken if deemed appropriate by the respective Scheme Director and the Rapid Prenatal SAG and Steering Committees.

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

This will only happen in cases of persistent poor performance (see Section 1.4 and notes). Once a Swiss or UK laboratory reaches the criteria for a persistent poor performance, the relevant Scheme Director is obliged to notify FOPH (Swiss) or NQAAP for Genetics (UK) respectively.

The Scheme Director will obtain ratification of the persistent poor performance/red status by the Rapid Prenatal Specialist Advisory Group. The Scheme Director in consultation with FOPH or NQAAP for Genetics will decide when the active persistent poor performance (red status) of the laboratory can be removed. The persistent poor performance will remain on record.

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

A persistent poor performance designation (red status) will lead to a further contact by the relevant Scheme Director informing them of the referral to the Chairman of FOPH and that the laboratory's identity will be revealed to the panel. The laboratory identity will remain confidential to the panel at all times. FOPH will assess each referral, taking into account the magnitude of the problem, the laboratory's previous record, its response to the contact by the relevant Scheme Director, and other considerations; and will make a response directly to the head of the referred laboratory. 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 laboratory.

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

A persistent poor performance designation (red status) will lead to a further contact by the relevant Scheme Director informing them of the referral to the Chairman of NQAAP (Genetics) with details of the laboratory's performance. The laboratory's identity will be revealed to the NQAAP panel and subsequently the Joint Working Group for Quality Assurance (JWG). The laboratory identity will remain confidential to the panel at all times. The Scheme Director will write to the laboratory informing them of the referral to NQAAP.

The NQAAP panel will assess each referral, taking into account the magnitude of the problem, the laboratory's previous record, its response to the contact by the relevant Scheme Director, and other considerations. The Panel will consider the best approach to improve the situation and the Chair will contact the laboratory 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 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(s) may be arranged.

The Chairman of NQAAP for Genetics will notify the relevant Scheme 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 persistent poor performance 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 Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues; the laboratory will be referred to the Care Quality Commission for further action.

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

Abbreviations: EQA: External Quality Assessment; ISO: International Organisation for Standardization; NQAAP: National Quality Assurance Advisory Panel; FOPH: Federal Office of Public Health; UKAS: United Kingdom accreditation service, UK NEQAS: United Kingdom National Quality Assessment Service.