



UK NEQAS MANAGEMENT PROCEDURE

Procedure for monitoring performance standards for Preimplantation Genetic Diagnosis EQA schemes

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1 Introduction

This procedure details the processes involved in determining the performance standard of each participating laboratory in the UK NEQAS for Molecular Genetics Preimplantation Genetic Diagnosis EQA schemes, maintaining a record of participant performance and monitoring the performance year to year.

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

Following UK Joint Working Group for Quality Assurance recommendations (October 2010) the subsequent 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/Joint Working Group for Quality Assurance (JWG) action as defined by the JWG are classed as “black”.

2 Data Monitoring

Performance data of each participant from 1998 to the current year are stored on the scheme website. Participants can access their own performance data via their own password protected account. They can only access their own laboratory scores.

Performance data is monitored by the Scheme Organiser. The results submitted by each laboratory for all scheme distributions and individual laboratory scores are stored on the scheme website and is password protected. Only the Scheme Organiser has access to the identity of all laboratories and their performance data.

A comparison of performance data between EQA rounds as well as a year-on-year comparison is performed by the Scheme Organiser. This includes performance in the same disease EQA scheme and between disease EQA schemes if appropriate. This ensures that any poor performance trends are identified promptly and action can be taken if deemed appropriate by the Scheme Organiser and the UK NEQAS for Molecular Genetics Steering Committee.

A record of all poor performance and persistent poor performance is kept by the Scheme Organiser.

3 Ratification of Criteria

The criteria for identifying poor performers and persistent poor performers are ratified by the UK NEQAS for Molecular Genetics Steering Committee. This document was ratified by the committee on 28th September, 2010.

The criteria are approved by the Molecular Preimplantation Genetic Diagnosis EQA working Group on 8th October, 2010.

The criteria are approved by the UK National Quality Assurance Advisory Panel - Genetics. This document was approved by the panel on 25th March, 2011.

4 Criteria for identifying Poor Performers (Amber status)

4.1 Criteria

The criteria for poor performance and persistent poor performance and the action taken when this arises have been established and are as follows:

The central purpose of external quality assurance is to ensure that laboratories are delivering a service of the highest possible quality. The Molecular Genetics Scheme maintains the principle of assessment by professional consensus and attempts to improve standards by education and peer group review rather than by censure or penalty. Performance criteria are necessary to allow an individual laboratory's performance to be measured against national standards and to identify any laboratory, which is failing to meet these criteria.

Participants who fall below the standards set out here are deemed to be performing poorly. These laboratories will be classed as "Amber" whilst the poor performance status stands.

When a serious genotyping error is identified, the Scheme Organiser will contact the participant as soon as the error comes to light. In this way it is intended that any consequences of the laboratory error will be rectified without delay.

Poor performance will be determined at the level of the individual EQA, rather than on the basis of the participant's average score across all disease schemes run by UK NEQAS for Molecular Genetics. However, the Scheme Organiser will review the laboratories performance in all schemes when poor performance is detected.

One clinical case scenario with appropriate samples is distributed per each round of EQA. This generally will include a couple requesting PGD and a sample from their affected child. The EQA is provided in two stages;

- (i) DNA feasibility study to determine if the participating laboratory can provide PGD for the case.
- (ii) Single cell embryo study for participants able to provide PGD for the case. Five mock embryos are analysed per each round of EQA.

Poor performance (amber status) for DNA feasibility study is defined as follows:

Genotyping	Scoring less than 1.6 on Genotyping for the DNA feasibility study.
Interpretation	Scoring less than 0.7 times the mean score the DNA feasibility study.. <i>Mean scores will be calculated to two decimal places. Individual participant's scores will be calculated precisely.</i>
Clerical Accuracy	<i>This category of marking will not contribute towards poor performance.</i>

Poor performance (amber status) for single cell "embryo" testing is defined as follows:

Genotyping	Scoring 0.0 for any one embryo tested <i>i.e. A score of 0.0 is given for any incorrect embryo genotype so poor performance will be given for a single genotyping error.</i>
Interpretation	Scoring 0.0 for any one embryo tested <i>i.e. A score of 0.0 is given for any incorrect interpretation of an embryo genotype.</i>
Clerical Accuracy	<i>This category of marking will not contribute towards poor performance.</i>

4.2 Incorrect advice given, correct advice not given

Where a report contains advice which is considered by the PGD Scheme Assessors to be dangerously erroneous, or when a report does not contain advice considered by the PGD Scheme Assessors to be essential, this will be sufficient to constitute Poor Performance, irrespective of the scores achieved in the categories above. This decision will be ratified by the Steering Committee.

4.3 Non-participation

Participation in each round of EQA for all diseases offered as a clinical service is a requirement both of the Molecular Genetics EQA Scheme. EQA participation is also a requirement of CPA (UK) Ltd/UKAS Medical Laboratory accreditation.

Non-registration for any PGD scheme offered for a disease which PGD is provided as a clinical service by the laboratory will be deemed poor performance. This will apply irrespective of previous performance scores. Laboratories will not be expected to continue participation if a clinical service is no longer provided but the laboratory should inform the EQA Scheme Organiser in writing when this occurs. Failure to inform the Scheme Organiser will result in poor performance due to non-participation. The Scheme Organiser will follow up any non-registration of previous participants.

If a laboratory (UK or non-UK) registers for an EQA scheme but fails to participate without informing the Scheme Organiser of a suitable reason for non-participation, then it will be deemed a poor performer due to non-participation.

4.4 Action following Genotyping Poor Performance

Once the scores for the EQA round have been finalised by all the Scheme Assessors, then the Scheme Organiser reviews the **genotyping** scores for each participating laboratory for all disease EQAs. If any participant has fallen below the acceptable performance standard described in Section 4.1 for genotyping then the Scheme Organiser will contact the participant informing them of their error, their laboratory's poor performance/amber status and request that the cause of the genotyping error is investigated. Depending on the type of genotyping error made, this initial contact will be either by telephone, email or letter (determined by the Scheme Organiser, normally within 10 working days). The laboratory is given a defined period (determined as reasonable by the Scheme Organiser) in which to respond to the Scheme Organiser with the cause of the error. At this point the participant may feel confident about addressing the problem internally but help and advice will be made available on request. The Scheme Organiser will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

If no satisfactory response is obtained within the given time period then the Scheme Organiser will resend the letter by email with a further 15 working day period for a response. If the laboratory continues to fail to provide a satisfactory response then a second poor performance is designated.

If a serious genotyping error is made then the Scheme Assessors inform the Scheme Organiser as soon as possible. The Scheme Organiser then contacts the laboratory immediately. This ensures that the laboratory is informed of the critical genotyping error within a short time frame and an investigation into the cause of the error can be initiated.

No extra rounds of EQA will be provided for PGD schemes but full support of the Molecular PGD EQA Working Group will be given via the Scheme Organiser and any help will be tailored to deal with the problematic issues in each laboratory.

This action will be followed for UK and non-UK participants.

4.5 Action following Interpretation Poor Performance

If any participant has fallen below the acceptable performance standard described in Section 4.1 for **interpretation** then the Scheme Organiser will contact the participant by letter (posted and emailed) after the appeals process informing them of their laboratory's poor performance status. At this point the participant may feel confident about addressing the problem internally but help and advice will be made available on request. The Scheme Organiser will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

No extra rounds of EQA will be provided for PGD schemes but full support of the Molecular PGD EQA Working group will be given via the Scheme Organiser and any help will be tailored to deal with the problematic issues in each laboratory.

This action will be followed for UK and non-UK participants.

5 Criteria for identifying Persistent Poor Performers

5.1 Criteria

Persistent Poor Performers will be defined as either:

- those participants who perform poorly for a disease in **three** out of any **six** consecutive EQA rounds.
- or
- those participants who perform poorly for a disease in any **two** consecutive rounds of EQA.

Performing poorly in any **one** of these categories will count towards Persistent Poor Performance.

Performing poorly on genotyping in one round of EQA and interpretation in the next two rounds will have the same consequences as performing poorly on genotyping for three rounds of EQA. If a participant performs poorly for more than one disease in more than one EQA, that laboratory's results will be reviewed by the Scheme Organiser and the Steering Committee and that participant may, at the discretion of the Steering Committee, be referred for Persistent Poor Performance even if they have not met the criteria for Persistent Poor Performance in any individual EQA.

Performing poorly in any **one** of these categories will count towards Persistent Poor Performance.

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 two rounds will have the same consequences as performing poorly on genotyping for three rounds of EQA. If a participant performs poorly for more than one disease in more than one EQA, that laboratory's results will be reviewed by the Scheme Organiser and the Steering Committee and that participant may, at the discretion of the Steering Committee, be referred for Persistent Poor Performance even if they have not met the criteria for Persistent Poor Performance in any individual EQA.

5.2 Action following identification of a Persistent Poor Performing UK laboratory

Once a UK laboratory reaches the criteria for Persistent Poor Performance/red status the Scheme Organiser is obliged to notify the National Quality Assessment Advisory Panel (NQAAP) - Genetics. The Scheme Organiser will obtain ratification of the persistent poor performance by the Steering Committee (either at the first Steering Committee meeting or by email). The Scheme Organiser will contact the Chair of NQAAP - Genetics with details of the laboratory's performance. The identity of the laboratory will be revealed to the panel and subsequently the Joint Working Group for Quality Assurance. The Scheme Organiser will write to the laboratory informing them of the referral to NQAAP.

The Panel will consider the best approach to improve the situation and 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 CPA (UK) Ltd, 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(s) may be arranged.

If persistent poor performance remains unresolved, the laboratory will be classed as "black" and 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-Genetics will notify the Scheme Organiser when the persistent poor performance/red status of the laboratory can be removed. The persistent poor performance will remain on record.

5.3 Action following identification of a persistent poor performing non-UK laboratory

Once a non-UK laboratory reaches the criteria for Persistent Poor Performance the Scheme Organiser will obtain ratification of the persistent poor performance by the Steering Committee (either at the first Steering Committee meeting or by email). The Scheme Organiser will write to the laboratory informing them of the laboratory's persistent poor performance/red status and offer help and advice in order to improve the service provided by the laboratory. The Scheme Organiser will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

The laboratory is given a defined period (appropriate to the situation) in which to respond to the Scheme Organiser. If no satisfactory response is obtained within the given time period then the Scheme Organiser will resend the letter by email and post (requiring a signature upon delivery) with a further 15 working day period for a response. If the laboratory continues to fail to provide a satisfactory response then the Scheme Organiser will telephone the primary contact of the laboratory to seek the required information. If contact is not successful then the Scheme Organiser will discuss the situation and suitable action with the Steering Committee at the next meeting (or by email if the next meeting is scheduled more than 2 calendar months time). The identity of the laboratory will not be disclosed to the Steering Committee.

6 Notes

Experience in the scheme suggests that referral to NQAAP will be very infrequent, since the majority of laboratories will correct any deficiencies before reaching that stage in the procedure. This is as it should be, since the consequences of a referral to NQAAP are serious, with implications for CPA (UK) Ltd accreditation as well as the obvious doubts that must arise about the quality of service to patients.

7 Associated Documentation

MP-NEQAS-FinalReport	Procedure for the preparation and distribution of the Final report.
MP-NEQAS-Appeals	Appeals procedure
MF-NEQAS-PPChecklist	Checklist for monitoring poor performers
MF-NEQAS-PPOverview	Ongoing list of scheme poor performers
MP-NEQAS-Performance	Procedure for monitoring performance for the general molecular EQAs
MP-NEQAS-PerformBldSpots	Procedure for monitoring performance standards for molecular testing on blood spots EQA
MP-NEQAS-MRAPP	Procedure for monitoring performance standards for Molecular Rapid Aneuploidy EQA