




# UK NEQAS MANAGEMENT PROCEDURE

**Procedure for monitoring performance standards for the molecular testing on blood spots External Quality Assurance 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 molecular testing on blood spots 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) these 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”.

The following schemes are provided by UK NEQAS for Molecular Genetics:

- Cystic fibrosis (CF) molecular testing on blood spots EQA
- Medium chain acyl Co-A dehydrogenase deficiency (MCADD) molecular testing for the common mutation (c.985A>G) on blood spots EQA
- MCADD extended molecular mutation screening on blood spots EQA

## 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. 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 25<sup>th</sup> January, 2011.

The criteria are approved by the UK Newborn Blood Spot Laboratory Quality Assurance Development Group on 16<sup>th</sup> February, 2011.

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

### 4 Criteria for identifying Poor Performers in blood spot EQA schemes (Amber status)

#### 4.1 Criteria

The criteria for 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 and international 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.

Poor performance will be determined at the level of the individual disease, ie. CF testing on blood spots 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.

When a serious genotyping error is identified, the Scheme Organiser will contact the participant as soon as the error comes to light (usually within 5 days of the scheme closing). In this way it is intended that any consequences of the laboratory error will be rectified without delay.

The blood spot EQA schemes are genotyping only exercises. An appropriate results *proforma* is electronically available to participating laboratories when the schemes are active so results can be submitted easily via the website. Three blood spot samples are distributed four times per year for each disease blood spot scheme.

Poor performance (amber status) for any one distribution for any one disease is defined as follows:

<b>Genotyping</b>	<b><i>Mean score for one disease distribution is less than 1.6 ie. a single genotyping error</i></b>
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## 4.2 Non-participation

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

If molecular testing on blood spots for that particular disease is offered as a clinical service by a laboratory and that laboratory does not register to participate in the disease molecular testing on blood spots scheme then the laboratory will be deemed a Poor Performer due to non-participation. This will apply irrespective of previous performance scores obtained for that scheme, eg. if molecular testing for the common MCADD mutation (c.985A>G) on blood spots is offered as a clinical service by a laboratory and that laboratory does not register to participate in the MCADD (common mutation) testing on blood spots scheme then the laboratory will be deemed a Poor Performer.. The Scheme Organiser will follow up any non-registration of previous participants.

Laboratories will not be expected to continue participation for any disease no longer offered as a clinical service but 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.

If a laboratory registers for the blood spot EQA scheme but fails to participate in any of the four rounds without informing the Scheme Organiser of a suitable reason for non-participation, then it will be deemed a Poor Performer due to non-participation.

## 4.3 Action following poor performance

Once the scores for the EQA round have been finalised by all the Scheme Assessors, then the Scheme Organiser reviews the mean genotyping score for each participating laboratory. If any participant has fallen below the acceptable performance standard described in Section 4.1 then the Scheme Organiser will write to the participant (usually within 5 working days of the scheme closing) informing them of their error, their laboratory's poor performance/amber status and request that the cause of the genotyping error is investigated. The laboratory is given a defined period (determined as reasonable by the Scheme Organiser, normally within 15 working days) 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.

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

No extra round of EQA will be dispatched to poor performers as there is regular EQA sample distribution throughout the year.

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

The following action will be taken by the Scheme Organiser if any English Neonatal Screening laboratory falls below the standards for Poor Performance described above:

The identity of the laboratory and the poor performance status will be disclosed to the Director of the UK Neonatal Screening Programme Centre by the Scheme Organiser as soon as the poor performance has been identified (at the same time as the Scheme Organiser contacts the laboratory, usually within 5 working days of the scheme closing).

## 5 Criteria for identifying Persistent Poor Performers in blood spot EQA schemes (Red status)

### 5.1 Criteria

Persistent Poor Performers will be defined as:

- those participants who perform poorly in **two** out of any **three** consecutive blood spot EQA rounds for the same disease.

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

### 5.2 Action following identification of a Persistent Poor Performing UK laboratory

Once a UK laboratory reaches the criteria for Persistent Poor Performance 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/red status by the Steering Committee (either at the first Steering Committee meeting or by email). The Scheme Organiser will contact the Chairman 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 (JWG). The Scheme Organiser will write to the laboratory informing them of the referral to NQAAP.

The following action will be taken by the Scheme Organiser if any English Neonatal Screening laboratory falls below the standards for Persistent Poor Performance described above:

The identity of the laboratory, the persistent poor performance status and the information that the laboratory has been referred to NQAAP will be disclosed to the Director of the UK Neonatal Screening Programme Centre by the Scheme Organiser. This will happen at the same time as the laboratory is referred 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/red status 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 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.

The Steering Committee will decide when the persistent poor performance/red status of the laboratory can be removed. The persistent poor performance will remain on record.

## **6 Notes**

**6.1** The UK NEQAS for Molecular Genetics Scheme Organiser will send the UK Newborn Screening Programme Centre Director copies all molecular blood spot EQA scheme reports as soon as they are published and declaring if any laboratory has been deemed a poor or persistent poor performer. Laboratory identities are not revealed in the scheme reports

**6.2** 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/UKAS accreditation as well as the obvious doubts that must arise about the quality of service to patients.

## 7 Associated Documentation

MF-NEQAS-PPChecklist	Checklist for monitoring poor performers
MF-NEQAS-PPOverview	Ongoing list of scheme poor performers
MP-NEQAS-PerformPGD	Procedure for monitoring performance standards for molecular Preimplantation Genetic Diagnosis EQA
MP-NEQAS-MRAPP	Procedure for monitoring performance standards for Molecular Rapid Aneuploidy EQA
MP-NEQAS-Performance	Procedure for monitoring performance standards for the general Molecular Genetics EQA scheme