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Document ControlVersion: **4.0**Document Authors: **Drs Sandi Deans & Ros Hastings**Date: **17th January 2011**Date of ratification by Steering Group(s): Molecular & Cytogenetic – **3rd March 2011**Date of agreement by NQAAP: **25th March 2011** Review Date: **25th March 2012****Poor Performance Criteria for the UKNEQAS Molecular Rapid Aneuploidy (MRA)
External Quality Assessment (EQA) scheme**

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 Organiser to monitor the performance of all UK NEQAS for Clinical Cytogenetics 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 Organiser 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.

As a consequence of the UK Joint Working Group for Quality Assurance 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/Joint Working Group for Quality Assurance (JWG) action as defined by the JWG are classed as "black".

Poor performance (amber status) is defined as follows:

In any one round of EQA, when 3 clinical cases are assessed.

Genotyping: Scoring less than 1.6 as a mean genotyping score for an EQA round.

Interpretation: Scoring less than 0.7 times the mean score for an EQA round.

The mean score will be calculated from all participating laboratories' interpretation scores to two decimal places. Individual participants' scores will be calculated precisely.

Clerical Accuracy: This category of marking will not contribute towards poor performance.

When a serious genotyping error is identified the Scheme Organiser will contact the participant as soon as the error comes to light (normally within 10 working days of the error being confirmed by the Scheme Assessors). In this way it is intended that any consequences of the laboratory error will be rectified without delay.

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Incorrect advice given, correct advice not given

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

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 CPA (UK) Ltd/UKAS Medical Laboratory accreditation. Non-registration by an UK laboratory for a disease EQA scheme for any test/disease offered as a clinical service by the laboratory in any round of EQA in which that test/disease is offered will be deemed Poor Performance for that test/disease in that year. This will apply irrespective of previous performance scores for that disease. 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. The Scheme Organiser will follow up any non-registration of previous participants.

If a laboratory (UK and 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.

Action following poor performing UK laboratory (amber status)

Once the scores for the EQA round have been finalised by all the Scheme Assessors, then the appropriate Scheme Organiser 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 Organiser will contact the participant informing them of their error, their laboratory's poor performance/amber status and request that the cause of any genotyping error is investigated. The laboratory is given a defined period (determined as reasonable by the Scheme Organiser, normally 15 working days) in which to respond to the Scheme Organiser with the cause of the error.

Genotyping poor performance will result in the distribution of an extra round of EQA. These distributions are designed to address the particular issue(s) that were identified during the previous EQA round(s). If performance from these additional rounds is satisfactory, conditions of participation will revert to those of other laboratories in the Scheme (i.e. no longer an active poor performance), although the poor performance categorisation will remain on record. If performance in these additional EQA rounds is poor, i.e. there are critical errors or omissions, then the laboratory will be designated a **persistent poor performer** and will be referred to NQAAP (see below).

Interpretation poor performance will result, if appropriate, in an extra round of EQA designed to target the specific laboratory problem (e.g. calculation errors) will be provided.

Action following poor performing non-UK laboratory (amber status)

Once the scores for the EQA round have been finalised by all the Scheme Assessors, then the appropriate Scheme Organiser 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 Organiser will contact the participant informing them of their error, their laboratory's poor performance/amber status and request

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that the cause of any genotyping error is investigated. Depending on the type of 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, normally 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.

No extra rounds of EQA are provided for non-UK 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.

Persistent Poor Performance (Red status) will be defined as:

Those participants who perform poorly in **two** out of any **three** consecutive EQA rounds.

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 Organiser. 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 Organiser, 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 Organisers and the Steering Committees.

Action following identification of a persistent poor performing (red status) 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 both Steering Committees by email. The appropriate 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 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

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such as CPA (UK) Ltd, and 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.

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 NQAAP-Genetics will notify the Scheme Organiser when the active persistent poor performance/red status of the laboratory can be removed. The persistent poor performance will remain on record.

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 both Steering Committees by email. The appropriate 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 both Steering Committees by email. The identity of the laboratory will not be disclosed to the Steering Committees.

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

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