

Clinical Cytogenetics Scheme Organiser:

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Document ControlVersion: **3.0**Document Authors: **Drs Sandi Deans & Ros Hastings**Date: **12th August 2009**Date of ratification by Steering Group(s): Molecular & Cytogenetic – **September 2009**Date of agreement by NQAAP: **12th March 2010**Review Date: **October 2010****Poor Performance Criteria for the UKNEQAS Molecular Rapid Aneuploidy (MRA)
External Quality Assessment (EQA) scheme**

Poor performance in this scheme will be independent of performance in other EQA schemes, whether molecular or cytogenetics. Poor performance is defined as follows:
In any one round of EQA, when 3 clinical cases are assessed.

Genotyping: Scoring less than 1.6 on genotyping 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.

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

Participation 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, Cytogenetics EQA scheme and of CPA Laboratory accreditation. Non-participation for any referral category offered as a clinical service by the laboratory in any round of EQA in which that disease is offered will be deemed Poor Performance for that tissue/disease in that EQA in that year. This will apply irrespective of previous performance scores for that scheme. Laboratories will not be expected to continue participation for any referral category no longer offered as a clinical service but should inform the relevant EQA Scheme Organiser in writing when this occurs

Persistent Poor Performers will be defined as either

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

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Notes:

1. 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.
2. 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. A participant who has performed poorly for more than one disease/tissue in more than one QA 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.
3. A participant who falls below the standards described above, thereby incurring a poor performance score for that round of EQA, will be alerted to this fact in writing by the Scheme Organiser. The Scheme Organiser will do so in a timely manner following the publication of the final scores. The Scheme Organiser will inform the participant that a written timely response to the poor performance classification is required and will define a period of time in which a response is required. This period of time will be defined as appropriate to each case by the Scheme Organiser. 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.
4. Additional rounds of EQA samples may be distributed between the usual times at the discretion of the Steering Committee(s). These distributions will be designed to address specific problems that have arisen from the usual rounds of EQA with the intention of speeding up the process of identifying Persistent Poor Performance. These additional rounds of EQA will be designed to address the particular issues that were identified during the EQA round. Such additional rounds will be governed by all Conditions of Participation, criteria for identifying Persistent Poor Performance and other procedures of the UK NEQAS for Molecular Genetics or UKNEQAS for Cytogenetics as detailed in their participant manuals. Participation in these additional rounds of EQA may be limited to laboratories identified as poor performers in a previous round.
5. Once a laboratory reaches the criteria for Persistent Poor Performance the Scheme Organiser is obliged to notify the Genetics National Quality Assessment Advisory Panel (NQAAP). The identity of the laboratory will be revealed to the panel and the Joint Working Group. The Panel will consider the best approach to improve the situation and will contact the laboratory directly requesting a response by a specific date. If no response is received by this date or if the response to this is deemed unsatisfactory the Chair of the Advisory Panel will write directly to the Head of Department or Chief Executive (if appropriate). If all of these measures fail the Chair of the Panel may request a visit to the laboratory by two Panel members. If no resolution can be achieved by these measures NQAAP will approach the Joint Working Group for advice on how to proceed.

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