

## PROCEDURE TO ASSESS PERFORMANCE AND POOR PERFORMANCE IN THE CLINICAL CYTOGENETICS MICROARRAY SCHEME

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### **1 Performance Criteria**

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

A laboratory's performance is externally assessed by its response to validated test materials distributed by the EQA scheme (including DNA). Performance is assessed in terms of analytical and interpretative achievement.

The Scheme produces a specific set of performance criteria (assessment objectives) for each EQA round. These criteria identify errors or omissions that are "**critical**", *i.e.* could lead to serious clinical consequences and therefore imply a significant lack of diagnostic skill or scientific knowledge and also errors or omissions that are "**non-critical**", *i.e.* may not have serious clinical consequences but still imply a lack of diagnostic skill or scientific knowledge. The measurement of performance will typically take the form of penalty points, *e.g.* -0.2, -0.5, -1.0 or -2.0, which reflect the scale of error or omission. All **Critical errors** are given 2 penalty points. The performance criteria will reflect the expectations of current professional and best practice guidelines (UK or European guidelines, as relevant) and ISO standards, if applicable.

Clerical errors are noted but do not attract penalty points unless they contribute to an error that is deemed "critical" or "non-critical".

#### **1.1 Analytical Performance**

Analytical considerations might include: undertaking insufficient analysis for the reason for referral, missing or incorrectly identifying an abnormality misinterpreting a benign variation, inaccurate size range given, inappropriate platform used, ISCN errors (major, which could affect interpretation; or minor errors), failure to provide a written description of the results, or failure to supply the practical resolution of platform.

#### **1.2 Interpretative Performance**

Interpretative considerations might include: failure to interpret the results correctly (which might include over-interpretation or making inappropriate conclusions based on the material available), failure to provide a correct clinical interpretation of the microarray findings (*e.g.* incorrect syndrome, or failure to consider an alternative interpretation), failure to include appropriate clinical advice or the provision of inaccurate advice (*e.g.* for onward referral, requests for parental bloods or confirmatory tissue, or inappropriate recurrence risk), or a report which is ambiguous or potentially misleading or dangerously erroneous.

The interpretation of a case is not scored if the analysis of a case falls below the standards set.

#### **1.3 "Non-Critical" errors identified in performance**

Errors and omissions are categorised as “non-critical” if they are unlikely to have serious clinical consequences, but still imply a lack of diagnostic skill or scientific knowledge. These errors/omissions usually incur penalties but not of the severity of a critical error (2 penalty points).

## 1.4 Appeals

There is an appeals procedure if the laboratory disagrees with their performance score. This is described in the documentation that accompanies the individual laboratory reports. The laboratory must appeal to the Scheme Organiser within three weeks of receipt of their individual laboratory report and include all supporting documentation with the appeal. The Steering Committee will review any appeals and make a final decision. The appeals process can take up to two months. The Scheme Organiser will write to the Head of Department with the outcome of the appeal as quickly as possible.

## 2 Performance Classification

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.

As 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”.

## 2. Definition of Poor Performance (amber status)

### 2.1.1 “Critical” errors identified in performance

**Errors and omissions are categorised as “critical” if they could have serious clinical consequences, and/or imply a significant lack of diagnostic skill or scientific knowledge (See Section 1).** Critical errors will be reviewed and agreed by the Steering Committee. One or more **critical** errors in any EQA round will normally result in a **poor performance** designation.

When a genotyping error of clinical significance to patient management is identified from a laboratory’s EQA submission, and confirmed by the assessors, the Scheme Organiser will inform that laboratory as soon as is practical. In this way it is intended that any consequences of the laboratory error will be rectified without delay.

A poor performance will be notified to the laboratory in its individual laboratory report. All the individual laboratory reports are issued simultaneously on completion of a particular EQA round. There is an appeals procedure if the laboratory disagrees with their poor performance designation (Section 1.4).

#### 2.1.1.1 Action for UK laboratories following a critical error (poor performance- amber status)

Normally the process for a critical error will involve additional EQA material distributed to, or requested from, the laboratory. 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 for 36 months. 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 Section 2.2).

#### 2.1.1.2 Action for non-UK laboratories following a critical error (poor performance- amber status)

The Scheme Organiser will initially contact the Head of the Department when his/her laboratory has a poor performance round informing them of their error, their laboratory’s poor performance (amber status) and

request that the cause of the analytical error is investigated, to discuss the performance issue, offering support and explaining the next steps in the assessment process. At this point the laboratory may feel confident about addressing the problem internally, but help and advice will be available on request. The Scheme Organiser will not reveal the identity of the laboratory to those providing such assistance unless the laboratory has specifically given permission to do so.

### **2.1.2 Non-Registration**

Registration in each EQA round for all referral categories/diseases offered as a clinical service is a requirement of the Cytogenetics EQA scheme. EQA participation is also a requirement CPA (UK) Ltd/UKAS Medical Laboratory accreditation and OECD guidelines. The Scheme Organiser will follow up any non-registration of previous participants. Non-registration for the microarray EQA scheme when offered as a clinical service by a UK laboratory will be deemed **poor performance** for that year unless an admissible reason is given. This will apply irrespective of previous performance scores for this EQA.

Laboratories will not be expected to continue participation for this EQA if it is 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.

### **2.1.3 Non-Participation**

If a UK or non-UK laboratory 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 performance** due to non-participation.

Late submissions online of data where no reasonable explanation has been communicated **beforehand** to the Scheme Organiser will also constitute **poor performance** for that distribution and any documentation submitted via the post will also be returned.

### **2.1.4 Non-Compliance**

UK and non-UK laboratories will be expected to respond to a poor performance notification sent by the Scheme Organiser, whether this is the completion of additional EQA rounds, or a recommendation to review the laboratory analytical or report procedures – laboratories will be normally given 15 working days to respond. If a laboratory fails to complete the additional EQA rounds, this will trigger a persistent poor performance designation. If the laboratory receives a recommendation to review their analytical or reporting policy but fails to inform the Scheme Organiser about what changes have been made, this will trigger a further poor performance.

A laboratory is expected to respond to any significant recommendations given in the final post appeals EQA report. Three or more warnings for the same omission/oversight within an EQA round within a 36 month rolling period will normally result in a **poor performance** designation.

If any participant has fallen below the acceptable performance standard described in this document for analysis 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 analysis 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, usually 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.

## **2.2 Definition of Persistent Poor Performance (red status)**

This is defined as:

- a) Three poor performances in any microarray EQA in which the laboratory participates, over 3 or more distributions of material, within a 36 month rolling period;
- b) Poor performance in an additional EQA distribution made to a UK laboratory because of a poor performance designation (see Section 2.1.1.1);
- c) A poor performance within one year following a previous persistent poor performance designation.

Route (b) aims to identify a persistent problem in a specific aspect of service very quickly; and route (c) aims to identify any recurrence of a problem quickly.

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 EQA scheme and between the constitutional, haematology-oncology, microarray and MRA 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 Cytogenetics Steering Committee.

Persistent poor performance is ratified by the Steering Committee.

### **2.2.1 Action following identification of a persistent poor performing UK laboratory - Intervention by the National Quality Assurance Advisory Panel (NQAAP)**

This will only happen in cases of persistent poor performance (see Section 2.2 and notes). Once a UK laboratory reaches the criteria for a persistent poor performance, the Scheme Organiser is obliged to notify NQAAP (Genetics).

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

NQAAP may request copies of the laboratory's reports, or standard operating procedures, for review; in which case, a team of assessors will examine these documents, and make recommendations about their accuracy, completeness, suitability and/or effectiveness to the Steering Committee; which in turn will report its considered conclusions to NQAAP via the Scheme Organiser.

All cases of persistent poor performance are also reported by the NQAAP Chair to the Joint Working Group on Quality Assurance (JWG). This is for information only and the identity of the laboratory will remain confidential to members of the JWG.

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.

### **2.2.2 Action following identification of a persistent poor performing non-UK laboratory**

Once a non-UK laboratory reaches the criteria for Persistent Poor Performance (see Section 2.2) the Scheme Organiser will obtain ratification of the persistent poor performance/red status by the Steering Committee 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 by email. The identity of the laboratory will not be disclosed to the Steering Committee.

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

### **2.3 Action for intervention by the Joint Working Group (black status) -UK labs only)**

If persistent poor performance remains unresolved or there is no response from the laboratory, 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 (black status) of the laboratory can be removed. The persistent poor performance will remain on record.

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**Notes:**

1. 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.
2. Abbreviations: EQA: External Quality Assessment; ISO: International Organisation for Standardization; NQAAP: National Quality Assurance Advisory Panel; UKAS: United Kingdom accreditation service; CPA: Clinical Pathology Accreditation; OECD: Organisation for economic co-operation and development.