**Brief guide to External Quality Assessment (EQA)** **unsatisfactory performance investigations**

There are a number of aspects that you should consider when performing an EQA unsatisfactory performance investigation:

* **All laboratories will occasionally have incidences of unsatisfactory performance in EQA**
* All incidences of unsatisfactory performance should be thoroughly investigated; investigations should be documented.
* All investigations should be reviewed by the departmental quality manager, departmental quality team (if one exists) and senior management team.
* Wherever possible all incidences of unsatisfactory performance should be classified to allow department/organisation wide trend analysis of EQA performance. Examples of classification might include:
  + Technical error, clerical error or problems with EQA programme
  + Pre analytical error, technical error, analytical error, post analytical error
* Please return this form within **14** days. If you have not completed your investigations in the allotted time please contact UKNEQAS for Leucocyte Immunophenotyping (UK NEQAS LI).
* If more time is required to complete your investigation, please contact UK NEQAS LI.
* For UK laboratories, EQA unsatisfactory performance forms will be provided to the relevant National Quality Assessment Advisory Panel (NQAAP) in cases of persistent unsatisfactory performance (see performance monitoring guides on our website for a definition of persistent unsatisfactory performance).
* Non return of EQA unsatisfactory performance forms will be reported to the relevant National Quality Assessment Advisory Panel (NQAAP) in circumstances of persistent unsatisfactory performance.
* Whilst UKNEQAS LI will review root cause analysis forms and may provide feedback, where appropriate, we are unable to classify the investigation as sufficient or otherwise.
* This document is only intended as a guide. Please supplement this document with any additional findings supported by as much objective data/evidence as possible. Please feel free to amend this document as you wish.

|  |  |
| --- | --- |
| Participant ID e.g. five-digit number beginning with 4 e.g. 40823 |  |

**1.0 External Quality Assessment Unsatisfactory Performance Form**

|  |  |  |
| --- | --- | --- |
| Investigation performed by, position: e.g. Joe Bloggs, Clinical Scientist |  | DD MM YYYY |
| **EQA Programme:** e.g**.** BCR-ABL1 Major Quantification or Low Level Leucocytes |  | |
| **Trial Issue:**  e.g. BCRQ 151601 or CD34 151601 |  | |
| Measurand: e.g. *BCR-ABL1* orLymphocyte subsets |  | |
| EQA sample type: e.g. lyophilised or stabilised blood |  | |
| Details of Method used: e.g. template, PCR type, analysis type, software or Flow cytometry |  | |
| Your laboratory’s result(s): e.g. Log Reduction = 0.40 or Absolute count =  3.25 cells/µL |  | |
| Acceptable result/ range: e.g. Log reduction between -0.20 and +0.20 or Robust mean = 54.98 cells/µL, Robust SD= 5.59 cells/µL |  | |
| Performance classification: e.g. Satisfactory, Action or Critical |  | |
| How relevant is the EQA scheme compared to the routine analysis performed by your laboratory e.g. Are matrix, marker and concentration level what you would expect clinically? | | |
|  | | |
| Do your laboratory’s result(s) in previous trial issue(s) in this EQA programme indicate a questionable or unsatisfactory trend? If yes, analysis of this trend should be provided: | | |
|  | | |

# 2. Initial Investigation (please tick as appropriate)

|  |  |  |
| --- | --- | --- |
| Was the EQA sample received in a satisfactory condition? | Yes | No |
|  |  |
| If no, please provide details. Could this condition explain the poor result? (e.g. vial was smashed and nucleic acid quality was compromised or plastic tube was broken and blood was spilled) | | |
|  | | |
| Was the EQA sample equivalent to a routine sample? YES NO | Yes | No |
|  |  |
| If no, please provide details. Could this explain the poor result? | | |
|  | | |
| Was the EQA sample tested as a routine sample? Including application of standard operating procedures, meeting local QC. YES NO | Yes | No |
|  |  |
| If no, could this be the cause for the poor result? | | |
|  | | |
| Is the EQA report evaluation based on results grouped according to method? | Yes | No |
|  |  |
| If yes, can this explain the poor result? | | |
|  | | |
| Based on the comments given above, should the relevancy of the EQA scheme be reviewed? | Yes | No |
|  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Was the initial EQA sample reanalysed after receipt of the related EQA report? | Yes | No |
|  |  |
| If yes, is the result comparable to your original result? | | |
|  | | |
| Was a repeat sample requested and reanalysed? YES NO | Yes | No |
|  |  |
| If yes, is the result comparable to your original result? | | |
|  | | |

**3. Clerical Investigation** (please tick as appropriate)

Typical clerical errors can be for example: transcription errors, data entry errors, EQA provider not informed of method change, incorrect units used.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Was the poor result due to a clerical error? | | |  | Yes | No | |
|  |  | |
| If yes, please describe the error: |  | | | | | |
| Corrected result: |  | | | | | |
| Is this result still questionable or unsatisfactory? If yes, the investigation should be continued. Go to section 4. If no, go to section 5. | | Yes | | | | No |
|  | | | |  |

# 4. Technical Investigation

The following aspects should be taken into consideration:

|  |
| --- |
| Analytical procedure e.g. were the reagents within expiration date? Was the correct procedure(s) followed? Was this in line with current national and/or international guidelines, where available? |
|  |
| Is test performed in line with manufacturers’ recommended methods, where available? If not, has the test been validated locally to ensure fitness for purpose? |
|  |
| Internal quality controls e.g. were the correct controls used in line with local, national and international guidelines. Please provide a summary of IQC results, where possible (attach charts etc). |
|  |
| Storage/preparation of the EQA item e.g. was adequate instruction provided with EQA sample(s)? Were instructions adhered to? |
|  |
| Equipment e.g. was **ALL** equipment used to process the EQA sample(s) adequately validated, maintained and operational (including both hardware and software)? |
|  |
| Environmental conditions e.g. were there any environmental conditions that may have adversely affected sample processing. |
|  |
| Training records, competency and authorisation e.g. Were operator(s) training records/competency complete? Was the appropriate authorisation performed? |
|  |
| EQA Procedures e.g. were specific procedures and competencies in place to process EQA samples? |
|  |
| Conclusion |
|  |

**5.0 Corrective/Preventative Actions and follow up review**

|  |  |  |  |
| --- | --- | --- | --- |
| What possible clinical impact is there on past and future routine results? | | | |
|  | | | |
| What procedures have been implemented to prevent reoccurrence of the performance issue(s)? e.g. issue corrected results for EQA or patient samples/ training of staff/ dissemination of knowledge/ SOP changes etc. | | | |
|  | | | |
| What procedures will be used to review performance to ensure your corrective actions have been successful? e.g. audit | | | |
|  | | | |
| FINAL CLASSIFICATION  e.g. Pre analytical error |  |  | |
| Laboratory Manager |  | sign | DD/MM/YYYY |
| Email address |  | | |
| Phone number |  | | |
| Quality Manager |  | sign | DD/MM/YYYY |
| Email address |  |  |  |
| Phone number |  | | |
| Logged in departmental quality management system? | Yes | | No |
|  | |  |
| DATIX/CAPA Reference Number, if applicable |  | | |
| Current accreditation body and status |  | | |
| Discussed at departmental quality/senior management meeting: | | | DD/MM/YYYY |
| Outcome: | | | |
|  | | | |