BMS EQA Scheme Protocol

Contents

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1. Scope

The following guidance is given for the general operation of BMS Micro's EQA Schemes. The aim of the protocol is to provide information of the structure, operation, reporting and assessment criteria of the overall EQA Schemes and shall be available to participating laboratories in a form which is easy to follow.

2. Participation

2.1 BMS Micro's EQA Schemes are open to all laboratories actively engaging in clinical diagnostic microbiology. Participating laboratories may be public laboratories or private laboratories. Application and enquiries to register interest in an EQA Scheme can be through the contact form on the 'contact us' section on the BMS Micro website, a general email to info@bmsmicro.com or email a BMS Micro personnel. Details required when registering interest include details of the main contact for the participant, the full address of the laboratory for delivery of samples, EQA Schemes of interest and any additional contacts to be included in correspondence.

2.2 An initial complimentary trial of a maximum of 2 EQA Schemes may be available at BMS Micro's discretion from the next scheduled Scheme Distribution. A trial sample is offered to allow potential participants to experience the full process of an EQA Scheme from start to finishing including the final report to ensure the EQA Scheme fits the participants required purpose.

2.3 Participants shall be made aware that samples distributed in BMS Micro EQA Schemes may contain microbiological pathogens listed in Hazard Groups 1 and 2 as specified in The Approved List of Biological Agents, HSE, MISC208, Rev 4, 2021. Participants shall ensure that their laboratory facilities and technical expertise are sufficient to ensure safe handling of samples received from BMS Micro EQA Scheme Distributions.

2.4 BMS Micro's EQA Schemes operate on an annual basis from January through to December each year. Participants may enrol on an EQA Scheme at any time through the year and may elect to withdraw from the EQA Scheme(s) with a notice period of two weeks before the distribution date as stated on the 1022 QSREC EQA Participant Schedule.

2.5 A legal framework for Terms and Conditions is available on request.

2.6 At the time of publication of this document, BMS Micro has sent correspondence to the National Quality Assurance Advisory Panel (NQAAP), which is a committee under the Royal College of Pathologists regarding membership. Terms of Reference WS10904 (c) 2023. As such, any matters of performance arising from participation in a BMS Micro EQA Scheme is restricted between the Participant, BMS Micro, from where advice may be sought by the participant and any third party that the Participant wishes.

3. Confidentiality

3.1 The identity of participants in BMS Micro EQA Schemes shall be confidential and known only to authorised personnel at BMS Micro who are directly involved in the operation of the EQA Scheme.

3.2 Participants shall be identified in reports and other areas by means of a Laboratory Identification Number. Laboratory ID numbers are allocated by BMS Micro and are not normally changed.

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Participating laboratories may request that their Laboratory ID number be changed where there is a valid reason to do so, such requests would be at the discretion of BMS Micro.

3.3 Participants can elect to waive confidentiality within an BMS Micro EQA Scheme for the purposes of discussions and/or mutual assistance, for example, to improve performance or where more than one laboratory exists within a Hospital Trust. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In most instances, the proficiency testing results can be provided to the relevant authority by the participants themselves.

3.4 When an interested party requires the EQA Scheme results to be directly provided by BMS Micro, the participants shall be made aware of the arrangement in advance of participation.

3.5 In exceptional circumstances, when a regulatory authority requires EQA Scheme results to be directly provided to the authority by BMS Micro, the affected participants shall be notified of this action in writing in advance.

4. EQA Schemes

For information on all BMS EQA Schemes available please 1030 QSREC EQA Key Dates document or the EQA page on the BMS Micro website: www.bmsmicro.com.

4. 1. Transportation

4.1.1 The time taken for the delivery of EQA Scheme samples to the participant delivery address is a key performance indictor. The target for delivery partners is set at 100% deliveries complete within 24 hours of distribution. Delivery partners are carefully and performance is monitored against delivery timescales. All transportation of EQA Scheme samples is monitored until delivery or declared as lost by the delivery partner.

4.1.2 All deliveries are distributed in accordance with ICAO Technical Instructions and the IATA Dangerous Goods Regulations (DGR) for the transport of UN3373 Biological substance, Category B. All members of BMS Micro who are actively involved in the preparation and packaging of EQA Scheme samples are required to hold valid training certificates on IATA “Dangerous Goods UN3733 Biological Substances by Air and Road”.

4.1.3 All samples have been validated against delivery timescales, including temperature profiling. We are grateful to laboratories who have assisted in this regard by returning temperature logging devices included in packaging. Temperature monitoring during transport of samples is a continual process.

4.1.4 Where any significant failures in transport are found, this includes inclement weather situations, then samples adversely affected will be repeated at the next available opportunity. This may include re-running an EQA Scheme Distribution entirely. Under circumstances of repeat sample deliveries then the cost of this will be met by BMS Micro, participants will not be required to pay additional fees.

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5. Submission of Results

5.1 Participants may submit more than one set of results without prior reference to BMS Micro. Multiple results may be submitted for example by using more than one appropriate method or from more than one member of the technical staff where competency or training evidence is being gathered.

5.2 At present participants are asked to submit results via e-mail to results@bmsmicro.com using the electronic or Word version of the Analysis Request Form by 11:59 pm on the deadline for the submission of results. Any results submitted after the deadline will be dealt with on a case-by-case basis by BMS Micro.

5.3 Once results have been submitted, participants are unable to amend or alter their results.

6. Potential Major Sources of Error

6.1 Participant laboratories accredited to ISO 15189:2022 Medical laboratories – Requirements for quality and competence are well served to be aware of potential major sources of error. For this reason, BMS Micro proposes not to detail this point for each of the EQA schemes.

7. Collusion or Falsification of Results

7.1 Collusion between laboratories or falsification of results is not permitted.

7.2 Preventing collusion between participants or falsification of results is not easily achieved other than to state that both are against the principles and benefits of properly executed EQA Schemes and against the best interests of participants.

7.3 Should BMS Micro suspects collusion between laboratories, a review of the laboratory's participation in EQA Schemes should be complete. Where evidence is found and substantiated, the initial course of action would be a written statement to the participants suspected of collusion and may lead to the potential suspension of participation in future EQA Schemes.

7.4 Should BMS Micro suspect falsification of results and where such evidence is substantiated then the initial course of action would be a written statement to the participants suspected of collusion and may lead to the potential suspension of participation in future EQA Schemes.

8. Information Supplied to Participants

8.1 All participants are supplied with the 1022 QSREC EQA Participant Schedule which provides participants with the contact details BMS Micro holds on records for the main contact, additional contacts, delivery address for EQA Scheme samples, EQA Schemes enrolled and Distribution dates.

8.2 Participant will have access to the 1026 QSEPT BMS EQA Scheme Protocol and the 1030 QSREC EQA Key Dates document. Both documents are available on the BMS Micro website: www.bmsmicro.com.

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8.3 Information on methods or procedures which participants shall use to store, handle, prepare and dispose of EQA Scheme samples as well as methods to be used to perform the tests requested are provided on the individual EQA Scheme Distribution Analysis Request Form.

9. Key Dates

9.1 Document 1030 QSREC titled Key Dates is available to all participants. The document covers a one-year period from January to December and for each EQA Scheme details the following information:

- EQA Code
- EQA Scheme description
- Number of distributions per year
- Number of samples per distribution
- Distribution number
- Sample numbers
- Scheduled date for despatch of samples
- Date for start of analysis
- Date for return of results
- Estimated date for issue of final report
- Key comments relevant to the round

10. Reporting and Assessment of Results

10.1 There is no prescribed rigid standard reporting format. Laboratories are asked to report their results in the way they would normally using a supplied Analysis Request Form.

10.2 There are currently two EQA schemes where reporting of WBCs is requested, these are Urine analysis and CSF analysis. In these Schemes the assessment of results is made by calculating a z-score. The z-score is a robust statistical method to determine how close and individual result is to the assigned value. The assigned value is taken from the consensus median of all numerical results submitted following the omission of gross outliers.

The z-score calculation has the following formula:
z = ((Lab Result) – (Assigned Value (Taken from Consensus Median)) / Target Std Deviation

The z score calculation has the following interpretation:
z = 0.00 to +/- 2.00 Satisfactory (95% normally distributed results)
z = +/- 2.00 to 3.00 Questionable (warning signal) (5% normally distributed results)
z = >+/- 3.00 Unsatisfactory (action signal) (<0.3% normally distributed results)
Participant results that are reported as a range, for example “0 – 10”, as less than “<” or greater than, “>”, or as “text” are excluded from each data set.

10.3 Assigned values for results submitted are normally based on consensus of reports submitted or on formulation where a particular organism is present by addition. Details of how the assigned value is arrived at are given in the summary reports submitted to all participants following each distribution.

10.4 Where different methods are possible and allowed to conduct the analysis in question this information will be given on the Analysis Request Form. There is no assessment or treatment

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difference given in the summary reports where different methods are permitted for analysis of samples in the EQA scheme.

10.4 Criteria for the evaluation of the performance of participants is given in individual EQA Scheme Assessment Criteria. A copy of the Assessment Criteria for an EQA Scheme is available from BMS Micro on request and is provided in each of the summary reports submitted to participants following each EQA Scheme Distribution.

10.5 Final EQA Reports are only released to participants enrolled on the EQA Scheme Distribution. No third party is involved in the receipt of the final EQA Report.

10.6 Participants are free to contact BMS Micro at any time should it be felt that an assessment has been wrongly attributed to EQA results submitted. All appeals and reassessment requests will be investigated by BMS Micro at a senior level and without delay. Issues for investigation are recorded fully and replies to appeals and reassessment requests are open to scrutiny. Where any issues remain unresolved, participants may elect to enter the complaint's procedure by submitting a Participant Complaints Form which is available on the BMS Micro website: www.bmsmicro.com to complaints@bmsmicro.com.

10.7 A continuous assessment method is under development where participants will be scored on successive EQA rounds and individual cumulative EQA assessment data covering a twelve-month period will be available to all participants. All participants will be notified separately as development progress allows.

11. References

11.1 ISO/IEC 17043:2023 Conformity assessment – General requirements for the competence of proficiency testing providers.

11.2 ISO 15189:2022 Medical laboratories – Requirements for quality and competence

11.3 ISO 13528:2022 Statistical methods for use in proficiency testing by interlaboratory comparison

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