General Terms and Conditions for the Participation in External Quality Assessment Surveys of ESfEQA

Status April 2022

1. Participation

The participation in the external quality assessment (EQA) surveys of ESfEQA is open to anyone who performs laboratory tests in their own practice or in a managed medical laboratory. The following conditions for participation apply.

2. Consent to conditions of participation

By registering with ESfEQA GmbH, the participant agrees to these general terms and conditions of participation.

3. Assignment of services

Individual parts of EQA schemes (e.g. pretesting of values, packaging and shipping) may be assigned to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA catalog

The ESfEQA portfolio of offered EQA schemes and the analytes contained in the individual programs are described in the ESfEQA catalog. Depending on the availability of samples and the number of participants ESfEQA reserves the right, not to offer the entire spectrum of analytes for each EQA survey or sample.

5. Schedule

The schedule is published in the catalog and on the ESfEQA website. It contains the deadlines for ordering, the testing period, and the deadline for result submission. After the deadline for ordering there is no entitlement for the acceptance of orders. Results have to be submitted to ESfEQA electronically or by fax-form until the closing date. The calendar date refers to the time zone at the place of business of ESfEQA in Heidelberg, Germany (GMT +1).

6. Cancelation of EQA surveys

ESfEQA reserves the right to cancel or postpone EQA surveys. This information will be provided to participants before the originally planned shipping date of the samples. In this case, ESfEQA tries to offer an alternative date in a timely manner.

7. Registration

For the participation in ESfEQA EQA surveys a registration is required. This can be done online, or the necessary information can be provided to ESfEQA in written form. The following information is required: laboratory name, name of the organization/hospital, name of participant, number of analytical devices, and e-mail address.

8. Ordering of samples.

The distribution of ESfEQA EQA surveys is usually carried out by international distributors. If there is no distributor available in the participant's region, sales can be carried out directly by ESfEQA. The ordering process between participants and distributors is the responsibility of the parties involved. As a rule, an EQA programme is ordered for a full calendar year. Orders placed during the year generally include the survey samples up to the end of the current calendar year.

9. Homogeneity and stability of EQA samples

The EQA survey samples selected by ESfEQA were examined and evaluated with regard to homogeneity and stability.

10. Designation of EQA samples

The EQA samples can be distinguished by their identifier. The identifier consists of the short name of the program, the year of the survey, the survey number and an index, when several samples are provided in a single survey. Thus, the sample with the labeling CM4_2022_01_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2022 and is sample “a” of the first survey. Samples with the same designation are not necessarily identical, i. e. different results can be measured de-

spite the same designation. ESfEQA makes the correct allocation to the original batch and thus to the target values.

11. Shipping of EQA samples

Shipping of the EQA samples takes place by postal or parcel service. Due to governmental restrictions, or insufficient stability, sample shipping of individual EQA programs to specific countries may be excluded.

12. Instructions for Use

Instructions for Use are provided to the participants for each EQA survey on the ESfEQA website (www.esfeqa.eu). A printout of the Instructions for Use is usually enclosed with the sample package. The Instructions for Use include instructions for the preparation of the samples, sample stability and the deadline for submission of results.

13. Use of EQA samples

Usually, EQA samples are to be handled like patient samples and measured in the same way as routine samples according to the instructions of the instrument and reagent manufacturers. They may only be used for the purpose of participating in an EQA survey and may not be used in a misappropriated manner. Generally, the usual precautions in the laboratory for potentially hazardous and potentially infectious samples apply to EQA samples.

14. Submission of survey results

Where applicable the submission of the results includes, in addition to the actual measured value, the indication of the method used, the instrument used and the reagent used. The input mask in the evaluation software application TEQA used by ESfEQA predetermines the required information for each EQA program. A list of methods, instruments and reagents is provided in the configuration section.

If the method, instrument or reagent used for the measurement by the participant is not included in this selection list, participants may add their method, instrument or reagent to this list through the input mask “coding request”. They can then select their added method, instrument and reagent to complete their configuration prior to entering their test results.

The selection of method, instrument and reagent as well as the submission of results are to be transmitted through the web-application TEQA. Participants receive the login data required for the entry of results from ESfEQA. The password consists of at least 8 characters, of which at least 2 are special characters. Username and password are to be treated confidentially by the participant.

As alternative to the result submission via the web-application TEQA, results can be submitted using forms, that can be sent to ESfEQA either by E-Mail (info@esfeqa.eu) or Fax (+49 6221 894669-90). The corresponding forms that are specific for each EQA program and survey are provided on the ESfEQA website. ESfEQA encourages the participants to submit their results online via the secured TEQA web application for the sake of data security and convenience.

ESfEQA evaluates all survey results that are submitted by the participants in due time. For loss or late arrival of their data the participant bears the risk. There is no claim for data assessment of test results arrived late.

Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. In general, result should be reported as measured, however, results specified “< test range’ (e.g. “< 10”) and “> test range” (e.g. “>2000“) are not valid. If the analyzer system displays such results, they shall be interpreted as follows: for results below the test range, the lower test range limit should be reported (e.g. “10”). For samples that have analyte concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit (e.g. “2000”) can be reported as the result. Several units are usually available for entering quantitative results. The units are converted into the standard unit used by ESfEQA.

Laboratories are obliged to treat their results confidentially and not to pass them on to third parties until the EQA survey report has been received. If ESfEQA becomes aware of the passing on or falsification of results or the collusion between participants, ESfEQA reserves the right to exclude those concerned from further participation in EQA surveys conducted by ESfEQA as well as to exclude the

issuance of reports.

15. Number of results per participant

For each EQA sample and analyte, up to 3 values per participant can be submitted. The values have to be determined by different analytical devices that are independent from each other.

16. Correction of transmitted results

Once the results have been submitted via the web-application TEQA and the participant realizes any need for changing the results, the participant can submit a change request via the TEQA web application. This option exists until the deadline of result submission of the particular survey. ESfEQA may change the participant results after checking and accepting the change request. A change request for results submitted by participants via the fax form can be sent to ESfEQA by e-mail or fax until the deadline or result submission. Participants who have submitted their results via the TEQA web application have to use the change request function in TEQA for any change request.

17. Evaluation of EQA results

For each analyte of ESfEQA EQA surveys, the type of target value determination and the acceptance criterion are predefined in advance. For quantitative parameters, the target value is usually the consensus value of the participant results. This value is calculated according to ISO/IEC 13528:2020-09' Statistical methods for use in proficiency testing by interlaboratory comparisons' using robust statistics.
Samples provided for testing of qualitative parameters are thoroughly tested with different analytical systems before being used as control material, thereby setting the target value.
System-specific differences are taken into account where appropriate and possible. The broadest possible distinction is made according to the method, instrument and reagent used (M, I, R group). The minimum number of results of an evaluation group is 5 values. If this number is not reached in the survey, the individual result has to be compared to the robust mean of the next larger group that can be evaluated. Usually, this is the group consisting of participants using the same method (M group) or the general group containing the results of all participants. The definition of the evaluation group is documented in the survey report.
The maximum permissible ranges of the target value of quantitatively determined analytes are defined in advance and can be retrieved from the ESfEQA website. The permissible range for each analyte is derived from its medical relevance as well as the reference interval. In the report display, the upper limit of the permissible range corresponds to a z-value of 3 and the lower limit to a z-value of -3.

18. Survey reports

In general, the participants will be provided with reports electronically via the TEQA web-application within 10 days for monthly programs and within three weeks for quarterly and semi-annual programs after the deadline for submission of the results. The reports include the results submitted by the participant and their assessment compared to the target values. The data is displayed both in tabular and illustrated form (e. g. Histogram, Shewart chart, Youden plot). The reports are intended for external quality assurance of laboratories. They may not be published, passed on or used for purposes other than quality assurance without the written consent of ESfEQA.

19. Fees

The fees for the participation are set and communicated to the participants by the responsible distributor of ESfEQA programs in their geographical area/country.

20. Certificates

Participants receive a certificate of participation for each EQA program they participate in.
In addition, the participants receive a certificate for the parameters for which they have met the specified performance criteria in the respective EQA survey. Both certificates are made available to the participants via the TEQA web-application. The certificates are issued simultaneously with the reports.

21. Loss and damage of EQA test material

In the event of loss of or damage to the sample material, ESfEQA shall, if possible and to the extent that an immediate complaint has been made, replace the sample material by sending replacement samples without acknowledging any claims. However, the contract is fulfilled on the date of dispatch of the original sample material.

22. Complaints and Objections

After receipt of an EQA survey report, a complaint or objection can be made within a period of 4 weeks. After expiry of this period, any claims by the participant on the basis of a complaint and objection are excluded. In the event of a justified complaint/objection, there is a claim for reimbursement of the amount paid for the EQA survey or for the conduction of a substitute EQA survey. It is for ESfEQA to decide on one of these two options. ESfEQA GmbH does not reimburse any costs incurred for reagents, time expenditure etc. unless ESfEQA GmbH is liable in accordance with paragraph 23 of these General Terms and Conditions for Participation.

23. Warranty

ESfEQA shall only be liable for damages of any kind in the case of intent and gross negligence, if the other prerequisites for claims are met. In all other respects, liability for damages of any kind, regardless of the basis of the claim, including liability for culpa in contrahendo, is excluded.

24. Confidentiality

Individual EQA data is kept confidential. It is only known to the corresponding participant, their distributor and ESfEQA employees. ESfEQA collects, processes and uses personal data of the participant only to the extent necessary for the performance of EQA surveys, the preparation of the reports and for the purpose of quality assurance. This includes the forwarding of the data identifiable by subscriber and device number for quality assurance measures to the respective manufacturer of the analytical systems (device and reagent).

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