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

*Status September 2016*

1. **Participation**
   The participation in the external quality assessment (EQA) surveys of ESfEQA is possible for everyone who performs laboratory tests in their own practice or in a managed medical laboratory. The following conditions for participation apply.

2. **Consent to conditions for participation**
   Upon registration by ESfEQA GmbH, the participant is in agreement with these general terms for participation.

3. **Assignment of services**
   Individual parts for EQA (e.g. pretesting of values, packaging and shipping) can be assigned to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. **ESfEQA catalog**
   The portfolio of the EQA services offered by ESfEQA and the analytes contained in the individual programs are described in the ESfEQA catalog. According to the sample availability and the number of participants, ESfEQA reserves the right to not offer the complete analyte list for each EQA test sample.

5. **Schedule**
   The schedule is published in the catalog and on the homepage of ESfEQA. It contains the binding deadlines for ordering, registration, testing period, deadline for result submission and latest point of time for the creation of the record. After the deadline for ordering and registration there is no claim for the acceptance of late orders and registrations. After the deadline for result submission, no further test results are accepted. 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 EQA surveys or to defer. This is being told to the participants before the originally planned shipping date of the samples. In this case, ESfEQA tries to offer an appropriate alternative date.

7. **Registration**
   For the participation at the ESfEQA EQA surveys a registration is required. This can be completed online or the required information can be conveyed to ESfEQA in written form. The following information is required: laboratory name, name of the organization/hospital, name of participant, address, phone and fax number, and e-mail address.

8. **Ordering of samples**
   Sales for ESfEQA EQA surveys normally take place through international distributors. If there is no distributor at hand in the country of the participant, the distribution may take place directly through ESfEQA. The order transaction between participant and distributor is the responsibility of both parties. As a rule, an EQA program is ordered for an entire calendar year. Orders in the course of the year will in general include the survey samples until the end of the respective calendar year.

9. **Homogeneity and stability of the EQA samples**
   The EQA test samples chosen by ESfEQA were tested and evaluated in regard to homogeneity and stability. The homogeneity of the samples is specified as $s_s \leq 0{,}3$ SD with $s_s$ as inter-sample standard deviation and SD as the standard deviation of the proficiency test.

10. **Labeling of the EQA samples**
    The EQA samples are identifiable by their labeling. It consists of the short name of the program, the year of transmission, the run and a marker, when several samples are being used for a program and run. Thus, the sample with the labeling CM4_2016_01_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2016 and is sample “a” of the first transmission.

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**11. Shipping of EQA samples**

Shipping of the EQA samples takes place by postal or parcel service until the dates published in the catalog. Due to governmental restriction, or insufficient stability, the shipping of individual EQA programs in specific countries can be excluded.

**12. Instructions for Use**

Instructions for Use are provided to the participants for each EQA program on the ESfEQA homepage. They contain instructions and other information for the preparatory treatment of the samples, the stability of the sample and the deadline for result submission.

**13. Use of EQA samples**

EQA samples are to be handled like patient samples and should be measured similarly as routine samples according to the test instructions of the reagent manufacturer. They may be used only for the purpose of participation at an EQA survey and not for purposes other than intended. Generally, the usual precautions in the laboratory for potential hazardous samples apply for the EQA samples.

**14. Input of test results**

Input of the measured values by the participant includes, when necessary, not only the actual measuring value but also the method used, the instrument used and the reagent used. The input mask of ESfEQA predetermines the required information for each EQA program. A list for methods, instruments and reagents is provided on the result entry form.

If the method, instrument or reagent used for the measurement by the participant is not contained in the list, participants convey this to ESfEQA through the input mask. The participant can use his/her selected method, instrument and reagent information immediately for the input of his test results.

The choice of method, instrument and reagent and the input of the measuring values are conveyed through the web portal of ESfEQA. The participant receives the login-information required for the input from ESfEQA. The password consists of at least 8 characters, thereof at least 2 special characters. User name and password are to be kept in confidence by the participant.

Alternatively to the online input, the data can be put in by a form, that is sent to ESfEQA either by E-Mail (info@esfeqa.eu) or Fax (+49 6221 894669-90). The EQA program specific form is provided on the ESfEQA homepage.

All test results of the EQA participants conveyed in due time are assessed by ESfEQA. For the loss or the late arrival of his/her data the participant bears the risk. There is no claim for data assessment of test results arrived late.

Quantitative measuring values are generally specified with a value and a unit. The choice of the amount of specified digits is decided by the participant. Input of results as “< measurement range” or “< 100” are not allowed. If the analysis system shows such values, they are to be interpreted by the participant, e.g. as 0 or as specification of the value of the lower measurement range. For results above the measuring range the sample may be diluted (if that is recommended in the individual application) or shall be reported as the upper measurement range.

For the input of quantitative results, several units are normally available. The units are converted into the standard unit used by ESfEQA. This standard unit is also used for the creation of the records.

**15. Number of results per participant**

For each EQA sample and analyte, up to 3 values per participant can be entered. The values have to be determined by different, independent from each other, analytic systems.

**16. Correction of transmitted results**

After the input of the results into the web-input mask, a correction or change by the participant is no longer possible. If inaccurate values are recognized by the participant, (s)he can convey this to ESfEQA in written form specifying the reason up until the deadline for submission of the EQA survey. After verification and acceptance of the correction request, the result can be changed by ESfEQA. The same procedure applies for results submitted by e-mail and fax.

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**17. Evaluation of EQA results**

For each analyte measured in the EQA program the kind of determination of target value and the acceptance criteria are predetermined. For quantitative parameters the target value normally is the consensus value. This value is calculated according to ISO/IEC 13528:2005 ‚Statistical methods for use in proficiency testing by interlaboratory comparisons' by robust statistics.
Qualitative samples are being tested thoroughly with differing systems before the usage as EQA samples. Thereby the target value is determined.
As far as reasonable and possible, system specific differences are being considered. The differentiation to the greatest possible extent takes place according to the method used, instrument, and reagent (M,I,R group). The minimum amount of results of an evaluation group is 5 values. If this amount is undercut, an evaluation in the superior group, e.g. all values, which have been measured with the same method (M group) takes place. The determination of the evaluation group is documented in the record.
The maximum allowable deviation from the target value of quantitative specified analytes is predetermined and can be found on the ESfEQA homepage. The interval was derived from the medical relevance and the reference interval. In the presentation of the report, the upper limit of the allowed range corresponds with a z-value of 3 and the lower limit with a z-value of -3.

**18. Creation of reports**

After the evaluation of the EQA survey, the participants receive reports, which are provided electronically. The reports contain the results submitted by the participant in comparison to the results of his peer group, a display and comparison of all peer groups, a graphic illustration of the data as histogram, a Shewhart-chart with the participant's previous results in the EQA surveys and in the case of quantitative surveys, which consist out of 2 samples, a Youden plot for the illustration of the z-values of both samples in comparison to other participants.

**19. Loss and damage of EQA test material**

In case of loss or damage of sample material, damages are compensated by ESfEQA GmbH when possible, without acknowledgement of any claims, by sending substitute test specimens when possible, if an immediate notification took place. However, the contract counts as fulfilled already at the posting date of the first shipping.

**20. Complaints**

After receipt of the EQA reports, complaints are possible within a period of 4 weeks. After the end of this period, the participant's claims on the basis of complaints are excluded. In case of justified complaints, a claim on performance of a substitute EQA survey exists. The eventual incidental costs for reagents, expenditure of time, etc. are not being compensated by ESfEQA, as long as ESfEQA is not liable according to cipher 21 of this conditions of participation.

**21. Guarantee**

For any type of loss, ESfEQA is liable only in the case of intention and gross negligence and in the case of presentation of the other eligibility requirements for claims.

**22. Confidentiality**

Individual EQA data is kept confidential. Data is disclosed to the participant, his or her distributor and the ESfEQA staff. ESfEQA collects, processes and uses personal data of the participant only as far as this is required for the performance of the EQA surveys, the creation of the records and for the purpose of quality assurance. This includes the forwarding of participant and device number identifiable data for the quality assurance measures to the individual manufacturer of the test system (device and reagent).

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