IfQ-Lübeck Institut für Qualitätssicherung Lübeck

Eine Einrichtung der EUROIMMUN Medizinische Labordiagnostika AG

D-23560 Lübeck · Seekamp 31 · Tel 0451/29288-233 · Telefax 5855-591
E-Mail ifq@euroimmun.de · Internet www.ifq-portal.de

Terms and Conditions for Participation and Information on the Quality Assessment Schemes of the IfQ Lübeck

The Institute for Quality Assurance Lübeck (henceforth called IfQ Lübeck) organises quality assessment schemes for laboratory external quality control.

1. Purpose of the quality assessment service

The quality assessment service is designed to evaluate the performance capabilities of participating laboratories, based on performed laboratory tests in comparison to reference values and results from other participating laboratories.
It provides an objective aid for assessing and determining the reliability of data obtained and for recognising problems. Based on the results, participating laboratories should introduce corrective measures, if necessary, to improve the quality of their services. Quality assessment schemes are held regularly in order to give the participating laboratories the chance to monitor their performance capabilities continuously. Participation in the quality assessment schemes should establish additional confidence for customers of participating laboratories.

Quality assessment schemes are not aimed at evaluating the products (test systems) used and should not be drawn on to assess the performance of the products.

The use of the quality assessment samples, certificates, participations certificates, reports and other information provided by the IfQ is only permitted within the framework of this intended use.

2. Costs

The participation fees for the quality assessment schemes are to be taken from the relevant valid price list (for Switzerland, please refer to the responsible EUROIMMUN subsidiary for information on the costs). Participants bear the costs for their reagents, time expenditure, etc.

3. Quality assessment samples

Quality assessment schemes take place twice a year, each time with three samples. “Real” clinically characterised samples are used preferably. These are obtained in collaboration with doctors or sample donors. The origin of each sample is known. The samples can be serum or plasma. Methods used by the participants must therefore be validated for both serum and plasma.

Determination of expected results

Expected results for quality assessment samples are determined before delivery of the samples in cooperation with competent external laboratories. A list of the reference laboratories is available on the quality assessment portal.
For each quality assessment scheme at least one reference laboratory is commissioned which is accredited for performance of the respective analysis according to the corresponding laboratory norm (e.g. DIN EN ISO 15189, DIN EN ISO/IEC 17025, DIN EN ISO 15195). The samples are measured and assessed by the appropriate reference laboratories. The qualitative result of the reference laboratories is taken as the expected result.

Stability/preservation

The quality assessment scheme samples are preserved, usually with sodium azide (< 1%). In individual cases, also other preservatives may be used. Avoid contact with the skin. Occasionally the used preservatives can interfere with certain test methods. To exclude such interference, consult the instructions in the test system used. Every quality assurance sample undergoes a stability check. In this check, transport and storage of the samples are simulated in stress tests. The stability check establishes that the sample is stable at the given storage temperature for the duration of the quality assessment round (generally 4 weeks).

Homogeneity

Quality assurance samples are fluid and are mixed before and during filling to ensure homogeneity. The homogeneity of the samples is determined during process validation of the filling process.

Safety warnings

Neither HBsAg, nor antibodies against HCV, HIV-1 or HIV-2 were detected in the quality assessment samples using CE-registered or FDA-approved test systems. Nevertheless, samples should be handled as carefully as infectious material.

4. Registration of participants

Any interested laboratory that routinely carries out the respective laboratory analyses can take part in the quality assessment, including those who are not customers of EUROIMMUN. Participants are required to register on the internet at www.ifq-portal.de. The quality assessment service portal allows participants to register for the different quality assessment schemes and later enter their results online. The e-mail address provided by the participant is used to provide effective communication between the IfQ Lübeck and the participants. Participants have to ensure

availability via this e-mail address. Participants are required to notify the IfQ Lübeck via the portal of any changes in their personal details (e.g. e-mail or delivery address) and to keep their details up to date. If the provided address is incorrect, participants are not entitled to a new delivery or refund.

5. Registration for quality assessment schemes, signing up for subscription, and procedure, revocation and termination

Registration, entering of results and issuing of reports take place online via the quality assessment portal. There, the dates for every quality assessment scheme are announced. Participants can apply to the quality assessment schemes during the registration period. The registered participants are informed on the start and end dates of the inscription phase via e-mail. By registering to the quality assessment schemes, the participant agrees to the terms and conditions of the IfQ in its relevant valid version, to be found in the quality assessment portal.
Registration for the quality assessment schemes can also be made via subscription. With registration via subscription, the participants are registered for all future quality assessment schemes offered by the IfQ until further notice. The participants can cancel the participation in the respective quality assessment scheme until the end of the registration period or cancel the subscription by this date. Revocation and cancellation can be done via e-mail. The conditions of participation apply in their relevant valid version. If the conditions of participation change, the participants are expressly informed about the change on the website (“Infobox: Changes in the conditions of participation”). Changed conditions of participation are published at the latest two weeks before the end of the registration period on the website and communicated via e-mail. An isolated revocation is not possible. The revocation always applies to the participation in the quality assessment scheme.

Despite careful planning it may happen that the sample contingent is used up before the end of the registration phase. There is no entitlement to the number of samples being extended. Early registration ensures participation.

After the end of the registration period, the quality assessment samples are sent by the IfQ Lübeck at the date announced in the portal. If samples are lost or damaged and the IfQ Lübeck is informed straightaway, replacements will be sent if possible. However, participants are not entitled to replacements. If a new delivery results in lateness or delayed service, there is no entitlement to the participant’s results being taken into account in the evaluation of the quality assessment round.

The participants commit to handle and store the quality assessment samples in the same way as routine samples and measure them in their own laboratory. Participants must state their method(s) used (routine method) together with the results. Results obtained under routine conditions must be entered online in the portal by the respective deadline. No additional determinations or further methods that are not used for routine samples may be used to obtain results. It is not permitted to enter test results which are consolidated from different methods.

If a test procedure consists of a screening test followed by a confirmatory test, both methods must be entered during registration on the portal, and results for the two methods must be given separately. If the confirmatory test is performed by an external laboratory this should be indicated. The certificate is only valid for tests performed by the participating laboratory; externally performed tests are therefore marked in the certificate.

Falsification and secret communication between participating laboratories contradicts the goal of external quality control and is therefore not permitted.

It is recommended that participants double-check that their results are entered correctly in the portal. Participants should also file a printout of their entry with their documentation. Errors in data entry can be corrected up until the deadline for entering the results. After the deadline no changes may be made to the entered results. In cases of necessity, for example faulty internet connection, results can be submitted to the IfQ Lübeck in writing (e.g. e-mail, fax). These will be entered into the portal by the quality assurance team, as long as the deadline is met. If results are not entered or transmitted within the time limit, no evaluation can be made. In this case, the costs are not refunded.

6. Evaluation, quality assurance report and issuing of certificates

The IfQ Lübeck evaluates the data promptly and places the evaluation online on the quality assessment portal. This includes the results of every participant (only available for the corresponding participant), a statistical total evaluation with anonymous and summarised results of all participating laboratories, and further helpful information (e.g. images from immunofluorescence tests, blot strips). Participants receive a message when the evaluation is available.

Qualitative evaluation is crucial for the granting of a certificate. If the qualitative results of the participant for all samples is in agreement with the expected values, the quality assessment scheme has been passed and a certificate will be issued.

Particularities of individual quality assessment schemes are to be found in detail in the respective information in the quality assessment portal. If a quality assessment scheme is not passed, the participant receives a participation confirmation instead of a certificate.

In the result evaluation for each participant, the following statistical information is given alongside a comparison of the participant's results and the expected results. These values are based on all participants who participated in the scheme using the same test system.

- Median of results*
- 68% result range*
- Number of participants
- Number of correct results (pass rate)

*if at least 6 participants gave a quantitative result

The median (mean value)
The median is the mean value of all measurement values when sorted by size, so that half of the values lie under the median and half over. If the number of measurement values is even, the arithmetic mean of the two middle values is taken as the median. The median rather than the arithmetic mean is used as a statistical parameter to reduce the influence of extreme values. Outlier tests are not performed.

The 68% result range gives the distribution range of quantitative results, within which the measurement values of 68% of the participants lie.

In the total evaluation the following information is given for each test that was used by participants in the quality assessment scheme:

- Number of participants
- Number of correct results (pass rate)

The certificates and participation confirmations of the IfQ Lübeck are sent to the participants via mail to the address provided. The complete quality assessment scheme reports are provided in the quality assessment portal.
Certificates, confirmations of participation and reports may be used within the framework of the intended used of the quality assessment schemes as described above. Misuse or tampering, or meaningful changes through manipulation of the documents, or by relating them with other documents is not allowed.

7. Queries

Complaints about the quality assessment carried out by the IfQ Lübeck should be sent in written form to the institute within 4 weeks of receiving the quality assessment report.
After this deadline complaints can no longer be considered.

If it should happen that a quality assessment scheme becomes invalid through a mistake by the IfQ Lübeck, an additional scheme will be offered free of charge (with the same conditions for participation).
Further claims on the IfQ Lübeck are excluded.

8. Declaration of confidentiality and data protection

The IfQ Lübeck treats all participant data as confidential. Merely the data required for invoicing are passed on to the responsible departments. In the quality assessment portal, the anonymised results of each quality assessment scheme are made accessible to the participants. The IfQ assures that the data entrusted to them will be handled according to the data protection regulations. The corresponding privacy policy of the IfQ can be found at: www.ifq-portal.de – Contact / site notice / data protection.

9. Miscellaneous

Further information about the quality assessment service can be found in the quality assessment portal.

The IfQ Lübeck reserves the right to exclude a laboratory if it repeatedly does not return results or if a participant has falsified data or has made secret consultations or has tried to. This also applies to attempts to influence employees of the IfQ Lübeck.

The IfQ reserves the right to introduce participant fees and to change individual quality assessment schemes with regard to their scope or to discontinue them completely.

For further issues the general terms and conditions of EUROIMMUN AG apply.

Please address any questions about the individual quality assessment schemes or the quality assessment service to the IfQ Lübeck by e-mail (ifq@euroimmun.de) or by telephone (+49 451 /29288-233).