

The image features a decorative graphic on the right side consisting of several overlapping circles and connecting lines. There are three circles: a large orange one in the middle, a smaller light orange one above it, and a light grey one below it. They are connected by dark blue lines with a white double-line effect. The text '10. Assessment— external quality assessment' is positioned to the left of the orange circle.

10. Assessment—
external quality
assessment

Role in quality management system

10-1: Overview

Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways. One of the commonly employed assessment methods is that of external quality assessment (EQA).



Definition of EQA

The term EQA is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory. The term EQA is sometimes used interchangeably with proficiency testing; however, EQA can also be carried out using other processes.

EQA is here defined as a system for objectively checking the laboratory's performance using an external agency or facility.

Types of EQA

Several EQA methods or processes are commonly used. These include:

1. Proficiency testing—external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared and reported to the laboratories.
2. Rechecking or retesting—slides that have been read are rechecked by a reference laboratory; samples that have been analyzed are retested, allowing for interlaboratory comparison.
3. On-site evaluation—usually done when it is difficult to conduct traditional proficiency testing or to use the rechecking/retesting method.

Another method of interlaboratory comparison is the exchange of samples among a set of laboratories, usually reserved for specialized tests for which no proficiency testing is available. This method is used by very specialized or sophisticated laboratories and therefore will not be further discussed in this chapter.

EQA benefits

Participation in an EQA programme provides valuable data and information, which:

- allows comparison of performance and results among different test sites;
- provides early warning for systematic problems associated with kits or operations;
- provides objective evidence of testing quality;
- indicates areas that need improvement;
- identifies training needs.

EQA helps to ensure customers, such as physicians, patients and health authorities, that the laboratory can produce reliable results.

Individual laboratories can use EQA to identify problems in laboratory practices, allowing for appropriate corrective action. EQA participation will help to evaluate reliability of methods, materials and equipment, and to evaluate and monitor training impact.

For laboratories performing public health–related testing, EQA can help to ensure that results from different laboratories during surveillance activities are comparable. EQA participation is usually required for accreditation. Also, EQA participation creates a network for communication, and can be a good tool for enhancing a national laboratory network. Samples received for EQA testing, as well as the information shared by the EQA provider, are useful for conducting continuing education activities.

Principal characteristics of an EQA scheme

EQA programmes vary, but principal characteristics include the following:

- EQA programmes can either be free of charge or require a fee. Free EQA programmes include those offered by a manufacturer to ensure equipment is working correctly, and those organized by a regional or national programme for quality improvement.
- Some EQA programmes are obligatory, either required by an accrediting body or by law. Others are voluntary, and the quality manager may choose to voluntarily participate in an EQA programme in order to achieve improvement in the quality of the laboratory's performance.
- The EQA programme can be organized at different levels: regional, national or international.
- Individual laboratory results are kept confidential, and generally are only known by the participating laboratory and the EQA provider. A summary is generally provided and allows comparison to the overall group.

- Some EQA schemes may address a single disease; for example, the EQA programme for tuberculosis. Others may address many kinds of laboratory tests, looking at the overall testing performance for microbiology. An example of this multidisease or test programme is the national microbiology EQA in France, which is obligatory.

Successful performance in an EQA programme reflects the effectiveness of the laboratory's quality management, and allows for recognition of laboratory quality by external groups.



EQA is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance.

10-2: Proficiency testing

Definitions

Proficiency testing, or PT, has been in use by laboratories for many years. It is the most commonly employed type of EQA, as it is able to address many laboratory methods. PT is available for most of the commonly performed laboratory tests, and covers a range of chemistry, haematology, microbiology and immunology testing. Most laboratorians are familiar with the PT process, and many laboratories employ some kind of PT.

Standards organizations recognize the importance of this tool, and the following are examples of formal definitions that are in use.

- ISO/IEC Guide 43-1:1997: "Proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel".
- Clinical and Laboratory Standards Institute: "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others".

Proficiency testing process

In the PT process, laboratories receive samples from a PT provider. This provider may be an organization (non-profit or for-profit) formed specifically to provide PT. Other providers of PT include central reference laboratories, government health agencies, and manufacturers of kits or instruments.

In a typical PT programme, challenge samples are provided at regular intervals. An optimal frequency will be 3–4 times yearly. If the programme cannot provide challenges with this frequency, the laboratory may be able to seek additional sources.

The laboratories participating in the programme analyze the samples and return their results to the central organization. Results are evaluated and analyzed, and the laboratories are provided with information about their performance and how they compared with other participants. The participating laboratories use the information regarding their performance to make appropriate changes and improvements.

Role of the laboratory

To be successful, PT instructions must be followed carefully, all paper work completed accurately and results submission deadlines met. All PT results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time.



Limitations

PT is a tool to measure laboratory performance. Therefore, there must be no difference in the treatment of PT samples and the patient's sample. PT providers make every effort to produce samples that exactly mimic, or closely resemble, usual samples received from patients. PT samples must be processed by normal testing method(s) and involve personnel who routinely perform the testing.

When PT is used for any purpose other than internal quality improvement, the provider or central organization generally prohibits the discussion of results with other laboratories. Some PT organizers send different samples to different groups of laboratories to avoid interlaboratory discussion.

PT participation is valuable only if the information received is directed to improvement in the laboratory.

It is important to remember that PT does have some limitations and it is not appropriate to use PT as the only means for evaluating the quality of a laboratory. PT results are affected by variables not related to patient samples, including preparation of the sample, matrix effects, clerical functions, selection of statistical methods of evaluation, and peer group definition. PT will not detect all problems in the laboratory, particularly those that address the pre-examination and post-examination procedures.

A single unacceptable result does not necessarily indicate that a problem exists in the laboratory.

10-3: Other external quality assessment methods

Using other EQA methods

In situations where it is difficult to provide appropriate external samples, or sometimes when normal laboratory quality control methods cannot be applied, other procedures have been developed and used for EQA. The primary examples and their uses are as follows:

- Rechecking/retesting has been used traditionally for EQA for microscopic slides for acid-fast bacilli (AFB), and for human immunodeficiency virus (HIV) rapid testing. It can also be used in other situations, but is not usually employed if traditional PT is feasible.
- On-site evaluation has proven a useful technique for the same situations—AFB examination and HIV rapid testing. It allows for an external evaluation of quality on-site, and can be conducted in conjunction with PT or rechecking/retesting.

These procedures can be time-consuming and costly, and so are used only when there are not good alternatives. It is essential to have a reference laboratory with the capacity to do the repeat testing; the use of a reference laboratory gives assurance that the re-examination process will give a dependable result. The turnaround for the retesting must be accomplished in a timely manner, allowing for immediate corrective actions. In some settings, transport of samples or slides to the reference laboratory will present problems.

Retesting process

This EQA method is used for HIV rapid testing. HIV rapid testing presents some special challenges, because it is often performed outside a traditional laboratory, and by persons who are not trained in laboratory medicine. Additionally, the kits are single use, and cannot be subjected to the usual quality control methods that laboratories employ. Therefore, retesting of some of the samples using a different process such as enzyme immunoassay (EIA) or enzyme-linked immunosorbent assay (ELISA) helps to assess the quality of the original testing.

Characteristically, the retesting is:

- done by a reference laboratory to ensure quality;
- performed on dried blood spots or serum collected at the time of the rapid test performance;
- not performed as a blinded process, as this is unnecessary.

The number of samples retested must provide statistically significant data in order to detect error. This becomes difficult in settings where small numbers of rapid tests are performed. A full discussion of the statistical issues in retesting is found in the Centres for Disease Control and Prevention and World Health Organization *Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach*.

Rechecking process

This method is most commonly used for acid-fast smears; the slides that were read in the original laboratory are “rechecked” in a central or reference laboratory. This allows for the accuracy of the original report to be evaluated, and also allows assessment of the quality of the slide preparation and staining.

The following principles are important when performing recheck procedures:

- The slides for re-examination must be collected randomly. Every effort should be made to avoid systematic sampling bias.
- Rechecking must be based upon statistical considerations. A common method is for the central laboratory to recheck 10% of negative and 100% of positive slides.
- When discrepancies occur, there should be procedures in place to resolve them.
- The outcome of rechecking must be analyzed for effective and timely feedback.

Advantage of performing blind recheck

It is usually recommended that rechecking be done in a blinded fashion, so that the laboratorian performing the retest does not know the original results. In the study carried out by Martinez et al.¹, random blinded rechecking provided more accurate estimates of AFB microscopy results than on the nonrandomly selected, nonblinded smears. This resulted in improved diagnosis and monitoring of treatment response.

On-site evaluation

A periodic visit by evaluators for on-site laboratory assessment is a type of EQA that has been used when other methods of EQA are not feasible or effective. Again, this method has most frequently been employed for assessment of sites performing AFB smears and those performing HIV rapid testing.

On-site evaluation can be a valuable tool to:

- obtain a realistic picture of laboratory practices by observing the laboratory under routine conditions in order to check that it is meeting quality requirements;
- provide information for internal process improvement;
- measure gaps or deficiencies—learn “where we are”;
- assist the laboratory in collecting information for planning and implementation of training, monitoring and corrective actions.

On-site evaluation for the purpose of EQA may be conducted by a central reference laboratory or other health authorities. On-site evaluation can be used together with retesting and rechecking schemes to provide more information about performance.

¹ Martinez A et al. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid-fast bacilli smears in a pilot project setting in Mexico. *International Journal of Tuberculosis and Lung Diseases*, 2005,9(3):301–305.

10-4: Comparison of external quality assessment methods

Comparison
of some
characteristics

Some of the characteristics of PT and rechecking are compared in the table below.

Comparison of proficiency testing (PT) and rechecking/retesting (RC)

Method/characteristics	PT	RC
Interlaboratory comparison	Yes	Yes
Simulated samples	Yes	No
Real samples	Yes/No	Yes
Time and resources needed	Less	More
Analytes evaluated	Many	Few

Summary of
comparison

Proficiency testing:

- gives a good, objective measure of the laboratory performance
- can be organized to address most kinds of laboratory testing
- is cost-effective and can therefore be used frequently.

Retesting/rechecking:

- is useful when it is difficult or impossible to prepare samples to test all of the testing process;
- is expensive and uses considerable staff time.

On-site evaluation:

- can give a true picture of a laboratory's overall performance, and offer real-time guidance for improvements that are needed;
- is probably the most costly, requiring staff time, travel time and expenses of those performing the evaluation.

10-5: Managing external quality assessment in the laboratory

Participation in EQA

All laboratories should participate in EQA challenges, and this should include EQA for all testing procedures performed in the laboratory, if possible. The benefits of this participation are considerable, and EQA provides the only means available to a laboratory to ensure that its performance is comparable to that of other laboratories.

For laboratories that are accredited, or that plan to seek accreditation, EQA participation is essential. ISO 15189 addresses EQA requirements for laboratories as follows.

- There is a requirement that the laboratory participate in interlaboratory comparisons.
- Where an established EQA scheme is not available, an alternate EQA mechanism will have to be considered for interlaboratory comparison, such as exchange of samples with other laboratories.
- The laboratory management shall monitor the results of EQA and participate in the implementation of corrective actions.

Management process

When participating in EQA programmes, the laboratory needs to develop a process for the management of the process. A primary objective is to assure that all EQA samples are treated in the same manner as other samples tested. Procedures should be developed that address:

- Handling of samples—These will need to be logged, processed properly and stored as needed for future use.
- Analyses of samples—Consider whether EQA samples can be tested so that staff do not recognize them as different from patient samples (blinded testing).
- Appropriate record keeping—Records of all EQA testing reporting should be maintained over a period of time, so that performance improvement can be measured.
- Investigation of any deficiencies—For any challenges where performance is not acceptable.
- Taking corrective action when performance is not acceptable—The purpose of EQA is to allow for detection of problems in the laboratory, and to therefore provide an opportunity for improvement.
- Communication of outcomes to all laboratory staff and to management.

EQA performance problems

If the laboratory performs poorly on EQA, the problems may lie anywhere along the path of workflow. All aspects of the process will need to be checked. Some examples of problems that may be identified include the following.

Pre-examination:

- The sample may have been compromised during preparation, shipping, or after receipt in the laboratory by improper storage or handling.
- The sample may have been processed or labelled improperly in the laboratory.

Examination:

- The EQA challenge materials may exhibit a matrix effect in the examination system used by the participating laboratory.
- Possible sources of analytical problems include reagents, instruments, test methods, calibrations and calculations. Analytical problems should be investigated to determine whether error is random or systemic.
- Competency of staff will need to be considered and evaluated.

Post-examination:

- The report format can be confusing.
- Interpretation of results can be incorrect.
- Clerical or transcription errors can be sources of error.

Incorrect data captured by the EQA provider is another possible source of error.

10-6: Summary

Summary

EOA is a system for objectively checking the laboratory's performance using an external agency or facility. All laboratories should participate in an EOA process for all tests performed, whenever possible. Accredited laboratories are required to participate in EOA.

There are several methods for conducting EOA. Traditional PT is available for many tests, is cost-effective and provides useful information. When PT is not practical or does not provide enough information, other methods should be employed.

There must be no difference in the treatment of a PT sample and a patient sample. The normal testing methods must be followed and the procedure must involve personnel who routinely perform the testing.

Key messages

- As EOA uses valuable resources, the laboratory should make the best use possible of its participation in EOA.
- EOA should not be punitive. It should be viewed as educational and used as a tool to help direct improvement efforts in the laboratory.
- EOA is one of the critical elements of a laboratory quality management system.