

Performance Specifications

Analytical quality goals

In Labquality the analytical quality goals of the quantitative parameters (analytes) in the EQA schemes are set by the Labquality expert groups. Quality goals are reviewed yearly in the expert group meetings and updated when necessary.

External quality assessment (EQA) scheme providers in laboratory medicine use analytical quality goals based on different philosophy depending on the purpose of use of the goals and current general quality level of the laboratories. Labquality's quality goals are educational which means that the set goals are strict if compared to the goals used for requirements of authorities or legislation. Labquality's quality goals are not meant to be used for administrative purposes.

The goals are essential for laboratories in their quality planning to ensure the analytical quality attained is appropriate for the needs of the clinical service. The strict quality goals guide laboratories to better performance and can be reached when the analytical system is functioning optimally.

Establishing quality goals - total analytical error (TE)

The criteria used for analytical quality goals are based on clinical needs, biological variation, state-of-the-art, comments by experts and reference intervals depending on the analyte concerned. Quality goals are usually expressed as per cents, although occasionally in units for some schemes.

The goals are set so that when the methods are correctly functioning, the result will be within the set limits with 95% probability. The different considerations can lead to different target limits depending on whether the priority is maximal allowable error or educational quality goals.

Labquality follows the accreditation standard ISO/IEC 17043 and statistical standard ISO 13528, which give requirements and guidelines on statistical methods and evaluation of performance used in EQA.

Evaluation of Performance

The target area for a result is determined as mean/median of the method group +/- quality goal. Deviation of a result from the assigned value is expressed as Diff %, with cumulative data reported as visual graphics on the reports.

Scoring in the microbiological schemes

In microbiological schemes, the scoring system is based on correct test result and clinical interpretation. The maximum score varies depending on the scheme design, for example on the number and features of the samples.

For more information please see EQAS Interpretation guidelines in LabScala.

References

- 1 Kenny D, Fraser C.G , Hyltoft Petersen P, Kallner A. Strategies to set Global Analytical Quality Specifications in Laboratory Medicine – Consensus agreement. Scan J Clin Lab Invest 1999; 59: 585
- 2 ISO/IEC 17043: 2015
- 3 ISO/IEC 13528: 2005