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Analytical quality goals

External quality assessment (EQA) scheme providers in laboratory medicine use analytical quality goals based on different philosophy depending on the purpose of the use of the goals and general quality level of the laboratories at time. 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. These strict analytical goals can be reached when the analytical system is functioning optimally.

Accreditation standard ISO/IEC CD 17043 which soon will be confirmed and statistical standard ISO 13528 give requirements and guidelines on statistical methods and evaluation of performance used in EQA. Different options are possible to choose to show the participants performance. Labquality follows ISO/IEC Guide 43-1:1997 and ILAC G13:2007 guidelines. Meeting the requirements of the future standard ISO/IEC CD 17043 are under process in Labquality.

In Labquality the analytical quality goals of the quantitative parameters (analytes) in the EQA schemes are set by the Labquality´s expert groups using the following guidelines.

Establishing quality goals

The criteria used for analytical quality goals are based on clinical needs, biological variation, state-of arts, comments by experts and reference intervals depending on the analyte concerned.

The quality goals of general clinical chemistry schemes for total analytical error (TE) are determined taking account imprecision and bias as follows:

The bias should be less than ¼ of the biological variation (CV_{bt}=within subject variation + between subject variation) or less than 1/16 of the reference interval.

The imprecision should be less than half of the within-subject biological variation (CV_{bw}) or the total imprecision should be less than the imprecision that can be achieved by the better 50% of laboratories in the external quality schemes.

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On these premises **the total analytical error (TE)** can be calculated

TE = ¼ CV_{bt} + 1.65 x ½ CV_{bw}

or

TE = [(reference interval/16 x100)/ mean of the reference interval] + 1.65 x1/2 CV_{bw}.

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.

The use of quality goals

For EQA scheme participating laboratories the quality goals are expressed as per cents and in few cases in units. 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 % and cumulative data reporting as visual graphics are included on the reports.

Scoring of laboratories results

In the schemes of laboratory medicine the scoring system has not showed to be very useful in all specialities for instance in general clinical chemistry.
In the microbiological schemes scoring system is based on correct test result and clinical interpretation. The maximum score is varying depending on the scheme design for example on the number of the samples and features of the samples.

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 43-1:1997
3 ILAC G13:2007
4 ISO IEC CD 17043
5 ISO 13528