

# A SCORING SYSTEM BASED ON THE BIOLOGICAL VARIATION

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In the past the ECAT Foundation introduced a model for the evaluation of the long-term analytical performance of a laboratory test by a particular laboratory-based on the results of external quality assessment surveys.

This model allows us to assess the long-term within-laboratory analytical coefficient of variation (LCVa), which represents imprecision, as well as the bias. Briefly, for each participant, linear regression is applied using the consensus values of each survey as the denominator (independent variable) and the corresponding laboratory values as the numerator (dependent variable). The slope and the variability of the regression line, the mean and the standard error of the consensus values as well as the mean value of the laboratory results are calculated. The formulae for the calculations are given below.

Bias: 
$$B = \frac{\sqrt{\frac{n-1}{n} \cdot (b-1)^2 \cdot s_x^2 + (\bar{Y} - \bar{X})^2}}{\bar{X}} \cdot 100\%$$

Imprecision: 
$$LCV_a = \frac{(s_{y|x} / b)}{\bar{X}} \cdot 100\%$$

(X) is the consensus value and ( $\bar{X}$ ) is the mean value for X. ( $s_x$ ) is the standard error of (X). (Y) is the laboratory value and ( $\bar{Y}$ ) is the mean value for Y. (b) is the slope and ( $s_{y|x}$ ) is the variability of the regression line, which is calculated on the basis of the least-square method. The number of laboratory results included is expressed by (n).

The presentation given will focus on the LCVa as a measure of a stable test performance over time. Data will be shown for Antithrombin and Protein C activity (both chromogenic and clotting-based assays).

In the presentation of Dr. Fraser the concepts of the use of the biological variation as a basis for analytical quality specifications were discussed. In the presentation of Dr. De Maat the assessment of the biological variation for both Antithrombin and Protein C was discussed.

In this presentation we combine the information of both presentations for the development of a scoring system.

In summary, the LCVa of an individual laboratory will be compared to the analytical quality specifications for imprecision for diagnostic testing. Criteria for minimum, desirable and optimum performance will be shown.

On the basis of these criteria laboratories can be graded. For instance, Grade A means an LCVa fulfilling the criteria for optimum performance.

The results of the evaluation for Antithrombin and Protein C will be shown.

With this approach the long-term analytical performance of a laboratory can be assessed and compared to objective criteria for analytical performance. This comparison shows the laboratory whether further improvement in the analytical quality is necessary.