

Quality Control Concepts

Term *Description in French*

2SD *Standard Deviation x 2. 95% of all results in a normal population fall within 2 SDs of the mean. Therefore, + or - 2 SD is considered an acceptable laboratory standard.*

Absolute Range Limit

Accuracy *Closeness to the true value or the measure of truth of a result.*

Control Product *Materials that are solutions of chemically stabilized red cells, white cells and/or analogs, and platelets. The most important characteristics of control materials are their stability and physical similarity to real patient samples. They are used to monitor the performance of an instrument or procedure.*

CV *Coefficient of Variation: The Standard Deviation expressed as a percentage of the mean. The smaller the CV, the more precise is the analytic method.*

$$\%CV = \frac{SD}{Mean} \times 100$$

Fixed Criteria Limit

Instruments Reporting *Number of reporting Peers. A minimum of 6 Instruments reporting provides better comparative results.*

Number of results *Number of results entered per parameter per level. Good Statistical analysis is based on a minimum of 10 Number of Results.*

Peer *An instrument from a group of similar instrument types, using the same control product of the same lot and level.*

PI *Precision Index: The ratio of a Lab's CV to the Group CV. PI is a measure of Relative Precision. A PI value between 0 and + 2 defines acceptable performance.*

$$\text{Precision Index} = \text{Your \%CV} / \text{Group \%CV}$$

Precision *Reproducibility of replicate analyses.*

Preliminary Report *Reports published before the end of a data collection month will be marked Preliminary after the Month /Year in the header. The date and time the report was generated is always at the bottom of the report.*

Rejected *Data outside the target limits for the control product used is rejected.*

Run *Set of internal quality control results of different parameters collected the same date and time from an instrument*

Sigma *Standard Deviation: A measure of the dispersion of a group of values around a mean, expressed in the units being measured.*

$$\text{SD} = \sqrt{\frac{\sum(\mathbf{x} - \bar{\mathbf{x}})^2}{\mathbf{N} - 1}}$$

SDI *Standard Deviation Index: The number of Group Standard Deviations by which a Lab's Mean differs from the Group Mean.*

SDI is a measure of Relative Accuracy.

Accuracy indicates how close Your Mean is to the Group Mean.

An SDI value between - 2 and + 2 defines acceptable performance.

$$\text{SDI} = (\text{Your Mean} - \text{Group Mean}) / \text{Group SD}$$

SD Range

Shift *An abrupt change in the pattern of data points on a plot, graph, or chart of data points.*

Target value *A peer group specific value published on the target sheet of the control product.*

Trend *A gradual change in the pattern of data points on a plot, graph, or chart of data points.*

xbar *The mathematical average for a group of data points.*

$$\bar{x} = \frac{\sum x}{N}$$