

Q.C. Concepts

Accuracy

Refers to how close or similar data is compared to the true value

Assay

Instrument specific values provided by the control manufacturer

Bias

The positive or negative difference from the peer group mean or true value

CV – Coefficient of Variation

Measures a method's performance over multiple runs (data dispersion compared to the mean). A small CV equals good precision.

CV is calculated as follows and is represented as a percentage:

$$\%CV = (SD \div \text{Mean}) \times 100\%$$

Note – The CV may be large on some parameters due to the small numeric value, i.e. differential parameters, and/or the small number of significant digits.

Levey-Jennings Graphs

The graphs provide a visual plot of the data compared to the assay value, peer group mean and 2 SD range from the peer group mean. Each mark on the graph indicates how far off the actual result was from the mean. This allows at-a-glance review of the data and helps identify trends, shifts and outliers. When the control values fall within the expected distribution, the values are classified as being “in-control” and results can be accepted.

Mean

Mathematical average of all data points. Any change in accuracy – known as a shift or trend – will be reflected as a change in the mean.

Peer Group

A grouping of similar instrument types for comparison

PI – Precision Index

Measure of relative precision. A value less than 1 indicates good lab precision. PI is calculated as follows and is represented as a percentage:

$$\%PI = \text{Your \%CV} \div \text{Group \%CV}$$

Precision

An indication of the amount of random error that exists in the data or process

SD - Standard Deviation

Refers to the precision within a set of data. The distance from the mean is measured in standard deviations. A high SD indicates a wide distribution of values and poor precision in the results.

S.D.I. – Standard Deviation Index

The S.D.I. is a calculated value for each parameter that indicates the degree of separation between the peer group mean and an individual lab's mean. This allows laboratories to quickly compare their results on each level of control to results from peers. The closer the S.D.I. is to zero, the closer that result is to the target mean. As a rule of thumb, an S.D.I. greater than 2.0 (+2 or -2), should be reviewed.

S.D.I. is calculated as follows:

$$\text{S.D.I.} = \frac{(\text{Your Mean} - \text{Peer Group Mean})}{\text{Peer Group SD}}$$

Shift

An abrupt change in the pattern of data points on a plot, graph or quality control file

TE - Total Error

Refers to how far results vary in total from the peer group mean or true value.

TE is calculated as follows:

$$\text{TE} = |\text{Bias}| + 2\text{SD}$$

Trend

A gradual change in the pattern of data points on a plot, graph or quality control file