

Statistical Analysis

❖ **Analysis of Data and Performance Evaluation:** Before statistical analysis of data, identification of blunders is done by following methods.

- Visual Review
- Grubbs Test
- Results that deviate from assigned value by more than $\pm 5SD$
- After removal of blunders/outliers, statistical analysis will be done on basis of number of result data as per below table.

Number of Result Data	Method of Analysis
More than 12 result data	Statistical analysis will be done as per Robust analysis (Algorithm A, Annex C of ISO 13528 standard).
Between 5 and 12 result data	Median will be used for evaluation.
Less than 5 result data	Statistical analysis will not be performed.

- The outlier identified are not included for determination of assigned value and standard deviation. Participant result (blunder/outlier) is excluded only for the purpose of determination of assigned value and standard deviation.
- Performance evaluation is conducted in terms of z score which is calculated using the following formula.

$$z \text{ score} = (X_i - X_{pt}) / \sigma_{pt}$$

Where: X_i = participant result

X_{pt} = assigned value

σ_{pt} = standard deviation

- Uncertainty of assigned value is calculated using following formula.

$$U(x_{pt}) = 1.25 \times \sigma / \sqrt{p}$$

Where: σ = standard Deviation

p = number of result data

- When uncertainty is $U(x_{pt}) > 0.3 \sigma_{pt}$, performance evaluation is done using z' - score (z' -prime) by taking into consideration the standard uncertainty of assigned value in denominator.

$$z' \text{ score} = (X_i - X_{pt}) / \text{SQRT} [(\sigma_{pt})^2 + U^2(x_{pt})]$$

Where: X_i = participant result

X_{pt} = assigned value

σ_{pt} = standard deviation

$U(x_{pt})$ = uncertainty of assigned value

Acceptance Criteria of z/z' score:

Criteria	Description
z/z' score ≤ 2.0	If your z/z' score lies between $\pm 2.0 z/z'$ score - considered to be Acceptable
$2.0 < z/z'$ score < 3.0	If your z/z' score lies between ± 2.0 to 2.99 - considered to be Questionable (warning signal)
z/z' score ≥ 3.0	If your z/z' score is $\pm 3.0 z/z'$ score or more then it - considered to be Unacceptable (action signal).

- ❖ **Coefficient of Variation (CV):** Coefficient of variation is the relative standard deviation (that is, the standard deviation expressed as a percentage of the mean). The CV is useful because it is independent of concentration.

$$\% \text{ CV} = (\text{Standard Deviation} / \text{Assigned value}) * 100$$

- **Percentage Deviation (%):** The mean bias of a laboratory results relative to assigned value, expressed as a percent.

$$\% \text{ D} = 100 \times (X_i - X_{pt}) / X_{pt}$$

Where: X_i = participant result

X_{pt} = assigned Value

- **EQAS Score for Evaluated Analyte:** (Number of Analytes with z or z' -score < 3) / (Number of Analytes reported) *100