



## QUALITY CONTROL

Quality control is a process that ensures the accuracy and reliability of test results. It involves the use of control materials and the implementation of quality control procedures.

### SYSTEM QUALITY CONTROL

System quality control involves the use of control materials to monitor the performance of the entire testing system, including the reagents, instruments, and personnel.

System quality control is essential for ensuring the accuracy and reliability of test results.

### PROCEDURAL CONTROLS

- Z-score control charts
- Mean and standard deviation control charts
- Levey-Jennings control charts

### LIQUID QUALITY CONTROL (LQC)

- Control materials
- Control charts
- Control procedures

### TEST RUN MESSAGES

Test run messages provide information about the status of the test run, including any errors or warnings that occur.

### LIMITATIONS

- Control materials may not represent all possible patient samples.
- Control charts may not detect all types of errors.
- Control procedures may not be applicable to all test systems.
- Control materials may have a limited shelf life.
- Control charts may not be suitable for all test methods.
- Control procedures may not be suitable for all test methods.
- Control materials may not be available for all test methods.
- Control charts may not be suitable for all test methods.
- Control procedures may not be suitable for all test methods.

### TEST CUT-OFF AND EXPECTED VALUES

Test cut-off and expected values are used to interpret test results. The test cut-off is the value above which a result is considered positive, and the expected value is the value that is expected for a given patient population.

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Percentile	ng/mL
95th	100
90th	80
50th	50
10th	20
5th	10

Percentile values are used to compare test results to a reference population. The 50th percentile is the median value, and the 95th percentile is the value above which 5% of the population falls.

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### PERFORMANCE CHARACTERISTICS

#### MEASUREMENT RANGE

Measurement range is the range of concentrations over which the test method is able to accurately measure the analyte.

#### HOOK EFFECT

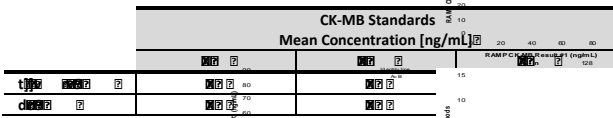
Hook effect is a phenomenon in which the test result is falsely low due to the presence of a very high concentration of the analyte.

#### DETECTION LIMIT

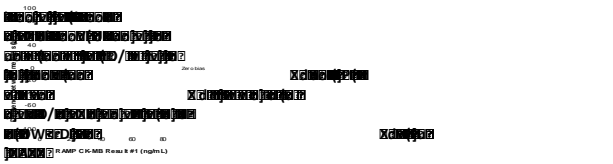
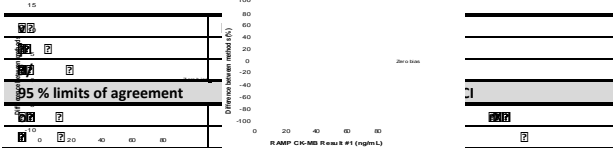
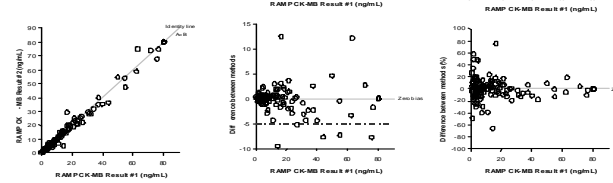
Detection limit is the lowest concentration of the analyte that can be reliably detected by the test method.

#### PRECISION

Precision is the degree to which the test results are reproducible. It is a measure of the variability of the test results.



### CLINICAL SITE EVALUATIONS OF ANALYTICAL PERFORMANCE



Population	n	Sy.x	Slope	Intercept [ng/mL]	Correlation Coefficient [r]
Population 1	100	100	1.0	0	1.0
Population 2	100	100	1.0	0	1.0

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### LINEARITY

Linearity is the ability of the test method to produce results that are directly proportional to the concentration of the analyte. It is a measure of the accuracy of the test method.

### INTERFERENCE

Interference is a phenomenon in which the test result is affected by the presence of other substances in the sample. It is a measure of the specificity of the test method.

Compound	Concentration
Compound 1	100
Compound 2	100
Compound 3	100
Compound 4	100
Compound 5	100

### ANALYTICAL SPECIFICITY

Analytical specificity is the ability of the test method to accurately measure the analyte in the presence of other substances. It is a measure of the specificity of the test method.

### CLINICAL EVALUATIONS

#### METHOD COMPARISON



Population	n	Sy.x	Slope	Intercept [ng/mL]	Correlation Coefficient [r]
Population 1	100	100	1.0	0	1.0
Population 2	100	100	1.0	0	1.0

### ANALYTICAL SENSITIVITY & SPECIFICITY

Analytical sensitivity and specificity are measures of the ability of the test method to accurately measure the analyte. Sensitivity is the ability to detect the analyte, and specificity is the ability to exclude other substances.

Population	n	[%]	s.e. <sup>a</sup>	95% CI <sup>b</sup>
Population 1	100	100	0.01	98-100
Population 2	100	100	0.01	98-100

### REFERENCES

References are provided for further information on the topics discussed in this document. They include scientific papers, books, and other sources of information.

- 1. [Reference 1]
- 2. [Reference 2]
- 3. [Reference 3]
- 4. [Reference 4]
- 5. [Reference 5]
- 6. [Reference 6]
- 7. [Reference 7]
- 8. [Reference 8]
- 9. [Reference 9]
- 10. [Reference 10]

### GLOSSARY OF SYMBOLS

EC REP	LOT	
Authorized Representative in European Community	Batch Code	Catalogue Number
Caution	CE Mark	Consult instructions for Use
Contains Sufficient for <n> Tests	Do Not Reuse	In vitro Diagnostic Medical Device
Harmful, Irritant	Manufacturer	Rx Only
Temperature Limit	Use-by Date	Prescription Use Only (U.S. Only)

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