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# Glossary

## Glossary of terms taken from the XP U 47-600-1, NF ISO 5725-1 standards and the Pr NF ISO 99999 (NF X 07-001) *International Vocabulary of Metrology (VIM)*

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**Glossary of technical terms for the validation of laboratory analytical methods in the framework of a quality process.**

### Method adoption
Prior to the 'routine' implementation of a duly characterised and validated molecular diagnostic method, method adoption is when the laboratory demonstrates its ability to undertake the analysis in question by showing that it has achieved the required performance level and/or the performance level announced in the characterisation and validation file for the method.

### Bias (NF ISO 5725-1 standard)
Difference between the expectation of the test result and an accepted reference value.
NOTE: bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

### Repeatability condition (VIM 2.21)
Condition of measurement in a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time.

### Reproducibility conditions
Conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment over a sufficiently long period of time to consider that they are different test series.

### Intermediate precision condition (VIM 2.23)
Condition of measurement in a set of conditions that includes the same measurement procedure, same location, and replicate measurements on the same or similar objects over an extended period of time, but may include other conditions involving changes.

### Accuracy
Closeness of agreement between a test result and the accepted reference value.

### Precision (of a measurement)
Closeness of agreement between test results obtained by replicate measurements under the same conditions
NOTE: precision depends only on the distribution of random errors and is not related to the true value or accepted reference value.

### Precision (of an analytical method)
Closeness of agreement between test results obtained through a set of measurements under stipulated conditions.
NOTE 1: precision depends only on the distribution of random errors and is not related to the true value or accepted reference value.
NOTE 2: precision includes repeatability and reproducibility. An analytical method is precise when it produces very similar results both for the same operator taking multiple measurements and operators using it in different locations.

### Trueness
Closeness of agreement between the average value obtained from a large series of test results and an accepted reference value.

### Limit of detection (VIM 4.18)
Measured value obtained by a given measurement procedure for which the probability of falsely claiming the absence of a component in a material is β given a probability βof falsely claiming its presence. This definition poses practical problems.

### Limit of quantification
Lowest and/or highest concentration of an analyte that can be quantified under the described experimental conditions for the method. It is the lowest and/or highest concentration in the range of validity.

### Mesurand ( VIM 4.3)
Quantity intended to be measured.

### Measurement (VIM 2.1)
Process of experimentally obtaining one or more values that can reasonably be attributed to a quantity.

### Repeatability
Closeness of agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.
NOTE: these conditions are called repeatability conditions. Repeatability conditions include: the same procedure, the same observer, the same measuring instrument used under the same conditions, the same location, repetition over a short period of time. Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

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## Reproducibility

Closeness of agreement between the results of measurements of the same measurand carried out under changed conditions of measurement.
NOTE: a valid statement of reproducibility requires specification of the conditions changed. The changed conditions may include: method of measurement, observer, measuring instrument, reference standard, location, conditions of use, time. Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results.

## Analytical specificity

Ability to uniquely distinguish a target agent in the presence of other agents that are genetically similar to the target of interest and/or occupy the same ecological niche.

## Diagnostic specificity

Proportion of known uninfected reference animals that test negative in an assay; uninfected reference animals that test positive are considered 'false positives'.

## Validation of an analytical method

Confirmation through tangible evidence that requirements for a specific use or intended application have been fulfilled.
Verification stage consisting in comparing defined performance criteria values obtained when characterising a method with those that are expected or have been assigned beforehand (acceptability limits, targets to be reached) and declaring the analytical method as valid or invalid.

## Verification

Provision of tangible evidence that a given entity fulfils specified requirements.