

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Application for Assay Evaluation - Glossary

Section V: Device/Assay Performance Characteristics	
General Characteristics	
Definition of a positive result:	Description of the method for determination of a positive result, for example, by comparison to a negative control or cutoff control, which contains the analyte
50% cutoff point:	Analyte concentration at which repeated tests on the same sample yield positive results 50% of the time and negative results for the other 50%.
Limit of Detection:	Lowest amount of analyte in a sample that can be detected with (stated, in this case 95%) probability. This value can also be called the <i>lower</i> limit of detection.
Limit of the Blank:	Highest measurement result that is likely to be observed (with a stated probability) for a blank sample.
Limit of quantification:	Lowest concentration of analyte that can be quantified
Upper linearity limit:	Highest calibrator in the linear range of the calibration curve
Lower linearity limit:	Lowest calibrator in the linear range of the calibration curve
Negative control:	Specimen lacking analyte used as a control to determine if the assay performance met acceptability criteria
Positive control:	Specimen containing specified amount of analyte used as a control to determine if the assay performance met acceptability criteria
Recommended method to validate repeatability of results:	Requirement to demonstrate repeatability of positive results for classification as positive
Assay validation criteria:	Criteria which must be met to accept an assay as valid, including the range of results for the negative and positive control, and criteria for calibration curves, if applicable
Sensitivity and Specificity	
Sensitivity for a single positive:	Proportion of cases giving a positive result tested one time only
Sensitivity for a reproducible positive:	Proportion of cases giving a positive result upon initial and repeat testing
Agreement with comparator results for positive specimens:	Proportion of positive specimens using comparator method that are positive when tested with experimental method
Specificity for a single negative:	Proportion of negative specimens giving a negative result tested one time only
Specificity for a reproducible negative:	Proportion of negative specimens giving a negative result upon initial and repeat testing
Agreement with comparator results for negative specimens	Proportion of negative specimens using comparator method that are negative when tested with experimental method
Positive predictive value	Percentage of all positive results that are true positives
Negative predictive value	Percentage of all negative results that are true negatives

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Precision

Intra-assay precision:	Degree of agreement among individual results when the test is repeated multiple times in the same assay, usually expressed as a mean, standard deviation and coefficient of variation
Inter-assay precision:	Degree of agreement among individual results when the test is repeated on more than one day, usually expressed as a mean, standard deviation and coefficient of variation

Other Performance Characteristics

Interfering specimen conditions:	Physical properties of the specimen, for example, turbidity, viscosity, discoloration that affect detection of the analyte
Interfering medications:	Medications that could affect detection of the analyte, for example piperacillin in the galactomannan assay
Interfering medical conditions:	Medical conditions that could affect detection of the analyte, for example rheumatoid factor in rheumatoid arthritis
Limitations of the assay:	Conditions known to reduce the accuracy of the assay, for example, cross reactions with other organisms, false positive results caused by contamination, were false negative results caused by antifungal therapy
Analytical specificity (e.g., cross-reactivity):	Ability to determine solely the measurable quantity it purports to measure
Analytical sensitivity	Lowest detectable concentration of the analyte it purports to measure