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**Guideline for evaluation of qualitative test performance
(English Translation)**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is formulated in accordance with the National Clinical Laboratory Standardization Committee (NCCLS) EP12-A Vol.22 No.14 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline and EP12-A2 Vol.28 No.3 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline-Second Edition.

This standard was drafted. National Health and Family Planning Commission Clinical Testing Center, Guangdong Provincial Hospital of Traditional Chinese Medicine, Beijing Chaoyang Hospital affiliated to Capital Medical University.

Introduction

Qualitative measurement is one of the most commonly used methods in clinical laboratories. It is widely used as a screening, diagnosis and treatment method for various diseases, but it is in the work, often because different manufacturers reagents, different methods and even different laboratories use the same reagents or methods to get different results, shadow the clinical application of the results of the qualitative test. In order to ensure the consistency and comparability of daily test results, the clinical laboratory will be the corresponding qualitative test.

Before the reagents, methods or detection systems are used for routine testing, performance verification or methodological comparison evaluation of the reagents, methods or detection systems is required.

Because each laboratory has different emphasis in experimental design, data analysis or interpretation of results, there are many methodological evaluations for qualitative determination.

Diverse. In order to ensure that the laboratory's qualitative measurement performance

verification or evaluation has rules to ensure the quality of laboratory qualitative testing, standard.

Qualitative measurement performance evaluation guide

1 Scope

This standard specifies the evaluation method for qualitative measurement performance. The qualitative measurements described in this standard are limited to only two test results (eg.

Positive/negative, reactive/non-reactive) methods. Semi-quantitative for negative results, 1, 2, 3, 4 or titers the precision and methodological comparison tests covered by this standard can only be used for their critical values.

This standard is applicable to laboratories carrying out various types of qualitative testing, as well as research or description of the diagnostic performance of qualitative diagnostic kits.

Manufacturers, regulators and laboratory inspectors.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

NCCLSGP10-A uses the receiver operating characteristic curve to evaluate the clinical accuracy of laboratory testing (Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristics (ROC) plots.

Approved Guideline, 1995)

3 Terms and definitions

The following terms and definitions apply to this document.

Bias bias

When two methods or two instruments perform the comparison experiment, the measured observation average value (measurement under repeated conditions) and the reference side of the measured method the difference between the measured values obtained by the method or the reference instrument.

C5~C95 interval C5~C95 interval Analyte concentration near the critical value, it can be considered that the analyte detection result outside this concentration range is always

negative (concentration $\leq C_5$)?? Finally positive (concentration $> C_{95}$).

Note 1: The existence of imprecision makes the detection results within this interval not always consistent.

Note 2: The letter C is an abbreviation of concentration, and the subscript (5, 50 or 95) indicates the percentage of positive results.

Note 3: C_5 is the analyte concentration when only 5% of the tested samples can be judged as positive, and C_{95} is the analyte when 95% of the tested samples can be judged as positive.

concentration.

50% concentration C_{50} Analyte concentration close to the critical value, repeated detection of a single sample of this concentration will yield 50% positive results and 50% negative Sexual results.

Accuracy

The proximity between the measured result of the analyte and the actual result.