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**INDUSTRY STANDARD OF THE
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**Guideline for performance characteristics of immunological
qualitative test
(English Translation)**

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Foreword

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

Introduction

There are many important routine test items for clinical qualitative immunoassays, with clear clinical significance and wide application. Clinical qualitative immunoassay results Comparable accuracy is the basic need for medical and health work. Enhancing and ensuring the accuracy and comparability of test results is the quality of clinical testing and management.

Improve the important content of the work. Quality management must have clear quality control indicators, clinical qualitative immunoassay important routine test items Analytical quality control indicators mainly include. precision, accuracy, analytical sensitivity (ie, the

minimum detection limit), and the ability to detect transformed serum disks Force, analysis of specificity (cross-reactivity) and interference factors.

Existing clinical qualitative immunoassay tests for important routine items have a large gap in detection performance, and even some commercial kits are the quality control indicators, etc. are not given in the book. In addition, the most important performance indicators for these reagents should currently be achieved in some projects.

Low requirements lack corresponding standards and regulations. Therefore, it is difficult for clinical laboratories to fully evaluate the performance of the reagents used and also make the test results the accuracy and comparability are hard to improve.

This standard will be used to determine the detection systems or reagents (including commercial and clinical) required for laboratories carrying out clinical qualitative immunoassays.

Laboratory-made reagents) interpret the interpretation and minimum requirements of analytical quality control indicators to ensure that clinical laboratories can evaluate correctly Related qualitative immunological reagents.

Clinical qualitative immunoassay analysis of important routine items Quality requirements

1 Scope

This standard stipulates the clinical qualitative immunoassay method and clinical qualitative immunological test important routine quality control indicators.

This standard applies to medical laboratories carrying out various clinical qualitative immunoassays.

2 Terms and definitions

The following terms and definitions apply to this document.

Accuracy

The closeness of the analyte to the actual result. The definition of accuracy in qualitative determination means that the sample is positive or negative Determine the degree of agreement between the results and their true results. This is usually achieved through methodological comparisons.

Analytical sensitivity Lower limit detectionlimits the lowest concentration level of the test substance can be repeatedly detected. The lower limit of determination may vary for different types of specimens.

Analytical specificity A test method only reacts to the test substance in the sample and does not react with other substances.

Analyte

The substances or ingredients tested in laboratory tests.

NOTE: Includes any element, ion, mixture, substance, factor, infectious substance, cell, organelle, (enzyme, hormone, or immunogen) activity, identity, presence, or absence, Concentration, activity, intensity, or other features that need to be determined.

Bias bias

The difference between the test result and the true value.

5% detection concentration 5% of detection concentration C5 A 5% positive result will result when the analyte is tested at a concentration of C5. When using a sample with a concentration less than C5 for repeatability testing, Continue to get a negative result.

Critical concentration critical concentration C50 Analyte concentrations at or near the critical value will yield 50% positive results when multiple samples are repeatedly tested at this concentration.

50% of negative results.