ICS 11.100.10
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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1789.6-2023

In vitro diagnostic test systems - Performance evaluation method - Part 6: Precision, diagnostic sensitivity and specificity of qualitative reagents

体外诊断检验系统 性能评价方法 第6部分：定性试剂的精密度、诊断灵敏度和特异性

Issued on: January 13, 2023 **Implemented on: January 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1.Structure and Drafting Rules for Standardization Documents" drafting. This document is part 6 of YY/T 1789 "Methods for Performance Evaluation of In Vitro Diagnostic Testing System". YY/T 1789 has been published in the following Lower part.

3.Limits of detection and limits of quantitation;

4.Linear interval and reportable interval;

5.Analytical specificity;

6.Precision, diagnostic sensitivity and specificity of qualitative reagents. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State

Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). This document was drafted by: Beijing Institute of Medical Device Testing, Beijing Shuimu Jiheng Biotechnology Co., Ltd., Kemei Diagnostics Technology Co., Ltd. Co., Ltd., Beijing Medical Device Evaluation and Inspection Center, Beijing You'an Hospital Affiliated to Capital Medical University, Sanxiang Biotechnology Co., Ltd. Company, Aiwei Technology Co., Ltd., Guilin Youlit Medical Electronics Co., Ltd., Zhuhai Livzon Reagent Co., Ltd. The main drafters of this document. Li Zheng, Yang Zongbing, Lin Xiyang, Zheng Jie, Lou Jinli, Deng Zhongping, Zhou Fengliang, Liu Yunpeng, Dai Junying.

In the performance evaluation of in vitro diagnostic medical device products, in vitro diagnostic instruments, reagents, calibrator, etc. participate together, reflecting the Therefore, YY/T 1789 adopts the concept of system to describe. The evaluation of analytical performance refers to the estimation of the reliability of the results of the measurement system for the detection of patient samples. Analytical Performance of In Vitro Diagnostic Test Systems Including precision, trueness, limit of detection and limit of quantitation, linear interval and reportable interval, analytical specificity, precision of qualitative reagents, diagnostic sensitivity sensitivity and specificity etc. YY/T 1789 is proposed to consist of the following parts.

1.Precision. The purpose is to provide manufacturers with the precision (including weight) of the in vitro diagnostic test system for quantitative testing. Refolding, intra-laboratory precision, and inter-laboratory precision) performance evaluation provides method guidance.

2.Correctness. The purpose is to provide the manufacturer with the correctness performance evaluation of the in vitro diagnostic test system for quantitative testing. Provides method guidance.

3.Limits of detection and limits of quantitation. The purpose is to provide manufacturers with the detection limit and Quantitation limit performance evaluation provides method guidance.

4.Linear interval and reportable interval. The purpose is to provide manufacturers with in vitro diagnostic test systems for quantitative testing Provide method guidance for linear interval and reportable interval performance evaluation.

5.Analytical specificity. The purpose is to provide manufacturers with analytical specificity for in vitro diagnostic test systems for quantitative testing. Provide methodological guidance for sexual performance evaluation.

6.Precision, diagnostic sensitivity and specificity of qualitative reagents. The purpose is to provide manufacturers with qualitative tests for in vitro diagnostics Provide method guidance for performance evaluation of precision, diagnostic sensitivity and specificity of diagnostic testing system. This document is mainly used to evaluate the precision, diagnostic sensitivity and specificity of qualitative reagents. The measurement results of

qualitative reagents are different from those reported by quantitative reagents. Usually, qualitative reagents only report qualitative results, such as negative and positive. The performance evaluation of qualitative reagents usually includes the precision, diagnostic sensitivity and specificity of qualitative reagents, etc. This document mainly focuses on the above evaluation items An introduction to the evaluation method. In vitro diagnostic test system performance evaluation method Part

1 Scope

YY/T 1789.6 is the part of the Chinese IVD performance evaluation series that deals with qualitative reagents, the tests that answer positive or negative rather than returning a number. Evaluating them takes different statistics from a quantitative assay: precision has to be expressed around the cut-off where the answer flips, and sensitivity and specificity have to be established against a defined reference with a defined population. This document specifies how those studies are designed, how many samples are needed and how the results are calculated and reported. Almost every infectious disease test, pregnancy test and rapid screening assay is qualitative. For a diagnostics manufacturer, this is the method a Chinese reviewer expects the performance claims in a registration dossier to have been generated by.

This document specifies the performance evaluation methods for the precision, diagnostic sensitivity and specificity of qualitative reagents for in vitro diagnostic test systems. This document applies to manufacturers' evaluation of the precision, diagnostic sensitivity and specificity of in vitro diagnostic test systems for qualitative tests. This document does not apply to the performance evaluation of in vitro diagnostic test systems whose results are reported as semiquantitative. This document does not apply to performance verification in medical laboratories, nor does it apply to product type inspection.

2 Normative references

The content in the following documents constitutes the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

YY/T 1441 General Requirements for Performance Evaluation of In Vitro Diagnostic Medical Devices

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 A set of operations for identifying or classifying substances based on their chemical or

physical properties. Examples. chemical reactions, solubility, relative molecular mass, melting point, radiation properties (emission, absorption), mass spectrometry, nuclear half-life. [Source: GB/T 29791.1-2013, A.3.43]

3.2 Measurement precision measurementprecision precision precision Under specified conditions, repeated measurements are made on the same or similar measured objects to obtain the degree of consistency between the measured indications or the measured values. Note 1 to entry. Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance and coefficient of variation under specified measurement conditions. Note

2.The specified conditions can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement or reproducibility conditions of measurement (see GB/T 6379.5). Note

3.Measurement precision is used to define measurement repeatability, intermediate measurement precision and measurement reproducibility. Note

4.Repeated measurements refer to results obtained on the same or similar samples in a manner that is not affected by previous results. [Source: GB/T 29791.1-2013, A.3.29]

3.3 C5~C95intervalC5~C95interval The analyte concentration near the critical value, it can be considered that the test results of the analyte outside this concentration range are always negative (concentration < C5) or always negative. Finally positive (concentration >C95). Note

1.The existence of imprecision makes the test results within this interval not always consistent.