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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1789.5-2023

In vitro diagnostic test systems - Performance evaluation method - Part 5: Analytical specificity

体外诊断检验系统 性能评价方法 第5部分：分析特异性

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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 the fifth part of YY/T 1789 "In vitro diagnostic test system performance evaluation method": YY/T 1789 has been issued The following sections:

--- Part 1: Precision;

--- Part 2: Correctness;

--- Part 3: Limits of detection and limits of quantitation;

--- Part 4: Linear interval and reportable interval;

--- Part 5: Analytical specificity;

--- Part 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 Inspection, Beijing Shuimu Jiheng Biotechnology Co:, Ltd:, Shenzhen Yahui Longsheng Biotechnology Co:, Ltd:, Nanfang Hospital of Southern Medical University, Fosun Diagnostics Technology (Shanghai) Co:, Ltd:, Dirui Medical Technology Co:, Ltd: Company, Beckman Coulter Trading (China) Co:, Ltd:, Guangzhou Wondfo Biotechnology Co:, Ltd: The main drafters of this document: Zhao Bingfeng, Yang Zongbing, Huang Tao, Zheng Lei, Fan Hua, Wu Huifan, Zhang Silu, Sun Yaling, Li Shengmin:

In the performance evaluation of in vitro diagnostic medical device products, in vitro diagnostic instruments, reagents, calibrator, etc: participate together, reflecting the Therefore, this series of standards uses 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 "Methods for Performance Evaluation of In Vitro Diagnostic Testing System" is proposed to be composed of the following parts:

--- Part 1: Precision: The purpose is to give the manufacturer 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:

--- Part 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:

--- Part 3: Limits of detection and limits of quantitation: The purpose is to provide the manufacturer with the detection limit and Quantitation limit performance evaluation provides method guidance:

--- Part 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:

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

--- Part 6: Precision, diagnostic sensitivity and specificity of qualitative reagents: The purpose is to provide manufacturers with in vitro diagnostic The precision, diagnostic sensitivity and specificity of the diagnostic test system: This document is intended primarily for the evaluation of assay specificity: Analytical specificity is also known as the selectivity of the analytical system, that is, the ability of the measurement system, using a specified measurement procedure, for one or more Measurements give measurements that do not depend on each other or on any other quantity in the system being measured: In laboratory medicine, the term analysis Specificity is used to describe the ability of a detection procedure to detect or measure only the presence of a measurand when other quantities are present in the sample: best when used The full term for analytical specificity is used to avoid confusion with diagnostic specificity: In vitro diagnostic test system performance evaluation method Part 5: Analytical Specificity

1 Scope

YY/T 1789.5 covers analytical specificity, the part of an IVD evaluation that asks what else the assay responds to. A test that measures the right thing but also responds to a structurally similar molecule, a common drug, haemolysis or lipaemia will produce confidently wrong results in exactly the patients who are sickest. This document sets out how interference and cross-reactivity studies are designed and run: which substances have to be challenged, at what concentrations, how the effect is quantified and how a significant interference is declared and reported in the instructions for use. It is the least glamorous part of an IVD dossier and one of the most scrutinised. For a diagnostics manufacturer, this is the protocol a Chinese reviewer expects the specificity claims to rest on.

This document specifies methods for evaluating the analytical specific performance of in vitro diagnostic test systems: This document is intended for use by manufacturers in evaluating the analytical specificity of in vitro diagnostic test systems for quantitative testing, based on quantitative measurements and passing Qualitative in vitro diagnostic test systems (such as enzyme-linked immunosorbent assay for pathogenic microorganism antigens or antibody detection kits) for threshold judgment results Assay specificity evaluation: This document does not apply to in vitro diagnostic test systems in which results are reported as nominal and ordinal scales, e:g: for blood cell identification, microbiological Performance evaluation of in vitro diagnostic test systems for substance identification, nucleic acid sequence identification, and urine particle identification: This document does not apply to performance verification in medical laboratories, nor does it apply to product type inspection:

2 Normative references

The contents of the following documents constitute 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:

GB/T 29791:1-2013 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part 1: Terms, definitions and common enquiries

YY/T 1441 General Requirements for Performance Evaluation of In Vitro Diagnostic Medical Devices WS/T 416-2013 Guidelines for interference experiments

3 Terms and Definitions

The following terms and definitions apply to this document: 3:1 interference System effect of a measurement caused by an influencing quantity which does not itself generate a signal in

the measuring system, but which causes a change in the indication increase or decrease: NOTE: Interference to the measurement results is related to the concept of assay specificity: The more specific a measurement procedure is relative to the other components of the sample, the less susceptible it is to these Analytical interference of compounds: [Source: GB/T 29791:1-2013, A:3:2] 3:

2 The capability of a measurement system, using a specified measurement procedure, to give measurement results for one or more measurands that are independent of each other and of the received Any other quantity in the system being measured: Example: The ability of a measurement system to measure plasma creatinine concentration undisturbed by glucose, uric acid, ketone bodies, or protein concentrations using the alkaline picric acid procedure: