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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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In vitro diagnostic test systems - Requirements for preparing manufacturer's reference materials for qualitative detection reagents

体外诊断检验系统 定性检测试剂企业参考品设置要求

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC 136). This document was drafted by: Center for Medical Device Evaluation, National Medical Products Administration; Beijing Institute for Medical Device Testing (Beijing Municipality). Medical Biological Protective Equipment Testing and Research Center), Beijing Medical Device Evaluation and Inspection Center, National Health Commission Clinical Laboratory Center, China National Institutes for Food and Drug Control, Beijing Shuimu Jiheng Biotechnology Co., Ltd., Beijing Wantai Biological Pharmacy Co., Ltd., and Shenzhen BGI Genomics Co., Ltd. Technology Co., Ltd., Shenzhen Mindray Bio-Medical Electronics Co., Ltd., bioMérieux Diagnostics Products (Shanghai) Co., Ltd., Zhengzhou Antusheng Material Engineering Co., Ltd. The main drafters of this document are. Jiao Tong, Li Cen, Tang Na, Dai Leiying, Sun Rong, Zhou Weiyan, Tian Yabin, Zhang Shuo, Xian Yangling, Zhang Yanyan, and Shi Xiaoyong. Wang Shaoying and Zhang Lihong. Qualitative test reagents for in vitro diagnostic testing systems Enterprise Reference Material Setting Requirements

1 Scope

YY/T 2001 tells an IVD manufacturer what its own reference panel has to contain. It specifies the general requirements for a manufacturer's reference materials for qualitative in vitro diagnostic reagents, and then the specific requirements for setting up the positive reference panel, the negative reference panel, the limit of detection panel and the precision panel. For a qualitative assay these four panels are the evidence base for every performance claim, and in Chinese registration they are examined as a defined set rather

than left to the manufacturer's discretion. For a company registering a qualitative IVD in China, whether an infectious disease assay, a rapid test or a molecular kit, this is the standard the in-house reference panel is judged against, and the document to read before the panel is built rather than after.

This document specifies the general requirements and specific requirements for enterprise reference materials for qualitative in vitro diagnostic reagents (hereinafter referred to as "enterprise reference materials"). Setting of sex reference material, setting of negative reference material, setting of detection limit reference material, setting of precision reference material. This document applies to the setting of enterprise reference materials for quality control of in vitro diagnostic reagent products for qualitative testing. This document does not apply to reagents for microbial identification or drug susceptibility testing, or cell culture media used for cell selection, induction, and differentiation.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Manufacturer's reference material A reference substance designed and prepared by a company to evaluate and control the performance characteristics of a product.

3.2 Reference material; RM It possesses sufficient uniformity and stability in one or more properties for calibration, assignment of values to other substances, or provision of quality assurance. substance. [Source: GB/T 19703-2020, 3.4]

3.3 sample Taken from one or more representative parts of a system, intended to provide relevant information about that system. Example. A portion of serum taken from the original sample of clotted blood. [Source: GB/T 29791.1-2013, 3.64]

4 General Requirements

The development process of enterprise reference materials fully considers matrix effects and biosafety risks, and can be referenced to the description in GB/T 15000.5. The uniformity and stability of the industrial reference sample should meet the requirements of the evaluation measurement procedure. The matrix and nucleic acid type of the enterprise reference material should be consistent with the actual clinical samples that are intended to be used. The genotype/subtype/serotype, concentration/titer, etc. of the enterprise's reference products should all be determined using diagnostic accuracy standards or other reasonable methods. The method is used for verification.

Note. The standard method for diagnostic accuracy is also known as the gold standard

method. The following special treatments may be considered when clinical samples exhibit the following conditions.