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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1882-2023

Treponema pallidum antibodies detection kit (luminescence immunoassay)

梅毒螺旋体抗体检测试剂盒（发光免疫分析法）

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Table of Contents

1 Scope
2 Normative references
3 Terms and Definitions
4 Requirements

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: 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: China National Institutes for Food and Drug Control, Zhengzhou Antu Bioengineering Co:, Ltd:, Kemei Diagnostics Technology Co:, Ltd: Co:, Ltd:, Abbott Trading (Shanghai) Co:, Ltd:, Roche Diagnostic Products (Shanghai) Co:, Ltd:, Sysmex Medical Electronics (Shanghai) Co:, Ltd: Division, Shenzhen New Industry Biomedical Engineering Co:, Ltd: The main drafters of this document: Xia Deju, Wang Xinming, Wang Jianmei, Wu Xiaojun, Cai Xiaorong, Su Jing, Yuan Jinyun: Treponema pallidum antibody detection kit (luminescence immunoassay)

1 Scope

YY/T 1882 is the Chinese standard for kits that detect antibodies to Treponema pallidum, the syphilis bacterium, by luminescence immunoassay. It sets out how such a kit is classified, the technical requirements it has to meet, the test methods that demonstrate them, and the labelling, packaging and storage rules. Syphilis serology is done on every blood donation and in routine antenatal screening in China, so these kits run in enormous volume and a false negative has consequences beyond the individual patient. Luminescence immunoassay is the automated chemistry that has displaced manual methods in Chinese laboratories, which is why it gets a standard of its own. For a diagnostics manufacturer this is the document an NMPA registration is assessed against, and the reference a hospital laboratory cites when qualifying a supplier.

This document specifies the requirements, test methods, identification, labeling and use of the Treponema pallidum antibody detection kit (luminescence immunoassay) Instructions, packaging, transportation and storage: This standard applies to sandwich method or

indirect method as the basic principle, using chemiluminescence immunoassay, immunofluorescence analysis, time analysis Differential immunofluorescence analysis for the qualitative detection of Treponema pallidum antibodies in human serum and/or plasma:

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 191 Packaging, storage and transportation icon marks GB/T 29791:

2 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part 2: In vitro diagnostic reagents for professional use

3 Terms and Definitions

This document does not have terms and definitions that need to be defined:

4 Requirements

1 Appearance Appearance should meet the following requirements:

a) The outer packaging should meet the requirements of the manufacturer;

b) The composition of the kit should be complete and meet the requirements of the manufacturer: 4:

2 Conformity rate of negative reference product Use the national negative reference product for testing, and the coincidence rate of the negative reference product should be >=18/20; or use the standardized negative reference product for testing, and the result The results should meet the corresponding requirements:

Note: See Appendix A for information on national negative reference products involved in this document: 4:

3 Conformity rate of positive reference products Use national positive reference materials for testing, and the coincidence rate of positive reference products should be >= 8/10; use or standardized positive reference materials for testing, and the results The results should meet the corresponding requirements:

Note: See Appendix A for information on national positive reference products involved in this document: