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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1893-2023

Y chromosome microdeletion detection kit

Y染色体微缺失检测试剂盒

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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 contents of this document may involve patents, and the issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: China Institute of Food and Drug Control, Henan Institute of Drug and Medical Device Inspection, Beijing Institute of Medical Device Inspection Research Institute (Beijing Medical Biological Protective Equipment Inspection and Research Center), Peking Union Medical College Hospital of the Chinese Academy of Medical Sciences, and Yuer Gene Technology (Suzhou) have Co., Ltd., Yaneng Biotechnology (Shenzhen) Co., Ltd., Guangzhou Daan Gene Co., Ltd., and Shanghai Toujing Life Technology Co., Ltd. The main drafters of this document. Yu Ting, Zhang Juanli, Sun Li, Yang Zhuo, Luo Junfeng, Han Jingyan, Lei Shuying, Liu Nansong, Jiang Xiwen, He Lirong, Guo Anliang, Qu Shoufang, Sun Nan, Hu Zebin. Y chromosome microdeletion detection kit

1 Scope

YY/T 1893 is the Chinese standard for kits that detect Y chromosome microdeletions, the AZF region losses that cause a large share of otherwise unexplained male infertility. The result changes what a couple is offered: some deletions predict that sperm retrieval will fail, and all of them are passed to a son conceived by ICSI, which makes the test a genetic counselling matter and not only a laboratory one. The document sets out how such a kit is classified, the technical requirements it has to meet, the test methods that demonstrate them, and the labelling and storage rules. Assisted reproduction volumes in China are large and the test is routine in the male workup. For a diagnostics manufacturer, this is the text a Chinese registration is assessed against.

This document specifies the requirements, test methods, labeling and instructions for use, packaging, transportation and storage of Y chromosome microdeletion detection kits. This document is applicable to Y chromosome microdeletion detection kits such as PCR-fluorescent probe method, PCR-capillary electrophoresis method, and biochip method. (hereinafter referred to as "test kit"). This document does not apply to detection kits based on next-generation sequencing methods.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 191 Packaging, storage and transportation pictorial mark

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

There are no terms or definitions to be defined in this document.

4 Requirements

4.1 Appearance Manufacturers should specify appropriate appearance requirements based on the packaging characteristics of the product. Generally, the kit should include the composition, properties, inner and outer packaging of each component. requirements for packaging and clear labeling.

4.2 Detection limit Test the national reference products or enterprise detection limit reference products whose total DNA content is not higher than 15ng/reaction or 3000 white blood cells/reaction. The results should be consistent with the expected results.

4.3 Compliance rate of positive reference products When testing national positive reference products or corporate positive reference products, the results should be consistent with the corresponding Y chromosome microdeletion type.

4.4 Compliance rate of negative reference products When testing national negative reference materials or corporate negative reference materials, the result should be that no Y chromosome is detected or no Y chromosome is detected within the detection range of the kit. Chromosomal microdeletion type.

4.5 Repeatability Test the enterprise's repetitive reference products 10 times each. The results of the same repetitive reference product should be consistent, and the requirements

are.