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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 1961-2025

Survival motor neuron gene (SMN) detection kit

运动神经元存活基因（SMN）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 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/TC136). This document was drafted by: China National Institutes for Food and Drug Control, BGI Genomics Co., Ltd., and Jiangsu Provincial Institute for Medical Device Testing. Jingliang Technology (Shenzhen) Co., Ltd., Guangzhou Darui Biotechnology Co., Ltd., Yaneng Biotechnology (Shenzhen) Co., Ltd., Shenzhen Hui Zhong Biotechnology Co., Ltd., Suzhou Tianlong Biotechnology Co., Ltd., Shanghai Wuseshi Medical Technology Co., Ltd., Jiangsu Shuoshi Biotechnology Co., Ltd. Joint-stock limited companies, Beijing Yuewei Gene Technology Co., Ltd., and Xiamen Bio-Xun Biotechnology Co., Ltd. The main drafters of this document are. Sun Nan, Xiang Jiale, Zhang Xiaoyan, Li Jinghua, Yang Xu, Lei Shuying, Yang Yongxian, Wang Xiaozhou, Li Mingyang, and Zhang Rong. Wang Chunfang, Chen Qionge, Qu Shoufang, Yu Ting. Motor neuron survival gene (SMN) detection kit

1 Scope

YY/T 1961 is the product standard for the SMN gene detection kit, used to diagnose spinal muscular atrophy and to screen carriers. It specifies the requirements, the marking, the labelling and the instructions for use of survival motor neuron gene detection kits, together with the packaging, transport and storage, and describes the corresponding test methods. SMN testing is technically awkward because SMN1 and SMN2 are nearly identical and the

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clinically meaningful result is a copy number rather than a presence or absence, so a kit standard has to address discrimination and quantitation together. With SMA therapies now available and newborn screening expanding, the assay has moved from rare-disease confirmation to population testing. For a manufacturer registering an SMN kit in China, this is the governing product standard.

This document specifies the requirements, labeling, instructions for use, packaging, and transportation of motor neuron survival gene (SMN) detection kits. The transport and storage methods are described, along with the corresponding experimental methods. This document applies to quantitative real-time PCR, PCR-fluorescent probe method, fluorescent PCR-capillary electrophoresis, and fluorescent PCR melting curve. The test kit was developed using [the method].

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2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 191 Pictorial Symbols for Packaging and Storage

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

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 The protein is widely expressed in various tissues and cells, participates in the assembly of the spliceosome protein complex, and is an essential housekeeping protein for the survival of eukaryotic cells.

Note. Pathogenic mutations in the SMN1 biallelic gene usually lead to SMA; 95% of SMA patients are homozygous for exon 7 of the SMN1 gene. The genotype-phenotype association is clear and missing.

3.2 The modifying gene for spinal muscular atrophy is located at 5q

13.2 and encodes the same SMN protein as SMN1.

Note. SMN2 and SMN1 sequences are highly homologous, differing by only 5 bases, with the C/T at position 6 of exon 7 (c.840) causing 90% of the differences. SMN2 mRNA exon 7 is selectively spliced, resulting in only 10% SMN2 expression of the full-length functional SMN protein. The patient carries copies of SMN2. The more numbers, the lighter the

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phenotype.

4 Requirements

4.1 Appearance Manufacturers should specify the appearance requirements for the kits.

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