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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1963-2025

Colorectal cancer related gene methylation detection kit (fluorescent PCR)

结直肠癌相关基因甲基化检测试剂盒（荧光PCR法）

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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 Guangzhou Da An Gene Co., Ltd. The company, Henan Provincial Institute for Drug and Medical Device Testing (Henan Provincial Vaccine Batch Release Center), Xiamen AmoyDx Biotechnology Co., Ltd., Guangzhou Kangliming Biotechnology Co., Ltd., Bocheng (Beijing) Technology Co., Ltd., Shanghai TransGen Biotech Co., Ltd., Shanghai Kun Yuan Health Technology Co., Ltd., Southern Medical University Southern Hospital, Shaanxi Provincial Institute for Food and Drug Control, Guangzhou Baochuang Biotechnology Co., Ltd. company. The main drafters of this document are. Qu Shoufang, Yu Jing, Jiang Xiwen, Zhang Juanli, Li Youcai, Li Meng, Liu Xingfeng, Guo Anliang, Liu Rui, Zheng Lei, and Cai Hu. Pan Tengfei, Min Hong, Wang Yuying, Yuan Fuqiang, Yu Ting, Zhang Wenxin, Jia Zheng, Sun Nan, Li Lili, Huang Jie. Colorectal cancer-related gene methylation detection kit (Fluorescent PCR method)

1 Scope

YY/T 1963 is the product standard for the colorectal cancer methylation test by fluorescent PCR, the molecular screening assay that reads DNA methylation markers from stool or blood. It specifies the requirements, the labelling and the instructions for use, together with the packaging, transport and storage of these kits, and describes the corresponding test methods. Methylation screening has become the main non-invasive alternative to colonoscopy in China, and a kit-level standard is what makes competing products

comparable on sensitivity, specificity and stability rather than on marketing claims. For a manufacturer or a distributor registering a colorectal methylation kit in China, this is the standard the specification and the registration test report are written against.

This document specifies the requirements for colorectal cancer-related gene methylation detection kits, labeling and instructions for use, as well as packaging, transportation and storage. The document describes the corresponding experimental methods. This document is applicable to the qualitative detection of colorectal cancer-related gene methylation status in peripheral blood plasma and stool samples, such as Septin9. Genes such as SDC2, BCAT1, SFRP2, TFPI2, NDRG4, and BMP3. This document applies to kits for methods such as fluorescent PCR and PCR fluorescent probe methods, but not to kits for high-throughput sequencing.

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 DNA methylation Under the catalysis of DNA methyltransferases, a methyl group is added to a base of a DNA molecule. The most common method is to... A methyl group is added to the 5th carbon atom of the CpG dinucleotide cytosine to form 5-methylcytosine (5mC).

3.2 bisulfite conversion DNA oxidative deamination was induced by bisulfite, converting unmethylated cytosine to uracil, while methylated cytosine remained unchanged. constant.

4 Requirements

4.1 Appearance The kit should meet the manufacturer's appearance requirements. All components of the kit should be complete and intact, with no liquid leakage.

4.2 Nucleic acid extraction function The nucleic acid extraction function should meet the following requirements.

a) For kits containing nucleic acid extraction components, the manufacturer should specify appropriate requirements for nucleic acid extraction and verify the nucleic acid extraction function. Evidence, such as fully considering interference factors present in the sample extraction process;

b) For kits that require sample extraction but do not contain nucleic acid extraction components, the manufacturer shall provide or specify the extraction kit and provide verification.