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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1892-2024

Breakpoint cluster region - Abelson leukemia virus (BCR-ABL) fusion gene detection kit

断裂点簇集区-艾贝尔逊白血病病毒(BCR-ABL)融合基因检测试剂盒

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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 of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Clinical Testing Laboratories and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: China Food and Drug Inspection Institute, Guangzhou Daan Gene Co., Ltd., Shanghai Ruiang Gene Technology Co., Ltd. Co., Ltd., Jiangsu Medical Device Inspection

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1 Scope

YY/T 1892 is the product standard for the BCR-ABL fusion gene detection kit. BCR-ABL is the Philadelphia chromosome translocation that defines chronic myeloid leukaemia, and its quantification is the model case of molecular monitoring in oncology: treatment response, the decision to continue or switch a tyrosine kinase inhibitor, and the possibility of stopping therapy altogether are all read off the transcript level on an international scale. That places unusual weight on the kit's quantitative accuracy and its traceability to that scale. The standard specifies the requirements, the labelling, the instructions for use and the packaging, transport and storage. For a manufacturer or a distributor registering a BCR-ABL kit in China, this is the governing product standard.

This document specifies the requirements, labeling, and test kits for the breakpoint cluster region-Abelson leukemia virus (BCR-ABL) fusion gene test. and instructions for use, packaging, transportation and storage, and describes the corresponding test methods. This document is applicable to the detection of breakpoint cluster region-Abelson leukemia virus (BCR-ABL) fusion in peripheral blood samples and bone marrow samples

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

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

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Requirements

4.1 Appearance The kit should meet the appearance requirements specified by the manufacturer. Appearance requirements include but are not limited to the following. the kit components are complete, the packaging It should be clean, without leakage or damage; the signs and labels should be clear.

4.2 Nucleic acid extraction function When applicable, the nucleic acid extraction function should meet the following requirements.

a) For kits containing nucleic acid extraction components, the manufacturer should make appropriate requirements for nucleic acid extraction and verify the nucleic acid extraction function. For example, fully consider the interference factors in the sample extraction process and the possible impact on the subsequent sample amplification process.

b) Samples that require extraction but do not contain nucleic acid extraction kits, the manufacturer's instructions or specified extraction kits, and verification material.

c) For kits that can be directly amplified without sample extraction, the manufacturer should be able to provide sufficient evidence to prove the anti-interference ability of the enzyme in its product. Disturbance.