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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1967-2025

Bead-based flow cytometric analyzer

流式点阵仪

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Table of Contents

1.Scope 1
2 Normative References 1
3.Terms and Definitions 1
4 Requirements 2
5.Test Methods 4
9 References 10

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: Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center), Sichuan Provincial Institute of Pharmaceutical Research and Testing. Medical Device Inspection and Testing Institute (Sichuan Provincial Medical Device Testing Center), Beijing Medical Device Evaluation and Inspection Center, Beijing Zhizhen Biotechnology Co., Ltd. Company, Beijing Human Intelligent Manufacturing Technology Co., Ltd., Luminex Trading (Shanghai) Co., Ltd., Hubei Provincial Medical Device Quality Supervision and Inspection Institute Research Institute, Hubei Xinzongke Virus Disease Engineering Technology Co., Ltd. The main drafters of this document are. Sun Li, Qu Qian, Jiang Yan, Qin Xiaokun, Meng Zekai, Yin Xiaoting, Li Sijin, Xu Peng, and Wan Xinxin. Flow cytometer

1 Scope

YY/T 1967 is the product standard for the bead-based flow cytometric analyser, the instrument that multiplexes immunoassays by reading coded microspheres in a flow stream. It specifies the requirements, the marking, the labelling, the instructions for use, the packaging, transport and storage of the analyser, and describes the corresponding test methods. Bead array platforms sit between a classical flow cytometer and a plate reader, and in China they are regulated as their own instrument class rather than folded into either.

As with other Chinese IVD instrument standards, the accompanying documentation is regulated together with the hardware. For a manufacturer or an importer of multiplex bead analysers seeking Chinese registration, this is the standard the type testing is run against.

This document specifies the requirements, marking, labeling and instructions for use, packaging, transportation and storage of flow cytometers, and describes the corresponding testing methods. method. This document applies to flow cytometers (hereinafter referred to as fractional cytometers) used in medical laboratories. Fractional cytometers are based on flow cytometry fluorescence technology and are used for... Qualitative and/or quantitative detection of various analytes, such as nucleic acids, proteins, peptides, and small molecules, in human samples.

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 4793.1 Safety requirements for electrical equipment for measuring, control and laboratory use - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 High-throughput detection equipment based on flow cytometry technology performs qualitative analysis by identifying coded microspheres and the target substances bound to their surfaces. And/or quantitative detection.

3.2 High-throughput multiplex detection technology based on coded microspheres and flow cytometry enables simultaneous qualitative analysis of multiple analytes in the same sample. And/or quantitative detection.

3.3 semi-automatic A device that requires external operation to perform some or all of the following tasks. sample and reagent addition, mixing, washing, incubation, amplification, hybridization, etc.