ICS 11.100
CCS C44

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1916-2023

Interleukin-6 (IL-6) testing kit (labelling immunoassay)

白介素6（IL-6）测定试剂盒（标记免疫分析法）

Issued on: September 5, 2023 **Implemented on: September 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

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 be subject to patents. The publisher of this document assumes no 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: Beijing Leadman Biochemical Co., Ltd., Chongqing Medical Device Quality Inspection Center, Beijing Medical Device Inspection Laboratory Research Institute, Shenzhen New Industry Biomedical Engineering Co., Ltd., Zhengzhou Antu Bioengineering Co., Ltd., Nanjing Novozan Medical Therapeutic Technology Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., and Zhonghan Shengtai Biotechnology Co., Ltd. The main drafters of this document. Li Ran, Luo Chunmei, Liu Yanchun, Wang Wenfeng, Chen Jing, Wang Huiying, Su Jianchen, and Wang Zhong. Interleukin 6 (IL-6) Assay Kit (labeled immunoassay)

1 Scope

YY/T 1916 is the Chinese standard for interleukin-6 test kits using labelled immunoassay. IL-6 rises early in sepsis, ahead of procalcitonin and well ahead of C-reactive protein, and it is used in Chinese emergency and intensive care to judge how severe an inflammatory response is and how it is trending under treatment. It also became a monitored marker in severe respiratory infection and in cytokine release syndrome after cellular therapy. 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, packaging and storage rules. Because the clinical use is serial monitoring, between-run precision matters as much as accuracy. For a diagnostics manufacturer, this is the text a Chinese registration is assessed against.

This document specifies the requirements, test methods and labeling of interleukin-6

(hereinafter referred to as "IL-6") assay kit (labeled immunoassay), Labeling and instructions for use, packaging, transportation and storage requirements. This document is applicable to kits for quantitative determination of IL-6 content in human serum, plasma or whole blood using labeled immunity as the reaction principle. Methodology Including fluorescent labeling immunochromatography, chemiluminescence, etc. This document does not apply to the evaluation of IL-6 calibrators and quality controls.

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 21415 Metrological traceability of measurement calibrators and control substance values assigned to biological samples for in vitro diagnostic medical devices origin

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 The appearance should meet the following requirements.

a) All components of the kit should be complete and complete, and there should be no leakage of liquids;

b) Packaging labels should be clear and easy to identify.

4.2 Traceability The source, assignment process and measurement uncertainty of IL-6 calibrators should be provided in accordance with GB/T 21415 and relevant regulations.

4.3 Detection limit The detection limit should be no higher than 3pg/mL.

4.4 Accuracy The accuracy should meet one of the following requirements. If applicable, the relative deviation method is preferred.