ICS 11.100.10
CCS C44

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1199-2023

Triglycerides assay kit (enzymic method)

甘油三酯测定试剂盒（酶法）

Issued on: January 13, 2023 **Implemented on: July 15, 2023**

Issued by: National Medical Products Administration

Table of Contents

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. This document replaces YY/T 1199-2013 "Triglyceride Determination Kit (Enzymatic Method)". Compared with YY/T 1199-2013, except for the structure In addition to adjustments and editorial changes, the main technical changes are as follows:

a) Modified the requirements for the linear interval (see 4.4,

4.4 of the.2013 edition);

b) Modified the accuracy requirements (see 4.5,

4.5 of the.2013 edition). Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). This document was drafted by: China Institute for Food and Drug Control, Jilin Medical Device Inspection Institute, Chongqing Medical Device Quality Inspection Center, Zhongsheng Beikong Biotechnology Co., Ltd., Beijing Leadman Biochemical Co., Ltd., Mike Biological Co., Ltd., Roche Diagnostics Broken Products (Shanghai) Co., Ltd., Siemens Medical Diagnostic Products (Shanghai) Co., Ltd., Shenzhen Mindray Biomedical Electronics Co., Ltd. The main drafters of this standard. Gao Fei, Chen Lijuan, Lan Hualin, Jin Ling, Ren Yikun, Shi Lijuan, Lai Lianlian, Han Hui, Wan Xianzi, Huang Jie. The release status of previous versions of this document and the documents it replaces are as follows:

---First published as YY/T 1199-2013 in.2013;

--- This is the first revision. Triglyceride Determination Kit (Enzymatic Method)

1 Scope

YY/T 1199 is the Chinese standard for triglyceride assay kits using enzymatic methods. Triglycerides are part of the lipid panel run on a very large share of Chinese adults, and the result feeds directly into cardiovascular risk scoring and into decisions about lipid-lowering treatment. The document sets out how such a kit is classified, the technical requirements it has to satisfy, the test methods that demonstrate them, and the labelling, instructions for use, packaging, transport and storage rules. Because the measurement is used for population-level risk stratification rather than for a single clinical decision, comparability between laboratories and between kits matters as much as accuracy within one. For a diagnostics manufacturer this is the document an NMPA registration is judged against.

This document specifies the requirements, test methods, identification, labeling and instructions for use, packaging, and transportation of triglyceride determination kits (enzymatic method) and storage etc. This document is applicable to the quality control of the triglyceride determination kit (enzymatic method) based on the principle of spectrophotometry, which is used for in vitro determination Quantitative determination of the amount of triglycerides (TG) in human serum or plasma.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 191 Packaging, storage and transportation icons

GB/T 29791.1 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part

3 Terms and Definitions

The terms and definitions defined in GB/T 29791.1 apply to this document.

4 Requirements

4.1 Appearance The appearance requirements of the kit should be specified. Visual inspection, the appearance should at least meet the following conditions.

a) Reagent (box) components are complete;

b) The appearance of the packaging is clean, without leakage or damage;

c) Signs and labels are clearly written.

4.2 Net content The net content of the liquid reagent should not be less than the marked amount.

4.3 Reagent blank The absorbance of the reagent blank should not be greater than 0.2 (at the wavelength specified by the manufacturer, at 37°C, with an optical path of 1.0cm).

4.4 Linear intervals In the interval [0.45,9.04]mmol/L, the linear correlation coefficient r should be >=0.9900. In the interval [0.45,2.00]mmol/L, the absolute deviation of linearity should be within the range of ±0.2mmol/L.