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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1883-2023

Rh blood system C, c, E, e blood grouping reagents (column agglutination test)

Rh血型C、c、E、e抗原检测卡（柱凝集法）

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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 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 Provincial Institute for Medical Device Testing, Changchun Boxun Biotechnology Co:, Ltd: The responsible company, Jiangsu Libo Pharmaceutical Biotechnology Co:, Ltd:, Mike Biological Co:, Ltd:, Bole Life Medical Products (Shanghai) Co:, Ltd: Co:, Ltd:, Osendo Medical Devices Trading (China) Co:, Ltd:, Beijing Jiuqiang Biotechnology Co:, Ltd: The main drafters of this document: Hu Zebin, Chen Lijuan, Chen Weijia, Wang Buqiang, Wang Xiaobo, Hou Lei, Lu Xiongzhang, Liu He, Huang Jie: Rh blood group C, c, E, e antigen test card (column agglutination method)

1 Scope

YY/T 1883 covers the reagent cards used to type the C, c, E and e antigens of the Rh blood group system by column agglutination. Rh typing beyond the D antigen matters in transfusion medicine and in pregnancy, where an unmatched minor Rh antigen can provoke antibodies that complicate every later transfusion or threaten a fetus. The document sets the requirements such a card has to meet and the test methods that verify them, covering the specificity and avidity of the antisera, the performance of the gel or bead column, the stability and the labelling. Column agglutination has largely replaced tube testing in Chinese blood banks because it is readable and automatable. For a manufacturer of blood grouping reagents this is the document a Chinese registration and a lot release are judged against.

This document specifies the requirements, test methods, labels and instructions for use of the Rh blood group C, c, E, e antigen test card (column agglutination method), package Packing, transportation and storage etc: This document is applicable to micro-columns filled

with materials such as gel and glass microbeads: Antibody, using the combination of immunohematology, particle sieving and centrifugation technology, for qualitative detection of C, c, E, Reagents for the detection of e4 antigens: This document does not apply to diagnostic reagents for Rh blood group C, c, E, e antigen detection for blood source screening:

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 icon marks GB/T 29791:

2 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part 2: In vitro diagnostic reagents for professional use

3 Terms and Definitions

This document does not have terms and definitions that need to be defined:

4 Requirements

1 Appearance The anti-C column, anti-E column, anti-c column, anti-e column and quality control column in the test card should be colorless, light yellow or uniform milky white; each column should be dry There should be a liquid layer on the surface of the inner filling, and the filling and liquid of each column should be uniform without foreign matter; after centrifugation, there should be no air bubbles, and the surface of the filling should not There should be a clear slope: 4:

2 Specificity Each column of the test card shall meet the following requirements:

a) The anti-C column should undergo agglutination reaction with normal RhC-positive red blood cells (including C antigen homozygous and heterozygous), and with RhC-negative Red blood cells were negative:

b) The anti-c column should undergo agglutination with normal Rhc-positive red blood cells (including homozygous and heterozygous c antigens), and with Rhc-negative red blood cells: Cells were negative:

c) The anti-E column should undergo agglutination reaction with normal RhE positive red blood cells (including E antigen homozygous and heterozygous), and with RhE negative Red blood cells were negative:

d) The anti-e column should undergo agglutination reaction with normal Rhe-positive red blood cells (including e-antigen homozygotes and heterozygotes), and with Rhe-negative red blood cells: Cells were negative: