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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1256-2024

Replacing YY/T 1256-2015

Ureaplasma nucleic acid detection kit

解脲脲原体核酸检测试剂盒

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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 1256-2015 "Ureaplasma urealyticum nucleic acid amplification detection kit" and is different from YY/T 1256-2015 except In addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) Added normative references GB/T 29791.1 and GB/T 29791.2 (see Chapter 3 and Chapter 7);

b) Deleted the naming and composition (see Chapter 4, Chapter 4 of the.2015 edition);

c) Added general requirements for reagents, including appearance, nucleic acid extraction function, internal standards and/or controls (see 5.1, 5.1.1, 5.1.2, 5.1.3);

d) Added traceability of Ureaplasma urealyticum nucleic acid quantitative reagent (see 5.2.1,

5.1 of the.2015 edition);

e) Change the accuracy item of Ureaplasma urea nucleic acid quantitative reagent to divide it into two items. accuracy and positive reference conformity rate (See 5.2.4, 5.2.5, and

5.1.3 of the.2015 edition);

f) Change the limit of quantification to the limit of detection (see 5.2.7,

5.1.6 of the.2015 edition);

g) Increase the stability of the Ureaplasma urealyticum nucleic acid quantification reagent (see 5.2.9);

h) Delete the genotyping test of Ureaplasma urealyticum nucleic acid qualitative reagent (see

6.2.3 of the.2015 edition);

1 Scope

YY/T 1256 is the product standard for the Ureaplasma nucleic acid detection kit. Ureaplasma urealyticum is a genital tract organism implicated in urethritis, infertility and adverse pregnancy outcomes, and it is difficult to culture, which is why molecular detection is the practical route and why the kits are used in large numbers in Chinese laboratories. The standard stipulates the classification, the technical requirements, the labelling, the instructions for use and the packaging, transport and storage, with the corresponding test methods. It sits under the general molecular kit standard YY/T 1182. For a manufacturer or a distributor registering a Ureaplasma assay in China, this is the standard the specification and registration testing follow.

This document stipulates the classification, technical requirements, labeling, instructions for use, packaging, transportation and storage of Ureaplasma urea nucleic acid detection kits. The corresponding test methods are described. This document is applicable to the nucleic acid detection kit for detecting ureaplasma in human urinary tract, reproductive tract and respiratory tract (hereinafter referred to as the kit). The methodologies include fluorescence PCR, constant temperature amplification, and PCR membrane hybridization.

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 29791.1 Information provided by the manufacturer of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

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

3.1 Ureaplasma It belongs to a group of the smallest prokaryotic microorganisms without cell walls, and is an obligate parasite of eukaryotic organisms. It can use its own Urease breaks down urea. Note

1.Currently, the 14 standard serotypes of Ureaplasma are divided into two major biogroups (or completely independent species) based on phenotype and genotype. Ureaplasma microtypingi Note

2.Ureaplasma urealyticum (biogroup 1) includes serotypes 1, 3, 6 and 14; Ureaplasma urealyticum (biogroup 2) includes serotypes 2, 3, 6 and 14. serotype 1, serotype 4, serotype 5, serotype 7, serotype 8, serotype 9, serotype 10, serotype 11, serotype 12 and serotype 13. Note

3.The Ureaplasma urealyticum referred to in this document includes Ureaplasma urealyticum and Ureaplasma urealyticum.

4 Categories

Can be classified as follows:

a) According to the determination of test results, it can be divided into quantitative detection kits and qualitative detection kits;

b) According to the principle of nucleic acid amplification, it can be divided into variable temperature amplification detection kit and isothermal amplification detection kit;

c) Classified according to methodology, common methodologies include. PCR fluorescent probe method, constant temperature amplification method, and PCR membrane hybridization method.