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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0656-2008

Automated blood culture systems

自动化血培养系统

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Foreword

This standard was proposed by the State Food and Drug Administration. This standard by the national medical clinical laboratory testing and in vitro diagnostic systems for Standardization Technical Committee (SAC/TC136) centralized. This standard is mainly drafted by: American BD Company, bioMerieux, France, Beijing Medical Device Testing. The main drafters of this standard. Tong Mingqing, Shen Ran, Wang Hui, XIAO Zhi-qiang. Automated blood culture systems

1 Scope

YY/T 0656 is the product standard for the automated blood culture system, the incubator and detection instrument that continuously monitors blood culture bottles for microbial growth. Bloodstream infection is a condition where time to result changes outcome directly, and these systems exist to shorten it: they detect the metabolic signature of growth hours before a bottle would look turbid to a technologist. Detection sensitivity across the range of organisms encountered, time to detection, false positive and false negative behaviour and the reliability of continuous incubation are therefore the properties that matter. For a manufacturer or a distributor of automated blood culture instruments and their bottles for the Chinese market, this is the governing product standard.

This standard specifies the automated blood culture system of terms, definitions, requirements, test methods, marking, labeling and instructions, packaging, transport and Storage. This standard applies to clinical laboratories through in vitro, detect human blood under normal conditions or other sterile body fluid (hereinafter referred to as no Bacteria humoral) automated blood culture system of microorganisms (hereinafter referred to as the blood culture system), and the apparatus comprises a blood culture medium supporting. The scope of the standard within the meaning of micro-organisms are bacteria and yeast-like fungi.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including

errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB 4793.1 measurement, control and laboratory use safety requirements for electrical equipment - Part 1. General requirements

GB/T 14710 Medical electrical equipment environmental requirements and test methods

3 Terms and Definitions

The following terms and definitions apply to this standard.

3.1 Clinical laboratory by in vitro detection of human blood or other body fluids in sterile microorganisms.

3.2 For in vitro human blood or other body fluids in sterile microbiological medium.

3.3 Clinical laboratory in vitro human blood or other body fluids in a sterile microbial continuous culture, automatically detect and determine the culture knot Fruit (positive or negative) of the system, which includes a blood culture system and its supporting medium.

3.4 Blood culture system detects blood culture medium in the presence of microorganisms.

3.5 In the culture period, blood culture system failed to detect blood in the culture medium with the presence of microorganisms.

3.6 Blood culture system determines a positive blood culture, but transferred after staining and no species of microorganisms present.

3.7 Blood culture system determines blood culture negative, but after staining and transferred species found in the presence of microorganisms.