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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1958-2025

17-alpha-hydroxyprogesterone testing kit (labelled immunoassay)

17alpha-羟孕酮测定试剂盒（标记免疫分析法）

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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 involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Shenzhen New Industries Biomedical Engineering Co., Ltd., Beijing Hospital, and Beijing Institute for Medical Device Testing. Institute (Beijing Medical Biological Protective Equipment Testing and Research Center), National Institute of Metrology, Shenzhen Yahuilong Biotechnology Co., Ltd. Company, Guangzhou Fenghua Biotechnology Co., Ltd., and Peking Union Medical College Hospital, Chinese Academy of Medical Sciences. The main drafters of this document are. Wang Wenfeng, Zhang Tianjiao, Liu Yanchun, Song Dewei, Zhang Ji, Tan Yuhua, and Yu Songlin. 17alpha-Hydroxyprogesterone Assay Kit (Label-based immunoassay)

1 Scope

YY/T 1958 is the product standard for the 17-alpha-hydroxyprogesterone assay kit by labelled immunoassay, the test used in newborn screening for congenital adrenal hyperplasia and in the endocrine workup of adults. It specifies the technical requirements, the marking, the labelling and the instructions for use, together with the packaging, transport and storage of the kit, and describes the corresponding test methods. Newborn screening assays carry a particular burden: they run on dried blood spots at population scale, where a false negative is missed disease and a false positive is an alarmed family, so precision near the cut-off is the whole game. For a manufacturer or a distributor registering a 17-OHP kit in China, this is the governing product standard.

This document specifies the technical requirements, labeling, marking, and instructions for

use of the 17alpha-hydroxyprogesterone assay kit (labeled immunoassay). The loading, transportation, and storage of the equipment are described, along with the corresponding testing methods. This document applies to the in vitro quantitative determination of human serum and blood using methods such as enzyme labeling, (electro)chemiluminescence labeling, and (time-resolved) fluorescent labeling. Immunoassay kit for 17alpha-hydroxyprogesterone content in plasma and heel blood (dried blood smears on filter paper). This document does not apply to.

a) Immunochromatographic reagent kit;

b) Calibrators and quality control products intended for separate sale.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 191 Pictorial Symbols for Packaging and Storage

GB/T 21415 Metrological Traceability of Calibrators and Control Substances for the Measurement of Quantities in Biological Samples of In Vitro Diagnostic Medical Devices Source

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and Definitions

This document does not contain any terms or definitions that need to be defined.

4 Requirements

4.1 Appearance The appearance must meet the following requirements.

a) The reagent kit should have all components, intact inner and outer packaging, and clear, easily identifiable labels;

b) There should be no leakage of liquid components.

4.2 Traceability Manufacturers shall provide information on the source, assignment process, and measurement uncertainty of 17alpha-hydroxyprogesterone calibrators in accordance with GB/T 21415 and relevant regulations. Content such as degree.

4.3 Limit of Detection For kits used to determine serum or plasma, the limit of detection

should not exceed

0.1 ng/mL; for kits used to determine heel prick blood, the limit of detection should not exceed [missing value].