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# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# YY/T 1911-2023

## Test method of coagulation for medical devices

医疗器械凝血试验方法

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# Table of Contents





## 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 be subject to patents. Release of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Jiangsu Medical Device Inspection Institute, Guangdong Medical Device Inspection Institute Medical Device Quality Supervision and Inspection Institute, Shenzhen Institute of Drug Inspection (Shenzhen Medical Device Testing Center). The main drafters of this document. Qiao Chunxia, Wang Shasha, Yang Lifeng, Wang Shuhan, Jiao Qinlian, Wang Wenjuan, Yang Wenrun, Liang Yongyi, Zhao Zenglin.

GB/T 16886.4-2022 provides the selection criteria for coagulation performance indicators and test methods of medical devices/materials in contact with blood. Therefore, no detailed test procedures and result judgment criteria are given. This document provides the in vitro coagulation properties of medical devices/materials in contact with blood. The test method can be used as the commonly used coagulation test method in GB/T 16886.4-2022 (see Table 2 in GB/T 16886.4-2022). Replenish. Other coagulation test methods may be used after validation. Medical device coagulation test methods

## 1 Scope

YY/T 1911 specifies how the effect of a medical device on blood coagulation is tested. Any device that contacts blood, from a catheter to an oxygenator to a stent, either activates the clotting cascade or does not, and the difference decides whether a patient throws a

thrombus or bleeds. This document sets out the coagulation endpoints to be measured, the blood contact model, the controls and the interpretation, so that a haemocompatibility claim rests on a defined method rather than on a general assertion. Coagulation is one of the categories a Chinese biological evaluation has to address for blood-contacting devices, and it is the one where results vary most between laboratories if the protocol is not fixed. For a manufacturer, this is the method a Chinese reviewer expects the coagulation data to have followed.

This document describes methods for in vitro coagulation testing of medical devices/materials in contact with blood. This document is applicable to the testing of coagulation properties of medical devices/materials.

## 2 Normative reference documents

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

GB/T 16886.4 Biological evaluation of medical devices Part

## 3 Terms and definitions

The terms and definitions defined in GB/T 16886.4 and GB/T 16886.12 apply to this document.

## 4 Selection of tests for interaction with blood

GB/T 16886.12 Biological evaluation of medical devices Part

## 5 Experimental controls

5.1 Blank control Blank plasma, use the same container as the test sample and other controls.

5.2 Positive control It is recommended to use glass beads. If other positive controls are selected, the suitability should be demonstrated.

5.3 Negative control High density polyethylene is recommended. If other negative controls are selected, the suitability should be demonstrated.

5.4 Comparative devices already on the market (optional) The design, materials and clinical use are similar to the test samples, and have been approved or long-term confirmed, and the safety has been recognized.