

ICS 11.040
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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1741-2021

Antithrombin III testing kit

抗凝血酶III测定试剂盒

(English Translation)

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Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by the State Drug Administration:

This standard is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee:

Introduction

In 1954, Seegers et al: first divided antithrombin into four types, and since then, the name of antithrombin III has been used: international health organization (WHO) established the first generation of international reference material (72/1) in 1978, which used the name of antithrombin III: by the UK National Biological the second generation of international reference materials (93/578) prepared by NIBSC and established by WHO in:1994, the third generation of national reference materials in:2010 the international reference product (08/258) no longer uses the nomenclature of "antithrombin III", but uses the nomenclature of "antithrombin": International Thrombosis and Hemostasis Antithrombin (ISTH) is also the term nomenclature: There are two types of products listed in the domestic market: antithrombin III assay kit and Antithrombin Assay Kit: Although the terminology and the names of international reference products have been unified internationally, in view of the fact that the names of international products use According to the actual registration situation of domestic products, antithrombin III is still used in the name of this standard:

The international unit of plasma antithrombin was established through a multi-center joint study based on the assignment of normal pooled plasma from each laboratory of: Each laboratory's pooled normal plasma was defined as 1 IU, and the public mean was assigned to the standard: Currently, many coagulation diagnostic products Manufacturers use "%" values in their calibration plasma, where 100% is equivalent to 1 IU, and in their calibration

plasma and/or diagnostic kits:

marked in the relevant documentation: Therefore, the use of "%" for plasma calibration or quality control is perfectly acceptable:

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Antithrombin III Assay Kit

1 Scope

This standard specifies the requirements, test methods, labels and instructions for use, packaging, transportation and storage of antithrombin III assay kits:

This standard applies to the antithrombin III assay kit (hereinafter referred to as the kit) based on the chromogenic substrate method of heparin cofactor activity, not A kit suitable for measuring the mass concentration of antithrombin III by turbidimetry:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document: For undated references, the latest version (including all amendments) applies to this document:

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 Requirements

3.1

Appearance

Appearance should meet the following requirements:

- a) The components of the kit should be complete and complete without leakage, and the labels should be clear and easy to identify;
- b) The liquid reagent should be a homogeneous solution;
- c) The lyophilized product is a homogeneous solution after reconstitution:

3.2

Capacity

The filling volume of the liquid properties reagent should not be less than the marked value:

3.3

Linearity

The linearity of the kit covers at least 20%~140%: In the linear interval, the slope of the linear regression equation is in the range of 1 ± 0.05 , and the correlation Coefficient $r \geq 0.980$:

3.4

Repeatability

The repeatability test uses samples at three concentration levels: high, medium, and low: The coefficient of variation (CV) of high-concentration samples should be $\leq 10\%$, and that of medium the coefficient of variation (CV) should be $\leq 10\%$, and the coefficient of variation (CV) for low-concentration samples should be $\leq 15\%$:

3.5

Accuracy

Select one of the following substances to repeat the test three times, and calculate the relative deviation respectively, and the relative deviation should not exceed $\pm 15.0\%$:

- a) Adopt recognized reference material or certified reference material (CRM);
- b) Adopt corporate reference materials traceable to recognized reference materials or certified reference materials:

3.6

Detection limit

The detection limit should not exceed 20%:

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