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JJF

NATIONAL METROLOGY TECHNICAL SPECIFICATION OF THE

PEOPLE'S REPUBLIC OF CHINA

JJF 1945-2021

Calibration Specification for Blood Coagulation Analyzers

凝血分析仪校准规范

(English Translation)

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Introduction

JJF 1071 "Rules for the Compilation of National Metrology Calibration Specifications", JJF 1001 "General Metrology Terms and Definitions" and JJF 1059.1 "Assessment and Representation of Measurement Uncertainty" together constitute the basic series of regulations supporting the formulation of this specification.

Fan. The calibration method and measurement characteristics mainly refer to JJF 1101-2019 "Temperature and Humidity Calibration of Environmental Test Equipment" Specification", YY/T 0659-2017 "Coagulation Analyzer" and CLSIH30-A2 Determination of Fibrinogen in Plasma Approvedguideline-secondedition).

This specification gives the relative indication error according to JJF 1059.1-2012 "Measurement Uncertainty Evaluation and Representation"

Example of measurement uncertainty and evaluation of calibration results.

This specification is published for the first time.

Coagulation Analyzer Calibration Specifications

1 Scope

This standard applies to the clinical analysis of blood coagulation and anticoagulation, fibrinolysis and antifibrinolysis of patients.

Calibration of coagulation analyzers, not suitable for platelet aggregation function and blood flow function testing, point-of-care testing (POCT) calibration of the instrument.

2 Reference documents this specification references the following documents.

JJF 1101-2019 Specification for temperature and humidity calibration of environmental test equipment YY/T 0659-2017 Coagulation analyzer CLSIH30-A2 Methodology Approval Guide for the Determination of Fibrinogen in Plasma - Second Edition (Procedure for dated references, only the dated version applies to this specification; for undated references the latest version (including all amendments) applies to this specification.

3 Terminology

Terms and definitions as defined in JJF 1101-2019, YY/T 0659-2017 and CLSIH30-A2 and the following apply to this specification.

3.1 reaction system the liquid phase system consisting of the sample and the added reagents is included to obtain sample-related parameters.

3.2 Channel

In one measurement cycle, the channel that can detect the reaction system and obtain the detection result.

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4 Overview

The coagulation analyzer (hereinafter referred to as the analyzer) is a system used for the detection of coagulation, anticoagulation and fibrinolysis.

It can be used for the diagnosis and differential diagnosis of hemorrhagic and thrombotic diseases, monitoring and curative effect of anticoagulation and thrombolytic therapy Observations provide valuable metrics. The detection items of the coagulation analyzer should at least include PT, APTT, FIB, TT Determination. The analyzer is divided into coagulation method, chromogenic substrate method and immunoturbidimetric method according to the test method.

The degree is divided into semi-automatic analyzers and fully automatic analyzers. Semi-automatic analyzers are divided into two categories according to the number of samples that can be detected at the same time.

Single and multi-channel analyzers.

Semi-automatic analyzers are generally composed of detection units, control units, data processing, display and printing units. Complete the automatic analyzer generally consists of automatic sampling unit, detection unit, control unit, data processing, display and printing unit, etc.

composition.

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