Chinastandards.org

ICS 17.020

JJF

NATIONAL METROLOGY TECHNICAL SPECIFICATION OF THE PEOPLE'S REPUBLIC OF CHINA

JJF 1752-2019

Calibration Specification for Automatic Closed Luminescence Immunoassay Analyzers

全自动封闭型发光免疫分析仪校准规范

(English Translation)

Implemented on: December 27, 2019

Issued by: State Administration for Market Regulation

Preview: page 1 of 3 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1752-2019

Chinastandards.org

Table of Contents

Introduction (II)

1 Scope (1)

2 References (1)

3 Overview (1)

4 Measurement characteristics (1)

4.1 Indication error (1)

4.2 Repeatability (1)

4.3 Carrying pollution rate (2)

4.4 Linear (2)

5 Calibration conditions (2)

5.1 Environmental conditions (2)

5.2 Calibration reference materials and reagents (2)

6 Calibration items and calibration methods (2)

6.1 Indication error (2)

6.2 Repeatability (2)

6.3 Carrying pollution rate (3)

6.4 Linear (3)

7 Expression of calibration results (3)

8 Recalibration time interval (4)

Appendix A Selection Principles of Calibration Standard Materials (5)

Appendix B. Contents and Format of Calibration Record and Calibration Certificate (6)

Appendix C Examples of Uncertainty Evaluation of Indication Error Measurement Results (9)

8 Recalibration time interval (4)

Appendix A Selection Principles of Calibration Standard Materials (5)

Appendix B. Contents and Format of Calibration Record and Calibration Certificate (6)

Appendix C Examples of Uncertainty Evaluation of Indication Error Measurement Results (9)

Preview: page 2 of 3 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1752-2019

Introduction

In the drafting of this specification, reference was made to YY/T 1155-2019 "Automatic Luminescence Immunoassay Analyzer" JJF 1071-2010 "National Metrology Calibration Regulations Writing Rules" requirements.

This specification is the first release.

Fully automatic closed-type luminescence immunoassay analyzer Calibration specifications

1 Scope

This specification is applicable to the calibration of fully automatic enclosed luminescence immunoanalyzers based on the principles of chemiluminescence and electrochemiluminescence.

2 Reference documents this specification refers to the following documents.

JJF 1001-2011 General Measurement Terms and Definitions JJF 1059.1 Evaluation and expression of measurement uncertainty YY/T 1155-2019 Automatic luminescence immunoassay analyzer for dated reference documents, only the dated version applies to this specification; for those without date references the latest version (including all amendments) is applicable to this specification.

3 Overview

The fully-automatic closed-type luminescence immunoassay analyzer (hereinafter referred to as immunoassay analyzer) is a sample detected by immunoassay Analytical instruments for specific targets in this book. The immune analyzer is usually composed of a computer system, internal servo system, loading unit, the cleaning unit, incubation unit and detection unit are composed (see Figure 1), usually only with the kit kit provided by the manufacturer the completion detection system completes the analysis of specific targets and is closed. The immune analyzer can be completed automatically according to the set procedure the entire analysis process such as sample addition, cleaning, incubation, detection, etc., through the detection of chemiluminescence or electrochemical the luminescence signal realizes the qualitative or quantitative detection of specific targets.

Figure 1 Schematic diagram of immune analyzer

4 Metering characteristics

4.1 Indication error According to the measurement result of the reference material specified in 5.2.1, the indication error is not greater than ± 15% Technical requirements given by the supplier.

4.2 Repeatability

Preview: page 3 of 3 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1752-2019