

JJF

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Calibration Specification for Specific Protein Analyzers
(English Translation)**

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Introduction

JJF 1071-2010 "Rules for the Preparation of National Measurement and Calibration Specifications", JJF 1001-2011 "General Measurement Terms and Definition" and JJF 1059.1-2012 "Evaluation and Expression of Uncertainty in Measurement" together constitute the basis for the formulation of this specification.

A series of basic documents.

This specification was formulated mainly with reference to GB/T 26124-2011 "Clinical Chemistry In Vitro Diagnostic Reagents (Kits)", CLSI EP06-A Evaluation of the linearity of quantitative measurement procedures. Guidance for the approval of statistical methods this specification is published for the first time.

Calibration Specifications for Specific Protein Analyzers

1 Scope

This specification applies to the calibration of the metrological performance of specific protein analyzers based on the immunoturbidimetry measurement principle.

2 References

This specification references the following documents.

JJF 1001-2011 General metrological terms and definitions JJF 1059.1-2012 Evaluation and Expression of Measurement Uncertainty JJF 1071-2010 Rules for writing national metrology and calibration specifications JJF 1265-2022 Biometric Terms and Definitions for any referenced document with a date, only the version with the date is applicable to this specification; for any referenced document without a date, the latest version (including all amendments) shall apply to this specification.

3 Terminology and units of measurement the terms and definitions defined in JJF 1001-2011, JJF 1265-2022 and the following apply to this specification.

3.1 Specific protein A general term for proteins in the body that perform certain physiological functions or exhibit pathological characteristics in disease states.

Note: Specific proteins are sometimes also called "specialty proteins".

For a given amount of a standard substance, the relationship between the measurement results obtained by two given measurement procedures and the other A property of a

reference material that indicates the degree of agreement between measurement results obtained with a given substance.

Note:

1 In the definition, the given standard substance is usually the calibrator, and the other specified substance is usually the daily sample.

2 The two measurement procedures involved in the determination are based on the calibration level relationship. Usually one standard material is the next higher in the calibration level.

The other is the next level standard material (calibrator).

3 The stability of interchangeable reference materials should be monitored regularly.

[Source. JJF 1001-2011, 8.16]

4 Overview

A specific protein analyzer is a protein analysis instrument that detects the content of specific proteins in serum, plasma or urine.

The specific protein analyzer measurement methods include immunoturbidimetry, immunofluorescence, gold label method, etc.

The principle of immunoturbidimetry is to use the reaction of antigen and antibody in a special reaction system to form soluble protein.

Under the action of the polymerization promoter in the dilution system, the complex precipitates from the reaction solution to form particles, making the reaction solution turbid.

The specific protein analyzer obtains the concentration of specific protein in the sample by detecting the scattered light or transmitted light intensity of the reaction solution.