YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.100

C 44

YY/T 0659-2017

Replacing YY/T 0658-2008 and YY/T 0659-2008

Blood coagulation analyzer

凝血分析仪

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Table of Contents

Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard integrates YY/T 0658-2008, *Semi-automated coagulation analyzer*, and YY/T 0659-2008, *Automated coagulation analyzer*. Compared with YY/T 0658-2008 and YY/T 0659-2008, in addition to editorial changes, the major technical changes are as follows:

-- it changes the standard name, from "*Semi-automated coagulation analyzer*" and "*Automated coagulation analyzer*" into "*Blood coagulation analyzer*";

-- it changes the scope, adds the specification that this Standard does not apply to the instruments for platelet aggregation function testing, hemorheological function testing and point-of-care testing, and add the specification that it only applies to the instruments for coagulation method (see Clause 1);

-- the text description in the normative references is drafted as specified in GB/T 1.1-2009;

-- all the normative reference documents are not dated, i.e. their latest editions apply to this Standard;

-- the terms and definitions of accuracy, precision, linearity and carry-over rate are the references to the commonly-used terms and definitions listed in GB/T 29791.1 (see Clause 3);

-- it changes the sample requirements in the precision items, adds the requirements for normal samples and deletes the requirements for abnormal samples (higher than 2 times of normal samples) (see 5.7);

-- it changes the requirements for the linearity index r, $r \geq 0.980$ (see 5.9);

-- it adds the requirements for the linearity deviation (see 5.9);

-- it changes the requirements for continuous working hours, changes the continuous working hours from 24 h into 8 h and changes the requirements (see 5.10);

-- it adds the safety requirements of GB 4793.9 and YY 0648 (see 5.13);

-- it adds the electromagnetic compatibility requirements of GB/T 18268.1 and GB/T 18268.26 (see 5.14);

-- it changes the test method of carry-over rate (see 6.6);

Blood coagulation analyzer

1 Scope

This Standard specifies the terms and definitions, product classification, technical requirements, testing methods, labelling, marking, instructions for use, packaging, transportation and storage for blood coagulation analyzers.

This Standard applies to blood coagulation analyzers which are used clinically for the analysis of coagulation-anticoagulation and fibrinolysis-antifibrinolysis of patients' blood. This Standard does not apply to the instruments for platelet aggregation function testing, hemorheological function testing and point-of-care testing.

2 Normative references

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

GB/T 191, *Packaging – Pictorial marking for handling of goods*

GB 4793.1, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

GB 4793.9, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*

GB/T 14710, *Environmental requirement and test methods for medical electrical equipment*

GB/T 18268.1, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

GB/T 18268.26, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 26: Particular requirements – In vitro diagnostic (IVD) medical equipment*

GB/T 29791.1, *In vitro diagnostic medical devices – Information supplied by the manufacturer(labelling) – Part 1: Terms, definitions and general requirements*

4 Product classification

4.1 Automation degree classification

Semi-automated and full-automated.

4.2 Channel type classification (semi-automated)

Single-channel, double-channel and multiple-channel.

5 Technical requirements

5.1 Preheating time

Preheating time shall be less than 30 min.

5.2 Temperature control

5.2.1 The temperature of the reaction system in the testing part and the thermostat part at the incubation location shall be controlled at 37.0°C ± 1.0°C.

5.2.2 The temperature of the reagent cooling location shall not be higher than 20°C.

5.3 Testing items and reporting units

The testing items shall at least include the determination of prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB) and thrombin time (TT). PT, APTT and TT are reported in s. The determination result of PT shall also be reported using the international normalized ratio (INR). The reporting unit of FIB is g/L or mg/dL. The reporting unit of coagulation factor activity (for full-automated analyzers) is U/L or %.

5.4 Channel difference (applicable to semi-automated analyzers)

The maximum difference between the results obtained from different channels is ≤ 10%.

5.5 Carry-over rate (applicable to full-automated analyzer)

5.5.1 The carry-over rate of sample concentration: the carry-over rate of FIB (g/L) shall be ≤ 10%.

5.5.2 The carry-over rate of FIB or TT to PT or APTT shall meet the nominal level of the manufacturer.

6.1.3 The relative humidity: ≤ 80%.

6.1.4 The atmospheric pressure: 86.0 kPa ~ 106.0 kPa.

NOTE: When the conditions specified in 6.1.1 ~ 6.1.4 are different from the nominal conditions of the manufacturer, the conditions specified for products shall prevail.

6.2 Preheating time

Carry out testing as required by the manufacturer after starting up.

6.3 Temperature control

Carry out testing in accordance with a method provided by the manufacturer.

6.4 Testing items and reporting units

Operate in accordance with the instrument instructions; use the parameters of all items set for instruments for verification. If necessary, instruments can be used together with matched reagents and plasma samples for testing verification.

6.5 Channel difference (applicable to semi-automated analyzers)

Under normal conditions, test continuously the PT, APTT, TT and FIB of the same normal sample for three times respectively in different channels. Calculate respectively the arithmetic mean value of the measured values in all channels ($\overline{X_i}$) and the overall mean value of the measured values in all channels ($\overline{X_{overall}}$); then calculate the channel difference (R) in accordance with Formula (1).

$$R = \frac{(\overline{X}_{max} - \overline{X}_{min})}{\overline{X}_{Overall}} \times 100\% \qquad \cdots\cdots (1)$$

where:

R – the difference between channels;

$\overline{X}_{max}$ – the maximum value of the arithmetic mean values of the values measured in all channels;

$\overline{X}_{min}$ – the minimum value of the arithmetic mean values of the values measured in all channels;

$\overline{X}_{overall}$ – the overall arithmetic mean value of the values measured in all channels.

6.6 Carry-over rate (applicable to full-automated analyzers)

6.6.1 Carry-over rate of sample concentration

concentration points; calculate the deviation and correlation coefficient r between the mean value measured and the theoretical value.

$$r=\frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2(Y-\overline{Y})^2}} \qquad \text{(6)}$$

where:

r – the correlation coefficient;

$\overline{X}$ – the mean value of X;

$\overline{Y}$ – the mean value of Y.

6.11 Continuous working hours

Test a normal sample for 3 times after starting up; calculate the mean value of the 3 results measured; maintain the coagulation analyzer continuously in the on state or ready state for 8 h; test the same normal sample for 3 times after 8 hours; calculate the mean value of the 3 results measured. Calculate the relative deviation of two mean values.

6.12 Appearance

Use the normal or corrected visual acuity to carry out visual inspection under natural light.

6.13 Environmental test

The method for environmental test shall be as specified in the applicable clauses of GB/T 14710.

6.14 Safety

The method for safety test method shall be as specified in the applicable clauses of GB 4793.1, 4793.9 and YY 0648.

6.15 Electromagnetic compatibility

The method for electromagnetic compatibility test shall be as specified in the applicable clauses of GB/T 18268.1 and GB/T 18268.26.

7 Labelling, marking and instructions for use

As specified in GB/T 29791.3.

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