

JJG

INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Verification Regulation of Blood Cell Analyzers (English Translation)

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1 Scope

This Regulation applies to the initial verification, subsequent verification and in-use verification of blood cell analyzers.

2 Normative References

The following document is referenced in this Regulation.

YY/T 0653-2008, Hematology Analyzer

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 Regulation.

3 General

Blood cell analyzers (hereinafter referred to as analyzers) are capable of measuring the red blood cell count (RBC), white blood cell count (WBC), blood platelet count (PLT) and hemoglobin concentration (HGB) in human blood, which are mainly used for blood tests by hospitals and scientific research departments and other departments.

The measuring methods for the red blood cell count in the analyzers include electrical impedance method, laser scattering method, fluorescent staining method and so on.

The method widely used is the electrical impedance method; gem hole is used as the sensor; after the sensor absorbs a fixed quantity of blood cell specimen, the blood cell count is converted into the corresponding electrical pulse count. The electrical pulse is

amplified, voltage discriminated and shaped; then the blood cell count is determined by measuring the electrical pulse count. The measurement of hemoglobin concentration is generally carried out in accordance with the colorimetric principle; the photoelectric element is used as the sensor; the sensor converts the variation of hemoglobin concentration into the variation of the corresponding voltage signal; the hemoglobin concentration is determined by measuring the variation of voltage after the voltage signal goes through amplification operation.

The apparatus consist of mechanical system, electrical system, testing system and control system and so on.

apparatus to preheat them; preset all switches and rotary knobs. The apparatus are verified in accordance with the routine procedures if their self-inspection is normal. For the apparatus having mode selection functions, set them to the whole blood measurement mode. Reagents, which are from the manufacturer or whose effectiveness can be proved, shall be used for the apparatus.

6.4.3 Blank value verification

Take an appropriate amount of apparatus blank diluent to pour into a clean measuring cup; repeat the measurement for 4 times. Discard the measured value for the first time; record the maximum values of the other 3 measured results, i.e. the blank values of RBC, WBC, PLT, HGB.

6.4.4 Carryover verification

Select one kind of standard substances of high and low values; mix up before use. In accordance with the sequence from high values to low values, carry out measurement continuously for 3 times. The measured values are respectively i_1 , i_2 , i_3 and j_1 , j_2 , j_3 .

Calculate the carryovers of RBC, WBC, PLT and HGB in accordance with Formula (1).

where,

CO - the carryover;

i_3 - the value of standard substance of a high value measured for the third time;

j_1 - the value of standard substance of a low value measured for the first time;

j_3 - the value of standard substance of a low value measured for the third time.

6.4.5 Verification of indication error

Take 3 ~ 5 kinds of blood cell standard substances of different concentrations within the commonly-used measuring range of the apparatus (take 5 kinds for the first verification);

carry out measurement continuously for 5 times after mixing up respectively; calculate respectively the relative error ΔT of indicating value of the apparatus in accordance with Formula (2); take ΔT having the maximum absolute value as the verification results of the indication error of RBC, WBC, PLT and HGB of the apparatus.

where,

Ts - the standard value of standard substance;

Annex B

Format of Inner-Pages of Verification Certificate/Verification Result
Letter

B.1 Format of the second page of verification certificate/verification result letter

Certificate No. xxxx - xxxx

Verification body authorization instructions.

Environmental conditions and site for verification

Temperature. °C Site.

Relative humidity. % Others.

Metrological standard apparatus used for verification

Name Measuring range

Uncertainty/accuracy grade/maximum allowable error

Metrological standard certificate no.

Valid until

Standard instruments used for verification

Name Measuring range

Uncertainty/accuracy grade/maximum allowable error

Metrological standard certificate no.

Valid until

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