YY

# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA



# YY/T 0653-2017

## Haematology analyzer

血液分析仪

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## Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009. The revision of this Standard is based on YY/T 0653-2008. Compared with YY/T 0653-2008, in addition to the editorial modifications, the main changes in this Standard are as follows: - modified the application scope of this Standard, changed it as "this Standard is applicable to the hematology analyzer that analyzes physical components in human blood and provides relative information" (see Clause 1); - the description in normative references is based on GB/T 1.1-2009; - for undated reference documents, the latest versions apply to this Standard; - the terms and definitions of accuracy, precision, linearity, carryover shall refer to the general term definitions listed in GB/T 29791.1 (see Clause 3); - modified the definition of hematology analyzer in the terms and definitions, specified that it is used for the detection of human blood sample (see Clause 3); - modified the description in the product classification, modified

4.1 as "analyzer with only blood cell count function", "two-group" in

4.2 as "dichotomous", deleted all "semi-automatic, fully automatic" (see Clause 4); - modified the provisions on atmospheric pressure in normal working conditions as "86.0kPa ~ 106.0kPa", added a NOTE. If the conditions in 5.1.1~

5.1.4 are inconsistent with the conditions stated in the manufacturer mark, the conditions specified in the product shall prevail (see 5.1); - modified the linearity, modified "linear deviation" as "allowed deviation range", added the requirements for linear correlation coefficient, modified HGB linear range (see 5.3); - modified instrument comparability to

accuracy, used fixed value fresh blood for testing (see 5.4, 6.5); - modified the reference range of normal blood WBC, RBC, HGB, PLT, HCT or MCV in precision (see 5.5.1, 5.61); - modified the accuracy test of five-classification analyzer white blood cell classification (see 5.6.2); Hematology analyzer

## 1 Scope

YY/T 0653 is the Chinese standard for haematology analyzers, the instruments that produce the full blood count, the most frequently ordered test in medicine. It sets the requirements such an analyzer has to meet and the test methods that verify them, covering the accuracy and precision of each measured parameter, linearity across the reportable range, carryover between samples, the background count and the flagging that tells an operator when a result needs a manual film. A count that is subtly wrong is not obviously wrong: it is acted on, and decisions about transfusion, chemotherapy and infection follow from it. Chinese manufacturers are major exporters of these instruments. The standard carries Amendment 1 of 2022, and this is the text a Chinese registration is judged against.

This Standard specifies the terms and definitions, product classification, technical requirements, test methods, labels, marks and instructions for use, packaging, transport and storage of hematology analyzer. This Standard is applicable to the hematology analyzer that analyzes physical components in human blood and provides relative information (hereinafter referred to as the analyzer). This Standard is NOT applicable to the reticulocyte testing.

## 2 Normative references

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

GB/T 191, Packaging and storage marks

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 an ability that gives the measured magnitude directly proportional to the measured value in the sample [

GB/T 29791.1-2013, Definition A.3.21]

3.7 carryover introduction of materials not belonging to it in the reaction mixture [

GB/T 29791.1-2013, Definition A.3.8]

## 4 Product classification

4.1 Analyzer with only blood cell count function.

4.2 Dichotomous blood analyzer. an analyzer capable of dividing white blood cells into large and small - dichotomous cells.

4.3 Triad blood analyzer. an analyzer capable of dividing white blood cells into large, medium, and small - triad cells.

4.4 Five-classification blood analyzer. an analyzer capable of dividing white blood cells into five types (neutrophils, lymphocytes, monocytes, eosinophils, basophils).



### 5.1 Normal working conditions

5.1.1 Power supply voltage. 220V ± 22V; 50Hz ± 1Hz;

5.1.2 Ambient temperature. 18°C ~ 25°C;

5.1.3 Relative humidity. <=80%;

### 5.1.4 Atmospheric pressure. 86.0kPa ~ 106.0kPa. NOTE. If the conditions in 5.1.1~

5.1.4 are inconsistent with the conditions stated in the manufacturer mark, the conditions specified in the product shall prevail.

5.2 Blank count The blank count of the analyzer shall meet the requirements of Table 1.

5.9 Safety Meet the requirements of the applicable provisions of GB 4793.1, GB 4793.9, YY 0648.

5.10 Environment Meet the requirements of the applicable provisions of GB/T 14710.

5.11 Electromagnetic compatibility Meet the requirements of the applicable provisions of GB/T 18268.1, GB/T 18268.26.

## 6 Test methods

6.1 Test conditions The test conditions shall meet the following requirements.

a) shall meet the normal working conditions specified in 5.1;

b) use reagents, quality control products and products for calibration recognized by the manufacturer; the products for calibration shall be traceable;

c) use the manufacturer's recommended sample anticoagulation method;

d) the analyzer shall reach a steady state before the test.

6.2 Blank count Use dilution solution as sample to perform the test 3 times continuously on the analyzer. Take the maximum value of three test results.



### 6.3 Linearity

6.3.1 Use linearity quality control products Operate according to the instructions for use of linearity quality control products. And calculate the linear deviation and relative linearity coefficients.

6.3.2 Use High value sample Take anticoagulated whole blood, centrifuge to remove plasma, make it into concentrated blood cells. Perform gradient dilution with own platelet-poor plasma/diluent for concentrated blood cells. Dilute at least 5 concentrations so that the high concentration value is close to the upper limit of the linear range,

6.9 Basic functions of analyzer Verify by inspection.

6.10 Appearance Perform visual inspection with normal or corrected vision under natural light.

6.11 Safety The safety test method shall comply with the requirements of the applicable provisions of GB 4793.1, GB 4793.9 and YY 0648.

6.12 Environment The environmental test method shall comply with the requirements of the applicable provisions of GB/T 14710.

6.13 Electromagnetic compatibility The electromagnetic compatibility test method shall comply with the requirements of the applicable provisions of GB/T 18268.1 and GB/T 18268.26.

## 7 Labels, marks and instructions for use

In accordance with the provisions of GB/T 29791.3.

## 8 Packaging, transport and storage

8.1 Packaging Analyzer packaging shall meet the following requirements.

a) the pictorial marks used in packaging shall comply with the provisions of GB/T 191;