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

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**Guidance on Blood Quality Monitoring for Whole Blood and
Ingredients
(English Translation)**

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Foreword

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

Drafting organizations of this standard. Shanghai Blood Center, Beijing Red Cross Blood Center, Tianjin Blood Center.

1 Scope

This standard specifies the monitoring methods for the quality of whole blood and blood components, and the principles of analysis and utilization of inspection results.

This standard applies to the monitoring of the collection, preparation and storage of whole blood and blood components at blood stations.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this document.

For undated references, the latest version (including all amendments) applies to this document.

Pharmacopoeia of the People's Republic of China GB 18469 Whole blood and blood component quality requirements National Clinical Laboratory Procedures

3 Terms and definitions

The following terms and definitions apply to this document.

Whole blood and blood component quality monitoring is the activity of sampling whole blood and blood component and checking its quality characteristics.

4.1 Sampling method

4.1.1 1% of the monthly supply of whole blood or at least 4 bags will be sampled every month. If the monthly supply of whole blood is less than 4 bags, the blood station will collect the samples according to the statistical process.

The sampling principle is to determine the sampling frequency by itself.

4.1.2 1% or at least 4 bags of blood components are drawn every month. If the blood components are prepared less than 4 bags per month, the blood station will collect statistics the principle of process sampling is to determine the sampling frequency by yourself.

4.2 Calculation of compliance rate

4.2.1

Whether the corresponding quality inspection items of unit whole blood and blood components in the sample meet the standards shall be judged according to the provisions of GB 18469.

4.2.2

The sample coincidence rate is calculated according to formula 1.

4.3.1 Label inspection

The label should include but not limited to the following items. name of the blood station and its license number, blood donation number or barcode, blood type, blood type, Blood collection date and time (preparation date and time), effective date and time, storage conditions, capacity, precautions.

4.3.2 Other quality characteristics inspection

The quality characteristics of whole blood and various blood components should be checked according to the methods described in Table 1 to Table 19.

4.3.3 Irradiated blood

4.3.3.1

The quality inspection requirements of irradiated blood preparations are the same as those of the original blood preparations.

4.3.3.2

In each blood irradiation process, an indicator method should be used to verify that the blood has been irradiated with an appropriate dose of radiation.

5 Analysis and utilization of inspection results

5.1

When analyzing the results of sampling of whole blood and blood components, the indicators that are caused by individual differences in blood donors and do not affect blood safety, such as If the inspection compliance rate is $\geq 75\%$, it can be considered that the blood collection, preparation, and storage processes are controlled.

5.2

When the results of sampling compliance rate do not meet the standard, the frequency and quantity of sampling should be increased, and the quality of the whole blood or blood components involved should be evaluated.

Perform systematic analysis of the cause of the bid, and take corrective and preventive measures.

5.3

Trend analysis. The blood station should regularly analyze the trend of blood quality monitoring results. When an abnormal trend occurs, respond to the various factors involved in the process.

Make an assessment, analyze the reasons, and take corrective and preventive measures when necessary.

Appendix A

(Normative appendix) Blood chyle level detection method A.1 Materials Appearance is more than 2 parts of light yellow transparent normal plasma, one clean glassware, physiological saline, 5mL disposable hard with uniform texture Several plastic test tubes, one 1mL pipette, and pictures for turbidity.

A.2 Detection method A.2.1 Mix equal amounts of more than 2 parts of normal plasma in clean glassware to prepare standard plasma, and take at least 2 mL in a test tube as normal Standard tube.

A.2.2 Take at least 2 mL of the plasma or supernatant separated by centrifugation of chyloblood into a tube.

A.2.3 Take the sample of chyle blood to be tested and add it to the test tube quantitatively, and then take the same amount of normal saline to dilute the sample, and take the samples with different dilution ratios.

The quality control and the standard tube are juxtaposed and closely attached to the turbidity picture, placed in a bright place, and the operator faces the light source to make the brightness of the light received by the two tubes consistent.

And the two tubes are transposed on the left and right, and the comparison is repeated, and the clarity of the graphics on the picture of the two tubes is visually checked to determine whether the sample tube is the same as the standard tube.

Therefore, if the sample tube to be tested at a certain dilution is mixed with the standard tube, compare the sample tube with a higher dilution to the standard tube until the picture on the picture after the two tubes the clarity of the graphics is the same.

A.2.4 The dilution factor is used as the chylo index to evaluate the degree of blood chylo. The greater the chylo index, the heavier the degree of blood chylo. Chyle index Chylemia ≤ 2 is defined as mild chylo, $2 < \text{chyle index} \leq 5$ is defined as moderate chylo, and chylo index > 5 is defined as severe chylo.

A.3 Other

Other validated methods can be used to detect the degree of blood chylo.

Appendix B

(Normative appendix) Capacity detection method B.1 Method Use a weighing instrument with a minimum scale of 0.1g to weigh the whole blood or blood components, and calculate the volume according to formula B.1.

B.2 The proportion of whole blood and blood components refer to the "Relative Density Determination Method" of the Four General Principles of the "Pharmacy of the People's Republic of China" to determine the proportion of whole blood and blood components. Or according to the following ratio Re-calculate whole blood and component blood volume.

- a) Specific gravity of whole blood. 1.050;
- b) Plasma specific gravity. 1.027;
- c) Specific gravity of platelet concentrate and apheresis. 1.030.

Appendix C

(Normative appendix) Other quality inspection items detection methods C.1 Sterility test refer to the "Law of Sterility Test" in the three general provisions of the "Pharmacopeia of