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

GB/T 48010-2026

**Single-use containers for the collection of specimens from
humans other than blood**

一次性使用人体非血液样本采集容器

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is modified to adopt ISO 6717:2021 "In vitro diagnostic medical devices - Single-use containers for collecting non-blood samples from the human body".

This document has undergone the following structural adjustments compared to ISO 6717:2021.

--Section 3.15 of ISO 6717:2021 has been removed, and subsequent entry numbers have been moved forward;

--Appendices E and F have been added.

The technical differences between this document and ISO 6717:2021, and the reasons therefor, are as follows.

--The term and definition of "expiration date" have been removed (see 3.15 of ISO 6717:2021), and the removal will not cause ambiguity;

-- ISO 15223-1 (see 11.3, 11.6) has been replaced with the normatively referenced YY/T 0466.1 for ease of use;

--Requirements for laboratory water have been added, and the normative reference GB/T 6682 (see A.1.1, B.1.1, C.1.2) has been added.

(D.1.1), to facilitate practical operation;

--The test conditions were modified (see A.2, D.2) to facilitate practical operation;

--The test standards have been changed (see A.4) to facilitate practical operation.

The following editorial changes have been made to this document.

--To align with existing standards, the standard name has been changed to "Disposable

Human Non-Blood Sample Collection Containers";

--Notes in the "Scope" chapter have been deleted;

-- ISO 6710:2017 has been replaced by YY/T 0314-2021, which is cited in the informational reference.

--The URLs for the ISO and IEC terminology databases have been removed from the terms and definitions section, and Note 1 in section 3.10 has been removed;

--Added notes to 11.3c) and 11.6d) in the logo and label section;

--Added a note to B.2.1 in Appendix B, and deleted Figure B.1;

--Added a description of the test conditions in C.1.4 of Appendix C;

--Added Appendix E (Informative) "Recommended Ambient Atmosphere Calibration Methods";

--Added Appendix F (Informative) "Test Method for Suction Volume of Pre-vacuum Collection Containers Used in High-Altitude Areas".

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Infusion Devices (SAC/TC 106).

Henan Provincial Drug Evaluation and Inspection Center (Henan Provincial Vaccine Inspection Center), Shandong Zhushi Pharmaceutical Group Co., Ltd., and Liuyang Sanli Medical Technology Development Co., Ltd.

Limited Liability Company, Weihai Weigao Blood Collection Consumables Co., Ltd.

1 Scope

This document specifies the dedicated disposable vacuum and non-blood samples intended for use in in vitro diagnostic examinations and for the collection and storage of non-blood human samples.

The requirements for vacuum collection containers are described, along with the corresponding test methods. This document does not specify auxiliary devices to be used with the collection containers.

Require.

This document applies to single-use non-blood sample collection containers for human samples, including but not limited to cerebrospinal fluid (CSF), feces, and other samples.

Staining samples of bodily fluids, saliva, semen, sputum, urine, and tissues.

This document does not apply to the following types of samples and instruments. special containers for cryopreservation, samples for nucleic acid testing, and swabs.

This document does not apply to sample containers used in forensic investigations.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories (GB/T 6682-2008, ISO 3696:1987, MOD) YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements

3 Terms and Definitions

Collection container Vacuum or non-vacuum apparatus for holding samples (3.16) with any attachments (3.5), additives (3.9) and caps (3.4).

[Source. YY/T 0314-2021, 3.4, modified] 3.2 Vacuum collection container the collection container (3.1) for collecting samples (3.16) using a vacuum method.

Note: The sample collection container is formed by the manufacturer during production (i.e., pre-vacuumed), or by the user before or during sample collection (3.16).

It was formed in the middle.

[Source. YY/T 0314-2021, 3.7, modified] 3.3 Receptacle sampling tube Part of a collection container (3.1) without a top cover (3.4) for holding samples (3.16).

Head closure

The components of a sealed collection container (3.1) consisting of several parts.

[Source. YY/T 0314-2021, 3.3]