

ICS 11.140
CCS C 48



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

GB/T 46937-2025

**Test method for the viral filtration efficiency (VFE) of medical
masks and materials - Bacteriophage Phi-X 174 aerosol method**

医用口罩及材料病毒过滤效率测试方法 Phi-X174噬菌体气溶胶法

Issued on: December 31, 2025

Implemented on: January 1, 2027

**Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC**

Table of Contents

1.Scope	1
2 Normative References	1
3.Terms and Definitions	1
4.Principle	2
5.Test conditions	2
6.Sample quantity and pretreatment conditions	2
7.Phage proliferation	2
7.1 Bacteriophages and Host Bacteria	2
7.2 Culture medium	2
7.3 Phage Proliferation	3
8.Virus Filtration Efficiency Detection Methods	4
8.1 Aerosol Generator	4
8.2 Bioaerosol Sampler	4
8.3 Sample Support	4
8.4 Virus Filtration Efficiency Detection System	5
8.5 Virus Filtration Efficiency Detection Methods	6
8 References	9

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. 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 Medical Protective Equipment Standardization Working Group (SAC/SWG30). This document was drafted by: Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center), Shandong Provincial Institute of Medical Device Testing and Research. Medical Device and Pharmaceutical Packaging Inspection and Testing Institute, Military Medical Research Institute of the Academy of Military Sciences of the Chinese People's Liberation Army, Henan Tuoren Medical Device Research Institute Limited Liability Company, Aomei Medical Supplies Co., Ltd., Guangdong Provincial Institute of Medical Device Quality Supervision and Inspection,

China Resources Medical Supplies (Henan) Co., Ltd. Company, Hefei Gaobeisi Medical and Health Products Co., Ltd., Hefei Medipu Medical and Health Products Co., Ltd. The main drafters of this document are. Liu Keyang, Huang Yongfu, Li Cui, Niu Yue, Liu Simin, Yang Wenhui, Yang Qiaoyang, Cao Mengjie, Liang Zexin, and Duan Shuxia. Gao Ming, Wu Jun, Li Zheng, Hu Guangyong, Xiong Wei. Test methods for virus filtration efficiency of medical masks and materials Phi-X174 bacteriophage aerosol method

1 Scope

GB/T 46937-2025 is the Chinese national standard covering how well a mask stops virus-sized particles - tested with a bacteriophage aerosol rather than a bacterial one, because the particles that carry a respiratory virus are far smaller than those the bacterial filtration test uses. First edition, in force from 1 January 2027, and one of the standards the pandemic made necessary. It was issued on 31 December 2025 and takes effect on 1 January 2027, as a first edition. The document is under the responsibility of the Standardization Administration of China. This page is published from the official record of the 2025 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document describes the use of bacteriophage Phi-X174 as a model microorganism to assess the viral aerosol filtration efficiency of medical masks and materials. The testing method. This document applies to medical masks and materials for which virus filtration efficiency evaluation is required. Virus filtration efficiency testing for other products or materials is also covered. Please refer to this document.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. 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 38517-2020 General Rules for Sampling and Analysis of Particulate Bioaerosols

GB/T 39990-2021 Technical requirements for particulate bioaerosol samplers

YY/T 0689-2008 Test Performance of Protective Clothing Materials Against Bloodborne Pathogens for Blood and Body Fluid Protective Equipment X174 phage assay method

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 bacteriophage A virus that infects bacteria.

Note. In this document, bacteriophage refers to Phi-X174.

3.2 lysis The process by which host bacteria are dissolved and destroyed due to the proliferation of bacteriophages.

Note. In this method, Escherichia coli serves as the host cell, and its lysis is caused by Phi-X174 infection.

3.3 Plaque Theoretically, a visible, translucent area forms on the upper layer of agar plates when a single bacteriophage infects and lyses the host cell.

3.4 Plaque-forming unit (PFU) Viral particles capable of infecting bacteria growing on the upper layer of lysed agar plates and producing plaques (3.3).

3.5 titer Concentration of active phages.

Note. Plaque formation units per milliliter (PFU/mL) are used.