ICS 11.100
CCS A 40

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 47486-2026

General technical requirements for vasculature-on-a-chip

血管芯片通用技术要求

Issued on: April 30, 2026 **Implemented on: May 1, 2027**

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

Table of Contents

Foreword

GB/T 47486-2026 | General technical requirements for vasculature-on-a-chip

GB/T 47486-2026 English version. General technical requirements for vasculature-on-a-chip ICS

40 National Standards of the People's Republic of China General technical requirements for vascular chips Published on 2026-04-

30 Implemented on 2027-05-

01 State Administration for Market Regulation The State Administration for Standardization issued a statement.

1.Scope This document defines the terminology and definitions for vascular chips, specifies the technical requirements, quality control settings, labeling, accompanying documentation, and packaging. The loading, transportation, and storage of the equipment are described, along with the corresponding testing methods. This document applies to the design, production, and testing of vascular chips based on microfluidic chips.

4.1 Appearance

4.1.1 The chip should have a complete structure and all components, with no leakage or damage.

4.1.2 The functional structural areas should be free of obvious scratches, damage or other obviously visible defects that affect the quality characteristics of the product.

4.2 Cell Source The cellular composition of vascular microarrays should be primarily composed of vascular endothelial cells, with the support of fibroblasts promoting the lumen

of the vascular endothelium. The generation of these cells can be further enhanced by introducing smooth muscle cells and pericytes to improve their structural and functional integrity. Cell sources can be obtained from human tissues. It is obtained through methods such as tissue separation and extraction, directed induction of stem cell differentiation, and cell line culture.

4.3 Component Performance

4.3.1 Light transmittance The cavity in the microfluidic chip used for vascular endothelial lumen culture has a spectral transmittance in the visible light range of 390nm to 780nm. The transmittance should not be less than 80% of the minimum transmittance of the chip and its associated materials.

4.3.2 Sealing performance The individual chambers within a microfluidic chip used for vascular endothelial lumen culture, as well as any part of the chip and its associated components, are all interconnected. Reagent crosstalk or leakage should not occur.

4.3.3 Operating Temperature Tolerance Microfluidic chips and their associated materials for vascular endothelial lumen culture are used within a working temperature range of ±20.0°C, and during experiments... The interval should be no less than

1.2 times the normal test condition working time; the appearance should be without deformation or damage; and the sealing performance test results should meet the requirements of 4.3.2. Require.

4.3.4 Biocompatibility Materials that are non-cytotoxic to vascular endothelial cells or tissues should be selected as substrates and auxiliary materials for microfluidic chips.

4.4 Biological performance

4.4.1 Shear stress on the blood vessel wall The magnitude of the fluid wall shear stress in the vascular chip should be clearly defined. The reference range for wall shear stress values is

0.1 Pa to

1 Pa = 10 dyn/cm2.

4.4.2 Biological Tissue Morphology The vascular endothelial cells in the vascular chip should have self-assembly capabilities, forming interconnected, highly branched structures with tight intercellular junctions. Hollow tubular structure. The resulting vascular structure should have clear luminal boundaries, a continuous network without large-area defects, and completely cover the pre-designed structure. The channels or three-dimensional matrix regions form a highly organized microvascular network structure.

4.4.3 Biological tissue activity It should be clearly understood that the vascular network in the vascular chip can simulate the function of endothelial cells in blood vessels under

physiological conditions and can achieve nitric oxide production. The normal secretion and timely clearance of active substances such as NO are crucial. When using the nitrate reductase method for detection, the NO secretion peak should not be lower than [value missing]. The concentration should be 0.2 μmol/L, and the relative standard deviation of each independent test result should not exceed 18%.

4.4.4 Perfusion and fluidity of vascular tissues It should be clearly understood that vascular chips can form a perfusion-enabled vascular network, and that this network can be interconnected through microchannels, reaction chambers, and micropumps. Other functional components simulate the sustainable blood flow within blood vessels under physiological conditions.

4.4.5 Vascular barrier function The barrier function of vascular chips should be clearly defined, and the barrier function should meet the following conditions.

a) The vascular endothelial lumen in the constructed vascular chip exhibits expression of one or more tight junction proteins (such as ZO-1);

b) Expression of tight junction proteins was observed under a microscope;

c) Tight junction proteins are expressed in a continuous circular pattern, rather than in a patchy distribution.

5.Quality Control Settings Ten chips should be randomly selected from each of the three consecutive batches of vascular chip products produced as samples. All samples should meet the repeatability criteria. Each component shall undergo independent testing, and its performance indicators shall meet the requirements of

4.1 to 4.4.Before leaving the factory, the product shall be manufactured in accordance with the "People's Republic of China..." According to the requirements of the Chinese Pharmacopoeia (2025 edition), detection of pathogenic microorganisms, including bacteria, fungi, mycoplasma, and certain viruses, must be conducted. All project results must be satisfactory.

6 Test Methods

6.1 Appearance Visual inspection.

6.2 Light transmittance According to GB/T 2410, the vascular endothelial culture chamber of the microfluidic chip should be placed in a spectrophotometer or an optical transilluminator that meets the wavelength requirements. The transmittance of the power meter is directly measured through its detection window (see Appendix A, A.2 for specific detection methods).

6.3 Sealing performance The sealing test shall be conducted according to Chapter 6 of GB/T 2423.23-2013 (see A.3 for specific test methods). The test conditions are as follows:

a) Test temperature. 1°C~5°C above the highest operating ambient temperature of the microfluidic chip;

b) Duration of conditional testing. Maintain at least

1.2 times the normal test condition operating time;

c) Method for detecting leakage. Visual inspection using a test liquid that provides a clear contrast to the background.

6.4 Operating temperature tolerance The microfluidic chip was tested for leakage under conditions deviating from its operating temperature by ±20.0°C (for a duration not less than

1.2 times the normal test duration). Check for leaks and observe the appearance for any deformation or damage (see A.4 for specific testing methods).

6.5 Biocompatibility According to GB/T 16886.5, cell morphology observation and cell activity analysis are used to detect microfluidic chip substrates and their attachments. To determine whether the material exhibits cytotoxicity (see A.5 for specific testing methods).

6.6 Shear stress on the blood vessel wall Based on the dynamic viscosity of the culture medium under constant temperature of 37°C, the preset flow rate, and the flow channel geometry of the vascular chip, the wall shear was calculated. Stress. Specifically, for a circular cross-section irrigation channel, the calculation is performed according to formula (1); for a rectangular cross-section irrigation channel, the calculation is performed according to formula (1). Calculate according to formula (2). The width of the irrigation channel should be at least 10 times its height. Subsequently, based on the target wall shear stress value, use the phase... The required culture medium volumetric flow rate (Q) is calculated by working backwards from the formula. The culture medium is then steadily and uniformly infused using a syringe pump at this calculated flow rate. The flow is injected into the vascular chip, thereby achieving the set wall shear stress within the chip. To ensure the accuracy of the flow rate, a micro-flow meter is used to monitor the injection pump. The actual output flow rate is calibrated to ensure reliable and stable injection conditions.

6.7 Biological Tissue Morphology Vascular endothelial cells are mixed with supporting cells (such as fibroblasts) in a specific ratio and then encapsulated in fibrin or collagen. The cell-gel complex was injected into the vascular culture chamber of a microfluidic chip, and the vascular complex was continuously perfused into the perfusion channel. Culture medium for endothelial growth factor. Under dynamic culture conditions (usually 5-7 days), vascular endothelial cells migrate, proliferate, and self-regulate in the matrix. Assembly ultimately forms a three-dimensional microvascular network with branches and interconnected lumens. This network can be visualized using techniques such as live-cell imaging and immunofluorescence staining. The resulting network is then subjected to morphological and functional verification (see A.6 for specific detection methods).

6.8 Biological tissue activity By constructing a circulating perfusion system consisting of a