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# NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA



# GB/T 47329-2026

## Assay method for collagenase activity and purity

胶原蛋白酶活性及纯度检测方法

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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. 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 and is under the jurisdiction of the National Working Group on Standardization of Enzymes and Tools (SAC/SWG11). This document was drafted by: DeepMind (Shandong) Biotechnology Co., Ltd., Huacan (Xiamen) Biopharmaceutical Co., Ltd., and Anhui Shengmeinuo. Biotechnology Co., Ltd., Huizhou Anbochen Technology Co., Ltd., Shenzhen Shanhai Innovation Technology Co., Ltd., Guangdong Marubi Biotechnology Co., Ltd. Limited Company, Shenzhen Hongrui Biotechnology Co., Ltd., Xiahe (Guangzhou) Optoelectronic Biotechnology Co., Ltd., Newspower Guangcai (Guangdong) Biotechnology Co., Ltd. Technology Co., Ltd., Wuhan Xinhua Yang Biotechnology Co., Ltd., Huahui Marine Polysaccharide Biotechnology (Shenzhen) Co., Ltd., Wuhan Hongren Biotechnology Co., Ltd. Wuyi Pharmaceutical Co., Ltd., Beijing Jianping Jinxing Biopharmaceutical Co., Ltd., Henan Sainote Biotechnology Co., Ltd., Hainan Huayan Collagen Technology Co., Ltd., Jiangsu Chuangjian Medical Technology Co., Ltd., Shenzhen Liying Biotechnology Co., Ltd., Hangzhou Newlong Biotechnology Co., Ltd. Limited Liability Company, Hangzhou Newlong Rishang Biological Products Co., Ltd., Fujian Saif Safety Technology Service Co., Ltd., Shandong University, Xiahe (Hangzhou) Biotechnology Co., Ltd. Biotechnology Co., Ltd., Fujian Nansheng Technology Co., Ltd., Xiahe (Shenzhen) Biotechnology Co., Ltd., Beijing Solarbio Technology Co., Ltd. Nansheng (Xiamen) Analytical Testing Co., Ltd., Datian Huacan Biotechnology Co., Ltd., Fudan University, Soochow University, Fujian Agriculture and Forestry University, Shanghai Jiaotong University, Zhejiang University of Commerce and Industry, Xiamen University. The main drafters of this document are. Chen

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Collagenase (EC 3.4.24.3) is a protein that, under physiological conditions, can hydrolyze the peptide bonds in the triple helix region of collagen. Enzymes include animal-derived collagenases and microbial-derived collagenases. Microbial-derived collagenases are derived from Clostridium and Vibrio, belonging to the M9 family. These are metalloproteinases of the same family, sharing similar structures, catalytic mechanisms, and substrate specificities. Microbial collagenases have been widely applied in life sciences. Research projects include animal tissue cell dissociation, collagen degradation, clinical wound debridement, scar elimination, and preparation of collagen peptides for the food industry. Developing national standards for the detection methods of collagenase activity and purity will promote production and use, and will be of great significance for advancing the industrialization of this type of tool enzyme. It is of great significance. Methods for detecting collagenase activity and purity



## 1 Scope

GB/T 47329-2026 is the Chinese national standard covering measuring collagenase - the enzyme used to dissociate tissue for cell isolation and in wound debridement, where the activity and the freedom from contaminating proteases decide whether the cells survive the process. First edition, in force since 1 July 2026. It was issued on 31 March 2026 and has been in force since 1 July 2026, 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 2026 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 a method for detecting the activity and purity of collagenases from microbial sources. This document applies to the detection of activity and purity of collagenases from microbial sources.

## 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 6682 Specifications and test methods for water used in analytical laboratories

## 3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Collagenase A protease that hydrolyzes peptide bonds in the triple helix region of collagen under physiological conditions (37°C, pH 7.0).

3.2 Using N-[3-(2-furanyl)acryloyl]-leucine-glycine-proline-alanine (FALGPA) as a substrate, at pH 7.5, At 25°C and in the presence of 10 mmol/L calcium ions, the amount of collagenase that can degrade 1 μmol of substrate per minute is defined as one activity level. unit.

## 4 Principles

4.1 Principle of Enzyme Activity Detection FALGPA is a synthetic polypeptide with a structure similar to that of collagen. It can be specifically hydrolyzed by all M9 family collagenases. The peptide bond between leucine and glycine in the FALGPA sequence causes a decrease in the absorbance (OD345) of this substrate at 345 nm. Therefore, by detecting the decrease in OD345 of the reaction system per unit time, the degradation rate of collagenase per minute can be calculated based on the standard curve. The number of moles of the substrate.

4.2 Principle of Enzyme Purity Detection Gel filtration chromatography is an effective method for separating protein mixtures based on differences in protein molecule size. Due to the nature of the gel filtration chromatography process... Proteins of different sizes elute at different positions in a chromatography column, so the proportion of the target protein can be determined by integrating the peak area.