

Global Sterility Testing Service Market 2026 by Company, Regions, Type and Application, Forecast to 2032

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Abstracts

According to our (Global Info Research) latest study, the global Sterility Testing Service market size was valued at US\$ 361 million in 2025 and is forecast to a readjusted size of US\$ 573 million by 2032 with a CAGR of 6.6% during review period.

Sterility Testing Service refers to outsourced testing services provided by third-party laboratories or quality control organizations. These services involve testing for microbial contamination and verifying the sterility of sterile pharmaceuticals, medical devices, biological products, and cell and gene therapy products, based on pharmacopoeias and regulatory guidelines (such as sterility testing methods, culture medium methods, and rapid microbiological methods). The core objective is to confirm that the product is free of viable microorganisms after manufacturing and packaging, thereby meeting regulatory requirements for market approval, batch release, and ongoing quality monitoring.

With the rapid growth of biopharmaceuticals, cell and gene therapy (CGT), vaccines, and sterile injectables, the demand for sterility testing is continuously increasing. In particular, the extremely high release speed requirements for small-batch, high-value products (such as CAR-T and mRNA vaccines) are driving the industry to upgrade from the traditional 14-day culture method to rapid microbial detection (RMM) and automated systems. To reduce CAPEX and compliance risks, pharmaceutical companies are increasingly outsourcing sterility testing to GMP-certified professional laboratories.

Simultaneously, stricter regulations and the increasing complexity of global supply chains are strengthening the importance of third-party testing. Regulatory agencies such as the FDA and EMA are imposing higher requirements on sterility assurance

levels (SAL), environmental monitoring, and batch release, prompting companies to establish continuous quality and global multi-site testing networks. This is driving the accelerated expansion of large CROs/CDMOs and specialized microbial testing institutions, resulting in a trend of increasing industry concentration and technological upgrades.

This report is a detailed and comprehensive analysis for global Sterility Testing Service market. Both quantitative and qualitative analyses are presented by company, by region & country, by Type and by Application. As the market is constantly changing, this report explores the competition, supply and demand trends, as well as key factors that contribute to its changing demands across many markets. Company profiles and product examples of selected competitors, along with market share estimates of some of the selected leaders for the year 2025, are provided.

Key Features:

Global Sterility Testing Service market size and forecasts, in consumption value (\$ Million), 2021-2032

Global Sterility Testing Service market size and forecasts by region and country, in consumption value (\$ Million), 2021-2032

Global Sterility Testing Service market size and forecasts, by Type and by Application, in consumption value (\$ Million), 2021-2032

Global Sterility Testing Service market shares of main players, in revenue (\$ Million), 2021-2026

The Primary Objectives in This Report Are:

To determine the size of the total market opportunity of global and key countries

To assess the growth potential for Sterility Testing Service

To forecast future growth in each product and end-use market

To assess competitive factors affecting the marketplace

This report profiles key players in the global Sterility Testing Service market based on the following parameters - company overview, revenue, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include Sigma-Aldrich, Charles River Laboratories, Nova Biologicals, Eurofins, SGS, Nelson Labs, Sartorius, Lucideon, Pacific BioLabs, Gillson Sciences, etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Market segmentation

Sterility Testing Service market is split by Type and by Application. For the period 2021-2032, the growth among segments provides accurate calculations and forecasts for Consumption Value by Type and by Application. This analysis can help you expand your business by targeting qualified niche markets.

Market segment by Type

Direct Inoculation

Membrane Filtration

Others

Market segment by Stage

Preclinical / Process Development Testing

Clinical Trial Batch Testing

Commercial Batch Release Testing

Post-Market Surveillance Testing

Market segment by Product

Sterile Pharmaceuticals & Injectables

Biologics & Vaccines

Cell & Gene Therapy Products

Others

Market segment by Application

Medical

Pharmaceutical

Others

Market segment by players, this report covers

Sigma-Aldrich

Charles River Laboratories

Nova Biologicals

Eurofins

SGS

Nelson Labs

Sartorius

Lucideon

Pacific BioLabs

Gillson Sciences

Viroxy

Contract Pharma

CPT Labs

Sartorius

IDEXX BioAnalytics

Lucideon

Pacific BioLabs

Market segment by regions, regional analysis covers

North America (United States, Canada and Mexico)

Europe (Germany, France, UK, Russia, Italy and Rest of Europe)

Asia-Pacific (China, Japan, South Korea, India, Southeast Asia and Rest of Asia-Pacific)

South America (Brazil, Rest of South America)

Middle East & Africa (Turkey, Saudi Arabia, UAE, Rest of Middle East & Africa)

The content of the study subjects, includes a total of 13 chapters:

Chapter 1, to describe Sterility Testing Service product scope, market overview, market estimation caveats and base year.

Chapter 2, to profile the top players of Sterility Testing Service, with revenue, gross margin, and global market share of Sterility Testing Service from 2021 to 2026.

Chapter 3, the Sterility Testing Service competitive situation, revenue, and global market share of top players are analyzed emphatically by landscape contrast.

Chapter 4 and 5, to segment the market size by Type and by Application, with consumption value and growth rate by Type, by Application, from 2021 to 2032.

Chapter 6, 7, 8, 9, and 10, to break the market size data at the country level, with revenue and market share for key countries in the world, from 2021 to 2026. and Sterility Testing Service market forecast, by regions, by Type and by Application, with consumption value, from 2027 to 2032.

Chapter 11, market dynamics, drivers, restraints, trends, Porters Five Forces analysis.

Chapter 12, the key raw materials and key suppliers, and industry chain of Sterility Testing Service.

Chapter 13, to describe Sterility Testing Service research findings and conclusion.

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