

Global Sterility Testing Service Supply, Demand and Key Producers, 2026-2032

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Abstracts

The global Sterility Testing Service market size is expected to reach \$ 573 million by 2032, rising at a market growth of 6.6% CAGR during the forecast period (2026-2032).

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 studies the global Sterility Testing Service demand, key companies, and key regions.

This report is a detailed and comprehensive analysis of the world market for Sterility Testing Service, and provides market size (US\$ million) and Year-over-Year (YoY) growth, considering 2025 as the base year. This report explores demand trends and competition, as well as details the characteristics of Sterility Testing Service that contribute to its increasing demand across many markets.

Highlights and key features of the study

Global Sterility Testing Service total market, 2021-2032, (USD Million)

Global Sterility Testing Service total market by region & country, CAGR, 2021-2032, (USD Million)

U.S. VS China: Sterility Testing Service total market, key domestic companies, and share, (USD Million)

Global Sterility Testing Service revenue by player, revenue and market share 2021-2026, (USD Million)

Global Sterility Testing Service total market by Type, CAGR, 2021-2032, (USD Million)

Global Sterility Testing Service total market by Application, CAGR, 2021-2032, (USD Million)

This report profiles major 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.

Stakeholders would have ease in decision-making through various strategy matrices used in analyzing the world Sterility Testing Service market

Detailed Segmentation:

Each section contains quantitative market data including market by value (US\$ Millions), by player, by regions, by Type, and by Application. Data is given for the years 2021-2032 by year with 2025 as the base year, 2026 as the estimate year, and 2027-2032 as the forecast year.

Global Sterility Testing Service Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

Global Sterility Testing Service Market, Segmentation by Type:

Direct Inoculation

Membrane Filtration

Others

Global Sterility Testing Service Market, Segmentation by Stage:

Preclinical / Process Development Testing

Clinical Trial Batch Testing

Commercial Batch Release Testing

Post-Market Surveillance Testing

Global Sterility Testing Service Market, Segmentation by Product:

Sterile Pharmaceuticals & Injectables

Biologics & Vaccines

Cell & Gene Therapy Products

Others

Global Sterility Testing Service Market, Segmentation by Application:

Medical

Pharmaceutical

Others

Companies Profiled:

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

Key Questions Answered

1. How big is the global Sterility Testing Service market?
2. What is the demand of the global Sterility Testing Service market?
3. What is the year over year growth of the global Sterility Testing Service market?
4. What is the total value of the global Sterility Testing Service market?
5. Who are the Major Players in the global Sterility Testing Service market?
6. What are the growth factors driving the market demand?

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