

# **Sterility Testing Market by Product (Kits & Reagents, Instrument, Services), Test (Membrane Filtration, Direct Inoculation), Application (Pharma, Biological Manufacturing, Medical Device Manufacturing), End User (Pharma, Biotech) & Region - Global Forecasts to 2028**

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## **Abstracts**

The global sterility testing market is expected to reach USD 1.9 billion in 2028 from USD 1.1 billion in 2023 at a CARG of 10.5%. Factors such as expanding pharmaceutical & biotechnology production capacities, increasing development of novel biopharmaceutical products, and rising investments in life sciences research are expected to drive market growth. However, the growing adoption of single-use technology and stringent regulatory guidelines for product approval are expected to restrain market growth to a certain extent.

“During the forecast period, the kits & reagent is expected to account as the fastest-growing segment .”

Based on product & service, the sterility testing market is divided into kits & reagents, instruments, and services. During the forecast period (2023-2028), the kits & reagents segment is also expected to be the fastest-growing segment in the sterility testing market. Kits are widely used in the pharmaceutical and biotechnology industries as it is easy to use. Moreover, the long shelf life of these products is contributing to their rising adoption in academic institutions and contract research organizations. Sterility testing is mandatory during the clinical and commercial manufacturing of pharmaceutical & biopharmaceutical products. Pharmaceutical & biotechnology companies adopt kits & reagents for sterility testing as it is cost-effective and time-efficient.

“In 2022, by application segment, pharmaceutical & biologics accounted for the biggest market share”

Based on application, the sterility testing market is divided into pharmaceutical & biologics manufacturing, medical device manufacturing, and other applications. In 2022, the pharmaceutical and biologics manufacturing segment accounted for the largest share of the application segment in the sterility testing market. Factors responsible for the growth in this segment include the growing, growing pharmaceutical and biopharmaceutical production capacity across the globe.

“In 2022, North America accounted for the largest regional share in this market”

The market for sterility testing was dominated by North America in 2022. Presence of manufacturing facilities of major pharmaceutical and biopharmaceutical firms in the region will contribute for the huge demand for sterility testing in North America. The market for sterility testing is anticipated to grow in the region as drug approval rates rise. Also, the demand for pharmaceuticals and biopharmaceuticals in North America are rising due to the rising prevalence of diseases and the expanding patient population. Moreover, the pharmaceutical and biotechnology sectors in North America make substantial R&D investments and are anticipated to experience rapid growth in the coming years.

#### Breakdown of primaries

The study contains insights from various industry experts, ranging from component suppliers to Tier 1 companies and OEMs. The break-up of the primaries is as follows:

By Respondent— Supply Side- 70%, Demand Side-30%

By Designation— CXOs and Directors- 30%, Executives - 25%, Managers - 45%

By Region— North America - 40%, Europe - 25%, APAC – 20%, RoW- 15%

The sterility testing market is dominated by a few globally established players such as Charles River Laboratories (US), Merck KGaA (Germany), bioMérieux SA (France), SGS SA (Switzerland), WuXi AppTec (China), Nelson Laboratories, LLC (US), Pacific BioLabs (US), Sartorius AG (Germany), Thermofisher Scientific Inc. (US), and Samsung

Biologics (South Korea). The study includes an in-depth competitive analysis of these key players in the sterility testing market with their company profiles, recent developments, and key market strategies.

#### Research Coverage:

The report segments the sterility testing market based on region (North America, Europe, Asia, and Rest of the World), by product & service (kits & reagents, instruments, and services), by test type (membrane filtration, direct inoculation, and other tests), by application (pharmaceuticals and biologicals, medical devices, and other applications), and by end user (pharmaceutical companies, biotechnology companies, and others ). The report also provides a comprehensive review of market drivers, restraints opportunities, challenges and trends in the sterility testing market.

#### Key Benefits of Buying the Report:

The report will help the leaders/new entrants in this market with information on the closest approximations of the revenue numbers for the overall market and the segments. This report will help stakeholders understand the competitive landscape and gain more insights to better position their businesses and plan suitable go-to-market strategies. The report also helps stakeholders understand the pulse of the sterility testing market and provides them with information on key market drivers, restraints, challenges, and opportunities.

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