

Pyrogen Testing Market Size Projected to Reach USD 3.17 Billion by 2032, Growing at a CAGR of 7.93% - SNS Insider

Global Pyrogen Testing Market Growth is Driven by Innovations in Biopharmaceuticals and Regulatory Advancements.

AUSTIN, TX, UNITED STATES, November 26, 2024 /EINPresswire.com/ -- The Global [Pyrogen Testing Market](#), valued at USD 1.60 billion in 2023 and is projected to reach USD 3.17 billion by 2032 with a CAGR of 7.93% during the forecast period of 2024-2032.



Pyrogen Testing Market Trends

The market is growing significantly in terms of pyrogen testing, with the rapid expansion of the pharmaceutical and biotechnology industries. Increasing demands for innovative therapeutics along with heightened investments by governments and manufacturing firms form the underpinnings of this growth trajectory. The European Federation of Pharmaceutical Industries and

Pyrogen testing is therefore of utmost importance for ensuring safety and quality in parenteral pharmaceutical products because it detects fever-causing substances, known as pyrogens, that can trigger unwanted responses in patients even in sterile medications. Regulatory agencies are now encouraging further developments in the methods of pyrogen testing. The European Directorate for the Quality of Medicines & Healthcare and the European Partnership for Alternative Approaches to Animal Testing make a call to replace old-fashioned rabbit pyrogen tests with much more humane, effective alternatives, likely in February 2023.

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Key Pyrogen Testing Market Players:

Associates of Cape Cod Inc.
Ellab A/S
Merck KGaA
GenScript
bioMérieux SA
Charles River Laboratories
Lonza
FUJIFILM Wako Chemicals U.S.A. Corporation (Pyrostar)
Thermo Fisher Scientific Inc.
Hyglos GmbH
WuXi AppTec.
others players

Market Analysis

Increased demand for biopharmaceuticals is enhancing the market growth of pyrogen testing. Interest in the market has grown due to advances made in biotechnology, including products such as monoclonal antibodies, gene therapies, vaccines, and growth hormones. More so, with a growing global population whose demographic is older, and with an increase in chronic diseases among its population, there will be a stronger need for constant innovation regarding biopharmaceutical safety protocols.

Mandatory new regulations to test all new biopharmaceutical products for pyrogens were introduced by the FDA in 2023, which emphasize the importance of pyrogen testing as it identifies any potential contaminants that could pose a threat to patient safety. Stronger safety standards for injectables and intravenous drugs continue to fuel innovation in pyrogen detection technologies, thereby fostering demand for these solutions and furthering the expansion of the market.

Segment Highlights

By Product

In 2023, the consumables segment dominated with more than 54% of the total share. This is because the market share in this segment is primarily bolstered by the high prevalence of chronic diseases that drive the demand for pharmaceuticals, biologics, and medical devices. The World Health Organization reported that chronic respiratory diseases cause around 4 million deaths yearly, creating a growing need for consumables such as kits and reagents to be used for pyrogen testing.

Conversely, the instruments segment is expected to grow at the highest CAGR during the forecast period, with drivers in the form of technological advancement. For example, Charles Rivers introduced PyroDetect System that offered innovative in vitro detection capability for endotoxins and non-endotoxin pyrogens.

By Test Type

The Limulus Amebocyte Lysate (LAL) test segment captured more than 44% of the market share in 2023. This market dominance is due to increased demand for reliable, animal-free testing methods. Regulatory initiatives, such as the European Pharmacopoeia's 2023 publication of 59 texts advocating for the replacement of rabbit pyrogen tests, have lent further strength to the LAL segment. Each one of these tests, such as turbidimetric, chromogenic, and gel clot, incorporates specific features of pyrogen detection.

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Key Market Segments

By Product

Consumables

Instruments

Services

By Test Type

LAL test (Chromogenic test, Turbidimetric test, Gel clot test)

In vitro pyrogen test

Rabbit test

By End-use

Pharmaceutical and biotechnology companies

Medical devices companies

Others

Regional Insights

North America dominated the pyrogen testing market, capturing over 38% of the revenue share in 2023. The region's advanced healthcare infrastructure, strong research ecosystem, and a high prevalence of chronic diseases drive this dominance. The U.S., in particular, benefits from the presence of major players like Pfizer Inc., Merck Group, and Amgen Inc., alongside a large pharmaceutical manufacturing base.

Europe holds a significant market share, driven by its rapidly growing biotechnology and pharmaceutical markets. The European Pharmacopoeia Commission's five-year initiative to phase out rabbit pyrogen testing underscores the region's commitment to advancing testing standards. Additionally, adopting animal-free methods aligns with regulatory and ethical standards, fostering market growth.

Recent Developments

Piscataway, NJ June 2024: GenScript Biotech Corporation introduced the GenScript FLASH Gene Service, an ultra-fast sequence-to-plasmid (S2P) solution that enhances gene synthesis processes. This innovation underscores the company's commitment to advancing synthetic biology.

Richmond, June 2024: FUJIFILM Wako Pure Chemicals Corporation announced the LumiMAT Pyrogen Detection Kit, a next-generation monocyte activation test for in vitro pyrogen detection, and the PYROSTAR Neo+, a recombinant protein reagent for the detection of bacterial endotoxins.

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