

# **Pyrogen And Endotoxin Testing Market Size, Share & Trends Analysis Report By Product (Instruments, Consumables, Services), By Technology (Bacterial Endotoxin Testing, Recombinant Endotoxin Detection), By Application, By End-use, By Region, And Segment Forecasts, 2026 - 2033**

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## **Abstracts**

The global pyrogen and endotoxin testing market size was estimated at USD 2.56 billion in 2025 and is projected to reach USD 4.46 billion by 2033, growing at CAGR of 7.22% from 2026 to 2033. The increasing demand for pyrogen and endotoxin testing products in the pharmaceutical and biotechnology industries is a significant driver of market growth.

The rapid expansion of these industries, coupled with the rising number of new therapeutic launches, is expected to propel the demand for pyrogen and endotoxin testing products further. This growth highlights the critical role of pyrogen and endotoxin testing in ensuring the safety and efficacy of pharmaceutical and biotechnological products.

Several regulatory bodies and governments are taking various initiatives to train and create awareness about pyrogen and endotoxin testing. Government initiatives worldwide are pivotal in accelerating this transition. In June 2024, the 179th session of the European Pharmacopoeia (Ph. Eur.) Commission marked a significant advancement for animal welfare and contemporary pyrogen and endotoxin testing practices. During this session, the Commission approved the removal of the Rabbit Pyrogen Test (RPT) from 57 revised texts and introduced a comprehensive new general chapter on Pyrogenicity. This decision effectively abolished the RPT requirement across

all Ph. Eur. texts, solidifying the transition toward in vitro testing methodologies, such as the Monocyte Activation Test (MAT).

The scope of the pyrogen and endotoxin testing industry is expanding significantly as technological advancements improve testing sensitivity, accuracy, and compliance with evolving regulatory standards. Increasing emphasis on ensuring the safety of pharmaceuticals, biologics, vaccines, and medical devices has driven the demand for advanced testing platforms capable of detecting both endotoxin and non-endotoxin pyrogens. The industry is gradually transitioning from traditional animal-based methods toward modern in vitro technologies that offer faster turnaround times and improved reproducibility. For instance, in May 2025, Minerva Biolabs GmbH introduced the NAT-MAT system, a next-generation pyrogen-detection platform that integrates the Monocyte Activation Test (MAT) with digital PCR. The system measures cytokine gene expression, including IL-1 $\beta$  and TNF- $\alpha$ , enabling more sensitive and rapid detection compared to conventional ELISA-based MAT assays. Such innovations highlight the expanding scope of advanced molecular and cell-based diagnostic technologies within pharmaceutical quality control processes.

In January 2026, BETMAT Biotechnology launched high-performance sustainable endotoxin testing services designed to meet evolving quality control requirements in pharmaceutical and medical device manufacturing. The new service focuses on providing reliable bacterial endotoxin testing (BET) solutions that comply with international pharmacopeial standards while supporting sustainability initiatives in laboratory testing. The service launch reflects the growing demand for efficient, standardized, and environmentally responsible endotoxin-detection technologies in pharmaceutical manufacturing. BETMAT's testing infrastructure incorporates advanced automated instrumentation and strict quality management systems aligned with global pharmacopeial requirements, including USP, EP, BP, and ChP, ensuring traceable and reliable results.

Furthermore, the development of integrated testing platforms is strengthening the role of automated, standardized pyrogen-detection solutions across pharmaceutical manufacturing workflows. The NAT-MAT platform includes ready-to-use macrophage cells, nucleic acid extraction kits, and a triplex digital PCR assay, enabling reliable and automated testing for both quality control and in-process monitoring. These developments reflect the growing shift toward comprehensive testing systems that can improve efficiency and reduce manual laboratory procedures.

In addition, the ability of such technologies to support complete pyrogen and endotoxin

testing creates opportunities to gradually replace traditional animal-based methods, such as the Rabbit Pyrogen Test. As regulatory agencies and industry stakeholders increasingly promote animal-free testing approaches, the adoption of advanced in vitro pyrogen detection technologies is expected to expand, thereby broadening the market scope and encouraging continued innovation in endotoxin and pyrogen and endotoxin testing solutions.

Increasing investment in R&D by the government and manufacturing companies for product development is one of the major factors contributing to the market's growth. New product development and launch is a key strategy adopted by manufacturers to maintain their dominance and to get maximum revenue share in the sector. As stated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), in 2023, the research-based pharmaceutical industry invested around USD 48.65 billion in R&D in Europe in 2022. Hence, the need for pyrogen and endotoxin testing products is anticipated to upsurge during the forecast period.

Furthermore, the pyrogen and endotoxin testing industry is driven by the increasing demand for therapeutic drugs. Several companies are actively involved in developing new drug therapies. For instance, in 2023, the FDA approved 55 new drugs. Pyrogen testing in drug development assesses the presence or absence of pyrogens in parenteral pharmaceutical products. Moreover, the sterility of any drug does not indicate that it is pyrogen-free. Therefore, drugs that are expected to be sterile must be tested for the presence of pyrogens to control febrile reactions in patients.

## Global Pyrogen And Endotoxin Testing Market Report Segmentation

This report forecasts revenue growth at global, regional, and country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the global pyrogen and endotoxin testing market report based on product, technology, application, end-use, and region.

### Product Outlook (Revenue, USD Billion, 2021 - 2033)

#### Consumables

##### Limulus Amebocyte Lysate (LAL) Endotoxin Test Kits

##### Chromogenic & Turbidimetric Reagents

Recombinant Factor C (rFC) Reagents

Monocyte Activation Test (MAT) Kits and Reagents

Control standard endotoxins and buffers

Endotoxin-free Lab Consumables

#### Instruments

Endotoxin Testing Systems

Microplate and Kinetic Readers

Automated Endotoxin Detection Systems

Incubators and Sample Preparation Units

#### Services

Contract Endotoxin and Pyrogen and Endotoxin Testing for IVD  
Manufacturers

Method Validation and Compliance Testing

Laboratory Contamination and Quality Assurance testing

Technology Outlook (Revenue, USD Billion, 2021 - 2033)

Bacterial Endotoxin Testing (BET)

Gel Clot Method

Chromogenic Method

Turbidimetric Method

Recombinant Endotoxin Detection

Pyrogen Detection

Monocyte Activation Test (MAT)

Rabbit Pyrogen Test

Application Outlook (Revenue, USD Billion, 2021 - 2033)

Product Safety & Batch Release Testing

Manufacturing Process & Raw Material Control

Validation & Regulatory Compliance Testing

Laboratory & Clinical Environment Contamination Control

End-use Outlook (Revenue, USD Billion, 2021 - 2033)

Pharmaceutical & Biopharmaceutical Companies

Medical Device Manufacturers

Biotechnology & Life Sciences Companies

Contract Research & Manufacturing Organizations (CROs & CDMOs)

Clinical & Diagnostic Laboratories

Regional Outlook (Revenue, USD Billion, 2021 - 2033)

North America

U.S.

Canada

Mexico

## Europe

Germany

UK

France

Italy

Spain

Sweden

Denmark

Norway

## Asia Pacific

China

Japan

India

South Korea

Australia

Thailand

## Latin America

Brazil

Argentina

## Middle East and Africa (MEA)

South Africa

Saudi Arabia

UAE

Kuwait

**This report can be delivered to the clients within 3 Business Days**

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