

Global Laboratory-developed Testing Market Growth (Status and Outlook) 2025-2031

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Abstracts

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The global Laboratory-developed Testing market size is predicted to grow from US\$ 3833 million in 2025 to US\$ 4834 million in 2031; it is expected to grow at a CAGR of 3.9% from 2025 to 2031.

Twenty-five years ago, the Food and Drug Administration (FDA) asserted in a draft document that 'home brew' tests-now commonly referred to as laboratory-developed tests (LDTs)-are subject to the same regulatory oversight as other in vitro diagnostics (IVDs)⁴. In 2010, the FDA began work on developing a proposed framework for future LDT oversight. Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation. While the proposed guidance has not been implemented, many questions regarding LDT oversight remain unresolved.

A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

LDTs can be used to measure or detect a wide variety of analytes (substances such as proteins, chemical compounds like glucose or cholesterol, or DNA), in a sample taken from a human body. Some LDTs are relatively simple tests that measure single analytes, such as a test that measures the level of sodium. Other LDTs are complex and may measure or detect one or more analytes. For example, some tests can detect many DNA variations from a single blood sample, which can be used to help diagnose a genetic disease. Various levels of chemicals can be measured to help diagnose a patient's state of health, such as levels of cholesterol or sodium.

While the uses of an LDT are often the same as the uses of FDA-cleared or approved in vitro diagnostic tests, some labs may choose to offer their own test. For example, a hospital lab may run its own vitamin D assay, even though there is an FDA-cleared test for vitamin D currently on the market.

The leading players in laboratory-developed testing include Quest Diagnostics, Roche, Illumina, Qiagen, and Eurofins, with the top three accounting for approximately 15% of the market.

North America is the largest market with more than 65% of the market, followed by Europe with about 15%.

LPI (LP Information)' newest research report, the "Laboratory-developed Testing Industry Forecast" looks at past sales and reviews total world Laboratory-developed Testing sales in 2024, providing a comprehensive analysis by region and market sector of projected Laboratory-developed Testing sales for 2025 through 2031. With Laboratory-developed Testing sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Laboratory-developed Testing industry.

This Insight Report provides a comprehensive analysis of the global Laboratory-developed Testing landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Laboratory-developed Testing portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Laboratory-developed Testing market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Laboratory-developed Testing and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Laboratory-developed Testing.

This report presents a comprehensive overview, market shares, and growth opportunities of Laboratory-developed Testing market by product type, application, key players and key regions and countries.

Segmentation by Type:

Commercial Service

R&D

Segmentation by Application:

Genetic Testing

Oncology

Infectious Disease

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Adaptive Biotechnologies Corporation

Quest Diagnostics

Roche

Illumina

Qiagen

Eurofins

Guardant Health

Biotheranostics

Adaptive Biotechnologies

Rosetta Genomics

Biodesix

Helix

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