

# Global Laboratory-developed Testing Supply, Demand and Key Producers, 2026-2032

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## Abstracts

The global Laboratory-developed Testing market size is expected to reach \$ 5189 million by 2032, rising at a market growth of 3.7% CAGR during the forecast period (2026-2032).

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)<sup>4</sup>. 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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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%.

This report studies the global Laboratory-developed Testing demand, key companies, and key regions.

This report is a detailed and comprehensive analysis of the world market for Laboratory-developed Testing, 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 Laboratory-developed Testing that contribute to its increasing demand across many markets.

### **Highlights and key features of the study**

Global Laboratory-developed Testing total market, 2021-2032, (USD Million)

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

U.S. VS China: Laboratory-developed Testing total market, key domestic companies, and share, (USD Million)

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

Global Laboratory-developed Testing total market by Type, CAGR, 2021-2032, (USD Million)

Global Laboratory-developed Testing total market by Application, CAGR, 2021-2032, (USD Million)

This report profiles major players in the global Laboratory-developed Testing 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 Adaptive Biotechnologies Corporation, Quest Diagnostics, Roche, Illumina, Qiagen, Eurofins, Guardant Health, Biotheranostics, Adaptive Biotechnologies, Rosetta Genomics, 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 Laboratory-developed Testing 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 Laboratory-developed Testing Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

#### Global Laboratory-developed Testing Market, Segmentation by Type:

Commercial Service

R&D

## Global Laboratory-developed Testing Market, Segmentation by Application:

Genetic Testing

Oncology

Infectious Disease

Others

## Companies Profiled:

Adaptive Biotechnologies Corporation

Quest Diagnostics

Roche

Illumina

Qiagen

Eurofins

Guardant Health

Biotheranostics

Adaptive Biotechnologies

Rosetta Genomics

Biodesix

Helix

## Key Questions Answered

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

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