

# Global Laboratory-developed Testing Market by Size, by Type, by Application, by Region, History and Forecast 2019-2030

https://marketpublishers.com/r/GF317F2CE3CCEN.html

Date: April 2024 Pages: 128 Price: US\$ 3,950.00 (Single User License) ID: GF317F2CE3CCEN

## **Abstracts**

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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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.



According to APO Research, The global Laboratory-developed Testing market is projected to grow from US\$ million in 2024 to US\$ million by 2030, at a Compound Annual Growth Rate (CAGR) of % during the forecast period.

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%.

**Report Includes** 

This report presents an overview of global market for Laboratory-developed Testing, market size. Analyses of the global market trends, with historic market revenue data for 2019 - 2023, estimates for 2024, and projections of CAGR through 2030.

This report researches the key producers of Laboratory-developed Testing, also provides the revenue of main regions and countries. Of the upcoming market potential for Laboratory-developed Testing, and key regions or countries of focus to forecast this market into various segments and sub-segments. Country specific data and market value analysis for the U.S., Canada, Mexico, Brazil, China, Japan, South Korea, Southeast Asia, India, Germany, the U.K., Italy, Middle East, Africa, and Other Countries.

This report focuses on the Laboratory-developed Testing revenue, market share and industry ranking of main manufacturers, data from 2019 to 2024. Identification of the major stakeholders in the global Laboratory-developed Testing market, and analysis of their competitive landscape and market positioning based on recent developments and segmental revenues. This report will help stakeholders to understand the competitive landscape and gain more insights and position their businesses and market strategies in a better way.

This report analyzes the segments data by Type and by Application, revenue, and growth rate, from 2019 to 2030. Evaluation and forecast the market size for Laboratory-developed Testing revenue, projected growth trends, production technology, application and end-user industry.

Descriptive company profiles of the major global players, including Adaptive



Biotechnologies Corporation, Quest Diagnostics, Roche, Illumina, Qiagen, Eurofins, Guardant Health, Biotheranostics and Adaptive Biotechnologies, etc.

Laboratory-developed Testing segment by Company

Adaptive Biotechnologies Corporation			
Quest Diagnostics			
Roche			
Illumina			
Qiagen			
Eurofins			
Guardant Health			
Biotheranostics			
Adaptive Biotechnologies			
Rosetta Genomics			
Biodesix			
Helix			
Laboratory-developed Testing segment by Type			

Commercial Service

R&D

#### Laboratory-developed Testing segment by Application

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**Genetic Testing** 

Oncology

Infectious Disease

Others

#### Laboratory-developed Testing segment by Region

North America

U.S.

Canada

Europe

Germany

France

U.K.

Italy

Russia

Asia-Pacific

China

Japan

South Korea

India



A	ust	ral	lia

China Taiwan

Indonesia

Thailand

Malaysia

Latin America

Mexico

Brazil

Argentina

Middle East & Africa

Turkey

Saudi Arabia

UAE

**Study Objectives** 

1. To analyze and research the global status and future forecast, involving, production, value, consumption, growth rate (CAGR), market share, historical and forecast.

2. To present the key manufacturers, capacity, production, revenue, market share, and Recent Developments.

3. To split the breakdown data by regions, type, manufacturers, and Application.

4. To analyze the global and key regions market potential and advantage, opportunity and challenge, restraints, and risks.



5. To identify significant trends, drivers, influence factors in global and regions.

6. To analyze competitive developments such as expansions, agreements, new product launches, and acquisitions in the market.

Reasons to Buy This Report

1. This report will help the readers to understand the competition within the industries and strategies for the competitive environment to enhance the potential profit. The report also focuses on the competitive landscape of the global Laboratory-developed Testing market, and introduces in detail the market share, industry ranking, competitor ecosystem, market performance, new product development, operation situation, expansion, and acquisition. etc. of the main players, which helps the readers to identify the main competitors and deeply understand the competition pattern of the market.

2. This report will help stakeholders to understand the global industry status and trends of Laboratory-developed Testing and provides them with information on key market drivers, restraints, challenges, and opportunities.

3. This report will help stakeholders to understand competitors better and gain more insights to strengthen their position in their businesses. The competitive landscape section includes the market share and rank (in volume and value), competitor ecosystem, new product development, expansion, and acquisition.

4. This report stays updated with novel technology integration, features, and the latest developments in the market.

5. This report helps stakeholders to gain insights into which regions to target globally.

6. This report helps stakeholders to gain insights into the end-user perception concerning the adoption of Laboratory-developed Testing.

7. This report helps stakeholders to identify some of the key players in the market and understand their valuable contribution.

**Chapter Outline** 

Chapter 1: Introduces the report scope of the report, executive summary of different

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market segments (product type, application, etc), including the market size of each market segment, future development potential, and so on. Revenue of Laboratorydeveloped Testing in global and regional level. It provides a quantitative analysis of the market size and development potential of each region and its main countries and introduces the market development, future development prospects, market space, and capacity of each country in the world. It offers a high-level view of the current state of the market and its likely evolution in the short to mid-term, and long term.

Chapter 2: Analysis key trends, drivers, challenges, and opportunities within the global Laboratory-developed Testing industry.

Chapter 3: Detailed analysis of Laboratory-developed Testing companies' competitive landscape, revenue, market share and industry ranking, latest development plan, merger, and acquisition information, etc.

Chapter 4: Provides the analysis of various market segments by type, covering the revenue, and development potential of each market segment, to help readers find the blue ocean market in different market segments.

Chapter 5: Provides the analysis of various market segments by application, covering the revenue, and development potential of each market segment, to help readers find the blue ocean market in different downstream markets.

Chapter 6: Provides profiles of key companies, introducing the basic situation of the main companies in the market in detail, including product descriptions and specifications, Laboratory-developed Testingrevenue, gross margin, and recent development, etc.

Chapter 7: North America (US & Canada) by type, by application and by country, revenue for each segment.

Chapter 8: Europe by type, by application and by country, revenue for each segment.

Chapter 9: China by type, and by application, revenue for each segment.

Chapter 10: Asia (excluding China) by type, by application and by region, revenue for each segment.

Chapter 11: MEALA by type, by application and by country, revenue for each segment.



Chapter 12: Concluding Insights of the report.



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