

# Laboratory-developed Testing Industry Research Report 2024

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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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

According to APO Research, The global Laboratory-developed Testing market was

valued at US\$ million in 2023 and is anticipated to reach US\$ million by 2030, witnessing a CAGR of xx% during the forecast period 2024-2030.

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 Scope

This report aims to provide a comprehensive presentation of the global market for Laboratory-developed Testing, with both quantitative and qualitative analysis, to help readers develop business/growth strategies, assess the market competitive situation, analyze their position in the current marketplace, and make informed business decisions regarding Laboratory-developed Testing.

The Laboratory-developed Testing market size, estimations, and forecasts are provided in terms of revenue (\$ millions), considering 2023 as the base year, with history and forecast data for the period from 2019 to 2030. This report segments the global Laboratory-developed Testing market comprehensively. Regional market sizes, concerning products by Type, by Application, and by players, are also provided. For a more in-depth understanding of the market, the report provides profiles of the competitive landscape, key competitors, and their respective market ranks. The report also discusses technological trends and new product developments.

## Key Companies & Market Share Insights

In this section, the readers will gain an understanding of the key players competing. This report has studied the key growth strategies, such as innovative trends and developments, intensification of product portfolio, mergers and acquisitions, collaborations, new product innovation, and geographical expansion, undertaken by these participants to maintain their presence. Apart from business strategies, the study includes current developments and key financials. The readers will also get access to the data related to global revenue, price, and sales by manufacturers for the period 2019-2024. This all-inclusive report will certainly serve the clients to stay updated and make effective decisions in their businesses. Some of the prominent players reviewed in the research report include:

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

Genetic Testing

Oncology

Infectious Disease

Others

## Laboratory-developed Testing Segment by Region

North America

United States

Canada

Europe

Germany

France

UK

Italy

Russia

Nordic Countries

Rest of Europe

Asia-Pacific

China

Japan

South Korea

Southeast Asia

India

Australia

Rest of Asia

Latin America

Mexico

Brazil

Rest of Latin America

Middle East & Africa

Turkey

Saudi Arabia

UAE

Rest of MEA

## Key Drivers & Barriers

High-impact rendering factors and drivers have been studied in this report to aid the readers to understand the general development. Moreover, the report includes restraints and challenges that may act as stumbling blocks on the way of the players. This will assist the users to be attentive and make informed decisions related to business. Specialists have also laid their focus on the upcoming business prospects.

## 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: Research objectives, research methods, data sources, data cross-validation;

Chapter 2: Introduces the report scope of the report, executive summary of different market segments (product type, application, etc), including the market size of each market segment, future development potential, and so on. 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 3: Provides the analysis of various market segments product types, covering the market size and development potential of each market segment, to help readers find the blue ocean market in different market segments.

Chapter 4: Provides the analysis of various market segments application, covering the market size and development potential of each market segment, to help readers find the

blue ocean market in different downstream markets.

Chapter 5: Introduces executive summary of global market size, regional market size, this section also introduces the market dynamics, latest developments of the market, the driving factors and restrictive factors of the market, the challenges and risks faced by companies in the industry, and the analysis of relevant policies in the industry.

Chapter 6: Detailed analysis of Laboratory-developed Testing companies' competitive landscape, revenue market share, latest development plan, merger, and acquisition information, etc.

Chapter 7, 8, 9, 10, 11: North America, Europe, Asia Pacific, Latin America, Middle East and Africa segment by country. 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.

Chapter 12: Provides profiles of key players, introducing the basic situation of the main companies in the market in detail, including revenue, gross margin, product introduction, recent development, etc.

Chapter 13: The main points and conclusions of the report.

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