

# Global Laboratory Developed Test Market 2024 by Company, Regions, Type and Application, Forecast to 2030

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## Abstracts

According to our (Global Info Research) latest study, the global Laboratory Developed Test market size was valued at USD 3620.6 million in 2023 and is forecast to a readjusted size of USD 4442.8 million by 2030 with a CAGR of 3.0% during review period.

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 Released in 2016, the draft guidance sparked an intense debate over potential LDT regulation.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 our research, the global market for medical devices is estimated at US\$ 603 billion in the year 2023, and will be growing at a CAGR of 5% during next six years. The global healthcare spending contributes to occupy 10% of the global GDP and is continuously rising in recent years due to the increasing health needs of the aging population, the growing prevalence of chronic and infectious diseases and the expansion of emerging markets. The medical devices market plays a significant role in the healthcare industry. The market is driven by several factors, including the increasing demand for advanced healthcare services globally, advancements in medical technology, growing geriatric population, rising healthcare expenditure, and increasing awareness about early disease diagnosis and treatment.

The Global Info Research report includes an overview of the development of the Laboratory Developed Test industry chain, the market status of Hospitals Laboratory (Clinical Biochemistry, Hematology), Clinical Research Organizations (Clinical Biochemistry, Hematology), and key enterprises in developed and developing market, and analysed the cutting-edge technology, patent, hot applications and market trends of Laboratory Developed Test.

Regionally, the report analyzes the Laboratory Developed Test markets in key regions. North America and Europe are experiencing steady growth, driven by government initiatives and increasing consumer awareness. Asia-Pacific, particularly China, leads the global Laboratory Developed Test market, with robust domestic demand, supportive policies, and a strong manufacturing base.

#### Key Features:

The report presents comprehensive understanding of the Laboratory Developed Test market. It provides a holistic view of the industry, as well as detailed insights into individual components and stakeholders. The report analysis market dynamics, trends, challenges, and opportunities within the Laboratory Developed Test industry.

The report involves analyzing the market at a macro level:

**Market Sizing and Segmentation:** Report collect data on the overall market size,

including the revenue generated, and market share of different by Type (e.g., Clinical Biochemistry, Hematology).

**Industry Analysis:** Report analyse the broader industry trends, such as government policies and regulations, technological advancements, consumer preferences, and market dynamics. This analysis helps in understanding the key drivers and challenges influencing the Laboratory Developed Test market.

**Regional Analysis:** The report involves examining the Laboratory Developed Test market at a regional or national level. Report analyses regional factors such as government incentives, infrastructure development, economic conditions, and consumer behaviour to identify variations and opportunities within different markets.

**Market Projections:** Report covers the gathered data and analysis to make future projections and forecasts for the Laboratory Developed Test market. This may include estimating market growth rates, predicting market demand, and identifying emerging trends.

The report also involves a more granular approach to Laboratory Developed Test:

**Company Analysis:** Report covers individual Laboratory Developed Test players, suppliers, and other relevant industry players. This analysis includes studying their financial performance, market positioning, product portfolios, partnerships, and strategies.

**Consumer Analysis:** Report covers data on consumer behaviour, preferences, and attitudes towards Laboratory Developed Test This may involve surveys, interviews, and analysis of consumer reviews and feedback from different by Application (Hospitals Laboratory, Clinical Research Organizations).

**Technology Analysis:** Report covers specific technologies relevant to Laboratory Developed Test. It assesses the current state, advancements, and potential future developments in Laboratory Developed Test areas.

**Competitive Landscape:** By analyzing individual companies, suppliers, and consumers, the report present insights into the competitive landscape of the Laboratory Developed Test market. This analysis helps understand market share, competitive advantages, and potential areas for differentiation among industry players.

Market Validation: The report involves validating findings and projections through primary research, such as surveys, interviews, and focus groups.

## Market Segmentation

Laboratory Developed Test market is split by Type and by Application. For the period 2019-2030, the growth among segments provides accurate calculations and forecasts for consumption value by Type, and by Application in terms of value.

### Market segment by Type

Clinical Biochemistry

Hematology

Immunology

Molecular Diagnostics

Other

### Market segment by Application

Hospitals Laboratory

Clinical Research Organizations

Academic Institutes

Specialty Diagnostic Centers

Other

### Market segment by players, this report covers

Quest Diagnostics

Thermo Fisher

Waters

Roche

Illumina

Qiagen

23andMe

Eurofins

Guardant Health

Biotheranostics

Adaptive Biotechnologies

Rosetta Genomics

Biodesix

Helix

Market segment by regions, regional analysis covers

North America (United States, Canada, and Mexico)

Europe (Germany, France, UK, Russia, Italy, and Rest of Europe)

Asia-Pacific (China, Japan, South Korea, India, Southeast Asia, Australia and Rest of Asia-Pacific)

South America (Brazil, Argentina and Rest of South America)

Middle East & Africa (Turkey, Saudi Arabia, UAE, Rest of Middle East & Africa)

The content of the study subjects, includes a total of 13 chapters:

Chapter 1, to describe Laboratory Developed Test product scope, market overview, market estimation caveats and base year.

Chapter 2, to profile the top players of Laboratory Developed Test, with revenue, gross margin and global market share of Laboratory Developed Test from 2019 to 2024.

Chapter 3, the Laboratory Developed Test competitive situation, revenue and global market share of top players are analyzed emphatically by landscape contrast.

Chapter 4 and 5, to segment the market size by Type and application, with consumption value and growth rate by Type, application, from 2019 to 2030.

Chapter 6, 7, 8, 9, and 10, to break the market size data at the country level, with revenue and market share for key countries in the world, from 2019 to 2024. and Laboratory Developed Test market forecast, by regions, type and application, with consumption value, from 2025 to 2030.

Chapter 11, market dynamics, drivers, restraints, trends and Porters Five Forces analysis.

Chapter 12, the key raw materials and key suppliers, and industry chain of Laboratory Developed Test.

Chapter 13, to describe Laboratory Developed Test research findings and conclusion.

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