

# **Global (North America, Europe, Asia-Pacific, South America, Middle East and Africa) Laboratory-developed Testing Market 2018, Forecast to 2023**

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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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

## **SCOPE OF THE REPORT:**

This report focuses on the Laboratory-developed Testing in global market, especially in

North America, Europe and Asia-Pacific, South America, Middle East and Africa. This report categorizes the market based on manufacturers, regions, type and application.

The leading manufactures mainly are Quest Diagnostics, Roche, Illumina, Qiagen, Eurofins. Quest Diagnostics is the largest manufacturer; its revenue of global market exceeds 5% in 2016. The next is Roche and Illumina.

There are mainly two type product of Laboratory-developed Testing market: Commercial Service and R&D. Commercial Service accounts the largest proportion; however, R&D still have high growth rate.

Geographically, the global Laboratory-developed Testing market has been segmented into North America, Europe, China, Japan, Southeast Asia, India and Other Regions. The North America held the largest share in the global Laboratory-developed Testing products market, its revenue of global market exceeds 68% in 2017. The next is Europe and Japan

The worldwide market for Laboratory-developed Testing is expected to grow at a CAGR of roughly 5.0% over the next five years, will reach 4030 million US\$ in 2023, from 3010 million US\$ in 2017, according to a new GIR (Global Info Research) study.

Market Segment by Manufacturers, this report covers

Adaptive Biotechnologies Corporation

Quest Diagnostics

Roche

Illumina

Qiagen

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 and Italy)

Asia-Pacific (China, Japan, Korea, India and Southeast Asia)

South America (Brazil, Argentina, Colombia etc.)

Middle East and Africa (Saudi Arabia, UAE, Egypt, Nigeria and South Africa)

Market Segment by Type, covers

Clinical Biochemistry

Critical Care

Haematology

Immunology

Microbiology

Molecular Diagnostics

Other Test Types

Market Segment by Applications, can be divided into

Academic Institutes

Clinical Research organizations

Hospitals laboratory

Specialty Diagnostic Centers

Other Type of Facilities

There are 15 Chapters to deeply display the global Laboratory-developed Testing market.

Chapter 1, to describe Laboratory-developed Testing Introduction, product scope, market overview, market opportunities, market risk, market driving force;

Chapter 2, to analyze the top manufacturers of Laboratory-developed Testing, with sales, revenue, and price of Laboratory-developed Testing, in 2016 and 2017;

Chapter 3, to display the competitive situation among the top manufacturers, with sales, revenue and market share in 2016 and 2017;

Chapter 4, to show the global market by regions, with sales, revenue and market share of Laboratory-developed Testing, for each region, from 2013 to 2018;

Chapter 5, 6, 7, 8 and 9, to analyze the market by countries, by type, by application and by manufacturers, with sales, revenue and market share by key countries in these regions;

Chapter 10 and 11, to show the market by type and application, with sales market share and growth rate by type, application, from 2013 to 2018;

Chapter 12, Laboratory-developed Testing market forecast, by regions, type and application, with sales and revenue, from 2018 to 2023;

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