

Global Laboratory Developed Tests (LDT) Market 2018 by Manufacturers, Countries, Type and Application, Forecast to 2023

<https://marketpublishers.com/r/GF2B1C61BC2EN.html>

Date: August 2018

Pages: 115

Price: US\$ 3,480.00 (Single User License)

ID: GF2B1C61BC2EN

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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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

SCOPE OF THE REPORT:

This report studies the Laboratory Developed Tests (LDT) market status and outlook of Global and major regions, from angles of players, countries, product types and end industries; this report analyzes the top players in global market, and splits the Laboratory Developed Tests (LDT) market by product type and applications/end industries.

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 manufactures mainly are Quest Diagnostics, Roche, Illumina, Qiagen, The global Laboratory Developed Tests (LDT) market is valued at xx million USD in 2017 and is expected to reach xx million USD by the end of 2023, growing at a CAGR of xx% between 2017 and 2023.

The Asia-Pacific will occupy for more market share in following years, especially in China, also fast growing India and Southeast Asia regions.

North America, especially The United States, will still play an important role which cannot be ignored. Any changes from United States might affect the development trend of Laboratory Developed Tests (LDT).

Europe also play important roles in global market, with market size of xx million USD in 2017 and will be xx million USD in 2023, with a CAGR of xx%.

Market Segment by Companies, 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)

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

Market Segment by Type, covers

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

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