

Global Laboratory-developed Testing Market Growth 2019-2024

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Abstracts

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 Released in 2014, the draft guidance sparked an intense debate over potential LDT regulation.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

The leading manufacturers 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

According to this study, over the next five years the Laboratory-developed Testing market will register a 5.0% CAGR in terms of revenue, the global market size will reach US\$ 4030 million by 2024, from US\$ 3010 million in 2019. In particular, this report presents the global market share (sales and revenue) of key companies in Laboratory-developed Testing business, shared in Chapter 3.

This report presents a comprehensive overview, market shares, and growth opportunities of Laboratory-developed Testing market by product type, application, key manufacturers and key regions and countries.

This study considers the Laboratory-developed Testing value and volume generated from the sales of the following segments:

Segmentation by product type: breakdown data from 2014 to 2019, in Section 2.3; and forecast to 2024 in section 11.7.

Clinical Biochemistry

Critical Care

Haematology

Immunology

Microbiology

Molecular Diagnostics

Other Test Types

Segmentation by application: breakdown data from 2014 to 2019, in Section 2.4; and forecast to 2024 in section 11.8.

Academic Institutes

Clinical Research organizations

Hospitals laboratory

Specialty Diagnostic Centers

Other Type of Facilities

This report also splits the market by region: Breakdown data in Chapter 4, 5, 6, 7 and 8.

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Spain

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The report also presents the market competition landscape and a corresponding detailed analysis of the major vendor/manufacturers in the market. The key manufacturers covered in this report: Breakdown data in in Chapter 3.

Adaptive Biotechnologies Corporation

Quest Diagnostics

Roche

Illumina

Qiagen

Eurofins

Guardant Health

Biotheranostics

Adaptive Biotechnologies

Rosetta Genomics

Biodesix

Helix

In addition, this report discusses the key drivers influencing market growth, opportunities, the challenges and the risks faced by key manufacturers and the market as a whole. It also analyzes key emerging trends and their impact on present and future development.

RESEARCH OBJECTIVES

To study and analyze the global Laboratory-developed Testing consumption (value & volume) by key regions/countries, product type and application, history data from 2014 to 2018, and forecast to 2024.

To understand the structure of Laboratory-developed Testing market by identifying its various subsegments.

Focuses on the key global Laboratory-developed Testing manufacturers, to define, describe and analyze the sales volume, value, market share, market competition landscape, SWOT analysis and development plans in next few years.

To analyze the Laboratory-developed Testing with respect to individual growth trends, future prospects, and their contribution to the total market.

To share detailed information about the key factors influencing the growth of the market (growth potential, opportunities, drivers, industry-specific challenges and risks).

To project the consumption of Laboratory-developed Testing submarkets, with respect to key regions (along with their respective key countries).

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

To strategically profile the key players and comprehensively analyze their growth strategies.

Contents

2019-2024 GLOBAL LABORATORY-DEVELOPED TESTING CONSUMPTION MARKET REPORT

1 SCOPE OF THE REPORT

- 1.1 Market Introduction
- 1.2 Research Objectives
- 1.3 Years Considered
- 1.4 Market Research Methodology
- 1.5 Economic Indicators
- 1.6 Currency Considered

2 EXECUTIVE SUMMARY

- 2.1 World Market Overview
 - 2.1.1 Global Laboratory-developed Testing Consumption 2014-2024
 - 2.1.2 Laboratory-developed Testing Consumption CAGR by Region
- 2.2 Laboratory-developed Testing Segment by Type
 - 2.2.1 Clinical Biochemistry
 - 2.2.2 Critical Care
 - 2.2.3 Haematology
 - 2.2.4 Immunology
 - 2.2.5 Microbiology
 - 2.2.6 Molecular Diagnostics
 - 2.2.7 Other Test Types
- 2.3 Laboratory-developed Testing Consumption by Type
 - 2.3.1 Global Laboratory-developed Testing Consumption Market Share by Type (2014-2019)
 - 2.3.2 Global Laboratory-developed Testing Revenue and Market Share by Type (2014-2019)
 - 2.3.3 Global Laboratory-developed Testing Sale Price by Type (2014-2019)
- 2.4 Laboratory-developed Testing Segment by Application
 - 2.4.1 Academic Institutes
 - 2.4.2 Clinical Research organizations
 - 2.4.3 Hospitals laboratory
 - 2.4.4 Specialty Diagnostic Centers
 - 2.4.5 Other Type of Facilities

2.5 Laboratory-developed Testing Consumption by Application

2.5.1 Global Laboratory-developed Testing Consumption Market Share by Application (2014-2019)

2.5.2 Global Laboratory-developed Testing Value and Market Share by Application (2014-2019)

2.5.3 Global Laboratory-developed Testing Sale Price by Application (2014-2019)

3 GLOBAL LABORATORY-DEVELOPED TESTING BY PLAYERS

3.1 Global Laboratory-developed Testing Sales Market Share by Players

3.1.1 Global Laboratory-developed Testing Sales by Players (2017-2019)

3.1.2 Global Laboratory-developed Testing Sales Market Share by Players (2017-2019)

3.2 Global Laboratory-developed Testing Revenue Market Share by Players

3.2.1 Global Laboratory-developed Testing Revenue by Players (2017-2019)

3.2.2 Global Laboratory-developed Testing Revenue Market Share by Players (2017-2019)

3.3 Global Laboratory-developed Testing Sale Price by Players

3.4 Global Laboratory-developed Testing Manufacturing Base Distribution, Sales Area, Product Types by Players

3.4.1 Global Laboratory-developed Testing Manufacturing Base Distribution and Sales Area by Players

3.4.2 Players Laboratory-developed Testing Products Offered

3.5 Market Concentration Rate Analysis

3.5.1 Competition Landscape Analysis

3.5.2 Concentration Ratio (CR3, CR5 and CR10) (2017-2019)

3.6 New Products and Potential Entrants

3.7 Mergers & Acquisitions, Expansion

4 LABORATORY-DEVELOPED TESTING BY REGIONS

4.1 Laboratory-developed Testing by Regions

4.1.1 Global Laboratory-developed Testing Consumption by Regions

4.1.2 Global Laboratory-developed Testing Value by Regions

4.2 Americas Laboratory-developed Testing Consumption Growth

4.3 APAC Laboratory-developed Testing Consumption Growth

4.4 Europe Laboratory-developed Testing Consumption Growth

4.5 Middle East & Africa Laboratory-developed Testing Consumption Growth

5 AMERICAS

5.1 Americas Laboratory-developed Testing Consumption by Countries

5.1.1 Americas Laboratory-developed Testing Consumption by Countries (2014-2019)

5.1.2 Americas Laboratory-developed Testing Value by Countries (2014-2019)

5.2 Americas Laboratory-developed Testing Consumption by Type

5.3 Americas Laboratory-developed Testing Consumption by Application

5.4 United States

5.5 Canada

5.6 Mexico

5.7 Key Economic Indicators of Few Americas Countries

6 APAC

6.1 APAC Laboratory-developed Testing Consumption by Countries

6.1.1 APAC Laboratory-developed Testing Consumption by Countries (2014-2019)

6.1.2 APAC Laboratory-developed Testing Value by Countries (2014-2019)

6.2 APAC Laboratory-developed Testing Consumption by Type

6.3 APAC Laboratory-developed Testing Consumption by Application

6.4 China

6.5 Japan

6.6 Korea

6.7 Southeast Asia

6.8 India

6.9 Australia

6.10 Key Economic Indicators of Few APAC Countries

7 EUROPE

7.1 Europe Laboratory-developed Testing by Countries

7.1.1 Europe Laboratory-developed Testing Consumption by Countries (2014-2019)

7.1.2 Europe Laboratory-developed Testing Value by Countries (2014-2019)

7.2 Europe Laboratory-developed Testing Consumption by Type

7.3 Europe Laboratory-developed Testing Consumption by Application

7.4 Germany

7.5 France

7.6 UK

7.7 Italy

7.8 Russia

7.9 Spain

7.10 Key Economic Indicators of Few Europe Countries

8 MIDDLE EAST & AFRICA

8.1 Middle East & Africa Laboratory-developed Testing by Countries

8.1.1 Middle East & Africa Laboratory-developed Testing Consumption by Countries (2014-2019)

8.1.2 Middle East & Africa Laboratory-developed Testing Value by Countries (2014-2019)

8.2 Middle East & Africa Laboratory-developed Testing Consumption by Type

8.3 Middle East & Africa Laboratory-developed Testing Consumption by Application

8.4 Egypt

8.5 South Africa

8.6 Israel

8.7 Turkey

8.8 GCC Countries

9 MARKET DRIVERS, CHALLENGES AND TRENDS

9.1 Market Drivers and Impact

9.1.1 Growing Demand from Key Regions

9.1.2 Growing Demand from Key Applications and Potential Industries

9.2 Market Challenges and Impact

9.3 Market Trends

10 MARKETING, DISTRIBUTORS AND CUSTOMER

10.1 Sales Channel

10.1.1 Direct Channels

10.1.2 Indirect Channels

10.2 Laboratory-developed Testing Distributors

10.3 Laboratory-developed Testing Customer

11 GLOBAL LABORATORY-DEVELOPED TESTING MARKET FORECAST

11.1 Global Laboratory-developed Testing Consumption Forecast (2019-2024)

11.2 Global Laboratory-developed Testing Forecast by Regions

11.2.1 Global Laboratory-developed Testing Forecast by Regions (2019-2024)

- 11.2.2 Global Laboratory-developed Testing Value Forecast by Regions (2019-2024)
- 11.2.3 Americas Consumption Forecast
- 11.2.4 APAC Consumption Forecast
- 11.2.5 Europe Consumption Forecast
- 11.2.6 Middle East & Africa Consumption Forecast
- 11.3 Americas Forecast by Countries
 - 11.3.1 United States Market Forecast
 - 11.3.2 Canada Market Forecast
 - 11.3.3 Mexico Market Forecast
 - 11.3.4 Brazil Market Forecast
- 11.4 APAC Forecast by Countries
 - 11.4.1 China Market Forecast
 - 11.4.2 Japan Market Forecast
 - 11.4.3 Korea Market Forecast
 - 11.4.4 Southeast Asia Market Forecast
 - 11.4.5 India Market Forecast
 - 11.4.6 Australia Market Forecast
- 11.5 Europe Forecast by Countries
 - 11.5.1 Germany Market Forecast
 - 11.5.2 France Market Forecast
 - 11.5.3 UK Market Forecast
 - 11.5.4 Italy Market Forecast
 - 11.5.5 Russia Market Forecast
 - 11.5.6 Spain Market Forecast
- 11.6 Middle East & Africa Forecast by Countries
 - 11.6.1 Egypt Market Forecast
 - 11.6.2 South Africa Market Forecast
 - 11.6.3 Israel Market Forecast
 - 11.6.4 Turkey Market Forecast
 - 11.6.5 GCC Countries Market Forecast
- 11.7 Global Laboratory-developed Testing Forecast by Type
- 11.8 Global Laboratory-developed Testing Forecast by Application

12 KEY PLAYERS ANALYSIS

- 12.1 Adaptive Biotechnologies Corporation
 - 12.1.1 Company Details
 - 12.1.2 Laboratory-developed Testing Product Offered
 - 12.1.3 Adaptive Biotechnologies Corporation Laboratory-developed Testing Sales,

Revenue, Price and Gross Margin (2017-2019)

12.1.4 Main Business Overview

12.1.5 Adaptive Biotechnologies Corporation News

12.2 Quest Diagnostics

12.2.1 Company Details

12.2.2 Laboratory-developed Testing Product Offered

12.2.3 Quest Diagnostics Laboratory-developed Testing Sales, Revenue, Price and

Gross Margin (2017-2019)

12.2.4 Main Business Overview

12.2.5 Quest Diagnostics News

12.3 Roche

12.3.1 Company Details

12.3.2 Laboratory-developed Testing Product Offered

12.3.3 Roche Laboratory-developed Testing Sales, Revenue, Price and Gross Margin

(2017-2019)

12.3.4 Main Business Overview

12.3.5 Roche News

12.4 Illumina

12.4.1 Company Details

12.4.2 Laboratory-developed Testing Product Offered

12.4.3 Illumina Laboratory-developed Testing Sales, Revenue, Price and Gross

Margin (2017-2019)

12.4.4 Main Business Overview

12.4.5 Illumina News

12.5 Qiagen

12.5.1 Company Details

12.5.2 Laboratory-developed Testing Product Offered

12.5.3 Qiagen Laboratory-developed Testing Sales, Revenue, Price and Gross Margin

(2017-2019)

12.5.4 Main Business Overview

12.5.5 Qiagen News

12.6 Eurofins

12.6.1 Company Details

12.6.2 Laboratory-developed Testing Product Offered

12.6.3 Eurofins Laboratory-developed Testing Sales, Revenue, Price and Gross

Margin (2017-2019)

12.6.4 Main Business Overview

12.6.5 Eurofins News

12.7 Guardant Health

- 12.7.1 Company Details
- 12.7.2 Laboratory-developed Testing Product Offered
- 12.7.3 Guardant Health Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)
- 12.7.4 Main Business Overview
- 12.7.5 Guardant Health News
- 12.8 Biotheranostics
 - 12.8.1 Company Details
 - 12.8.2 Laboratory-developed Testing Product Offered
 - 12.8.3 Biotheranostics Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)
 - 12.8.4 Main Business Overview
 - 12.8.5 Biotheranostics News
- 12.9 Adaptive Biotechnologies
 - 12.9.1 Company Details
 - 12.9.2 Laboratory-developed Testing Product Offered
 - 12.9.3 Adaptive Biotechnologies Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)
 - 12.9.4 Main Business Overview
 - 12.9.5 Adaptive Biotechnologies News
- 12.10 Rosetta Genomics
 - 12.10.1 Company Details
 - 12.10.2 Laboratory-developed Testing Product Offered
 - 12.10.3 Rosetta Genomics Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)
 - 12.10.4 Main Business Overview
 - 12.10.5 Rosetta Genomics News
- 12.11 Bidesix
- 12.12 Helix

13 RESEARCH FINDINGS AND CONCLUSION

List Of Tables

LIST OF TABLES AND FIGURES

Figure Picture of Laboratory-developed Testing

Table Product Specifications of Laboratory-developed Testing

Figure Laboratory-developed Testing Report Years Considered

Figure Market Research Methodology

Figure Global Laboratory-developed Testing Consumption Growth Rate 2014-2024 (K Units)

Figure Global Laboratory-developed Testing Value Growth Rate 2014-2024 (\$ Millions)

Table Laboratory-developed Testing Consumption CAGR by Region 2014-2024 (\$ Millions)

Figure Product Picture of Clinical Biochemistry

Table Major Players of Clinical Biochemistry

Figure Product Picture of Critical Care

Table Major Players of Critical Care

Figure Product Picture of Haematology

Table Major Players of Haematology

Figure Product Picture of Immunology

Table Major Players of Immunology

Figure Product Picture of Microbiology

Table Major Players of Microbiology

Figure Product Picture of Molecular Diagnostics

Table Major Players of Molecular Diagnostics

Figure Product Picture of Other Test Types

Table Major Players of Other Test Types

Table Global Consumption Sales by Type (2014-2019)

Table Global Laboratory-developed Testing Consumption Market Share by Type (2014-2019)

Figure Global Laboratory-developed Testing Consumption Market Share by Type (2014-2019)

Table Global Laboratory-developed Testing Revenue by Type (2014-2019) (\$ million)

Table Global Laboratory-developed Testing Value Market Share by Type (2014-2019) (\$ Millions)

Figure Global Laboratory-developed Testing Value Market Share by Type (2014-2019)

Table Global Laboratory-developed Testing Sale Price by Type (2014-2019)

Figure Laboratory-developed Testing Consumed in Academic Institutes

Figure Global Laboratory-developed Testing Market: Academic Institutes (2014-2019)

(K Units)

Figure Global Laboratory-developed Testing Market: Academic Institutes (2014-2019)
(\$ Millions)

Figure Global Academic Institutes YoY Growth (\$ Millions)

Figure Laboratory-developed Testing Consumed in Clinical Research organizations

Figure Global Laboratory-developed Testing Market: Clinical Research organizations
(2014-2019) (K Units)

Figure Global Laboratory-developed Testing Market: Clinical Research organizations
(2014-2019) (\$ Millions)

Figure Global Clinical Research organizations YoY Growth (\$ Millions)

Figure Laboratory-developed Testing Consumed in Hospitals laboratory

Figure Global Laboratory-developed Testing Market: Hospitals laboratory (2014-2019)
(K Units)

Figure Global Laboratory-developed Testing Market: Hospitals laboratory (2014-2019)
(\$ Millions)

Figure Global Hospitals laboratory YoY Growth (\$ Millions)

Figure Laboratory-developed Testing Consumed in Specialty Diagnostic Centers

Figure Global Laboratory-developed Testing Market: Specialty Diagnostic Centers
(2014-2019) (K Units)

Figure Global Laboratory-developed Testing Market: Specialty Diagnostic Centers
(2014-2019) (\$ Millions)

Figure Global Specialty Diagnostic Centers YoY Growth (\$ Millions)

Figure Laboratory-developed Testing Consumed in Other Type of Facilities

Figure Global Laboratory-developed Testing Market: Other Type of Facilities
(2014-2019) (K Units)

Figure Global Laboratory-developed Testing Market: Other Type of Facilities
(2014-2019) (\$ Millions)

Figure Global Other Type of Facilities YoY Growth (\$ Millions)

Table Global Consumption Sales by Application (2014-2019)

Table Global Laboratory-developed Testing Consumption Market Share by Application
(2014-2019)

Figure Global Laboratory-developed Testing Consumption Market Share by Application
(2014-2019)

Table Global Laboratory-developed Testing Value by Application (2014-2019)

Table Global Laboratory-developed Testing Value Market Share by Application
(2014-2019)

Figure Global Laboratory-developed Testing Value Market Share by Application
(2014-2019)

Table Global Laboratory-developed Testing Sale Price by Application (2014-2019)

Table Global Laboratory-developed Testing Sales by Players (2017-2019) (K Units)

Table Global Laboratory-developed Testing Sales Market Share by Players (2017-2019)

Figure Global Laboratory-developed Testing Sales Market Share by Players in 2017

Figure Global Laboratory-developed Testing Sales Market Share by Players in 2018

Table Global Laboratory-developed Testing Revenue by Players (2017-2019) (\$ Millions)

Table Global Laboratory-developed Testing Revenue Market Share by Players (2017-2019)

Figure Global Laboratory-developed Testing Revenue Market Share by Players in 2017

Figure Global Laboratory-developed Testing Revenue Market Share by Players in 2018

Table Global Laboratory-developed Testing Sale Price by Players (2017-2019)

Figure Global Laboratory-developed Testing Sale Price by Players in 2018

Table Global Laboratory-developed Testing Manufacturing Base Distribution and Sales Area by Players

Table Players Laboratory-developed Testing Products Offered

Table Laboratory-developed Testing Concentration Ratio (CR3, CR5 and CR10) (2017-2019)

Table Global Laboratory-developed Testing Consumption by Regions 2014-2019 (K Units)

Table Global Laboratory-developed Testing Consumption Market Share by Regions 2014-2019

Figure Global Laboratory-developed Testing Consumption Market Share by Regions 2014-2019

Table Global Laboratory-developed Testing Value by Regions 2014-2019 (\$ Millions)

Table Global Laboratory-developed Testing Value Market Share by Regions 2014-2019

Figure Global Laboratory-developed Testing Value Market Share by Regions 2014-2019

Figure Americas Laboratory-developed Testing Consumption 2014-2019 (K Units)

Figure Americas Laboratory-developed Testing Value 2014-2019 (\$ Millions)

Figure APAC Laboratory-developed Testing Consumption 2014-2019 (K Units)

Figure APAC Laboratory-developed Testing Value 2014-2019 (\$ Millions)

Figure Europe Laboratory-developed Testing Consumption 2014-2019 (K Units)

Figure Europe Laboratory-developed Testing Value 2014-2019 (\$ Millions)

Figure Middle East & Africa Laboratory-developed Testing Consumption 2014-2019 (K Units)

Figure Middle East & Africa Laboratory-developed Testing Value 2014-2019 (\$ Millions)

Table Americas Laboratory-developed Testing Consumption by Countries (2014-2019) (K Units)

Table Americas Laboratory-developed Testing Consumption Market Share by Countries

(2014-2019)

Figure Americas Laboratory-developed Testing Consumption Market Share by Countries in 2018

Table Americas Laboratory-developed Testing Value by Countries (2014-2019) (\$ Millions)

Table Americas Laboratory-developed Testing Value Market Share by Countries (2014-2019)

Figure Americas Laboratory-developed Testing Value Market Share by Countries in 2018

Table Americas Laboratory-developed Testing Consumption by Type (2014-2019) (K Units)

Table Americas Laboratory-developed Testing Consumption Market Share by Type (2014-2019)

Figure Americas Laboratory-developed Testing Consumption Market Share by Type in 2018

Table Americas Laboratory-developed Testing Consumption by Application (2014-2019) (K Units)

Table Americas Laboratory-developed Testing Consumption Market Share by Application (2014-2019)

Figure Americas Laboratory-developed Testing Consumption Market Share by Application in 2018

Figure United States Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure United States Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Canada Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Canada Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Mexico Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Mexico Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Table APAC Laboratory-developed Testing Consumption by Countries (2014-2019) (K Units)

Table APAC Laboratory-developed Testing Consumption Market Share by Countries (2014-2019)

Figure APAC Laboratory-developed Testing Consumption Market Share by Countries in 2018

Table APAC Laboratory-developed Testing Value by Countries (2014-2019) (\$ Millions)

Table APAC Laboratory-developed Testing Value Market Share by Countries (2014-2019)

Figure APAC Laboratory-developed Testing Value Market Share by Countries in 2018
Table APAC Laboratory-developed Testing Consumption by Type (2014-2019) (K Units)
Table APAC Laboratory-developed Testing Consumption Market Share by Type (2014-2019)
Figure APAC Laboratory-developed Testing Consumption Market Share by Type in 2018
Table APAC Laboratory-developed Testing Consumption by Application (2014-2019) (K Units)
Table APAC Laboratory-developed Testing Consumption Market Share by Application (2014-2019)
Figure APAC Laboratory-developed Testing Consumption Market Share by Application in 2018
Figure China Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure China Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Figure Japan Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure Japan Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Figure Korea Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure Korea Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Figure Southeast Asia Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure Southeast Asia Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Figure India Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure India Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Figure Australia Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)
Figure Australia Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)
Table Europe Laboratory-developed Testing Consumption by Countries (2014-2019) (K Units)
Table Europe Laboratory-developed Testing Consumption Market Share by Countries (2014-2019)
Figure Europe Laboratory-developed Testing Consumption Market Share by Countries in 2018
Table Europe Laboratory-developed Testing Value by Countries (2014-2019) (\$ Millions)
Table Europe Laboratory-developed Testing Value Market Share by Countries (2014-2019)
Figure Europe Laboratory-developed Testing Value Market Share by Countries in 2018
Table Europe Laboratory-developed Testing Consumption by Type (2014-2019) (K

Units)

Table Europe Laboratory-developed Testing Consumption Market Share by Type (2014-2019)

Figure Europe Laboratory-developed Testing Consumption Market Share by Type in 2018

Table Europe Laboratory-developed Testing Consumption by Application (2014-2019) (K Units)

Table Europe Laboratory-developed Testing Consumption Market Share by Application (2014-2019)

Figure Europe Laboratory-developed Testing Consumption Market Share by Application in 2018

Figure Germany Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Germany Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure France Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure France Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure UK Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure UK Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Italy Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Italy Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Russia Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Russia Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Spain Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Spain Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Table Middle East & Africa Laboratory-developed Testing Consumption by Countries (2014-2019) (K Units)

Table Middle East & Africa Laboratory-developed Testing Consumption Market Share by Countries (2014-2019)

Figure Middle East & Africa Laboratory-developed Testing Consumption Market Share by Countries in 2018

Table Middle East & Africa Laboratory-developed Testing Value by Countries (2014-2019) (\$ Millions)

Table Middle East & Africa Laboratory-developed Testing Value Market Share by Countries (2014-2019)

Figure Middle East & Africa Laboratory-developed Testing Value Market Share by Countries in 2018

Table Middle East & Africa Laboratory-developed Testing Consumption by Type (2014-2019) (K Units)

Table Middle East & Africa Laboratory-developed Testing Consumption Market Share

by Type (2014-2019)

Figure Middle East & Africa Laboratory-developed Testing Consumption Market Share by Type in 2018

Table Middle East & Africa Laboratory-developed Testing Consumption by Application (2014-2019) (K Units)

Table Middle East & Africa Laboratory-developed Testing Consumption Market Share by Application (2014-2019)

Figure Middle East & Africa Laboratory-developed Testing Consumption Market Share by Application in 2018

Figure Egypt Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Egypt Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure South Africa Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure South Africa Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Israel Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Israel Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure Turkey Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure Turkey Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Figure GCC Countries Laboratory-developed Testing Consumption Growth 2014-2019 (K Units)

Figure GCC Countries Laboratory-developed Testing Value Growth 2014-2019 (\$ Millions)

Table Laboratory-developed Testing Distributors List

Table Laboratory-developed Testing Customer List

Figure Global Laboratory-developed Testing Consumption Growth Rate Forecast (2019-2024) (K Units)

Figure Global Laboratory-developed Testing Value Growth Rate Forecast (2019-2024) (\$ Millions)

Table Global Laboratory-developed Testing Consumption Forecast by Countries (2019-2024) (K Units)

Table Global Laboratory-developed Testing Consumption Market Forecast by Regions

Table Global Laboratory-developed Testing Value Forecast by Countries (2019-2024) (\$ Millions)

Table Global Laboratory-developed Testing Value Market Share Forecast by Regions

Figure Americas Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure Americas Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Figure APAC Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure APAC Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Figure Europe Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure Europe Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Middle East & Africa Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Middle East & Africa Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure United States Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure United States Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Canada Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Canada Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Mexico Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Mexico Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Brazil Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Brazil Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure China Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure China Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Japan Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Japan Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Korea Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Korea Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Southeast Asia Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Southeast Asia Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure India Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure India Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Australia Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Australia Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Germany Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Germany Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure France Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure France Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure UK Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure UK Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Italy Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Italy Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Russia Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Russia Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Spain Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Spain Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure Egypt Laboratory-developed Testing Consumption 2019-2024 (K Units)
Figure Egypt Laboratory-developed Testing Value 2019-2024 (\$ Millions)
Figure South Africa Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure South Africa Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Figure Israel Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure Israel Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Figure Turkey Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure Turkey Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Figure GCC Countries Laboratory-developed Testing Consumption 2019-2024 (K Units)

Figure GCC Countries Laboratory-developed Testing Value 2019-2024 (\$ Millions)

Table Global Laboratory-developed Testing Consumption Forecast by Type (2019-2024) (K Units)

Table Global Laboratory-developed Testing Consumption Market Share Forecast by Type (2019-2024)

Table Global Laboratory-developed Testing Value Forecast by Type (2019-2024) (\$ Millions)

Table Global Laboratory-developed Testing Value Market Share Forecast by Type (2019-2024)

Table Global Laboratory-developed Testing Consumption Forecast by Application (2019-2024) (K Units)

Table Global Laboratory-developed Testing Consumption Market Share Forecast by Application (2019-2024)

Table Global Laboratory-developed Testing Value Forecast by Application (2019-2024) (\$ Millions)

Table Global Laboratory-developed Testing Value Market Share Forecast by Application (2019-2024)

Table Adaptive Biotechnologies Corporation Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Adaptive Biotechnologies Corporation Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Adaptive Biotechnologies Corporation Laboratory-developed Testing Market Share (2017-2019)

Table Quest Diagnostics Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Quest Diagnostics Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Quest Diagnostics Laboratory-developed Testing Market Share (2017-2019)

Table Roche Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Roche Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Roche Laboratory-developed Testing Market Share (2017-2019)

Table Illumina Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Illumina Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Illumina Laboratory-developed Testing Market Share (2017-2019)

Table Qiagen Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Qiagen Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Qiagen Laboratory-developed Testing Market Share (2017-2019)

Table Eurofins Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Eurofins Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Eurofins Laboratory-developed Testing Market Share (2017-2019)

Table Guardant Health Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Guardant Health Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Guardant Health Laboratory-developed Testing Market Share (2017-2019)

Table Biotheranostics Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Biotheranostics Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Biotheranostics Laboratory-developed Testing Market Share (2017-2019)

Table Adaptive Biotechnologies Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Adaptive Biotechnologies Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Adaptive Biotechnologies Laboratory-developed Testing Market Share (2017-2019)

Table Rosetta Genomics Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Rosetta Genomics Laboratory-developed Testing Sales, Revenue, Price and Gross Margin (2017-2019)

Figure Rosetta Genomics Laboratory-developed Testing Market Share (2017-2019)

Table Biondesix Basic Information, Manufacturing Base, Sales Area and Its Competitors

Table Helix Basic Information, Manufacturing Base, Sales Area and Its Competitors

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