

# Global PD-L1 Testing and Therapeutics Market - 2025 -2033

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## Abstracts

### Global PD-L1 Testing and Therapeutics Market: Industry Outlook

The global PD-L1 Testing and Therapeutics market reached US\$ 52.05 billion in 2023, with a rise of US\$ 57.82 billion in 2024, and is expected to reach US\$ 159.84 billion by 2033, growing at a CAGR of 11.6% during the forecast period 2025-2033.

The Global PD-L1 Testing and Therapeutics Market is experiencing significant growth due to the increasing use of immuno-oncology therapies and biomarker-driven precision medicine in cancer care. PD-L1 testing, primarily through immunohistochemistry assays, is crucial for detecting PD-1/PD-L1 inhibitors and ensuring appropriate patient selection across various cancer types. The market is dominated by blockbuster drugs like Merck's Keytruda, Bristol Myers Squibb's Opdivo, Roche's Tecentriq, AstraZeneca's Imfinzi, and Regeneron/Sanofi's Libtayo. Competition from Novartis, BeiGene, Pfizer, BioNTech, and Summit Therapeutics is also increasing. North America is expected to dominate the market due to advanced healthcare infrastructure and high immunotherapy uptake, followed by Europe and Asia-Pacific markets.

### Dynamics: Drivers & Restraints

#### Driver: Rising Adoption of Immuno-Oncology and Precision Medicine

The Global PD-L1 Testing and Therapeutics Market is driven by the rise in immuno-oncology therapies and precision medicine. PD-L1 testing helps oncologists identify patients who benefit from PD-1/PD-L1 inhibitors, improving treatment efficacy and reducing high-cost therapies. The expanding FDA- and EMA-approved indications for drugs like pembrolizumab, nivolumab, and atezolizumab cover various cancers,

accelerating demand for companion diagnostics and integrating PD-L1 biomarker analysis into standard cancer care.

For instance, in June 2025, Merck has approved KEYTRUDA, its anti-PD-1 therapy, for adult patients with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) expressing PD-L1. The FDA-approved test determined that the therapy can be used as a single agent, continued as adjuvant treatment in combination with radiotherapy, and as a single agent. The treatment is approved by the FDA.

#### Restraint: High Cost of Testing and Therapeutics

The high cost of PD-L1 testing and immunotherapy drugs is a significant barrier to market growth. Companion diagnostic assays can be costly, especially in resource-limited settings. Therapeutics, such as PD-1/PD-L1 inhibitors, can cost thousands of dollars per treatment cycle, limiting patient access in low- and middle-income countries. Even in developed markets, reimbursement barriers and cost-containment pressures can slow adoption rates, potentially hindering market penetration despite strong clinical demand.

#### Segmentation Analysis

The global PD-L1 testing and therapeutics market is segmented based on product type, testing type, indication, end user, and region.

#### Product Type:

The PD-L1 Therapeutics from the product type segment the expected to have 57.81% of the PD-L1 Testing and Therapeutics market share.

The PD-L1 therapeutics segment in the Global PD-L1 Testing and Therapeutics Market is driven by several factors, including the expansion of approved indications for leading drugs like pembrolizumab, nivolumab, atezolizumab, and durvalumab, particularly in high-burden cancers like first-line metastatic NSCLC, adjuvant settings in resected NSCLC, and unresectable Stage III disease.

The U.S. FDA and EMA have also approved PD-L1 inhibitors for rare or aggressive cancers like triple-negative breast cancer and cervical cancer. Survival benefits from landmark trials have shifted treatment guidelines towards earlier-line PD-L1 blockade, boosting prescription volumes. The pipeline is diversifying with next-generation PD-L1

drugs and bispecific antibodies under development by companies like BioNTech, Pfizer, and Summit Therapeutics. Combination regimens with chemotherapy, targeted therapies, and checkpoint inhibitors are expanding market potential.

For instance, in August 2025, Akeso, Inc. has been approved by China's National Medical Products Administration and the U.S. Food and Drug Administration to initiate a global, multicenter, randomized Phase II registrational trial (COMPASSION-36/AK104-225) to evaluate cadonilimab, Akeso's first-in-class PD-1/CTLA-4 bispecific antibody, in combination with lenvatinib for the treatment of advanced hepatocellular carcinoma in patients previously treated with atezolizumab and bevacizumab.

### Geographical Share Analysis

The North America global PD-L1 Testing and Therapeutics market was valued at 42.1% market share in 2024

The North America region dominates the Global PD-L1 Testing and Therapeutics Market due to advanced healthcare infrastructure, high immunotherapy adoption rates, and strong regulatory and reimbursement frameworks. The U.S. FDA's proactive approval of PD-1/PD-L1 inhibitors has enabled rapid market entry for drugs like pembrolizumab, nivolumab, atezolizumab, and durvalumab. The widespread availability of companion diagnostics and high cancer incidence rates fuel uptake. Favorable reimbursement policies from Medicare, Medicaid, and private insurers reduce financial barriers. The presence of leading pharmaceutical innovators and ongoing clinical trials solidify the region's dominance in innovation and market penetration.

For instance, in March 2025, The FDA has approved pembrolizumab, along with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy, for first-line treatment in adults with advanced HER2-positive gastric or GEJ adenocarcinoma expressing PD-L1 (CPS ≥1).

### Global PD-L1 Testing and Therapeutics Market – Major Players

The major players in the PD-L1 Testing and Therapeutics market include Agilent Technologies (Dako), Roche/Ventana Medical Systems, Merck & Co., Inc, Bristol Myers Squibb, AstraZeneca, Regeneron Pharmaceuticals, and Summit Therapeutics Inc among others.

## Key Developments

In February 2025, Leica Biosystems is pleased to announce the launch of two new primary antibodies, PD-L1 and HER2, developed to support cancer research and therapy development. These antibodies, widely used in studying breast, lung, and other cancers, underscore our commitment to empowering pharmaceutical partners with high-quality assays.

The global PD-L1 Testing and Therapeutics market report delivers a detailed analysis with 59 key tables, more than 56 visually impactful figures, and 195 pages of expert insights, providing a complete view of the market landscape.

## Contents

### **1. MARKET INTRODUCTION AND SCOPE**

- 1.1. Objectives of the Report
- 1.2. Report Coverage & Definitions
- 1.3. Report Scope

### **2. EXECUTIVE INSIGHTS AND KEY TAKEAWAYS**

### **3. MARKET HIGHLIGHTS AND STRATEGIC TAKEAWAYS**

- 3.1. Key Trends and Future Projections

### **4. SNIPPET BY PRODUCT TYPE**

- 4.1. Snippet by Testing Type
- 4.2. Snippet by Indication

### **5. SNIPPET BY END USER**

- 5.1. Snippet by Region

### **6. DYNAMICS**

#### 6.1. Impacting Factors

##### 6.1.1. Drivers

- 6.1.1.1. Rising Adoption of Immuno-Oncology and Precision Medicine
- 6.1.1.2. Expansion of Approved Indications for PD-1/PD-L1 Inhibitors

##### 6.1.2. Restraints

- 6.1.2.1. High Cost of Testing and Therapeutics
- 6.1.2.2. Reimbursement and Access Barriers in Some Markets

##### 6.1.3. Opportunity

- 6.1.3.1. Development of Multiplex and NGS-based biomarker panels
- 6.1.3.2. Growth in Bispecific and Multi-target Immunotherapies

##### 6.1.4. Impact Analysis

### **7. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET: STRATEGIC INSIGHTS AND INDUSTRY OUTLOOK**

- 7.1. Market Leaders and Pioneers
  - 7.1.1. Emerging Pioneers and Prominent Players
  - 7.1.2. Established leaders with largest largest-selling Brand
  - 7.1.3. Market leaders with established products & Services
- 7.2. Product Developments and Breakthroughs
- 7.3. Regulatory and Reimbursement Landscape
  - 7.3.1. North America
  - 7.3.2. Europe
  - 7.3.3. Asia Pacific
  - 7.3.4. South America
  - 7.3.5. Middle East & Africa
- 7.4. Porter's Five Force Analysis
- 7.5. Supply Chain Analysis
- 7.6. Patent Analysis
- 7.7. SWOT Analysis
- 7.8. Unmet Needs and Gaps
- 7.9. Recommended Strategies for Market Entry and Expansion
- 7.10. Pricing Analysis and Price Dynamics

## **8. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET: BY PRODUCT TYPE**

- 8.1. Introduction
  - 8.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type
  - 8.1.2. Market Attractiveness Index, By Product Type
- 8.2. PD-L1 Therapeutics\*
  - 8.2.1. Introduction
  - 8.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)
- 8.3. PD-L1 Testing (Diagnostics)

## **9. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET: BY TESTING TYPE**

- 9.1. Introduction
  - 9.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type
  - 9.1.2. Market Attractiveness Index, By Testing Type
- 9.2. Immunohistochemistry (IHC)\*
  - 9.2.1. Introduction
  - 9.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)
- 9.3. Next-Generation Sequencing (NGS)

## **10. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET: BY INDICATION**

### 10.1. Introduction

10.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication

10.1.2. Market Attractiveness Index, By Indication

### 10.2. Non-Small Cell Lung Cancer\*

10.2.1. Introduction

10.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)

### 10.3. Triple-Negative Breast Cancer

### 10.4. Head and Neck Squamous Cell Carcinoma

### 10.5. Esophageal Squamous Cell Carcinoma

### 10.6. Others

## **11. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET: BY END USER**

### 11.1. Introduction

11.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

11.1.2. Market Attractiveness Index, By End User

### 11.2. Hospitals\*

11.2.1. Introduction

11.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)

### 11.3. Cancer Specialty Clinics

### 11.4. Diagnostic Laboratories

### 11.5. Others

## **12. GLOBAL PD-L1 TESTING AND THERAPEUTICS MARKET REGIONAL MARKET ANALYSIS AND GROWTH OPPORTUNITIES**

## **13. INTRODUCTION**

### 13.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Region

13.1.1. Market Attractiveness Index, By Region

### 13.2. North America

13.2.1. Introduction

13.2.2. Key Region-Specific Dynamics

13.2.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type

13.2.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type

13.2.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication

13.2.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

13.2.7. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

13.2.7.1. U.S.

13.2.7.2. Canada

13.2.7.3. Mexico

13.3. Europe

13.3.1. Introduction

13.3.2. Key Region-Specific Dynamics

13.3.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type

13.3.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type

13.3.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication

13.3.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

13.3.7. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

13.3.7.1. Germany

13.3.7.2. U.K.

13.3.7.3. France

13.3.7.4. Spain

13.3.7.5. Italy

13.3.7.6. Rest of Europe

13.4. South America

13.4.1. Introduction

13.4.2. Key Region-Specific Dynamics

13.4.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type

13.4.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type

13.4.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication

13.4.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

13.4.7. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

13.4.7.1. Brazil

13.4.7.2. Argentina

13.4.7.3. Rest of South America

13.5. Asia-Pacific

13.5.1. Introduction

13.5.2. Key Region-Specific Dynamics

13.5.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type

13.5.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type

13.5.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication

13.5.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

13.5.7. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

13.5.7.1. China

- 13.5.7.2. India
- 13.5.7.3. Japan
- 13.5.7.4. South Korea
- 13.5.7.5. Rest of Asia-Pacific

## 13.6. Middle East and Africa

- 13.6.1. Introduction
- 13.6.2. Key Region-Specific Dynamics
- 13.6.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Product Type
- 13.6.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Testing Type
- 13.6.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By Indication
- 13.6.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

## 14. COMPETITIVE LANDSCAPE AND MARKET POSITIONING

## 15. COMPETITIVE OVERVIEW AND KEY MARKET PLAYERS

- 15.1. Market Share Analysis and Positioning Matrix
- 15.2. Strategic Partnerships, Mergers & Acquisitions
- 15.3. Key Developments in Product Portfolios and Innovations
- 15.4. Company Benchmarking

## 16. COMPANY PROFILES

- 16.1. Agilent Technologies (Dako)\*
  - 16.1.1. Company Overview
    - 16.1.1.1. Product Portfolio
    - 16.1.1.2. Product Description
    - 16.1.1.3. Product Key Performance Indicators (KPIs)
    - 16.1.1.4. Historic and Forecasted Product Sales
    - 16.1.1.5. Product Sales Volume
  - 16.1.2. Financial Overview
    - 16.1.2.1. Company Revenue
    - 16.1.2.2. Geographical Revenue Shares
    - 16.1.2.3. Revenue Forecasts
  - 16.1.3. Key Developments
    - 16.1.3.1. Mergers & Acquisitions
    - 16.1.3.2. Key Product Development Activities
    - 16.1.3.3. Regulatory Approvals, etc.
    - 16.1.3.4. SWOT Analysis

- 16.2. Roche/Ventana Medical Systems
- 16.3. Merck & Co., Inc.
- 16.4. Bristol Myers Squibb
- 16.5. AstraZeneca
- 16.6. Regeneron Pharmaceuticals
- 16.7. Summit Therapeutics Inc (LIST NOT EXHAUSTIVE)

## **17. ASSUMPTIONS AND RESEARCH METHODOLOGY**

- 17.1. Data Collection Methods
- 17.2. Data Triangulation
- 17.3. Forecasting Techniques
- 17.4. Data Verification and Validation

## **18. APPENDIX**

- 18.1. About Us and Services
- 18.2. Contact Us

## List Of Tables

### LIST OF TABLES

Table 1 Global PD-L1 Testing and Therapeutics Market Value, By Product Type, 2025, 2029 & 2033 (US\$ Billion)

Table 2 Global PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2025, 2029 & 2033 (US\$ Billion)

Table 3 Global PD-L1 Testing and Therapeutics Market Value, By Indication, 2025, 2029 & 2033 (US\$ Billion)

Table 4 Global PD-L1 Testing and Therapeutics Market Value, By End User, 2025, 2029 & 2033 (US\$ Billion)

Table 5 Global PD-L1 Testing and Therapeutics Market Value, By Region, 2025, 2029 & 2033 (US\$ Billion)

Table 6 Global PD-L1 Testing and Therapeutics Market Value, By Product Type, 2025, 2029 & 2033 (US\$ Billion)

Table 7 Global PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 8 Global PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2025, 2029 & 2033 (US\$ Billion)

Table 9 Global PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 10 Global PD-L1 Testing and Therapeutics Market Value, By Indication, 2025, 2029 & 2033 (US\$ Billion)

Table 11 Global PD-L1 Testing and Therapeutics Market Value, By Indication, 2022-2033 (US\$ Billion)

Table 12 Global PD-L1 Testing and Therapeutics Market Value, By End User, 2025, 2029 & 2033 (US\$ Billion)

Table 13 Global PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 14 Global PD-L1 Testing and Therapeutics Market Value, By Region, 2025, 2029 & 2033 (US\$ Billion)

Table 15 Global PD-L1 Testing and Therapeutics Market Value, By Region, 2022-2033 (US\$ Billion)

Table 16 North America PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 17 North America PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 18 North America PD-L1 Testing and Therapeutics Market Value, By Indication,

2022-2033 (US\$ Billion)

Table 19 North America PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 20 North America PD-L1 Testing and Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 21 Europe PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 22 Europe PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 23 Europe PD-L1 Testing and Therapeutics Market Value, By Indication, 2022-2033 (US\$ Billion)

Table 24 Europe PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 25 Europe PD-L1 Testing and Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 26 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 27 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 28 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, By Indication, 2022-2033 (US\$ Billion)

Table 29 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 30 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 31 South America PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 32 South America PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 33 South America PD-L1 Testing and Therapeutics Market Value, By Indication, 2022-2033 (US\$ Billion)

Table 34 South America PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 35 South America PD-L1 Testing and Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 36 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, By Product Type, 2022-2033 (US\$ Billion)

Table 37 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, By Testing Type, 2022-2033 (US\$ Billion)

Table 38 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, By Indication, 2022-2033 (US\$ Billion)

Table 39 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 40 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 41 Agilent Technologies (Dako): Overview

Table 42 Agilent Technologies (Dako): Product Portfolio

Table 43 Agilent Technologies (Dako): Key Developments

Table 44 Roche/Ventana Medical Systems: Overview

Table 45 Roche/Ventana Medical Systems: Product Portfolio

Table 46 Roche/Ventana Medical Systems: Key Developments

Table 47 Merck & Co., Inc.: Overview

Table 48 Merck & Co., Inc.: Product Portfolio

Table 49 Merck & Co., Inc.: Key Developments

Table 50 Bristol Myers Squibb: Overview

Table 51 Bristol Myers Squibb: Product Portfolio

Table 52 Bristol Myers Squibb: Key Developments

Table 53 AstraZeneca: Overview

Table 54 AstraZeneca: Product Portfolio

Table 55 AstraZeneca: Key Developments

Table 56 Regeneron Pharmaceuticals : Overview

Table 57 Regeneron Pharmaceuticals : Product Portfolio

Table 58 Regeneron Pharmaceuticals : Key Developments

Table 59 Summit Therapeutics Inc: Overview

Table 60 Summit Therapeutics Inc: Product Portfolio

Table 61 Summit Therapeutics Inc: Key Developments

## List Of Figures

### LIST OF FIGURES

Figure 1 Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 2 Global PD-L1 Testing and Therapeutics Market Share, By Product Type, 2024 & 2033 (%)

Figure 3 Global PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 4 Global PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 5 Global PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 6 Global PD-L1 Testing and Therapeutics Market Share, By Region, 2024 & 2033 (%)

Figure 7 Global PD-L1 Testing and Therapeutics Market Y-o-Y Growth, By Product Type, 2023-2033 (%)

Figure 8 PD-L1 Therapeutics PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 9 PD-L1 Testing PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 10 Global PD-L1 Testing and Therapeutics Market Y-o-Y Growth, By Testing Type, 2023-2033 (%)

Figure 11 Immunohistochemistry (IHC) Testing Type in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 12 Next-Generation Sequencing (NGS) Testing Type in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 13 Global PD-L1 Testing and Therapeutics Market Y-o-Y Growth, By Indication, 2023-2033 (%)

Figure 14 Non-Small Cell Lung Cancer Indication in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 15 Triple-Negative Breast Cancer Indication in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 16 Head and Neck Squamous Cell Carcinoma Indication in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 17 Esophageal Squamous Cell Carcinoma Indication in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 18 Others Indication in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 19 Global PD-L1 Testing and Therapeutics Market Y-o-Y Growth, By End User, 2023-2033 (%)

Figure 20 Hospitals End User in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 21 Cancer Specialty Clinics End User in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 22 Diagnostic Laboratories End User in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 23 Others End User in Global PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 24 Global PD-L1 Testing and Therapeutics Market Y-o-Y Growth, By Region, 2023-2033 (%)

Figure 25 North America PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 26 North America PD-L1 Testing and Therapeutics Market Share, By Product Type, 2024 & 2033 (%)

Figure 27 North America PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 28 North America PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 29 North America PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 30 North America PD-L1 Testing and Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 31 Europe PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 32 Europe PD-L1 Testing and Therapeutics Market Share, By Product Type, 2024 & 2033 (%)

Figure 33 Europe PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 34 Europe PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 35 Europe PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 36 Europe PD-L1 Testing and Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 37 Asia-Pacific PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 38 Asia-Pacific PD-L1 Testing and Therapeutics Market Share, By Product Type,

2024 & 2033 (%)

Figure 39 Asia-Pacific PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 40 Asia-Pacific PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 41 Asia-Pacific PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 42 Asia-Pacific PD-L1 Testing and Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 43 South America PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 44 South America PD-L1 Testing and Therapeutics Market Share, By Product Type, 2024 & 2033 (%)

Figure 45 South America PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 46 South America PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 47 South America PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 48 South America PD-L1 Testing and Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 49 Middle East and Africa PD-L1 Testing and Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 50 Middle East and Africa PD-L1 Testing and Therapeutics Market Share, By Product Type, 2024 & 2033 (%)

Figure 51 Middle East and Africa PD-L1 Testing and Therapeutics Market Share, By Testing Type, 2024 & 2033 (%)

Figure 52 Middle East and Africa PD-L1 Testing and Therapeutics Market Share, By Indication, 2024 & 2033 (%)

Figure 53 Middle East and Africa PD-L1 Testing and Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 54 Agilent Technologies (Dako): Financials

Figure 55 Roche/Ventana Medical Systems: Financials

Figure 56 Merck & Co., Inc.: Financials

Figure 57 Bristol Myers Squibb: Financials

Figure 58 AstraZeneca: Financials

Figure 59 Regeneron Pharmaceuticals : Financials

Figure 60 Summit Therapeutics Inc: Financials

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