

Global IVD ELISA Reagents Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global IVD ELISA Reagents market size is predicted to grow from US\$ 1610 million in 2025 to US\$ 2243 million in 2032; it is expected to grow at a CAGR of 4.9% from 2026 to 2032.

IVD ELISA Reagents refer to complete in vitro diagnostic reagent systems based on enzyme-linked immunosorbent assay technology for detecting pathogen antigens or antibodies, autoantibodies, hormones, tumor-related markers, and specialty protein biomarkers in human serum, plasma, and other clinical specimens. A typical product generally includes pre-coated microplates, enzyme-labeled antibodies or antigens, calibrators, controls, sample diluents, wash buffers, chromogenic substrates, stop solutions, and related auxiliary components. These reagents are widely used in infectious disease screening, blood safety testing, autoimmune disease diagnostics, endocrine and reproductive testing, and selected specialty biomarker assays. Key upstream materials include recombinant antigens, monoclonal and polyclonal antibodies, horseradish peroxidase or alkaline phosphatase conjugates, polystyrene microplates, bovine serum albumin, buffering salts, chromogenic substrates, stabilizers, preservatives, and medical-grade packaging materials. Major downstream customers include hospital clinical laboratories, blood centers and blood screening institutions, independent medical laboratories, public health and disease control agencies, and diagnostic reagent distribution channels. The overall gross margin of the global IVD ELISA reagent industry in 2025 is estimated at approximately 48%-59%.

The global market for IVD ELISA reagents has entered a mature stage, with demand supported by infectious disease serology, blood safety screening, autoimmune disease testing, endocrine diagnostics, and selected specialty biomarker applications. Although ELISA products continue to face pressure from chemiluminescence immunoassays,

molecular diagnostics, and more automated testing platforms, they still retain practical value in batch-based workflows, established laboratory routines, broad assay menu coverage, and cost-sensitive testing environments. They remain particularly relevant in blood centers, public health laboratories, regional diagnostic facilities, and markets where testing systems are expected to balance reliability with operating efficiency. The competitive structure is becoming increasingly segmented, as routine screening assays are more exposed to scale and price competition, while specialty assays rely more heavily on clinical differentiation, stability, and brand credibility.

Looking ahead, the industry is likely to evolve through a combination of pressure on conventional assays, stronger emphasis on specialty applications, and continued optimization of product portfolios. Routine infectious disease screening products will remain under competitive pressure as large laboratories in mature markets continue to adopt more automated platforms. At the same time, ELISA reagents still offer room for expansion in autoimmune diagnostics, disease monitoring, specialty proteins, and selected applications involving alternative specimen types. Recent official industry activity, including asset acquisitions and new assay launches, indicates that the segment is not simply declining, but is instead shifting toward higher-value and more clinically differentiated applications. Future competition will increasingly depend on assay quality, regulatory readiness, specimen compatibility, and the depth of clinical utility rather than on the simple expansion of conventional menus.

The main growth drivers remain persistent needs in infectious disease surveillance, blood safety, autoimmune disease recognition, and specialty diagnostics. In addition, high-quality ELISA reagents continue to play a useful role in public health programs, disease management, and differentiated clinical testing strategies. The ongoing evolution of European IVD regulation is also reshaping the market by requiring stronger quality systems, more rigorous performance evaluation, and more comprehensive lifecycle management. While these requirements raise compliance costs, they also help reduce low-quality fragmented supply and favor manufacturers with durable product registration capabilities and stronger international operating discipline. Meanwhile, several companies continue to strengthen their specialty diagnostic portfolios, suggesting that regulatory pressure and clinical demand are jointly driving market upgrading rather than simple market contraction.

The key constraints are also clear. Highly standardized screening assays are more vulnerable to procurement pressure, pricing competition, and technological substitution, which limits both profitability and long-term growth potential. Smaller suppliers without differentiated assays, sufficient regulatory resources, or robust quality management

systems may find it increasingly difficult to defend their positions. In addition, ELISA reagent development requires careful control of antigen and antibody selection, conjugation processes, reagent stability, and lot-to-lot consistency. Manufacturers that want to operate across regions must also navigate different regulatory expectations and laboratory usage habits, which increases the burden of validation, registration, and after-sales support. Overall, the market is expected to remain stable, but future competitive advantage will increasingly depend on specialty assay depth, regulatory strength, scenario adaptability, and resilient supply capabilities.

LPI (LP Information)' newest research report, the 'IVD ELISA Reagents Industry Forecast' looks at past sales and reviews total world IVD ELISA Reagents sales in 2025, providing a comprehensive analysis by region and market sector of projected IVD ELISA Reagents sales for 2026 through 2032. With IVD ELISA Reagents sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world IVD ELISA Reagents industry.

This Insight Report provides a comprehensive analysis of the global IVD ELISA Reagents landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on IVD ELISA Reagents portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global IVD ELISA Reagents market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for IVD ELISA Reagents and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global IVD ELISA Reagents.

This report presents a comprehensive overview, market shares, and growth opportunities of IVD ELISA Reagents market by product type, application, key players and key regions and countries.

Segmentation by Type:

Antigen Detection

Antibody Detection

Hormone Detection

Other

Segmentation by Assay Output:

Qualitative Assays

Semi-quantitative Assays

Quantitative Assays

Segmentation by Assay Format:

Sandwich ELISA

Indirect ELISA

Other

Segmentation by Application:

Hospitals and Clinical Laboratories

Blood Centers and Plasma Screening Institutions

Independent Medical Laboratories

Other

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Bio-Rad Laboratories

Rewvity

Sebia

Tecan Group

BioVendor Group

Trinity Biotech

Dia.Pro Diagnostic Bioprobes

Vircell

SERION Diagnostics

DRG International

Demeditec Diagnostics

Mediagnost

AESKU.GROUP

Monobind

Diagnostics Biochem Canada

Epitope Diagnostics

Beijing Wantai Biological Pharmacy Enterprise

Shanghai Kehua Bio-engineering

Livzon Pharmaceutical Group

Daan Gene

InTec PRODUCTS

J. Mitra & Co.

Meril Life Sciences

Tulip Diagnostics

Medical & Biological Laboratories

GenBody

Contents

1 SCOPE OF THE REPORT

- 1.1 Market Introduction
- 1.2 Years Considered
- 1.3 Research Objectives
- 1.4 Market Research Methodology
- 1.5 Research Process and Data Source
- 1.6 Economic Indicators
- 1.7 Currency Considered
- 1.8 Market Estimation Caveats

2 EXECUTIVE SUMMARY

- 2.1 World Market Overview
 - 2.1.1 Global IVD ELISA Reagents Market Size (2021-2032)
 - 2.1.2 IVD ELISA Reagents Market Size CAGR by Region (2021 VS 2025 VS 2032)
 - 2.1.3 World Current & Future Analysis for IVD ELISA Reagents by Country/Region (2021, 2025 & 2032)
- 2.2 IVD ELISA Reagents Segment by Type
 - 2.2.1 Antigen Detection
 - 2.2.2 Antibody Detection
 - 2.2.3 Hormone Detection
 - 2.2.4 Other
 - 2.2.5 IVD ELISA Reagents Market Size by Type
 - 2.2.5.1 IVD ELISA Reagents Market Size CAGR by Type (2021 VS 2025 VS 2032)
 - 2.2.5.2 Global IVD ELISA Reagents Market Size Market Share by Type (2021-2026)
- 2.3 IVD ELISA Reagents Segment by Assay Output
 - 2.3.1 Qualitative Assays
 - 2.3.2 Semi-quantitative Assays
 - 2.3.3 Quantitative Assays
 - 2.3.4 IVD ELISA Reagents Market Size by Assay Output
 - 2.3.4.1 IVD ELISA Reagents Market Size CAGR by Assay Output (2021 VS 2025 VS 2032)
 - 2.3.4.2 Global IVD ELISA Reagents Market Size Market Share by Assay Output (2021-2026)
- 2.4 IVD ELISA Reagents Segment by Assay Format
 - 2.4.1 Sandwich ELISA

2.4.2 Indirect ELISA

2.4.3 Other

2.4.4 IVD ELISA Reagents Market Size by Assay Format

2.4.4.1 IVD ELISA Reagents Market Size CAGR by Assay Format (2021 VS 2025 VS 2032)

2.4.4.2 Global IVD ELISA Reagents Market Size Market Share by Assay Format (2021-2026)

2.5 IVD ELISA Reagents Segment by Application

2.5.1 Hospitals and Clinical Laboratories

2.5.2 Blood Centers and Plasma Screening Institutions

2.5.3 Independent Medical Laboratories

2.5.4 Other

2.5.5 IVD ELISA Reagents Market Size by Application

2.5.5.1 IVD ELISA Reagents Market Size CAGR by Application (2021 VS 2025 VS 2032)

2.5.5.2 Global IVD ELISA Reagents Market Size Market Share by Application (2021-2026)

3 IVD ELISA REAGENTS MARKET SIZE BY PLAYER

3.1 IVD ELISA Reagents Market Size Market Share by Player

3.1.1 Global IVD ELISA Reagents Revenue by Player (2021-2026)

3.1.2 Global IVD ELISA Reagents Revenue Market Share by Player (2021-2026)

3.2 Global IVD ELISA Reagents Key Players Head office and Products Offered

3.3 Market Concentration Rate Analysis

3.3.1 Competition Landscape Analysis

3.3.2 Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

3.4 New Products and Potential Entrants

3.5 Mergers & Acquisitions, Expansion

4 IVD ELISA REAGENTS BY REGION

4.1 IVD ELISA Reagents Market Size by Region (2021-2026)

4.2 Global IVD ELISA Reagents Annual Revenue by Country/Region (2021-2026)

4.3 Americas IVD ELISA Reagents Market Size Growth (2021-2026)

4.4 APAC IVD ELISA Reagents Market Size Growth (2021-2026)

4.5 Europe IVD ELISA Reagents Market Size Growth (2021-2026)

4.6 Middle East & Africa IVD ELISA Reagents Market Size Growth (2021-2026)

5 AMERICAS

- 5.1 Americas IVD ELISA Reagents Market Size by Country (2021-2026)
- 5.2 Americas IVD ELISA Reagents Market Size by Type (2021-2026)
- 5.3 Americas IVD ELISA Reagents Market Size by Application (2021-2026)
- 5.4 United States
- 5.5 Canada
- 5.6 Mexico
- 5.7 Brazil

6 APAC

- 6.1 APAC IVD ELISA Reagents Market Size by Region (2021-2026)
- 6.2 APAC IVD ELISA Reagents Market Size by Type (2021-2026)
- 6.3 APAC IVD ELISA Reagents Market Size by Application (2021-2026)
- 6.4 China
- 6.5 Japan
- 6.6 South Korea
- 6.7 Southeast Asia
- 6.8 India
- 6.9 Australia

7 EUROPE

- 7.1 Europe IVD ELISA Reagents Market Size by Country (2021-2026)
- 7.2 Europe IVD ELISA Reagents Market Size by Type (2021-2026)
- 7.3 Europe IVD ELISA Reagents Market Size by Application (2021-2026)
- 7.4 Germany
- 7.5 France
- 7.6 UK
- 7.7 Italy
- 7.8 Russia

8 MIDDLE EAST & AFRICA

- 8.1 Middle East & Africa IVD ELISA Reagents by Region (2021-2026)
- 8.2 Middle East & Africa IVD ELISA Reagents Market Size by Type (2021-2026)
- 8.3 Middle East & Africa IVD ELISA Reagents Market Size by Application (2021-2026)
- 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 & Growth Opportunities

9.2 Market Challenges & Risks

9.3 Industry Trends

10 GLOBAL IVD ELISA REAGENTS MARKET FORECAST

10.1 Global IVD ELISA Reagents Forecast by Region (2027-2032)

10.1.1 Global IVD ELISA Reagents Forecast by Region (2027-2032)

10.1.2 Americas IVD ELISA Reagents Forecast

10.1.3 APAC IVD ELISA Reagents Forecast

10.1.4 Europe IVD ELISA Reagents Forecast

10.1.5 Middle East & Africa IVD ELISA Reagents Forecast

10.2 Americas IVD ELISA Reagents Forecast by Country (2027-2032)

10.2.1 United States Market IVD ELISA Reagents Forecast

10.2.2 Canada Market IVD ELISA Reagents Forecast

10.2.3 Mexico Market IVD ELISA Reagents Forecast

10.2.4 Brazil Market IVD ELISA Reagents Forecast

10.3 APAC IVD ELISA Reagents Forecast by Region (2027-2032)

10.3.1 China IVD ELISA Reagents Market Forecast

10.3.2 Japan Market IVD ELISA Reagents Forecast

10.3.3 Korea Market IVD ELISA Reagents Forecast

10.3.4 Southeast Asia Market IVD ELISA Reagents Forecast

10.3.5 India Market IVD ELISA Reagents Forecast

10.3.6 Australia Market IVD ELISA Reagents Forecast

10.4 Europe IVD ELISA Reagents Forecast by Country (2027-2032)

10.4.1 Germany Market IVD ELISA Reagents Forecast

10.4.2 France Market IVD ELISA Reagents Forecast

10.4.3 UK Market IVD ELISA Reagents Forecast

10.4.4 Italy Market IVD ELISA Reagents Forecast

10.4.5 Russia Market IVD ELISA Reagents Forecast

10.5 Middle East & Africa IVD ELISA Reagents Forecast by Region (2027-2032)

10.5.1 Egypt Market IVD ELISA Reagents Forecast

- 10.5.2 South Africa Market IVD ELISA Reagents Forecast
- 10.5.3 Israel Market IVD ELISA Reagents Forecast
- 10.5.4 Turkey Market IVD ELISA Reagents Forecast
- 10.6 Global IVD ELISA Reagents Forecast by Type (2027-2032)
- 10.7 Global IVD ELISA Reagents Forecast by Application (2027-2032)
 - 10.7.1 GCC Countries Market IVD ELISA Reagents Forecast

11 KEY PLAYERS ANALYSIS

11.1 Bio-Rad Laboratories

- 11.1.1 Bio-Rad Laboratories Company Information
- 11.1.2 Bio-Rad Laboratories IVD ELISA Reagents Product Offered
- 11.1.3 Bio-Rad Laboratories IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
- 11.1.4 Bio-Rad Laboratories Main Business Overview
- 11.1.5 Bio-Rad Laboratories Latest Developments

11.2 Revvity

- 11.2.1 Revvity Company Information
- 11.2.2 Revvity IVD ELISA Reagents Product Offered
- 11.2.3 Revvity IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
- 11.2.4 Revvity Main Business Overview
- 11.2.5 Revvity Latest Developments

11.3 Sebia

- 11.3.1 Sebia Company Information
- 11.3.2 Sebia IVD ELISA Reagents Product Offered
- 11.3.3 Sebia IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
- 11.3.4 Sebia Main Business Overview
- 11.3.5 Sebia Latest Developments

11.4 Tecan Group

- 11.4.1 Tecan Group Company Information
- 11.4.2 Tecan Group IVD ELISA Reagents Product Offered
- 11.4.3 Tecan Group IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
- 11.4.4 Tecan Group Main Business Overview
- 11.4.5 Tecan Group Latest Developments

11.5 BioVendor Group

- 11.5.1 BioVendor Group Company Information

- 11.5.2 BioVendor Group IVD ELISA Reagents Product Offered
- 11.5.3 BioVendor Group IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
- 11.5.4 BioVendor Group Main Business Overview
- 11.5.5 BioVendor Group Latest Developments
- 11.6 Trinity Biotech
 - 11.6.1 Trinity Biotech Company Information
 - 11.6.2 Trinity Biotech IVD ELISA Reagents Product Offered
 - 11.6.3 Trinity Biotech IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.6.4 Trinity Biotech Main Business Overview
 - 11.6.5 Trinity Biotech Latest Developments
- 11.7 Dia.Pro Diagnostic Bioprobes
 - 11.7.1 Dia.Pro Diagnostic Bioprobes Company Information
 - 11.7.2 Dia.Pro Diagnostic Bioprobes IVD ELISA Reagents Product Offered
 - 11.7.3 Dia.Pro Diagnostic Bioprobes IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.7.4 Dia.Pro Diagnostic Bioprobes Main Business Overview
 - 11.7.5 Dia.Pro Diagnostic Bioprobes Latest Developments
- 11.8 Vircell
 - 11.8.1 Vircell Company Information
 - 11.8.2 Vircell IVD ELISA Reagents Product Offered
 - 11.8.3 Vircell IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.8.4 Vircell Main Business Overview
 - 11.8.5 Vircell Latest Developments
- 11.9 SERION Diagnostics
 - 11.9.1 SERION Diagnostics Company Information
 - 11.9.2 SERION Diagnostics IVD ELISA Reagents Product Offered
 - 11.9.3 SERION Diagnostics IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.9.4 SERION Diagnostics Main Business Overview
 - 11.9.5 SERION Diagnostics Latest Developments
- 11.10 DRG International
 - 11.10.1 DRG International Company Information
 - 11.10.2 DRG International IVD ELISA Reagents Product Offered
 - 11.10.3 DRG International IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.10.4 DRG International Main Business Overview

- 11.10.5 DRG International Latest Developments
- 11.11 Demeditec Diagnostics
 - 11.11.1 Demeditec Diagnostics Company Information
 - 11.11.2 Demeditec Diagnostics IVD ELISA Reagents Product Offered
 - 11.11.3 Demeditec Diagnostics IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.11.4 Demeditec Diagnostics Main Business Overview
 - 11.11.5 Demeditec Diagnostics Latest Developments
- 11.12 Mediagnost
 - 11.12.1 Mediagnost Company Information
 - 11.12.2 Mediagnost IVD ELISA Reagents Product Offered
 - 11.12.3 Mediagnost IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.12.4 Mediagnost Main Business Overview
 - 11.12.5 Mediagnost Latest Developments
- 11.13 AESKU.GROUP
 - 11.13.1 AESKU.GROUP Company Information
 - 11.13.2 AESKU.GROUP IVD ELISA Reagents Product Offered
 - 11.13.3 AESKU.GROUP IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.13.4 AESKU.GROUP Main Business Overview
 - 11.13.5 AESKU.GROUP Latest Developments
- 11.14 Monobind
 - 11.14.1 Monobind Company Information
 - 11.14.2 Monobind IVD ELISA Reagents Product Offered
 - 11.14.3 Monobind IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.14.4 Monobind Main Business Overview
 - 11.14.5 Monobind Latest Developments
- 11.15 Diagnostics Biochem Canada
 - 11.15.1 Diagnostics Biochem Canada Company Information
 - 11.15.2 Diagnostics Biochem Canada IVD ELISA Reagents Product Offered
 - 11.15.3 Diagnostics Biochem Canada IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)
 - 11.15.4 Diagnostics Biochem Canada Main Business Overview
 - 11.15.5 Diagnostics Biochem Canada Latest Developments
- 11.16 Epitope Diagnostics
 - 11.16.1 Epitope Diagnostics Company Information
 - 11.16.2 Epitope Diagnostics IVD ELISA Reagents Product Offered

11.16.3 Epitope Diagnostics IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.16.4 Epitope Diagnostics Main Business Overview

11.16.5 Epitope Diagnostics Latest Developments

11.17 Beijing Wantai Biological Pharmacy Enterprise

11.17.1 Beijing Wantai Biological Pharmacy Enterprise Company Information

11.17.2 Beijing Wantai Biological Pharmacy Enterprise IVD ELISA Reagents Product Offered

11.17.3 Beijing Wantai Biological Pharmacy Enterprise IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.17.4 Beijing Wantai Biological Pharmacy Enterprise Main Business Overview

11.17.5 Beijing Wantai Biological Pharmacy Enterprise Latest Developments

11.18 Shanghai Kehua Bio-engineering

11.18.1 Shanghai Kehua Bio-engineering Company Information

11.18.2 Shanghai Kehua Bio-engineering IVD ELISA Reagents Product Offered

11.18.3 Shanghai Kehua Bio-engineering IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.18.4 Shanghai Kehua Bio-engineering Main Business Overview

11.18.5 Shanghai Kehua Bio-engineering Latest Developments

11.19 Livzon Pharmaceutical Group

11.19.1 Livzon Pharmaceutical Group Company Information

11.19.2 Livzon Pharmaceutical Group IVD ELISA Reagents Product Offered

11.19.3 Livzon Pharmaceutical Group IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.19.4 Livzon Pharmaceutical Group Main Business Overview

11.19.5 Livzon Pharmaceutical Group Latest Developments

11.20 Daan Gene

11.20.1 Daan Gene Company Information

11.20.2 Daan Gene IVD ELISA Reagents Product Offered

11.20.3 Daan Gene IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.20.4 Daan Gene Main Business Overview

11.20.5 Daan Gene Latest Developments

11.21 InTec PRODUCTS

11.21.1 InTec PRODUCTS Company Information

11.21.2 InTec PRODUCTS IVD ELISA Reagents Product Offered

11.21.3 InTec PRODUCTS IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.21.4 InTec PRODUCTS Main Business Overview

11.21.5 InTec PRODUCTS Latest Developments

11.22 J. Mitra & Co.

11.22.1 J. Mitra & Co. Company Information

11.22.2 J. Mitra & Co. IVD ELISA Reagents Product Offered

11.22.3 J. Mitra & Co. IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.22.4 J. Mitra & Co. Main Business Overview

11.22.5 J. Mitra & Co. Latest Developments

11.23 Meril Life Sciences

11.23.1 Meril Life Sciences Company Information

11.23.2 Meril Life Sciences IVD ELISA Reagents Product Offered

11.23.3 Meril Life Sciences IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.23.4 Meril Life Sciences Main Business Overview

11.23.5 Meril Life Sciences Latest Developments

11.24 Tulip Diagnostics

11.24.1 Tulip Diagnostics Company Information

11.24.2 Tulip Diagnostics IVD ELISA Reagents Product Offered

11.24.3 Tulip Diagnostics IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.24.4 Tulip Diagnostics Main Business Overview

11.24.5 Tulip Diagnostics Latest Developments

11.25 Medical & Biological Laboratories

11.25.1 Medical & Biological Laboratories Company Information

11.25.2 Medical & Biological Laboratories IVD ELISA Reagents Product Offered

11.25.3 Medical & Biological Laboratories IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.25.4 Medical & Biological Laboratories Main Business Overview

11.25.5 Medical & Biological Laboratories Latest Developments

11.26 GenBody

11.26.1 GenBody Company Information

11.26.2 GenBody IVD ELISA Reagents Product Offered

11.26.3 GenBody IVD ELISA Reagents Revenue, Gross Margin and Market Share (2021-2026)

11.26.4 GenBody Main Business Overview

11.26.5 GenBody Latest Developments

12 RESEARCH FINDINGS AND CONCLUSION

List Of Tables

LIST OF TABLES

Table 1. IVD ELISA Reagents Market Size CAGR by Region (2021 VS 2025 VS 2032) & (\$ millions)

Table 2. IVD ELISA Reagents Annual Sales CAGR by Country/Region (2021, 2025 & 2032) & (\$ millions)

Table 3. Major Players of Antigen Detection

Table 4. Major Players of Antibody Detection

Table 5. Major Players of Hormone Detection

Table 6. Major Players of Other

Table 7. IVD ELISA Reagents Market Size CAGR by Type (2021 VS 2025 VS 2032) & (\$ millions)

Table 8. Global IVD ELISA Reagents Market Size by Type (2021-2026) & (\$ millions)

Table 9. Global IVD ELISA Reagents Market Size Market Share by Type (2021-2026)

Table 10. Major Players of Qualitative Assays

Table 11. Major Players of Semi-quantitative Assays

Table 12. Major Players of Quantitative Assays

Table 13. IVD ELISA Reagents Market Size CAGR by Assay Output (2021 VS 2025 VS 2032) & (\$ millions)

Table 14. Global IVD ELISA Reagents Market Size by Assay Output (2021-2026) & (\$ millions)

Table 15. Global IVD ELISA Reagents Market Size Market Share by Assay Output (2021-2026)

Table 16. Major Players of Sandwich ELISA

Table 17. Major Players of Indirect ELISA

Table 18. Major Players of Other

Table 19. IVD ELISA Reagents Market Size CAGR by Assay Format (2021 VS 2025 VS 2032) & (\$ millions)

Table 20. Global IVD ELISA Reagents Market Size by Assay Format (2021-2026) & (\$ millions)

Table 21. Global IVD ELISA Reagents Market Size Market Share by Assay Format (2021-2026)

Table 22. IVD ELISA Reagents Market Size CAGR by Application (2021 VS 2025 VS 2032) & (\$ millions)

Table 23. Global IVD ELISA Reagents Market Size by Application (2021-2026) & (\$ millions)

Table 24. Global IVD ELISA Reagents Market Size Market Share by Application

(2021-2026)

Table 25. Global IVD ELISA Reagents Revenue by Player (2021-2026) & (\$ millions)

Table 26. Global IVD ELISA Reagents Revenue Market Share by Player (2021-2026)

Table 27. IVD ELISA Reagents Key Players Head office and Products Offered

Table 28. IVD ELISA Reagents Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

Table 29. New Products and Potential Entrants

Table 30. Mergers & Acquisitions, Expansion

Table 31. Global IVD ELISA Reagents Market Size by Region (2021-2026) & (\$ millions)

Table 32. Global IVD ELISA Reagents Market Size Market Share by Region (2021-2026)

Table 33. Global IVD ELISA Reagents Revenue by Country/Region (2021-2026) & (\$ millions)

Table 34. Global IVD ELISA Reagents Revenue Market Share by Country/Region (2021-2026)

Table 35. Americas IVD ELISA Reagents Market Size by Country (2021-2026) & (\$ millions)

Table 36. Americas IVD ELISA Reagents Market Size Market Share by Country (2021-2026)

Table 37. Americas IVD ELISA Reagents Market Size by Type (2021-2026) & (\$ millions)

Table 38. Americas IVD ELISA Reagents Market Size Market Share by Type (2021-2026)

Table 39. Americas IVD ELISA Reagents Market Size by Application (2021-2026) & (\$ millions)

Table 40. Americas IVD ELISA Reagents Market Size Market Share by Application (2021-2026)

Table 41. APAC IVD ELISA Reagents Market Size by Region (2021-2026) & (\$ millions)

Table 42. APAC IVD ELISA Reagents Market Size Market Share by Region (2021-2026)

Table 43. APAC IVD ELISA Reagents Market Size by Type (2021-2026) & (\$ millions)

Table 44. APAC IVD ELISA Reagents Market Size by Application (2021-2026) & (\$ millions)

Table 45. Europe IVD ELISA Reagents Market Size by Country (2021-2026) & (\$ millions)

Table 46. Europe IVD ELISA Reagents Market Size Market Share by Country (2021-2026)

Table 47. Europe IVD ELISA Reagents Market Size by Type (2021-2026) & (\$ millions)

Table 48. Europe IVD ELISA Reagents Market Size by Application (2021-2026) & (\$ millions)

Table 49. Middle East & Africa IVD ELISA Reagents Market Size by Region (2021-2026) & (\$ millions)

Table 50. Middle East & Africa IVD ELISA Reagents Market Size by Type (2021-2026) & (\$ millions)

Table 51. Middle East & Africa IVD ELISA Reagents Market Size by Application (2021-2026) & (\$ millions)

Table 52. Key Market Drivers & Growth Opportunities of IVD ELISA Reagents

Table 53. Key Market Challenges & Risks of IVD ELISA Reagents

Table 54. Key Industry Trends of IVD ELISA Reagents

Table 55. Global IVD ELISA Reagents Market Size Forecast by Region (2027-2032) & (\$ millions)

Table 56. Global IVD ELISA Reagents Market Size Market Share Forecast by Region (2027-2032)

Table 57. Global IVD ELISA Reagents Market Size Forecast by Type (2027-2032) & (\$ millions)

Table 58. Global IVD ELISA Reagents Market Size Forecast by Application (2027-2032) & (\$ millions)

Table 59. Bio-Rad Laboratories Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 60. Bio-Rad Laboratories IVD ELISA Reagents Product Offered

Table 61. Bio-Rad Laboratories IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 62. Bio-Rad Laboratories Main Business

Table 63. Bio-Rad Laboratories Latest Developments

Table 64. Revvity Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 65. Revvity IVD ELISA Reagents Product Offered

Table 66. Revvity IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 67. Revvity Main Business

Table 68. Revvity Latest Developments

Table 69. Sebia Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 70. Sebia IVD ELISA Reagents Product Offered

Table 71. Sebia IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 72. Sebia Main Business

Table 73. Sebia Latest Developments

Table 74. Tecan Group Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 75. Tecan Group IVD ELISA Reagents Product Offered

Table 76. Tecan Group IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 77. Tecan Group Main Business

Table 78. Tecan Group Latest Developments

Table 79. BioVendor Group Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 80. BioVendor Group IVD ELISA Reagents Product Offered

Table 81. BioVendor Group IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 82. BioVendor Group Main Business

Table 83. BioVendor Group Latest Developments

Table 84. Trinity Biotech Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 85. Trinity Biotech IVD ELISA Reagents Product Offered

Table 86. Trinity Biotech IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 87. Trinity Biotech Main Business

Table 88. Trinity Biotech Latest Developments

Table 89. Dia.Pro Diagnostic Bioprobes Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 90. Dia.Pro Diagnostic Bioprobes IVD ELISA Reagents Product Offered

Table 91. Dia.Pro Diagnostic Bioprobes IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 92. Dia.Pro Diagnostic Bioprobes Main Business

Table 93. Dia.Pro Diagnostic Bioprobes Latest Developments

Table 94. Vircell Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 95. Vircell IVD ELISA Reagents Product Offered

Table 96. Vircell IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 97. Vircell Main Business

Table 98. Vircell Latest Developments

Table 99. SERION Diagnostics Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 100. SERION Diagnostics IVD ELISA Reagents Product Offered

Table 101. SERION Diagnostics IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 102. SERION Diagnostics Main Business

Table 103. SERION Diagnostics Latest Developments

Table 104. DRG International Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 105. DRG International IVD ELISA Reagents Product Offered

Table 106. DRG International IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 107. DRG International Main Business

Table 108. DRG International Latest Developments

Table 109. Demeditec Diagnostics Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 110. Demeditec Diagnostics IVD ELISA Reagents Product Offered

Table 111. Demeditec Diagnostics IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 112. Demeditec Diagnostics Main Business

Table 113. Demeditec Diagnostics Latest Developments

Table 114. Mediagnost Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 115. Mediagnost IVD ELISA Reagents Product Offered

Table 116. Mediagnost IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 117. Mediagnost Main Business

Table 118. Mediagnost Latest Developments

Table 119. AESKU.GROUP Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 120. AESKU.GROUP IVD ELISA Reagents Product Offered

Table 121. AESKU.GROUP IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 122. AESKU.GROUP Main Business

Table 123. AESKU.GROUP Latest Developments

Table 124. Monobind Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 125. Monobind IVD ELISA Reagents Product Offered

Table 126. Monobind IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 127. Monobind Main Business

Table 128. Monobind Latest Developments

Table 129. Diagnostics Biochem Canada Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 130. Diagnostics Biochem Canada IVD ELISA Reagents Product Offered

Table 131. Diagnostics Biochem Canada IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 132. Diagnostics Biochem Canada Main Business

Table 133. Diagnostics Biochem Canada Latest Developments

Table 134. Epitope Diagnostics Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 135. Epitope Diagnostics IVD ELISA Reagents Product Offered

Table 136. Epitope Diagnostics IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 137. Epitope Diagnostics Main Business

Table 138. Epitope Diagnostics Latest Developments

Table 139. Beijing Wantai Biological Pharmacy Enterprise Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 140. Beijing Wantai Biological Pharmacy Enterprise IVD ELISA Reagents Product Offered

Table 141. Beijing Wantai Biological Pharmacy Enterprise IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 142. Beijing Wantai Biological Pharmacy Enterprise Main Business

Table 143. Beijing Wantai Biological Pharmacy Enterprise Latest Developments

Table 144. Shanghai Kehua Bio-engineering Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 145. Shanghai Kehua Bio-engineering IVD ELISA Reagents Product Offered

Table 146. Shanghai Kehua Bio-engineering IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 147. Shanghai Kehua Bio-engineering Main Business

Table 148. Shanghai Kehua Bio-engineering Latest Developments

Table 149. Livzon Pharmaceutical Group Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 150. Livzon Pharmaceutical Group IVD ELISA Reagents Product Offered

Table 151. Livzon Pharmaceutical Group IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 152. Livzon Pharmaceutical Group Main Business

Table 153. Livzon Pharmaceutical Group Latest Developments

Table 154. Daan Gene Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 155. Daan Gene IVD ELISA Reagents Product Offered

Table 156. Daan Gene IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 157. Daan Gene Main Business

Table 158. Daan Gene Latest Developments

Table 159. InTec PRODUCTS Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 160. InTec PRODUCTS IVD ELISA Reagents Product Offered

Table 161. InTec PRODUCTS IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 162. InTec PRODUCTS Main Business

Table 163. InTec PRODUCTS Latest Developments

Table 164. J. Mitra & Co. Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 165. J. Mitra & Co. IVD ELISA Reagents Product Offered

Table 166. J. Mitra & Co. IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 167. J. Mitra & Co. Main Business

Table 168. J. Mitra & Co. Latest Developments

Table 169. Meril Life Sciences Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 170. Meril Life Sciences IVD ELISA Reagents Product Offered

Table 171. Meril Life Sciences IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 172. Meril Life Sciences Main Business

Table 173. Meril Life Sciences Latest Developments

Table 174. Tulip Diagnostics Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 175. Tulip Diagnostics IVD ELISA Reagents Product Offered

Table 176. Tulip Diagnostics IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 177. Tulip Diagnostics Main Business

Table 178. Tulip Diagnostics Latest Developments

Table 179. Medical & Biological Laboratories Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 180. Medical & Biological Laboratories IVD ELISA Reagents Product Offered

Table 181. Medical & Biological Laboratories IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 182. Medical & Biological Laboratories Main Business

Table 183. Medical & Biological Laboratories Latest Developments

Table 184. GenBody Details, Company Type, IVD ELISA Reagents Area Served and Its Competitors

Table 185. GenBody IVD ELISA Reagents Product Offered

Table 186. GenBody IVD ELISA Reagents Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 187. GenBody Main Business

Table 188. GenBody Latest Developments

List Of Figures

LIST OF FIGURES

Figure 1. IVD ELISA Reagents Report Years Considered

Figure 2. Research Objectives

Figure 3. Research Methodology

Figure 4. Research Process and Data Source

Figure 5. Global IVD ELISA Reagents Market Size Growth Rate (2021-2032) (\$ millions)

Figure 6. IVD ELISA Reagents Sales by Geographic Region (2021, 2025 & 2032) & (\$ millions)

Figure 7. IVD ELISA Reagents Sales Market Share by Country/Region (2025)

Figure 8. IVD ELISA Reagents Sales Market Share by Country/Region (2021, 2025 & 2032)

Figure 9. Global IVD ELISA Reagents Market Size Market Share by Type in 2025

Figure 10. Global IVD ELISA Reagents Market Size Market Share by Assay Output in 2025

Figure 11. Global IVD ELISA Reagents Market Size Market Share by Assay Format in 2025

Figure 12. IVD ELISA Reagents in Hospitals and Clinical Laboratories

Figure 13. Global IVD ELISA Reagents Market: Hospitals and Clinical Laboratories (2021-2026) & (\$ millions)

Figure 14. IVD ELISA Reagents in Blood Centers and Plasma Screening Institutions

Figure 15. Global IVD ELISA Reagents Market: Blood Centers and Plasma Screening Institutions (2021-2026) & (\$ millions)

Figure 16. IVD ELISA Reagents in Independent Medical Laboratories

Figure 17. Global IVD ELISA Reagents Market: Independent Medical Laboratories (2021-2026) & (\$ millions)

Figure 18. IVD ELISA Reagents in Other

Figure 19. Global IVD ELISA Reagents Market: Other (2021-2026) & (\$ millions)

Figure 20. Global IVD ELISA Reagents Market Size Market Share by Application in 2025

Figure 21. Global IVD ELISA Reagents Revenue Market Share by Player in 2025

Figure 22. Global IVD ELISA Reagents Market Size Market Share by Region (2021-2026)

Figure 23. Americas IVD ELISA Reagents Market Size 2021-2026 (\$ millions)

Figure 24. APAC IVD ELISA Reagents Market Size 2021-2026 (\$ millions)

Figure 25. Europe IVD ELISA Reagents Market Size 2021-2026 (\$ millions)

Figure 26. Middle East & Africa IVD ELISA Reagents Market Size 2021-2026 (\$ millions)

Figure 27. Americas IVD ELISA Reagents Value Market Share by Country in 2025

Figure 28. United States IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 29. Canada IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 30. Mexico IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 31. Brazil IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 32. APAC IVD ELISA Reagents Market Size Market Share by Region in 2025

Figure 33. APAC IVD ELISA Reagents Market Size Market Share by Type (2021-2026)

Figure 34. APAC IVD ELISA Reagents Market Size Market Share by Application (2021-2026)

Figure 35. China IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 36. Japan IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 37. South Korea IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 38. Southeast Asia IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 39. India IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 40. Australia IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 41. Europe IVD ELISA Reagents Market Size Market Share by Country in 2025

Figure 42. Europe IVD ELISA Reagents Market Size Market Share by Type (2021-2026)

Figure 43. Europe IVD ELISA Reagents Market Size Market Share by Application (2021-2026)

Figure 44. Germany IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 45. France IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 46. UK IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 47. Italy IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 48. Russia IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 49. Middle East & Africa IVD ELISA Reagents Market Size Market Share by Region (2021-2026)

Figure 50. Middle East & Africa IVD ELISA Reagents Market Size Market Share by Type (2021-2026)

Figure 51. Middle East & Africa IVD ELISA Reagents Market Size Market Share by Application (2021-2026)

Figure 52. Egypt IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 53. South Africa IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 54. Israel IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 55. Turkey IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 56. GCC Countries IVD ELISA Reagents Market Size Growth 2021-2026 (\$ millions)

Figure 57. Americas IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 58. APAC IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 59. Europe IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 60. Middle East & Africa IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 61. United States IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 62. Canada IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 63. Mexico IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 64. Brazil IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 65. China IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 66. Japan IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 67. Korea IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 68. Southeast Asia IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 69. India IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 70. Australia IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 71. Germany IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 72. France IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 73. UK IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 74. Italy IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 75. Russia IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 76. Egypt IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 77. South Africa IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 78. Israel IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 79. Turkey IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

Figure 80. Global IVD ELISA Reagents Market Size Market Share Forecast by Type (2027-2032)

Figure 81. Global IVD ELISA Reagents Market Size Market Share Forecast by Application (2027-2032)

Figure 82. GCC Countries IVD ELISA Reagents Market Size 2027-2032 (\$ millions)

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