

IVD and LDT For Autoimmune Diseases Market Size, Share and Growth Outlook 2026: By Type (In Vitro Diagnostics (IVD), Laboratory Developed Tests (LDT)), By Technology, By Application, By End User, Companies to 2034.

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Abstracts

The global IVD and LDT For Autoimmune Diseases Market size is forecast to increase from \$6.18 Billion in 2026 to \$12.74 Billion in 2034 at a CAGR of 9.46% between 2026 and 2034.

The IVD and LDT For Autoimmune Diseases market report provides detailed analysis and outlook of IVD and LDT For Autoimmune Diseases segments including By Type (In Vitro Diagnostics (IVD), Laboratory Developed Tests (LDT)), By Technology (Immunoassays, Clinical Chemistry, Hematology, Coagulation, Microbiology, Molecular Diagnostics), By Application (Rheumatoid Arthritis, Systemic Lupus Erythematosus (SLE), Psoriasis, Crohn's Disease, Ulcerative Colitis, Type 1 Diabetes, Multiple Sclerosis, Systemic Sclerosis, Addison's Disease, Ankylosing Spondylitis, Alopecia Areata, Antiphospholipid Antibody Syndrome, Narcolepsy, Uveitis), By End User (Hospitals and Clinics, Clinical Laboratories, Academic and Research Institutes) across global and regional markets. Further, analysis and outlook across 21 countries in North America, Europe, Asia Pacific, Middle East, Africa, and South America are provided in the study.

IVD and LDT For Autoimmune Diseases Industry Overview

Advanced Autoantibody Testing and Biomarker Profiling Expand Autoimmune Diagnostics

The IVD and LDT for Autoimmune Diseases industry is evolving rapidly as clinical laboratories adopt high-throughput immunodiagnostic technologies capable of detecting complex autoimmune disorders earlier and with greater precision. Rising demand for accurate autoimmune disease stratification, disease activity monitoring, and personalized treatment selection is accelerating investment in automated immunoassays, biomarker-based diagnostics, and laboratory-developed testing platforms. Clinical laboratories are increasingly integrating multi-analyte technologies, inflammatory biomarker profiling, and companion diagnostic solutions to address the diagnostic challenges associated with heterogeneous autoimmune disorders. The industry is also witnessing growing convergence between autoimmune therapeutics and diagnostics, enabling more comprehensive disease management through integrated testing strategies.

Werfen Strengthens High-Throughput Autoimmune Testing Through Aptiva Expansion

Werfen expanded its autoimmune diagnostics portfolio after receiving FDA 510(k) clearance for Aptiva Antiphospholipid Syndrome Immunoglobulin G and Immunoglobulin M reagents. The assays utilize particle-based multi-analyte technology to enable semi-quantitative detection of clinically relevant autoantibodies associated with both primary and secondary antiphospholipid syndrome. Operating on the fully automated Aptiva platform, the reagents support high-volume laboratory workflows with processing capacity reaching up to 960 tests during an eight-hour shift. The approval expands the Aptiva portfolio to eighteen FDA-cleared autoimmune analytes, reinforcing the industry's movement toward consolidated autoimmune testing platforms that combine automation, scalability, and broad disease coverage within routine laboratory operations.

VolitionRx, MBL, and Roche Advance Biomarker-Driven Autoimmune Disease Monitoring

Biomarker innovation continues to broaden the scope of autoimmune disease diagnostics and disease monitoring. VolitionRx entered a distribution agreement with Medical & Biological Laboratories Co., Ltd. to expand access to the Nu.Q Discover platform across clinical and pharmaceutical research environments. The technology measures neutrophil extracellular trap activation and nucleosome biomarkers in real time, supporting development of IVD and laboratory-developed test applications for difficult-to-diagnose autoimmune and inflammatory conditions. Roche further advanced the integration of diagnostics and autoimmune disease management through expansion of its core laboratory immunodiagnostic and clinical chemistry portfolio. Alongside successful Phase III validation of its therapeutic antibody for primary membranous

nephropathy, Roche introduced automated biomarker tracking capabilities that enable high-throughput monitoring of autoantibody activity and kidney function decline. These developments reflect increasing industry emphasis on combining disease detection, progression monitoring, and therapeutic management within unified diagnostic workflows.

IVD and LDT For Autoimmune Diseases Market Trends, Growth Drivers, Competitive Landscape, and Future Opportunities

The global IVD and LDT For Autoimmune Diseases market is witnessing increasing investments in innovation, product development, digital transformation, artificial intelligence integration, healthcare infrastructure expansion, and strategic partnerships across developed and emerging economies. Key Companies in the industry include- Abbott Laboratories, F. Hoffmann-La Roche Ltd, Siemens Healthineers AG, Danaher Corporation (Beckman Coulter), Thermo Fisher Scientific Inc., bioMérieux, Inc., Bio-Rad Laboratories, Inc., Quest Diagnostics Incorporated, Agilent Technologies, Inc., EUROIMMUN Medizinische Labordiagnostika AG (PerkinElmer). The IVD and LDT For Autoimmune Diseases market is expected to remain one of the most closely watched segments in the global healthcare industry, with companies focusing on niche market segments. As healthcare systems across the US, Europe, Asia-Pacific, Latin America, and Middle East & Africa continue to prioritize efficiency, access, and innovation, the IVD and LDT For Autoimmune Diseases industry outlook remains shaped by rising healthcare expenditure, demographic change, digital transformation, and product innovation.

The report provides detailed market analysis including-

- Growth IVD and LDT For Autoimmune Diseases Market size outlook across 3 scenarios- High growth, reference, and Low growth cases

- Market Trends, Drivers, Potential Opportunities, and Challenges faced by IVD and LDT For Autoimmune Diseases companies

- Porter's Five forces analysis- Bargaining power of buyers and sellers, Threat of Substitutes and new entrants, and Intensity of competitive rivalry

- Detailed SWOT Analysis of global and regional IVD and LDT For Autoimmune Diseases markets

Competitive analysis including business description, product analysis, and financial profiles

Key country specific analysis detailing key factors shaping the short-term and long-term outlook

Recent industry developments and news including mergers, acquisitions, product launches, expansions, and company announcements

IVD and LDT For Autoimmune Diseases Market Competitive Benchmarking and Company Analysis

Leading companies in IVD and LDT For Autoimmune Diseases industry include- Abbott Laboratories, F. Hoffmann-La Roche Ltd, Siemens Healthineers AG, Danaher Corporation (Beckman Coulter), Thermo Fisher Scientific Inc., bioMérieux, Inc., Bio-Rad Laboratories, Inc., Quest Diagnostics Incorporated, Agilent Technologies, Inc., EUROIMMUN Medizinische Labordiagnostika AG (PerkinElmer). The IVD and LDT For Autoimmune Diseases market remains moderately to highly fragmented, with competition expected to intensify as companies accelerate investments in innovation, geographic expansion, strategic partnerships, and portfolio diversification through 2034. In developed markets such as the United States, Germany, France, the United Kingdom, and Canada, competition is increasingly centered on innovation, reimbursement positioning, and value-based healthcare solutions. Meanwhile, emerging markets including China, India, Brazil, and countries across the Middle East and Africa continue to present significant opportunities for expansion due to rising healthcare expenditure, growing patient populations, and increasing access to healthcare services.

What to expect in US IVD and LDT For Autoimmune Diseases Markets in 2026 and beyond- Market Size, Share, Growth Rate, and Forecast to 2034

The US healthcare expenditure is forecast to reach \$8.2 Trillion in 2034 from \$5.5 Trillion in 2026 based on the National Health Expenditure Accounts (NHEA) data. With an aging population, rising chronic disease burden, and increasing migration toward minimally invasive and outpatient care, the IVD and LDT For Autoimmune Diseases market remains one of the strongest-performing segments in the country.

The US IVD and LDT For Autoimmune Diseases Companies are opting new business models, optimized pricing models, industry partnerships, and AI-enabled back end

transformations to enhance efficiency and cost management. The US IVD and LDT For Autoimmune Diseases market faces successive waves of challenging trends, with strong opportunities across select segments. The CMS plan to implement Medicaid from 2027 is driving states to build eligibility verification systems throughout 2026. Looking ahead to 2034, we anticipate stronger results underpinned by opportunities exist across IVD and LDT For Autoimmune Diseases industry. On the medical device front, over 7,000 device manufacturers continue to gain from increasing demand from demand for implantable devices, surgical instruments, monitoring equipment, and diagnostic systems.

Canada- Proximity to the US and healthcare similarities to EU5 countries fuel sales of Canadian IVD and LDT For Autoimmune Diseases markets

Canada's strong IVD and LDT For Autoimmune Diseases sales performance is underpinned by an aging population and a well-developed healthcare infrastructure. Steady growth in new brand spending in rural and urban locations fuel the long-term prospects of small and medium-sized enterprises across medical, diagnostic, and therapeutic devices. The Canadian IVD and LDT For Autoimmune Diseases market presents significant opportunities for U.S. exporters of medical devices, with the U.S. being Canada's largest trading partner for this sector. Potential advantages including specialized materials, advanced manufacturing techniques, and digital technologies support the launch of new products in the country.

Germany IVD and LDT For Autoimmune Diseases Trends and Perspectives to 2034- Financial sustainability, hospital restructuring, demographic pressures, and digitization of care delivery continue to shape the German healthcare industry.

Germany continues to remain the largest IVD and LDT For Autoimmune Diseases market in Europe, driven by over €600 Billion healthcare expenditure, €12 Billion medical device R&D expenditure, statutory health insurance system covering 90% German population, nationwide rollout of the electronic patient record (ePA), and large-volume of IVD and LDT For Autoimmune Diseases population. In particular, Research and development in Germany fuels the commercialization of cutting-edge technologies. Companies across the Germany IVD and LDT For Autoimmune Diseases industry value chain are focusing on both domestic markets and exports. The country is also driving digital adoption with the Hospital Future Act driving hospitals to upgrade their information systems by 2027. Over the forecast period, aging population, rising healthcare costs, and increasing procedural volumes drive the IVD and LDT For Autoimmune Diseases market outlook.

France Market Size, Growth Rate, and Forecast Analysis to 2034- Universal healthcare system, high public healthcare expenditure, and strong government support IVD and LDT For Autoimmune Diseases sales through 2034

France IVD and LDT For Autoimmune Diseases companies are emphasizing on opportunities for rapid, at-scale innovation to boost profitability over the long-term. The country's National Health Insurance spending target (ONDAM) estimates 3.7% growth in the country's healthcare expenditure. Over the forecast period, expenditure control measures, chronic disease management initiatives, workforce reforms, and efforts to improve system efficiency drive the long-term prospects.

The biggest 2026 policy frame is the PLFSS 2026. The law sets the Maladie branch spending target at €271.4 billion for 2026 and fixes the ONDAM at €117.5 billion for city care, €112.8 billion for health establishments, and €18.3 billion for elderly-care establishments and services. France's market is also being pulled by demographics. INSEE estimates that on 1 January 2026 France had 69.1 million inhabitants, with 22% aged 65 or over. INSEE also reported that 2025 births were 645,000 and deaths were 651,000, producing a negative natural balance of about 6,000 for the first time since the end of the Second World War.

UK IVD and LDT For Autoimmune Diseases Market Size, Share, and Growth Projections to 2034- Rapid growth driven by new and existing brands across the industry value chain

Small high-need consumer segments remain key priority of IVD and LDT For Autoimmune Diseases distributors in the UK industry. Continuous launch of new products coupled with high expenditures support the market outlook. The UK Government financing remains the dominant funding source at 81.3% of total healthcare expenditure, or ?280 billion in 2025. According to the ONS, total healthcare spending grew 7.7% nominally and 3.9% in real terms from 2024 to 2025. Similarly, out-of-pocket spending was ?49 billion (14.1%) and voluntary health insurance was ?9.5 billion (2.8%). The market is driven by rapid digital adoption with NHS England's plan to give more than 500,000 staff access to new AI tools.

China IVD and LDT For Autoimmune Diseases Market Growth Drivers, Revenue Trends, and Forecast- Medical insurance coverage is rapidly expanding over the past few years

China IVD and LDT For Autoimmune Diseases market is undergoing a structural shift from hospital-centric care toward a more integrated system emphasizing primary care, outpatient services, and long-term care. Chinese local players are emerging as a strong pillar of IVD and LDT For Autoimmune Diseases industry, offering opportunities for both competition and partnership. Over the forecast period, new and innovative product launches remain key elements driving market outlook. China's healthcare industry is increasingly centered on expanding healthcare capacity, improving access to advanced treatments, and reducing dependence on imported technologies.

The National Healthcare Security Administration reported that by end-2024, China's basic medical insurance covered 1.32662 billion people and the coverage rate was 95%. Regional disparities in consumer spending trends continue to become more pronounced in the Chinese IVD and LDT For Autoimmune Diseases industry. Over the forecast period, demand will keep shifting toward geriatrics, chronic disease management, rehabilitation, long-term care, and outpatient care, while pricing pressure will remain intense in drugs and consumables because reimbursement.

India IVD and LDT For Autoimmune Diseases Market Landscape: Current Size and Long-Term Growth Outlook - Increased pricing pressures in US market is encouraging domestic vendors to expand across India

Indian IVD and LDT For Autoimmune Diseases market is witnessing the rapid emergence of an ecosystem that brings together diverse companies across the industry value chain. Further, large-scale healthcare public and private investments and a steady growth in chronic conditions is driving sales of pharmaceuticals and medical devices. Further, non-retail channel is experiencing volume decrease and patients are migrating to the retail. Indian medical device firms are also combining precision engineering with lower labor costs to make world-class diagnostics, robotics, and critical care devices.

Brazil IVD and LDT For Autoimmune Diseases market remains price-driven, with products domestically manufactured and accessibility offering potential opportunities

Healthcare expenditure in Brazil exceeds 10% of GDP, with the country among the highest healthcare spenders in Latin America. ANS reported 53.2 million medical-plan beneficiaries in December 2025, while IBGE projects a steady rise in older-age cohorts, with people aged 60+ already representing about 23% of the population. The price sensitive market access is broad through the public system, private coverage adds a sizeable premium layer, and reimbursement, procurement, and hospital efficiency remain key buying drivers.

Middle East and Africa IVD and LDT For Autoimmune Diseases Industry Trends and Perspectives to 2034

According to the World Bank, the Middle East and North Africa population exceeds 500 million, while Sub-Saharan Africa's population exceeds 1.2 billion, making the broader MEA region one of the fastest-growing healthcare demand centers globally. The GCC countries including Saudi Arabia, United Arab Emirates, Qatar, and Kuwait continue to account for a disproportionately large share of regional healthcare spending.

Government-led programs such as Saudi Arabia's Vision 2030 are accelerating investments in hospital infrastructure, private-sector participation, medical technology adoption, and healthcare digitalization. On the other hand, South Africa, Egypt, Nigeria, and Kenya remain key healthcare markets due to their large populations, expanding private healthcare sectors, and growing investments in healthcare delivery systems.

IVD and LDT For Autoimmune Diseases Market Segmentation

By Type

In Vitro Diagnostics (IVD)

Laboratory Developed Tests (LDT)

By Technology

Immunoassays

Clinical Chemistry

Hematology

Coagulation

Microbiology

Molecular Diagnostics

By Application

Rheumatoid Arthritis

Systemic Lupus Erythematosus (SLE)

Psoriasis

Crohn's Disease

Ulcerative Colitis

Type 1 Diabetes

Multiple Sclerosis

Systemic Sclerosis

Addison's Disease

Ankylosing Spondylitis

Alopecia Areata

Antiphospholipid Antibody Syndrome

Narcolepsy

Uveitis

By End User

Hospitals and Clinics

Clinical Laboratories

Academic and Research Institutes

Leading Companies in IVD and LDT For Autoimmune Diseases Industry (2026)

Abbott Laboratories

F. Hoffmann-La Roche Ltd

Siemens Healthineers AG

Danaher Corporation (Beckman Coulter)

Thermo Fisher Scientific Inc.

bioMérieux, Inc.

Bio-Rad Laboratories, Inc.

Quest Diagnostics Incorporated

Agilent Technologies, Inc.

EUROIMMUN Medizinische Labordiagnostika AG (PerkinElmer)

Countries Included

North America- US, Canada, Mexico

Europe- Germany, France, UK, Spain, Italy, Nordics, Others

Asia Pacific- China, India, Japan, South Korea, Australia, Southeast Asia,
Others

Latin America- Brazil, Argentina, Others

Middle East and Africa- Saudi Arabia, UAE, Other Middle East, South Africa,
Other Africa

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Laboratory Developed Tests (LDT)

By Technology

Immunoassays

Clinical Chemistry

Hematology

Coagulation

Microbiology

Molecular Diagnostics

By Application

Rheumatoid Arthritis

Systemic Lupus Erythematosus (SLE)

Psoriasis

Crohn's Disease

Ulcerative Colitis

Type 1 Diabetes

Multiple Sclerosis

Systemic Sclerosis

Addison's Disease

Ankylosing Spondylitis

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F. Hoffmann-La Roche Ltd

Siemens Healthineers AG

Danaher Corporation (Beckman Coulter)

Thermo Fisher Scientific Inc.

bioMérieux, Inc.

Bio-Rad Laboratories, Inc.

Quest Diagnostics Incorporated

Agilent Technologies, Inc.

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I would like to order

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By Type (In Vitro Diagnostics (IVD), Laboratory Developed Tests (LDT)), By Technology,
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