

# **U.S. IVD and LDT for Autoimmune Diseases Market Size Study, By Type (IVD, LDT), By Technology (Immunoassays, Clinical Chemistry, Molecular Diagnostics), By Application (Psoriasis, Crohn's Disease), and Regional Forecasts 2022-2032**

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## **Abstracts**

The U.S. IVD and LDT for Autoimmune Diseases Market is poised to achieve substantial growth in the forecast period, driven by the rising prevalence of autoimmune disorders and advancements in diagnostic technologies. In 2023, the market was valued at USD 2.51 billion and is expected to grow at a robust CAGR of 6.6% through 2032. With over 50 million Americans grappling with autoimmune diseases annually, the demand for innovative diagnostic solutions is rapidly increasing. Laboratory-developed tests (LDTs) and in vitro diagnostics (IVD) are pivotal in meeting this demand, offering enhanced accuracy, speed, and reliability in disease detection.

Recent advancements in the field underscore the market's dynamism. For example, the FDA's updated regulatory framework, finalized in April 2024, classifies all IVDs, including LDTs, as medical devices. This shift in oversight is aimed at ensuring safety, reliability, and efficacy in diagnostic testing, which aligns with the broader trend of prioritizing patient outcomes in healthcare. Additionally, significant technological progress, such as next-generation sequencing (NGS), is revolutionizing the landscape by enabling comprehensive genomic analysis for diseases like rheumatoid arthritis and other autoimmune disorders.

The increasing penetration of LDTs in clinical settings has led to innovative breakthroughs, such as Mayo Clinic's biomarker discoveries in 2022, which have significantly enhanced diagnostic precision. However, challenges persist, including stringent regulatory hurdles and ongoing legal debates, which could potentially restrict

market entry for some LDT solutions.

Regionally, North America is a dominant player, underpinned by cutting-edge research and well-established healthcare infrastructure. Meanwhile, applications such as psoriasis diagnostics continue to hold the largest market share due to heightened awareness and targeted initiatives, while Crohn's disease diagnostics exhibit the fastest growth rate, reflecting the urgent need for effective solutions in managing inflammatory bowel diseases.

Major market players included in this report are:

Abbott Laboratories

Agilent Technologies, Inc.

Adaptive Biotechnologies Corporation

Bio-Rad Laboratories, Inc.

Thermo Fisher Scientific, Inc.

F. Hoffmann-La Roche Ltd.

Quest Diagnostics, Inc.

Siemens Healthcare GmbH

PerkinElmer, Inc.

bioMérieux, Inc.

Beckman Coulter, Inc.

Mayo Foundation for Medical Education and Research

Moleculara Labs

Omega Diagnostics Group PLC

## SQI Diagnostics

The detailed segments and sub-segments of the market are explained below:

### By Type:

IVD

LDT

### By Technology:

Immunoassays

Clinical Chemistry

Hematology

Coagulation

Microbiology

Molecular Diagnostics

Others

### By Application:

Psoriasis

Crohn's Disease

Rheumatoid Arthritis

Systemic Lupus Erythematosus

Multiple Sclerosis

Diabetes Type 1

Uveitis

Antiphospholipid Antibody Syndrome

Ankylosing Spondylitis

Addison's Disease

Alopecia Areata

Systemic Sclerosis

Ulcerative Colitis

Narcolepsy

Others

By Region:

North America

U.S.

Europe

UK

Germany

France

Spain

Italy

Rest of Europe

Asia Pacific

China

India

Japan

Australia

South Korea

Rest of Asia Pacific

Latin America

Brazil

Mexico

Rest of Latin America

Middle East & Africa

Saudi Arabia

South Africa

Rest of Middle East & Africa

Years considered for the study are as follows:

Historical year – 2022

Base year – 2023

Forecast period – 2024 to 2032

Key Takeaways:

Market Estimates & Forecasts for 10 years from 2022 to 2032.

Annualized revenues and regional level analysis for each market segment.

Detailed analysis of geographical landscape with country-level analysis of major regions.

Competitive landscape with information on major players in the market.

Analysis of key business strategies and recommendations on future market approaches.

Analysis of competitive structure of the market.

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