

Global Autoimmune Disease Diagnostics Market - Products, Disease Types and Test Types

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Abstracts

Autoimmune diseases occur when the immune system mistakenly attacks healthy cells, causing inflammation, tissue damage, and organ dysfunction. They can be systemic, affecting multiple organs as in rheumatoid arthritis or lupus, or localized, targeting specific organs such as in type 1 diabetes or celiac disease. Diagnosing these conditions is complex due to overlapping symptoms, requiring a combination of clinical evaluation, patient history, and specialized laboratory testing. Common diagnostic tools include autoantibody detection assays like ANA and RF tests, organ-specific antibody analysis, inflammatory markers such as C-reactive protein and ESR, and imaging or biopsy studies for confirmation. Early and accurate diagnosis is essential for effective disease management and improved patient outcomes. Advances in genomics, proteomics, bioinformatics, and artificial intelligence are transforming the field, enabling more precise, personalized, and predictive diagnostic solutions that enhance clinical decision-making.

The global autoimmune disease diagnostics market is estimated at USD 6.2 billion in 2025 and projected to reach USD 10.2 billion by 2032, registering a CAGR of 7.4% during 2025 to 2032. Growth is driven by the rising prevalence of over 100 autoimmune disorders, including lupus, multiple sclerosis, and rheumatoid arthritis, alongside lifestyle and environmental factors that elevate risk. Growing awareness, government initiatives, and supportive reimbursement policies in developed economies are encouraging early testing. Rapid progress in immunoassays, biomarker research, molecular diagnostics, and next-generation sequencing has improved diagnostic speed and accuracy, while AI-enabled analytics enhance data interpretation. The expansion of point-of-care and at-home testing, supported by microfluidics-based platforms, is improving accessibility across regions. Strengthened healthcare infrastructure in Asia-Pacific, rising global health expenditure, and strategic collaborations between pharmaceutical and diagnostic

firms are accelerating innovation. With aging populations, preventive healthcare trends, and the shift toward precision medicine, autoimmune disease diagnostics are becoming central to next-generation healthcare delivery.

Autoimmune Disease Diagnostics Regional Market Analysis

North America accounts for the largest share of the global autoimmune disease diagnostics market, estimated at 41% in 2025, supported by a high disease burden, advanced healthcare systems, favorable reimbursement policies, and strong presence of leading diagnostic companies. The United States anchors this leadership with extensive adoption of ELISA, chemiluminescence, and AI-based diagnostic platforms, complemented by robust R&D investments and broad insurance coverage. In contrast, Asia-Pacific is set to expand the fastest, recording a CAGR of 8.7% from 2025 to 2032, driven by rising prevalence of autoimmune conditions, improved healthcare access, and government-supported screening initiatives. China leads the region with its vast patient base and large-scale diagnostic programs, while India emerges as the fastest-growing market owing to expanding infrastructure, affordable test kits, and greater disease awareness. Japan continues to play a pivotal role in precision diagnostics, particularly for thyroid and celiac disorders, supported by national health programs and its aging population. The region's growth is reinforced by domestic manufacturing incentives, international partnerships, and increasing investments in healthcare innovation.

Autoimmune Disease Diagnostics Market Analysis by Product

Reagents & consumables represent the largest product category in the autoimmune disease diagnostics market, holding 68% of the share in 2025, owing to their recurring demand in high-volume laboratory testing and the increasing use of advanced assay kits for rapid, reliable results. Their continuous consumption in ELISA, immunofluorescence, and multiplex immunoassays, requiring specialized reagents, antibodies, and buffers, sustains this dominance. Expanding diagnostic networks, from hospitals to independent labs, further amplifies demand, while innovations in biomarkers and assay design drive the need for customized, high-precision reagents. Meanwhile, instruments, though smaller in share, are expected to post the fastest growth exceeding 8% CAGR during 2025-2032, driven by technological progress in lab automation, multiplex platforms, and AI-integrated systems enabling high-throughput, accurate, and rapid testing. The growing focus on early detection and automation supports steady instrument adoption, despite higher initial costs and longer replacement cycles.

Autoimmune Disease Diagnostics Market Analysis by Disease Type

Systemic autoimmune diseases lead the market in 2025 with a 63% share and are projected to grow at the fastest CAGR of 7.6% through 2032. Their dominance is attributed to the complexity of multi-organ conditions like rheumatoid arthritis, lupus, and multiple sclerosis that require comprehensive antibody panels and frequent monitoring. Rheumatoid arthritis holds the largest portion within this group at 36.7% in 2025, reflecting its widespread prevalence and the need for early biomarker-based detection through RF and anti-CCP assays. Multiple sclerosis, on the other hand, is emerging as the fastest-growing condition with a 8.3% CAGR, fueled by expanding biomarker research and the emphasis on early intervention to manage progression.

Autoimmune Disease Diagnostics Market Analysis by Test Type

Among test types, Antinuclear Antibody (ANA) tests hold the leading share of 31% in 2025, reflecting their central role in early detection and ongoing monitoring of autoimmune conditions. Their extensive use in hospitals and diagnostic laboratories is reinforced by continuous improvements in ELISA, indirect immunofluorescence, and multiplex assay technologies that enhance accuracy and throughput. Growing disease awareness, expansion of diagnostic facilities, and rising healthcare investment further sustain this segment's strong position. Meanwhile, Autoantibodies & Immunologic Tests are set to record the fastest growth, at 7.8% CAGR between 2025 and 2032, driven by their precision in detecting early-stage autoantibodies, the adoption of multiplexed and AI-assisted platforms, and increasing use in personalized medicine. The need for accurate, rapid, and cost-effective diagnostic solutions continues to fuel robust growth across both ANA and autoantibody testing segments worldwide.

Autoimmune Disease Diagnostics Market Report Scope

This global report on Autoimmune Disease Diagnostics analyzes the market based on product, disease type, and test type. In addition to providing profiles of major companies operating in this space, the latest corporate and industrial developments have been covered to offer a clear panorama of how and where the market is progressing.

Key Metrics

Historical Period: 2022-2024

Base Year: 2025

Forecast Period: 2025-2032

Units: Value market in US\$

Companies Mentioned: 15

Autoimmune Disease Diagnostics Market by Geographic Region

North America (The United States, Canada, and Mexico)

Europe (Germany, France, the United Kingdom, Italy, Spain, and Rest of Europe)

Asia-Pacific (Japan, China, India, South Korea, and Rest of Asia-Pacific)

South America (Brazil, Argentina, and Rest of South America)

Rest of World

Autoimmune Disease Diagnostics Market by Product

Reagents & Consumables

Instruments

Autoimmune Disease Diagnostics Market by Disease Type

Systemic Autoimmune Diseases

Rheumatoid Arthritis (RA)

Multiple Sclerosis (MS)

Systemic Lupus Erythematosus (SLE)

Psoriasis

Other Systemic Autoimmune Diseases (Including Scleroderma, Sjogren's Syndrome, Dermatomyositis, Mixed Connective Tissue Disease, Behcet's Syndrome, Sarcoidosis, Myasthenia Gravis, and others)

Localized Autoimmune Diseases

Type 1 Diabetes

Inflammatory Bowel Disease (IBD)

Thyroid Disorders

Other Localized Autoimmune Diseases (Including Idiopathic Thrombocytopenic Purpura (ITP), Celiac Disease, Addison's Disease, Guillain-Barre Syndrome, Autoimmune Hepatitis, Primary Biliary Cirrhosis, and others)

Autoimmune Disease Diagnostics Market by Test Type

Antinuclear Antibody (ANA) Tests

Autoantibodies and Immunologic Tests

Complete Blood Count (CBC)?

C-reactive Protein (CRP) Test

Urinalysis

Other Tests (Including Molecular Diagnostics, Inflammatory Markers, Point-of-care tests, Imaging diagnostics, and Emerging Tests)

Contents

PART A: GLOBAL MARKET PERSPECTIVE

1. INTRODUCTION

Product Outline

Autoimmune Diseases

Types of Autoimmune Diseases

Systemic Autoimmune Diseases

Rheumatoid Arthritis (RA)

Multiple Sclerosis (MS)

Systemic Lupus Erythematosus (SLE)

Psoriasis

Scleroderma

Sjogren's Syndrome

Dermatomyositis

Mixed Connective Tissue Disease (MCTD)

Behcet's Syndrome

Sarcoidosis

Myasthenia Gravis

Organ-specific/Localized Autoimmune Diseases

Type 1 Diabetes

Celiac Disease

Graves Disease

Hashimoto Thyroiditis

Addison Disease

Inflammatory Bowel Disease (IBD)

Idiopathic Thrombocytopenic Purpura (ITP)

Guillain-Barre Syndrome

Autoimmune Hepatitis

Primary Biliary Cirrhosis

Autoimmune Disease Diagnostics

Antinuclear Antibody (ANA) Tests

Enzyme-linked immunosorbent assay (ELISA)

Complete Blood Count (CBC)

Inflammatory Markers

C - reactive Protein (CRP) Test

Rheumatoid Factor

Erythrocyte Sedimentation Rate (ESR)
Urinalysis
Imaging Diagnostics
Emerging Tests
Point-of-care (POC) ANA testing
Flow Cytometry-Based Assays

2. KEY MARKET TRENDS

Artificial Intelligence(AI) Revolutionizing Autoimmune Disease Diagnostics
Rising Global Burden of Multiple Sclerosis Accelerates Demand for Advanced Autoimmune Diagnostics
Next-Generation Biosensors Accelerate Precision in Autoimmune Testing
Immunology and Antigen-Specific Therapies are Reshaping The Autoimmune Disease Diagnostics Landscape
Precision Medicine and Multi-Target Therapies Drive Growth in Autoimmune Diagnostics

3. KEY MARKET PLAYERS

Abbott Laboratories
AESKU.GROUP GmbH
Beckman Coulter, Inc.
bioMerieux SA
Bio-Rad Laboratories, Inc.
EUROIMMUN
F. Hoffmann-La Roche Ltd
Grifols, S.A.
Hemagen Diagnostics, Inc.
Labcorp Holdings Inc.
Quest Diagnostics Incorporated
Siemens Healthineers AG
Thermo Fisher Scientific, Inc.
Trinity Biotech PLC
Werfen, S.A.

4. KEY BUSINESS AND PRODUCT TRENDS

October 2025

Targeted Genomics Unveils CeliacDx Consumer-Initiated Testing Service
Predicta Biosciences Announces \$23.4M Series A Funding for Scale up of Novel
Diagnostic and Analytics Platform

September 2025

Diasorin Announces Launch of Novel Immunodiagnostic Assay for Grave's Disease
July 2025

Agilus Diagnostics and Sebia Launch Advanced Anti-MCV Antibody Test in India for
Early Detection of Rheumatoid Arthritis

June 2025

Breakthrough Blood Test Detects Coeliac Disease in Gluten-Free Individuals
April 2025

Grifols and IBL Forge Strategic Partnership to Develop Advanced Biomarker Panels
May 2025

EUROIMMUN from Revvity Announces Launch of IDS i20 Analytical Random
Access Platform

Additional developments included in the main report

5. GLOBAL MARKET OVERVIEW

Global Autoimmune Disease Diagnostics Market Overview by Product Type

Autoimmune Disease Diagnostics Product Type Market Overview by Global Region
Reagents & Consumables
Instruments

Global Autoimmune Disease Diagnostics Market Overview by Disease Type

Global Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type
Systemic Autoimmune Diseases Diagnostics Market Overview by Global Region
Global Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type
Localized Autoimmune Diseases Diagnostics Market Overview by Global Region

Global Autoimmune Disease Diagnostics Market Overview by Test Type

Autoimmune Disease Diagnostics Tests Market Overview by Global Region
Antinuclear Antibody (ANA) Tests
Autoantibodies and Immunologic Tests
Complete Blood Count (CBC)
C-reactive Protein (CRP) Test
Urinalysis Tests
Other Diagnostics Tests

PART B: REGIONAL MARKET PERSPECTIVE

REGIONAL MARKET OVERVIEW

6. NORTH AMERICA

Key Market Dynamics Supporting Growth

Market Pattern & Diagnostic Landscape

Strategic Implications for Industry Participants

North American Autoimmune Disease Diagnostics Market Overview by Geographic Region

North American Autoimmune Disease Diagnostics Market Overview by Product Type

North American Autoimmune Disease Diagnostics Market Overview by Disease Type

North American Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

North American Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

North American Autoimmune Disease Diagnostics Market Overview by Test Type

Country-wise Analysis of North American Autoimmune Disease Diagnostics Market

THE UNITED STATES

United States Autoimmune Disease Diagnostics Market Overview by Product Type

United States Autoimmune Disease Diagnostics Market Overview by Disease Type

United States Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

United States Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

United States Autoimmune Disease Diagnostics Market Overview by Test Type

CANADA

Canadian Autoimmune Disease Diagnostics Market Overview by Product Type

Canadian Autoimmune Disease Diagnostics Market Overview by Disease Type

Canadian Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Canadian Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Canadian Autoimmune Disease Diagnostics Market Overview by Test Type

MEXICO

Mexican Autoimmune Disease Diagnostics Market Overview by Product Type

Mexican Autoimmune Disease Diagnostics Market Overview by Disease Type

Mexican Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Mexican Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Type

Mexican Autoimmune Disease Diagnostics Market Overview by Test Type

7. EUROPE

Key Market Dynamics Supporting Growth

Market Pattern & Diagnostic Landscape

Strategic Implications for Industry Participants

European Autoimmune Disease Diagnostics Market Overview by Geographic Region

European Autoimmune Disease Diagnostics Market Overview by Product Type

European Autoimmune Disease Diagnostics Market Overview by Disease Type

European Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

European Localized Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

European Autoimmune Disease Diagnostics Market Overview by Test Type

Country-wise Analysis of European Autoimmune Disease Diagnostics Market

GERMANY

German Autoimmune Disease Diagnostics Market Overview by Product Type

German Autoimmune Disease Diagnostics Market Overview by Disease Type

German Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

German Localized Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

German Autoimmune Disease Diagnostics Market Overview by Test Type

FRANCE

French Autoimmune Disease Diagnostics Market Overview by Product Type

French Autoimmune Disease Diagnostics Market Overview by Disease Type

French Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

French Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

French Autoimmune Disease Diagnostics Market Overview by Test Type

THE UNITED KINGDOM

United Kingdom Autoimmune Disease Diagnostics Market Overview by Product

Type

United Kingdom Autoimmune Disease Diagnostics Market Overview by Disease

Type

United Kingdom Systemic Autoimmune Diseases Diagnostics Market Overview by

Sub-Type

United Kingdom Localized Autoimmune Diseases Diagnostics Market Overview by

Sub-Type

United Kingdom Autoimmune Disease Diagnostics Market Overview by Test Type
ITALY

Italian Autoimmune Disease Diagnostics Market Overview by Product Type

Italian Autoimmune Disease Diagnostics Market Overview by Disease Type

Italian Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Italian Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Italian Autoimmune Disease Diagnostics Market Overview by Test Type

SPAIN

Spanish Autoimmune Disease Diagnostics Market Overview by Product Type

Spanish Autoimmune Disease Diagnostics Market Overview by Disease Type

Spanish Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

Spanish Localized Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

Spanish Autoimmune Disease Diagnostics Market Overview by Test Type

REST OF EUROPE

Rest of Europe Autoimmune Disease Diagnostics Market Overview by Product Type

Rest of Europe Autoimmune Disease Diagnostics Market Overview by Disease

Type

Rest of Europe Systemic Autoimmune Diseases Diagnostics Market Overview by

Sub-Type

Rest of Europe Localized Autoimmune Diseases Diagnostics Market Overview by

Sub-Type

Rest of Europe Autoimmune Disease Diagnostics Market Overview by Test Type

8. ASIA-PACIFIC

Key Market Dynamics Supporting Growth

Overall Market Growth Pattern

Strategic Implications

Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Geographic

Region

Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Product Type

Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Disease Type

Asia-Pacific Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

Asia-Pacific Localized Autoimmune Diseases Diagnostics Market Overview by Sub-

Type

Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Test Type
Country-wise Analysis of Asia-Pacific Autoimmune Disease Diagnostics Market

JAPAN

Japanese Autoimmune Disease Diagnostics Market Overview by Product Type

Japanese Autoimmune Disease Diagnostics Market Overview by Disease Type

Japanese Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Japanese Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Japanese Autoimmune Disease Diagnostics Market Overview by Test Type

CHINA

Chinese Autoimmune Disease Diagnostics Market Overview by Product Type

Chinese Autoimmune Disease Diagnostics Market Overview by Disease Type

Chinese Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Chinese Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Chinese Autoimmune Disease Diagnostics Market Overview by Test Type

INDIA

Indian Autoimmune Disease Diagnostics Market Overview by Product Type

Indian Autoimmune Disease Diagnostics Market Overview by Disease Type

Indian Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Indian Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Indian Autoimmune Disease Diagnostics Market Overview by Test Type

SOUTH KOREA

South Korean Autoimmune Disease Diagnostics Market Overview by Product Type

South Korean Autoimmune Disease Diagnostics Market Overview by Disease Type

South Korean Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

South Korean Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

South Korean Autoimmune Disease Diagnostics Market Overview by Test Type

REST OF ASIA-PACIFIC

Rest of Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Product Type

Rest of Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Disease Type

Rest of Asia-Pacific Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Rest of Asia-Pacific Localized Autoimmune Diseases Diagnostics Market Overview
by Sub-Type

Rest of Asia-Pacific Autoimmune Disease Diagnostics Market Overview by Test
Type

9. SOUTH AMERICA

Key Market Dynamics Supporting Growth

Market Pattern & Diagnostic Landscape

Strategic Implications for Industry Participants

South American Autoimmune Disease Diagnostics Market Overview by Geographic
Region

South American Autoimmune Disease Diagnostics Market Overview by Product Type

South American Autoimmune Disease Diagnostics Market Overview by Disease Type

South American Systemic Autoimmune Diseases Diagnostics Market Overview by
Sub-Type

South American Localized Autoimmune Diseases Diagnostics Market Overview by
Sub-Type

South American Autoimmune Disease Diagnostics Market Overview by Test Type

Country-wise Analysis of South American Autoimmune Disease Diagnostics Market

BRAZIL

Brazilian Autoimmune Disease Diagnostics Market Overview by Product Type

Brazilian Autoimmune Disease Diagnostics Market Overview by Disease Type

Brazilian Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-
Type

Brazilian Localized Autoimmune Diseases Diagnostics Market Overview by Sub-
Type

Brazilian Autoimmune Disease Diagnostics Market Overview by Test Type

ARGENTINA

Argentine Autoimmune Disease Diagnostics Market Overview by Product Type

Argentine Autoimmune Disease Diagnostics Market Overview by Disease Type

Argentine Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-
Type

Argentine Localized Autoimmune Diseases Diagnostics Market Overview by Sub-
Type

Argentine Autoimmune Disease Diagnostics Market Overview by Test Type

REST OF SOUTH AMERICA

Rest of South America Autoimmune Disease Diagnostics Market Overview by
Product Type

Rest of South America Autoimmune Disease Diagnostics Market Overview by Disease Type

Rest of South America Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Rest of South America Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Rest of South America Autoimmune Disease Diagnostics Market Overview by Test Type

10. REST OF WORLD

Rest of World Autoimmune Disease Diagnostics Market Overview by Product Type

Rest of World Autoimmune Disease Diagnostics Market Overview by Disease Type

Rest of World Systemic Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Rest of World Localized Autoimmune Diseases Diagnostics Market Overview by Sub-Type

Rest of World Autoimmune Disease Diagnostics Market Overview by Test Type

PART C: GUIDE TO THE INDUSTRY

NORTH AMERICA

EUROPE

ASIA-PACIFIC

PART D: ANNEXURE

RESEARCH METHODOLOGY

FEEDBACK

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