

Autoimmunity Diagnostics Market by Product (Consumables, Instruments), Test Type (Routine, Autoantibody, Inflammatory, Urinalysis Tests), Disease (RA, SLE, MS, IBD), End User (Clinical Laboratories, Hospitals & Clinics) - Global Forecast to 2031

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Abstracts

The autoimmune disease diagnosis market is projected to reach USD 8.98 billion by 2031 from USD 5.57 billion in 2025, at a CAGR of 8.3% during the forecast period. This growth is driven by the rising prevalence of autoimmune disorders, increasing awareness of early diagnosis, and technological advancements such as multiplex immunoassays and biomarker-based tests. Additionally, the growing adoption of automated platforms and supportive government initiatives contribute to increased testing volumes and improved diagnostic accuracy.

By disease type, the systemic autoimmune diseases segment accounted for the largest market share in 2024.

Based on disease type, the global autoimmune disease diagnosis market is segmented into systemic autoimmune diseases and organ-specific autoimmune diseases. The systemic autoimmune diseases segment accounted for the largest market share in 2024. The large share of this region is attributed to the widespread prevalence of conditions such as rheumatoid arthritis, systemic lupus erythematosus, and multiple sclerosis. These diseases typically affect multiple organs and systems, necessitating frequent and comprehensive diagnostic evaluations. The complexity of diagnosis, reliance on advanced immunological tests, and the need for continuous disease monitoring drive higher demand for diagnostic solutions in this segment.

By end user, the clinical laboratories segment accounted for the largest market share during the forecast period.

Based on end users, the autoimmune disease diagnosis market is segmented into clinical laboratories, hospitals & clinics, and other end users. Among these, the clinical laboratories segment accounted for the largest market share owing to specialized expertise, advanced diagnostic technologies, and high-throughput capabilities. Equipped with automated platforms such as ELISA, chemiluminescence, and immunofluorescence, these laboratories can perform complex tests with high accuracy and efficiency. Their role as centralized testing hubs allows them to process large sample volumes at reduced per-test costs.

Asia Pacific: The fastest-growing region in the autoimmune disease diagnosis market during the forecast period.

The autoimmune disease diagnosis market is segmented into North America, Europe, the Asia Pacific, Latin America, and the Middle East & Africa. The Asia Pacific market is expected to grow at the highest CAGR during the forecast period. The high growth rate of the region is primarily driven by the rising prevalence of autoimmune diseases, increasing healthcare expenditure, the growing adoption of advanced diagnostic technologies, and heightened awareness about early disease detection across emerging economies. Additionally, improvements in healthcare infrastructure and supportive government initiatives further contribute to market expansion in the Asia Pacific region.

The break-up of the profile of primary participants in the autoimmune disease diagnosis market:

By Company Type: Tier 1 - 40%, Tier 2 - 30%, and Tier 3 – 30%

By Designation: C-level - 27%, D-level - 18%, and Others - 55%

By Region: North America - 51%, Europe - 21%, the Asia Pacific - 18%, Latin America – 6%, and the Middle East & Africa- 4%

The key players in the market are Thermo Fisher Scientific Inc. (US), Siemens Healthineers AG (Germany), Abbott Laboratories (US), Bio-Rad Laboratories, Inc. (US),

Grifols S.A. (Spain), Werfen S.A. (Spain), F. Hoffmann-La Roche Ltd. (Switzerland), Exagen Inc. (US), Trinity Biotech plc (Ireland), Tecan Group Ltd. (Switzerland), Danaher Corporation (US), BIOSYNEX SA (France), QuidelOrtho Corporation (US), Revvity, Inc. (US), bioMérieux SA (France), DiaSorin S.p.A. (Italy), Becton, Dickinson and Company (US), SD Biosensor, INC. (Korea), Cambridge Life Sciences Ltd (UK), A. Menarini Diagnostics s.r.l (Italy), Sebia (France), KRONUS (US), Erba Group (Czech Republic), AESKU.GROUP GmbH (Germany), Medsource Ozone Biomedicals Pvt. Ltd. (India), and Epitope Diagnostics Inc. (US).

Research Coverage:

This research report categorizes the autoimmune disease diagnosis market by product (consumables and instruments), by test type (routine laboratory tests, inflammatory tests, autoantibodies and immunologic tests, urinalysis tests, and other tests), by disease type (systemic autoimmune diseases and organ-specific autoimmune diseases), by end user (clinical laboratories, hospitals & clinics, and other end users), and by region (North America, Europe, the Asia Pacific, Latin America, and the Middle East & Africa). The report's scope covers detailed information regarding the major factors, such as drivers, restraints, opportunities, and challenges influencing the growth of the autoimmune disease diagnosis market. A thorough analysis of the key industry players has provided insights into their business overview, solutions, key strategies, acquisitions, and agreements. New product launches and recent developments associated with the autoimmune disease diagnosis market. This report covers the competitive analysis of upcoming startups in the autoimmune disease diagnosis market ecosystem.

Reasons to buy this report:

The report will help the market leaders/new entrants with information on the closest approximations of the revenue numbers for the overall autoimmune disease diagnosis market and the subsegments. This report will help stakeholders understand the competitive landscape and gain more insights to position their businesses better and plan suitable go-to-market strategies. The report also helps stakeholders understand the market pulse and provides information on key market drivers, restraints, opportunities, and challenges.

The report provides insights on the following pointers:

Analysis of key drivers (High incidence of autoimmune diseases, rising

awareness related to early disease diagnosis, growing number of r&d activities for innovative diagnostic solutions, advancements in diagnostic technologies), restraints (high capital requirements), opportunities (utilization of biosensors for autoimmune disease diagnosis, growth potential of emerging economies, growing number of reagent rental agreements), and challenges (complexities associated with diagnosis of autoimmune diseases, shortage of skilled professionals) influencing the growth of the autoimmune disease diagnosis market.

Product Development/Innovation: Detailed insights on upcoming technologies, research & development activities, and new product launches in the autoimmune disease diagnosis market.

Market Development: Comprehensive information about lucrative markets – the report analyses the autoimmune disease diagnosis market across varied regions.

Market Diversification: Exhaustive information about new products, untapped geographies, recent developments, and investments in the autoimmune disease diagnosis market.

Competitive Assessment: In-depth assessment of market shares, growth strategies, product offerings of leading players like F. Hoffmann-La Roche Ltd. (Switzerland), Abbott Laboratories (US), Revvity, Inc. (US), Thermo Fisher Scientific Inc. (US), and Siemens Healthineers AG (Germany).

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