

Global Fecal Calprotectin Assays Market Growth 2026-2032

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Abstracts

The global Fecal Calprotectin Assays market size is predicted to grow from US\$ 213 million in 2025 to US\$ 385 million in 2032; it is expected to grow at a CAGR of 8.8% from 2026 to 2032.

Fecal Calprotectin Assays are in vitro diagnostic reagents designed to qualitatively, semi-quantitatively or quantitatively detect calprotectin in human stool specimens as a non-invasive biomarker of intestinal inflammation. Commercial products are primarily based on enzyme linked immunosorbent assay, immunoturbidimetric assay, chemiluminescent immunoassay, fluorescence immunoassay and lateral flow immunochromatographic technologies, with quantitative laboratory assays representing an important form of routine clinical testing. Product configurations range from microplate reagent kits and analyzer-specific reagent packs to rapid test cassettes and fluorescence-based point-of-care formats, and commonly incorporate dedicated calibrators, controls and stool extraction systems. Fecal Calprotectin Assays are principally used in the initial evaluation of suspected inflammatory bowel disease, differentiation of inflammatory bowel disease from functional gastrointestinal disorders such as irritable bowel syndrome, and ongoing management of established Crohn's disease and ulcerative colitis, including disease activity assessment, treatment-response monitoring and relapse-risk evaluation. The market therefore combines centralized laboratory immunodiagnostics with increasingly automated and rapid-testing workflows across gastroenterology and clinical laboratory settings.

Key Findings

Quantitative assays represent the principal commercial format across centralized laboratory and automated testing workflows

Europe has the highest concentration of established fecal calprotectin assay manufacturers and specialist diagnostic suppliers

The competitive structure combines multinational IVD groups with specialist gastrointestinal diagnostics companies and regional POCT manufacturers

Market Trends

The Fecal Calprotectin Assays market is shifting from conventional manual ELISA workflows toward faster and more automated testing formats. Immunoturbidimetric assays are increasingly integrated into routine clinical chemistry analyzers, while chemiluminescent and fluorescence immunoassays enable higher-throughput or shorter-turnaround testing. At the same time, lateral flow products are evolving from visually interpreted qualitative tests toward reader-assisted quantitative and semi-quantitative formats. Product development is increasingly focused on broader analytical ranges, improved stool extraction consistency, reduced hands-on time and compatibility with existing laboratory platforms. These changes are gradually positioning fecal calprotectin as a more standardized routine biomarker rather than a specialist test limited to dedicated gastroenterology laboratories.

Market Dynamics

Drivers

Growth is supported by the expanding clinical use of non-invasive intestinal inflammation biomarkers in inflammatory bowel disease pathways. Fecal calprotectin testing can reduce unnecessary invasive diagnostic procedures in selected patients, support differentiation between inflammatory and functional gastrointestinal disorders, and provide repeatable monitoring for established Crohn's disease and ulcerative colitis. Increasing adoption of treat-to-target disease management, greater use of biologic therapies and the need for objective follow-up biomarkers further support recurrent testing demand. Automation on mainstream chemistry and immunoassay platforms is also lowering workflow barriers for general clinical laboratories.

Restraints

Market expansion is constrained by variability in assay-specific reference ranges, cut-off interpretation and pre-analytical stool handling. Different extraction devices, analytical

platforms and calibration systems may generate results that are not fully interchangeable, limiting standardization across institutions. In addition, fecal calprotectin is a marker of intestinal inflammation rather than a disease-specific biomarker, so elevated values may require additional clinical assessment. Price pressure from high-volume laboratory tenders and lower-cost rapid-test manufacturers can also compress reagent ASPs, particularly in mature and emerging markets with increasing supplier competition.

Opportunities

The strongest opportunities lie in wider integration of fecal calprotectin into routine IBD monitoring pathways and expansion beyond specialist gastroenterology centers. Automated immunoturbidimetric and chemiluminescent products can penetrate medium- and high-throughput laboratories that already operate compatible analyzers, while fluorescence and reader-based rapid tests can extend access to outpatient and decentralized settings. Emerging markets also offer room for increased penetration as awareness of IBD rises and laboratories shift from outsourced testing toward local testing. Further opportunities exist in digital patient monitoring, where home sample collection or near-patient testing may be linked with longitudinal disease-management programs.

Challenges

Long-term challenges include achieving stronger harmonization between assay systems, improving consistency of stool extraction and maintaining clinically meaningful cut-offs across different patient populations. Manufacturers also face the need to balance analytical performance with lower testing costs as laboratories consolidate purchasing volumes. Competition is intensifying as established gastrointestinal diagnostics specialists, multinational IVD companies and Asian POCT manufacturers increasingly address the same clinical workflow. Maintaining differentiation therefore depends on platform compatibility, automation, analytical range, turnaround time, clinical evidence and the ability to secure long-term laboratory adoption.

Industry Chain Analysis

The upstream segment of the Fecal Calprotectin Assays industry mainly comprises monoclonal and polyclonal antibody suppliers, recombinant antigen and calibrator producers, immunoassay membranes, latex particles, enzymes, chemiluminescent substrates, fluorescence labels, buffers, plastics and stool extraction components. These materials are converted by IVD manufacturers into ELISA kits,

immunoturbidimetric reagents, analyzer-specific chemiluminescent packs, fluorescence test devices and lateral flow cassettes. Product value is created through antibody performance, assay calibration, analytical validation, manufacturing consistency, regulatory registration and platform integration rather than through raw material cost alone.

The downstream segment consists primarily of hospital laboratories, independent clinical laboratories, gastroenterology centers and selected decentralized testing settings. Automated products generate value through laboratory throughput and reduced manual handling, while rapid formats compete through turnaround time and accessibility. Reagents are recurring consumables, so installed analyzer access, distributor coverage, clinician familiarity and repeat-testing frequency are important determinants of lifetime customer value. Stool extraction systems and dedicated consumables can strengthen supplier lock-in but remain secondary to the core assay reagent economics.

Segment Insights

By assay principle, the market is structurally divided among enzyme linked immunosorbent assays, immunoturbidimetric assays, chemiluminescent immunoassays, fluorescence immunoassays and lateral flow immunochromatographic assays. ELISA remains an established reference format with broad manufacturer participation, while immunoturbidimetric testing has gained importance because it can be integrated into routine chemistry workflows and processed at higher throughput. Chemiluminescent assays strengthen automation within immunodiagnostic laboratories, whereas fluorescence and lateral flow formats address rapid and decentralized testing needs.

By result format, quantitative assays form the core of clinical disease management because serial numerical values support assessment of inflammatory activity and response to therapy. Semi-quantitative and qualitative products remain relevant in rapid screening and lower-complexity testing environments, particularly where analyzer infrastructure is limited. The market is therefore moving toward higher automation and quantitative output while maintaining a distinct role for simpler rapid-testing formats.

Downstream Market Opportunities

The largest long-term clinical opportunity remains management of established inflammatory bowel disease, where repeated testing can support disease activity

assessment, treatment-response monitoring and relapse-risk evaluation without repeated invasive procedures. Initial evaluation of patients with persistent gastrointestinal symptoms is another important demand source, particularly when clinicians need to distinguish probable inflammatory disease from functional disorders before referring patients for endoscopy. Wider adoption in outpatient gastroenterology, community laboratories and decentralized testing could increase testing frequency while shortening the interval between clinical symptoms and objective inflammatory assessment.

Regional Insights

Europe represents the most developed supplier cluster for Fecal Calprotectin Assays, with a dense concentration of specialist gastrointestinal diagnostics companies in Switzerland, Germany, Italy, Spain, Norway, Belgium, France and other European markets. The region benefits from established IBD management pathways, broad laboratory familiarity with fecal calprotectin and a diverse mix of ELISA, immunoturbidimetric, chemiluminescent and rapid-testing suppliers. North America is characterized by strong participation from multinational IVD groups and established specialist suppliers, with automation and regulatory clearance remaining important competitive factors.

Asia-Pacific is developing through a combination of established Japanese and Korean manufacturers and a growing Chinese POCT and immunodiagnosics manufacturing base. Japan has differentiated automated fecal-testing platforms, while China has expanded rapidly across fluorescence immunoassay, lateral flow, immunoturbidimetric and chemiluminescent formats. India has a smaller but identifiable domestic manufacturing base. Southeast Asia and Taiwan remain more dependent on imported products and regional distribution networks, creating opportunities for both international manufacturers and cost-competitive Asian suppliers.

Competitive Landscape Analysis

The competitive landscape is moderately fragmented and includes both multinational IVD groups and highly specialized gastrointestinal diagnostics manufacturers. B?HLMANN Laboratories is a major specialist participant with ELISA, immunoturbidimetric and rapid quantitative solutions, while DiaSorin, Phadia under Thermo Fisher Scientific, Inova Diagnostics under Werfen, EIKEN CHEMICAL and Revvity-related businesses compete through automated immunodiagnostic or fecal-testing platforms. Specialist manufacturers including R-Biopharm, EUROSPITAL,

Sentinel CH, Calpro, ALPCO, ORGENTEC, BioSystems and Immundiagnostik maintain strong positions in defined assay technologies or regional laboratory channels. Asian manufacturers including Boditech Med, Getein Biotech, Hangzhou AllTest, Xiamen Wiz Biotech, Sichuan Orienter and Agappe Diagnostics broaden competition in fluorescence immunoassay, rapid testing and cost-sensitive markets. Competitive differentiation increasingly depends on assay standardization, analytical range, compatibility with installed analyzers, stool extraction workflow, regulatory coverage and the ability to support recurrent testing programs rather than on reagent price alone.

Report Scope

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

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

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Fecal Calprotectin Assays 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 Fecal Calprotectin Assays.

This report presents a comprehensive overview, market shares, and growth opportunities of Fecal Calprotectin Assays market by product type, application, key manufacturers and key regions and countries.

Market Segmentation

Segmentation by Type:

Enzyme Linked Immunosorbent Assay

Immunoturbidimetric Assay

Chemiluminescent Immunoassay

Fluorescence Immunoassay

Lateral Flow Immunochromatographic Assay

Other

Segmentation by Result Format:

Quantitative

Semi Quantitative

Qualitative

Other

Segmentation by Application:

Initial IBD Evaluation and Differential Diagnosis

Established IBD Disease Management

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 analysing the company's coverage, product portfolio, its market penetration.

B?HLMANN Laboratories AG

DiaSorin S.p.A.

Phadia AB

Inova Diagnostics, Inc.

EIKEN CHEMICAL CO., LTD.

Rewvity, Inc.

R-Biopharm AG

EUROSPITAL S.p.A.

SENTINEL CH. SpA

Calpro AS

ALPCO

ORGENTEC Diagnostika GmbH

BioSystems S.A.

Boditech Med Inc.

Getein Biotech, Inc.

Hangzhou AllTest Biotech Co., Ltd.

Xiamen Wiz Biotech Co., Ltd.

Sichuan Orienter Bioengineering Co., Ltd.

Agappe Diagnostics Ltd.

Immundiagnostik AG

Alfresa Pharma Corporation

DiaSource ImmunoAssays S.A.

Epitope Diagnostics, Inc.

ScheBo Biotech AG

Vitassay Healthcare, S.L.U.

Certest Biotec S.L.

VEDA.LAB

Shijiazhuang Hipro Biotechnology Co., Ltd.

Guangzhou Forreal Biotechnology Co., Ltd.

AccuBioTech Co., Ltd.

Zhejiang Wantaifu Biotechnology Co., Ltd.

Famid Biomedical Technology Tianjin Co., Ltd.

Key Questions Addressed in this Report

What is the 10-year outlook for the global Fecal Calprotectin Assays market?

What factors are driving Fecal Calprotectin Assays market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do Fecal Calprotectin Assays market opportunities vary by end market size?

How does Fecal Calprotectin Assays break out by Type, by Application?

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