In Vitro Diagnostics (IVD) Quality Control Market by Product & Service (QC (Plasma, Serum, Blood), Solutions), Technology (Immunoassay, MDx, Microbiology, Hematology), Manufacturer (Third-party, OEM), End User (Hospitals, Labs) - Global Forecast to 2030

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Report description:

The IVD quality controls market is valued at an estimated USD 1.65 billion in 2025 and is projected to reach USD 2.15 billion by 2030, at a CAGR of 5.5% during the forecast period.

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IVD quality controls play a critical role in ensuring the accuracy, reliability, and consistency of diagnostic test results across clinical laboratories and healthcare facilities. The growing adoption of third-party quality controls is one of the major drivers of the IVD quality controls market. Unlike instrument-specific controls, third-party solutions offer greater flexibility, compatibility across multiple platforms, and longer shelf life. They provide unbiased performance assessment and consistent analyte stability, helping laboratories maintain reproducible and reliable results. With increasing regulatory and accreditation requirements, laboratories are favoring third-party controls to ensure compliance while optimizing workflow efficiency. The rising use of multianalyte controls further enhances demand, allowing simultaneous monitoring of multiple assays and reducing operational costs. Hospitals and clinical laboratories, in particular, are adopting these solutions to support high-volume testing and diverse diagnostic applications. This shift toward third-party quality controls continues to drive innovation, adoption, and sustained growth in the global IVD quality controls market.
"By product & service, the quality control products segment dominated the IVD quality controls market in 2024."
By product & service, the IVD quality controls market is segmented into quality control products, data management solutions, and

quality assurance services. In 2024, quality control products held the largest share, driven by the increasing number of diagnostic tests and the need for accurate, reliable, and reproducible results. Regulatory and accreditation requirements further support their adoption, as laboratories aim to maintain compliance and ensure patient safety. Quality control products enable consistent performance monitoring across multiple assays and platforms, helping reduce errors and improve workflow efficiency. The rising use of third-party and multianalyte controls has further strengthened this segment, allowing simultaneous testing of multiple analytes while optimizing operational costs. Overall, QC products remain the backbone of laboratory quality management, making them the dominant segment within the IVD quality controls market.

"By manufacturer type, the third-party controls segment is projected to achieve the highest growth during the forecast period."

By manufacturer type, the IVD quality controls market is segmented into third-party controls and original equipment manufacturer (OEM) controls. Third-party controls are projected to be the fastest-growing segment during the forecast period. Their compatibility across multiple platforms, longer shelf life, and unbiased performance assessment make them increasingly preferred by laboratories. Third-party controls also support multianalyte testing and standardized QC procedures, helping laboratories improve workflow efficiency and ensure reproducible results. While OEM controls remain important for instrument-specific applications, the growing demand for versatile, cost-effective, and reliable solutions continues to drive the rapid adoption of third-party controls globally.

"The Asia Pacific is projected to be the fastest-growing regional market during the forecast period."

The market for IVD quality controls is categorized into North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa. The Asia Pacific is anticipated to be the fastest-growing region in the IVD quality controls market during the forecast period, driven by the rapid development of healthcare infrastructure and increasing investment in advanced diagnostic technologies. The region is witnessing a growing number of clinical laboratories, hospitals, and diagnostic centers, which is boosting the demand for reliable and accurate quality control products. Rising awareness about the importance of early disease detection, coupled with regulatory initiatives to improve laboratory standards, is further supporting market growth. Additionally, the expanding patient population and the rising prevalence of chronic and infectious diseases are creating strong demand for quality control solutions to ensure accuracy and reproducibility.

Breakdown of the profiles of primary participants in the IVD quality controls market:

- By Company Type: Tier 1 (40%), Tier 2 (30%), and Tier 3 (30%)
- By Designation: C-level Executives (27%), Director-level Executives (18%), and Others (55%)
- By Region: North America (51%), Europe (21%), Asia Pacific (18%), Latin America (6%), and the Middle East & Africa (4%)

The key players in the IVD quality controls market are Bio-Rad Laboratories, Inc. (US), Thermo Fisher Scientific Inc. (US), Abbott (US), LGC Limited (UK), F. Hoffmann-La Roche Ltd. (Switzerland), Randox Laboratories Ltd. (UK), Siemens Healthineers AG (Germany), QuidelOrtho Corporation (US), Danaher Corporation (US), Sysmex Corporation (Japan), Bio-Techne Corporation (US), Microbix Biosystems Inc. (Canada), Microbiologics, Inc. (US), ZeptoMetrix (US), Fortress Diagnostics (UK), Helena Laboratories Corporation (US), Streck, Inc. (US), SERO AS (Norway), Maine Molecular Quality Controls, Inc. (US), Sun Diagnostics, LLC (US), Alpha-Tec (US), Grifols, S.A. (Spain), ConeBioproducts (US), Eurotrol B.V. (Netherlands), and Biorex Diagnostics (UK).

Research Coverage:

This research report categorizes the IVD quality controls market by product & service (quality control products, data management solutions, and quality assurance services), technology (immunoassays, clinical chemistry, molecular diagnostics, microbiology, hematology, coagulation & hemostasis, and other technologies), manufacturer type [third-party controls ([independent controls, instrument-specific controls), original equipment manufacturer controls], end user (hospitals, clinical laboratories, academic & research institutes, and other end users), and region (North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa).

The scope of the report covers detailed information regarding the major factors, such as drivers, restraints, opportunities, and challenges influencing the growth of the IVD quality controls market. A detailed analysis of the key industry players has been done to provide insights into their business overview, solutions, key strategies, acquisitions, and agreements. A competitive analysis of upcoming startups in the IVD quality controls market ecosystem is covered in this report.

Reasons to Buy this Report:

The report will help market leaders/new entrants in this market with information on the closest approximations of the revenue numbers for the overall IVD quality controls market and the subsegments. It will also help stakeholders understand the competitive landscape and gain more insights to better position their businesses and plan suitable go-to-market strategies. The report also helps stakeholders understand the pulse of the market and provides them with information on key market drivers, restraints, opportunities, and challenges.
The report provides insights into the following pointers:
- Analysis of key drivers (increasing number of accredited clinical laboratories, growing adoption of third-party quality controls, rising demand for external quality assessment support, rising geriatric population and subsequent growth in prevalence of chronic and infectious diseases, and increasing adoption of PoC instruments in developed regions), opportunities (rising demand for multianalyte controls and increasing growth opportunities in emerging economies), restraints (additional costs and budget constraints in hospitals and laboratories and unfavorable reimbursement scenario for IVD tests), and challenges (stringent product approval process and lack of regulations for clinical laboratory accreditation in several emerging countries) influencing the growth of the IVD quality controls market.
- Product Development/Innovation: Detailed insights on upcoming technologies, research & development activities, and new product launches in the IVD quality controls market
- Market Development: Comprehensive information about lucrative markets across varied regions
- Market Diversification: Exhaustive information about products, untapped geographies, recent developments, and investments in the IVD quality controls market
- Competitive Assessment: In-depth assessment of market shares, growth strategies, and product offerings of leading players like Bio-Rad Laboratories, Inc. (US), Thermo Fisher Scientific Inc. (US), Abbott (US), LGC Limited (UK), and F. Hoffmann-La Roche Ltd. (Switzerland)

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