IVD Quality Control Market Assessment, By Source [Plasma, Whole Blood, Urine], By Product [Quality Control Products, Data Management Solutions, Quality Assessment Services], By Application [Oncology, Cardiology, Neurology, Infectious Diseases, Autoimmune Disorders, Others], By Technique [Molecular Diagnostics, Coagulation/Hemostasis, Hematology, Microbiology, Immunochemistry/Immunoassay, Clinical Chemistry/Biochemistry, Others], By End-user [Hospitals and Clinics, Diagnostic Laboratories, IVD Manufacturers, CROs, Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global IVD quality control market is projected to witness a CAGR of 4.77% during the forecast period 2024-2031F, growing from USD 1.32 billion in 2023 to USD 1.91 billion in 2031F. Various factors shape the global IVD quality control market, including an increased focus on developing new and innovative products, increased integration of advanced technologies, rise in demand for immunoassay products, increased popularity of data management solutions, and dominance of North America.
Several factors are controlling the global IVD quality control market, including fostering innovations and developing new products. Manufacturers are always trying to create new and better disposable surgical instruments that will increase surgical efficiency, patient safety, and affordability. This requires investigating cutting-edge components, styles, and features to satisfy the changing demands of the medical field. The global IVD quality control market is integrating cutting-edge technology, including artificial

intelligence, data management systems, and automation. These technological developments enhance the precision, effectiveness, and accessibility of quality control procedures in diagnostic testing.

The global IVD quality control market is anticipated to be dominated by the immunoassay/immunochemistry segment. This is because an increasing variety of immunoassay tests are available, which offer quick, easy, and precise findings for target identification and quantification. Since they make data storage, processing, and reporting more efficient, data management systems are becoming increasingly popular in the global IVD quality control industry. These technologies facilitate data integrity, increase overall operational efficiency, and simplify quality control procedures for laboratories.

For example, a global leader in clinical diagnostic products and life science research, Bio-Rad Laboratories, Inc., announced in September 2023 the introduction of its PTC Tempo 48/48 and PTC Tempo 384 Thermal Cyclers, intended to facilitate polymerase chain reaction (PCR) applications in basic and translational research, process development, and quality control. The newest models in Bio-Rad's traditional PCR heat cyclers lineup are the PTC Tempo 48/48 and PTC Tempo 384 Thermal Cyclers. The PTC Tempo Thermal Cyclers are designed with an updated, user-friendly interface and adaptable connectivity options, including the ability to monitor data on the BR.io cloud platform to streamline protocol administration.

Increased Focus on Developing PCR Tests in the Market

The global IVD quality control market is witnessing an increased focus on the development of PCR tests. Applications and methods for polymerase chain reaction have been created, refined, and employed in the last several years for a variety of clinical fields. The creation of quality standards for these new PCR methods has been necessary to comply with both good laboratory practice (GLP) and (inter)national guidelines, as is the case with any "in-house" assay whose results impact clinical decision-making. Quality standards have previously been established for "classical" diagnostic tests like ELISAs and culture-based assays, and there are also established recommendations for both quality assurance and quality control for new PCR-based assays that are constantly being developed and improved.

For example, the GENE-UP BREWPRO Yeast Slurry (YS) is a novel diagnostic quality control PCR test that was introduced in May 2024 by bioMerieux, Inc., a global leader in in vitro diagnostics. Its purpose is to precisely identify impurities in raw yeast materials and yeast propagations to guarantee fermentation of the highest caliber. The solution, which was created in partnership with White Labs, has specialized targets designed specifically for yeast slurries and an optimized sample prep with higher sensitivity. Present-day brewing industry quality control test kits are made to identify possible spoilers in the final product rather than in the yeast slurries themselves.

Increased Integration of Advanced Technologies is Driving the Market

Innovation is essential for improving quality control, and the tremendous transition in the diagnostics industry is bolstering the growth of the global IVD quality control market. The diagnosis procedure is being completely transformed by cutting-edge technology, including automation, machine learning, and artificial intelligence. These developments have the potential to increase the precision, effectiveness, and dependability of quality control procedures, producing test results that are more reliable and consistent. The diagnostics industry's quality control procedures have seen a substantial transformation because of the incorporation of Internet of Things (IoT) technologies. Diagnostic tools with IoT capabilities may continually track several variables, including equipment performance, humidity, and temperature. Proactive quality control procedures are made possible by the quick detection of any deviations from ideal operating conditions made possible by this real-time data collection.

For example, Bio-Rad Laboratories Inc. revealed in August 2023 that they will leverage AWS Systems Manager to build an Internet of Things device that will enhance their Next-Generation Quality Control Informatics Solution. AWS Systems Manager is a comprehensive and secure resource management tool that can be used in hybrid and multi-cloud scenarios. Without requiring any extra IT support, it connects to the instrument, the lab information system, middleware, and other software through an edge device that serves as a bridge between the lab and the cloud.

The Rise in Demand for Immunoassay Products is Boosting Market Growth

Immunoassay products are an important part of the global IVD quality control market. IVD kits and reagent variance are evaluated and tracked using immunoassay-based quality control tools. Any variations in performance can be found and fixed by comparing several IVD products to standardized immunoassay controls. Immunoassay-based quality control products can be used to identify the cause of problems in diagnostic testing. Potential causes of error, such as reagent quality, instrument performance, or operator technique, can be found and fixed by comparing results from control samples to predicted values.

For instance, Siemens Healthineers AG introduced Atellica CI Analyzer, a small testing equipment designed to address lab problems, in July 2023. With its unique features, the Atellica CI Analyzer is carefully built to maximize downtime and boost lab productivity and profitability. Labs can provide more consistent sample turnaround times thanks to automated maintenance and quality control scheduling, micro-volume aspiration, and random-access sampling. The independence of the immunoassay and chemistry engines ensures that throughput is unaffected if one of them needs to stop.

Data Management Solutions are Popular in the Market

Data management solutions offer a centralized platform for storing, organizing, and managing all data about quality control procedures in the IVD industry. In this way, a single source for quality control data is produced, incorporating information from several diagnostic devices, laboratory information systems (LIS), and other locations. Data management systems offer safe data storage, access controls, and audit trails to guarantee the accuracy and traceability of quality control data. Real-time monitoring of quality control parameters, including test results, reagent stability, and equipment performance, can be facilitated by data management solutions. All these factors make data management solutions an important factor driving the growth of the global IVD quality control market.

For instance, with the introduction of new waters_connect for IVD and QUAN Review Application in May 2024, Waters Corporation simplified the clinical data review process. ExceptionFocused Review (xfR) enables users to quickly identify and address errors that require attention. Its key features include reducing data review time by up to 50% (in comparison to Waters TargetLyn Software) and providing a one-screen dashboard that summarizes key parameters like standards, calibration, and quality control, all grouped for a streamlined view.

North America is Dominating the IVD Quality Control Market

The global IVD quality control market is dominated by North American nations, especially the United States, for several important reasons, including the existence of several accredited clinical laboratories. The United States boasts a well-respected healthcare system and many accredited clinical laboratories that follow tight quality control guidelines. The healthcare systems in North America have embraced cutting-edge diagnostic technologies like immunoassays and molecular diagnostics with great speed. The requirement for quality control procedures to guarantee the precision and dependability of test results has increased because of the growing usage of these technologies.

For example, Next Gen Diagnostics announced on June 11, 2024, that it would open its first laboratory in the United States in Cambridge, Massachusetts. The facility will offer United States customers and partners fully integrated, affordable bacterial sequencing and bioinformatics services. This ability is enhanced by NGD's best-in-class fully automated bioinformatics, which offers comprehensive analysis of cohort phylogeny, resistance elements, and phenotype, delivered and visualized in a robust user interface, as well as quality control and relatedness determination validated in several publications.

Future Market Scenario (2024-2031F)

- The global IVD quality control market is expected to see a rise in demand for multi-analyte controls, which contain numerous analytes of interest.
- Point-of-care testing adoption in the global IVD quality control market is motivated by the need for quick, easy-to-use, and trustworthy diagnostic tools that improve patient outcomes and expedite processes.
- It is anticipated that the increased focus on developing environmentally friendly and sustainable products will drive the growth of the global IVD quality control market.
- In the global IVD quality control market, companion diagnostics, which direct the use of particular treatment products, are becoming increasingly popular.

Key Players Landscape and Outlook

Many major companies in the global IVD quality control market are forming alliances to expand in the industry. Major players can build more sophisticated and comprehensive quality control products by collaborating with other businesses to make use of complementary skills, technology, and resources. Through alliances, prominent players can better serve the different needs of the diagnostics industry by broadening the scope of their quality control solutions and diversifying their product portfolios. Investing heavily in R&D and obtaining regulatory licenses is necessary to develop products with quality control.

For example, top AI software provider Bioz, Inc., dedicated to scientific research, announced in January 2024 that it has partnered with top worldwide diagnostics provider Randox Laboratories Ltd. The organization, which is well-known for its creative research

and development, provides a wide range of superior goods and services, such as quality controls, toxicology solutions, modern diagnostic devices, and clinical chemistry reagents. Using this creative partnership, Bioz has integrated Bioz Badges as dynamic, real-time widgets into the product pages of Randox Laboratories' website. These widgets offer real-time scientific application data, including excerpts from peer-reviewed scientific articles that are specifically connected to the use of the product. This collaboration aims to help academics make evidence-based decisions by raising exposure and brand awareness.

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*Companies mentioned above DO NOT hold any order as per market share and can be changed as per information available during research work.

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