

Molecular Quality Controls Market Opportunity, Growth Drivers, Industry Trend Analysis, and Forecast 2025-2034

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Abstracts

The Global Molecular Quality Controls Market was valued at USD 215.2 million in 2024 and is projected to expand at a CAGR of 6.8% from 2025 to 2034. Molecular quality controls serve as essential reference materials in molecular diagnostics, ensuring accuracy, consistency, and reliability in test results. These controls play a critical role in laboratories by helping monitor assay performance, identify potential errors, and comply with stringent regulatory guidelines. The rising demand for precise diagnostic solutions is a major factor fueling market expansion, as healthcare providers increasingly rely on molecular testing for infectious diseases, cancer detection, and genetic analysis. Additionally, the growing incidence of infectious diseases and genetic disorders has amplified the need for continuous advancements in molecular diagnostics.

In 2023, the molecular quality controls market was valued at USD 203.5 million. Based on product type, the market is categorized into independent controls and instrument-specific controls. The independent controls segment held USD 116.7 million in revenue in 2024 and is projected to grow at a CAGR of 6.7% through 2034. Independent controls are manufactured separately from test kits, enabling objective evaluation of molecular assay performance. These controls help laboratories detect batch-to-batch variations, reagent instability, and instrument malfunctions, ensuring reliable and consistent results. They also support external quality assessment programs and proficiency testing, which are crucial for meeting regulatory standards.

By analyte type, the market is segmented into single-analyte and multi-analyte controls. The single-analyte controls segment accounted for 58.4% of the market share in 2024, generating USD 125.7 million in revenue. These controls allow for precise monitoring of specific target analytes, minimizing cross-reactivity risks associated with multi-analyte

controls. Their high stability ensures consistent performance over time, reducing assay variability and supporting quality assurance in molecular testing.

In terms of application, the market is divided into infectious disease diagnostics, oncology testing, genetic testing, and other areas. The infectious disease diagnostics segment held 48.2% of the market in 2024. Molecular diagnostics play a crucial role in early pathogen detection, even before symptoms manifest. Molecular quality controls are essential in ensuring the accuracy of these rapid assays over time by serving as an early detection mechanism for potential reagent degradation or assay failures.

Based on end use, the market is segmented into hospitals, diagnostic laboratories, academic and research institutes, contract research organizations, and other users. The diagnostic laboratories segment accounted for 34.5% of total revenue in 2024. These laboratories handle large volumes of molecular tests for infectious diseases, oncology, and genetic disorders, making them primary adopters of molecular quality controls.

North America accounted for USD 87.1 million in revenue in 2024 and is expected to reach USD 164.7 million by 2034. The US led the region with USD 75.5 million in revenue in 2023. The increasing prevalence of infectious diseases and cancer in the country is a key factor driving demand for molecular quality controls, alongside stringent FDA regulations ensuring the accuracy of molecular diagnostic tests.

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