Molecular Quality Controls - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

Market Report | 2025-07-01 | 110 pages | Mordor Intelligence

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Report description:

Molecular Quality Controls Market Analysis

The Molecular Quality Controls Market size is estimated at USD 225.31 million in 2025, and is expected to reach USD 312.70 million by 2030, at a CAGR of 6.78% during the forecast period (2025-2030). Robust growth rests on three forces: the United States Food and Drug Administration's (FDA) Laboratory Developed Tests (LDT) Final Rule, the global push for ISO 15189:2022 accreditation, and laboratories' rapid shift from single-analyte to multiplex and next-generation sequencing (NGS) testing. Independent, third-party controls remain the default tool for demonstrating analytic accuracy, while instrument-specific controls gain momentum as laboratories integrate automation and middleware. Demand is reinforced by oncology's expanding need for comprehensive genomic profiling, rising external-quality assessment (EQA) mandates, and the clinical move toward point-of-care molecular platforms that must still meet centralized quality standards. Conversely, high per-run control costs, supply bottlenecks for rare pathogen reference materials, and overlapping regulatory pathways temper near-term spending.

Global Molecular Quality Controls Market Trends and Insights

Rising Test-Volume in Molecular Diagnostics

Diagnostic laboratories processed unprecedented volumes during the COVID-19 public-health emergency, with the FDA authorizing 291 molecular assays, demonstrating the scalability of high-throughput platforms. Post-pandemic, volume remains elevated as labs extend molecular testing to pharmacogenomics, antimicrobial resistance surveillance, and hereditary cancer

panels. Each multiplex target adds validation layers, compelling laboratories to rely on robust third-party controls to avoid analytical drift. Digital QC dashboards integrated with laboratory information systems have trimmed manual verification steps by 62.5%, underscoring technology's role in managing rising workloads.

Increasing Adoption of Third-Party QC for ISO 15189 Accreditation

ISO 15189:2022 raises the bar for risk management and for point-of-care integration, pushing laboratories toward externally sourced controls that demonstrate traceability and independence. The first U.S. accreditation under the new version signaled an early inflection toward global compliance momentum. Laboratories have three years to transition, anchoring sustained demand for molecular quality controls market products.

High Per-Run Cost of Molecular QC Materials

The economics of molecular quality controls present significant challenges for laboratories operating under constrained budgets, particularly as test complexity increases. NGS assays cut the overall cost of patient care compared with sequential PCR yet still demand expensive multi-analyte controls that can account for 4-7% of per-sample cost, a margin non-trivial to small laboratories. Fixed control costs scale poorly when test volumes are modest, prompting labs to stretch replacement intervals and potentially compromise analytical robustness.

Other drivers and restraints analyzed in the detailed report include:

Growing Incidence of Cancer and Genetic Disorders / Stricter External-Quality Assessment Mandates / Complex Multi-Agency Regulatory Pathway /

For complete list of drivers and restraints, kindly check the Table Of Contents.

Segment Analysis

Independent controls dominated with a 58.11% molecular quality controls market share in 2024, reflecting laboratories' preference for vendor-neutral verification tools that satisfy ISO 15189 documentation requirements and mitigate platform bias. Bio-Rad's Unity Data Management network, active in 38,000 labs, illustrates how third-party controls aggregate peer comparisons to detect systemic deviations quickly. Independent products span multi-analyte panels for respiratory pathogens to custom oncology variants, allowing labs to standardize across diverse instruments.

Instrument-specific controls, though smaller, are projected to post a 7.55% CAGR through 2030 as automation and integrated sample-to-answer platforms expand. Manufacturer-tuned stability and lot-to-lot consistency save validation time, a decisive advantage in high-throughput environments. Yet vendor-lock fears linger, keeping independent controls the reference option for proficiency schemes. The molecular quality controls market therefore gravitates toward a dual-sourcing model in which labs deploy independent controls for accreditation while relying on instrument-specific materials for daily workflow continuity.

PCR-based products retained 69.52% revenue in 2024, anchored by high-volume infectious disease testing where turnaround time and cost trump breadth. These controls typically contain stabilized viral or bacterial nucleic acids encapsulated in non-infectious particles for biosafety.

NGS-based controls, however, are advancing at a 7.23% CAGR, reflecting oncology's shift toward multi-gene panels and the rising use of comprehensive genomic profiling in hereditary disorders. Sample-preparation QC kits assess library complexity, fragment size, and adapter ligation efficiency before sequencing, reducing costly reruns. The molecular quality controls market size for NGS

panels is poised to expand as reimbursement improves and sequencing costs continue to decline. Isothermal amplification controls occupy niche use cases such as point-of-care STI testing, where rapid qualitative answers suffice.

The Molecular Quality Controls Market Report is Segmented by Product Type (Independent Controls, Instrument-Specific Controls), Technology (PCR-Based, NGS-Based, Isothermal/Other NAAT), Application (Infectious Diseases, Oncology, and More), End-User (Clinical Laboratories, IVD Manufacturers and CROs, and More), and Geography (North America, Europe, and More). The Market Forecasts are Provided in Terms of Value (USD).

Geography Analysis

North America led with 38.14% revenue in 2024, buoyed by strong reimbursement, high test volume, and the FDA's framework that elevates third-party controls from best practice to regulatory necessity. CLIA's stricter performance thresholds compound demand as laboratories widen QC frequency to retain accreditation. Canada's modernization of medical-device regulations supports accelerated pathways for innovative quality controls, sustaining steady regional growth.

Asia-Pacific is the fastest-growing geography with an 8.33% CAGR, propelled by government genomics programs and expanding private diagnostic chains. Japan's reimbursement of NGS oncology panels and South Korea's investment in cell-and-gene therapy manufacturing both translate to higher QC consumption for NGS workflows. China's domestic instrument makers increasingly embed QC lot-tracking software, amplifying local demand. Despite fragmented regulations, the molecular quality controls market benefits from APAC's push to harmonize quality standards with ISO 15189 and IVDR principles, fostering cross-border product adoption.

Europe exhibits consistent mid-single-digit growth as IVDR implementation compels laboratories and manufacturers to upgrade quality documentation. The United Kingdom's National Health Service awards central laboratory contracts that require ISO 15189:2022 compliance, embedding QC use in procurement templates. Middle East & Africa and South America remain nascent but show double-digit incremental gains where new reference laboratories open. In these regions, infectious-disease surveillance projects funded by multilateral agencies often stipulate third-party controls, giving suppliers an early foothold.

List of Companies Covered in this Report:

Abbott Laboratories / Bio-Rad Laboratories / Roche / Thermo Fisher Scientific / LGC Clinical Diagnostics (incl. SeraCare) / ZeptoMetrix / Microbiologics / Randox Laboratories / Quidel-Ortho Corporation / bioMerieux / Qnostics / Siemens Healthineers / Seegene / Meridian Bioscience / Exact Diagnostics / Asuragen (a Bio-Techne brand) / Grifols Diagnostic Solutions /

Additional Benefits:

The market estimate (ME) sheet in Excel format /
3 months of analyst support /

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7 Market Opportunities & Future Outlook
7.1 White-space & Unmet-need Assessment

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