

Medical Device Analytical Testing Outsourcing Market Size, Share & Trends Analysis Report By Services, By Therapeutic Areas, By End Use, By Device Type, By Region, And Segment Forecasts, 2025 - 2030

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Abstracts

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Medical Device Analytical Testing Outsourcing Market Growth & Trends

The global medical device analytical testing outsourcing market size is estimated to reach USD 10.53 billion by 2030, expanding at a CAGR of 8.3% from 2025 to 2030, according to a new report by Grand View Research, Inc. Several medical device companies outsource analytical testing operations to decrease business risks, accelerate product market entrance, and lower expenses. As a result of this considerable rise in spending levels, medical device original equipment manufacturers (OEMs) quickly shift to outsourcing as a cost-cutting technique. The testing requirements of medical device manufacturers (MDMs) reflected variations in the medical/healthcare market as it recovered from the COVID-19 slowdown.

In 2021, the need for European Medical Device Regulation (MDR) remediation standards, as well as the ever-increasing regulatory demands in the leachables & extractables (E&L) arena, accounted for a significant portion of the testing effort. However, due to delays and a lack of external resources and labor, labs' ability to expand capacity has been limited. Regulatory authorities are focusing on testing technique validation, especially data quality, including repeatability and reproducibility. There is also a trend of more deterministic testing methods. This enables companies to acquire more statistically reliable data to determine if their products meet the criteria. For example, the medical device sector and testing labs confront considerable hurdles in

adopting ISO 10993-18:2020 E&L testing regulations while still meeting FDA expectations.

The FDA had requested the use of conservative techniques to reduce areas of ambiguity or potential inaccuracy in E&L testing throughout 2021. Furthermore, intensifying competition in the medical device industry is expected to create growth opportunities for the market. In such an intensely competitive environment, companies must reduce the time to market. Considering that the approval processes for medical devices are not simple, companies need a better understanding of updated regulatory norms and protocols. Not all companies have such expertise; hence, outsourcing these functions to a specialized firm is a better option for medical device companies. Recent studies have shown significant opportunities for both suppliers and buyers in the medical device industry.

For smaller companies, outsourcing manufacturing, and development functions is an effective alternative to cut costs. For larger companies, outsourcing activities enable them to focus on core business activities and drive future growth. Based on end-uses, the hospital segment accounted for the largest revenue share in 2022 due to high patient volume and increased hospital management budget allocation for these surgeries. The reprocessed devices segment is projected to witness the fastest CAGR during the forecast period due to the low prices of these devices. They cost about 30 to 40% less than new devices; thus, the demand for such products is significant in price-sensitive low- and medium-income countries.

Medical Device Analytical Testing Outsourcing Market Report Highlights

Material characterization dominated the market and accounted for a share of 18.1% in 2024. Material characterization is crucial for maintaining quality, mitigating risks, ensuring regulatory compliance, and optimizing cost and time efficiency.

The cardiology segment led the market with a revenue share of 22.2% in 2024 due to the high demand for cardiovascular devices as a result of the increased prevalence of related conditions.

Asia Pacific medical device analytical testing outsourcing market is expected to register the fastest CAGR of 8.9% in the forecast period. This is owing to the region's large population base, low per capita income, and demand for accessible treatment solutions.

North America medical device analytical testing outsourcing market dominated the global market with a revenue share of 39.1% in 2024. This can be attributed to the presence of various multinational players, such as Charles River Laboratories, WuXi AppTec, and SGS SA

Moreover, the increased need for scrutiny pertaining to the quality of devices and reorganizing of classes is a key factor expected to impose additional testing requirements on manufacturers. These requirements can be met by partnering with laboratories that perform tests at an affordable price rather than installing in-house analytical tools

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