

IVD Devices Contract Manufacturing Market Size and Forecast (2021 - 2034), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Service Type (Full-device Manufacturing, Sub-assembly and Components, and Materials-specific Services), Device Type (IVD consumables, IVD equipment), and Geography (North America, Europe, Asia Pacific, Middle East and Africa, and South and Central America)

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Abstracts

According to our new research study on “IVD Devices Contract Manufacturing Market Forecast to 2034 -Global Analysis - by Device Type, Service Type, and Geography,” the market is anticipated to grow from US\$ 23.95 billion in 2025 to US\$ 67.79 billion by 2034, with a CAGR of 12.3% during 2026-2034. The IVD devices contract manufacturing market growth is attributed to the increasing prevalence of chronic diseases, technological advancements and innovation, and cost efficiencies through outsourcing.

Manufacturing In Vitro Diagnostics (IVD) devices through contract (OEM) is when Original Equipment Manufacturers (OEMs) outsource their production to a specialized, third-party company that designs, fabricates, assembles, tests, packages, and ensures regulatory compliance of IVD products, including diagnostic kits, analyzers, reagents, and point-of-care devices. Through this model, OEMs are able to lower their capital expenditures, gain access to advanced technologies, and quickly scale their production, while complying with quality standards (ISO13485 / FDA regulations) and reducing time-to-market by focusing their internal resources on the development and ultimate

innovation for diagnostics. Integration of AI and automation in IVD contract manufacturing, the rise of point-of-care and at-home testing devices, and the expansion of molecular diagnostics and precision medicine manufacturing are expected to be major IVD devices contract manufacturing market trends in the coming years.

The IVD devices contract manufacturing market in North America is segmented into the US, Canada, and Mexico. The North America IVD devices contract manufacturing market is expanding owing to advanced healthcare infrastructure and high healthcare expenditure, fostering collaborations between diagnostic developers and contract manufacturers. The US holds the largest market share, followed by Canada. The demand for IVD devices contract manufacturing in the region is fueled by the advanced technological capabilities, robust regulatory oversight, and a focus on innovation to meet the demands of precision diagnostics.

The IVD contract manufacturing market in the US is characterized by advanced technological capabilities and robust regulatory oversight. Additionally, the IVD contract manufacturing industry is focused on innovating to meet the specific needs of precision diagnostics. The FDA has developed comprehensive guidelines for study of IVDs and encourages clinical investigation through its guidance document, which supersedes earlier guidance documents related to IVD studies. The FDA's framework for IVD contract manufacturing allows IVD developers to outsource manufacturing to a contract manufacturer that specializes in producing IVDs under cGMP regulations, which provides IVD developers with the ability to accelerate their time to market while still maintaining compliance with quality standards.

A prominent example is Beckman Coulter's RESOURCE Contract Manufacturing Services that make antibody cocktails to customer specifications using antibodies from several sources and manufactured in cGMP facilities in order to minimize pipetting, QC steps, and reagent waste for flow cytometry applications. BD Biosciences provides contract manufacturing of multicolor panels in liquid, lyophilized, or dried formats, supporting companion diagnostics with more than 45 years flow cytometry experience and US FDA 21 CFR Part 11, compliant capabilities. Argonaut Manufacturing Services, an FDA, registered CDMO, offers custom formulation and fill, finish for IVD reagents, with clinical to commercial stage scalability.

Statistics point out that about 3.3 billion IVD tests are made every year in 12, 000 laboratories in the US, revealing the enormous volume that is pushing the contract manufacturing market. Among the trends are an increase in the use of automated, ready, to use reagents and AI integration for data analysis, e.g. Simoa platform for

ultrasensitive biomarker detection which achieved less than 10% CVs in multi, center studies. Moreover, the focus on companion diagnostics has resulted in more than 60 million IVD tests sold worldwide by major companies such as BD, with a significant contribution of US, based production. Outsourcing is a good strategy for reducing the costs of manufacturing inside the company, e.g. clinical trial batch production of 3, 000 vials on average for oncology IVDs.

The US Food and Drug Administration, World Bank Data, National Health Service (NHS), FDA (Food and Drug Administration), EMA (European Medicines Agency), and WHO (World Health Organization) are among the primary and secondary sources referred to while preparing the IVD devices contract manufacturing market report.

Reason to buy

Saves and reduces time required for identifying the market growth, size, leading players, and segments in the global IVD devices contract manufacturing market.

Highlights key business priorities to assist companies in realigning their business strategies

Emphasizes key findings and recommendations that uncover emerging industry trends in the global IVD devices contract manufacturing market, enabling stakeholders across the value chain to craft effective long-term strategies

Develop/modify business expansion plans by analyzing substantial growth prospects in mature and emerging markets

Scrutinizes in-depth global IVD devices contract manufacturing market trends, along with factors driving the market, as well as those hindering it

Enhances the decision-making process by understanding the strategies that underpin commercial interest with respect to client products, segmentation, pricing, and distribution

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