

## Point-of-Care Diagnostics Devices and Equipment Market 2019 Global Trend, Segmentation and Opportunities, Forecast 2022

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## **Executive Summary**

The point-of-care diagnostics devices and equipment market consists of sales of point-of-care (POC) diagnostics devices and equipment and related services. Point-of-care diagnostics devices and equipment are designed to aid physicians in performing medical diagnostic testing at or near the point of care, for immediate knowledge on diseases or conditions. Point-of-care diagnostics are segmented into cardio metabolic monitoring kits, infectious diseases testing kits, cardiac and cancer markers excluding blood glucose monitoring kits.

The global point-of-care diagnostics devices and equipment market was valued at about \$9.3 billion in 2018 and is expected to grow to \$11.35 billion at a CAGR of 5.1% through 2022.

The point-of-care diagnostic devices and equipment market has been geographically segmented into North America, Western Europe, APAC, Eastern Europe, South America and Middle East & Africa. The North America is the largest market for point-of-care diagnostic devices and equipment and is expected to continue to be the largest market during the forecast period.

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An increase in the incidence of target diseases is driving the POC devices and equipment market globally. The rising incidence of chronic diseases, like diabetes, rheumatism, or cancer is increasing steadily worldwide due to poor lifestyle choices and increasing obesity, thus driving the growth of POC devices and equipment market. For example, according to American Heart Association cardiovascular disease is listed as the underlying cause of death for 0.84 million deaths in the US in 2016, approximately 1 of every 3 deaths.

The POC diagnostics devices and equipment market is expected to slow down due to stringent regulatory policies, which increases the gestational period before the product enters market. POC devices and equipment manufacturers are required to obtain multiple FDA clearances before launching their product into the market. The entire process of approval consumes a lot of time, thereby restraining the market growth.

Over-the-Counter (OTC) testing is being termed as an important trend driving the growth of point of care diagnostics market. FDA has approved OTC test kits for cholesterol, fecal occult blood, pregnancy and HIV/HCV. This method would improve the access to testing and early detection of

the disease. These testing kits may generate more revenue than prescription tests over the forecast period due to ease of using the kits, increased home care and self-testing, and rise in availability and adoption rate.

Point of care devices are regulated by the U.S. Food and Drug Administration (FDA) and all the diagnostic laboratory tests regulated by the clinical laboratory improvement amendments of 1988 (CLIA) that is administered by the centers for Medicare & Medicaid services (CMS). As these devices measure the biomarker levels in the body they are classified as class II (requiring 510[k] approval), or III devices (requiring the more tedious premarket approval). On the contrary, to the stringent approvals by FDA, China has a moderately lenient approval mechanism. Therefore, the top companies are using partnership approach with local vendors and distributors to expand their market share.

Major players in the market are Abbott, F. Hoffmann-La Roche, Siemens Healthineers, Danaher and Beckman Coulter.

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NORAH TRENT WISE GUY RESEARCH CONSULTANTS PVT LTD +1 646-845-9349 email us here

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