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United States In Vitro Diagnostics Market Assessment, By Product Type [Instruments, Reagents & Consumables, Data Management Software], By Techniques [Immunodiagnostics, Clinical Chemistry, Molecular Diagnostics, Microbiology, Hematology, Coagulation & Haemostasias, Urinalysis, Others] By Settings [Laboratories, Point-of-Care], By Application [Infectious Diseases, Diabetes, Drug Testing/ Pharmacogenomics, Autoimmune Diseases, Cardiology, Oncology, HIV/AIDS, Nephrology, Gastroenterology, Others], By End-user [Clinical Laboratories, Hospitals, Point-of-care testing centers, Others], By Region, Opportunities and Forecast, 2016-2030F

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Abstracts

United States in vitro diagnostics market size was valued at USD 32.84 billion in 2022, and is expected to reach USD 56.43 billion in 2030, with a CAGR of 7% for the forecast period between 2023 and 2030F. United States in vitro diagnostics (IVD) market is a critical component of the country's healthcare sector, playing a pivotal role in disease detection, monitoring, and management. IVD refers to medical devices, reagents, and systems used to analyze biological specimens such as blood, urine, tissue, and other bodily fluids outside the body. These tests aid in diagnosing diseases, guiding treatment decisions, and monitoring patient health, contributing to better patient outcomes and

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cost-effective healthcare.

In recent years, the United States IVD market has experienced significant growth, driven by factors such as the rising prevalence of chronic diseases like diabetes, cardiovascular disorders, and cancer. The aging population contributes to the increased demand for IVD products, as elderly individuals require frequent medical monitoring and diagnostic testing. Advancements in technology and the integration of automation have further propelled market growth by streamlining workflows, reducing turnaround times, and improving the accuracy of test results.

The market is highly competitive, with numerous well-established players as well as innovative startups driving continuous research and development. Key areas of focus include personalized medicine, point-of-care testing, and companion diagnostics.

Growing Prevalence of Infectious Diseases

The United States in vitro diagnostics market has experienced a growing prevalence of infectious diseases, which has significantly impacted the market. The surge in infectious diseases has been driven by various factors, including globalization, increased international travel, population density, and changes in disease patterns. It has led to a higher demand for accurate and rapid diagnostic tests to identify infectious agents and facilitate prompt treatment. The IVD market has responded to the rising challenge by developing advanced diagnostic technologies and assays that can quickly detect a wide range of pathogens, including viruses, bacteria, and fungi.

These innovations have enabled healthcare professionals to efficiently diagnose infectious diseases, implement timely interventions, and effectively control outbreaks. The growing awareness of the importance of early detection and disease monitoring has contributed to the expansion of the IVD market in the United States. As a result, the industry has witnessed increased investments in research and development, leading to the introduction of more sensitive, specific, and user-friendly diagnostic tools, thereby fostering better management of infectious diseases nationwide.

For instance, during July 2022, Fujirebio Inc.'s Lumipulse G ?-Amyloid Ratio (1-42/1-40) test became the first diagnostic laboratory test to be cleared by the United States Food and Drug Administration (FDA) for assisting in the diagnosis of Alzheimer's disease.

Innovations in In Vitro Diagnostics Instruments

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The United States in vitro diagnostics market has witnessed significant innovations in diagnostic instruments, revolutionizing healthcare practices. Cutting-edge advancements have enhanced the accuracy, speed, and accessibility of diagnostic tests. Miniaturization and automation have led to the development of portable and point-of-care devices, empowering healthcare providers to conduct rapid and precise diagnostics at the patient's bedside. In the United States in vitro diagnostics market, integration with digital health technologies, such as artificial intelligence and telemedicine, have expanded data analysis capabilities and remote patient monitoring, optimizing disease management. These innovations have streamlined workflows, reduced turnaround times, and ultimately improved patient outcomes. Additionally, advancements in molecular diagnostics, including nucleic acid testing and next-generation sequencing, bolster personalized medicine approaches, tailoring treatments to individual patients' needs.

The market penetration of in-vitro diagnostic (IVD) instruments in the country is on the rise due to the growing technological advancements. Portable instruments like Roche Diagnostics' cobas 4800 and Cepheid's GeneXpert, among others, have played a significant role in this trend.

Abbott unveiled its most recent transcatheter aortic valve implantation (TAVI) system, NavitorTM, on December 6 2022 , introduced this minimally invasive device for individuals in India affected by severe aortic stenosis, facing high or extreme surgical risks. The Navitor valve marks a step forward in TAVI (also known as TAVR, or transcatheter aortic valve replacement) treatments, incorporating pioneering features such as a distinctive design aimed at averting blood leakage around the valve.

In November 2021, Roche unveiled the cobas 5800 System, a cutting-edge molecular testing platform designed for diagnosing infectious diseases such as sexually transmitted diseases and respiratory infections.

Advancement in Oncology

In the United States in vitro diagnostics market, Oncology is projected to experience the highest growth due to the rising number of cancer cases in the United States. Additionally, there is a growing demand for self-care devices and Point-of-Care (POC) diagnostics in the country to address chronic diseases, which is expected to fuel market growth in the coming years. The most prevalent types include breast, prostate, colorectal, lung, stomach, and liver cancers. Moreover, cancer-causing viruses like Human Papillomavirus, Hepatitis B Virus, and Hepatitis C Virus are responsible for

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around 20% of cancer-related deaths. In the United States the number of cancer cases is anticipated to surge by approximately 70% over the next two decades, resulting in an increased demand for early-stage diagnosis through clinical testing. Consequently, there will be an upswing in the adoption of in vitro diagnosis to cope with the rising cancer cases in the region.

Furthermore, in August 2022, the United States Food and Drug Administration provided clearance for the use of a blood based Divitum Tka biomarker assay to monitor disease progression in patients with metastatic breast cancer (MBC). Similarly, in November 2020, the Food and Drug Administration approved the FoundationOne Liquid CDx test (Foundation Medicine, Inc.), a liquid biopsy next-generation sequencing-based device, as a companion diagnostic tool for detecting multiple biomarkers in cell-free DNA extracted from plasma specimens.

Impact of COVID-19

In the United States in vitro diagnostics market, the COVID-19 pandemic has brought significant attention to in vitro diagnostics, driven by the rising demand for IVD kits and reagents to diagnose SARS-CoV-2 infections worldwide swiftly and accurately. The outbreak is expected to have a positive effect on the market, as in vitro diagnostics play a crucial role in testing various biological samples, aiding in the diagnosis of infectious diseases like COVID-19. Testing continues to be a vital measure in controlling the pandemic. Additionally, the industry dynamics have shifted, with an increasing number of companies concentrating on introducing tests for home-based COVID-19 testing.

Additionally, in 2021, the United States Food and Drug Administration placed a high priority on home-based molecular diagnostic tests. During the same year, BATM Advanced Communications Ltd. introduced its molecular diagnostics self-test kit for detecting COVID-19. These tests facilitate early disease detection and reduce the likelihood of substitutes. Consequently, the surge in demand for newly developed emergency-use-permitted IVD tests, specifically designed for COVID-19 detection, had a positive impact on the market.

For example, Kroger's announcement in May 2021, about the availability of Abbott’s BinaxNOW COVID-19 Ag Card for self-testing, is likely to boost the adoption of the product and aid in managing SARS-CoV-2. Furthermore, in April 2021, Abbott revealed its plans to distribute the BinaxNOW COVID-19 Ag Self-Test to prominent retailers like Walgreens, Walmart, and CVS Pharmacy in the United States, further expanding its market reach. Moreover, in January 2020, Quest Diagnostics partnered with Memorial

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Hermann Health System to enhance diagnostic services in Houston by providing 21 hospital laboratories with improved, cost-effective, and high-quality solutions. These developments are poised to have a significant impact on the market's growth.

Key Players Landscape and Outlook

Prominent industry players are adopting market strategies focused on strategic collaborations and partnerships, achieved through mergers and acquisitions in the country. The companies are prioritizing technological advancements to meet customer demands, such as fully automated systems that deliver rapid and precise results.

During July 2022, Roche made an announcement that the Elecsys Amyloid Plasma Panel had received breakthrough device designation from the United States Food and Drug Administration (FDA). The groundbreaking solution was designed to facilitate the early detection of Alzheimer's disease.

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*Companies mentioned above DO NOT hold any order as per market share and can be changed as per information available during research work

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