

Japan In Vitro Diagnostics Market Assessment By Product Type [Instruments, Reagents and Consumables, Data Management Software], By Techniques [Immunodiagnosics, Clinical Chemistry, Molecular Diagnostics, Microbiology, Hematology, Coagulation and 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, FY2017-FY2031F

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Abstracts

Japan In Vitro Diagnostics Market size was valued at USD 2.5 billion in FY2023 and is expected to reach USD 3.5 billion in FY2031 with a CAGR of 4.2% for the forecast period between FY2024 and FY2031. The Japan in vitro diagnostics (IVD) market has witnessed significant growth and innovation, solidifying its position as a crucial component in the healthcare sector. IVD refers to medical tests conducted on samples like blood, urine, and tissues outside the human body to diagnose diseases and conditions. This market has experienced steady expansion in Japan due to factors such as an aging population, rising healthcare awareness, and technological advances. The

country's aging demographic has contributed to an increased demand for accurate and efficient diagnostic tools, particularly for age-related diseases like cancer, diabetes, and cardiovascular conditions. This has propelled investments in research and development, creating cutting-edge IVD technologies that offer faster results and improved accuracy.

Japan's commitment to technological advancement is evident in its adoption of automation, molecular diagnostics, and point-of-care testing. These advancements have streamlined diagnostic procedures, enabling quicker diagnoses and informed medical decisions. Additionally, collaborations between research institutions, healthcare providers, and industry players have fostered a conducive environment for innovation. Regulatory agencies like the Pharmaceuticals and Medical Devices Agency (PMDA) oversee the approval and quality control of IVD products, ensuring patient safety and product efficacy. Market players are focused on complying with these regulations while continuously refining their offerings. The Japan in vitro diagnostics market presents opportunities for domestic and international companies to contribute to the evolving healthcare landscape.

Advancement in Immunodiagnosics

In Japan, significant advancements in immunodiagnosics within the field of in vitro diagnostics have propelled healthcare efficacy. Cutting-edge technologies such as enzyme-linked immunosorbent assays (ELISAs), polymerase chain reaction (PCR) techniques, and flow cytometry have been integrated into diagnostic protocols, enabling rapid and accurate identification of various diseases. Collaborations between academia, industry, and research institutions have fostered the development of novel biomarkers and reagents for improved disease detection, monitoring, and personalized treatment. Additionally, automated platforms have streamlined laboratory processes, enhanced efficiency, and reduced turnaround times. The convergence of nanotechnology and immunodiagnosics has led to innovative biosensors capable of detecting minute biomolecular interactions with heightened sensitivity. Japan's dedication to innovation and robust regulatory framework continue to drive the evolution of immunodiagnostic technologies, ultimately enhancing patient care through early and precise disease diagnosis.

In December 2022, bioMérieux unveiled the CE-mark approval for VIDAS KUBE, the advanced automated immunoassay system designed for the VIDAS product line.

Introduction of Latest Technologies

Japan is at the forefront of introducing cutting-edge technologies in vitro diagnostics (IVD). The nation's innovation landscape showcases remarkable advancements such as microfluidic lab-on-a-chip systems, enabling rapid and accurate biomarker analysis with minimal sample volumes. Next-generation sequencing (NGS) applications have also gained traction, revolutionizing genetic and genomic testing by offering comprehensive insights into diseases. AI-driven diagnostic algorithms enhance precision and speed, aiding in early disease detection and personalized treatment strategies. Additionally, Japan has embraced point-of-care testing (POCT) devices that facilitate on-the-spot medical assessments, which are crucial for remote and resource-limited settings. These technologies not only bolster the efficiency of healthcare delivery but also contribute significantly to Japan's position as a global leader in IVD innovation.

DiaCarta Inc., a molecular diagnostics company, declared in July 2022 that it had been granted the CE-IVD Mark for its recently developed QuantiVirus SARS-CoV-2 & Flu A/B test.

Enhanced Progress through Key Player Collaboration

The Japan in vitro diagnostics market experienced remarkable progress by fostering collaboration among key industry players. Manufacturers, researchers, and regulatory bodies collectively drove innovation, streamlined regulatory processes, and expedited product development by pooling resources, knowledge, and expertise. Collaborative efforts led to the creation of advanced diagnostic technologies, such as point-of-care testing and personalized medicine solutions, thus addressing Japan's evolving healthcare needs. Sharing data and best practices improved diagnostic accuracy and accelerated the availability of cutting-edge tests for various diseases. Moreover, collaboration aided in aligning industry practices with regulatory requirements, ensuring timely market access for novel diagnostics.

In July 2021, Sysmex Corporation established a worldwide strategic partnership with QIAGEN N.V to collaborate on the advancement of cancer companion diagnostics.

Rise in Infectious Diseases

In Japan in vitro diagnostics market has witnessed a concerning surge in infectious diseases, prompting a heightened focus on in vitro diagnostics. This upswing can be attributed to increased global travel, urbanization, and evolving pathogens. In response, the Japanese healthcare system has intensified its reliance on in vitro diagnostics to

identify infectious agents accurately and swiftly. These diagnostic tools encompass a range of technologies, including molecular assays, immunoassays, and nucleic acid testing, enabling healthcare professionals to diagnose infections and initiate appropriate treatments promptly. This emphasis on advanced diagnostics not only aids in efficient disease management but also plays a pivotal role in containing outbreaks and preventing their spread. As Japan grapples with the complexities of emerging infectious diseases, robust in vitro diagnostics serve as a cornerstone of its strategy to safeguard public health.

In April 2023, Oxford Nanopore Technologies plc and bioMérieux SA joined forces to improve global health results by investigating specific possibilities for introducing nanopore sequencing to infectious disease diagnostics.

Impact of COVID-19

As of March 23, 2022, more than 6.15 million individuals in Japan have been affected by the COVID-19 illness, with a corresponding death toll of 27,246. Throughout 2020, the growth of the Japan IVD (In Vitro Diagnostics) market was impeded by the COVID-19 pandemic, causing delays in routine procedures due to social constraints and precautionary measures. Nevertheless, with the gradual relaxation of social restrictions by governments, the downward trajectory in business revenues began to stabilize and reach a plateau before the onset of the third quarter in 2020. The global landscape remains overshadowed by the looming menace of novel coronavirus, wreaking havoc in the lives of countless individuals. Essential strategies for curbing its impact involve extensive testing and swift hospitalization to mitigate its spread. In this context, in-vitro diagnostics emerge as a pivotal element in ramping up testing efforts. Stakeholders within the in-vitro diagnostic market are diligently working on innovating novel technologies that enable widespread testing within a condensed timeframe.

As an example, during April 2021, Sysmex Corporation secured approval for in vitro diagnostics in Japan, enabling them to manufacture and market the Detect Amp SARS-CoV-2 RT-PCR Kit. This kit is designed to identify the RNA of the novel coronavirus (SARS-CoV-2), which is responsible for COVID-19.

Key Players Landscape and Outlook

The Japan in vitro diagnostics (IVD) market exhibits a robust landscape, with key players contributing to its growth and innovation. The outlook for the Japan IVD market remains promising, driven by factors such as the increasing geriatric population, rising

chronic diseases, and a demand for precise and rapid diagnostic solutions. Advancements in personalized medicine, digitalization, and the emphasis on preventive healthcare further contribute to the market's anticipated growth, with key players continually striving to introduce cutting-edge technologies and cater to evolving medical needs.

Bio-Rad Laboratories, Inc. introduced their CFX Opus 96 Dx System and CFX Opus 384 Dx System for In Vitro Diagnostics in October 2021. These systems bring forth enhanced accuracy and precision, aiming to refine assay development and streamline workflows, consequently bolstering productivity for both diagnostic testing and research purposes. Both the CFX™ Opus 96 Dx Real-Time PCR System and the CFX™ Opus 384 Dx Real-Time PCR System are open systems capable of multiplexing up to five targets, enabling efficient IVD assay development and testing.

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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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