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Global In-vitro Diagnostics Market Assessment, By Product Type [Instruments, Reagents and Consumables, Data Management Software], By Techniques [Immunodiagnostics, Clinical Chemistry, Molecular Diagnostics, Microbiology, Hematology, Coagulation and Hemostasis, 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

Global In-vitro diagnostics market is projected to witness a CAGR of 5.52% during the forecast period 2022-2030F, growing from USD 107.71 billion in 2022 to USD 165.55 billion in 2030. In-vitro diagnostics (IVD) refers to medical instruments designed to conduct diagnostic tests on biological samples like blood, urine, and tissues. These tests are crucial in identifying and tracking infectious diseases, autoimmune disorders, and various medical conditions. Additionally, they are utilized to assess adjustments in drug therapy at regular intervals.

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The market for IVD devices is experiencing significant growth due to increasing demand for and adoption of these devices. This expansion is further propelled by key players' heightened investments in research and development, aiming to innovate products and explore new applications for IVD techniques. The British In-vitro Diagnostic Association says these tests significantly impact around 70% of clinical decisions. Furthermore, technological advances in diagnostics sustain a tendency for continual market expansion.

The rising prevalence of chronic diseases like cancer and genetic anomalies across the globe is raising the demand for more in-vitro diagnostics procedures. Growing awareness about early diagnosis can save significant prospective patients and is driving the call for in-vitro diagnostics products. The efficacy of in-vitro diagnostics in diagnosing and predicting the future occurrence of diseases is further propelling the market growth.

In January 2023, QIAGEN announced the launch of EZ2 Connect MDx for diagnostic laboratories. EZ2 Connect MDx can help labs purify DNA and RNA from 24 samples simultaneously within 30 minutes with a high degree of automation. The device has gained the EU’s CE-IVD compliance marking valid in the European Union and in other countries as well.

High Prevalence of Knee-Associated Osteoarthritis

The increasing incidence of various diseases, including genetic, cardiovascular, and neurological conditions, substantially strains the healthcare system. The effective utilization of In Vitro Diagnostics (IVD) for early disease detection enables physicians to implement suitable treatments more efficiently. For instance, based on a factsheet by the WHO in September 2022, Non-Communicable Diseases (NCDs) accounted for 41 million deaths, representing approximately 74% of all global fatalities.

In the global in vitro diagnostics market, the increasing burden of diseases can be effectively addressed through enhanced awareness of early diagnosis and the optimal use of in-vitro diagnostics (IVD) at both patient and physician levels. The aging population's heightened vulnerability to various conditions, including hypertension, diabetes, cardiovascular, liver, and kidney diseases, has resulted in greater adoption of homecare IVD devices.

For example, as reported by the United Nations in January 2023, the global population of individuals aged 65 years and older was 761 million in 2021, and this number is

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projected to increase to 1.6 billion by 2050. The population of those aged 80 years or older is growing even faster.

Increasing Adoption of Point-of-Care Testing Devices

As the burden of diseases continues to increase, medical device companies are diligently working on developing technologically advanced diagnostic devices. In response, hospitals and laboratories are growing inclined towards point-of-care testing devices, seeking accurate real-time data. Point-of-care (PoC) testing is conducted near the patient, typically requiring only a small blood sample, and delivers rapid test results for immediate clinical decision-making. This capability enables doctors to make prompt treatment decisions without waiting for results from a central laboratory.

FUJIFILM Sonosite, Inc. revealed its plans to introduce the Sonosite PX ultrasound system in India in January 2023. This new product launch aims to enhance clinician ergonomics and efficiency for improved medical performance.

For instance, in August 2023, Anbio Biotechnology launched a handheld analyzer based on the LAMP (Loop-Mediated Isothermal Amplification) diagnostic technique for rapid point-of-care testing to enter the point-of-care testing market.

Increasing Funding and Government Support

In the global in vitro diagnostics market, government organizations, associations, and agencies are actively promoting the utilization of IVD through awareness initiatives, thereby fostering market growth. The World Health Organization (WHO) has introduced a model list of Essential In-Vitro Diagnostics for primary healthcare and medical facilities equipped with clinical laboratories to emphasize the importance of addressing diseases based on their burden and prevalence. These categories are further subdivided to cover general IVDs and specific diseases.

For instance, in November 2023, the National Institute for Health and Care Research under the United Kingdom government awarded a fund of GBP 3 million to Newcastle Health-tech Research Centre to support a five-year program and develop innovative technology solutions in in-vitro diagnostics for improved and efficient diagnosis of people across the country.

Dominance of Immunodiagnostics and Growth in Molecular Diagnostics

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The immunodiagnostics segment is anticipated to be the leading segment during the assessment period in the market with 35.22% of value share in 2022 while the molecular diagnostics segment is expected to grow at a significantly higher pace with a CAGR of 7.1% during the forecast period. Rising cases of infectious diseases is resulting in a higher value share of the immunodiagnostics segment. The advances in the field of genetic and molecular research and its vast applications in diagnostics are driving the high growth rate for the molecular diagnostics segment.

For instance, in November 2023, based on the tried-and-true gold standard technology of the LightCycler Systems that came before it, Roche announced the launch of the LightCycler PRO System. This novel technology bridges the gap between in vitro diagnostics and translational research while raising the standard for performance and usability. Roche's molecular PCR testing offering, which features options for a range of healthcare professionals, is further enhanced with the LightCycler PRO System.

Reagents and Consumables is the Leading Segment

Based on product type, the in-vitro diagnostics market is segmented into reagents and consumables, instruments, and data management software. The reagents and consumables segment are anticipated to be the leading segment covering more than 65% of value share throughout the assessment period, owing to the regular consumption and frequent refiling of these in diagnostic laboratories. Instruments and software usually come in packages and are one-time purchases unlike reagents and consumables, thus contributing a lower share of revenue to the market. Growing demand for in-vitro diagnostic procedures is expected to propel the market share of these segments in the forecast years.

For instance, in June 2023, Kaneka Corporation received authorization for “KANEKA Immunochromatography Flu A/B & SARS-CoV-2 Ag” to manufacture and sell it. “KANEKA Immunochromatography Flu A/B & SARS-CoV-2 Ag” can detect COVID-19 (SARS-CoV-2) and influenza virus antigens in single sample collection. Earlier, the product was launched in May as an in-vitro diagnostic reagent. The suggested retail price of the product is 19,800 yen (for 10 tests) including taxes.

North America Dominates the In-vitro Diagnostics Market

North America is exerting its dominance in the In-vitro Diagnostics market. With high investment in research and development activities, technological advancements by key players, and highly advanced healthcare infrastructure in North American countries like

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the United States and Canada, the region is expected to dominate the market with the highest value share. The supportive government initiatives and favorable reimbursement scenario for managing the growing number of surgical procedures is also embracing the growth of the market in the region. Manufacturers are also gaining benefits from regulatory approvals and further market expansion. As per the American College of Rheumatology, approximately, 790,000 knee surgeries are performed annually in the United States.

For instance, in April 2023, the USFDA approved the MISHA Knee System, manufactured by Moximed, Inc. for marketing in the United States. MISHA Knee System is an implant placed alongside the knee joint which helps in reducing the weight load and saving knee damage without removing the knee joint.

Future Market Scenario (2023 – 2030F)

Growing prevalence of chronic diseases like cancer across the globe is driving the demand in the global in-vitro diagnostics market.

Growing technological advancement enhances the efficacy of diagnostic systems and is anticipated to propel market growth.

Immunodiagnostics is the leading segment in the in-vitro diagnostics market due to the high growth of infectious diseases while molecular diagnostics has the highest CAGR due to vast applications.

In-vitro diagnostics solutions will adapt to technological advancements to meet the needs of various customer segments.

Key Players Landscape and Outlook

Key participants in the In-vitro Diagnostics market include F. Hoffmann-La Roche AG, Abbott Laboratories, Danaher Corporation, Siemens Healthineers AG, Thermo Fisher Scientific Inc., BD characterizes this landscape, as these companies compete to outperform one another in terms of patient compliance, safety, accuracy, and unique features. The market prognosis remains positive, owing to increased demand for in-vitro diagnostics procedures. In-vitro diagnostics manufacturers are actively involved in designing innovative solutions. Collaborations and developing technologies are projected to increase competition in this fast-paced market.

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In January 2024, Roche announced a definitive agreement to acquire LumiraDx's point-of-care technology. Roche agreed to pay USD 295 million for the acquisition and up to USD 55 million for funding the venture until the deal gets completed in mid-2024. The acquisition offers a wide range of immunoassay and clinical chemistry tests to Roche, which have the potential for additional high-medical value in the future. The major focus area includes LumiraDx's CE-marked HbA1c test.

In March 2023, Abbott revealed that its Alinity I laboratory instrument, designed for diagnosing traumatic brain injuries (TBIs) and assessing concussions using two biomarkers, has obtained FDA approval, and is now set for commercial launch.

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*Companies mentioned above DO NOT hold any order as per market share and can be

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