AI in In-vitro Diagnostics Market Assessment, By Component Type [Software, Services, Hardware], By Technology [Machine Learning, Natural Language Processing, Context-Aware Computing, Computer Vision, Others], By Application [Cancer, Diabetes, Infectious Diseases, Cardiovascular, Others], By End-user [Hospitals, Diagnostic Imaging Centers, Pathology Centers, Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

The global AI in in-vitro diagnostics market is projected to witness a CAGR of 26.56% during the forecast period 2024-2031, growing from USD 649.44 million in 2023 to USD 4274.75 million in 2031. AI in in-vitro diagnostics market is positively influenced by factors like growing demand for accurate and rapid diagnostics, technical advancements in AI and machine learning, improved data analytics capabilities, regulatory support, and growing emphasis on data-driven prognosis of diseases. The automation and digitization of radiology patient imaging procedures drive the need for AI-based tools to improve diagnostic accuracy and reduce radiologist workload, further enhancing the market growth.
However, inadequate AI workforce and ambiguous regulatory guidelines for medical software across different countries, concerns around data security and privacy, data bias, and limitation of reagent-based assays in IVD techniques are some of the challenges in AI in in-vitro diagnostic market.
For instance, in October 2023, Roche announced a collaboration with Ibex and Amazon Web Services to enhance the adoption of AI-enabled digital pathology solutions for improving cancer diagnoses. Under this collaboration, Roche's Navify Digital Pathology software platform is offering Ibex's Artificial Intelligence (AI) algorithms for the diagnosis of breast and prostate cancer and this solution runs on Amazon Web Services.

Growing Demand for Accurate and Rapid Diagnostics

The growing demand for accurate and rapid diagnostics is significantly impacting the integration of AI in in-vitro diagnostics. AI is revolutionizing the in-vitro diagnostics landscape by enhancing diagnostic accuracy, efficiency, and patient outcomes. The influx of big data and technological advances are driving opportunities for the application of AI in in-vitro diagnostics, leading to improvements in medical diagnostics, monitoring, and treatment decision-making. The unique capability of AI to eliminate human errors through machine learning algorithms enables accurate and rapid diagnostics, leading to further expansion of the market. Key players invest in innovative products to speed up the diagnostic process and provide reliable results.

For instance, in February 2023, Cardio Diagnostics Holdings announced the launch of PrecisionCHD, an integrated epigenetic-genetic blood test for early detection of coronary heart diseases. PrecisionCHD is anticipated to detect coronary heart disease with greater than 75% sensitivity in both men and women. It utilizes DNA methylation and single nucleotide polymorphism biomarkers alongside AI algorithms for precision diagnostics.

Advancements in Machine Learning Algorithms

The healthcare industry is undergoing rapid transformation with the advancements in machine learning algorithms for in-vitro diagnostics. AI-assisted laboratory analysis, deep learning for cancer diagnosis, and smart diagnostic systems are some notable developments that have emerged. These innovations in cloud computing and AI have the potential to drastically improve healthcare decision-making. AI-linked universal diagnostic systems validated through large clinical trials for various diseases are some of the most promising applications. The integration of AI in cell-based oncology tests, clinical decision support, reflex testing, error detection, and imaging analysis is expected to bring about significant changes in the laboratory landscape and the healthcare industry. Ultimately, this will make healthcare more efficient and effective, further strengthening the market.

In August 2023, Celegence launched CAPTIS Copilot, which is a cutting-edge document automation and literature review solution for the life sciences industry. This enterprise cloud-based platform is designed specifically for the device and diagnostic industry and uses pre-trained large language models (LLM) and Reinforcement Learning from Human Feedback (RLHF). CAPTIS Copilot is a cloud-based solution that significantly enhances the ability of device and IVD manufacturers to increase innovation. It also empowers clinical, regulatory, and medical writing teams to be more efficient and productive with their time.

Regulatory Emphasis on AI-based In-vitro Diagnostics Solutions

Regulatory support is crucial for ensuring the safety and effectiveness of AI-based in-vitro diagnostics solutions. The U.S. Food and Drug Administration (FDA) regulates AI-driven medical products, including in-vitro diagnostic devices. In the European Union, the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) have been updated to include a classification system that specifies the regulatory pathways for in-vitro diagnostic devices, including those utilizing AI. Many other authorities worldwide are also implementing similar regulatory support initiatives, further contributing to AI's growth in the in-vitro diagnostics market.

For instance, in May 2023, Tempus received United States FDA approval for its xT CDx, a next-generation sequencing-based in vitro diagnostic device. xT CDx is a 648-gene next-generation sequencing test for solid tumor profiling, including microsatellite instability status and companion diagnostic claims for colorectal cancer patients.

Dominance of Software Segment

Component-wise, the major revenue in AI in in-vitro diagnostics market is mainly driven by software components. AI-based algorithm-based software is incorporated into the equipment used for in-vitro diagnostics, such as PCR instruments, NGS equipment, and others. The software component holds a major share in the AI-based diagnostics market due to its ability to improve diagnostic accuracy, efficiency, and quality and its rapid penetration rates in the healthcare sector. The increasing demand for AI-powered software tools and cloud-based solutions and the growing number of AI-based diagnostic startups and investments in the field drive this.

For instance, in March 2023, Visiopharm, a renowned provider of AI-powered precision pathology software, introduced a new and advanced Ki67 algorithm that offers diagnostic decision support to pathologists. The algorithm has received clearance under the European In-Vitro Diagnostic Regulations (IVDR) and is entirely automated, making it easy for pathologists to become fully productive without requiring manual steps.

Cancer Application Segment Dominates the Market

Cancer is the primary area where AI-based diagnostic solutions are being developed. This is because AI has the potential to significantly improve the accuracy, speed, and reliability of cancer diagnosis, prognosis, and treatment. AI-based tools have shown

promising results in various aspects of oncology, such as risk assessment, early diagnosis, patient prognosis estimation, and treatment selection. Moreover, AI technology has gone beyond diagnosing cancer and has been able to provide precise grading of in situ carcinomas and more, which has led to better cancer care for patients.

In February 2023, Ibex Medical Analytics (Ibex) announced that its Galen Prostate solution received the CE mark under the In Vitro Diagnostic Medical Devices Regulation (IVDR) for assisting pathologists in the primary diagnosis of prostate biopsies. It is the first standalone AI-based cancer diagnostics product certified under the IVDR.

North America Dominates the Market

North America dominates the AI in in-vitro diagnostics market with a high revenue share due to the higher AI implementation rate in the medical industry. However, a study conducted by Pew Research Center found that 60% of Americans would be uncomfortable with their healthcare provider relying on AI. Despite this, physicians and medical students in the USA have shown a high acceptance of clinical AI. AI-based in-vitro diagnostics solutions allow practitioners to receive clean data quickly, leading to more accurate diagnoses and cutting annual US healthcare costs, further expanding the market growth. FDA approvals play a significant role in the dominance of the North America region.

For instance, in November 2023, Lunit announced that it had got FDA approval for an AI-powered Lunit INSIGHT DBT solution. The solution is designed to analyze images generated by 3D Breast Tomosynthesis (DBT) equipment, which provides a quick and precise breast cancer diagnosis compared to traditional 2D mammography screenings.

Future Market Scenario (2024 – 2031F)

- Growing demand for rapid and precise diagnostic solutions drives the growth of the AI in in-vitro diagnostics market.
- Advancements in machine learning algorithms to manage predictive and diagnostic data have significantly contributed to the drastic growth of AI in in-vitro diagnostics market.
- Cancer application segment is anticipated to dominate the AI in in-vitro diagnostics market due to the emergence of large number of AI-based diagnostics solutions in recent times.
- Regulatory support for ensuring the safety and efficacy of AI-based in-vitro diagnostics solutions has brought lucrative growth in the market.

Key Players Landscape and Outlook

The key participants in the AI in in-vitro diagnostics market include Alphabet Inc., Siemens Healthineers AG, Microsoft Corporation, Koninklijke Philips N.V., and GE Healthcare Technologies Inc. These companies contribute to the growth and development of the AI in in-vitro diagnostics market through technological innovations, strategic partnerships, and market expansion. Many startups are coming with innovative products and large-cap players are acquiring them for market expansion.

In August 2023, Huma partnered with Google to use its generative AI technology 'Med-PaLM 2' to streamline its disease-management digital product, a SaMD platform. The partnership aims to use Google's generative AI platform for automating clinical summary reports from incoming data.

In April 2023, Canon Medical announced the complete acquisition of Minaris Medical. Through this acquisition, canon aims to expand its in-vitro diagnostics offerings. Minaris Medical is a leading provider of in-vitro diagnostic reagents and automated analyzer systems. Canon Medical has diagnostic imaging as its core business and with this acquisition, it can effectively expand its business in the in-vitro diagnostics segment.

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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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