Immunodiagnostics Market Forecast to 2030 - COVID-19 Impact and Global Analysis by Product [Enzyme-Linked Immunosorbent Assays (ELISA), Chemiluminescence Immunoassays (CLIA), Radioimmunoassays (RIA), and Others], Clinical Indication (Infectious Diseases, Hepatitis+HIV, Endocrinology, Gastrointestinal, Metabolics, and Others), End User (Hospitals, Clinics, Diagnostic Laboratories, Academic & Research Institutes, and Others), and Geography

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Report description:

The immunodiagnostics market size is expected to reach US$ 34,487.80 million by 2030 from US$ 19,218.89 million in 2022; it is estimated to record a CAGR of 7.6% from 2022 to 2030.

Immunodiagnostics is referred as a diagnostic methodology that primarily uses antigen-antibody reaction as its primary means of detection. Antibodies specific for a desired antigen can be conjugated with a radiolabel, fluorescent label, or color-forming enzyme and are used as a probe to detect it. The speed, accuracy and simplicity of such tests has led to the development of rapid techniques for the diagnosis of disease, microbes and even illegal drugs in vivo.

Point-of-care testing (POCT) has become critical to patient-centric healthcare due to the need for rapid diagnostic results to determine accurate and faster treatments. A shift from centralized point-of-care testing to decentralized testing has resulted in easy access to these diagnostics. Immunoassay testing helps monitor chronic conditions and detect pathogens, such as bacteria and viruses. Advanced point-of-care devices enable rapid screening of up to three components from a single sample. Also, the point-of-care diagnostics (POCD) inclined toward mobile healthcare (mH) smart devices could revolutionize personalized

healthcare monitoring and management, paving the way for next-generation POCTs. The management of infectious diseases can be significantly improved by POCTs, particularly in developing countries where access to timely medical care is challenging and healthcare infrastructure is outdated and sparse. Additionally, the technologically developed diagnostic kits leading to fewer manual errors propel the immunodiagnostics market. Several market players are developing innovative immunodiagnostic products. For instance, Thermo Fisher Scientific has developed immunodiagnostic products such as enzyme-linked immunoassay (ELISA) reagents and buffers, antibodies and detection probes, linking mechanisms, blocking buffers and detergents, detection substrates, and capture surfaces, as well as services such as bioconjugation and detection. Further, in September 2020, Roche launched the SARS-CoV-2 Rapid Antigen Test, which is used in POC settings to help healthcare professionals identify the infection within 15 minutes in people suspected of carrying the virus.

In April 2021, DiaSorin introduced the LIAISON IQ, a new immunodiagnostic Point-of-Care (POC) reader, and the LIAISON QuickDetect COVID TrimericS Ab test, developed with Lumos Diagnostics for countries accepting the CE Mark. Using a fingerstick of human capillary blood, this test for the LIAISON IQ identifies specific IgG antibodies against SARS-CoV-2 Spike Protein in 10 minutes.

In April 2021, Chembio Diagnostics, Inc. launched an FDA Emergency Use Authorization-approved, in-licensed rapid point-of-care COVID-19/Flu A&B test for use in traditional and decentralized testing settings. The rapid immunoassay test requires no instrumentation and produces results in 15 minutes.

WHO applauded the test kit developers for efforts taken to innovate and respond to the masses' requirements during the COVID-19 crisis. According to the American Society for Clinical Pathology, in March 2020, the Cepheid Xpert Xpress SARS-CoV-2 test became the first POC COVID-19 detection assay to receive Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA).

Likewise, the use of immunodiagnostics in cancer treatment is increasing. In oncology, an immunodiagnostic test can confirm the presence of a solid tumor by detecting known tumor-associated antigens or antibodies. These advantages and indications are driving the immunodiagnostics market growth.

Based on product, the immunodiagnostics market is segmented into enzyme-linked immunosorbent assays (ELISA), chemiluminescence immunoassays (CLIA), radioimmunoassays (RIA), and others. Based on clinical indication, the market is divided into infectious diseases, Hepatitis+HIV, endocrinology, gastrointestinal, metabolics, and others. By end user, the immunodiagnostics market is categorized into hospitals, clinics, diagnostic laboratories, academic & research institutes, and others. Geographically, the immunodiagnostics market is segmented into North America (the US, Canada, and Mexico), Europe (France, Germany, the UK, Spain, Italy, and the Rest of Europe), Asia Pacific (China, India, Japan, Australia, South Korea, and the Rest of APAC), the Middle East & Africa (Saudi Arabia, the UAE, South Africa, and the Rest of MEA), and South & Central America (Brazil, Argentina, and the Rest of South & Central America).

The World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), Industrial Biotechnology Leadership Forum (IBLF), International Diabetes Federation (IDF), and Ministry of Health and Prevention (MoHaP) are a few key primary and secondary sources referred to while preparing the report on the immunodiagnostics market.

Based on product, the immunodiagnostics market is segmented into enzyme-linked immunosorbent assays (ELISA), chemiluminescence immunoassays (CLIA), radioimmunoassays (RIA), and others. The enzyme-linked immunosorbent assays (ELISA) segment held the largest immunodiagnostics market share in 2022. The chemiluminescence immunoassays (CLIA) segment is anticipated to record a significant growth rate during the forecast period. Enzyme-linked immunosorbent assay (ELISA) frequently measures antibodies, proteins, antigens, and glycoproteins in biological samples. ELISA is used for HIV diagnosis, pregnancy tests, and cytokine or soluble receptor measurement (from cell supernatant or serum). It has replaced

radioimmunoassay (RIA) to become one of the most common and reliable diagnostic tools. Moreover, the ELISA technique advancement led to the development of quantitative PCR, fluorogenic, and electro-chemiluminescent reporters to generate signals. Further, ELISA, along with lateral flow immunoassays, was widely used during the COVID-19 pandemic to identify individuals having antibodies developed against SARS-CoV-2, thus driving the immunodiagnostics market growth.

Immunodiagnostics Market: Competitive Landscape and Key Developments

Abbott Laboratories, F. Hoffmann-La Roche Ltd, DiaSorin SpA, Danaher Corp, Thermo Fisher Scientific Inc, PerkinElmer Inc, Shenzhen Mindray Bio-Medical Electronics Co Ltd, bioMerieux SA, Svar Life Science AB, and Siemens Healthineers AG are a few key companies operating in the immunodiagnostics market. These companies adopt product innovation strategies to meet evolving customer demands, which allows them to maintain their brand name.

A few of the recent developments in the global immunodiagnostics market are mentioned below:

- In May 2023, Thermo Fisher Scientific announced that the US FDA had cleared its immunoassays, B R A H M S PlGF plus KRYPTOR and B R A H M S sFlt-1 KRYPTOR novel biomarkers. These immunoassays assess risks and clinical management of preeclampsia, a severe pregnancy complication.

- In April 2023, Thermo Fisher Scientific announced a partnership with ALPCO-GeneProof, a global leader in diagnostics. The partnership has helped to bring TaqPath Menu | GeneProof PCR kits into the market.

- In July 2022, Abbott Diagnostics announced its participation in American Association for Clinical Chemistry (AACC) 2022. In the exhibition, the company demonstrated its diagnostics systems and analyzers.

- In May 2022, Roche and The Global Fund to Fight AIDS, Tuberculosis and Malaria joined forces to build and strengthen diagnostic capacity and pandemic preparedness in low-and middle-income countries fighting against HIV and tuberculosis (TB).

- In September 2022, Mindray launched the ToRCH Panel. With this panel, the company offers high-quality assays to meet different clinical needs. Mindray ToRCH kits support diverse sample types with less quality controls and sample volumes, which ensures great ease and convenience during clinical detection.

- In May 2022, Thermo Fisher Scientific announced that the Phadia 2500+ series of instruments are available for autoimmune testing in the US. The family of high-capacity, intuitive lab instruments supplied by Thermo Fisher Scientific, the world leader in serving science, offers reliable and unparalleled high throughput for both allergy diagnostics and autoimmune testing.

- In July 2022, Roche announced the launch of the Elecsys HCV Duo immunoassay in countries that accept the CE Mark. The Elecsys HCV Duo immunoassay enables a significantly earlier diagnosis of active HCV infection, making it possible to get patients appropriate care sooner to stop both the disease progression and transmission.

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