ELISpot and FluoroSpot Assays Market Assessment, By Product [Assay Kits, Analyzers, Ancillary Products], By Application [Diagnostic Applications, Research Applications], By End-user [Hospital and Clinical Laboratories, Research Institutes, Contract Manufacturing Companies, Pharmaceutical and Biopharmaceutical Companies], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global ELISpot and FluoroSpot assays market is projected to witness a CAGR of 8.45% during the forecast period 2024-2031, growing from USD 321.23 million in 2023 to USD 614.68 million in 2031.
Due to its excellent sensitivity, the enzyme-linked immunospot (ELISpot) assay is frequently used to diagnose various medical disorders. They are very adaptable and are frequently used to measure human and mouse T cells that are specific to an antigen. Numerous diagnostic applications employ several types of ELISpot tests, such as Granzyme B ELISpot, TGF-Beta 1 ELISpot, Fluorescent ELISpot, and IFN-gamma ELISpot. Particularly well suited for secreted proteins, such as cytokines from active cells, are the ELISpot and Fluorescent ImmunoSpot (FluoroSpot) tests. The market for ELISpot and FluoroSpot assays is expected to develop due to the rising prevalence of chronic diseases, a rise in awareness of the need for prompt diagnosis, and the growing use of the assay.
Additionally, the rise in healthcare spending supports the potential for growth in emerging countries for the ELISpot and FluoroSpot assay. The popularity of personalized medicine is a crucial factor in promoting the market's growth. However, factors that could impede market expansion include rising prices, a lack of high-quality detection reagents, and the inaccessibility of the ELISpot and FluoroSpot assays for underdeveloped nations, which can be seen as development and growth opportunities in the market. Operation issues encountered when performing diagnostic tests and inconsistent material usage lead to market player competition, which presents businesses with growth prospects.
For instance, Virax Biolabs Group Limited announced the launch of an early access program for its proprietary SARS-Cov-2

ViraxImmune T-cell-based test in September 2023, intended solely for research purposes. The early access program offers unique access to advanced immunological evaluation discoveries for selected research organizations. Virax Biolabs Group Limited's T-cell-based test was designed to determine whether memory T-cells specific to the SARS-Cov-2 virus are activated. The test version is designated as Research Use Only (RUO). It is accomplished by mixing a peptide pool that covers specific viral protein sequences with an ELISpot assay. Peripheral blood mononuclear cells must be isolated from blood samples for the test and these cells must then be transferred onto an ELISpot plate that has already been coated by the company.

Growing Prevalence of Chronic Diseases to Fuel the Market Growth

The rising prevalence of chronic diseases is fueling the market growth of ELIspot and FLUROspot tests. The incidence of chronic diseases such as cancer, diabetes, cardiovascular diseases, and autoimmune diseases has increased dramatically worldwide, requiring advancements in diagnostic and therapeutic tools. ELIspot and FLUROspot assays have emerged as important technologies due to their sensitivity and specificity in detecting and quantifying immune responses. For instance, ELIspot and FLUROspot assays in oncology help assess the T-cell responses to cancer vaccines and immunotherapies, guiding treatment decisions and tracking therapeutic outcomes. The American Cancer Society estimated that there were 609,820 cancer deaths and 1,958,310 new cancer cases in the United States in 2023. Prostate cancer incidence rose by 3% a year on average. Similarly, in autoimmune diseases, these assays are instrumental in identifying autoreactive T-cells, aiding in diagnosing and managing conditions such as rheumatoid arthritis, tuberculosis, and multiple sclerosis. As per the World Health Organization's (WHO) 2023 report, 5.8 million men, 3.5 million women, and 1.3 million children worldwide were predicted to have contracted tuberculosis (TB) in 2022.

The rise in the prevalence of chronic diseases has spurred many research and development activities, leading to a demand for advanced immunoassay systems such as ELIspot and FLUROspot. Pharmaceutical and biotech companies use these assays in pre-clinical and clinical trials to assess the urgency of new therapeutic immune responses. Furthermore, the increasing awareness and adoption of drug personalization have emphasized the importance of accurate immune monitoring, which has led to the use of ELIspot and FLUROspot assays, increasing the emphasis. As healthcare systems worldwide continue to grapple with the burden of chronic diseases, the market for these assays is poised for robust growth, driven by the need for effective diagnostic and monitoring solutions.

Increasing Demand for Personalized Medicine

The ELIspot and FLUROspot assays market is developing substantially, mostly due to the rising need for personalized treatment. Accurate and trustworthy diagnostic instruments are essential for personalized medicine, accommodating medical care according to individual traits such as genetics and biomarkers. In this context, the use of ELIspot and FLUROspot assays, which are renowned for their excellent sensitivity and specificity in identifying and measuring cellular immune responses, is growing. With ELIspot assays, cytokine-secreting cells can be found at the single-cell level, providing a clear perspective on the status of the immune system. It is essential for personalized medicine, which frequently entails tracking patients' immune responses to customize therapies, especially in autoimmune disorders, infectious diseases, and malignancies.

The demand for accurate, high-throughput, and adaptable assays, such as ELIspot increases as treatments become more customized, which propels the market expansion. The same concept applies to FLUROspot assays, which integrate fluorescence detection with ELIspot principles to allow multiplexing or the simultaneous detection of several cytokines or other released chemicals from distinct cells. For instance, Agilex Biolabs Pty Ltd, an Australian bioanalytical laboratory, stated in April 2022 that it would expand its operations in the United States. Agilex Biolabs Pty Ltd has expanded to San Diego and opened a new facility in South Australia to investigate large-molecule treatments. The newly established laboratory is equipped with state-of-the-art bioanalytical equipment and procedures, including digital droplet quantitative RT-PCR analysis and the EliSPOT/FluoroSPOT multi-spot reader, which is used to detect highly sensitive molecules.

Personalized medicine benefits from multiplexing since it allows thorough immune profiling from small patient samples. The capacity to obtain a comprehensive understanding of immune responses unique to a patient speeds up the creation and refinement of customized treatments. Further driving its use, the developments in assay technologies, including automated platforms and better reagent formulations, increase the frequency of use of ELIspot and FLUROspot assays. As personalized medicine continues to grow, driven by advancements in genomics and biotechnology, the demand for sophisticated immune monitoring tools is expected to rise, sustaining the market growth for ELIspot and FLUROspot assays.

Increasing Dominance of Assay Kits

Assay kits are essential for drug development, environmental monitoring, and life science research. These applications encompass investigating disease pathways, identifying potential therapeutic candidates, and assessing the production processes of biopharmaceuticals. Due to factors such as the rising prevalence of chronic illnesses and the growing use of these goods for vaccine development in clinical studies, the assay kits segment continues to have a significant share in the market.

In the United States, there were an anticipated 2,060 bone cancer-related fatalities and 3,610 new cases in 2021, according to the American Society of Clinical Oncology's 2022 report. Since they are employed in the diagnosis of autoimmune disorders, including multiple sclerosis, rheumatoid arthritis, and other conditions, it is expected that the prevalence of these diseases will propel the expansion of this market. Additionally, during the forecast period, innovation in ELISpot assay kits and the usefulness of assay kits in research activities are anticipated to propel the industry expansion. As a result, the test kit segment will grow over the projection period due to the widespread usage of assays for research studies and clinical trials.

For instance, the T-Cell Select reagent kit by Oxford Immunotec Ltd. was approved by the FDA in September 2022. The kit streamlines the process of the T-SPOT.TB test, an internationally regulated ELISPOT IGRA that identifies latent tuberculosis (TB) infection, for use in in-vitro diagnostic (IVD) procedures in accredited laboratories. It was launched to reduce the amount of time and money spent in labs while testing for tuberculosis. The CEO of PerkinElmer's Oxford Immunotec Ltd. division claimed that automation closes the gap between the ELISPOT and ELISA laboratory operations, enabling more laboratories to perform T-SPOT assays.

North America to Dominate Global ELISpot and FluoroSpot Assays Market Share

North America is anticipated to lead the ELISpot and FluoroSpot assay market for the forecast period due to an increase in the prevalence of infectious and chronic diseases. According to the American Cancer Society's Cancer Statistics 2022, leukaemia, lymphoma, and breast cancer will be among the 1,918,030 new cases of cancer expected to be diagnosed in the United States in 2022. Furthermore, one million Americans have chronic hepatitis B infections, which can result in chronic illnesses, including liver cancer, according to data released by the American Academy of Paediatrics in March 2022. It is anticipated to fuel the expansion of the ELISPOT assay, which is very helpful in diagnosing infectious diseases and raising the demand for vaccinations.

Additionally, the market is expanding due to technical developments in ELISpot and FluoroSpot test kits and analyzers. The major factor propelling the regional market's expansion is the substantial research that numerous research institutes do in collaboration with many pharmaceutical companies. The adoption and expansion of the market in the area are anticipated to be fueled by the rapidly developing infrastructure, significant government investments in research and development, and the rising demand for innovative medicinal medications in nations such as the United States and Canada.

Future Market Scenario (2024 □ 2031F)

Factors contributing to the anticipated growth of the ELISpot and FluoroSpot assays market are the increasing prevalence of chronic disorders, the increasing geriatric population, and the increasing demand for personalized medicines. Also, the rising population and sedentary lifestyles are factors that will propel the market growth in the future. As technology advances, we can expect the introduction of advanced technologies. Players in the market are expanding at an unparalleled rate, introducing cost-effective and efficient technologies. For instance, ProImmune Ltd. introduced the B-cell ELISpot assay service in April 2022. A technique for assessing the immune response of B cells, which are essential for the body's defense against infections, immunological modulators, vaccinations, and medicinal medications, is the B cell ELISpot assay. Researchers can measure the number of B cells that produce a specific antibody in response to a certain stimulation to evaluate the effectiveness of vaccines or the potency of medicinal medications.

Key Players Landscape and Outlook

Several companies are expanding their business by planning and adopting new strategies. They are complying with new strategic initiatives for launching new assays, facilitating research and development, and increasing their presence in the market. New product launches, agreements based on contracts, acquisitions and mergers, investments, and partnerships are a few ways through which they are trying to achieve a higher market share.

In June 2022, Becton, Dickinson and Company and CERTEST BIOTEC, S.L worked together to develop a molecular diagnostic test for the virus that causes monkeypox, a rare illness closely linked to the smallpox virus. The partnership seeks to enhance the identification and treatment of cases of monkeypox. The assay will use the Becton, Dickinson, and Company MAXTM open system

reagent suite as part of the cooperation to validate the CerTest VIASURE Monkeypox CE/IVD molecular test on the BD MAXTM System. Users of the BD MAXTM will have access to the assay, which could contribute to our understanding of the disease's global spread.
Laboratory Corporation of America and Xcell Biosciences Inc. collaborated in April 2022 to strengthen and enhance vital laboratory operations, emphasizing cell and gene therapies. Laboratory Corporation of America can enhance its comprehensive suite of CGT capabilities through this arrangement, further supporting several other biotech and pharmaceutical companies.

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