

Lateral Flow Assay Market Forecast to 2028 - COVID-19 Impact and Regional Analysis by Product Type (Kits & Reagents and Lateral Flow Readers), Application (Clinical Testing, Veterinary Diagnostics, Food Safety & Environment Testing, and Drug Development & Quality Testing), Technology (Sandwich Assay, Competitive Assays, and Multiplex Detection Assay), and End User (Hospitals & Clinics, Pharmaceutical & Biotechnology Companies, Diagnostics Laboratories, Homecare, Veterinary Clinics, and Others)

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Abstracts

The lateral flow assay market size was valued at US\$ 8.50 billion in 2022 and is projected to reach US\$ 12.18 billion by 2028; it is estimated to grow at a CAGR 6.7% during 2023–2028. The increasing geriatric population favors the lateral flow assay market growth.

Lateral flow assay (LFA), known as lateral flow immunochromatographic assay, is a simple paper-based device intended for detecting the presence or absence of a target analyte in a liquid sample (matrix) without the need for specialized or costly equipment. The lateral flow assay is used in medical diagnostics, home testing, point-of-care testing, and other laboratory applications. The projected growth of the lateral flow assay market is attributed to the growing use of at-home diagnostic devices based on lateral flow assays and the growing demand for point-of-care testing. However, inconsistent assay results due to procedural limitations hamper the lateral flow assay market growth.

Lateral flow assay-based point-of-care (POC) diagnostic tools are rapid, easy-to-use, and low-cost paper-based procedures, which are specifically perceived to be beneficial in resource-limited settings and industrialized countries. These tests are increasingly replacing prolonged, conventional laboratory methods. No training and complex infrastructures are required to run POC diagnostic tests. Thus, these tests cost less than conventional laboratory diagnostic techniques. POC testing tools are expected to be a crucial revenue pocket in the lateral flow assay market because of their prominent role in combating the burgeoning disease burden. Many companies are engaged in developing innovative lateral flow assay-based POC devices for infectious disease diagnosis, drugs-of-abuse screening, pregnancy (using hCG levels) and ovulation confirmation, and blood protein marker measurement.

In July 2022, Hemex Health, a US-based medical diagnostic device company, and Mylab Discovery Solutions, an Indian startup, joined forces to create diagnostic solutions to transform frontline healthcare. In India, they launched the Gazelle PathoCatch COVID-19 FIA test as a collaborative diagnostic solution for point-of-care (POC) testing.

The rising popularity of POC testing and ongoing developments in lateral flow assay based POC testing fuel the growth of the lateral flow assay market.

Many market players and research institutes operating in the lateral flow assay market are developing advanced technologies to expand their product portfolios and increase their market shares. Rising immunodeficiency disease prevalence, product approvals, and collaborations are among the factors driving the lateral flow assay market size.

A few of the recent developments related to lateral flow assay market are mentioned below:

In March 2023, Roche announced the FDA approval of the Ventana PD-L1 (SP263) assay to identify patients with non-small cell lung cancer, determining if they are eligible for treatment with Libtayo, a PD-1 inhibitor developed by Regeneron.

In December 2022, Roche announced FDA 510(k) clearance for its Elecsys Beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys Phospho-Tau (181P) CSF (pTau181) assays. The assays measure beta-amyloid (1-42) and phospho-tau (181P) concentrations in cerebrospinal fluid of adults (age 55 and above), who are being tested for Alzheimer's disease and other causes of cognitive impairment to generate a

pTau181/Abeta42 ratio value. The assays can detect Alzheimer's pathology in earlier disease stages when changes in the levels of these biomarkers occur.

In June 2021, Thermo Fisher Scientific launched its CE-IVD-marked TaqPath COVID-19 Fast PCR Combo Kit 2.0. The first-generation TaqPath COVID-19 CE-IVD RT-PCR Kit and the TaqPath COVID-19 Combo Kit, using a different assay design, received CE-IVD certification and emergency use authorization, respectively, in March 2020.

In April 2021, Hologic acquired Mobidiag Oy, a privately held French developer of molecular diagnostic tests and instrumentation, for ~US\$ 795 million. Hologic intends to invest in assay development to drive the growth of the Novodiag platform.

Lateral Flow Assay Market, By Product Type-Based Insights

The lateral flow assay market, based on product type, is bifurcated into kits & reagents and lateral flow readers. In 2022, the kits & reagents segment held a larger share of the market. However, the lateral flow reader segment is expected to register a higher CAGR during the forecast period. The Lateral flow devices offer various benefits that allow faster decision-making. The surge in lateral flow devices was witnessed after combining reader technology in the lateral flow devices. Reader technology helps enhance lateral flow device features by storing or producing quantitative data. Moreover, constant advancements in reader technology have made lateral flow devices more flexible, versatile, customizable, and easy to read.

Lateral Flow Assay Market, By Application-Based Insights

The lateral flow assay market, by application, is segmented into clinical testing, veterinary diagnostics, food safety & environment testing, and drug development & quality testing. In 2022, the clinical testing segment held the largest share of the lateral flow assay market. Further, the food safety & environment testing segment is expected to register the fastest CAGR during the forecast period. In food safety testing, lateral flow test (LFT) is used for analyzing the presence of drug residues, pathogens, food additives, and other illegal additives. This test can provide result within 24 hours and offers maximum benefits to the food industry. Increasing demand for quicker testing from food companies is the primary factor promoting the lateral flow assay market growth of this segment.

Lateral Flow Assay Market, By Technology-Based Insights

Based on technology, lateral flow assay market is segmented into sandwich assays, competitive assays, and multiplex detection assays. In 2022, the sandwich assays segment held the largest share of the market. Most commonly used sandwich lateral flow assay is in pregnancy test. This assay technology was also used for detection of COVID-19 cases in point-of-care detection technique. By April 2023, according to World Health Organization (WHO), there have been 764,474,387 confirmed cases of COVID-19. The growing demand for home testing for COVID-19 due to the risk of acquiring other diseases due to COVID-19 is fueling the growth of sandwich lateral flow assay segment. However, the market for the multiplex detection assays segment is expected to grow at the fastest CAGR during the forecast period.

Lateral Flow Assay Market, By End User-Based Insights

Based on End User, the lateral flow assay market is segmented into hospitals & clinics, pharmaceutical & biotechnology companies, diagnostic laboratories, home care, veterinary clinics, and others. In 2022, the hospitals & clinics segment held the largest share of the lateral flow assay market. The others segment is further expected to register the highest CAGR during the projected period. The others segment includes academic & research institutes and research & development centers. Many research institutes are rapidly developing different diagnostic methods.

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