

# **U.S. And Europe Lateral Flow Assay Market Size, Share & Trends Analysis Report Product (Kits & Reagents, Lateral Flow Readers), By Application, By Technique, By Test Type, By End Use, By Country, And Segment Forecasts, 2025 - 2030**

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## **Abstracts**

This report can be delivered to the clients within 1 Business Day

### **U.S. And Europe Lateral Flow Assay Market Growth & Trends**

The U.S. and Europe lateral flow assay market size is anticipated to reach USD 6.97 billion by 2030 and is projected to grow at a CAGR of 5.48% from 2025 to 2030, according to a new report by Grand View Research, Inc. This growth is driven by the increasing decentralization of diagnostic services, rapid adoption of point-of-care testing (POCT), advancements in rapid testing technologies, and the positive shift toward self-testing strategies. In addition, the rising prevalence of infectious diseases and heightened awareness of rapid test kits during the COVID-19 pandemic have created favorable conditions for the lateral flow assay market's expansion.

The integration of digital technologies into lateral flow devices is another pivotal trend. Smartphone-based readers, as well as highly customized stand-alone LFA readers, have allowed users to obtain semi-quantitative or fully quantitative results from traditionally qualitative assays. These technologies not only have the potential to improve diagnostic accuracy but also enable real-time data sharing for epidemiological tracking and disease management. The increasing prevalence of infectious diseases throughout the world is a key driver fueling the expansion of the lateral flow assay market. These diseases necessitate novel diagnostic techniques for efficient treatment to stop the rising mortality rate.

The high prevalence of infectious diseases worldwide has been a major driver for the market growth. These diseases necessitate novel diagnostic techniques for efficient treatment to stop the rising mortality rate. The COVID-19 pandemic, in particular, highlighted the need for rapid and accessible diagnostic tools, leading to a surge in demand for LFAs. Beyond COVID-19, other infectious threats have emerged. For instance, in 2025, a highly pathogenic avian influenza A (H5N1) virus infection resulted in a fatality in Louisiana, USA, despite the use of personal protective equipment that was deemed inadequate. According to the Centers for Disease Control and Prevention (CDC), while the general public faces a low risk, individuals working closely with infected animals—such as farmers, veterinarians, and wildlife facility staff—remain highly vulnerable. In 2024, 67 human cases of avian influenza were reported, with 40 linked to dairy cattle and 23 associated with poultry farms. In response, the UK proactively secured 5 million doses of the H5 vaccine to mitigate potential risks in 2025.

Advancements in LFA technology have significantly improved the sensitivity, specificity, and overall performance of these assays, thereby expanding their applications. In December 2021, Eurofins Technologies introduced the RapidScan ST5-W lateral flow reader, designed for field and in-process testing applications that require qualitative to semi-quantitative test results. Traditionally, commercial LFA test strips utilize the red coloration of gold nanoparticles (GNPs) or colored beads for detection. LFAs have proven highly sensitive in diagnosing diseases like HIV-AIDS, Hepatitis B, and C and assessing immune responses against SARS-CoV-2.

Advanced signal amplification techniques, including silver enhancement and GNP-enzyme conjugation (such as horseradish peroxidase), have significantly improved detection capabilities. Furthermore, integrating electrochemical sensing, Surface-Enhanced Raman Spectroscopy (SERS), fluorescence detection, and nanoparticles have enhanced the specificity of LFAs, allowing for multiplex detection and faster diagnostics. Future advancements, including next-generation chips, DNA amplification, and CRISPR-based technologies, hold the potential to improve LFA performance further. The use of quantum and nanomaterials is also being explored to boost sensitivity.

The convenience and accessibility of home-based testing have led to increased adoption of LFAs among consumers. In September 2024, InBios International Inc., a leading developer of diagnostic tests for emerging infectious diseases, obtained 510(k) clearance from the USFDA for its SCoV-2 Ag Detect Rapid Test. Featuring a patent-pending design, this user-friendly rapid antigen test requires no additional equipment or mixing, can be stored at room temperature, and delivers results in just 20 minutes—

offering a simple and accessible COVID-19 testing solution for home use. Beyond COVID-19, InBios International Inc. has secured a USD 16.5 million project aimed at enhancing the design of its Active Melioidosis Detect Plus (AMD Plus) device. The funding will support performance validation and regulatory approvals, demonstrating the growing investment in LFA-based diagnostics for infectious diseases beyond the pandemic. In December 2024, the USFDA approved the OraQuick HIV Self-Test, a qualitative immunoassay designed to detect antibodies to HIV-1 and HIV-2 in oral fluid samples. Intended for over-the-counter (OTC) use, this test offers individuals a discreet and reliable way to screen for HIV at home, contributing to early diagnosis and timely medical intervention.

## U.S. And Europe Lateral Flow Assay Market Report Highlights

The kits & reagents segment led the market with the largest revenue share of 68.48% in 2024, driven by technological advancements and rising demand for rapid diagnostics. Innovations in assay sensitivity, specificity, and ease of use have significantly contributed to market expansion.

Based on application, the clinical testing segment led the market with the largest revenue share of 77.18% in 2024. This growth is fueled by the increasing prevalence of infectious diseases and chronic conditions, along with the rising demand for rapid diagnostic solutions.

Based on technique, the sandwich assay segment led the market with the largest revenue share of 39.66% in 2024, driven by its accuracy, affordability, and ease of use. These assays are particularly valuable in low-resource healthcare settings, as they do not require trained personnel. Sandwich assays are commonly used to detect larger analytes that contain two epitopes or binding sites.

Based on test type, the lateral flow immunoassay (LFIA) segment led the market with the largest revenue share of 65.10% in 2024, solidifying its position as a widely used platform for rapid diagnostics since its introduction in the mid-1980s. Due to their ease of use, cost efficiency, and quick results, LFIA tests are highly adaptable, allowing for administration by healthcare professionals and patients at home.

Based on end use, the hospitals & clinics segment led the market with the largest revenue share of 35.99% in 2024. As primary diagnostic and treatment centers, hospitals and clinics play a crucial role in driving LFA adoption across the U.S. and Europe.

The U.S. market is experiencing robust growth, driven by continuous product innovation, strategic investments, and strong government support. Advances in LFA technology have significantly enhanced sensitivity and broadened applications, fueling market expansion.

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