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Global Hepatitis C Virus (HCV) Self-Test Kits Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global Hepatitis C Virus (HCV) Self-Test Kits market size is predicted to grow from US$ 2.93 million in 2025 to US$ 15.15 million in 2032; it is expected to grow at a CAGR of 25.3% from 2026 to 2032.

Hepatitis C Self-Test Kits are single-use in vitro diagnostic products designed to enable untrained users to independently collect a specimen, perform an anti-HCV antibody test and interpret the screening result in a private or decentralized setting. Current commercial products are primarily rapid immunochromatographic lateral-flow assays and can be divided by specimen type into oral fluid-based and blood-based HCV self-tests. Oral fluid products emphasize non-invasive sampling and simplified operation, while blood-based products mainly use capillary fingerstick whole blood and typically incorporate a lancet, specimen transfer component, assay buffer and test cassette. Current products generally provide qualitative anti-HCV results within approximately 15–25 minutes without an analytical instrument. Hepatitis C Self-Test Kits are used across home-based self-testing, community-based organizations, harm-reduction services and healthcare-facility-assisted self-testing programs. A reactive result serves as an initial screening indication and is followed by confirmatory testing and linkage to care under the applicable HCV diagnostic pathway. WHO defines HCV self-testing as a process in which individuals collect their own specimen, perform the test and interpret the result, and recommends it as an additional approach to expand HCV testing access.

Key Findings

Oral fluid-based and blood-based products represent the two validated product segments in the current Hepatitis C Self-Test Kits market

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Demand remains program-led, with home, community, harm-reduction and assisted healthcare settings forming the principal application structure

Market Trends

The Hepatitis C Self-Test Kits industry is moving from clinical validation and small-scale pilot programs toward broader public-health implementation. WHO introduced its HCV self-testing recommendation in 2021 and published a dedicated self-testing implementation toolkit in 2025 covering country planning, product selection, registration, procurement, supply-chain management and scale-up, creating a clearer framework for national adoption. Product development is also becoming more diversified. OraQuick establishes the oral-fluid format as a highly simplified non-invasive option, while First Response, ConfiSign and other blood-based products expand competition around fingerstick sampling and lower-cost manufacturing. Existing products generally use rapid immunochromatographic technology and return results within roughly 15–25 minutes. Over the longer term, the market is expected to evolve toward a broader mix of quality-assured products, lower average procurement prices and stronger integration between self-testing, confirmatory diagnosis and treatment referral rather than toward major changes in the underlying assay principle.

Market Dynamics

Drivers

The principal demand driver is the persistent HCV diagnosis gap combined with the need to decentralize testing beyond conventional healthcare facilities. WHO continues to identify substantial numbers of people with HCV who remain unaware of their infection status, while self-testing can reduce dependence on facility-based testing, provide greater privacy and extend screening to populations that are difficult to reach through routine services. WHO prequalification of the first HCV self-test in 2024 and the subsequent implementation toolkit have also strengthened the institutional basis for procurement and adoption in public-health programs.

Restraints

Hepatitis C Self-Test Kits remain screening products rather than stand-alone diagnostic endpoints. Current products detect anti-HCV antibodies and therefore cannot independently determine whether a reactive user has an active current infection; reactive results require confirmatory testing and linkage into the healthcare system. This

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additional diagnostic step limits the ability of self-testing to operate as a completely independent consumer testing pathway. Market expansion is also constrained by product pricing relative to conventional professional HCV rapid tests, uneven national registration status, limited consumer awareness and the project-based nature of many public-health procurement programs.

Opportunities

The largest structural opportunity lies in converting HCV self-testing from localized demonstration programs into routine components of national hepatitis elimination strategies. High-burden and underdiagnosed populations provide a substantial addressable testing pool, particularly where facility-based testing coverage is limited. Community distribution, harm-reduction services, home delivery and assisted self-testing can improve access among people who inject drugs and other underserved populations. Wider entry of blood-based products from established rapid-diagnostic manufacturers can also expand procurement options and reduce unit costs, allowing programs to screen larger populations within fixed healthcare budgets. WHO's scale-up framework provides countries with standardized guidance on product selection, registration and procurement, supporting this transition.

Challenges

The key industry challenge is ensuring that rapid expansion does not weaken quality assurance, correct test use or linkage to confirmatory diagnosis. HCV self-testing requires clear instructions, reliable specimen collection and accurate user interpretation under diverse literacy, language and healthcare settings. Regulatory requirements remain heterogeneous across countries, while WHO-prequalified HCV self-test availability is still highly limited; OraQuick Hepatitis C Self-Test remains the clearly listed HCV self-test in the current WHO prequalification database. Public-health purchasing can also be volatile because large orders may depend on donor funding, national pilots and periodic procurement cycles, making annual supplier revenue and shipment volumes less predictable than in mature retail self-testing categories.

Industry Chain Analysis

The upstream supply chain for Hepatitis C Self-Test Kits consists primarily of recombinant HCV antigens and related biological reagents, colloidal-gold conjugation materials, nitrocellulose membranes, absorbent and sample pads, plastic test housings, assay buffers, fingerstick lancets for blood-based products and consumer-oriented packaging materials. Midstream manufacturers perform antigen selection and

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conjugation, lateral-flow strip production, cassette assembly, buffer filling, kit integration, quality control, stability validation and regulatory registration. Product design at this stage is particularly important because self-tests must convert laboratory and professional rapid-test chemistry into procedures that can be reliably performed by untrained users. OraQuick uses oral fluid with an immunochromatographic lateral-flow format, while First Response and ConfiSign use blood-based rapid immunochromatographic formats.

Downstream distribution is led by public-health procurement programs, community organizations, harm-reduction services, healthcare facilities supporting self-testing, pharmacies and other authorized consumer channels. Value creation is increasingly shifting from basic test-strip manufacturing toward product usability, regulatory qualification, quality assurance, user instructions, distribution capability and post-test linkage systems. Manufacturing capacity itself is unlikely to represent the principal industry bottleneck: established RDT producers operate platforms substantially larger than current HCV self-test demand, including InTec, which reports more than 500 million annual test-person equivalents across its broader diagnostic portfolio. Consequently, regulatory access, program funding, procurement qualification and demand creation currently have greater influence on market expansion than physical test-production capacity.

Segment Insights

By product type, the Hepatitis C Self-Test Kits market is divided into Oral Fluid-Based HCV Self-Test and Blood-Based HCV Self-Test, with Other remaining a residual category. The oral-fluid segment is represented most prominently by OraQuick Hepatitis C Self-Test, which uses oral fluid and became the first WHO-prequalified HCV self-test in July 2024. This format offers an important usability advantage because it eliminates fingerstick blood collection and simplifies self-administration, giving it a strong position in large public-health and community programs where ease of use is critical.

Blood-based HCV self-tests are developing into the broader supplier segment. First Response uses whole blood and provides results within 15–20 minutes, while ConfiSign uses approximately 10 ?L of capillary fingerstick whole blood with a 15–25 minute reading window; Boson's product is also positioned for private at-home antibody testing using blood-derived specimens. The increasing number of blood-based suppliers is expected to intensify procurement competition and support declining average selling prices. The segment therefore offers meaningful expansion potential in price-sensitive public-health markets even though oral-fluid testing currently has stronger visibility in

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international quality-assured procurement.

Downstream Market Opportunities

Downstream opportunities are concentrated in settings where conventional facility testing has difficulty reaching sufficient screening coverage. Home-Based Self-Testing provides privacy and convenience for individuals who may not proactively visit healthcare facilities; Community-Based Organization Self-Testing supports targeted outreach to populations with lower engagement in routine healthcare; Harm Reduction Site Self-Testing provides a particularly relevant pathway for people who inject drugs; and Healthcare Facility Assisted Self-Testing enables users to retain control of the testing process while receiving operational support when required. These applications are complementary rather than mutually substitutive from a service-delivery perspective, allowing national programs to combine multiple distribution models according to local epidemiology and healthcare infrastructure. WHO's implementation framework explicitly supports adaptation of self-testing delivery models across health and community systems.

Regional Insights

The Hepatitis C Self-Test Kits market remains geographically fragmented and program-driven rather than centered on a mature global retail market. Africa and selected Asian markets have become important implementation and procurement regions because HCV self-testing can complement decentralized screening programs and reach populations that remain outside conventional testing systems. WHO notes that national-level HCV self-testing implementation projects have demonstrated feasibility and acceptability, supporting broader adoption in low- and middle-income markets. These regions therefore represent significant medium-term volume opportunities, although demand can fluctuate with national program design and external healthcare funding.

The supply side has a different geographic structure. The United States is important through OraSure and its WHO-prequalified oral-fluid platform, while China, India and South Korea have developed an increasingly relevant manufacturing base for rapid blood-based and self-testing products. Europe, Japan and other developed markets remain strategically relevant for future regulatory and consumer-channel expansion, but the current industry structure is still more strongly influenced by international public-health procurement than by mass-market pharmacy retailing. This geographic divergence between manufacturing centers and implementation markets is likely to remain a defining feature during the early commercialization stage.

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Competitive Landscape Analysis

The competitive landscape remains concentrated among a small number of validated manufacturers rather than a broad pool of conventional HCV diagnostic companies. The confirmed core supplier group consists of OraSure Technologies, Inc., InTec PRODUCTS, INC., Premier Medical Corporation Private Limited, GenBody Inc. and Xiamen Boson Biotech Co., Ltd. OraSure has the strongest current international quality-assurance position because OraQuick Hepatitis C Self-Test became the first WHO-prequalified HCV self-test and remains the clearly listed HCV self-test in the WHO prequalification database. Premier Medical and GenBody strengthen competition in blood-based self-testing, with First Response explicitly designed for lay users and approved by CDSCO for export only, while ConfiSign is designed for untrained users and manufactured under a Korean MFDS export-only manufacturing approval. Boson contributes an additional at-home blood-based product, while InTec adds large-scale RDT manufacturing capability to the supplier base. Competitive differentiation therefore currently depends less on fundamentally different assay technologies and more on regulatory qualification, specimen convenience, product usability, manufacturing cost, public-health procurement access and the ability to support linkage-to-care programs.

Report Scope

LPI (LP Information)' newest research report, the “Hepatitis C Virus (HCV) Self-Test Kits Industry Forecast” looks at past sales and reviews total world Hepatitis C Virus (HCV) Self-Test Kits sales in 2025, providing a comprehensive analysis by region and market sector of projected Hepatitis C Virus (HCV) Self-Test Kits sales for 2026 through 2032. With Hepatitis C Virus (HCV) Self-Test Kits sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world Hepatitis C Virus (HCV) Self-Test Kits industry.

This Insight Report provides a comprehensive analysis of the global Hepatitis C Virus (HCV) Self-Test Kits landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Hepatitis C Virus (HCV) Self-Test Kits portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms’ unique position in an accelerating global Hepatitis C Virus (HCV) Self-Test Kits market.

This Insight Report evaluates the key market trends, drivers, and affecting factors

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shaping the global outlook for Hepatitis C Virus (HCV) Self-Test Kits and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Hepatitis C Virus (HCV) Self-Test Kits.

This report presents a comprehensive overview, market shares, and growth opportunities of Hepatitis C Virus (HCV) Self-Test Kits market by product type, application, key players and key regions and countries.

Market Segmentation

Segmentation by Type:

Oral Fluid-Based HCV Self-Test

Blood-Based HCV Self-Test

Other

Segmentation by Regulatory Status:

WHO-Prequalified HCV Self-Test

Export-Approved HCV Self-Test

Other

Segmentation by Application:

Home-Based Self-Testing

Community-Based Organization Self-Testing

Harm Reduction Site Self-Testing

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Healthcare Facility Assisted Self-Testing

Other

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

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Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

OraSure Technologies, Inc.

Premier Medical Corporation Private Limited

GenBody Inc.

InTec PRODUCTS, INC.

Xiamen Boson Biotech Co., Ltd.

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