

# All about the first self-test for Hepatitis C virus approved by WHO

The World Health Organisation (WHO) has approved the first self-test for Hepatitis C, aiming to make testing more accessible and eliminate the disease.



*The new self-test, called the OraQuick HCV self-test, has been prequalified by the WHO.*

## In Short

- WHO has approved the OraQuick HCV self-test, which can diagnose Hepatitis C in 20 minutes
- This self-test is expected to increase access to Hepatitis C testing and treatment
- It detects Hepatitis C virus antibodies in fingerstick and venipuncture

The World Health Organisation (WHO) has approved the first self-test for Hepatitis C (HCV), aiming to make testing and diagnosis more accessible and help eliminate the disease.

Every day, [3,500 people die from viral hepatitis](#). Of the 50 million people with Hepatitis C, only 36% were diagnosed, and 20% had received treatment by the end of 2022.

The new self-test, called the OraQuick HCV self-test, is made by OraSure Technologies and has been prequalified.

The OraQuick HCV test was previously approved by the US Foods and Drugs Administration (FDA) for detecting HCV antibodies in fingerstick and venipuncture (blood from veins) whole blood.

"Our simple platform enables healthcare providers to deliver an accurate diagnosis in 20 minutes," according to the OraSure Technologies website.

The product builds on the OraQuick HCV Rapid Antibody Test, which has been used by healthcare professionals since 2017. This self-test is designed for individuals to use on their own and includes everything needed to perform the test.

In 2021, WHO recommended Hepatitis C self-testing (HCVST) to complement existing testing services.

This was based on evidence that self-testing increases access to services, especially for those who might not seek testing otherwise.

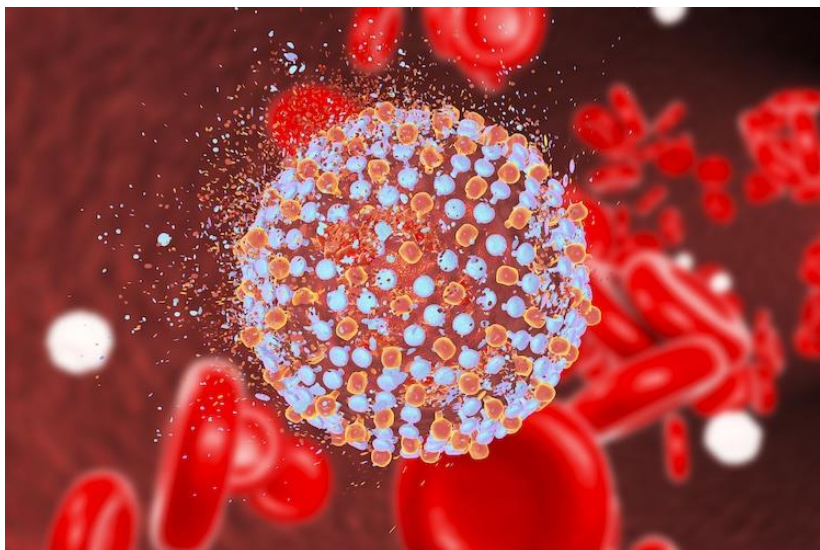
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National projects supported by Unitaaid have shown that self-testing is well-received, practical, and empowers people by giving them more control and access to care without stigma.

Dr Meg Doherty, WHO Director for the Department of Global HIV, Hepatitis, and STI Programmes, said, "Adding this product to the WHO pre-qualification list offers a safe and effective way to expand HCV testing and treatment, ensuring more people get the diagnosis and treatment they need, helping us move towards eliminating HCV."

WHO's pre-qualification (PQ) program for in vitro diagnostics (IVDs) evaluates tests, [including those for HCV antibodies, against quality, safety, and performance standards.](#)

This program supports countries in achieving high-quality diagnosis and treatment.

Dr. Rogério Gaspar, WHO Director for the Department of Regulation and Prequalification, said, "The availability of a WHO prequalified HCV self-test gives low- and middle-income countries access to safe and affordable self-testing options, crucial for diagnosing 90% of all people with HCV."

WHO will continue to assess more HCV self-tests, support evidence-based implementation, and work with communities to ensure these options are available globally.

Prequalification of medicines is a service provided by WHO to assess the quality, safety and efficacy of medicinal products.

**News Source:**

<https://www.indiatoday.in/health/story/all-about-the-first-self-test-for-hepatitis-c-virus-approved-by-who-2568679-2024-07-18>