Hepatitis C self-testing

WHAT IS A SELF-TEST?

A self-test is conducted in a private location like one's home, either alone or with a friend, and can produce results within 15 to 20 minutes. Kits for self-testing are increasingly available, and more and more people are using them. Commonly used self-testing kits are available for diabetes, pregnancy, sexually transmitted infections, HIV, and, more recently, for COVID-19. These kits use samples such as finger prick blood, urine, saliva, nasal swabs, etc. There are also self-testing kits for hepatitis C virus (HCV), which are currently in use, but for research purposes only.

WHAT IS HEPATITIS C SELF-TESTING?

Hepatitis C self-testing, or HCVST, is a process by which a person collects his or her own sample, such as blood or oral fluid, to perform a rapid test to check for the presence of hepatitis C antibodies, getting results within 20 minutes.

Currently, there are no stringent regulatory authority (SRA)-approved HCVST kits available. However, research is being done to determine whether some of the SRA- or national regulatory-approved, professional-use, high performance hepatitis C rapid diagnostic test kits can be adapted for HCVST use.

Given that there is some similarity between HIV self-testing (HIVST) and HCVST, 40 countries have started adopting HIVST for HCV in 2021.15% of countries in the Western Pacific region have started adopting HIVST for HCV, while the South-East Asia region have yet to adopt HIVST. However, with the extensive evidence available for HIVST, it is likely that HCVST has the potential to increase uptake of hepatitis C testing.

WHAT DOES WHO SAY ABOUT HEPATITIS C SELF-TESTING?

Of the estimated 58 million people living with chronic HCV in 2019, the World Health Organization (WHO) suggests that only 21% were diagnosed, of which only 13% received treatment. Several factors, including poor access to testing services, stigma and discrimination, contribute to such a low uptake of HCV testing services. In a similar trend, the South-East Asia region has a diagnosis rate of only 7%, of which 5% received treatment. The Western Pacific region has diagnosed 25%, of which 10% received treatment.

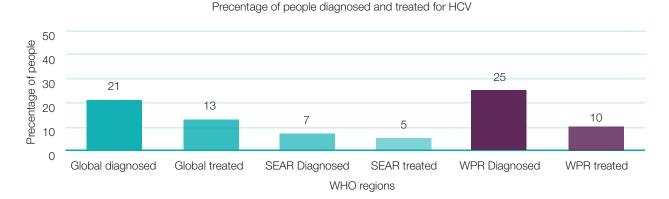
In the new guidelines "Recommendations and guidance on hepatitis C virus self-testing", which were published in July 2021, WHO recommended the use of HCVST as a supplementary methodology to HCV testing services. Based on the evidence, experience and lessons learnt from HIVST, this new recommendation allows countries to make decisions about implementation and scale-up of HCVST to address the current low uptake of testing services and achieve global elimination targets by 2030.

BRAND	SAMPLE USED	MANUFACTURER
CareStart EZ HCV®	Finger prick blood	AccessBio, Inc., Somerset, USA
First Response®	Finger prick blood	Premier Medical Corporation Pvt Ltd., Gujarat, India
OraQuick®	Oral fluid	OraSure, Bethlehem, PA, USA
SD Bioline HCV®	Finger prick blood	Abbott Rapid Diagnostics (Pty) Ltd., Jena, Germany

Figure 1: Some brands currently being studied for HCVST

WHY IS HEPATITIS C SELF-TESTING IMPORTANT?

HCVST is an option that provides private and confidential results for those who may prefer self-care options. Fear of stigma, discrimination and social exclusion contribute to people not accessing facility-based testing for hepatitis C, so HCVST offers a solution to testing and treatment, if needed. However, it is important that any positive result of HCVST be followed by appropriate linkages to further services, including confirmatory RNA testing and treatment.



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WHO RECOMMENDATION ON HEPATITIS C VIRUS SELF-TESTING (HCVST)

HCVST self-testing should be offered as an additional approach to HCV testing services (strong recommendation, moderate-certainty evidence).

Remarks

- HCVST needs to be followed by linkage to appropriate post-test services, including confirmation of viraemic infection, treatment, care and referral services, according to national standards.
- It is desirable to adapt HCVST service delivery and support options to the national and local context, which
 includes community preferences.
- Communities, including networks of key and vulnerable populations and peer-led organisations, need to be meaningfully and effectively engaged in developing, adapting, implementing and monitoring HCVST programmes.

WHAT DO HIGH-RISK GROUPS THINK OF HCVST?

Various studies were undertaken to check the usability and acceptability of the HCVST kits in different countries, including India, Indonesia, Malaysia, and Vietnam. High-risk groups like people living with HIV, people who inject drugs, men who have sex with men, female sex workers, healthcare workers and the general population participated in these studies. Most of the study participants thought that HCVST should be distributed in ways that reduce stigma to have a safe way to increase early diagnosis and access to HCV treatment. Most of the participants in the studies found the HCVST kits were easy to use, highly acceptable and would recommend their use to friends and family.

WHAT CAN WE DO TO PROMOTE HCVST IN OUR OWN SETTINGS?

Community and advocacy groups have played a major role in enabling access to various services both for HIV and HCV. The same role is now needed to promote and ensure access to HCVST. Some of the actions needed for this are:

- 1. Increased understanding of HCVST and their benefits for high-risk groups;
- 2. Highlighting the need for HCVST to be used as an additional testing approach in national HCV management programmes;
- 3. Developing and adapting strategies for implementing HCVST based on local context;
- 4. Advocating to enable fast track approval of HCVST kits by national regulatory bodies;
- 5. Advocating to enact or update national policies that are supportive of HCVST, with clear pathways for referral mechanisms, chronic infection confirmation testing, care and treatment services.

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