

The World Health Organization (WHO) has announced a significant step forward in the fight against Hepatitis C with the prequalification of the first self-test for the virus. This development is expected to play a critical role in expanding access to testing and diagnosis, ultimately accelerating global efforts to eliminate Hepatitis C.

The self-test, called OraQuick HCV, is manufactured by OraSure Technologies and builds upon their existing WHO-prequalified rapid antibody test used by healthcare professionals. Designed for lay users, the OraQuick HCV self-test provides individuals with a convenient and private way to check for Hepatitis C infection at home.

“Every day, thousands of lives are lost to viral hepatitis,” says Dr. Meg Doherty, Director of WHO’s Department of Global HIV, Hepatitis and STI Programmes. “This self-test offers a safe and effective way to increase access to testing and treatment, ensuring more people receive the care they need.”

WHO’s prequalification program rigorously evaluates in vitro diagnostics, including those for Hepatitis C. This process ensures tests meet strict quality, safety, and performance standards, providing countries with confidence in their use.

“The availability of a WHO-prequalified self-test is particularly important for low- and middle-income countries,” says Dr. Rogério Gaspar, Director of WHO’s Department of Regulation and Prequalification. “It provides them with access to safe and affordable testing options, a crucial step towards diagnosing 90% of people with Hepatitis C.”

With the prequalification of this first self-test, WHO remains committed to evaluating additional tests, supporting evidence-based implementation strategies, and working with communities to expand access to testing options globally. This collaborative effort holds immense promise for achieving the goal of eliminating Hepatitis C worldwide.