



OraSure Technologies

Diagnosing the Undiagnosed

OraQuick® HCV Rapid Antibody Test

- Rapid, point-of-care testing with lab-accurate results
- >98% accuracy with oral fluid, >99% with blood
- Multiple specimen collection types, including oral fluid

The only rapid test that meets most major international regulatory requirements:

**FIRST
AND
ONLY**

- WHO prequalified
- FDA approved¹
- Health Canada approved²
- CE-marked



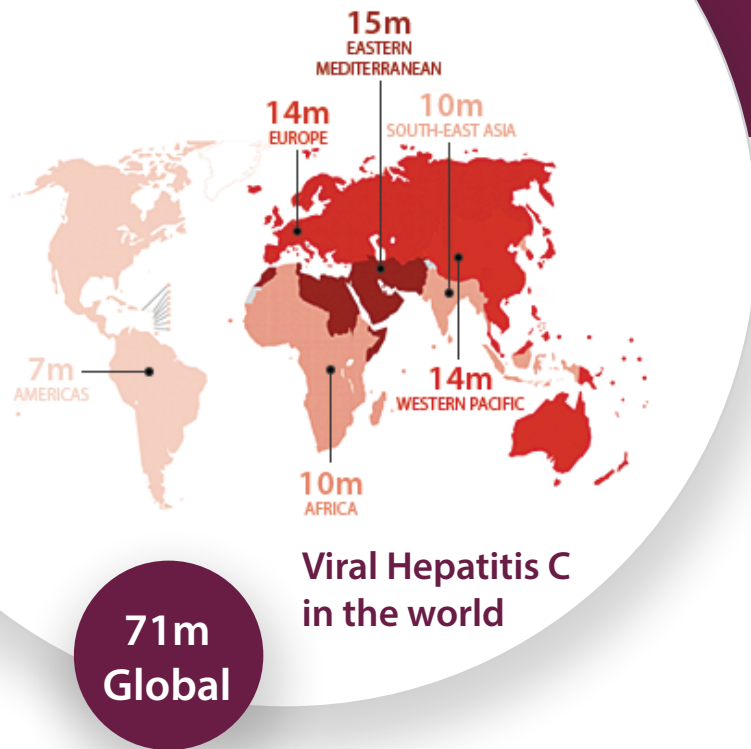
OraQuick, the rapid oral fluid test that helps diagnose the undiagnosed.

OraQuick® Rapid Antibody Test
HCV



Linking Hard to Reach Populations to Care

Why Screen for Hepatitis C?



Hepatitis C is a global epidemic

1.34 million deaths
per year from hepatitis³

71 million people
chronically infected with HCV globally³

1.75 million new infections
per year³

22% increase in deaths
due to hepatitis since 2010⁴

Untreated viral hepatitis can lead to death by cirrhosis and hepatocellular carcinoma

CURE HEPATITIS C in as little as 8 weeks with new treatments³

Cure rates up to **99%**

Over **1 million**
people treated
every year

5.5 million
people treated
for Hepatitis C

Treatment is cost-effective and a course of treatment can be as little as \$200

194 Member states of **WHO**
committed to eliminating viral hepatitis as a public health threat by **2030**

The world is focusing on elimination

WHO has set a goal of eliminating viral hepatitis by 2030 by:

- Reducing new infections by 90%
- Reducing mortality by 65%

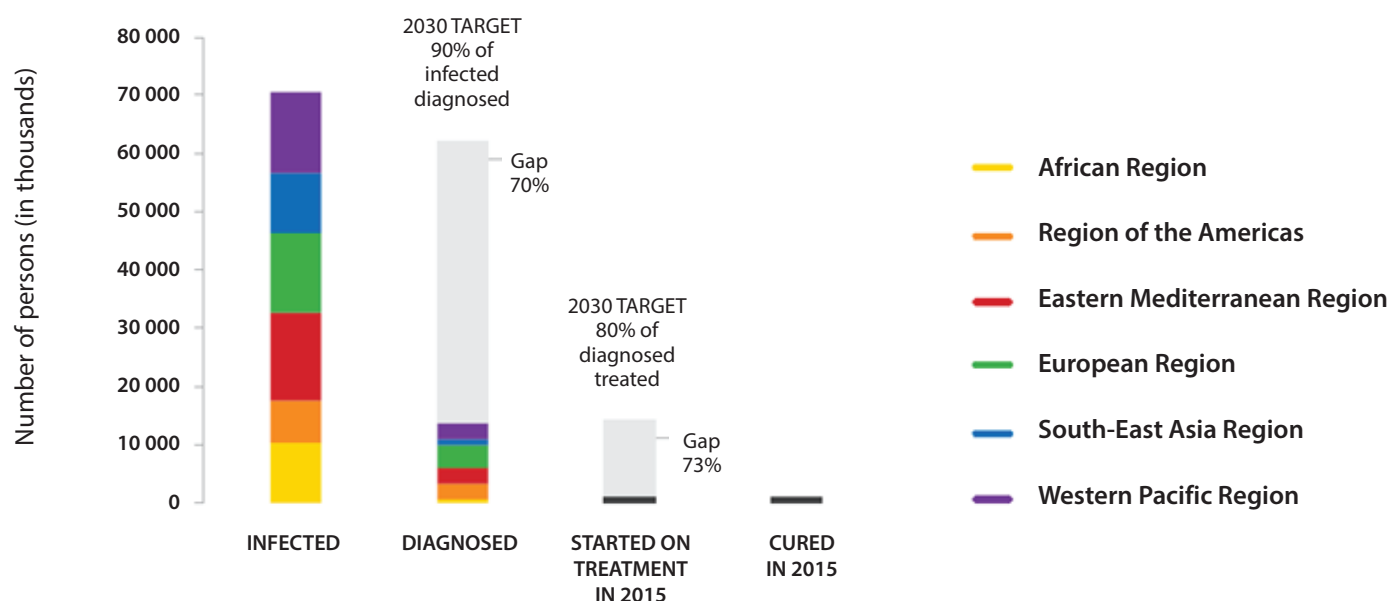
43 countries have developed national elimination plans and 36 additional countries are currently developing elimination plans.

Linking countries to eliminate viral hepatitis

Why utilize the OraQuick® HCV Rapid Antibody Test?

Traditional testing methods are not identifying chronically infected patients. Only 20% of chronic HCV infections have been diagnosed.³

Populations most at risk are the most in need of accurate, oral rapid point-of-care assays.



Substance users – Unsafe healthcare procedures and injection drug use were the leading causes of new HCV infections, accounting for most of the 1.75 million new infections

Low-resource settings – Low- and middle-income countries account for the largest proportion of persons living with HCV (72%), yet access to testing and treatment is more limited in these countries

Rapid testing has several advantages

Easy to perform

Does not require expensive equipment or trained medical personnel

Immediate results

Better accessibility and flexibility in various settings

Oral fluid rapid testing has even more benefits

Does not require venipuncture or fingerstick

Patients prefer oral fluid to venipuncture or fingerstick

Increased testing acceptance due to preference for oral fluid collection⁵

Protects medical personnel from undesirable biohazards⁶

OraQuick HCV Rapid Antibody test is currently being used as the primary outreach tool in several elimination programs

OraQuick® Rapid Antibody Test
HCV

Clinically proven



Easy-to-use



Patient friendly



Linking patients to care



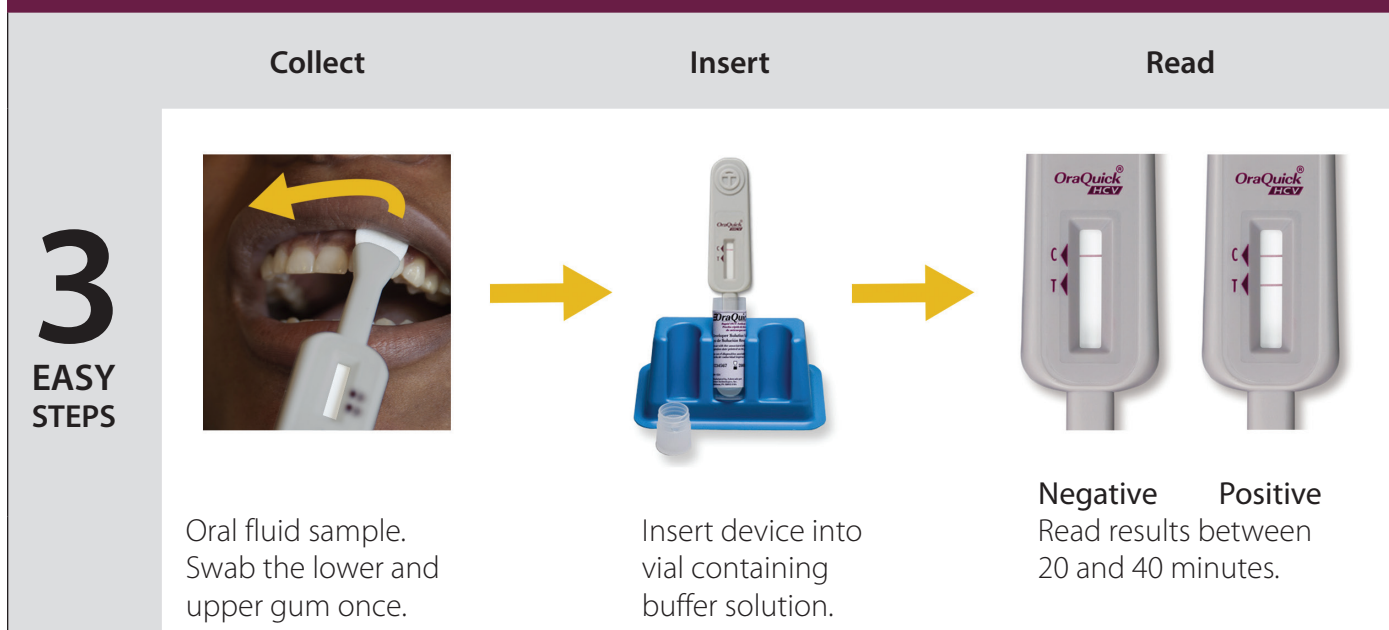
Flexible



ACCURATE. Reliable result with >98% accuracy⁷

Sample	Sensitivity	Specificity
Oral Fluid	98,1% (95%CI: 96,9-99,0)	99,6% (95%CI: 99,2-99,9)
Fingerstick Blood	99,7% (95%CI: 99,0-100,0)	99,9% (95%CI: 99,6-100,0)
Venous Blood	99,7% (95%CI: 99,0-100,0)	99,9% (95%CI: 99,5-100,0)
Plasma	99,9% (95%CI: 99,3-100,0)	99,9% (95%CI: 99,5-100,0)
Serum	99,9% (95%CI: 99,3-100,0)	99,9% (95%CI: 99,6-100,0)

SIMPLE, EASY 3-STEP PROCEDURE that requires less than 2 minutes of hands-on time



FAST. Test and result delivery in 20 minutes for immediate linkage to care

The versatile testing platform is ideally suited for both clinical and non-clinical settings, including: hospitals, clinics, pharmacies, villages and rural settings.

1 Oral fluid is not approved by US FDA.

2 Oral fluid is not licensed by Health Canada.

3 WHO, Global Hepatitis Report, 2017.

4 WHO. Viral hepatitis: a hidden killer gains visibility, 2017.

5 Drobnik, Ann et al. "Public Health Implications of Rapid Hepatitis C Screening With an Oral Swab for Community-Based Organizations Serving High-Risk Populations." *American Journal of Public Health* 101.11 (2011): 2151–2155. PMC. Web. 7 July 2017. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222414/>

6 WHO. Hepatitis C FAQs for Health Professionals, 2017.

7 Performance characteristics found in CE marked IFU.