

Xpert®
HCV VL
Fingerstick



Point-of-Care Molecular Testing

Xpert® HCV VL Fingerstick

Hepatitis C Testing and Linkage to Care

CE **IVD** *In Vitro* Diagnostic Medical Device
Not available in all countries. Not available in the United States.

 **Cepheid®**
A better way.



The Xpert® HCV VL Fingerstick test is an exciting new tool which simplifies HCV testing so that patients can receive their results on-site in less than an hour in a single visit. This reduces waiting times for results and offers the opportunity to enhance linkage to care and initiate HCV treatment on the same day. This may be particularly useful for remote/regional settings and among people who inject drugs.”

Associate Professor Jason Grebely, BSc PhD
The Kirby Institute, UNSW Sydney, Australia



The Goal

Elimination of Hepatitis C by 2030

Viral hepatitis is one of the leading causes of death globally with 1.34 million deaths per year, as many as HIV/AIDS, tuberculosis or malaria. Both hepatitis B and C viruses cause 80% of liver cancer cases in the world.¹

The WHO global health sector strategy to eliminate Viral Hepatitis C as a major public health threat by 2030 identifies the key role of diagnostics and linkage to care.²

- Individuals at highest risk of transmitting HCV, such as people who inject drugs, prisoners, and men who have sex with men, have poor access to testing and therefore treatment.²
- Complicated multi-step diagnostic pathways based on antibody screening and RNA confirmation take time and represent barriers that discourage at risk populations from testing.^{3,4,5}



The Need

Simplification of the diagnostic pathway to improve linkage to care

- Until now, confirmation of a positive antibody-based test requires venepuncture, preparation and transport of blood specimens, laboratory expertise, and days/weeks to obtain results.⁴
- A final diagnosis of active HCV infection may require up to 5 visits.³
- A simple one-step pathway, with a fast RNA diagnostic at the point of care, may have the potential to simplify testing algorithms, increase diagnosis rates, and lead to increased linkage to care.



The Solution

Xpert HCV VL Fingerstick on the GeneXpert® System

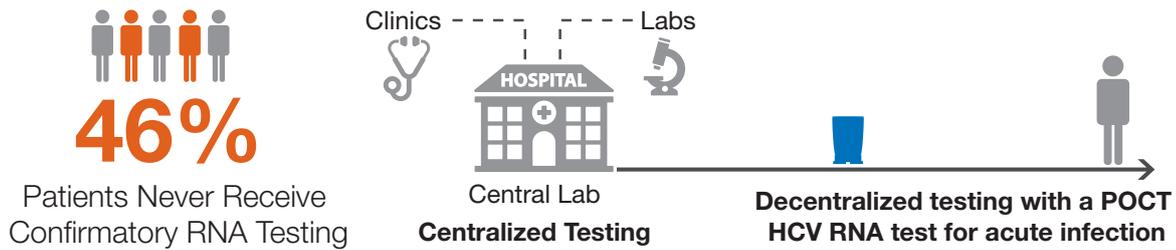
- Collect a drop of blood via fingerstick, transfer the blood to a test cartridge and run the test.
- Fast diagnosis of HCV RNA from capillary whole blood and venous blood samples
- Flexible and portable system, thanks to a cartridge-based design.
- Quantitative RNA results available in less than 1 hour at the point of care.



The Impact

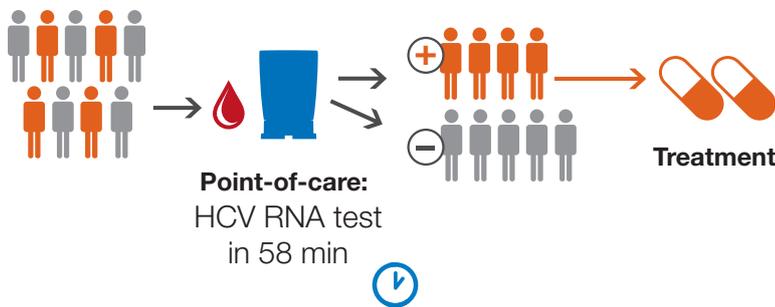
Xpert HCV VL Fingerstick enables a simplified approach to testing.

The Need for Molecular Test at POC



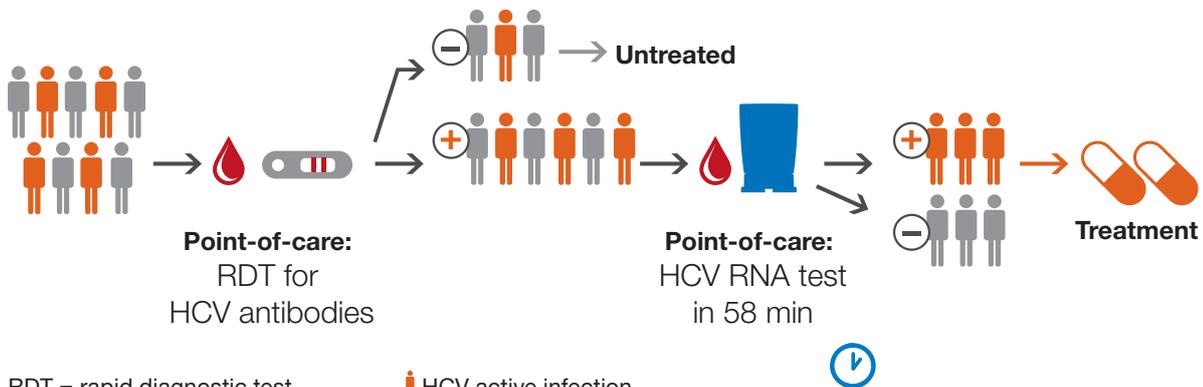
One-Step Diagnosis Strategy

Direct test for HCV RNA and near patient testing could replace screening* based on anti- HCV antibody testing by direct identification of viremic patients.⁶



Two-Step Diagnosis Strategy

Ensure HCV antibody positive patients receive reflex testing for HCV RNA.



RDT = rapid diagnostic test
POC = point of care

HCV active infection
 HCV negative

* Not available in the United States. Not intended for the distribution in the United States.



Workflow

3 Easy Steps

Total hands-on time: <1 minute

1

Collect 100µl blood in the Minivette provided



2

Transfer sample to the cartridge



3

Insert cartridge in the system and start the test



➤ Xpert® HCV VL Fingerstick is an *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for the detection and quantification of Hepatitis C Virus (HCV) RNA in human venous and capillary fingerstick EDTA whole blood from patients with a suspicion of HCV infection, with results delivered in 58 minutes.

CATALOG NUMBER

Xpert HCV VL Fingerstick (10 tests)GXHCV-FS-CE-10

COLLECTION DEVICES (NOT INCLUDED IN KIT):

Sarstedt Minivette® POCT 100 µlMinivette100E-100

References:

1. Global Summary Report- World Hepatitis Day 2017- World Hepatitis Alliance.
2. WHO Global health sector strategy on viral hepatitis 2016-2021. June 2016. <http://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en/>
3. Grebely et al. Hepatitis C point-of-care diagnostics: in search of a single visit diagnosis. Expert Rev Mol Diagn. 2017 Dec;17(12):1109-1115. <https://www.ncbi.nlm.nih.gov/pubmed/29088981>
4. Cooper. Rapid HCV RNA testing: removing the final obstacle to elimination. Lancet Gastroenterol Hepatol. 2017 Jul;2(7):468-469. <https://www.ncbi.nlm.nih.gov/pubmed/28442272>
5. Grebely et al. Evaluation of the Xpert HCV Viral Load point-of-care assay from venepuncture-collected and finger-stick capillary whole-blood samples: a cohort study. Lancet Gastroenterol Hepatol. 2017 Jul;2(7):514-520. <https://www.ncbi.nlm.nih.gov/pubmed/28442271>
6. European association for the study of liver. EASL recommendations on Treatment of Hepatitis C 2018. J Hepatol (2018). <https://doi.org/10.1016/j.jhep.2018.03.026>

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