Xpert® HCV

Point-of-care Hepatitis C RNA Test that Enables Same Day Linkage to Care



The Need

- Underdiagnosis of HCV remains one of the most significant barriers to HCV elimination and public health with only 49%– 55% of people with chronic HCV disease aware of their infection status.[1]
- A diagnostic algorithm for HCV infection that requires multiple tests and multiple clinical appointments results in patients being lost before being treated.[2]
- Simplifying the diagnostic pathway can shorten time to treatment, reduce loss to follow up, and prevent the risk of onward transmission.[2]
- Tests that detect active HCV infection, performed in CLIA waived settings have the potential to reach more people and improve overall diagnosis and linkage to care rates.[1]

The Solution

- Xpert HCV is a CLIA waived test that can be performed using a fingerstick capillary whole blood sample in point of care settings. The test can be used to determine the HCV infection status of individuals at risk of HCV with or without antibodies to HCV, and can therefore be utilized as part of a one-step testing algorithm for active HCV infection.
- Xpert HCV can be used as part of a "test and treat" model of care, potentially saving time between initial evaluation and treatment initiation, retaining more patients in care, and has the ability to increase the number of infections cured.

The Impact

- **Simplifies HCV diagnosis:** Xpert HCV detects viral RNA and does not require antibody testing, enabling a one-step testing algorithm for detection, speeding up the time to treatment and reducing the number of patients lost to follow up[3]
- **Improves access to testing for those at highest risk:** HCV RNA point-of-care testing can be delivered in settings to reach and diagnose individuals at highest risk of infection[3]
- **Increases diagnosis and linkage to care:** same day results can increase uptake of treatment, reduce risk of transmission and prevent loss to follow up

1 Page and Feinberg. What Hepatitis C Virus (HCV) Diagnostic Tools Are Needed to Advance Diagnosis of Current HCV Infection in Outreach Settings and in a Nonclinical Setting? JID 2024, https://doi.org/10.1093/infdis/jiad269

2 Applegate TL, Fajardo E, Sacks JA. Hepatitis C Virus Diagnosis and the Holy Grail. Infect Dis Clin North Am. 2018;32(2):425-445. doi:10.1016/j.idc.2018.02.010

3 WHO, Updated Recommendations on Simplified Service Delivery and Diagnostics for Hepatitis C Infection Policy Brief 2022. https://iris.who.int/bitstream/handle/10665/357086/9789240052697-eng.pdf?sequence=1

Xpert® HCV

Product Reference Sheet — FDA CLIA waived

Test Reagent Kit	Xpert HCV
Catalog Number	GXHCV -10
Technology	Reverse Transcription PCR (Real-Time Reverse Transcription PCR)
Targets	HCV RNA genotypes 1–6
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Collection	K2 EDTA Microtainer
Sample Type	Fingerstick capillary whole blood (collected in K2 EDTA-containing capillary collection tubes)
Sample Extraction	Automated/Integrated
Precision Pipetting	Not Required
TAT	41–60 minutes with EAT for detected results*
Probe Check Control (PCC)	✓
Sample Volume Adequacy (SVA)	✓
Sample Stability	K2 EDTA capillary whole blood may be stored in the Microtainer at 2–30 °C for up to 4 hours
Limit of Detection	LOD WHO reference material: 35 IU/mL genotype 1a, 136 IU/mL genotype 5 (WHO 6th International Standard)^
Kit Storage	2–28 °C
Commercial Controls	Refer to Instructions for Use or Contact Cepheid Technical Support

* Early Assay Termination is the earliest time to result for detected results.
^ For other genotypes please refer to the Xpert HCV package insert.

US-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries.

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