Cepheid®
A better way.

Highly Sensitive Results for Effective Treatment

Xpert® HCV Viral Load

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

“Cepheid’s Xpert® HCV Viral Load test delivers results in hours rather than days. It is a very sensitive test for confirmation of infection and monitoring of HCV, and will assist in better patient management.”

Pr. Jean-Michel Pawlotsky M.D., Ph.D.
Professor of Medicine at the University of Paris-Est

Director of the National Reference Center for Viral Hepatitis B, C and Delta

Director of the Department of Virology at the Henri Mondor University Hospital in Créteil, France

Director of the Department of Molecular Virology and Immunology at the Institut Mondor de Recherche Biomédicale

The Need

An estimated 185 million people, 3% of the world’s population, have been infected with HCV.[1] An estimated 399,000 people died from HCV in 2016.[2]

The primary objective of anti-HCV treatment is the sustained virologic response (SVR), defined as undetectable HCV RNA by a sensitive test 12 or 24 weeks after the end of treatment.[3] With increasing numbers of patients achieving SVR following treatment, eradication of HCV is being discussed for the first time.[4]

The need for a fast HCV viral load test with flexibility to adapt to any throughput requirements and random access for urgent samples is greater than ever.

An ultrasensitive, easy to use HCV viral load test with the flexibility to adapt to any throughput is critical as a companion test for newly developed drug regimens.

The Solution

Xpert HCV Viral Load is a quantitative test that provides on-demand molecular testing for diagnosis* and monitoring of HCV.

Based on the GeneXpert® technology, Xpert HCV Viral Load utilises automated reverse transcriptase polymerase chain reaction (RT-PCR) using fluorescence to detect and quantify RNA.

Xpert HCV Viral Load quantifies HCV genotypes 1–6 over the range of 10 to 100,000,000 IU/mL.

Redefining Simple

Sensitive[5]
- LOD of 4.0 IU/mL in EDTA plasma (95% CI 2.8–5.2)^
- LOD of 6.1 IU/mL in serum (95% CI 4.2–7.9)^

Easy
- Minimal hands-on time
- Run daily or on-demand
- No daily maintenance or liquid waste management

Flexible
- 105 minutes run time with a viral load trend report#
- Provide timely results for 1 to 345 tests on demand†
- Random access 24/7 availability
- Quantification standards run in every test for fixed cost per reportable result independent of daily volume

* Interpretation in conjunction with other clinical and laboratory findings.
^ HCV genotype 1 (WHO 4th International standard).
# Trend report available for patients’ viral load measured multiple times on the same GeneXpert system.
† Operational throughput on Infinity-80; internal analysis.

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

The Impact

- **Improve Patient Care:** Simplified workflow and on demand testing reduces hands-on time
- **Increase Efficiency:** Fast results enable earlier adjustment to appropriate therapy
- **Patient Centered Diagnostics:** Same day results and treatment decisions can potentially reduce anxiety and time for multiple clinical appointments

Move your lab forward

- **No Waiting:** Ability to run any test anytime with 24/7 on demand and random access testing
- **Flexible:** Adaptable to meeting throughput requirements
- **Improve Sample Processing:** Speed up results turnaround time to meeting clinical need and deliver a better service

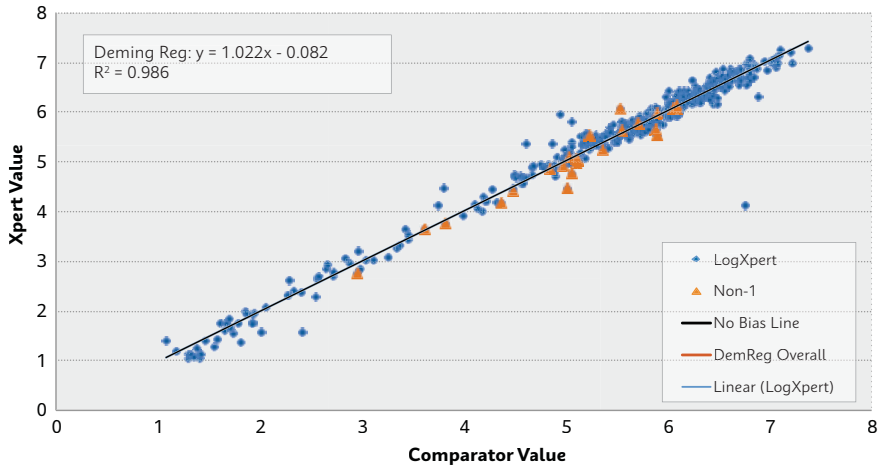
Performance[5]

A multisite study was conducted to evaluate the performance of Xpert HCV Viral Load relative to a comparator method using fresh and frozen human plasma specimens collected from HCV infected individuals. Of the 607 specimens, 389 were within the quantitation range of the both assays including 26 specimens that were HCV non-1 genotypes (2, 2a, 2b, 2c, 3, 3a, 4 & 6) and one mixed genotype (HCV 1 & 6).

The limit of detection (LOD) of the HCV VL was determined by testing eight different dilutions prepared from a HCV genotype 1 reference standard in HCV negative EDTA plasma and serum with 3 reagents lots. The HCV RNA concentration that can be detected with a positivity rate of greater than 95% was determined by Probit regression analysis.

- The maximum observed LOD with Probit analysis for HCV genotype 1 in EDTA plasma is 4.0 IU/mL (95% CI 2.8–5.2)
- The maximum observed LOD with Probit analysis for HCV genotype 1 in serum is 6.1 IU/mL (95% CI 4.2–7.9)

Xpert vs. Comparator (LOG cp/mL)



Specimen	Concentration (IU/mL)	Positivity Rate (%)
WHO (Plasma)	0.5[a]	49
	1	65
	2	85
	3	96
	4	93
	6	99
	8	100
	10	100
WHO (Serum)	0.5[a]	40
	1	64
	2	88
	3	96
	4	97
	6	99
	8	97
	10	100

HCV non-1 genotypes are represented as triangles. A single outlier was not included in the analysis.

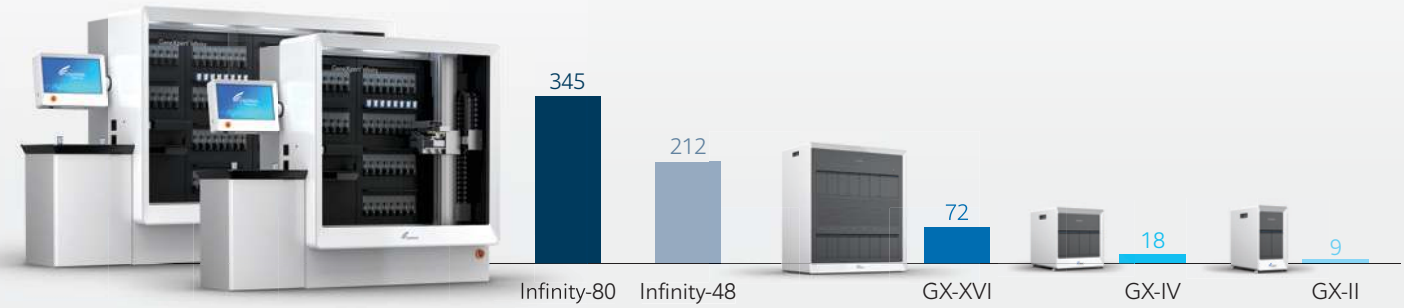
a 0.5 IU/mL was added day 2 due to the high positivity rate observed at 1 IU/mL after day 1

Workflow: 2 Easy Steps

1 Transfer at least 1 mL of plasma or serum into the cartridge

2 Insert cartridge and start test

System Throughput* *8-hr shift*



* Operational throughput per 8-hr shift based on HCV Viral Load testing, internal analysis.

Catalog Information

Xpert® HCV Viral Load	10 tests	GXHCV-VL-CE-10

References:

1 Mohd Hanafiah K, et al. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. Hepatology 2013; 57(4): 1333-42.

2 WHO. Hepatitis C. Accessed Jul 2021. https://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c

3 Ghany MG, et al. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009 Apr;49 (4):1335-74.

4 Graham CS, et al. A Path to Eradication of Hepatitis C in Low-and-Middle-Income Countries. Antiviral Res. 2015 Jan 20; pii: S0166-3542(15)00005-4.

5 Xpert HCV Viral Load. Instructions for Use.

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