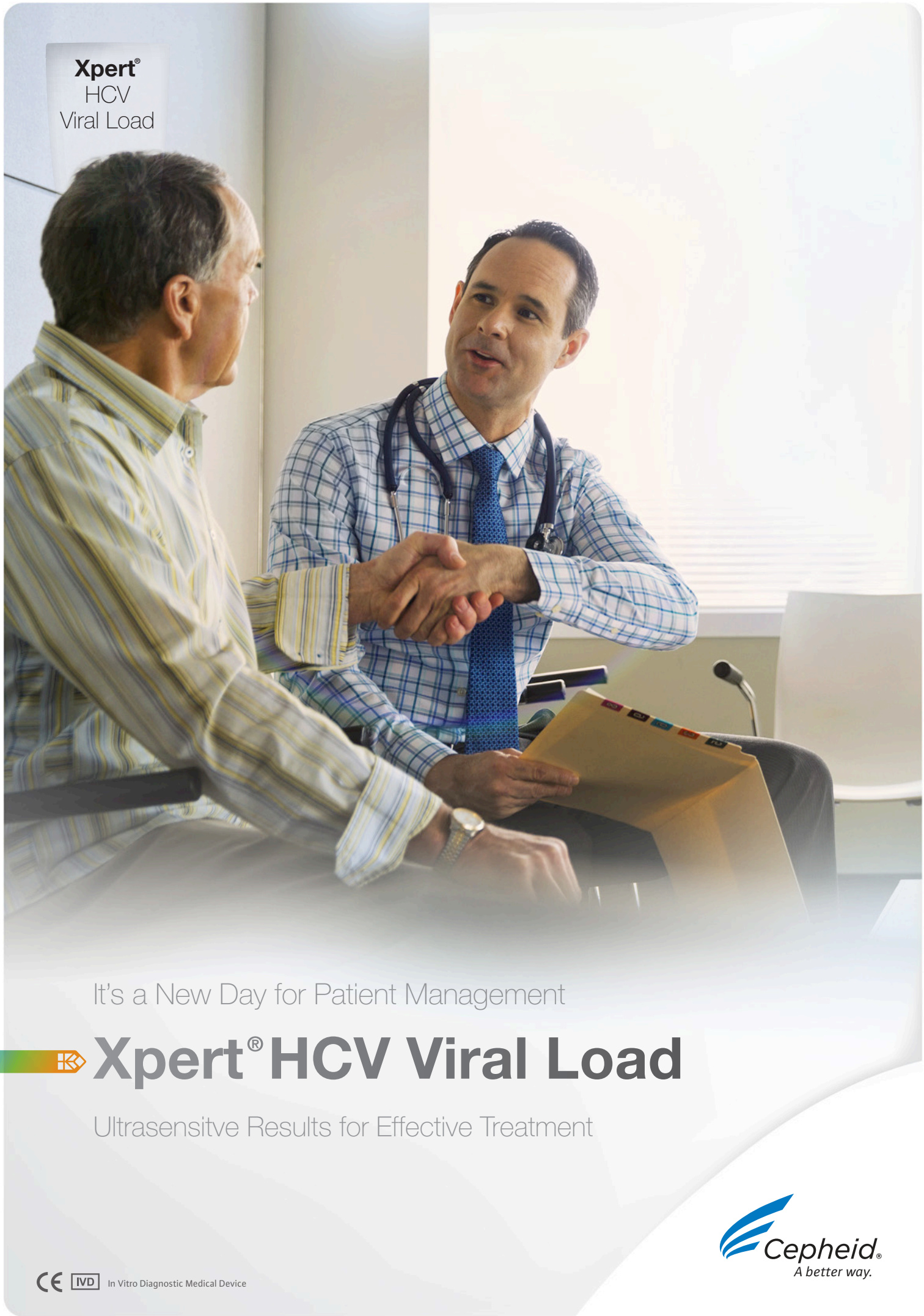


It's a New Day for Patient Management

Xpert® HCV Viral Load

Ultrasensitve Results for Effective Treatment

CE IVD In Vitro Diagnostic Medical Device

Cepheid®
A better way.

Cepheid's Xpert® HCV Viral Load test delivers results in hours rather than days — with the simplicity and ease of use of a point-of-care test. 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] Each year, 350,000 to 500,000 people die from HCV-related liver disease.[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]

Existing HCV viral load tests are complicated to use, require complex technical settings and highly trained technicians to operate.

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

Ultrasensitive

- 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

- <1 minute hands-on time
- Run daily or on-demand
- No requirements for PCR room settings
- No daily maintenance or liquid waste management

Flexible

- 105 minutes run time with a viral load trend report#
- Compatible with any lab volume
- Providing up to 345 viral load results per 8 hours†
- Random access 24/7 availability
- 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.

† Operational throughput on Infinity-80; internal analysis.

THE IMPACT

- **Improve Patient Care:** *Same day results support better clinical decisions*
- **Increase Efficiency:** *Highly sensitive quantitative viral loads of HCV enable earlier adjustments to therapy*
- **Strengthen Communities:** *Quick decisions can help reduce transmission*

Move your lab forward

- **No Waiting:** *Deliver individual patient results when they're most needed*
- **Simple & Organised:** *True 24/7 random access accommodates other urgent test requests*
- **Flexible:** *Adapt to any throughput requirement*
- **Improve Service:** *Run more than one test simultaneously*

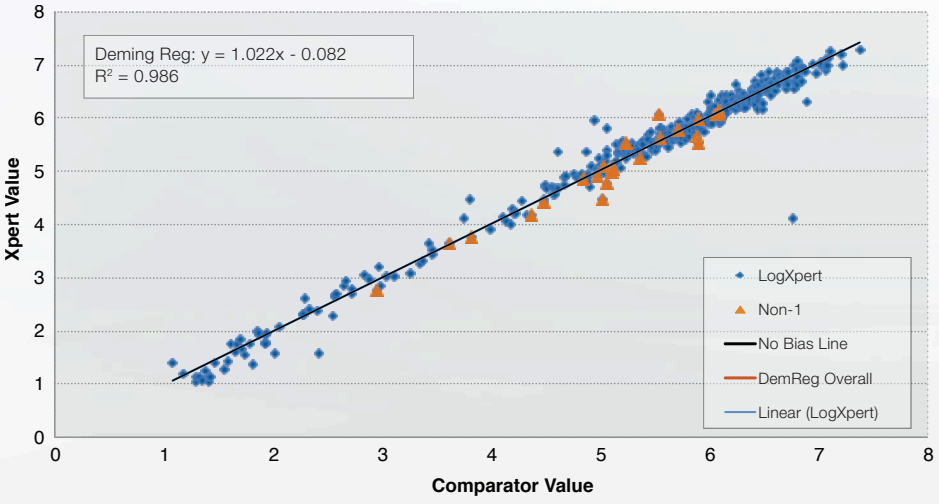
PERFORMANCE

A multi-site 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 23 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 V. COMPARATOR (LOG IU/ML)



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

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

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

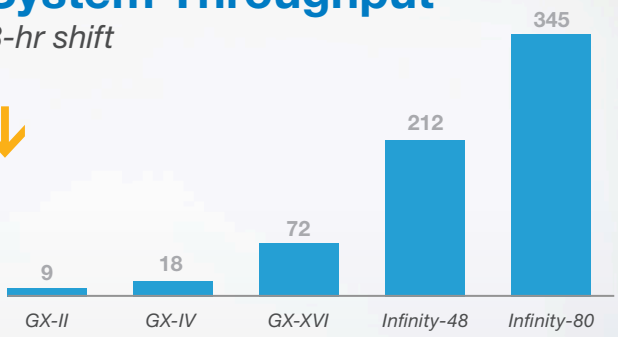
Total hands-on time: <1 minute

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

2 Scan, load cartridge and start test

System Throughput*

8-hr shift



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

Xpert® HCV Viral Load provides reliable, on-demand results in less than 2 hours.

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 Fact Sheet N° 164. Updated April 2014. Accessed April 2015 at http://www.who.int/mediacentre/factsheets/fs164/en/
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. [Epub ahead of print].

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