

**Xpert®**  
HIV-1  
Viral Load



Monitoring for Quality of Life.



# Xpert® HIV-1 Viral Load

Flexibility for personalised care. Putting the patient first.



*Xpert® HIV-1 Viral Load delivers excellent performance as required for routine patient follow-up with the advantages of being simple and flexible enough to accommodate any daily test volume as well as any urgent single analysis.”*



**Prof. Jean-Christophe Plantier**

*Head of the Virology laboratory, laboratory associated to the HIV French National Reference Center Rouen University Hospital, Rouen, France*



**THE NEED**

The World Health Organization estimates that 35 million people worldwide are currently living with HIV/AIDS.<sup>1</sup>

Today, measurement of blood plasma HIV-1 RNA concentration (known as HIV viral load) using nucleic acid-based molecular diagnostic assays has been established as the standard of care in assessing HIV-positive patient prognosis and response to antiretroviral therapy. Assessment of viral load levels is a strong predictor of the rate of disease progression and, by itself or in combination with CD4 T-cell counts, has great prognostic value.<sup>2-7</sup>

Existing HIV-1 viral load tests are complicated to use, require complex technical settings and highly trained technicians to operate. These complex systems require daily maintenance to prevent contamination issues and lack the flexibility needed to provide rapid answers when required.

The need for a rapid HIV viral load test with flexibility to adapt to any throughput requirements and random access for urgent samples is greater than ever because each individual patient deserves better care.



**THE SOLUTION**

**Xpert HIV-1 Viral Load is a quantitative test that provides on-demand molecular testing.**

Based on the GeneXpert technology, Xpert HIV-1 Viral Load automates the test process including RNA extraction, purification, reverse transcription and cDNA real time quantitation in one fully integrated cartridge.

**Redefining Simple**

**Easy**

- Run daily or on-demand
- No requirements for PCR room settings
- No daily maintenance or liquid waste management

**Rapid**

- 90 minutes run time with a viral load trend report\*
- No batch, no delay
- <1 minute hands-on time

**Flexible**

- Compatible with any lab volume
- Providing up to 403 viral load results per 8 hours<sup>^</sup>
- Random access 24/7 availability
- Run multiple different tests on the same platform at any time
- Fixed cost per reportable result independent of daily volume

\* Trend report available for patients' viral load measured multiple times on the same GeneXpert.

<sup>^</sup> Operational throughput on Infinity-80; internal analysis.



# THE IMPACT



- **Improve Patient Care:** *Same day results support better clinical decisions*
- **Increase Efficiency:** *Rapid results enable earlier adjustments to appropriate therapy*
- **Strengthen Communities:** *Quick decisions can help reduce drug resistance*

## 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*



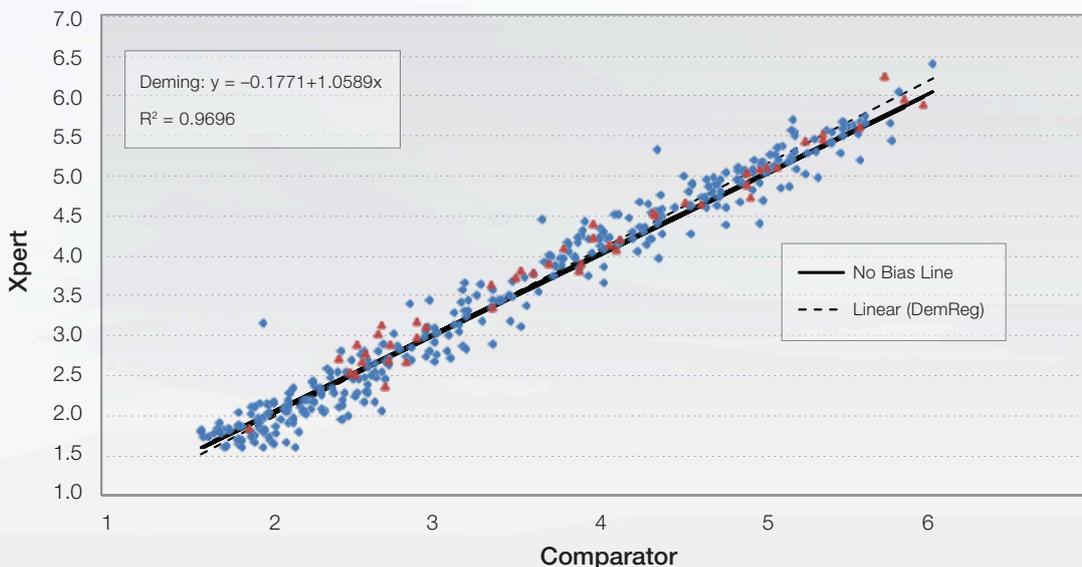
# PERFORMANCE

A multi site study across Europe and the USA was conducted to evaluate the performance of the HIV-1 Viral Load test relative to a comparator method using 724 fresh and frozen human plasma specimens collected from HIV-1 infected individuals. Of the 724 specimens, 390 were within the quantitation range of both tests including 47 HIV-1 Group M non-B subtypes with A-like, C and C-like, D, F, G, H, J, AE, AG and other circulating recombinant forms (CRFs).

The HIV-1 viral load test limit of quantification (LOQ) is 40 cp/mL and the limit of detection (LOD) for the HIV-1 subtype B in EDTA plasma was evaluated with two different sets of standards on three different lots of the test using Probit analysis:

- LOD with WHO 3rd international standards: 18.3 cp/mL (95%CI 15.9-20.8)
- LOD with VQA (Viral Quality Assurance laboratory) reference material: 15.3 cp/mL (95%CI 13.5-17.0)

## XPERT VS. COMPARATOR METHOD (LOG CP/ML)



HIV-1 Group M Non-B subtypes are represented as red triangles.

**WORKFLOW:**

## 2 Easy Steps

Total hands-on time: <1 minute



- 1 Transfer at least 1 mL of plasma into the cartridge

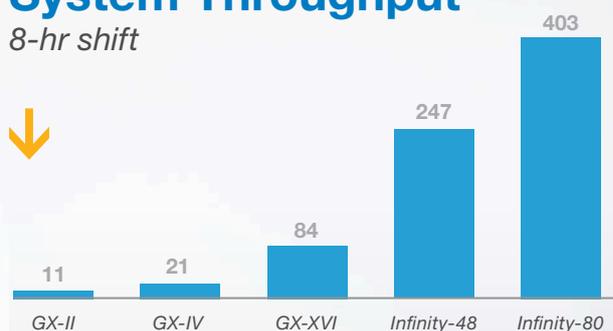


- 2 Scan, load cartridge and start test



## System Throughput

8-hr shift



\* Operational throughput per 8-hr shift based on HIV-1 Viral Load testing, internal analysis.

➤ **Xpert® HIV-1 Viral Load provides individual on-demand viral load measurements in real time for HIV-1.**

CATALOG INFORMATION

Xpert HIV-1 Viral Load (10 tests) .....GXHIV-VL-CE-10

**References:**

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7. Saag MS, et al. HIV viral load markers in clinical practice. Nat Med. 1996 Jun;2(6):625-9.

**CORPORATE HEADQUARTERS**

904 Caribbean Drive  
Sunnyvale, CA 94089 USA

TOLL FREE +1.888.336.2743  
PHONE +1.408.541.4191  
FAX +1.408.541.4192

**EUROPEAN HEADQUARTERS**

Vira Soleih  
81470 Maurens-Scopont France

PHONE +33.563.82.53.00  
FAX +33.563.82.53.01  
EMAIL cepheid@cepheideurope.fr

www.Cepheidinternational.com