Xpert® HIV-1 Viral Load

Supporting National Programs from High-Throughput Reference Labs to Near-Patient Testing
THE NEED

The World Health Organization estimates that 35 million people worldwide are currently living with HIV/AIDS. Less than 30% of HIV patients have access to viral load representing severe market shortcomings and a high opportunity for intervention.

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.

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 in order to support UNAIDS 90-90-90 targets to end the AIDS epidemic.

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*
- 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.
* Operational throughput on Infinity-80; internal analysis.

Dr. Susanna Cefca
Chief Scientific Officer, DREAM Program, Community of S. Egidio, Blantyre, Malawi

"The Xpert® HIV-1 Viral Load test is designed with resource limited settings in mind. It is simple, rapid and can be run in any healthcare setting."
THE IMPACT

- **Improve Patient Care:** Reduce loss to follow up between sample collection and reporting results to critical patients
- **Increase Efficiency:** Rapid results enable earlier adjustments to appropriate therapy
- **Strengthen Communities:** Quick decisions can help reduce drug resistance and lower transmission

**Designed for Near-Patient Testing and High-Throughput Labs**
- **No Waiting:** Deliver rapid individual patient results in 1 visit to support UNAIDS 90-90-90 targets
- **Simple & Organised:** True 24/7 random access accommodates other urgent test requests (e.g. Xpert® MTB/RIF)
- **Flexible:** Modular system can adapt to any throughput requirement from Health Clinics to National Reference Laboratories
- **Improve Service:** Run HIV & MTB/RIF tests simultaneously on the same instrument

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 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.
**References:**

2. UNITAID MARKET DYNAMICS DASHBOARD. Update December 2014. Based on unpublished CHAI estimates reported to UNITAID.

**CATALOG INFORMATION**

**Xpert HIV-1 Viral Load**

<table>
<thead>
<tr>
<th>CARTRIDGE</th>
<th>AMOUNT</th>
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<tr>
<td>GXHIV-VL-CE-10</td>
<td>10 tests</td>
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**REFERENCES:**

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