The Power of Early Knowledge.

Xpert® HIV-1 Qual

Faster intervention for better patient care.

CE IVD In Vitro Diagnostic Medical Device

Cepheid®
A better way.

Xpert® HIV-1 Qual is so sensitive it can detect HIV infection before seroconversion. This technology enables us, for the first time, to diagnosis primary HIV infection in persons with high risk at the point-of-care, which will likely lead to lasting benefits in management of HIV infection and in reducing HIV transmission. The GeneXpert® System is fast, easy to use, and is well adapted to our growing needs."

Michael Meulbroek

Chair of BCN Checkpoint, Barcelona, Spain (community-based detection centre for HIV and other STIs)

THE NEED

The World Health Organization estimates that 35 million people worldwide are currently living with HIV/AIDS.[1]

Infected individuals generally develop an acute infection characterized by flu-like symptoms in a period of days to weeks after initial exposure.[2] Acute HIV infections typically last less than 14 days[3] and are associated with high levels of viremia prior to a detectable immune response.[4-6] Therefore, HIV-1 nucleic acid testing can be more sensitive than standard serologic testing in detection of acute infection.

The need for a highly sensitive HIV qualitative test to detect HIV infection early in high risk and vulnerable populations is greater than ever. To improve patient care for all patients and reduce viral transmission in communities, a rapid answer on a whole blood (WB) or dried blood spot (DBS) sample is necessary.

THE SOLUTION

Xpert HIV-1 Qual is a qualitative test that provides on-demand molecular testing for early diagnosis.

Based on the GeneXpert technology, Xpert HIV-1 Qual provides a total nucleic acid based test for RNA and proviral DNA in one fully integrated cartridge.

Redefining Simple

Easy

- 100 µl of WB or 1 DBS (60-70 µL)
- Simple near-patient workflow
- No requirements for PCR room settings
- No daily maintenance or liquid waste management

Rapid

- 92 minutes run time
- No batch, no delay
- <1 minute hands-on time

Flexible

- Providing up to 394 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

* Operational throughput on Infinity-80; internal analysis.

THE IMPACT

- **Greater Sensitivity:** *Detect HIV infections up to 7-10 days before seroconversion*
- **Improve Patient Care:** *Same day results support better clinical decisions*
- **Increase Efficiency:** *Rapid results enable quicker entry into care and treatment for high risk patients*
- **Strengthen Communities:** *Quick decisions can help reduce morbidity or mortality*

Get Answers Earlier

Xpert® HIV-1 Qual detected HIV-1 on average nine days* earlier than a panel of HIV-1 antibody tests and five days* earlier than a panel of HIV-1 antigen p24 tests.^

PERFORMANCE

The limit of detection (LOD) of the HIV-1 Qual test was determined for both WB and DBS procedures by testing two different HIV-1 subtype B reference standards including the Viral Quality Assurance Laboratory (VQA) reference material of the AIDS Clinical Trials Group and the WHO 3rd International Standard NIBSC code 10/152 diluted in HIV-1 negative EDTA WB.

The HIV-1 Qual test LOD is 278 cp/mL for WB samples and the LOD for the DBS samples is 668 cp/mL (using WHO 3rd International Standards).

- LOD WB samples with VQA reference material: 203 cp/mL (95%CI 181-225)
- LOD DBS samples with VQA reference material: 531 cp/mL (95%CI 474-587)

CLINICAL PERFORMANCE

Performance characteristics of Xpert HIV-1 Qual were evaluated at two institutions in Africa. Subjects included individuals whose routine care called for collection of WB or DBS specimens for HIV-1 testing. The CE-marked comparator assay was validated for DBS and not for WB therefore Xpert HIV-1 Qual WB results were compared to the DBS comparator method.

XPERT HIV-1 QUAL PERFORMANCE (WB) VS. COMPARATOR (DBS)

		Comparator – DBS		
		Positive	Negative	Total
Xpert HIV-1 Qual – WB	Positive	54	1[a]	55
	Negative	1[b]	50	51
	Total	55	51	106

PPA: 98.2% (95% CI: 90.3-100)
NPA: 98.0% (95% CI: 89.6-100)

a. Upon retesting, specimen was Xpert POS / comparator POS
b. Upon retesting, specimen was Xpert NEG / comparator POS

XPERT HIV-1 QUAL PERFORMANCE (DBS) VS. COMPARATOR (DBS)

		Comparator – DBS		
		Positive	Negative	Total
Xpert HIV-1 Qual – DBS	Positive	194	3[a]	197
	Negative	9[b]	193	202
	Total	203	196	399

PPA: 95.6% (95% CI: 91.8-98)
NPA: 98.5% (95% CI: 95.6-99.7)

a. Upon retesting, 1 of 3 specimens was Xpert NEG / comparator NEG, and 2 of 3 specimens were Xpert POS / comparator POS
b. Upon retesting, 5 of 9 specimens were Xpert POS / comparator POS, 3 of 9 specimens were Xpert NEG / comparator POS, and 1 of 9 was Xpert NEG / comparator NEG.

* Internal Analysis. Antibody tests: Abbott HIV 1/2 EIA, Abbott PRISM HIV-1/2, Abbott Murex HIV 1.2.O HIV, Bio-Rad GS HIV-1/HIV-2 Plus O EIA, Siemens HIV 1/O/2 Enhanced ADVIA Centaur. Antigen p24-tests: Abbott, Coulter HIV-1 p24 Antigen, Innogenetics RL29, Perkin Elmer Alliance HIV-1 p24 ELISA

^ Data in Xpert HIV-1 Qual Package Insert.

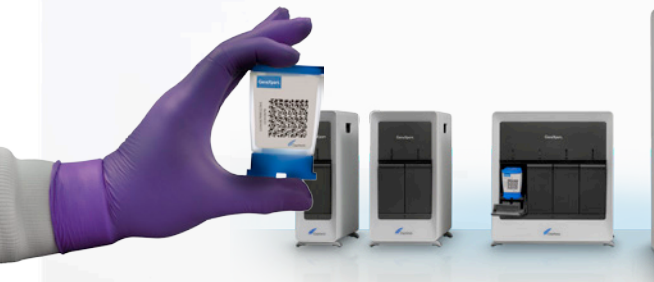
WORKFLOW:

2 Easy Steps

Total hands-on time: <1 minute

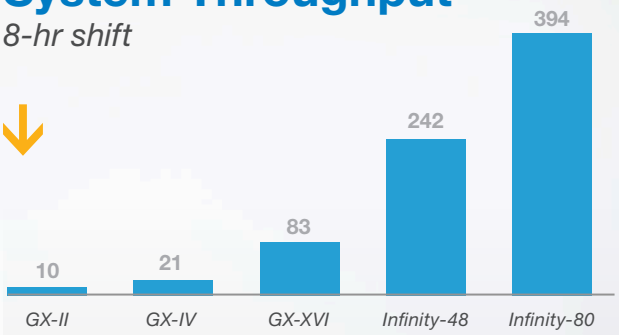
1 Transfer 750 µL of sample reagent and 100 µL of whole blood into the cartridge

2 Scan, load cartridge and start test



System Throughput*

8-hr shift



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

Xpert® HIV-1 Qual provides same day detection of HIV-1 nucleic acid in individuals at risk for HIV-1 infection.*

CATALOG INFORMATION

Xpert HIV-1 Qual (10 tests) GXHIV-QA-CE-10

* Not intended for donor blood screening.

References:

1. WHO. HIV/AIDS Fact sheet N°360. Updated Nov 2014.
2. Aids.gov. Aids Signs and Symptoms. Accessed May 2015. https://www.aids.gov/hiv-aids-basics/hiv-aids-101/signs-and-symptoms/
3. O'Brien M, et al. Should we treat acute HIV infection? Curr HIV/AIDS Rep. 2012 Jun;9(2):101-10.
4. Kahn JO, et al. Acute human immunodeficiency virus type 1 infection. N Engl J Med. 1998 Jul 2;339(1):33-9.9.
5. Daar ES, et al. Transient high levels of viremia in patients with primary human immunodeficiency virus type 1 infection. N Engl J Med. 1991 Apr 4;324(14):961-4.
6. Clark SJ, et al. High titers of cytopathic virus in plasma of patients with symptomatic primary HIV-1 infection. N Engl J Med. 1991 Apr 4;324(14):954-60.

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