

A Molecular Point-of-Care Test That Delivers Actionable Results in Minutes*







The Need

There were an estimated 39.0 million people living with HIV at the end of 2022.1

Infected individuals with acute infection can develop flu-like symptoms in a period of days to weeks after initial exposure.² Acute HIV infections are typically characterized by the lack of anti-HIV antibodies and the presence of viremia.² Therefore, HIV-1 nucleic acid testing is 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.



Xpert® HIV-1 Qual XC is so sensitive it can detect HIV infection before seroconversion. This technology enables us, for the first time, to diagnose primary HIV infection in high risk persons 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

BCN Checkpoint founder-president, Checkpoint,

A community-based organization for men who have sex with men and transgender women



The Solution

Xpert HIV-1 Qual XC (extended coverage) is an *in vitro* nucleic acid amplification test for the qualitative detection of HIV-1 total nucleic acids, on the automated GeneXpert® system.

Xpert HIV-1 Qual XC is intended to aid in the diagnosis of HIV-1 infection in conjunction with clinical presentation and other laboratory markers in infant, adolescent, and adult populations.

Now Improved:

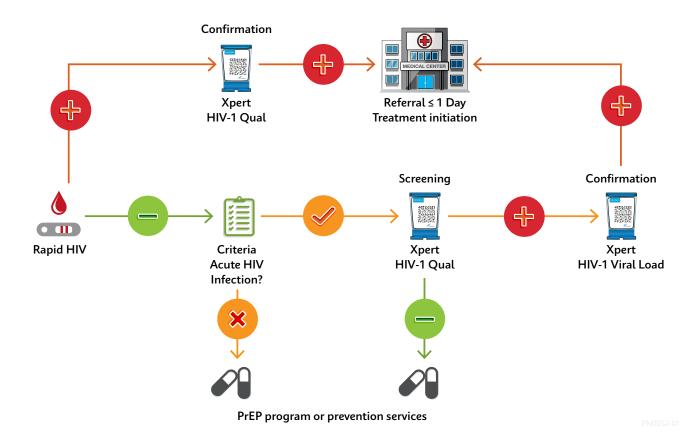
- Extended coverage for HIV-1 strains with dual target detection
- 2 protocols; 100ul capillary/EDTA venous WB or a single DBS
- Simply load the sample and run the test. No additional preparation required for WB or DBS
- · Includes point-of-care testing
- Improved cartridge chemistry with addition of sample adequacy control (SAC) to verify human specimen and removal of guanidinium thiocyanate (GTC) for safer cartridge disposal
- · WHO pre-qualified

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



The Impact

- Improve access to HIV testing: Designed for near patient testing in any setting allowing faster delivery of results and medical follow up. Simple sample collection and testing with results around ~91 minutes.
- **Detect acute infections:** Earlier detection than serology based methods provides an important opportunity to improve management of those at risk of recent infections and prior to initiating PrEP
- **Reduce time from testing to treat:** Fast track initiation of treatment with point-of-care HIV-1 nucleic acid test confirmation



 $Source: Molecular\ Point-of-Care\ Testing\ as\ Part\ of\ an\ Integrated\ Approach\ to\ Achieve\ Earlier\ Diagnosis\ and\ Treatment\ of\ HIV,\ presented\ at\ IAS2020,\ M\ Meulbroek.$

Xpert HIV-1 Qual XC Workflow:

2 Easy Steps



Whole Blood Sample

Transfer 100 μ L of WB into the cartridge



Dried Blood Sample

Use tweezers to transfer the card of DBS into the cartridge



$\left(2\right)$

Scan, load cartridge and start test



Catalog Information

Xpert HIV-1 Qual XC 10 tests GXHIV-QA-XC-CE-10

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries.

* Xpert HIV-1 Qual XC test run time ~91 minutes.

REFERENCES:

- 1 Global HIV & AIDS statistics Fact sheet | UNAIDS Accessed August 2023.
- 2 National Institute of Health, Fact Sheet: The stages of HIV Infection. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/early-acute-and-recent-hiv-infection#:~:text=Acute%20HIV%20infection%20occurs%20soon%20after%20transmission%20and,after%20infection%2C%20during%20which%20anti-HIV%20antibodies%20become%20detectable. Accessed Sept 2023.

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