Bring Answers to Life

Xpert® HIV-1 Qual

Urgent results for early intervention
THE NEED

The World Health Organization estimates that 35 million people worldwide are currently living with HIV/AIDS. Of those infected, 2.1 million represent new infections and an estimated 240,000 are children. One-third of all people living with HIV reside in nine countries in southern Africa, which only account for 2% of the global population. Without timely HIV testing and therapy initiation, one-third of HIV-infected infants will die before their first birthday and more than 50% will die before reaching two years old.

Early diagnosis of HIV infection in infants is a necessity; however, many patients are lost to follow-up while waiting for an early test. A highly sensitive HIV qualitative test is needed for detecting HIV infection in pediatric patients 18 months of age or younger. To reduce loss to patient follow-up, a near-patient, same-day HIV PCR test on whole blood (WB) or dried blood spot (DBS) is critical to expand access for high risk patients and infants.

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 modular design of the GeneXpert® System means that a point-of-care health clinic can run the exact same cartridge-based test as a national reference laboratory. This is a unique and powerful tool that will help us provide timely and actionable diagnostics for HIV-infected infants without compromising accuracy of results.”

Dr. Appolinaire TIAM, MBChB, DipHIVMan, MMed.
Country Director, Elizabeth Glaser Pediatric AIDS Foundation/Lesotho
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 immediate intervention to save lives at birth
• Strengthen Communities: Quick decisions can help reduce morbidity or mortality in HIV-infected infants

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.a

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)

<table>
<thead>
<tr>
<th>Comparator – DBS</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert HIV-1 Qual – WB</td>
<td>Positive</td>
<td>54</td>
<td>1*</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>1*</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>55</td>
<td>51</td>
</tr>
</tbody>
</table>

Positive Percent Agreement: 98.2% (95% CI: 90.3–100)
Negative Percent Agreement: 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)

<table>
<thead>
<tr>
<th>Comparator – DBS</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert HIV-1 Qual – DBS</td>
<td>Positive</td>
<td>194</td>
<td>3*</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>9*</td>
<td>193</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>203</td>
<td>196</td>
</tr>
</tbody>
</table>

Positive Percent Agreement: 95.6% (95% CI: 91.8–98)
Negative Percent Agreement: 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.

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**Xpert® HIV-1 Qual** provides same day detection of HIV-1 nucleic acid in infants and 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: