Patients Come First

Rapid On-Demand Testing for Virology

Expanding Access by Redefining Simple
Rapid On-Demand Testing for Better Patient Management

At Cepheid, improving the patient experience is our first priority. We are committed to delivering the most innovative and comprehensive virology products for the detection of HIV, hepatitis C and hepatitis B. We are focused on providing rapid and actionable results that improve patient outcomes and reduce complications in these most vulnerable populations.

REDEFINING SIMPLE

- No batch, no delay
- Run daily or on-demand
- <1 minute hands-on time
- Compatible with any lab volume
- No requirements for PCR room settings
- No daily maintenance or liquid waste management
- 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

Xpert® HIV-1 Viral Load

The need for a rapid, random access HIV viral load test with the flexibility to adapt to any throughput requirement, from urgent samples to high volume labs, is greater than ever.

Xpert HIV-1 Viral Load is a quantitative test for the monitoring of HIV-1 infection.

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.

Easy → Rapid → Flexible

- 1 mL of plasma
- 90 minutes run time with a viral load trend report*
- LOQ of 40 cp/mL
- Providing up to 403 viral load results per 8 hours*

A near patient, sensitive HIV qualitative test is needed for early infant diagnosis to save lives at birth, and to detect HIV infection earlier in high risk populations to reduce viral transmission.

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

Xpert HIV-1 Qual provides a total nucleic acid based test for RNA and proviral DNA in one fully integrated cartridge.

Easy → Rapid → Flexible

- 100 μL of whole blood (WB) or 1 dried blood spot (DBS) (60-70 μL)
- 92 minutes run time
- LOD of 203 cp/mL for WB and 531 cp/mL for DBS
- Providing up to 394 results per 8 hours*

* Not available for diagnostic use. Projected release 2016/2017 ex-US.
* Trend report available for patients’ viral load measured multiple times on the same GeneXpert.
* Operational throughput on Infinity-80; internal analysis.
An ultrasensitive, easy to use HCV viral load test with the flexibility to adapt to any throughput is a critical companion test for newly developed drug regimens.

Xpert HCV Viral Load is a quantitative test that provides on-demand molecular testing for diagnosis and monitoring of HCV.

Xpert HCV Viral Load automates reverse transcriptase polymerase chain reaction (RT-PCR) using fluorescence to detect and quantify RNA.

Sensitive → Easy → Flexible

- LOD of 4.0 IU/mL in EDTA plasma\(^1\)
- LOD of 6.1 IU/mL in serum\(^2\)
- 105 minutes run time with a viral load trend report\(^*\)
- Providing up to 345 viral load results per 8 hours\(^*\)

A simple, rapid HBV DNA test is needed for better long-term patient management.

Xpert HBV Viral Load is a quantitative test for the evaluation and management of chronic HBV infection.

Worldwide there are an estimated 240 million people chronically infected with hepatitis B virus (HBV). Between 20 and 30% of people with chronic HBV will develop major complication of cirrhosis and hepatocellular carcinoma and 780,000 people will die each year due to chronic HBV.\(^1\)

Currently available treatment fails to eradicate the virus in most patients, requiring potentially lifelong treatment and monitoring.

Cepheid is committed to deliver HBV Viral Load to provide a full portfolio of virology products that will increase access and improve patient management.

\(^1\) Interpretation in conjunction with other clinical and laboratory findings.
\(^2\) HCV genotype 1 (WHO 4th International standard)
\(^*\) Trend report available for patients’ viral load measured multiple times on the same GeneXpert.
\(^*\) Operational throughput on Infinity-80; internal analysis.

Complex Technology Made Simple

With over 8,000 systems installed worldwide, Cepheid’s GeneXpert® System has established itself as the platform of choice because it remains the only system capable of delivering any test, anytime, anywhere in the healthcare system.

From primary health care clinics for near patient testing to the largest reference labs, the GeneXpert System means scalability, ease-of-use, fewer disposables to stock, a single maintenance schedule and a smaller footprint.

VIROLOGY PORTFOLIO

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CATALOG INFORMATION

For In Vitro Diagnostic Use. Not for Distribution in the U.S.