

# The Complete Test Solution for Hepatitis and HIV

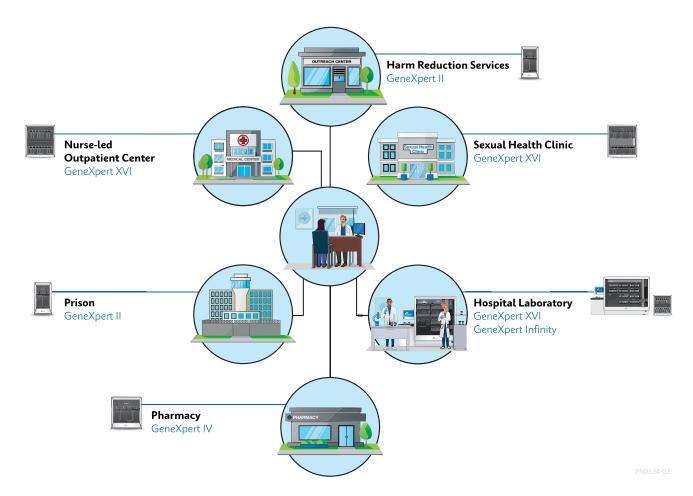
Simplify Diagnostic Pathways and Expand Access to Testing

### • Delivering Accurate, Fast, Simple On-demand Testing with PCRplus

Cepheid is committed to delivering a higher level of PCR excellence by bringing together speed, accuracy, and flexibility for unmatched testing that can be done virtually anywhere — enabling better patient care.

### **Virology Testing Solutions Designed to Reach Your Patients**

From near-patient testing in community or decentralized clinical setting to large references lab testing, the GeneXpert<sup>®</sup> system provides a solution that is easy to implement and delivers fast, high quality results.



**Consolidate Hepatitis and HIV Viral Load Testing** 

- Lab quality results in any setting
- Testing on demand. No batch, no delay
- Throughput and size flexibility to suit your needs
- Highest quality results assured every time with quantification standards and control run with every sample tested
- No additional consumables or reagents to manage
- HIV, HBV and HCV testing on the same platform at any time and any throughput
- Fixed cost per sample with integrated controls and standards

Speed, plus Accuracy, plus Flexibility

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

### Laboratory-Quality Diagnostic PCR Testing at the Point of Care



#### Xpert<sup>®</sup> HIV-1 Qual XC

The Xpert HIV-1 Qual XC is a highly sensitive HIV-1 diagnostic point-of-care test for early detection of acute infections and Early Infant Diagnosis.

## **5** 79 mins Whole Blood (WB) and 91 mins Dried Blood Spot (DBS) run time

- Extended coverage for HIV-1 strains with dual target detection
- Using 100ul capillary/EDTA venous WB or a single DBS
- Simply collect sample, load into the cartridge, and run the test. No additional preparation required for WB or DBS
- Limit of detection 161 cp/mL from whole blood<sup>^</sup> and 706 cp/mL from DBS<sup>^</sup>
- · Simplified workflow for near patients



#### Xpert<sup>®</sup> HCV VL Fingerstick

The Xpert HCV VL Fingerstick pointof-care test detects and quantifies HCV directly from a drop of blood, simplifying the diagnostic pathways to speed up linkage to care and monitoring sustained virological response.

### **58 minutes** run time

- + 100 $\mu l$  human fingerstick EDTA whole blood or venous EDTA whole blood
- Genotypes 1–6 over range 100 to 10<sup>8</sup> IU/mL
- Limit of detection 35 IU/mL for HCV genotype 6e<sup>\*#</sup>
- · Simply collect sample, load cartridge, and run test



#### Xpert<sup>®</sup> HIV-1 Viral Load XC

Xpert HIV VL XC is the next generation dual target quantification test for monitoring patients.

### **90 minutes** run time

- Extended coverage for HIV-1 strains with dual target detection.
- 1 mL of plasma
- HIV-1 Group M,\* Group N, Group O, and Group P over linear range 40–10<sup>7</sup>cp/mL
- LOD is 13.6cp/mL for HIV-1 subtype B\*#



#### Xpert<sup>®</sup> HBV Viral Load

Xpert HBV Viral Load simplifies quantification of HBV DNA from human serum or plasma and enables testing flexibility that can be performed in any setting.

#### **59 minutes** run time

- 0.6 or 1 mL of EDTA plasma or serum
- Genotypes A–H over range 10 to 10<sup>9</sup> IU/mL
- LOD 3.22 IU/mL plasma and 5.99IU/mL for genotype<sup>\*#</sup>



#### Xpert<sup>®</sup> HCV Viral Load

The Xpert HCV Viral Load test quantifies HCV RNA in human plasma and serum from patients. It simplifies confirmation of infection in anti HCV positive individuals, monitoring of HCV viral load and has high sensitivity to predict sustained virological response.

#### **J** 105 minutes run time

- 1 mL EDTA plasma or serum
- Genotypes 1–6 over range 10 to 10<sup>8</sup> IU/mL
- LOD 4.0 IU/mL plasma and 6.1 IU/mL genotype 1<sup>\*#</sup>

- \* For other types please refer to the Package Insert
- ^ WHO international reference standard
- # Please refer to relevant Package Insert for LOD data on other types

## **Complex Technology Made Simple**

With more than 40,000 systems installed worldwide, Cepheid's GeneXpert<sup>®</sup> system has established itself as the platform of choice for healthcare providers. It's capable of delivering any test, at anytime, anywhere in the healthcare system — with throughput flexibility from one up to 596 tests per 8 hour shift.\*

### **2 Easy Steps**



Transfer sample per package insert to the cartridge





and start test

Scan, load cartridge,

2

#### **CATALOG INFORMATION**

Xpert® HIV-1 Viral Load XC	10 tests	GXHIV-VL-XC-CE-10
Xpert® HIV-1 Qual XC	10 tests	GXHIV-QA-XC-CE-10
Xpert <sup>®</sup> HCV VL Fingerstick	10 tests	GXHCV-FS-CE-10
Xpert® HCV Viral Load	10 tests	GXHCV-VL-CE-10
Xpert® HBV Viral Load	10 tests	GXHBV-VL-CE-10

Sarstedt Minivette® POCT 100 µl

**COLLECTION DEVICES** (Not Included in Kit): Minivette100E-100

Operational throughput per 8 hour shift based on HBV Viral Load testing Internal data

FAX

Please refer to the Package Inserts

CE-IVD. In Vitro Diagnostic Medical Device. Not available in all countries. Not available in the United States.

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