



XPert® HBV VIRAL LOAD

| | |
|---|--|
| Test Reagent Kit | Xpert HBV Viral Load |
| Catalog Number | GXHBV-VL-CE-10 |
| Technology | Real-Time qPCR (Real-Time Quantitative PCR) |
| Target | HBV DNA genotypes A-H |
| Batch or On-Demand | On-demand |
| Minimum Batch Size | 1 |
| Sample Types | 0.6 mL – 1 mL or serum or Plasma (EDTA) |
| Sample Extraction | Automated/Integrated |
| Precision Pipetting | 0.6 mL of serum or plasma |
| TAT | <60 minutes |
| Hands-On Time | <1 minute |
| Controls: Process and Quantification | Sample Volume Adequacy (SVA); High and Low Internal Quantification Standards (IQS-H/IQS-L) Lot Specific Parameter (LSP) |
| Controls: Probe Function/Detection | Probe Check Control (PCC) |
| Limit of Detection <i>(for HBV genotype A (4th WHO International Standard), for other genotypes refer to the Package Insert)</i> | Probit analysis – plasma: LOD WHO reference material: 3.20 IU/mL Probit analysis – serum: LOD WHO reference material: 5.99 IU/mL |
| Limit of Quantitation | 10 IU/mL |
| Linear Range | 10 IU/mL – 1,000,000,000 IU/mL |
| Sample Storage | Whole blood: 2–35°C up to 24 hours; 2–8°C up to 3 days Plasma and serum: 2–35°C up to 24 hours; 2–8°C up to 7 days; frozen –80 to –20°C up to 6 six weeks |
| Kit Storage | 2–35°C |
| Commercial Controls | Refer to Product Insert or Contact Cepheid Technical Support |

Refer to Package Insert Xpert HBV Viral Load 301-5878, Rev. A.



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

CORPORATE HEADQUARTERS

904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE +1.888.336.2743
PHONE +1.408.541.4191
FAX +1.408.541.4192

EUROPEAN HEADQUARTERS

Vira Solelh
81470 Maurens-Scopont France

PHONE +33.563.82.53.00
FAX +33.563.82.53.01
EMAIL cepheid@cepheideurope.fr

www.Cepheidinternational.com