



# XPert® TESTS: VIRAL LOAD

<b>Test Reagent Kit</b>	Xpert® HBV Viral Load	Xpert® HCV Viral Load	Xpert® HIV-1 Viral Load
<b>Catalog Number</b>	GXHBV-VL-CE-10	GXHCV-VL-CE-10	GXHIV-VL-CE-10
<b>Technology</b>	Real-Time qPCR (Real-Time Quantitative PCR)		
<b>Targets</b>	HBV DNA genotypes A-H	HCV RNA genotypes 1-6	HIV-1 Group M subtypes A, B, C, D, AE, F, G, H, AB, AG, J, K and Group N and Group O
<b>Batch or On-Demand</b>	On-demand		
<b>Minimum Batch Size</b>	1		
<b>Sample Types</b>	0.6-1mL plasma (EDTA) or serum	1mL plasma (EDTA) or serum	1mL plasma (EDTA)
<b>Sample Extraction</b>	Automated/Integrated		
<b>Precision Pipetting</b>	1mL with disposable pipette provided or 0.6mL using precision pipette	Single use disposable pipette provided	Single use disposable pipette provided
<b>TAT</b>	<60 minutes	105 minutes	90 minutes
<b>Hands-On Time</b>	<1 minute		
<b>Controls</b>	High and Low Internal Quantification standards (IQS-H/IQS-L)		
	Lot Specific Parameters (LSP)	—	—
<b>Controls: Probe Function/Detection</b>	Probe Check Control (PCC)		
<b>Limit of Detection (for other genotypes refer to the Package Insert)</b>	<b>Probit analysis – plasma:</b> LOD WHO reference material: 3.20 IU/mL;  <b>Probit analysis - serum:</b> LOD WHO reference material: 5.99 IU/mL <i>HBV genotype A</i>	<b>Probit analysis – plasma:</b> LOD WHO reference material: 4.0 IU/mL  <b>Probit analysis – serum:</b> LOD WHO reference material: 6.1 IU/mL <i>HCV genotype 1</i>	<b>Probit analysis – plasma:</b> LOD WHO reference material: 18.3 cp/mL  <b>LOD VQA reference material:</b> 15.3 cp/mL <i>HIV-1 Subtype B</i>
<b>Lower Limit of Quantitation</b>	10 IU/mL	10 IU/mL	40 cp/mL
<b>Linear Range</b>	10 to 10 <sup>9</sup> IU/mL	10 to 10 <sup>8</sup> IU/mL	40 to 10 <sup>7</sup> cp/mL
<b>Sample Storage</b>	<b>Whole blood*:</b> 2-35°C for up to 24 hours or at 2-8°C for up to 3 days prior to plasma/serum preparation  <b>Plasma and serum:</b> 2-35°C up to 24 hours; 2-8°C up to 7 days; Frozen at -80 to -20°C for 6 weeks	<b>Whole blood*:</b> 15-30°C for up to 24 hours or at 2-8°C for up to 3 days prior to plasma/serum preparation.  <b>Plasma and serum:</b> 15-35°C up to 24 hours; 2-8°C up to 3 days; frozen -70 to -18°C for 6 weeks	<b>Whole blood^:</b> 15-30°C for up to 8 hours, 15-25°C for up to 24 hours or at 2-8°C for up to 72 hours, prior to plasma preparation  <b>Plasma:</b> 15-30°C for up to 24 hours, at 2-8°C for up to 6 days or frozen -70 °C and -18°C for up to 6 weeks
<b>Kit Storage</b>	2-35°C	2-28°C	2-28°C
<b>Commercial Controls</b>	Refer to Package Insert or Contact Cepheid Technical Support		

\* Whole blood should be collected in K2-EDTA tubes, EDTA-PPT or serum collection tubes

^ Whole blood should be collected in BD Vacutainer® PPTM Plasma Preparation Tubes for Molecular Diagnostic Test Methods, or in sterile collection tubes using either EDTA or ACD as the anticoagulant.



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

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