Cepheid®

CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System, in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485, European IVD Directive, the Canadian Medical Devices Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® HBV Viral Load

Cepheid Catalogue Part No.: GXHBV-VL-CE-10

Kit Lot No.: 1001444804

Cartridge Lot No.: 30202

Kit Expiration Date: 2026-02-01

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility ◉ Solna ○ Sunnyvale
Cepheid AB
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SE-171 54 Solna
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Functional Testing according to D51114 Rev: D

Test Description	*Acceptance Criteria*	*Test Result*
LOW Positive	HBV DETECTED: 1.26-1.70 log10 IU/mL	Passed
HIGH Positive	HBV DETECTED: 5.54-5.86 log10 IU/mL	Passed
Negative	HBV NOT DETECTED	Passed

☐ If checked this document is produced electronically and valid without a wet signature.

20240903

Signature of Quality Assurance **Date**

Name: Robert Fiedler

Title: QA Analyst