



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.: 1001517624

Cartridge Lot No.: 31901

Kit Expiration Date: 2027-05-30

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna Sunnyvale

Functional Testing according to D51114 Rev: E

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|--------------------------------|---|---------------------------|
| LOW Positive | HBV DETECTED: 1.26-1.70 log ₁₀ IU/mL | Passed |
| HIGH Positive | HBV DETECTED: 5.54-5.86 log ₁₀ IU/mL | Passed |
| Negative | HBV NOT DETECTED | Passed |

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

William Palmén

William Palmén (02/02/2026 11:30:28 GMT+1)

02/02/2026

Signature of Quality Assurance

Date

Name: William Palmén

Title: QA Analyst