



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 and the Canadian Medical Devices Regulations (CMDR).

Product Name: Xpert® HBV Viral Load

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

Kit Lot No.: 1000780167

Cartridge Lot No.: 17101

Kit Expiration Date: 2024-06-30

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden


Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna Sunnyvale Newark

Functional Testing according to D51114 Rev: C

<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

 2023-03-11
Signature of Quality Assurance Date

Name: Alexander Avramidis

Title: QA Analyst