



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 Device Regulations (CMDR).

Product Name: Xpert® HBV Viral Load

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

Kit Lot No.: 1000276691

Cartridge Lot No.: 15302

Kit Expiration Date: 2022-11-20

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility


Solna

Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing according to D21898 Rev.:

Test Description	Acceptance Criteria	Test Result
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


Signature of Quality Assurance

20210730
Date

Name: William Palmén

Title: QA Analyst