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 and the Canadian Medical Device Regulations (CMDR).

Product Name: Xpert® HBV Viral Load

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

Kit Lot No.: 1000289196

Cartridge Lot No.: 15402

Kit Expiration Date: 2022-12-25

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.: 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

20210918

Signature of Quality Assurance **Date**

Name: Annelie Eriksson

Title: QA Analyst