Cepheid®
A better way.

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® HCV VL Fingerstick

Cepheid Catalogue Part No.: GXHCV-FS-CE-10

Kit Lot No.: 1000180074

Cartridge Lot No.: 12501

Kit Expiration Date: 2020-09-20

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 D27172 Rev.: D

Test Description	*Acceptance Criteria*	*Test Result*
LOW Positive	HCV DETECTED: 2.29-2.67 $\log_{10}$ IU/mL	Passed
HIGH Positive	HCV DETECTED: 5.50-5.90 $\log_{10}$ IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

20191220

Signature of Quality Assurance **Date**

Name: Marie Bah

Title: QA Manager Release