

## 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<sup>®</sup> HCV VL Fingerstick

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

**Kit Lot No.:** 1001456579

**Cartridge Lot No.:** 15801

**Kit Expiration Date:** 2025-11-09

**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 D51113 Rev: B***

<b><i>Test Description</i></b>	<b><i>Acceptance Criteria</i></b>	<b><i>Test Result</i></b>
LOW Positive	HCV DETECTED: 2.29 - 2.67 log <sub>10</sub> IU/mL	Passed
HIGH Positive	HCV DETECTED: 5.50 - 5.90 log <sub>10</sub> IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

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

Sara Mustafa Abdulla  
Sara Mustafa Abdulla (Nov 22, 2024 09:50 GMT+1)

**Signature of Quality Assurance**

**Date**

**Name:** Sara Mustafa Abdulla

**Title:** QA Analyst