



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® Factor II & Factor V

Cepheid Catalogue Part No.: GXFIIFV-10

Kit Lot No.: 1001357872

Cartridge Lot No.: 09401

Kit Expiration Date: 2025-11-30

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA



Solna



Sunnyvale



Lodi

Functional Testing according to D16900, Rev. R

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Normal (wild-type)	FII normal; FV normal	Passed
Homozygous Mutant	FII homozygous; FV homozygous	Passed

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

12/18/2023

Signature of Quality Assurance,

Date

Name: Thuy Tien Nguyen

Title: Quality Systems Specialist