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.: 1001461395

Cartridge Lot No.: 09903

Kit Expiration Date: 2026-11-22

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. T

Test Description	*Acceptance Criteria*	*Test Result*
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

Molly Doan
Molly Doan (Dec 10, 2024 13:58 PST)

Dec 10, 2024

Signature of Quality Assurance, **Date**

Name: Molly Doan

Title: Quality Systems Specialist

301-6224 Rev B CofA FIIFV

Final Audit Report 2024-12-10

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