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.: 1001438374

Cartridge Lot No.: 09703

Kit Expiration Date: 2026-07-19

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

Tanja Reed
Tanja Reed (Aug 5, 2024 08:15 PDT)

Aug 5, 2024

Signature of Quality Assurance, **Date**

Name: Tanja Reed

Title: Quality Systems Specialist

1001438374

Final Audit Report 2024-08-05

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