# 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.:** 1001423257

**Cartridge Lot No.:** 09504

**Kit Expiration Date:** 2026-03-29

**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 (Apr 15, 2024 11:16 PDT)

Apr 15, 2024

**Signature of Quality Assurance,** **Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist

# 301-6224 Rev B CofA FIIFV

Final Audit Report 2024-04-15

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|---|---|
| Created: | 2024-04-15 |
| By: | Molly Doan (molly.doan@cepheid.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAttoSu9rSlp-fTYnIJvi5AlRr7DgXR1fm |

## "301-6224 Rev B CofA FIIFV" History

Document created by Molly Doan (molly.doan@cepheid.com)
2024-04-15 - 6:14:46 PM GMT

Document emailed to Molly Doan (molly.doan@cepheid.com) for signature
2024-04-15 - 6:16:27 PM GMT

Document e-signed by Molly Doan (molly.doan@cepheid.com)
Signature Date: 2024-04-15 - 6:16:35 PM GMT - Time Source: server

Agreement completed.
2024-04-15 - 6:16:35 PM GMT