Cepheid

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 Device Regulations (CMDR).

Product Name: Xpert® Factor II & Factor V

Cepheid Catalogue Part No.: GXFIIFV-10

Kit Lot No.: 1000676746

Cartridge Lot No.: 08903

Kit Expiration Date: 2024-12-29

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ○ Solna ◉ Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Normal (wild-type)	FII normal; FV normal	Passed
Homozygous Mutant	FII homozygous; FV homozygous	Passed

MStacybelle 17JAN 2023

Signature of Quality Assurance **Date**

Name: Ma Stacybelle Peralta

Title: Quality Systems Specialist