



## 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® BCR-ABL Ultra

Cepheid Catalogue Part No.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Solna     Sunnyvale

*Functional Testing*

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	NEGATIVE [Sufficient ABL transcript]	Passed
~0.01% (IS)	POSITIVE	Passed
~0.1% (IS)	POSITIVE	Passed

  
Signature of Quality Assurance

01/05/2023  
Date

Name:

Title: