

Title:

Quality Systems Specialist

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 and ISO 13485.

Cepheid Catalogue Kit Lot No.: 10014			
Cartridge Lot No.:			
Kit Expiration Date			
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA		Manufacturing Facility Cepheid 121 N Guild Avenue Lodi, CA 95240 USA	Solna Sunnyva Lodi
Functional Testing Test Description	g according to D3	Acceptance Criteria	Test Result
Positive	BV POSITIVE; Candida group DETECTED; Candida glab-krus DETECTED; TV DETECTED		Pąssed
Negative	BV NEGATIVE; Candida group NOT DETECTED; Candida glab-krus NOT DETECTED; TV NOT DETECTED		Passed
If checked, this	document is produc	ced electronically and therefore valid with	out a wet signature

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