



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 Devices Regulations (CMDR).

Product Name: Xpert Bladder Cancer Monitor

Cepheid Catalogue Part No.: GXBLAD-CM-CE-10

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Solna Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
NEGATIVE	NEGATIVE	PASS
LOW POSITIVE	POSITIVE	PASS
HIGH POSITIVE	POSITIVE	PASS



Signature of Quality Assurance

23 Sep 19

Date

Name:

Title: