



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 Bladder Cancer Detection

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

Kit Lot No.: 1001434043

Cartridge Lot No.: 21901

Kit Expiration Date: 2026-05-24

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna

Sunnyvale

Lodi

Functional Testing according to D22403, Rev. G

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	Negative	Passed
LOW Positive	Positive	Passed
HIGH Positive	Positive	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

8/20/2024

Signature of Quality Assurance

Date

Name: Mai Kue

Title: Quality System Specialists