



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 Monitor

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

Kit Lot No.: 1001465221

Cartridge Lot No.: 22102

Kit Expiration Date: 2026-12-27

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

01/14/2025

Signature of Quality Assurance

Date

Name: Robert Tucker

Title: Quality Systems Specialist