

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.: 1001434045

Cartridge Lot No.: 21902

Kit Expiration Date: 2026-05-24

Legal Manufacturer Manufacturing Facility

Cepheid Cepheid

904 Caribbean Drive 121 N Guild Avenue

Sunnyvale, CA 94089 USA Lodi, CA 95240

USA

Functional Testing according to D22403, Rev. G

Test Description	Acceptance Criteria	Test Result
Negative	Negative	Passed
LOW Positive	Positive	Passed
HIGH Positive	Positive	Passed

8/20/2024

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

Signature of Quality Assurance

Date

Name: Mai Kue

Title: Quality System Specialists

Solna

Lodi

Sunnyvale