

Xpert® Bladder Cancer Detection Datasheet — CE-IVD

Test Reagent Kit Xpert Bladder Cancer Detection

Catalog Number GXBLAD-CD-CE-10

Technology Real-time RT-PCR

Targets Five mRNA targets UPK1B, IGF2, CRH, ANXA10, ABL1

Batch or On-Demand On-Demand

Minimum Batch Size 1

Sample Types Voided Urine (not first morning void)

Sample Extraction Automated/integrated

TAT Approximately 90 minutes

Controls: Sample
Adequacy Control

ABL1

Controls: Probe Function/Detection

Probe Check Control

Controls: Internal

Control

Armored RNA®

Xpert Bladder Cancer Detection Performance vs. Cystoscopy/Histology

(N=895 study subjects) Overall Low Grade High Grade

Sensitivity 75.8% 52.2% 88.4%

Specificity 84.6% N/A

Negative 97.8% Predictive Value

Positive Predictive Value

Sample Storage

& Stability

Urine samples in Xpert Urine Transport Reagent tubes are stable up to 7 days at 2–28 °C

Kit Storage 2–28 °C

Additional Required

Materials

Xpert Urine Transport Reagent Kit Catalog Number: GXUTR-CE-30

Commercial Controls

Available via independent 3rd party

Contact Technical Support (Email: techsupport@cepheid.com) for additional information

CE-IVD. In Vitro Diagnostic Medical Deveice. Not available in all countries. Not available in the United States.

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