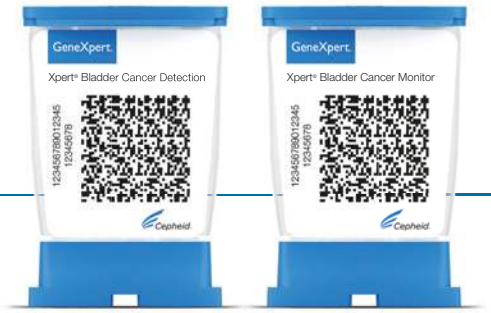
Cepheid
A better way.

Xpert® Bladder Cancer Detection
Xpert® Bladder Cancer Monitor

Two non-invasive urine tests that deliver accurate and actionable results



The Need

Hematuria is one of the most common symptoms of bladder cancer.[1] Almost all patients with bladder cancer present hematuria, but less than 10% of patients with hematuria are diagnosed with bladder cancer.[1]

Patients diagnosed with non-muscle invasive bladder cancer (NMIBC) have high recurrence and progression, requiring frequent follow-ups.[11]

The European Association of Urology (EAU) and the American Urological Association (AUA) recommend cystoscopy and histology to diagnose patients with hematuria and cystoscopy for surveillance of patients diagnosed with NMIBC and not treated with radical cystectomy.[2,3] The standard methods are invasive, painful, relatively expensive, operator-dependent, and often imperfect.[3]

The Solution

The **Xpert® Bladder Cancer Detection** is intended as an aid to detect the presence of bladder cancer in patients with hematuria suspected of having bladder cancer.[9]

The **Xpert® Bladder Cancer Monitor** is intended as an aid to monitor the recurrence of bladder cancer in patients previously diagnosed with bladder cancer.[10]

The Xpert® Bladder Cancer Detection and Xpert Bladder Cancer Monitor tests are non-invasive, easy to implement, fast, and painless biomarker tests with high negative predictive values.[9,10] Both tests utilize voided urine specimens to measure the level of five target mRNAs (ABL1, CRH, IGF2, UPK1B, ANXA10) in a self-contained cartridge and can be performed in any size urology lab without a traditional PCR lab setup.[9,10]

The Impact

- Fast and noninvasive test to detect or exclude bladder cancer and determine the need for further diagnostic follow-up.[4,5]
- Enables use of clinically relevant and readily available urine specimens to avoid unnecessary procedures and discomfort.[4,6]
- Helps detect early onset and recurrence of bladder cancer before it is detectable by cystoscopy.[5,7,8]

1 Tae Jeong Oh, Ji Yong Lee, Yangyei Seo, Min A. Woo, Jae Sung Lim, Yong Gil Na, Ki Hak Song, Bo-Ram Bang, Justin Junguek Lee, Ju Hyun Shin, Sungwhan An, Evaluation of Sensitive Urine DNA-Based PENK Methylation Test for Detecting Bladder Cancer in Patients with Hematuria, The Journal of Molecular Diagnostics, Volume 25, Issue 9, 2023, Pages 646-654, ISSN 1525-1578, https://doi.org/10.1016/j.jmoldx.2023.05.003.

2 EAU Guidelines. Edn. presented at the EAU Annual Congress Milan 2023.

3 Chang SS, Boorjian SA, Chou R. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline. AUA/SUO Joint Guideline: Published 2016; Amended 2020 [Internet]. https://www.auanet.org/. 2020 [cited 2021 Jun 21]. Available from: https://www.auanet.org/guidelines/guidelines/bladder-cancer-non-muscle-invasive-guideline

4 Palou J, Brausi M, Catto JWF. Management of Patients with Normal Cystoscopy but Positive Cytology or Urine Markers. Eur Urol Oncol. 2020;3(4):548–54.

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9 Xpert Bladder Cancer Detection Instructions for Use. 301-2414.

10 Xpert Bladder Cancer Monitor Instructions for Use. 301-5933.

11 11. Witjes JA. Follow-up in non-muscle invasive bladder cancer: facts and future. World J Urol. 2021 Nov;39(11):4047-4053. doi: 10.1007/s00345-020-03569-2. Epub 2020 Dec 26. PMID: 33367941; PMCID: PMC8571151.

Xpert® Bladder Cancer Detection

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert Bladder Cancer Detection
Catalog Number	**CE-IVD** 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 Type	Voided Urine (not first morning void)
Sample Volume	4 ml
Sample Extraction	Automated/integrated
Precision Pipetting	Not Required
Off-board Sample Preparation Time	Approximately 5 minutes
TAT	Approximately 90 minutes
Controls: Sample Adequacy Control	ABL1
Controls: Probe Function/Detection	Probe Check Control (PCC)
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	N/A

Negative Predictive Value	97.8%	
Positive Predictive Value	28.1%	
System & Software	**GeneXpert Dx System** GeneXpert Dx software version 4.7b or higher	**GeneXpert Infinity** Xpertise software version 6.4b or higher
Sample 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	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support	

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Xpert® Bladder Cancer Monitor

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert Bladder Cancer Monitor
Catalog Number	**CE-IVD** GXBLAD-CM-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 Type	Voided Urine (not first morning void)
Sample Volume	4 ml
Sample Extraction	Automated/integrated
Precision Pipetting	Not Required
Off-board Sample Preparation Time	Approximately 5 minutes
TAT	Approximately 90 minutes
Controls: Sample Adequacy Control	ABL1
Controls: Probe Function/Detection	Probe Check Control (PCC)
Controls: Internal Control	Armored RNA®

Xpert Bladder Cancer Monitor Performance vs. Cystoscopy/Histology

(N=255 study subjects)	**Overall**	**Low Grade**	**High Grade**
Sensitivity	75.0%	63.2%	84.0%
Specificity	80.6%	N/A	N/A

Negative Predictive Value	93.9%	
Positive Predictive Value	44.6%	
System & Software	**GeneXpert Dx System** GeneXpert Dx software version 4.7b or higher	**GeneXpert Infinity** Xpertise software version 6.4b or higher
Sample 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	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support	

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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