



A non-invasive urine test  
that delivers accurate and  
actionable results

■ Xpert® Bladder Cancer Detection





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Most patients with blood in their urine do not have cancer. We recently demonstrated that using molecular diagnostic urine tests can greatly help us identify those patients who need the most thorough investigations.<sup>1,2</sup> Based upon the promising performance of Xpert® Bladder Cancer Detection we are currently investigating how we might use this assay in our haematuria patients.”

**Prof. Dr. Bernd Jürgen Schmitz-Dräger,  
Urologie 24, Nuremberg and Dept. of Urology  
and Pediatric Urology, University Hospital,  
Erlangen, Germany**



## The Need

Early and accurate diagnosis of bladder cancer is critical in patients with hematuria.<sup>3</sup>

- Four out of five people with bladder cancer have blood in their urine<sup>4</sup>
- But 80–90% of patients with visible hematuria, and over 95% of patients with non-visible hematuria do NOT have cancer
- There are many known causes of hematuria including urinary tract infection, nephrolithiasis (stones), etc<sup>4</sup>
- In patients with hematuria, it can be difficult to decide which patients might have cancer and which patients might have a different condition
- Primary care physicians are sometimes reluctant to refer patients with visible or significant microscopic hematuria to urology for further investigation<sup>5</sup>



## The Solution

Xpert Bladder Cancer Detection is a non-invasive biomarker test for patients with hematuria that is used in conjunction with other clinical measures.

- Five mRNA biomarkers were intensively validated for the detection of bladder cancer
- The non-invasive and painless test uses voided urine samples
- The test is performed using a self-contained cartridge and system, and can be performed in any size urology lab
- Each cartridge contains three controls for dependable results
- Sample stability for up to 7 days in Xpert® Urine Transport Reagent
- The test enables flexible testing as required

Coverage, plus  
Accuracy, plus  
Peace of mind

That's the PCR<sub>plus</sub> advantage.  
From Cepheid.



## The Impact

A test that helps clinicians gain additional information for patients with hematuria.

- Non-invasive test to reduce patients' anxiety, pain, and embarrassment<sup>6</sup>
- High negative predictive value may help patients avoid unnecessary procedures and discomfort<sup>7</sup>
- Easy to implement and train
- Robust test and workflow with decentralized laboratory testing

## Performance

Delivers high sensitivity and NPV for low and high-grade bladder cancer.<sup>8</sup>

### Xpert® Bladder Cancer Detection vs. Cystoscopy/Histology<sup>8</sup>

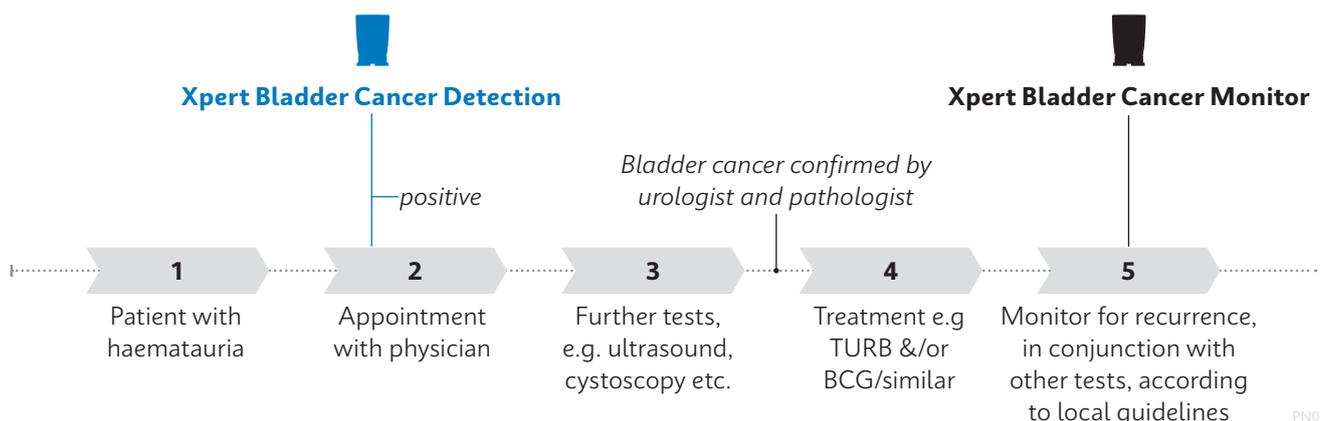
	Cystoscopy/Histology		Total
	Positive	Negative	
Xpert Bladder Cancer Detection	50	128	178
	16	701	717
Total	66	829	895

<i>Sensitivity:</i>	75.8% (95% CI: 64.2–84.5)	<i>NPV:</i>	97.8% (95% CI: 96.4–98.6)
<i>Specificity:</i>	84.6% (95% CI: 81.9–86.9)	<i>Accuracy:</i>	83.9% (95% CI: 81.4–86.2)
<i>PPV:</i>	28.1% (95% CI: 22.0–35.1)	<i>Prevalence:</i>	7.4% (95% CI: 5.8–9.3)

PN0039-01

Xpert Bladder Cancer Detection was evaluated at sites in the E.U. and North America. Subjects included individuals presenting with symptoms of bladder cancer.<sup>8</sup> For study purposes, symptomatic patients were defined as those presenting with macroscopic (gross) or asymptomatic microhaematuria within 12 weeks of enrollment into the study. Results of Xpert Bladder Cancer Detection were compared to cystoscopy, with histology confirmation of positive and suspicious cystoscopies.



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## Workflow: 3 Easy Steps

Easy to perform test provides results in approximately 90 minutes.

1

Transfer approx. 4.5 mL of voided urine into the urine transport reagent tube. Invert to mix well.



2

Place 4 mL of this mixture into the sample chamber of the cartridge.



3

Insert cartridge and **start test**



PN0037-01

### Catalog Information

Xpert® Bladder Cancer Detection	10 tests	GXBLAD-CD-CE-10
Xpert Urine Transport Reagent Kit	30 sets	GXUTR-CE-30

#### REFERENCES:

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- 5 Yafi FA, et al. Patients with microscopic and gross hematuria: practice and referral patterns among primary care physicians in a universal health care system. *Can Urol Assoc J* 2011;5(2):97-101.
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- 7 Todenhöfer, et al. Prognostic relevance of positive urine markers in patients with negative cystoscopy during surveillance of bladder cancer. *BMC Cancer.* 2015 Mar 19;15:155.
- 8 Bladder Cancer Detection Package Insert. Sunnyvale, USA 301-2414 Rev F March 2023.

#### CORPORATE HEADQUARTERS

904 Caribbean Drive  
Sunnyvale, CA 94089 USA

TOLL FREE +1.888.336.2743  
PHONE +1.408.541.4191  
FAX +1.408.541.4192

#### EUROPEAN HEADQUARTERS

Vira Solelh  
81470 Maurens-Scopont France

PHONE +33.563.82.53.00  
FAX +33.563.82.53.01  
EMAIL [cepheid@cepheideurope.fr](mailto:cepheid@cepheideurope.fr)

[www.Cepheidinternational.com](http://www.Cepheidinternational.com)

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