

Xpert®
Bladder
Cancer
Detection



Xpert® Bladder Cancer Detection

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

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

 **Cepheid®**
A better way.



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 investigation.^{1,2} Based upon the promising performance of the Xpert® Bladder Cancer Detection we are currently investigating how we might use this assay in our haematuria patients."

Prof. Dr. Bernd Jürgen Schmitz-Dräger, Schön Hospital Nuremberg Fürth, Urology Practice



The Need

Early and accurate diagnosis of bladder cancer is critical in patients with hematuria.³

- Four out of five people with bladder cancer have blood in their urine
- 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), etc⁴
- 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 investigation⁵
- Over 20,000 bladder cancer cases are estimated to be missed annually in the U.S.⁶



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
- High NPV and sensitivity increase help to rule out high-grade tumors
- 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



The Impact

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

- Non-invasive test to reduce patients' anxiety, pain, and embarrassment⁷
- High negative predictive value may help patients avoid unnecessary procedures and discomfort⁸
- Easy to implement and train
- Robust test and workflow that does not require a PCR laboratory



Performance

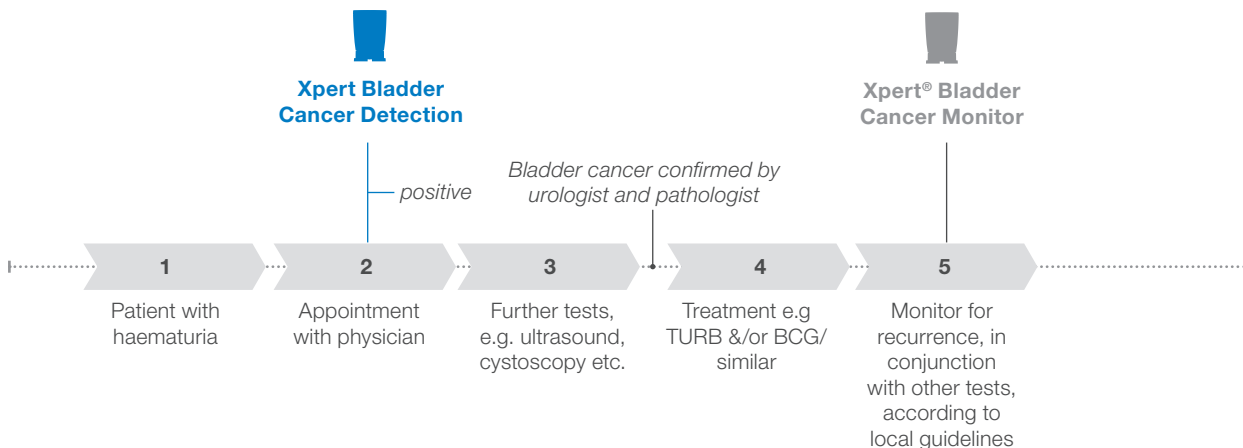
Delivers high sensitivity and NPV for low and high-grade bladder cancer.

Xpert® Bladder Cancer Detection vs. Cystoscopy/Histology⁹

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

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

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





Workflow

3 Simple 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.



CATALOG NUMBER

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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4. Avellino G et al. Diagnosis and Management of hematuria. *Surg Clin North Am.* 2016 Jun;96(3): 503-15.
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. Biardeau X, et al. Prospective evaluation of anxiety, pain, and embarrassment associated with cystoscopy and urodynamic testing in clinical practice. *Can Urol Assoc J.* 2017 Mar-Apr; 11(3-4): 104-110.
8. 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.
9. Xpert Bladder Cancer Detection Package Insert. Sunnyvale, USA 2016.

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