

A non-invasive test for the risk stratification of urothelial cancer



Allows for the option of in-clinic or in-home sampling

Cxbladder Detect is a genomic urine test that analyzes biomarker genes to help risk stratify urothelial cancer in patients presenting with hematuria.

Make the most of your time and clinical resources. Cxbladder Detect helps de-intensify clinical work-up in patients with a low probability of UC, reducing the need for further invasive procedures, while prioritizing those that require immediate care.

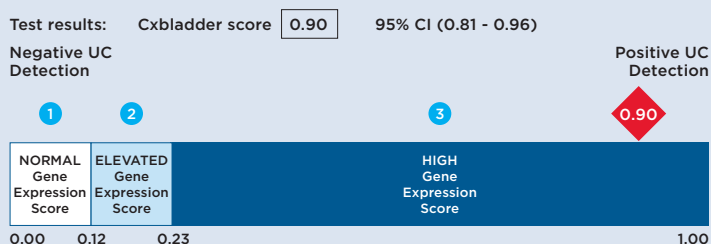
Resolve diagnostic dilemmas. Cxbladder Detect is an objective test that is more reliable than subjective cytology testing.



Using Cxbladder Detect in your practice

- Enables reliable risk stratification prior to cystoscopy. Safely de-intensifies clinical workup in patients with a low probability Detect test result.
- Spares patients with a low probability test result the discomfort, anxiety and risks of an invasive procedure.
- An effective adjunct when other tests are inconclusive. Resolves atypical cytology and equivocal cystoscopy.

A DETAILED CXBLADDER DETECT TEST REPORT IS DELIVERED TO YOUR PRACTICE



- 1 NORMAL Gene Expression Score:**
A score of < 0.12 has a Negative Predictive Value (NPV) of 97%. High probability of NO Urothelial Carcinoma (UC)
- 2 ELEVATED Gene Expression Score:**
A score of $0.12 \leq \text{score} < 0.23$ has an NPV of 94%. Low probability of UC, however a change in the pattern of gene expression of the biomarkers from what is normal suggests further clinical evaluation
- 3 HIGH Gene Expression Score:**
A score of ≥ 0.23 has a Positive Predictive Value (PPV) of 68%. High probability of UC

Cxbladder is a precision test that delivers exceptional performance and clinically actionable results.

- The performance of the Cxbladder suite of tests is supported by over 25 peer reviewed publications
- Cxbladder tests have been used by over 5,000 urologists in more than 100,000 patients.

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A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria

O'Sullivan P, Sharples K, Dalphin M, et al. J Urol 2012;188:741-7

Overview: A multicenter clinical study conducted on a prospective cohort of 485 patients with a recent history of hematuria, who were undergoing investigation for possible urological cancer.

Conclusion: Cxbladder Detect outperformed comparative tests as an adjunct to cystoscopy.

SENSITIVITY OF URINE DETECTION TESTS IN CLINICAL STUDY*

Tumour stage	Cxbladder Detect	Cytology	NMP22 BladderChek	NMP22 ELISA
Tis	100%	100%	0%	0%
Ta	68%	35%	38%	35%
T1	100%	69%	50%	75%
T2	100%	100%	22%	67%
T3	100%	100%	50%	100%
High grade Tumours	97%	83%	38%	69%
Upper tract Tumours	100%	50%	0%	75%
Overall sensitivity	82%	56%	38%	50%
Specificity	85%	96%	96%	88%

* Cystoscopy used as the reference standard

** 94% specificity when the higher 0.23 cut point on the Test Report is used

Evaluation of Cxbladder and adjudication of atypical cytology and equivocal cystoscopy

Konety, B, Shore, N, Kader, AK, et al. Eur Urol 2019.

Overview: A total of 1784 consecutive, prospectively recruited patients with hematuria or previously diagnosed UC provided 852 samples with both local cytology and Cxbladder results; 153 had atypical cytologies and 14 had both atypical cytology and equivocal cystoscopy.

Conclusion: Cxbladder correctly adjudicated all patients diagnosed with UC among those with atypical cytology and equivocal cystoscopy, and outperformed cytology for accurately identifying patients who do not have UC.

- Cxbladder detected 86 of 94 tumors, including 45 of 46 HG tumors; Sn = 91.5%, NPV = 97.4%
- Cxbladder correctly adjudicated all 153 cytology atypical results.
- Cxbladder correctly ruled out 47 of the 153 samples, Rule-out rate of 31%.
- 26 out of 26 with UC were detected by Cxbladder.
- Cxbladder correctly adjudicated 14 samples with atypical cytology and equivocal cystoscopy (2 samples with UC, one \geq T1, and one CIS).

Cxbladder Detect lets you spend less time looking for UC that isn't there, so you can spend more time with those that require immediate care.

Learn more

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