Cx bladder™

The difference in cancer detection

Introduction

The difference in cancer detection

Cxbladder

Cxbladder is a non-invasive laboratory test for the detection of bladder cancer that gives you actionable results, which can make a meaningful difference in your patient's treatment.

This clinically validated test measures the gene expression levels of five biomarkers, that represent a bladder cancer signature. Cxbladder detects changes in gene expression for bladder cancer and helps rule out cancer in patients showing normal gene expression - quickly, easily and non-invasively.

Overview

- A urine-based detection test to determine the likelihood of bladder cancer in patients presenting with haematuria
- Facilitates early detection of bladder cancer and helps rule out bladder cancer-free patients[1]
- Effective adjunct to cystoscopy
- Can be used to replace other urine-based tests or replace the need for CT / IVP in some instances
- Easy to use - a complete sampling system is provided for collection and shipment of the patient's urine to our laboratory

Your interpretation, our science

Over a decade of research has led to this state-of-the-art molecular diagnostic test that is used to provide a score to aid in diagnosing bladder cancer.

This research has identified that messenger RNA (mRNA) levels of specific biomarkers are present at higher levels in urine samples of patients that are positive for bladder cancer than in urine samples of patients who are negative for the disease[2].

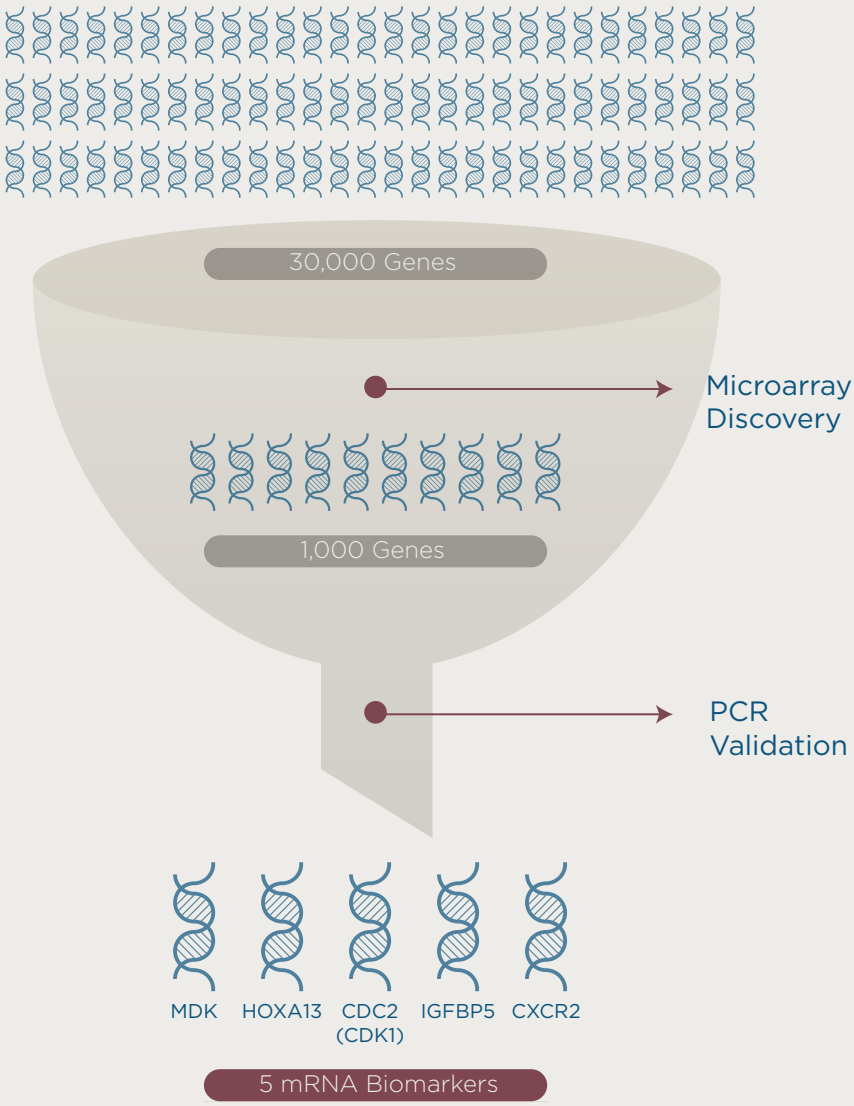
[1] O'Sullivan et al: A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria, J Urol 2012; 188: 741-747

[2] Holyoake et al: Development of a multiplex RNA urine test for the detection and stratification of transitional cell carcinoma of the bladder, Clin Cancer Res 2008; 14(3): 742-749

Cxbladder Biomarker Gene Descriptions

- **MDK: Blood vessel growth and cell migration**
  Principally involved in cell proliferation, migration and angiogenesis in cancer cells.
- **HOXA13: Cell differentiation**
  Principally involved in cell differentiation and the morphogenesis and differentiation of the genitourinary tracts.
- **CDC2 (CDK1): Cell division**
  Cyclin dependent kinase. Essential to mitotic cell cycle: cell proliferation.
- **IGFBP5: Programmed cell death**
  Acts as an anti-apoptotic gene.
- **CXCR2: Inflammation**
  Mediates neutrophil migration to sites of inflammation. Moderates non-malignant inflammation (False Positives).

The difference
between practice and theory



The difference
between confidence and doubt

Cxbladder is more reliable and objective than many other urine-based cancer detection tests. With its high sensitivity, Cxbladder makes an effective adjunct to cystoscopy, providing a higher level of confidence in diagnostic test results.

The Cxbladder cancer detection test has been validated by a multicentre clinical study conducted on a prospective cohort of 485 patients with a recent history of gross haematuria, who were undergoing investigation for possible urological cancer.[1]

Clinical evidence from this multicentre study supports the efficacy of Cxbladder, which outperformed comparative tests as an adjunct to cystoscopy:

- → Negative predictive value (NPV) of 97%
- → Detected 100% of T1-T3, Tis and upper tract tumours
- → Detected 97% of high-grade tumours
- → Overall sensitivity of 82%

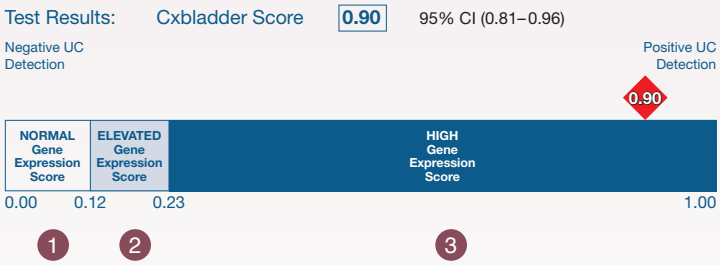
Sensitivity of Urine Detection Tests in Clinical Study*

	Cxbladder	Cytology	NMP22 BladderChek	NMP22 ELISA
Tumour Stage				
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 a reference standard

The difference
between action and reaction

Cxbladder gives you actionable results that can make a meaningful difference in your patient's diagnosis and treatment. We will give you the information you need to be proactive – every step of the way.



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 ≤ 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

How Cxbladder can be used in your practice:

- → Replace the need for other urine-based tests in primary workup
- → Complement cystoscopy for bladder cancer detection
- → Detect urothelial tumours not visible by cystoscopy
- → Replace the need for CT / IVP in primary workup in some instances
- → Improve patient compliance with accurate, non-invasive testing

Other applications may include:

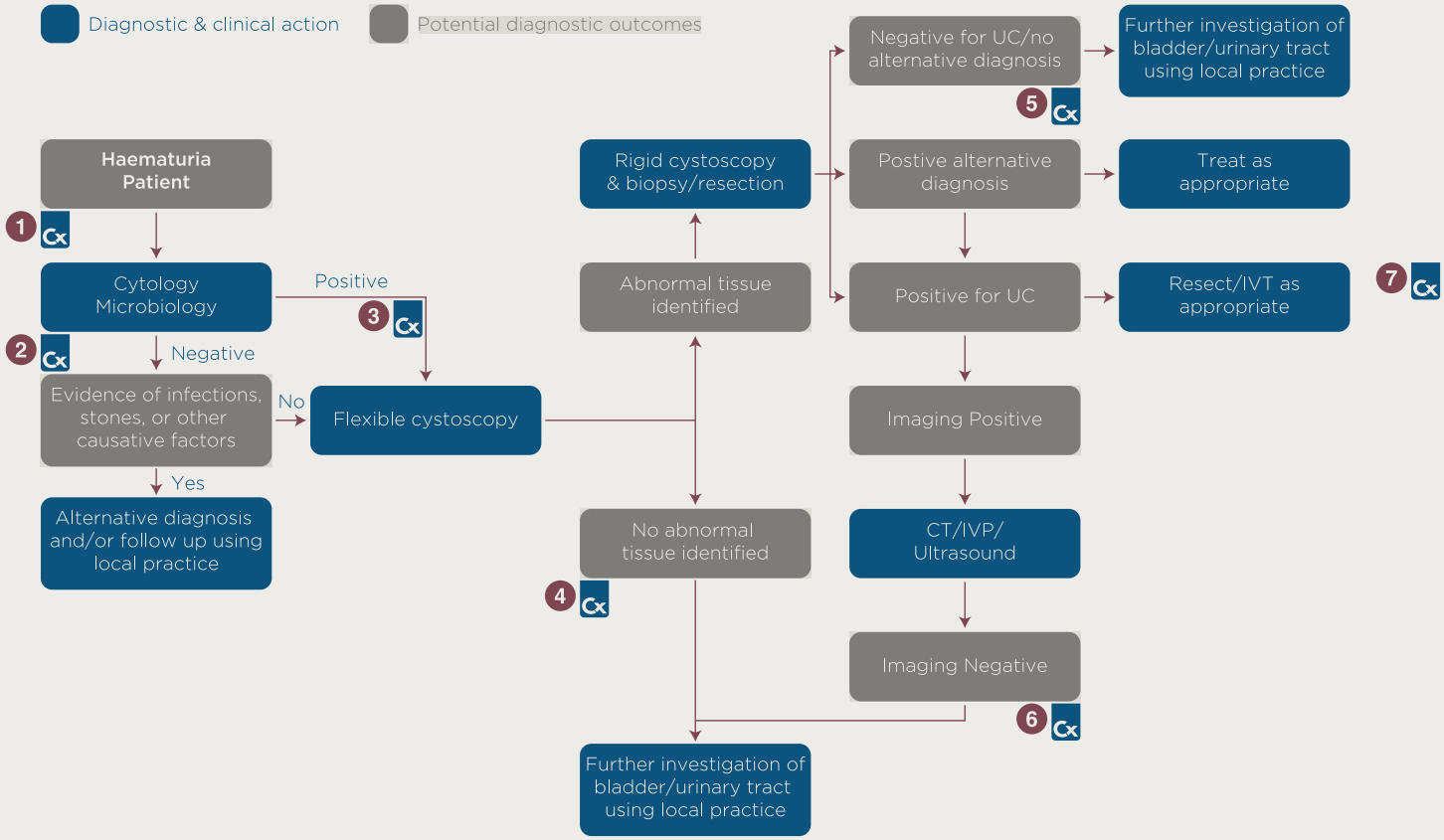
- → Complement cystoscopy for monitoring bladder cancer recurrence
- → Increase the interval between surveillance cystoscopies in certain circumstances
- → Triage patients presenting with micro-haematuria that do not need a full workup
- → Evaluate patients in 'at-risk' populations
- → Patient priorisation in high throughput settings

Cxbladder can be used early in the clinical pathway to support early detection. It can also be used as an adjunct to other tests to confirm the presence or absence of UC, giving you greater confidence in your diagnosis.

Bladder Cancer Detection Legend

1. Replace need for other urine-based testsn in primary workup
2. Follow up atypical or negative cytology
3. Triage out patients showing normal gene expression
4. Detect UC not visible by cystoscopy (e.g., upper tract of Tis) and/or replace the need for CT/IVP, or confirm absence of UC with high NPV
5. Confirm absence of UC with high NPV
6. Confirm absence of UC with high NPV
7. Post diagnosis applications may include monitoring for UC recurrence

Where Cxbladder fits in the bladder cancer detection clinical pathway



The difference
between simplicity and complexity

The Cxbladder sampling system was developed with the support of leading urologists and nurses to ensure efficiency and ease of use. The process is simple and straight-forward:

Ordering

- Customer support teams on call to answer questions about the test
- Sales representatives available for in-office support

Sample Collection

- A complete sampling system is provided for the collection of a patient's urine
- Sampling system contains a proprietary Cxbladder liquid (RNA preservative reagent to stabilise patient specimen)
- Only a small sample of urine is needed and no contact with urine is required
- Sampling process easy enough for patients to perform at home

Shipment and Analysis

- The sample is sent to our qualified laboratory for analysis
- Pre-paid and pre-labelled packaging provided (collection centres available in some areas)
- Refrigeration is not required
- Results available within five business days from sample receipt

Reporting

- A detailed Cxbladder test report is delivered to your practice
- Secure delivery options available

The difference
between commitment and compromise

We are here to support you. Cxbladder is supported by a committed, dedicated team of professionals. For further information on how Cxbladder can make a difference for you and your patients, and to inquire about ordering a Cxbladder test, please contact one of our trained sales specialists at:

0800-CXBLADR (0800-2925-237)
info@cxbladder.com
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Cxbladder is a laboratory developed test for the detection of bladder and other urinary tract cancers and is only to be used under the guidance of a healthcare professional. Results provided by this test should be interpreted in conjunction with other clinical information to make decisions about patient medical care.

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