

Ordering Cxbladder is simple and straightforward

1 Ordering Cxbladder

To order a Cxbladder test, please contact your Pacific Edge Diagnostics Account Executive or Customer Service at:

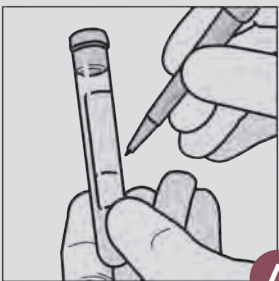
0800-CXBLADR (0800-2925-237)

info@cxbladder.com

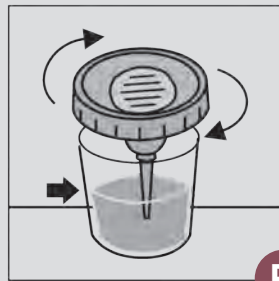
www.cxbladder.com



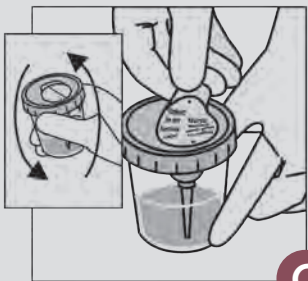
2



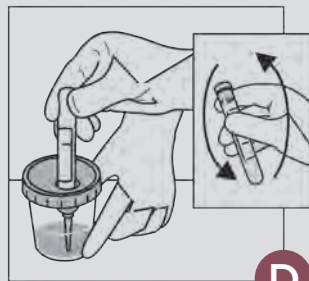
A



B



C



D

Cxbladder sample collection

A complete Cxbladder urine sampling system will be sent to you for the collection of your patient's urine. You can also choose for the sampling system to be sent direct to your patient. The collection process requires only a small sample of fresh mid-stream urine, preferably from the second void of the day.

- A** Label Cxbladder tube with patient details.
- B** Ask patient to void directly into the Cxbladder collection cup until 1/3 of the cup is filled. Reseal the cup.
- C** Invert cup several times to agitate the sample. Peel back protective sticker to expose rubber-covered needle.
- D** Push the Cxbladder tube onto the rubber-covered needle and hold in position until the flow stops. Remove tube and invert several times. Place in the supplied specimen bag.

These instructions are for demonstration purposes only. Please refer to the full instructions for use supplied with the Cxbladder Urine Sampling System.

3

Cxbladder shipment and analysis

Prior to shipping, please complete the supplied Test Requisition Form (TRF) and enclose with sample in the provided packaging for shipment.

Follow the shipping instructions on the TRF in order to send your patient's sample to our qualified laboratory for analysis via pre-paid shipping packaging.

Results will be available within five business days from sample receipt.

4

Cxbladder test reporting

Once the analysis is complete, a detailed Cxbladder test report will be securely delivered to your practice.

Please see reverse side for further details on Cxbladder test reporting



Cxbladder gives you actionable results

Sample test report

Clinician
Clinic
Address 1
Address 2
City State Province Postcode
Country

Patient Name: Surname, Givenname
Patient DOB: DD-MTH-YYYY
Gender: Male
Patient NHI No: xxxxxx
Sample ID: PETEST
Collection Date: DD-MTH-YYYY
Receipt Date: DD-MTH-YYYY
Report Date: DD-MTH-YYYY
Specimen Source: Urine
Status: FINAL

Assay Description and Clinical Use:

Cxbladder is a quantitative assay that uses RT-qPCR to measure five mRNA biomarkers (CDC2, MDK, IGFBP5, HOXA13 and CXCR2) in a small sample of a patient's urine. An algorithm is applied to the measured quantities of these biomarkers to calculate the composite Cxbladder score. The Cxbladder score ranges from 0.00 to 1.00. Test results are intended to aid in the detection of Urothelial Carcinoma (UC) when used in conjunction with standard clinical assessment.

Test Results: Cxbladder Score 0.90 95% CI (0.81–0.96)

Negative UC Detection Positive UC Detection

Comments:

Results Interpretation:

The Cxbladder test was developed and validated on 476 patients recruited under an international multicentre clinical study of patients presenting with macro haematuria. The patients were allocated to a group of 317 for development and 159 for validation. 100% of T1, T2, and T3 tumours were placed in the "HIGH Gene Expression Score" region and 67% of the Ta tumours in the "ELEVATED or HIGH Gene Expression Score" regions. A Cxbladder score of greater than or equal to 0.12 has a sensitivity of 82% and a specificity of 82%. The test is a development from the clinical study published in J. Urology (2012) 188:741-747.

NORMAL Gene Expression Score < 0.12	A score of < 0.12 has an NPV of 97%. High probability of NO Urothelial Carcinoma.
ELEVATED Gene Expression Score 0.12 ≤ score < 0.23	A score of 0.12 ≤ score < 0.23 has an NPV of 94%. Low probability of Urothelial Carcinoma, however a change in the pattern of gene expression of the biomarkers from what is normal suggests further clinical evaluation.
HIGH Gene Expression Score ≥ 0.23	A score of ≥ 0.23 has a PPV of 68%. High probability of Urothelial Carcinoma.

Peter Gootjes, MB ChB, Laboratory Director:

Disclaimer: This is a high complexity clinical test which was developed by and its performance characteristics determined by Pacific Edge Ltd. This test is for clinical purposes and is intended to aid the clinician in detecting bladder cancer. It should not be regarded as investigational or for research only. This test has not been approved by the US Food and Drug Administration (FDA) and such approval is not required. The laboratory is regulated under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

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Tel: 0800 CXBLADR (0800 2925-237) Fax: (03) 479-5801 Email: info@cxbladder.com Web: www.cxbladder.com
07-MTS-101-NZ-REV0 Cxbladder is a trademark of Pacific Edge Ltd Under license from Pacific Edge Ltd

Sample Cxbladder test report

The Cxbladder test provides actionable results that are intended to aid in the detection of Urothelial Carcinoma (UC) when used in conjunction with standard clinical assessment.

Each Cxbladder test is given a score between 0.00 and 1.00, based on the measured quantity of five mRNA biomarkers that represent a bladder cancer signature (CDC2, MDK, IGFBP5, HOXA13 and CXCR2).

This sample Cxbladder test report shows a Cxbladder score of 0.90 (HIGH Gene Expression Score - High Probability of UC).

What do the results mean?

- 1 NORMAL Gene Expression Score (High Probability of NO UC)**
The pattern of expression of the five biomarker genes is typical for healthy individuals.
- 2 ELEVATED Gene Expression Score (Low Probability of UC)**
The pattern of expression of the five biomarker genes shows a trend in alteration from what is typical for a normal individual. Suggests further clinical evaluation is required.
- 3 HIGH Gene Expression Score (High Probability of UC)**
The pattern of gene expression of the five biomarker genes is altered from what is typical for a normal individual.

Test Results: Cxbladder Score 0.90 95% CI (0.81–0.96)

Negative UC Detection Positive UC Detection