

COMBINED USE OF CXBLADDER PRODUCTS SHOWS SIGNIFICANT OUTPERFORMANCE

- **A pivotal, peer-reviewed paper, accepted for publication in the Journal of Urology, demonstrates the significant clinical and patient benefits from the use of a combination of Cxbladder products to correctly identify haematuria patients, who have urothelial cancer (UC)¹ and also, further segregate those patients with high-impact tumours (HIT) requiring priority investigation.**
- **Of significant importance, the study concluded that the sequential use of the Cxbladder products achieved 4.8 times greater efficiency in accurately assigning patients to the physician's prioritisation of investigation than the latest American Urology Association (AUA) 2020 guidelines.**

Cancer diagnostics company, Pacific Edge Limited, is pleased to advise that a new scientific and clinical paper validating the diagnostic performance of its fourth Cxbladder test, Cxbladder Resolve (CxbR), has been accepted for publication in the Journal of Urology. The Journal of Urology is the official Journal of the AUA and the most widely read and highly cited journal in the field of Urology.

Cxbladder Resolve was designed for use by a physician following a patient's initial evaluation using both Cxbladder Triage (CxbT) and Detect (CxbD). Those patients that test positive to CxbT and then also test positive to CxbD, will receive the Cxbladder Resolve (CxbR) test. CxbR accurately identifies those patients with a high-impact tumour (HIT), who require high priority intervention by their urologist. High-impact tumours are those that have the highest probability of invasion and progression and where early detection is critical for a successful outcome.

The paper titled 'Cxbladder for prioritising high-risk urothelial cancer patients' evaluates the use of Cxbladder Resolve, alone and in combination with other Cxbladder tests, to identify and prioritise patients at high risk for urothelial carcinoma/cancer' (UC)². Cxbladder Resolve was developed on 863 haematuria³ patients recruited in the US, New Zealand and Australia; and then tested, both separately and in combination with other Cxbladder tests, on a further 548 Kaiser Permanente patients, with outstanding results.

Of note, Cxbladder Resolve correctly identified all patients with high-impact tumours, allowing those patients to be prioritised for further investigation.

The paper concluded that Cxbladder Resolve has high sensitivity (92.4%) and specificity (93.8%) and correctly identified all high-impact tumours. In addition, sequential use of Cxbladder tests accurately segregated patients with a low vs high probability of high-impact tumours, enabling the prioritisation of physician resources for these patients.

With the sequential use of Cxbladder tests for each patient (Triage, followed by Detect, followed by Resolve):

- 87.6% of patients were correctly ruled out from requiring further workup (negative predictive value 99.4%)
- 100% of high-impact tumours were accurately identified for prioritised investigation in both study cohorts

¹ Urothelial carcinoma/cancer includes bladder cancer and cancers of the upper urinary tract

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³ Haematuria is blood in the urine and a key indicator of bladder cancer.

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CEO of Pacific Edge, David Darling, said: “Our long-standing strategy has been to develop a suite of Cxbladder products that can be used alone or in combination to address unmet needs across the entire clinical pathway for urothelial cancer. This is a pivotal paper for urologists, outlining the significant increase in clinical resolution that can be achieved from using the multiple Cxbladder products in this fashion. This is the first time that the clinical benefits of this novel approach have been validated.

“The paper confirmed that the combined use of three of our Cxbladder products for each patient, using just one urine sample, can firstly rule out those who do not have cancer, then accurately identify those with cancer and finally, segregate out those with high-impact tumours for priority investigation. This approach provides significant benefit to both physicians and patients, substantially reducing the number of patients requiring further work up while prioritising those patients with high impact tumours.

“A significant outcome confirmed by this paper is the outperformance of Cxbladder used in this format where the sequential use of the three Cxbladder tests achieved 4.8 times greater efficiency in accurately assigning patients to the physician’s prioritisation of investigation, than the latest AUA guidelines. We expect this outcome to support additional AUA guideline inclusion and greater adoption of Cxbladder.”

“A testament to the quality of this study (where the primary author is one of the key Kaiser Permanente’s urologists), is that it shows the successful use of Cxbladder on Kaiser Permanente patients, supporting our now established relationship with one of the US’s largest healthcare provider and payers.”

Feedback from the Journal’s independent peer reviewers during the publication process was very positive, highlighting the potential for the study to *“change the diagnostic paradigm for patients presenting with hematuria, better identifying high-risk patients and decreasing the time to tumor diagnosis.”*

Additionally, *“This series of urine based tests appears to represent an exciting pathway for hematuria workups better stratifying risk of malignancy, and perhaps obviating the need for cystoscopy in workup of many patients with hematuria.”*

Reviewers noted that *“The study is novel, as results of CxbR have not been reported before (vs CxbT and CxbD). Based on the high-negative predictive value achieved in the cohort, the purported clinical value of the study is to allow clinicians to triage patients with high risk for expedited workup by sending them straight to transurethral resection and avoiding cystoscopy and CT scans in those that are low priority.”*

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OVERVIEW www.pacifedge.co.nz www.pacifedgedx.com

Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. Its Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The company’s products have been tested and validated in international multi-centre clinical studies.

ABOUT Cxbladder Triage www.cxbladder.com

Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients with haematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial carcinoma.

ABOUT Cxbladder Detect www.cxbladder.com

Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor www.cxbladder.com

Cxbladder Monitor allows urologists to monitor bladder cancer patients for recurrence of the disease. Bladder cancer has a recurrence rate of 50-80% and requires life-long surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer (UC) whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

ABOUT Cxbladder Resolve www.cxbladder.com

Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.