

## CXBLADDER MONITOR ADOPTED BY WAITEMATA DISTRICT HEALTH BOARD

### **Cxbladder Monitor to replace cystoscopy in clinical evaluation for low risk surveillance patients**

Cancer diagnostics company, Pacific Edge Limited (NZX:PEB), has received approval for its latest Cxbladder diagnostic technology, Cxbladder Monitor, from Waitemata District Health Board (WDHB) through the national procurement services of healthAlliance.

Under the WDHB program, selected low risk patients who are undergoing routine surveillance following a previous diagnosis and treatment for bladder cancer will receive a Cxbladder Monitor test. If the test rules out bladder cancer, it means these patients will not require a clinic appointment or have to undergo an invasive cystoscopy procedure.

Brent Pownall, Commercial Director of Pacific Edge Diagnostics, said: "This is another significant achievement for Pacific Edge. To have our newest product, Cxbladder Monitor, adopted so readily at Waitemata DHB, and patients to potentially be spared from undergoing a cystoscopy, is huge. The positive impact of this initiative, demonstrated by the urology team at North Shore Hospital in changing their approach to managing this group of surveillance patients, cannot be underestimated."

*Dr Madhu Koya, Clinical Director of Urology at Waitemata DHB said: "The approach we are taking with Cxbladder is about ensuring that we deliver the best possible care for our patients and clients, living our values of compassion, connectedness, continuous improvement and leadership. In this case, we have adopted the cutting edge Cxbladder Monitor test to improve the lives of some of our bladder cancer surveillance patients with this simple to use, non-invasive urine test. This avoids the inconvenience and anxiety of a visit to the hospital clinic, and the invasive cystoscopy that goes with it, and provides the peace of mind that there is no recurrence of the disease. This is all about what is best for the patient."*

*"We have been involved in the clinical evaluation of the Cxbladder products over a number of years. We trialled Cxbladder Monitor with patients and in our clinics soon after it launched and quickly recognised its utility in allowing us to change how we manage our low risk bladder cancer patients for follow up, while at the same time improving their care with this convenient urine test," Dr Koya said.*

Cxbladder Monitor, which was launched in New Zealand in December 2015, combines both genotypic biomarkers from a small quantity of a patient's urine and patient clinical information to accurately identify those patients who have a low probability of having recurrent urothelial carcinoma (UC), or bladder cancer. Results from clinical trials showed a high test sensitivity and high negative predictive value for Cxbladder Monitor, required to accurately rule out a recurrence of UC. The initial trial results also demonstrated superior performance over all other urine-based tests and were presented at the American Urological Association's 2016 Annual Meeting in May, in San Diego, CA.

CEO of Pacific Edge, David Darling, commented: "This highlights the value in our approach to developing a suite of Cxbladder products that address multiple needs across the entire diagnostic, treatment and management pathway for bladder cancer. Pacific Edge now has all of its current Cxbladder tests being deployed in a wide variety of clinical settings, and in multiple markets – the company is now truly a 'one stop shop' of bladder cancer detection and management tests."

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**OVERVIEW** [www.pacifedge.co.nz](http://www.pacifedge.co.nz) [www.pacifedgedx.com](http://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. 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.

Pacific Edge has three proprietary, novel, accurate, molecular diagnostic products in-market providing actionable results, and better detection and management of urothelial cancer. Cxbladder Detect and Cxbladder Triage are available through the company's dedicated CLIA certified laboratories for customers in New Zealand, Australia and the USA. Cxbladder Monitor launched in New Zealand in December 2015 and is anticipated being available in the US in 2016.

**ABOUT Cxbladder Triage** [www.cxbladder.com](http://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 hematuria 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](http://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 was launched in 2013 in the USA and is commercially available in New Zealand, Australia and the USA as a Laboratory Developed Test (LDT) from the company's CLIA certified laboratories. Cxbladder Detect provides physicians and 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](http://www.cxbladder.com)

Cxbladder Monitor, the third test in the Cxbladder portfolio for urologists, is a proprietary, non-invasive, molecular diagnostic test that combines genomic biomarkers measured from a small quantity of a patient's urine, with patient specific clinical factors to better monitor bladder cancer patients for recurrence. 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.

Refer to [www.cxbladder.com](http://www.cxbladder.com) for more information.