

# **CXBLADDER DEMAND RESILIENT DESPITE COVERAGE LOSS**

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today reports resilient demand for its tests in the three months to the end of June 2025 (Q1 26) despite to loss of Medicare coverage in April 2025 and the disruption caused from the transition of US customers from Detect to Triage.

The company also reports positive discussions with Medicare Administrative Contractor Novitas following Pacific Edge lodging a Medicare reconsideration request based on evidence not considered in the review that led to the non-coverage decision. The new evidence includes the ground-breaking STRATA<sup>1</sup> randomized control study demonstrating the clinical utility of Cxbladder Triage and the new AUA microhematuria guideline.

US TLT in Q1 26 was down 11.9% to 5,717 tests from 6,490 in Q4 25 with the drop in volumes largely due to the disruption of asking physicians to switch from Cxbladder Detect to Triage for hematuria evaluation. Pacific Edge accelerated the decision to discontinue Detect in the US market following the inclusion of Triage in the new American Urological Association Microhematuria guideline and the non-coverage determination.

Cxbladder Triage represented around 77% of US TLT in June 2025 up from 22% in Q4 25, the quarter prior to the decision to discontinue Detect. Meanwhile, Detect tests received for processing (which our customer service attempts to transition to Triage tests with clinician approval) made up only 6% of all tests received for the month of June 2025, down from the 59% received in Q4 25 the last quarter before the determination became effective.

Total laboratory throughput (TLT) in Q1 26 fell 8.9% to 6,900 from the 7,577 tests in Q4 25.

Our sales force efficiency metric in Q1 26 was 381 compared to 406 tests per sales FTE in Q4 25 reflecting the disruptions caused by switching customers from Detect to Triage, which requires additional patient information.

The requirement to provide an advanced beneficiary notice (ABN) with a Cxbladder Monitor test has also impacted volumes, but insulates the company from running unpaid tests, because the ABN informs the patient they may be held financially responsible for the test if Medicare denies payment. Tests per unique US ordering clinician (our preferred metric for measuring customer commitment to Cxbladder) were 6.3, down from the 7.1 tests in Q4 25.

Meanwhile, the volumes from our key contracted US customers such as Kaiser Permanente are unaffected by the determination.

Asia Pacific volumes were up 8.8% to 1,183 from 1,087 in Q4 25, a move that reflected volume growth in all markets; Australia Southeast Asia and New Zealand.

The Q1 26 investor update also covers:

- The publication of data demonstrating the Analytical Validation of Triage Plus in *Diagnostics*<sup>2</sup>. This publication is one of two pieces of clinical evidence Pacific Edge requires to support a reconsideration request from Novitas regarding the Medicare coverage of Triage Plus
- A preview of the company's annual meeting on 6 August 2025 in Auckland and the detail of the company's ~\$21 million capital raising.

## Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

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## **OVERVIEW**

### Pacific Edge: <a href="http://www.pacificedgedx.com">www.pacificedgedx.com</a>

Pacific Edge Limited (NZX/ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

### Cxbladder: www.cxbladder.com

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.