bladder

AUSTRALIAN AND NEW ZEALAND CLINICIANS

Cxbladder Bulletin: November 2026

Coverage news, clinical evidence, and practice updates from the Cxbladder team.

Dear Colleagues,

Welcome to the November 2026 edition of the Cxbladder Bulletin.

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COVERAGE POLICY

US Medicare coverage for Triage Plus & Triage confirmed

Last week we were pleased to announce the publication of a final LCD for Urine-based Biomarkers in Patients with Microhematuria (DL40378), confirming US Medicare coverage for Cxbladder Triage Plus and Triage in the evaluation of intermediate-risk patients.

Cxbladder Triage Plus and Triage are the only tests covered within the LCD, and the final policy, once it takes effect on December 20, will streamline the use and reimbursement of the tests in eligible Medicare patients.

> *"The final LCD is a significant milestone for Pacific Edge, Medicare patients, urologists, and the broader healthcare system. It provides clear guidance on the eligible haematuria patients for which Triage and Triage Plus should be reimbursed and recognises the important role that validated, non-invasive urine-based biomarkers can play in helping physicians make better-informed decisions about cystoscopy."*
>
> — Dr Peter Meintjes, Chief Executive, Pacific Edge

The final LCD can be accessed here →

CLINICAL EVIDENCE

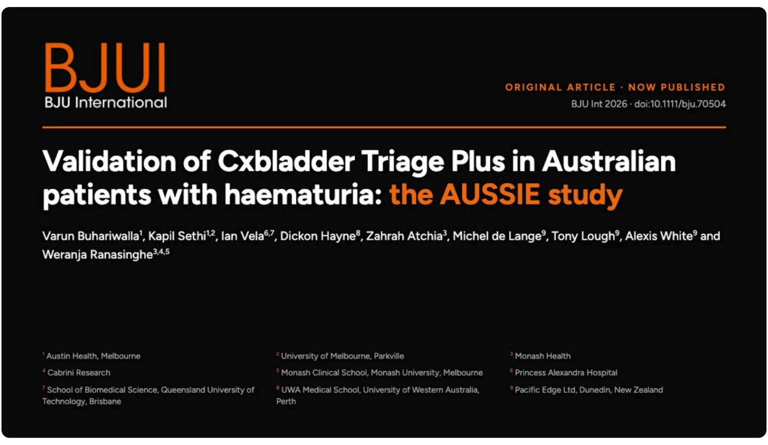
AUSSIE study validates Triage Plus in Australian patients

Last month we were pleased to confirm the publication of the AUSSIE study in *BJU International*[1]. The Australian study provides important new evidence that Cxbladder Triage Plus performs consistently across different patient populations and health systems, and further strengthens the clinical case for usage in the risk stratification of patients presenting with haematuria.

The study — the second peer reviewed clinical validation of Triage Plus and the first in an Australian population — reproduces the performance seen in the DRIVE study[6] and gives clinicians and hospitals local peer-reviewed evidence supporting use of the test to help rule out urothelial cancer and defer an invasive cystoscopy and unnecessary imaging in patients with a low probability of disease.

The AUSSIE study enrolled 691 evaluable patients presenting with visible (gross) or non-visible (micro) haematuria across four Australian hospital urology clinics between September 2023 and August 2025:

- The test-negative rate (anticipated rule-out rate) was 74%. This highlights the potential economic value of Triage Plus for health providers, as a higher test-negative rate creates greater opportunity for health systems to avoid unnecessary cystoscopies and their associated costs.
- The study analysed microhaematuria and gross haematuria patients separately, with test-negative rates of 81% in microhaematuria (NPV 100%) and 70% in gross haematuria (NPV 98%).
- Within the microhaematuria population, test-negative rates were 100% in low-risk patients (NPV 100%), 89% in intermediate-risk patients (NPV 100%), and 76% in high-risk patients (NPV 99%). These results provide a clear demonstration of the utility of Triage Plus across the spectrum of haematuria risk.
- NPV remained at or above 99% across all microhaematuria risk categories, while the proportion of patients testing negative appropriately declined as underlying disease risk increased.



BJUI
BJU International

ORIGINAL ARTICLE · NOW PUBLISHED
BJU Int 2026 · doi:10.1111/bju.70504

Validation of Cxbladder Triage Plus in Australian patients with haematuria: the AUSSIE study

Varun Buhariwalla[1], Kapil Sethi[1,2], Ian Vela[6,7], Dickon Hayne[8], Zahrah Atchia[3], Michel de Lange[9], Tony Lough[9], Alexis White[9] and Weranja Ranasinghe[3,4,5]

[1] Austin Health, Melbourne
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[3] Monash Health
[4] Cabrini Research
[5] Monash Clinical School, Monash University, Melbourne
[6] Princess Alexandra Hospital
[7] School of Biomedical Science, Queensland University of Technology, Brisbane
[8] UWA Medical School, University of Western Australia, Perth
[9] Pacific Edge Ltd, Dunedin, New Zealand

Read the study published in BJU International →

CLINICAL PRACTICE

Triage Plus for haematuria evaluation: enhanced risk stratification

Triage Plus is a next generation Cxbladder test that combines mRNA and DNA biomarkers to enhance[2] the risk stratification of patients presenting with haematuria, reducing unnecessary cystoscopies in patients with a low probability of urothelial cancer, while prioritizing those who need immediate care.

- With an NPV of 99% or greater, Triage Plus increases the rate of UC rule out in patients with a low probability of disease (71–84% ROR[3,6]), allowing you to defer those patients who do not stand to benefit from an invasive cystoscopy.
- Triage Plus enables the identification of high-risk patients with high specificity and PPV (98% specificity and up to 75% PPV when the higher 0.54 cut point on the test report is used).
- Triage Plus builds on the performance of Cxbladder Triage, a test now included in the AUA/SUFU Microhaematuria Guideline, supported with "Grade A" evidence.

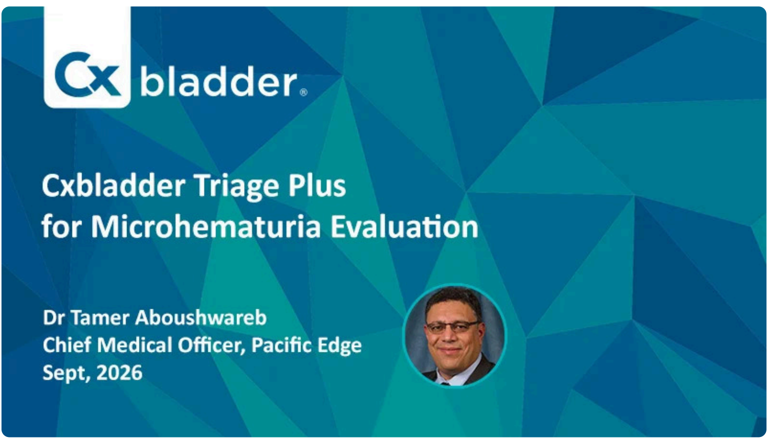
Contact us to learn more →

VIDEO WEBINAR

Triage Plus for microhaematuria evaluation

In September, Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb presented an overview of Triage Plus for doctors and clinical teams. During the session he discussed:

- Nuances in haematuria evaluation
- The advantages of urine-based genomic testing supported with real world evidence
- The development and clinical validation of Triage Plus, our second generation Cxbladder test for haematuria evaluation, including active studies
- Practical considerations in the use of Triage Plus



Cx bladder

Cxbladder Triage Plus
for Microhematuria Evaluation

Dr Tamer Aboushwareb
Chief Medical Officer, Pacific Edge
Sept, 2026

Watch the video →

REAL-WORLD DATA

New Zealand pathway evidence shows faster care and fewer referrals

In September, a new real world experience study from the Canterbury Health System in New Zealand was published in the *ANZ Journal of Surgery*[4].

The study, building on the clinical utility previously established by Davidson et al (2019 and 2020[5]), described the key benefits of clinical use in a real public health system, following the 2018 decision in Canterbury to replace urine cytology with Cxbladder Triage and upper tract imaging as the first-line primary care work-up for haematuria. The key outcomes for patients, physicians and health systems were clear: faster access to specialist care, faster time to first operative treatment for bladder cancer, and fewer avoidable referrals.

Christchurch Hospital, New Zealand

Eaton and colleagues audited 4,512 haematuria referrals to Christchurch Hospital between March 2013 and December 2021, comparing the period before and after Cxbladder Triage was added to the Canterbury pathway. Under that pathway, patients with a negative Cxbladder Triage result and normal upper tract imaging were considered at very low probability of bladder cancer and did not require referral for specialist assessment and cystoscopy, unless symptoms persisted and repeat investigation was required.

The results were clinically impactful:

- Median waiting time from primary care referral to urological specialist appointment reduced by 14.8 days, from 57.8 days to 43.0 days.
- Median waiting time from referral to first operative treatment for bladder cancer reduced by 15.0 days, from 78.0 days to 63.0 days.
- Monthly haematuria referrals to specialist urology fell from 45.7 to 38.8 — a reduction of 6.9 referrals per month, or approximately 83 fewer referrals per year, driving economic savings for hospitals.

CLINICAL ADOPTION

Pacific Edge secure first blanket agreement within the US Veterans Affairs system

In September Pacific Edge secured its first facility-level Blanket Purchase Agreement (BPA) within the Veterans Administration (VA) system — a five-year BPA allocating ~US$1.3m for Cxbladder testing with the Marion, Illinois VA for Triage Plus and Monitor.

BPAs are not required for VA facilities to order Cxbladder, but they provide an important practical step, streamlining test access. Furthermore, given the predominantly high-risk VA patient population, the BPA demonstrates demand for Cxbladder testing, while generating additional real-world clinical evidence in this population to complement the core evidence established through the DRIVE[6] study.

CLINICAL FOCUS

Delays diagnosing bladder cancer in women highlights role for genomic testing

A recent **ABC News article**, "Women's bladder cancer symptoms dismissed as UTIs, perimenopause amid calls for more awareness," highlights an important challenge in the investigation of haematuria in women: symptoms may initially be attributed to more common causes such as urinary tract infection or perimenopause, potentially delaying investigation for bladder cancer.

The article describes women experiencing recurrent urinary symptoms and haematuria before bladder cancer was ultimately diagnosed. One woman featured experienced a four-year interval between first presenting to her GP with a suspected bladder infection and being diagnosed with stage-three bladder cancer.

Although around three-quarters of Australians diagnosed with bladder cancer are men, outcomes for women are poorer. The article reports five-year survival of approximately 50% for women compared with almost 60% for men, with experts highlighting later-stage presentation among women as an important concern.

This disparity is also reflected in the literature. Although bladder cancer is more common in men, studies have reported that women are more likely to present with advanced disease at diagnosis[7] and experience poorer outcomes[8].

Experts interviewed by ABC called for greater awareness and earlier escalation of recurrent UTI-like symptoms.

Cxbladder can streamline risk stratification, potentially accelerating diagnosis

For women presenting with visible or non-visible haematuria, Cxbladder testing can streamline risk stratification and potentially accelerate early diagnosis of UC.

The recently published AUSSIE study[1] provides relevant supporting data. Cxbladder Triage Plus was used to evaluate 691 patients referred for cystoscopy following presentation with gross or microhaematuria. The study reported 89% sensitivity, 79% specificity, 99% negative predictive value, and a 74% overall test-negative rate (anticipated rule out rate).

Contact us to learn more →

EVENTS

Engaging clinical teams at UAA 2026: Cxbladder for haematuria evaluation, NMIBC surveillance

In September the team travelled to Manila for the Urological Association of Asia (UAA) Congress. There was strong interest in Cxbladder, and it was great speaking with all of those clinicians who made the trip. We used the opportunity to discuss the use of Cxbladder Triage Plus for haematuria evaluation and Cxbladder Monitor for NMIBC surveillance, presenting new evidence and suggested clinical pathways.

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PILIPINAS
23rd UAA
UROLOGICAL ASSOCIATION OF ASIA CONGRESS
LOOK CLOSER

The Cxbladder team at the UAA 2026 Congress, Manila

Contact us

For further information on any of the articles above or the Cxbladder suite, we invite you to email us at **info@cxbladder.com** or to reach out to your local Cxbladder representative.

PacificEdge®
CANCER DIAGNOSTICS

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[1] Buhariwalla, V., Sethi, K., Vela, I., Hayne, D., Atchia, Z., de Lange, M., Lough, T., White, A. and Ranasinghe, W. (2026), Validation of Cxbladder Triage Plus in Australian patients with haematuria: the AUSSIE study. BJU Int. https://doi.org/10.1111/bju.70504.

[2] Triage Plus delivers significant improvement in NPV, Sensitivity, PPV and Specificity over our established Cxbladder Triage and Detect tests.

[3] Harvey et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Haematuria Patients for Urothelial Carcinoma. Diagnostics. 2025; 15(14):1739. https://doi.org/10.3390/diagnostics15141739.

[4] Eaton, D., Kerdemelidis, M., Losco, G., Mark, S., Patu, M., Elliot, N., & Frampton, C. (2026). Cxbladder triage in haematuria assessment reduces time from referral to specialist assessment and bladder cancer treatment and improves equity for Māori. ANZ Journal of Surgery.

[5] Davidson, PJ, McGeoch, G, Shand, B. Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J 2019; 132:1497; Davidson P, McGeoch G, Shand B. Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527.

[6] Savage et al. (2026). Diagnostic performance of Cxbladder Triage Plus for the identification and stratification of patients at risk for urothelial carcinoma: The multicenter, prospective, observational DRIVE study. Urologic oncology, 44(1), 65.e13–65.e20. https://doi.org/10.1016/j.urolonc.2025.10.008.

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