Cxbladder

ASIAN 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 US patients.

> *"The final LCD is a significant milestone for patients, urologists, and the broader healthcare system. It recognizes 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

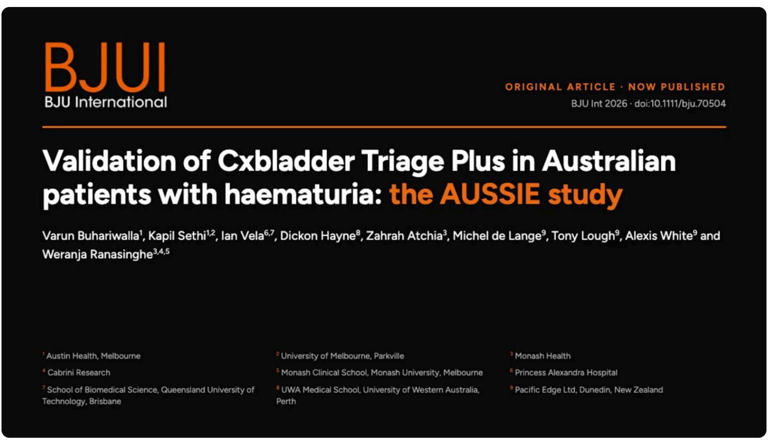
AUSSIE study validates Triage Plus in Australian patients

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.

The study reproduces the performance seen in the DRIVE study[2] 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) hematuria across four Australian hospital urology clinics between September 2023 and August 2025:

- Test-negative rates of 81% in microhematuria (NPV 100%) and 70% in gross hematuria (NPV 98%). The overall test-negative rate (anticipated rule-out rate) was 74%.
- NPV remained at or above 99% across all microhematuria risk categories, while the proportion of patients testing negative appropriately declined as underlying disease risk increased.
- 16 tumors were identified by Cxbladder Triage Plus but not identified by imaging.
- All high-grade tumors (32/32) including CIS were detected by Cxbladder Triage Plus.



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

Read the study published in BJU International →

CLINICAL PRACTICE

Triage Plus for hematuria evaluation: enhanced risk stratification

Triage Plus is a next generation Cxbladder test that combines mRNA and DNA biomarkers to enhance[3] the risk stratification of patients presenting with hematuria, 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[2,4]), 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).

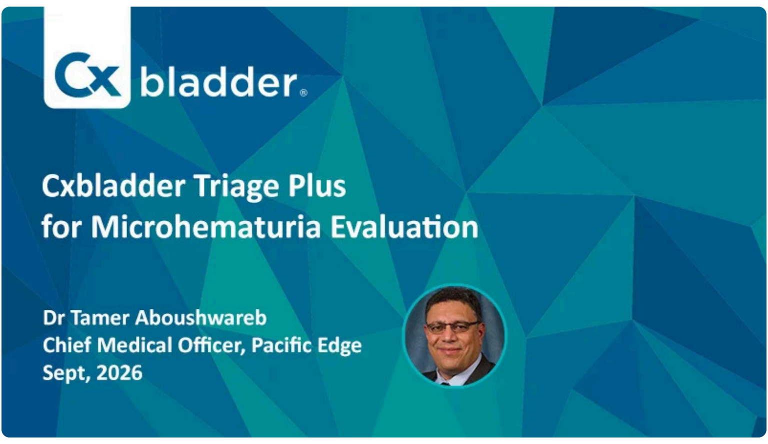
Contact us to learn more →

VIDEO WEBINAR

Triage Plus for microhematuria 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:

- Considerations in hematuria 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 hematuria evaluation, including active studies
- Practical considerations in the use of Triage Plus



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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*[5].

Building on the clinical utility previously established by Davidson et al (2019 and 2020[6]), the study 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 hematuria.

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 hematuria 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 the 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 hematuria 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.

EVENTS

Engaging clinical teams at UAA 2026: Cxbladder for hematuria 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 the clinicians who made the trip. We used the opportunity to discuss the use of Cxbladder Triage Plus for hematuria evaluation and Cxbladder Monitor for NMIBC surveillance, presenting new evidence and suggested clinical pathways.

UAA
UROLOGICAL ASSOCIATION OF ASIA CONGRESS
PILIPINAS
Cxbladder

The Cxbladder team at the UAA 2026 Congress, Manila

CLINICAL FOCUS

Delays diagnosing bladder cancer in women highlights role for genomic testing

A recent Australian **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 hematuria in women: symptoms may initially be attributed to more common causes such as urinary tract infection or perimenopause, potentially delaying investigation for 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 inequality 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 hematuria, 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 microhematuria. 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 →

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

[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 hematuria: the AUSSIE study. BJU Int. https://doi.org/10.1111/bju.70504.

[2] 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.

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

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

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

[6] Davidson, PJ, McGeoch, G, Shand, B. Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of hematuria 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 hematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527.

[7] Pignot, G., Barthélémy, P., & Borchiellini, D. (2024). Sex Disparities in Bladder Cancer Diagnosis and Treatment. Cancers, 16(23), 4100. https://doi.org/10.3390/cancers16234100.

[8] Mungan N, Kiemeney L, van Dijck J, van der Poel H, Witjes J. (2000) Gender differences in stage distribution of bladder cancer. Urology, 55, 368-371.