

The Cxbladder Bulletin

Dear Customers and Friends of Cxbladder,

Welcome to the October 2024 edition of the Cxbladder Bulletin. In this issue:

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Real World Evidence for Cxbladder to Feature at WSAUA

New data demonstrating the clinical and economic value of Pacific Edge's Cxbladder cancer diagnostic tests will be in the spotlight at the 100th annual meeting for the Western Section of the American Urological Association (WSAUA) in Kauai, Hawaii.

WSAUA begins next week and we look forward to spending time with all of those who will be making the trip.

Five abstracts on Cxbladder will be presented at the meeting, which runs from 27 October to 1 November 2024 and is the largest regional AUA meeting and one of the premier events in the United States' urological calendar.

The abstracts include two independent studies: one from Southern California Permanente Medical Group (KP SoCal) on real-world evidence of Cxbladder Triage's clinical utility in assisting clinicians with hematuria evaluation, and another from the physicians at the University of Southern California highlighting Cxbladder Monitor's role in helping clinicians reduce the clinical and economic burden on cancer patients under surveillance for cancer recurrence.

Alongside these studies, Pacific Edge will present two other abstracts on the clinical value of Cxbladder Monitor: one outlining how incorporating the test into the surveillance protocol for non-muscle invasive bladder cancer (NMIBC) patients can save healthcare payers as much as US\$680 per patient over five years, and another highlighting patient enthusiasm for integrating Cxbladder Monitor into their surveillance regimen. Pacific Edge conducted the economic benefits study with Germany's Coreva Scientific, while the patient perception study was undertaken in conjunction with the non-profit bladder cancer patient advocacy organization the Bladder Cancer Advisory Network (BCAN).

Lastly, Pacific Edge will also present the protocol for its LOBSTER study, an observational study to demonstrate the clinical validity of Cxbladder Monitor and the next generation test Cxbladder Monitor+ in bladder cancer surveillance¹.

If you're planning to attend WSAUA please email us at us.info@cxbladder.com and let us know so we can arrange to meet.

Review [our WSAUA press release](#) to learn more about the five abstracts.

¹ The Monitor+ assay incorporates DNA biomarkers of bladder cancer in addition to the RNA biomarkers used in the first generation Monitor test.

Kaiser Permanente Reports on Real World Utility of Cxbladder in New Abstract

Southern California Permanente Medical Group (KP SoCal) is experiencing the benefits from deploying Cxbladder Triage in a consistent clinical pathway.

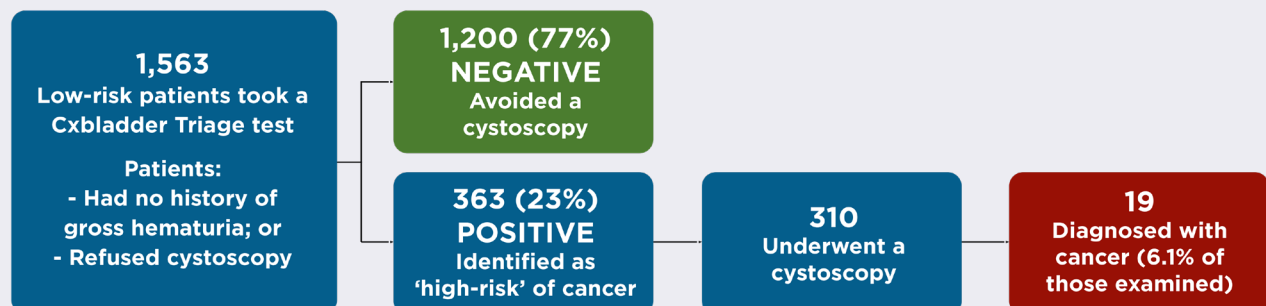
In an abstract covering the results of a large clinical study that will be presented to the Western Section of the American Urological Association (WSAUA) later this month, KP SoCal has detailed how it is using Cxbladder Triage to improve the evaluation of patients presenting with hematuria.

The authors of the abstract said: "Incorporating a highly reliable urine biomarker into clinical workflows for hematuria reduced the burden of cystoscopy substantially, improving patient satisfaction, urology access, and lowering overall cost of care."

Kaiser Permanente is working toward a peer reviewed publication based on the complete data to be published in time for the AUA conference next year.

The Kaiser study involved 1,563 low-risk patients with no history of gross hematuria or those who declined cystoscopy. It showed that 1200 or 77% of the patients tested, were able to avoid an invasive cystoscopy. This not only boosted patient satisfaction but also improved access to urological care by freeing up resources and time for other patients. Of the 363 patients flagged as high-risk, 310 underwent cystoscopy, leading to 19 confirmed cancer

CLINICAL UTILITY: PRELIMINARY RESULTS OF THE KAISER STUDY



Video: Bridging the Gap in Microhematuria Evaluation

Dr Yair Lotan and Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb discuss the results of the STRATA study, a randomized controlled trial showing Cxbladder Triage can more effectively risk stratify microhematuria patients vs AUA Guidelines. Click the image below or [this link](#) to launch the video in a browser window.



Tamer Aboushwareb, MD, PhD

Pacific Edge Diagnostics

Yair Lotan, MD

UT Southwestern Medical Center

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AUA Seeks Hematuria Guideline Peer Review

Pacific Edge is awaiting the outcome of the American Urological Association (AUA) review of its microhematuria guidelines.

The recent publication of our STRATA¹ study in the Journal of Urology provides an opportunity to influence positive language around the use of Cxbladder in the evaluation of microhematuria. As a randomized controlled trial of the test - the first study of this kind for a urine biomarker for hematuria evaluation - STRATA has delivered the evidence that meets the standard typically required for guideline committees to consider a change to standards of care. The guidelines review also follows the publication of an editorial in the Journal of Urology in September² supporting the use of Cxbladder to reduce unnecessary cystoscopies and clinicians to evaluate patients both presenting with hematuria and those under surveillance for bladder cancer recurrence.

A draft of the revised guideline was made available to AUA members last month under strict conditions of confidentiality for peer review. Finalization of the standard and publication is expected in the coming months.

¹ Lotan et al. A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

² Anderson. The Future of Cystoscopy for Detecting Urothelial Carcinoma Vol. 212, 399-400, September 2024.

AUA Journal of Urology Editorial Supports Cxbladder

Pacific Edge welcomes an editorial in the American Urological Association's Journal of Urology supporting the use of Cxbladder to reduce unnecessary cystoscopies on patients at risk of bladder cancer.

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Published in the September issue¹, the editorial - entitled 'What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma?' - focuses heavily on evidence pointing to the clinical value of Cxbladder in helping clinicians to evaluate patients both presenting with hematuria and those under surveillance for bladder cancer recurrence, specifically citing the recent STRATA² study that demonstrated the clinical utility of Cxbladder Triage.

The editorial notes: "Although these novel biomarker studies raise important questions about evaluating patients at risk for UCB³, these tests have the potential to improve the management of our patients with suspected UCB who would otherwise require an invasive procedure for diagnosis. This also holds true for nonmuscle-invasive bladder cancer patients who require cystoscopic surveillance."

Pacific Edge Chief Executive Dr Peter Meintjes said: "We are delighted to see our Cxbladder test recognized in the Journal of Urology editorial. Such supportive commentary on our recent clinical evidence in such an influential urology journal shows how leading urologists are coming to understand the clinical value of our tests in hematuria evaluation and monitoring patients for the recurrence of bladder cancer.

Authored by Journal of Urology Assistant Editor Christopher Anderson, the editorial first critiques the AUA's guidelines for the evaluation of asymptomatic microscopic hematuria, which it says results in urologists performing many unnecessary cystoscopies and missing opportunities to evaluate at-risk patients.

It then focuses on the clinical evidence to overcome these limitations, regularly referencing Pacific Edge's STRATA study, which was published in the May edition of the Journal of Urology. The study showed clinicians undertook 59% fewer cystoscopies if they were able to use the information generated by a Cxbladder Triage test. The editorial also notes the potential cost savings that come from reducing unnecessary procedures using non-invasive urine-based biomarkers such as Cxbladder.

The editorial concludes by acknowledging the continued need for cystoscopy in bladder cancer diagnosis but underscores the importance of reducing negative cystoscopies.

"If these biomarkers are employed in the first-line setting, it may ultimately improve appropriate hematuria referrals to urology and avoid the referral delays that some hematuria patients face... we are challenged to understand these tests, educate patients about them, and determine how to best incorporate them into our practice."

¹ Anderson C. What Is the Future of Cystoscopy for Detecting Urothelial Carcinoma? J Urol. Vol. 212, 399-400, Sept. 2024.

² Lotan et al. A multicenter prospective randomized controlled trial comparing Cxbladder triage to cystoscopy in patients with microhematuria. The safe testing of risk for asymptomatic microhematuria trial. J Urol. Published online May 3, 2024.

³ Urothelial Bladder Carcinoma.

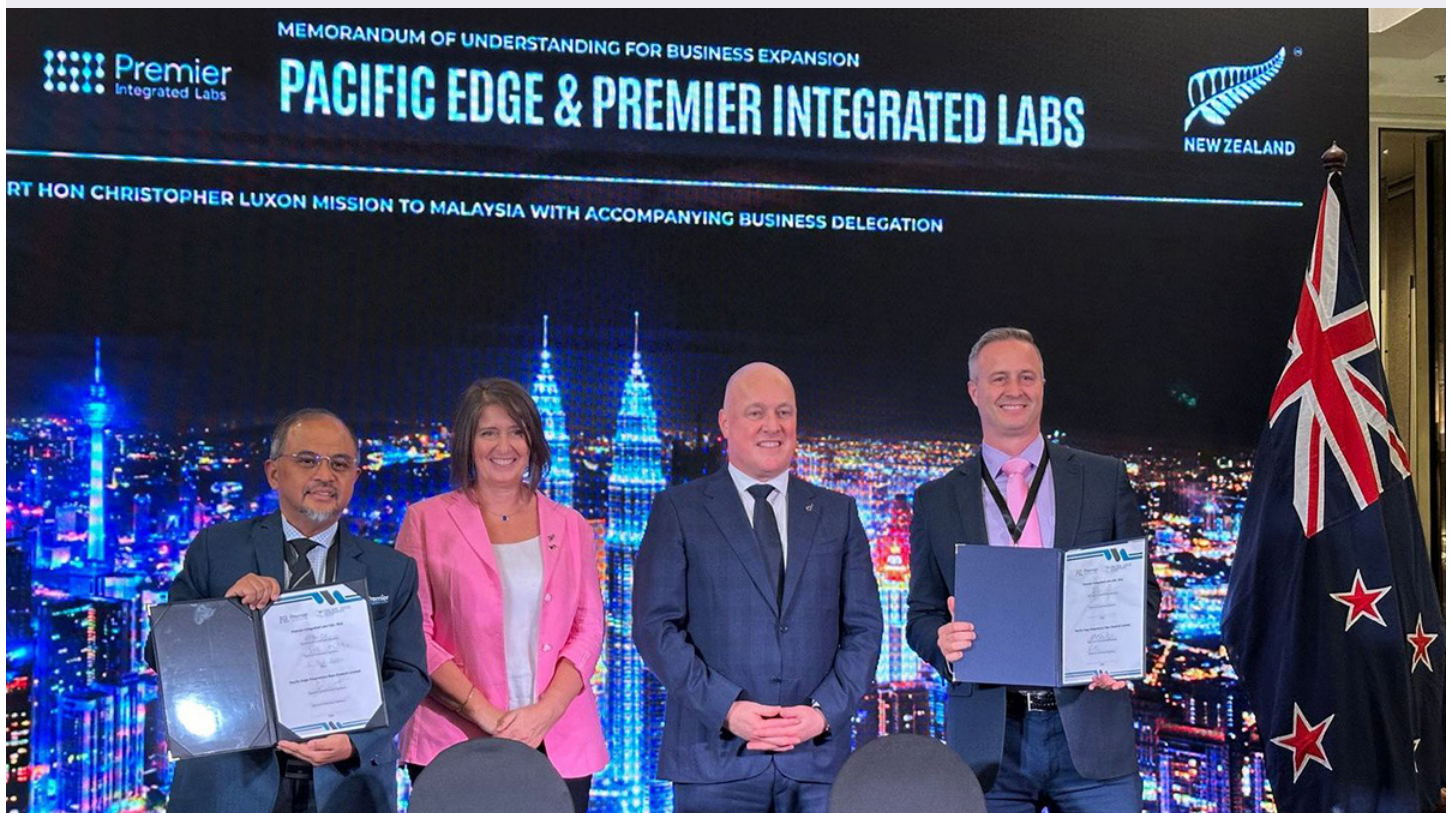
Pacific Edge on the Podium at UAA in Bali

New evidence of Cxbladder's clinical utility was presented to the Urological Association of Asia (UAA) in early September.

Dr Arjun Guduguntla of Northern Health in Melbourne presented preliminary data on a proposed novel surveillance schedule using Cxbladder Monitor for patients on annual bladder surveillance. Meanwhile, Pacific Edge Chief Executive Dr Peter Meintjes presented data from the groundbreaking STRATA study¹, which is the first time clinical utility evidence from the randomized controlled trial has been presented to an APAC audience.

Prior to the activities at the UAA Congress Dr Meintjes visited Malaysia for a ceremonial signing of a lab partnering agreement with Premier Integrated Labs. The event was supported by New Zealand Trade and Enterprise and attended by New Zealand Prime Minister, the Right Honourable Christopher Luxon. Premier Integrated Labs is the sole supplier of laboratory services to Malaysia's IHH Healthcare, which operates the three largest individual hospitals in Malaysia. This partnership represents a further expansion of Cxbladder's availability across key international markets.

¹Lotan et al. A multicenter prospective randomized controlled trial comparing Cxbladder triage to cystoscopy in patients with microhematuria. The safe testing of risk for asymptomatic microhematuria trial. J Urol. Published online May 3, 2024.



Medicare Update

Cxbladder remains a covered test as we wait for Novitas to finalize its draft LCD following the conclusion of the comment period in September 2023 and a CMS authorized extension from July 26, 365 days from the original publication of the draft and the date Novitas was statutorily obliged to finalize or withdraw the LCD.

Our representations to Novitas were strongly supported by leading US Urological Societies - the AUA, LUGPA, and AACU; alongside our industry partners, the Coalition for 21st Century Medicine (C21); and by the American Clinical Laboratory Association (ACLA). A number of key urologic opinion leaders also voiced their support through formal submissions.

We believe the environment is now more favorable for Pacific Edge given the publication of the STRATA¹ study on the clinical utility of Triage and its reception within the broader urology community. Furthermore, we have informed Novitas of our latest publication in the journal 'Diagnostics' on the Analytical Validation of Triage, Detect and Monitor that was developed after a recent update to our protocols.²

¹ Lotan et al. A multicenter prospective randomized controlled trial comparing Cxbladder triage to cystoscopy in patients with microhematuria. The safe testing of risk for asymptomatic microhematuria trial. J Urol. Published online May 3, 2024.

² Harvey et al (2024) Analytical Validation of Cxbladder Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics, 2024; 14(18):2061.

Upcoming Events

Come and see us at any upcoming event:

Date	Event Name	Location
Oct 27-Nov 1	WSAUA	Kauai, HI
Nov 14-16	LUGPA	Chicago, IL
Dec 4-6	SUO	Dallas, TX

Contact Us

Pacific Edge Diagnostics USA

Hershey Center for Applied Research, 1214 Research Boulevard, Suite 2000, Hummelstown, PA 17036, USA

P: 1-855-CXBLADR (1-855-292-5237)

E: us.info@cxbladder.com or visit us online at www.cxbladder.com