



Cxbladder News Bulletin: April 2025

Dear Customers and Friends of Cxbladder,

Welcome to the April 2025 edition of the Cxbladder Bulletin. In this issue:

- Cxbladder Incorporated into AUA Clinical Guideline
- SESAUA Video: Cxbladder Triage: Risk Stratification for Patients with Microhematuria
- Cxbladder's Clinical Utility To Be in Focus at AUA 2025
- Cxbladder Monitor Delivers Savings Versus AUA Standard of Care
- Customer Portal Launch

Cxbladder Incorporated into AUA Clinical Guideline

On February 27th, the AUA published a significant amendment to its Microhematuria Guideline¹, incorporating language for the use of urine-based biomarkers in intermediate-risk patients. The update specifically mentioned Cxbladder Triage as the first and only urine-based biomarker with supporting 'Grade A' evidence.

Guideline Statement 13: "In appropriately counseled intermediate-risk patients who want to avoid cystoscopy and accept the risk of forgoing direct visual inspection of the bladder urothelium, clinicians may offer urine cytology or validated urine-based tumor markers (Table 5) to facilitate the decision regarding utility of cystoscopy. Renal and bladder ultrasound should still be performed in these cases."

In addition, the guideline states: "The highest level of evidence was an evaluation of Cxbladder Triage based on an RCT comparing a marker-based approach versus standard of care routine cystoscopy to evaluate MH. In this study, the marker had a NPV of 99%"

With the inclusion of these statements, the AUA amendment specifically references recent evidence generated from the STRATA Study² following its publication in the Journal of Urology in May 2024. The study demonstrated in a randomized controlled trial, a first for any urine biomarker, that Cxbladder Triage could safely and effectively reduce cystoscopies by as much as 59% without missing tumors.

Pacific Edge Chief Medical Officer Dr Tamer Aboushwareb commented: "Cxbladder is the only test supported by a Grade A evidence from the AUA Guideline panel and the update reflects the strength of the evidence supporting Triage and will help to reduce the burden of unnecessary cystoscopies in patients of lower risk, resulting in less patient discomfort and less morbidity, and improved access to care by reducing wait times."

Pacific Edge Chief Executive Dr Peter Meintjes said: "We are very pleased that Cxbladder Triage has been acknowledged with its inclusion in the AUA guideline. This is an outstanding result for patients across the US, and a reflection of the role genomic tests now play in the standard of care for bladder cancer patients as they have already done for prostate, breast, colon and other cancers."

View the amended AUA Clinical Guideline for the Management of Microhematuria [here](#).

Video: AUA Guideline Success Featured at SESAUA

A Pacific Edge symposium – Cxbladder Triage: Risk Stratification for Patients with Microhematuria – attracted significant interest at the Annual Meeting of the Southeastern Section of the American Urological Association (SESAUA) in mid-March.

SESAUA was the first opportunity for Pacific Edge to promote Cxbladder Triage since its inclusion in the AUA Microhematuria Guideline. The symposium was a standing room only event and was led by Dr Zachary Klaassen, Urologic Oncologist and Associate Professor of Urology; Wellstar MCG Health and the Georgia Cancer Center. It covered the details of the guideline, and the benefits Cxbladder Triage offered in reducing the burden of unnecessary cystoscopies for those with a lower risk of cancer, resulting in less patient discomfort and morbidity.

Click the image below or [this link](#) to launch the video in a browser window.

SESAUA Lunch Symposium

presented by Pacific Edge Diagnostics

TITLE:
Cxbladder Triage: Risk Stratification for Patients with Microhematuria

SPEAKER:



Zachary Klaassen, MD, MSc
Urologic Oncologist, Associate Professor of Urology
Residency Program Director
Ronald W. Lewis, MD Endowed Chair for Urologic Education
Wellstar MCG Health;
Georgia Cancer Center

Cxbladder's Clinical Utility To Be in Focus at AUA 2025

AUA 2025 kicks off in Las Vegas this Saturday. We look forward to speaking with those of you who are planning to attend and invite you to visit us at booth #2239. We also invite you to attend one of several sessions during the event where Cxbladder's clinical and economic value in evaluating patients presenting with hematuria is set to be a focal point.

Further detail on planned AUA 2025 sessions:

Key Milestone: Cxbladder Triage Incorporated into AUA Microhematuria Guideline

The highlight for Pacific Edge and Cxbladder will be the Plenary: Afternoon Session (Saturday April 26, 1:20–1:50 PM) where leading urologists will discuss the new AUA Microhematuria Guideline¹, which for the first time incorporated language for the use of urine-based biomarkers for intermediate-risk patients.

The new guideline says urologists may use urine-based biomarkers for appropriately counseled intermediate-risk patients presenting with microhematuria to assist their decision on whether to defer a cystoscopy. It specifically mentions Cxbladder Triage as the only urine-based biomarker test that has 'Grade A' evidence from a randomized controlled trial — the STRATA Study², which demonstrated the test can reduce cystoscopies by up to 59% without compromising tumor detection.

The session will be led by Vanderbilt University Medical Center Professor Daniel Barocas, Mayo Clinic Professor of Urology Stephen Boorjian — who are both members of the guideline panel — as well as University of Virginia Professor of Urology Tracy Downs and University of North Carolina, Chapel Hill, Associate Professor of Urology & Co-Director Urologic Oncology Mary Westerman.

Kaiser Permanente Real-World Data Validates Cxbladder's Clinical Utility and Safety

A second key presentation at the meeting will be delivered during the Bladder Cancer: Epidemiology & Evaluation I session (Saturday, April 26, 1:00–3:00 PM). The study³ by Kaiser Permanente Southern California reinforced existing evidence on the Clinical Utility of Cxbladder Triage, in safely reducing patients presenting with hematuria from unnecessary cystoscopies.

The retrospective study compared the new clinical pathway that includes evaluation of microhematuria patients with Cxbladder Triage to inform the decision to offer the patient a cystoscopy and imaging. It matched 3,353 Kaiser patients that received Triage, with an equal number of patients with similar risk that received the prior standard of care without Cxbladder Triage. The primary endpoints were to compare the number of cystoscopies and imaging procedures between the new standard of care incorporating Triage and the prior standard of care that did not.

The study found:

- In patients with 'Low Probability' Triage scores, the cystoscopy rate was 3.8% versus 46.5% in the standard of care patients.
- In patients with 'High Probability' Triage scores, the cystoscopy rate was 73.4% versus

45.7% in the standard of care patients.

- The overall bladder cancer detection rate between the Triage patients and the standard of care patients was similar.

The authors of the study concluded: “These data reveal that Cxbladder Triage testing resulted in significantly decreased cystoscopy and imaging utilization in those classified as low risk without any negative patient outcomes, while simultaneously demonstrating increases in the cystoscopy and bladder cancer detection rate in the physician directed protocol group.”

The DRIVE Study Expands Evidence Base for Cxbladder Triage Plus

The Clinical Validation of Cxbladder Triage Plus⁴ in a Veterans population will be presented at the Urological Society for American Veterans meeting on Monday, April 28 (7:30 AM–12:00 PM) by one of the study’s investigators Dr Kyoko Sakamoto of the San Diego VA medical center.

The DRIVE Study⁵ (Detection and Risk Stratification In Veterans Presenting with Hematuria) evaluated the prognostic performance of Cxbladder Triage Plus compared to cystoscopy. It showed that Triage Plus demonstrated similarly high-performance characteristics in the veterans’ population when compared with the proof-of-concept study by Lotan et al. in 2022⁶.

The authors of the study concluded: “Cxbladder Triage Plus demonstrated clinical validity in this VA population with gross hematuria or microhematuria, with high sensitivity and specificity. These findings indicate that Triage Plus may be safely used to rule out or detect [urothelial cancer] in patients with hematuria.”

If you have any questions in the lead up to AUA 2025, please reach out and contact your local Cxbladder representative. You can also email us at us.info@cxbladder.com.

Cxbladder

Why Gamble when the Evidence Speaks for Itself?

Come see us at **booth #2239**

AUA-2025 *Las Vegas* | April 26-29

Cxbladder Monitor Delivers Savings Versus AUA Standard of Care

A new health economics study has shown that the inclusion of Cxbladder Monitor into bladder cancer recurrence surveillance protocols can save healthcare payers as much as \$686⁷ per patient over a five year surveillance period.

The study⁸ accepted for publication in the JU Open Plus journal, compared the American Urological Association (AUA) bladder cancer surveillance protocols, with a new protocol that included Monitor in the surveillance program nine months after diagnosis. Under the Cxbladder protocol, cystoscopies were deferred if the Monitor test returned negative results, postponing invasive examinations until the next routine check-up.

Compared to the AUA standard of care, Cxbladder Monitor reduced mean total costs by \$68,621 for 100 patients over 5 years or \$137 per patient per year. Additionally, this approach reduced the number of cystoscopies by 129 examinations per 100 patients (0.31 per patient per year), with no difference in delayed cancer diagnosis, highlighting both the economic and clinical efficiencies of the Cxbladder Monitor test.

Customer Portal Launch

In March we were pleased to launch a Clinician Customer Portal as part of our EMR service offering designed to further optimize clinic workflow.

The Customer Portal, designed to be secure and easy to use, allows for the streamlined online ordering and resulting of tests within the Cxbladder suite.

- Information is entered via a step-by-step workflow that guides the user through the ordering process, allowing for the request to be saved as a Draft ensuring no work is lost
- The Customer Experience is improved by having a secure reporting portal for patient results that can only be viewed by authenticated users logging in using Single Sign-On (SSO) – no more emails or faxes
- Test Status and Results can be searched and filtered via Clinician, Patient Name, Date Range, and Test Type
- The Customer Portal contains a Learning and Resourcing area containing information and videos on Cxbladder

For more information on the Customer Portal and access, please contact us at:
us.info@cxbladder.com

Contact Us

P: 1-855-292-5237

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

¹ Barocas DA, Lotan Y, Matulewicz RS, Raman JD, Westerman ME, Kirkby E, Pak L, Souter L. Updates to Microhematuria: AUA/SUFU Guideline (2025). J Urol. doi: 10.1097/JU.0000000000004490.

² Lotan et al. (2024). 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.

³ Loo R.K., et al (2025) Clinical Utility of a Urine Biomarker (Cxbladder Triage) Compared to a Standard of Care for Microscopic Hematuria Evaluations in a Large Independent Delivery Network. Abstract submitted to the AUA 2025 meeting.

⁴ Cxbladder Triage Plus is a next generation Cxbladder UBTM test that combines an analysis of mRNA and DNA markers to further improve clinical utility and efficiency. As a single test for hematuria evaluation, Triage Plus is optimized for the risk stratification of patients presenting with microhematuria. Timing for the launch of Cxbladder Triage Plus in countries across the Asia Pacific Region is to be confirmed. For more information, please email us at cs-pedusa@pacificedgedx.com.

⁵ Savage S.J., et al (2025) The Prognostic Performance of Cxbladder Triage Plus for the Identification and Priority Evaluation of Veterans at Risk for Urothelial Carcinoma: The Drive Study, Abstract submitted to the AUA 2025 meeting.

⁶ Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.

⁷ All references to dollar amounts in this item are US dollars.

⁸ Mark Tyson MD, MPH, John P. Sfakianos MD, Daniel A Shoskes MD, Tobias Muench, Kim Seemann, Rhodri Saunders, Siamak Daneshmand. Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-Muscle Invasive Bladder Cancer; article accepted for publication

