

Cxbladder Bulletin: November 2025

Dear Customers and Friends of Cxbladder,

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

- DRIVE publication provides clinical validation of Cxbladder Triage Plus
- Urology Times reviews DRIVE study
- Watch Now: Webinars From the Grand Rounds in Urology Microhematuria Hub
 - The Utility of Cxbladder Triage In Microhematuria Evaluation: Expert
 Discussion featuring Dr. Evan Goldfischer, Dr. Kristen Scarpato, Dr. Ronald Loo,
 and Dr. Jay Jhaveri
 - The 2025 AUA/ SUFU Microhematuria Guideline: Dr. Jason Hafron reviews
 - o Industry Perspective: Cxbladder Triage AUA/ SUFU Guideline Inclusion: Grand Rounds host Diane Newman speaks with Dr. Jay Jhaveri
- Streamline Ordering and Resulting with our Cxbladder Customer Portal

DRIVE Publication Provides Clinical Validation of Triage Plus

We're pleased to confirm that our DRIVE Study — which demonstrates the clinical validity of Cxbladder Triage Plus in a US veterans population — has been published in the Journal of Urologic Oncology¹.

Cxbladder Triage Plus is a next generation Cxbladder test that employs a novel combination of mRNA and DNA markers to extend best in class performance. Triage Plus enhances the identification and prioritization of patients who require immediate care, while deferring those with a low probability of UC who do not stand to benefit from cystoscopy. As a single test for both gross and microhematuria which requires a urine sample only - no information on

additional patient factors is required - Triage Plus is designed to deliver superior performance over first generation Cxbladder tests while simplifying the ordering process.

The DRIVE Study evaluated the performance of Cxbladder Triage Plus when compared to cystoscopy combined with histopathologic confirmation of urothelial cancer. It confirmed the performance characteristics of Triage Plus established via the Analytical Validation publication (Harvey et al. 2025²) in a patient population independent of the development dataset utilized in the proof-of-concept study by Lotan et al. in 2023³.

The authors of the DRIVE study concluded: "Cxbladder Triage Plus demonstrated clinical validity in this veterans 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."

The US launch of Cxbladder Triage Plus is expected shortly.

Figure 1: Results from the DRIVE study. Triage Plus demonstrated a higher specificity and sensitivity than first generation Cxbladder assays.

Test	Sensitivity	Specificity	Negative Predictive Value	Positive Predictive Value	Test Negative Rate
Cxbladder Triage	93%	38%	98.5%	11%	35%
Cxbladder Triage Plus Intermediate risk patients	94%	77%	99.3%	26%	71%
Cxbladder Triage Plus High risk patients		95%		51%	90%

Urology Times Reviews DRIVE Study

Leading industry platform Urology Times reviews the DRIVE study, now published in Urologic Oncology¹.

Click here to read the article or click the image below.



Urology Times[®]

Study validates diagnostic performance of Cxbladder Triage Plus Test

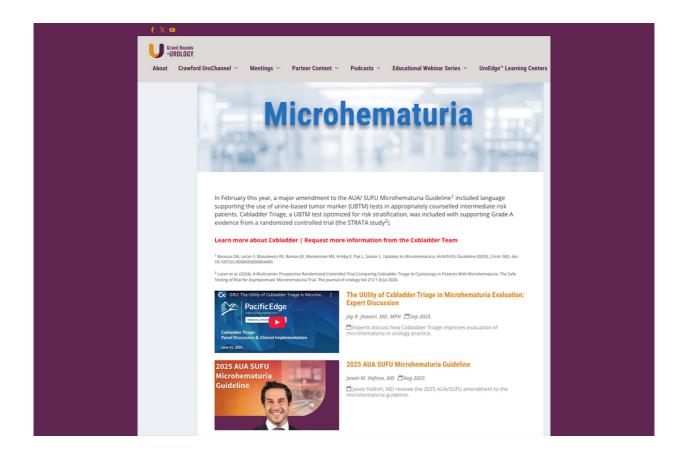
News | Articles

Grand Rounds in Urology Launches Microhematuria Hub

Earlier this year a major amendment to the AUA/ SUFU Microhematuria Guideline⁴ included language supporting the use of urine-based tumor marker (UBTM) tests in appropriately counselled intermediate risk patients. Cxbladder Triage, a UBTM test optimized for risk stratification, was included with supporting Grade A evidence from a randomized controlled trial (the STRATA study⁵).

In November, Grand Rounds in Urology, an authoritative source for educational webinars, podcasts, and articles alongside industry news and information on key meetings, launched a Microhematuria hub designed to provide guidance and further analysis of the Guideline update.

Click here or the image below to review the Microhematuria Hub.



Featured webinars on the Grand Rounds Microhematuria Hub include:

- The Utility of Cxbladder Triage in Microhematuria Evaluation: Expert discussion featuring Dr. Evan Goldfischer, Dr. Kristen Scarpato, Dr. Ronald Loo, and Dr. Jay Jhaveri. Click here to view the webinar.
- The 2025 AUA/ SUFU Microhematuria Guideline: A review by Dr. Jason Hafron.

 Click here to view the webinar.
 - Industry Perspective Cxbladder Triage AUA/SUFU Microhematuria Guideline
- Inclusion: Pacific Edge Senior Medical Director Dr Jay Jhaveri discusses the implications with Grand Rounds' host Diane Newman. Click here to view the webinar.

Streamline Ordering and Resulting With Our Customer Portal

The Cxbladder Customer Portal, part of our CxConnect service offering, is a secure and easy to use platform that streamlines the online ordering and resulting of tests within the Cxbladder suite. It's ideal for community-based urology clinics and access is provided to all customers as a practice benefit at no cost

- Information is entered via a step-by-step workflow that guides the user through the ordering process.
- The Cxbladder Portal gives your team quick and secure access to Cxbladder results from both desktop and mobile devices.

- Test Status and Results can be searched and filtered via Clinician, Patient Name, Date Range, and Test Type.
- Past results for a clinic will be pre-loaded upon registration, and the results of all Cxbladder tests ordered from that point on will be available via the portal regardless of where the order originated.
- The Cxbladder Portal includes a Learning and Resource area with accessible information and video guides designed to enhance the value Cxbladder can offer your practice and your patients.

Going forward all new and existing customers will have the opportunity to use the portal as a centralized hub to order Cxbladder for their patients and to view the results of all Cxbladder tests, including those ordered historically.

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



Contact Us

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- (1) Savage et al. (2025) 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, S1078-1439(25)00405-3.
- (2) Harvey, J.C. et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics 2025, 15, 1739.
- (3) Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.
- (4) 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.000000000004490

(5) 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.



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