

With added DNA markers to better risk stratify hematuria patients



A next generation Cxbladder test with enhanced performance!

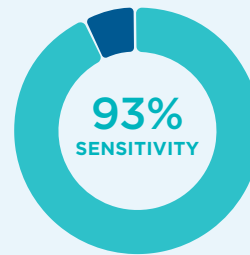
Cxbladder Triage Plus is a non-invasive genomic test that employs a novel combination of mRNA and DNA markers to extend best in class performance.

Optimize your clinical practice, allowing physicians to focus on high risk patients and procedures.

Triage Plus enhances risk stratification, reducing unnecessary cystoscopies in patients with a low probability of urothelial cancer, while prioritizing those who need immediate care.

Give patients the best experience possible.

Triage Plus spares patients with a low probability of disease the discomfort, anxiety and risks of an invasive procedure.



✓ **Simplified ordering**

- One test for micro and gross hematuria.
- Requires a urine sample only. No additional patient factors are necessary.

* 98% specificity and 75% PPV when higher 0.54 test report cut point used.

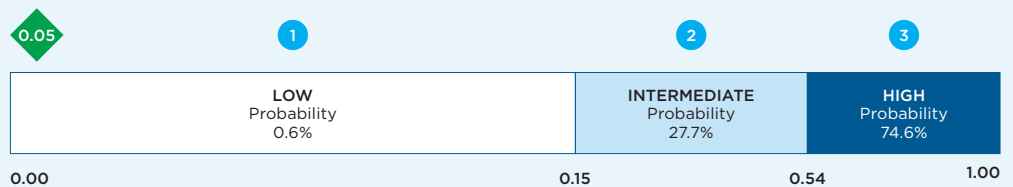
Using Cxbladder Triage Plus in your practice

- Enhances risk stratification, Identifying those with lowest and highest risk of UC.
- Increases the rate of UC rule out in patients with a low probability of disease.
- Enables the identification of high-risk patients with high specificity and PPV*.
- Allows for the option of in-home sampling.

* 98% specificity and 75% PPV when higher 0.54 cut point on test report is used.

Your practice will receive a detailed Cxbladder Triage Plus Test Report

Test results: Cxbladder Triage Plus score **0.05** 95% CI (0.81 - 0.96)




1	LOW Probability: An NPV of 99.4% for scores <0.15. Low probability of urothelial carcinoma (UC).
2	INTERMEDIATE Probability: A sensitivity of 93.6% and a specificity of 90.8% for scores ≥ 0.15 and < 0.54. Increased probability of UC.
3	HIGH Probability: A PPV of 74.6% for scores > 0.54 with a specificity of 98.2% in the analytical validation cohort. High probability of UC.

With analytical and clinical validation shown in published studies^{1,2}, Triage Plus builds on the performance of Cxbladder Triage, a test now included in the AUA/SUFU Microhematuria Guideline³, supported with "Grade A" evidence from the STRATA RCT.⁴

1. 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>.
 2. 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. Advance online publication. <https://doi.org/10.1016/j.urolonc.2025.10.008>
 3. Barocas et al. (2025). Updates to Microhematuria: AUA/SUFU Guideline (2025). *The Journal of urology*, 213(5), 547-557. <https://doi.org/10.1097/JU.00000000000004490>.
 4. 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) 41-51.

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Diagnostic Performance of Cxbladder Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.

Savage et al. (2025) Urologic Oncology, S1078-1439(25)00405-3

Overview:

A double blind, prospective observational trial, evaluating performance characteristics of Cxbladder Triage and Triage Plus.

- Multi-site recruitment of patients with hematuria in United States Veterans Affairs* medical centers.
- 615 patients underwent all routine clinical investigations and provided urine samples for Cxbladder testing.
- Performance of Cxbladder tests were evaluated compared to cystoscopy or ureteroscopy and pathology as the gold standard of care.
- This study represents an external clinical validation of the Triage Plus algorithm for risk stratification using 5 mRNA and 6 DNA SNV biomarkers.

Conclusion:

Cxbladder Triage Plus delivered improved diagnostic performance versus Cxbladder Triage and Detect in patients presenting with hematuria. The test enhances the prioritization of high-risk patients while deferring low-risk patients who do not stand to benefit from cystoscopy.

Summary of key clinical outcomes:

- Triage Plus had higher specificity, and sensitivity than first-generation Cxbladder assays.
- The test reduced the number of hematuria patients who required further evaluation compared to American Urological Association (AUA) risk stratification.
- Performance was similar in patients with gross hematuria or microhematuria, across AUA risk categories.
- 171/615 patients tested positive by Triage Plus and 45/48 tumors were detected.

* Veterans Affairs provides medical care for ex-service men and women.

CXBLADDER TEST PERFORMANCE IN PATIENTS WITH HEMATURIA

Test	N	Sensitivity	Specificity	PPV	NPV	Rule Out Rate
Triage Plus						
Triage Plus score < 0.15	587	0.94	0.77	0.26	0.993	0.71
Triage Plus score ≥ 0.54	587	0.6	0.95	0.51	0.965	0.90
Triage	580	0.93	0.38	0.11	0.985	0.35
Detect						
Detect score ≤ 0.12	584	0.65	0.77	0.20	0.960	0.74
Detect score ≥ 0.23	584	0.52	0.93	0.39	0.958	0.89

Triage Plus had higher specificity, and sensitivity than first-generation Cxbladder assays.

Spend less time looking for UC that isn't there and more time with those who need it the most. Maximize the value of your time and clinical resources.

Learn more

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