



TRIAGE – DETECT – MONITOR
 The genomic test for the detection and management of bladder cancer

Patient Presentation	Hematuria Pathway		Surveillance Pathway
	Cxbladder Triage	Cxbladder Detect	Cxbladder Monitor
	Hematuria Evaluation	Primary Detection	UC Surveillance
	Low Risk Rule Out	Rule In/Rule Out	Rule Out
Chronic Microhematuria	X	X	
Young, non-smoker, no occupational exposure	X	X	
Gross Hematuria*	X	X	
Atypical Cytology		X	
Discrepant Results		X	
Renal Insufficiency		X	
Surveillance for UC			X
Test Results	Rule Out NPV = 98.5% Sensitivity = 95.1% ¹	Rule In / Rule Out NPV = 97% Sensitivity = 82% PPV= 68% Specificity = 94% 100% Tis, T1, T2, and T3 Detection in Clinical Trials ²	Rule Out NPV = 96-97% Sensitivity = 91-93% ^{3,4}
Suggested Use	Low Risk Patient Rule Out prior to Full Workup	As Adjunct or 3 weeks post cystoscopy to Adjudicate Atypia or Discrepant Results	Rule Out for Patients ≥ 9 months Post Confirmed Diagnosis

* No visible blood in collection tube

X = Optimized for these patient type examples

1. Kavalieris L, O'Sullivan PJ, Suttie JM, et al. A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) from a urine sample to triage out patients presenting with hematuria who have a low probability of urothelial carcinoma. *BMC Urol* 2015;15:23.
 2. O'Sullivan P, Sharples K, Dalphin M, et al. A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. *J Urol* 2012; 188:741-7.
 3. Kavalieris L, O'Sullivan PJ, Frampton C, et al. Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. *J Urol* 2017;197:6,1419-1426.
 4. Lotan Y, O'Sullivan P, Raman JD, Shariat SF, Kavalieris L, Frampton C, et al. Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. *Urologic Oncology: Seminars and Original Investigations*. Elsevier; 2017; 1-8.

Accurate, reliable
In-Home Sampling
for Bladder Cancer:
As easy as



PATIENT IN-HOME SAMPLING WORKFLOW

1

Clinic Responsibility

- Clinic informs the patient of a Cxbladder test order that is being shipped to the patient's home
- Clinic completes the ordering forms and sends to Pacific Edge via Fax/Share File
 - Electronic TRF
 - Statement of Medical Necessity

2

Pacific Edge Responsibility

Pacific Edge:

- Ships Cxbladder In-Home Sampling System to the Patient's Home
- Instructs Patient on Sampling Process
- Informs Patient of Financial Responsibility
- Runs Cxbladder Test
- Delivers a Cxbladder Test Result to Clinic in 4-5 days

3

Patient Follow-Up

- Clinic schedules Follow-up Telemedicine, Phone Consult, or Office visit to review results

Choose the appropriate patient and order the test, we do everything else.

Then get the test result and schedule a follow up Telemedicine, phone consult, or office visit to discuss results and next steps.

Cxbladder

Proven Performance in 11 peer-reviewed publications for: Primary Detection - Surveillance - Adjudicating atypical cytology
Used by over 1,800 Urologists in more than 40,000 patients

Discover more at Cxbladder.com
or call 1-855-292-5237