

Alternative Strategies to Deliver Urology Care/Bladder Cancer Investigation during COVID-19 and Beyond

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Biomarkers for UC

HEMATURIA EVALUATION

UC SURVEILLANCE

CXBLADDER



Four biomarkers are involved in varying aspects of cell growth, division, and proliferation and show differential expression in cancers of the urinary tract

MDK
(Midkine)
Cell proliferation, migration, and angiogenesis in cancer cells

HOXA13
(member of homeobox genes)
Cell differentiation; morphogenesis and differentiation of GU tracts

CDC2/CDK1
(cell division control protein 2)
Mitotic cell cycle: cell proliferation

IGFBP5
(Insulin-like growth factor binding protein 5)
Anti-apoptotic gene

High expression of the fifth biomarker is indicative of inflammation of the bladder tissue

CXCR2
(Interleukin 8 receptor B)
Mitigation of neutrophil migration to areas of inflammation

LOW RISK

Triage

HIGH RISK

Detect

SURVEILLANCE

Monitor

Cxbladder is a non-invasive urine-based test for the detection or rule out of bladder cancer

- Clinically validated test that measures gene expression levels of 5 biomarkers that represent a bladder cancer signature
- Together with patient clinical factors, individual gene concentrations are inputted into an algorithm to generate a final numerical output

Cxbladder Products

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

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European Association of Urology



Bladder Cancer

Evaluation of Cxbladder and Adjudication of Atypical Cytology and Equivocal Cystoscopy

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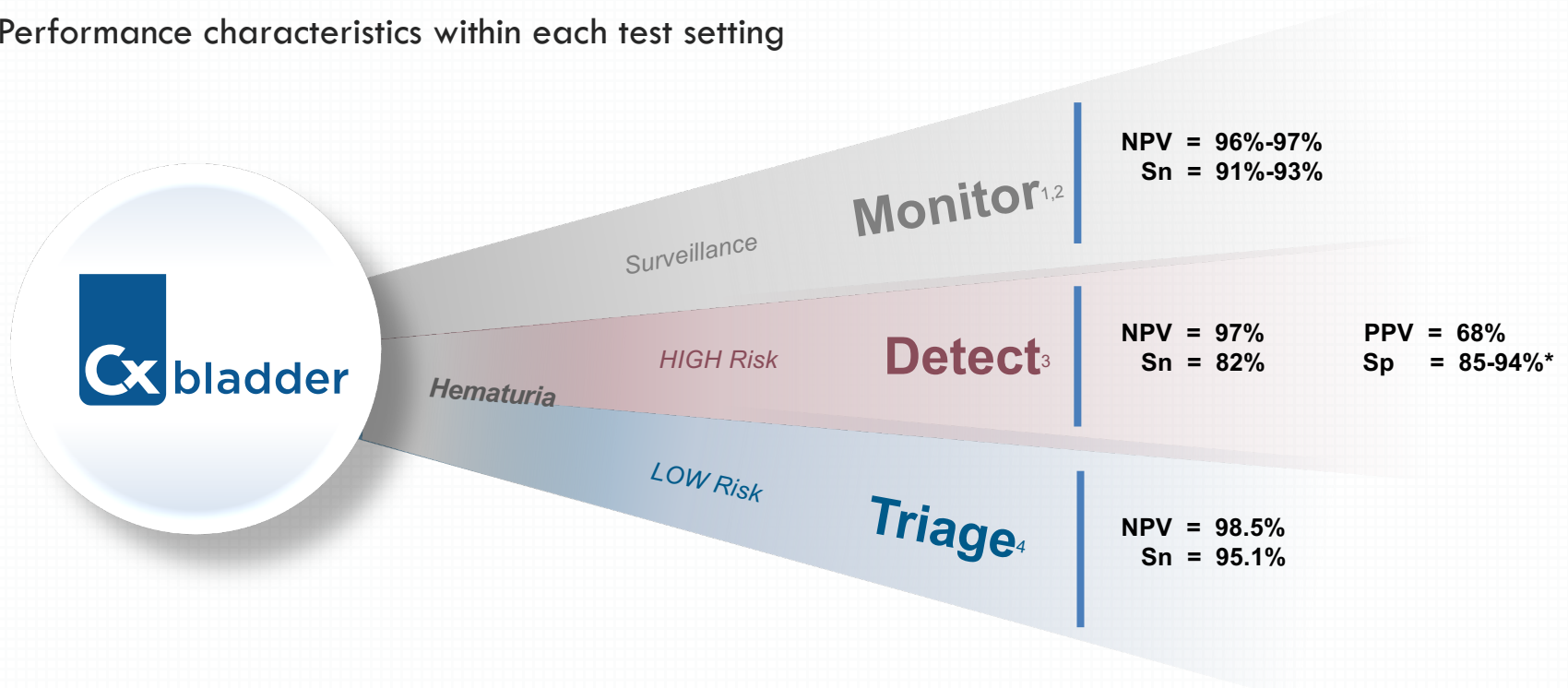
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Study Conclusions

- Cxbladder significantly outperformed urine cytology for identifying patients with UC
- Cxbladder correctly adjudicated all atypical cytology and atypical cytology with equivocal cystoscopy
- Cxbladder and cystoscopy were concordant for all positive cases previously categorized as atypical by local cytology, including all positive UC cases that were atypical for cytology and equivocal for cystoscopy.
- Significant utility is gained from the inclusion of Cxbladder in the evaluation of patients for UC in both hematuria and monitoring settings, with 35% of patients avoiding cystoscopies
- Cxbladder, either as a reflex to cytology or as a replacement for cytology, would remove the diagnostic dilemma associated with atypical cytology results and equivocal cystoscopy.

Cxbladder Products

Performance characteristics within each test setting



*85% overall, 94% in High Gene Expression Zone

1. Kavalieris L, et al. *J Urol.* 2017;197:6,1419-26; 2. Lotan Y, et al. *Urol Oncol.* 2017;1-8; 3. O'Sullivan P, et al. *J Urol.* 2012; 188:741-7; 4. Kavalieris L, et al. *BMC Urol.* 2015;15-23

Use of Telemedicine/Alternative Strategies Post COVID-19 – Temporary or the New Paradigm

The Cxbladder Test: To identify at Risk patients in either NMIBC surveillance or unresolved hematuria

The Value Proposition:

- At risk populations: e.g. elderly, immunosuppressed
- Clinic access issues: e.g. geography, transportation
- Rapid adoption and reimbursement for telemedicine
- Clinic efficiencies scheduling: economics healthcare
- Optimize all HCPs (APP, RN, MA)

Patient Selection Considerations

Surveillance Pathway

- ≥ 6 Months from a primary diagnosis, ≥ 9 Months from a recurrent diagnosis
- ≥ 3 Weeks from prior cystoscopy
- ≥ 6 weeks from BCG/Mitomycin/Immune modulating therapy

Cxbladder

- Voided urine only
- No gross hematuria at time of sample collection
- No active UTI

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

Contact

Cxbladder Assist
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