



URO17™

Developing the Most Sensitive and Specific Urine Test for Bladder Cancer

Bladder Cancer is the 6th most common cancer in the USA with 81,000 new cases annually.

There are currently over 6.7 million patients with hematuria who need an accurate and non-invasive diagnostic test.

- High recurrence rate of bladder cancer requires frequent monitoring.
- Low-grade tumors are more difficult to detect and make early detection difficult.
- Current urine tests for bladder cancer provide insufficient information, and are not considered reliable tools for monitoring or detecting new cases in patients with hematuria.
- There is a significant unmet clinical need for a non-invasive, highly sensitive, and specific test for bladder cancer.

Solution:

URO17™ Urine Test

The most sensitive and specific urine test for bladder cancer

URO17™ is an immunocytochemical test based on a novel biomarker. Published study reports **100% sensitivity and 96% specificity** for detecting bladder cancer from urine samples*.



The URO17™ test enhances cytology and can complement cystoscopy for more efficient monitoring, an increased detection rate, and a better patient outcome

URO17™

Clinical Study

Introduction to the clinical study:

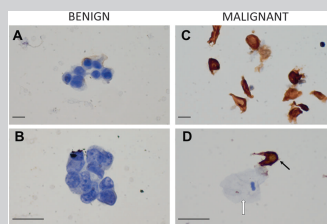
The aims of the current study were to explore the accuracy of Keratin 17 — a novel biomarker used in the URO17 test, as a potential diagnostic biomarker in bladder tissue specimens and to further determine if K17 can also detect urothelial cancer in urine cytology specimens.

Summary of Clinical Study Outcomes:

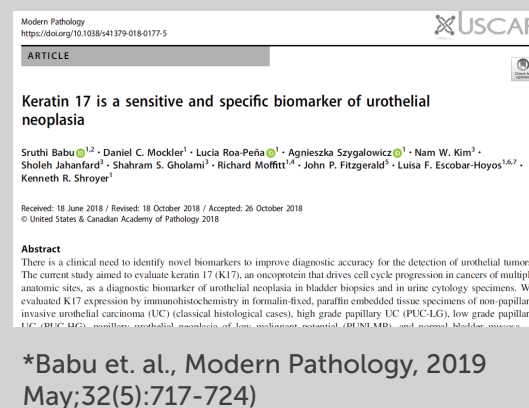
URO17 immunocytochemistry has a higher sensitivity and specificity than cytologic examination for urothelial carcinoma.

Test	Cytology ^a % (95%CI)	K17 ICC ^b % (95%CI)
Sensitivity ^c	80 (61–91)	100 (90–100)
Specificity ^c	93 (82–98)	96 (89–99)
PPV	87 (68–95)	91 (79–97)
NPV	89 (77–95)	100 (95–100)

CI confidence Interval, PPV positive predictive value, NPV negative predictive value



ICC study performed on 112 urine specimens.



URO17: The most sensitive and specific urine test for bladder cancer

	Cytology	NMP22	CX Bladder	UroVysion	Cystoscopy	URO17™
Sensitivity	56%	79%	82%	69%	98%	100%
Specificity	96%	84%	85%	78%	94%	96%

Sathianathen et al., 2018, Blick et al., 2011

The URO17 test is an immunocytochemical test that detects bladder cancer from urine samples.

Most Sensitive and Specific • 100% Sensitivity & 96% Specificity

Compatible • with all standard immunohistochemistry systems

Gold Standard Potential • testing suggests URO17™ test could improve accuracy of cytology and cystoscopy in monitoring recurrence cases, and detection of new cases in patients with hematuria



Collect urine sample and send to the lab using provided lab slip



Discuss the lab report with your patient

URO17 is now available through selected reference laboratories. For more information please talk to your KDx Account Manager or visit our website.

KDx Diagnostics Inc.
A Delaware Incorporation
www.kdxdiagnostics.com