



# 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:

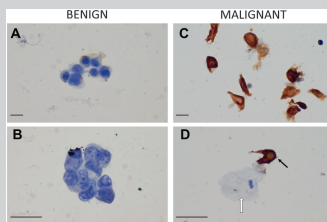
The aims of the current study were to explore the accuracy of Keratin 17 — a novel biomarker used in the URO17 test, as a potential diagnostic biomarker in bladder tissue specimens and to further determine if K17 can also detect urothelial cancer in urine cytology specimens.

### Summary of Clinical Study Outcomes:

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

| Test                     | Cytology <sup>a</sup> % (95%CI) | K17 ICC <sup>b</sup> % (95%CI) |
|--------------------------|---------------------------------|--------------------------------|
| Sensitivity <sup>c</sup> | 80 (61–91)                      | 100 (90–100)                   |
| Specificity <sup>c</sup> | 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.

Modern Pathology  
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ARTICLE

**Keratin 17 is a sensitive and specific biomarker of urothelial neoplasia**

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**Abstract**  
There is a clinical need to identify novel biomarkers to improve diagnostic accuracy for the detection of urothelial tumors. The current study aimed to evaluate keratin 17 (K17), an oncoprotein that drives cell cycle progression in cancers of multiple anatomic sites, as a diagnostic biomarker of urothelial neoplasia in bladder biopsies and in urine cytology specimens. We evaluated K17 expression by immunohistochemistry in formalin-fixed, paraffin embedded tissue specimens of non-papillary invasive urothelial carcinoma (UC) (classical histological cases), high grade papillary UC (PUC-HG), low grade papillary UC (PUC-LG), non-invasive urothelial neoplasia of low-malignant potential (ONL), and normal bladder mucosa.

**\*Babu et. al., Modern Pathology, 2019 May;32(5):717-724**

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

|             | Cytology | NMP22 | CX Bladder | UroVysion | Cystoscopy | URO17™      |
|-------------|----------|-------|------------|-----------|------------|-------------|
| Sensitivity | 56%      | 79%   | 82%        | 69%       | 98%        | <b>100%</b> |
| Specificity | 96%      | 84%   | 85%        | 78%       | 94%        | <b>96%</b>  |

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