

# Oncuria® Multiplex Immunoassay for Bladder Cancer

*The only diagnostic that detects 10 biomarkers consistent with bladder cancer*

## This 10-biomarker test has been developed for:



- Early detection of bladder cancer in patients presenting with hematuria
- Monitoring people with non-muscle-invasive or muscle-invasive bladder cancer for recurrence
- Predicting whether patients with intermediate- to high-risk, early-stage bladder cancer will respond to bacillus Calmette-Guérin (BCG) therapy

The immunoassay is performed using Luminex® xMAP technology. The physical components of the multiplex assay, a library of detection and capture antibodies, and the secondary reagents have undergone extensive optimization for consistent implementation. Analytical validation of the test has assessed selectivity, sensitivity, specificity, accuracy, linearity, dynamic range, and detection threshold, using voided urine as the test matrix.

## Detecting De Novo or Monitoring Bladder Cancer

A combinatorial analysis of all 10 biomarkers achieved a sensitivity of 93% when 3 key clinical factors (age, race, and gender) were included in a diagnostic nomogram for the detection of bladder cancer.

Assess the risk of bladder cancer in patients with:

A history of bladder cancer who are on tumor surveillance and who do not have chronic kidney disease (GFR <45 mL/min)

Hematuria and without chronic kidney disease (GFR <45 mL/min)



## Predicting Response to BCG

A combinatorial analysis of all 10 biomarkers achieved an accuracy of 82% in a diagnostic nomogram for predicting response to intravesical BCG therapy in patients with intermediate- or high-risk non-muscle-invasive bladder cancer (NMIBC).

Assess the risk of rapid failure (recurrence or persistence) in patients who fulfill all of the following conditions:

Have recently been diagnosed with intermediate- or high-risk NMIBC

Have had their tumor transurethrally resected/biopsied and are to begin intravesical BCG therapy

Do not have chronic kidney disease (GFR <45 mL/min)

## Biomarkers

VEGF-A	MMP-9	IL-8	ANG	MMP-10
CA9	PAI-1, SERPIN E1	SDC1	APOE	A1AT, SERPIN A1

**Service Name: Oncuria® Bladder Cancer Test**

**Intended Use: LDT**

**Catalog Number : DC-03-1001**



## Samples Collection and Processing

- Midstream voided urine collected in a sterile specimen container
- Store at 4°C until processed
- Centrifuge
- Output the results from Luminex



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