

A Valuable Diagnostic Aid to Predict Response to BCG Therapy

Oncuria® Multiplex Immunoassay for Bladder Cancer

Intravesical bacillus Calmette-Guérin (BCG) has been the standard therapy for treating patients with intermediate- to high-risk non-muscle-invasive bladder cancer (NMIBC) to avoid disease recurrence and progression.

40% of patients

with NMIBC will fail intravesical BCG therapy¹

30% of patients

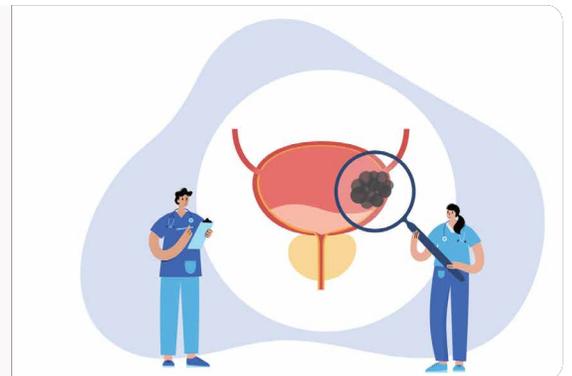
will have tumor recurrence

15% of patients

will see cancer progression despite BCG therapy

Identifying patients who will not benefit from BCG therapy will help to mitigate adverse events and streamline the use of such therapy, especially since there is a BCG shortage.

Oncuria® Predict is a unique 10-protein biomarker test that can be used to help predict whether patients with intermediate- to high-risk early-stage bladder cancer will experience rapid failure after treatment with BCG



A prospective clinical study was conducted (N = 64)² to identify patients in whom BCG was ineffective against tumor recurrence. Predictive models were derived using supervised learning and cross-validation analyses. Model performance was assessed using ROC curves.

The 10-biomarker model resulted in:

- Sensitivity of Oncuria Predict of 81.8%
- Specificity of Oncuria Predict of 84.9% for the prediction of high-grade disease recurrence (rapid recurrence with 12 to 18 months of starting BCG)
- AUC of 0.8971 (95% CI, 0.8000-0.9942)

AUC, area under the curve; ROC, receiver operator characteristic.



When key pathologic features of the tumor were included in this study:

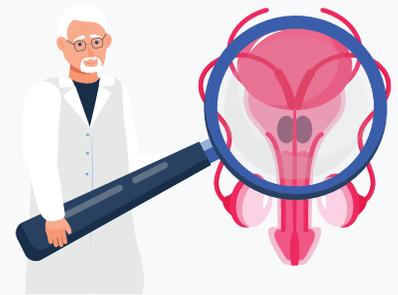
- Sensitivity of Oncuria Predict was 90.0%
- Specificity of Oncuria Predict was 86.8% for the prediction of high-grade disease recurrence (rapid recurrence within 12 to 18 months of starting BCG)
- AUC was 0.916 (95% CI, 0.818-1.000)

Tumor recurrences were recorded and stratified by disease invasiveness:

- NMIBC (stages Ta, Tis, T1) high-grade in 81.8% of patients
- Muscle invasive bladder cancer (MIBC; stage \geq T2) high-grade in 18.2% of patients

Patients with high probability of rapid recurrence based on Oncuria Predict results could be counseled about:

- Intravesical chemotherapy (mitomycin C, gemcitabine, or other agents)
- Early cystectomy
- Immuno-oncology therapy (for those patients not responding to BCG)



References

1. Zlotta AR, Fleshner NE, Jewett MA. The management of BCG failure in non-muscle-invasive bladder cancer: an update. *Can Urol Assoc J.* 2009 Dec;3 (6 Suppl 4):S199-205. doi: 10.5489/cuaj.1196. PMID: 20019985; PMCID: PMC2792453

2. Murakami K, Kamat AM, Dai Y, et al. Application of a multiplex urinalysis test for the prediction of intravesical BCG treatment response: a pilot study. *Cancer Biomark.* 2022;33(1):151-157. doi:10.3233/CBM-210221

This laboratory developed test (LDT) is performed at DiaCarta Laboratory and is designed to test certain proteins known to assist in determining the risk score of bladder cancer from urinary specimens. The test is not cleared or approved by the U.S. Food and Drug Administration (FDA). For questions about this test or to speak with a DiaCarta Support Specialist, please call (800) 246-8878.