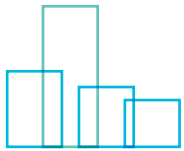


# REDUCE FOLLOW-UP CYSTOSCOPIES WITH 99% NPV

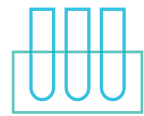
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Superior Results - Highest NPV,  
Sensitivity and Specificity



Not Effected by  
BCG, Hematuria, Infections



Simple Urine Test

# HOW IT WORKS

Methylation of the DNA is a set of 'switches' that activate or deactivate specific genes in order to allow different cell types to perform their role. It is therefore a powerful tool to distinguish between cell types. Cancer cells show changes in methylation pattern compared to healthy cells, and if one could "read" these methylation changes against a large background of healthy cells, one would be able to detect the presence of tumors in body fluids, such as urine and blood. This is exactly what Nucleix does.



Bladder

- Methyl Group (CH<sub>3</sub>)
- EpiCheck™ unique methylation biomarker



Bladder cancer

## SIMPLE PROCESS, SUPERIOR RESULTS

Nucleix's products are based on 2 main technology platforms that are applied to Bladder EpiCheck:



### BIOCHEMICAL ASSAY:

- Analyzes DNA from urine and detects subtle disease-specific DNA methylation changes
- Allowing detection of cancer DNA molecules in a noise of over 200,000 non-cancerous DNA molecules
- Requiring only small amounts of DNA
- Simple laboratory assay
- Requires no bisulfite conversion

### SOFTWARE TOOL:

- Allocates new methylation biomarkers in the entire genome using an empirical approach
- Builds panel of highly informative biomarkers
- Outputs yes/no + EpiScore (0-100) representing methylation levels at panel
- Automatic software analysis for objective, repeatable and precise results

OUTSTANDING  
RESULTS

OPERATOR  
INDEPENDENT

EASY TO  
ADOPT

# PERFORMANCE RESULTS

## EUROPEAN PIVOTAL STUDY

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**99%**

**NPV**

(excluding Ta-LG)

**92%**

**SENSITIVITY**

(excluding Ta-LG)

**88%**

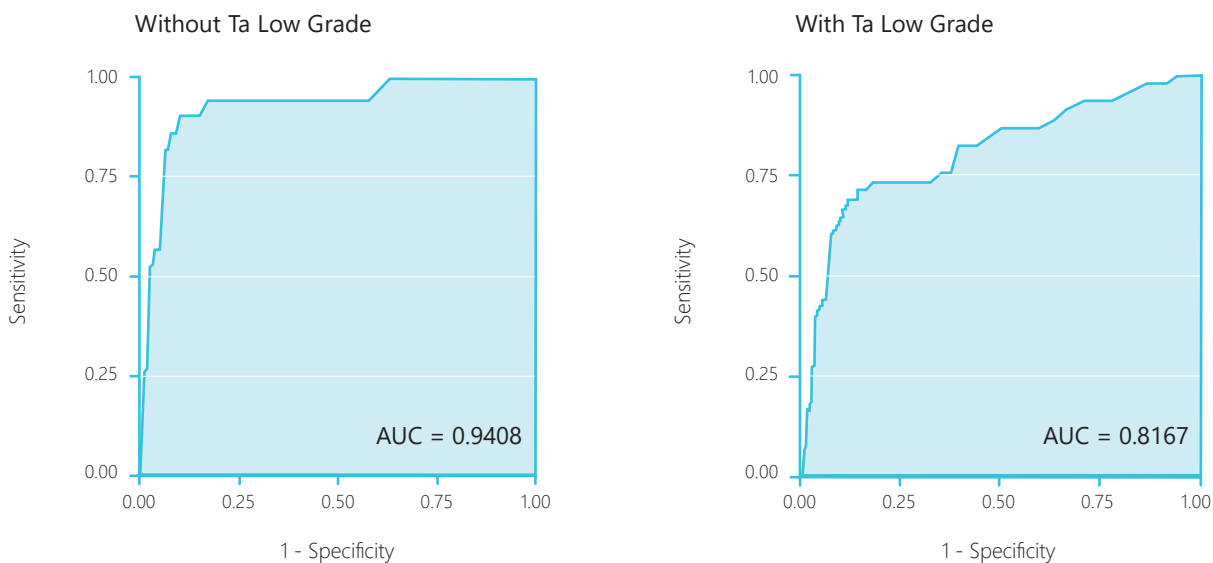
**SPECIFICITY**

A prospective, blinded, single arm, single visit, multicenter study including 440 (353 in final analysis) patients in their first year of follow up after resection (TURBT) of primary or recurrent bladder cancer. Bladder EpiCheck performance was compared to the gold standard which included cystoscopy, cytology and pathology.

Participating medical centers: Radboud University Medical Center, Nijmegen, The Netherlands. Vall D'Hebron University Medical Center, Barcelona, Spain. Meir Medical Center, Kfar-Saba, Israel. Universitätsklinikum Tübingen, Tübingen, Germany. ZGT Hospital, Hengelo, The Netherlands.

The Bladder EpiCheck tests were performed in two independent laboratories, Synlab Jena Oncoscreen in Jena Germany and The Clinical Microbiology Laboratory at Meir Medical Center in Kfar Saba, Israel.

## ROC CURVES



Witjes et al. Performance of the Bladder EpiCheck™ Methylation Test for Patients Under Surveillance for Non-muscle-invasive Bladder Cancer: Results of a Multicenter, Prospective, Blinded Clinical Trial. *European Urology Oncology* 2018;1:307-313

Nucleix is collaborating with leading medical centers and lab chains around Europe and USA.



Nucleix Ltd. develops, manufactures and markets highly innovative and non-invasive molecular cancer diagnostic tests. Our highly sensitive and specific tests are based on identification of subtle changes in methylation patterns. Nucleix technology is based on a combination of a new biochemical platform in conjunction with sophisticated algorithms.

Our first product Bladder EpiCheck™ is a urine test for monitoring of bladder cancer, that has shown superior NPV, sensitivity and specificity.

Nucleix pipeline includes a blood test for lung cancer screening, using its proprietary and highly innovative technology. Nucleix is backed up by leading investors and funds such as OrbiMed Advisors - the world's largest biomedical VC fund.



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