

# Are you being monitored for bladder tumor recurrence?

The **Bladder EpiCheck®** is a non-invasive, highly sensitive and specific urine biomarker test that can easily be implemented in the follow-up of non-muscle invasive bladder cancer (NMIBC). A negative test result rules out high-risk tumors with 99% certainty [1].

**The information inside can help you and your treating physician to improve your bladder cancer follow-up approach.**



Superior Results - Highest NPV, Sensitivity and Specificity



Not Effected by BCG, Hematuria, Infections



Simple Urine Test

# BENEFITS OF BLADDER EPICHECK®

- ✓ **Non-invasive** - performed on a urine sample
- ✓ **Conveniently collected** - urine can be collected at the hospital, or at home
- ✓ **Objective** - independent automatic interpretation
- ✓ **Fast results**
- ✓ **Highly accurate** - in detecting high-grade bladder cancer
- ✓ **Rules-out high-grade tumors with 99% certainty** - with a negative result
- ✓ **May reduce the number of cystoscopies** - if test is negative and based on the decision of the treating urologist



## NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

Bladder cancer is the **tenth most common cancer worldwide** with approximately 550,000 newly diagnosed patients every year. The incidence of bladder cancer is the highest in Europe and North America and the lowest in Sub-Saharan Africa, Mexico and some Middle Eastern and Central Asian countries [2].

Early stages of bladder cancer (stages Ta, CIS and T1) are limited to the inner bladder lining, not penetrating the muscle.

- **Ta:** a papillary tumor with a long, thin, finger-like structure growing on the inner bladder lining
- **TIS (CIS):** superficial flat tumor on the inner bladder lining
- **T1:** a tumor invading through the inner bladder lining, but not into the underlying muscle layer

Because these tumors do not invade the deeper muscle layer, these tumors are called NMIBC. **NMIBC represents the majority of diagnosed bladder cancers.**

Tumor cells are classified into low- or high-grade, depending on their appearance under the microscope. Low-grade tumor cells appear like normal bladder cells, whereas high-grade tumor cells look abnormal and tend to grow and spread faster. Ta and T1 tumors can either be low- or high grade, whereas CIS tumors are always high-grade.

Treatment includes a transurethral resection of bladder tumor (TURBT) to remove the tumor. Additional local washing with chemo- or immunotherapy may be needed to reduce the risk of recurrence.

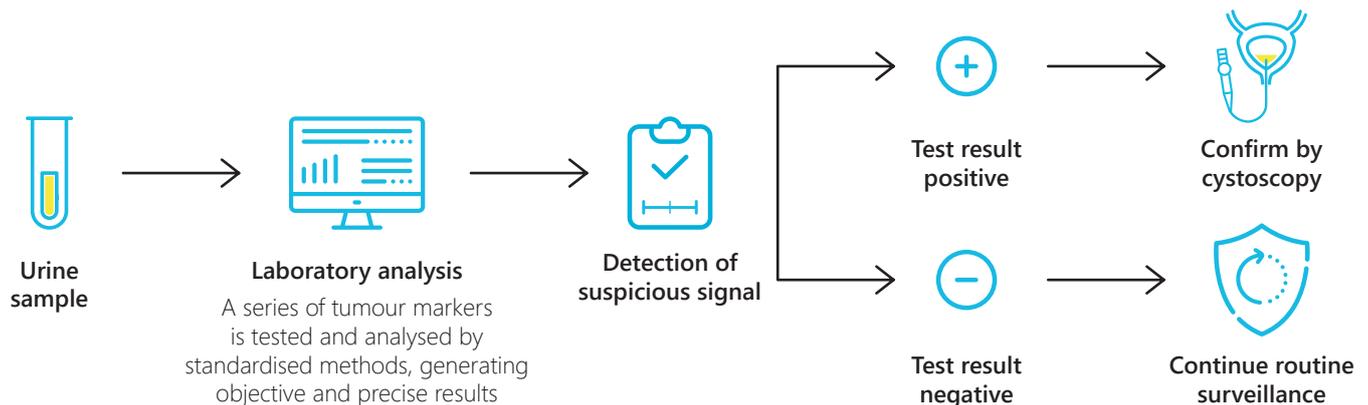
**The high risk of disease recurrence requires regular follow-up of patients after tumor resection.**

Standard follow-up procedures are cystoscopy combined with cytology to detect tumor recurrence. Discomfort and pain are usually associated with cystoscopy wherein a thin tube with a camera is inserted through the urethra. This procedure is performed at an outpatient clinic in the hospital, or in the urologist's office. Follow-up procedures are usually scheduled every 3 months in the beginning and then twice-yearly and eventually annually.

# WHAT IS BLADDER EPICHECK®

- ✓ **A simple, non-invasive urine test**
- ✓ **A unique molecular identification technology of epigenetic changes in DNA**

The test analyzes disease-specific changes in 15 DNA methylation markers to identify cancerous cells in the urine. It is designed to monitor for recurrence of bladder cancer in NMIBC patients. The Bladder EpiCheck® biomarker test is approved by the European Union (CE) for detection of bladder cancer recurrence in conjunction with cystoscopy.



## WHO IS ELIGIBLE FOR THE TEST?

NMIBC patients > 22 years undergoing monitoring for bladder cancer recurrence.

## CLINICAL TRIAL PERFORMANCE OF BLADDER EPICHECK®

A prospective, multi-center clinical trial performed in leading medical centers in the Netherlands, Germany, Spain and Israel demonstrated:

- ✓ 88% specificity - **The test correctly identifies 88% of healthy individuals**
- ✓ 99% negative predictive value - **A negative (favorable) result rules out high-grade tumors with 99% certainty**

"This test could serve as a rule-out test and help to avoid unnecessary cystoscopic procedures in NMIBC follow-up since high-grade recurrences would be instantly detected with high confidence." [1]

## REFERENCES

1. Witjes et al. Eur Urol Oncol 2018;1(4):307-313
2. Ferlay et al. Global cancer observatory: cancer today 2018; <https://gco.iarc.fr/today>. Accessed October 2020

The Bladder EpiCheck® biomarker test is an in vitro diagnostic technology to detect bladder cancer-associated DNA methylation patterns in urine. It is intended for use as a noninvasive method for monitoring of tumor recurrence in conjunction with cystoscopy in patients previously diagnosed with bladder cancer.

# AN EXPERT AND A PATIENT SHARE THEIR EXPERIENCE ON THE BENEFITS OF USING BLADDER EPICHECK® FOR BLADDER CANCER SURVEILLANCE



## PROF. DR. WITJES, RADBOUD UMC,

Nijmegen, The Netherlands [1,2]

“Application of this test could reduce the current burden of repeat cystoscopy and cytology tests, for example, by alternating between the follow-up gold standard and Bladder EpiCheck®.”



## GERARD LENSVELT, DUSSEN,

The Netherlands Bladder cancer patient since 2002 [3]

“I think I had about 65 cystoscopies. But with the Bladder EpiCheck® you undergo cystoscopy, 3 months later you do the Bladder EpiCheck® test. Your physician gives you your test result within 14 days. The advantage is that you only need a cystoscopy 2 times per year and you don't need to go to the hospital. That's less burdensome for me, and for the other patients”



## ARE YOU A NON-MUSCLE-INVASIVE BLADDER CANCER PATIENT WHO IS BEING MONITORED FOR RECURRENCE OF A BLADDER TUMOUR?

Ask your treating physician for more information on how you might benefit from the Bladder EpiCheck® urine test and how it could impact your bladder cancer check-up approach.

### REFERENCES

1. Witjes JA, Morote J, Cornel EB, et al. Eur Urol Oncol 2018;1:307-13.
2. <https://youtu.be/SGrZDXmp9FU>
3. <https://youtu.be/utNgB0Y8jOw>

