



## Surveillance of Non-Muscle-Invasive Bladder Cancer (NMIBC) Patients with Non-invasive Monitoring

### ■ Xpert® Bladder Cancer Monitor





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Current available methods, like cystoscopy and cytology, have several limitations. The sensitive detection of urine biomarkers by non-invasive methods could support the surveillance of NMIBC patients and reduce discomfort.”

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## The Need

- After initial diagnosis, the early detection of recurrence is crucial for successful management of bladder cancer patients<sup>1,2</sup>
- Due to high recurrence rates, frequent follow up by cystoscopy, urine cytology and other methods are required for many years<sup>3,4</sup>
- Unfortunately, cystoscopy often misses Carcinoma in Situ (CIS) cases and sometimes also misses papillary tumors<sup>5</sup>
- After invasive cystoscopy procedures, many patients experience pain, bleeding, and infections<sup>5,6</sup>
- Better, non-invasive, and painless methods for monitoring of bladder cancer are needed<sup>5-7</sup>

## The Solution

- Xpert® Bladder Cancer Monitor is a non-invasive biomarker test for monitoring NMIBC patients for recurrence in conjunction with other clinical measures
- After testing hundreds of known tumor markers, the five strongest bladder cancer indicator mRNAs were identified and selected
- The resulting assay has been extensively validated for bladder cancer monitoring in independent studies<sup>8,9,12,13</sup>
- Using voided urine, the test is easy to perform within 90-minutes and uses self-contained cartridges and an automated system<sup>8-10</sup>
- The assay was developed to have high sensitivity and a high negative predictive value, especially for aggressive high-grade tumors
- The test can be performed in any size urology lab and does not require a traditional PCR lab set up.
- Every cartridge contains three controls for reliable results
- Samples are stable for up to 7 days in Xpert® Urine Transport Reagent at 2–28 °C<sup>10</sup>
- External controls<sup>4</sup> are available<sup>11</sup>

Coverage, plus  
Accuracy, plus  
Peace of mind

That's the PCR<sub>plus</sub> advantage.  
From Cepheid.

## The Impact

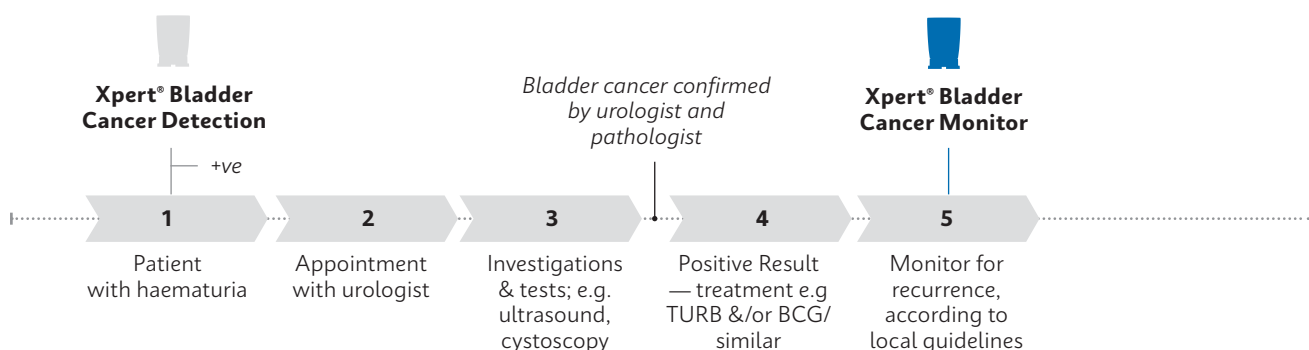
- A non-invasive bladder cancer test can reduce patients' anxiety and pain<sup>6</sup>
- Non-invasive monitoring tests can complement traditional methods and might help some patients avoid invasive procedures<sup>7</sup>
- Reducing anxiety for patients about testing discomfort can improve monitoring compliance and ensure early detection of bladder cancer recurrence<sup>14</sup>
- Aggressive high-grade tumors can be ruled out with high certainty due to the high negative predictive value, reassuring patients and their doctors
- 90 min time-to-result facilitates patient management

## Performance

Xpert® Bladder Cancer Monitor has a high NPV and sensitivity for all tumors independent of grade.<sup>10</sup>

<b>Sensitivity:</b>	75.0% (95% CI: 60.6–85.4)	<b>PPV:</b>	44.6% (95% CI: 33.8–55.9)
<b>Specificity:</b>	80.6% (95% CI: 74.7–85.3)	<b>Accuracy:</b>	79.6% (95% CI: 74.2–84.1)
<b>NPV:</b>	93.9% (95% CI: 89.4–96.4)	<b>Prevalence:</b>	17.3% (95% CI: 13.1–22.4)

Performance characteristics of Xpert Bladder Cancer Monitor were evaluated at sites in the U.S., Canada and E.U. Subjects included individuals with an initial diagnosis or recurrence of bladder cancer within nine months prior to enrollment. Results of the Xpert Bladder Cancer Monitor were compared to cystoscopy, with histology confirmation of positive and suspicious cystoscopies.



## Workflow: 3 Easy Steps

1

Transfer approx. 4.5 mL of voided urine into the urine transport reagent tube. Invert to mix well.



2

Place 4 mL of this mixture into the sample chamber of the cartridge.



3

Insert cartridge and start test (run time 85 min).<sup>10</sup>



PN0122-01

## Catalog Information

Xpert® Bladder Cancer Monitor	10 tests	GXBLAD-CM-CE-10
Xpert® Urine Transport Reagent Kit	30 sets	GXUTR-CE-30

### References:

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- Xpert® Bladder Cancer Monitor Package Insert 301-5933, Rev. E Sep 2021
- Controls can be ordered at Maine Molecular Quality Controls <http://www.mmqci.com/products/c104.html>
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