

Bladder CARE™

Bladder Cancer Urine Test



PATIENT

Name: John Doe
Date of Birth: 07/16/1962
Sex: Male
Age: 56
State of Residence: CA, USA

PHYSICIAN

Name: Jane Doe, M.D.
Address: 1492 Woodfield Rd.
Address line 2: Somewhere, CA, USA
Acct#: 12345-A
Tel: (123) 456-7890

SAMPLE

Sample ID: BCT00001
Collection Date: 11/20/2018
Received Date: 11/28/2018
Report Date: 12/05/2018

Patient Summary Report

RESULT:

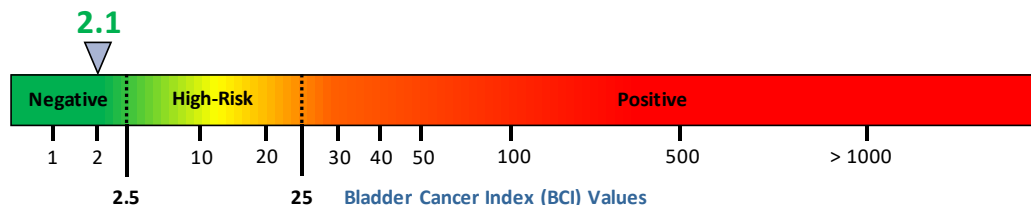
Negative

High-Risk

Positive

Patients with a Bladder Cancer Index (BCI) lower than 2.5 are considered bladder cancer negative, while patients with BCI between 2.5 and 25, and higher than 25 are classified as high-risk, and positive respectively for the presence of bladder cancer.

The probability that a patient is affected by bladder cancer increases with the increase of the BCI value.



Additional Clinical Information

The patient is reported to have urge to urinate, dysuria, and cloudy urine at the time of urine sample collection.

Additional Sample Information

Urine volume: 372.5 ml
Urine color: Dark yellow
Processed volume: 100 ml
DNA concentration: 5.8 ng/ml
Total DNA: 58 ng

Report Date:

12/05/2018



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Laboratory Director Signature:

Jess Savala, Jr., M.D.,
Laboratory Director

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Interpretation of the Results

Result of Bladder CARE™ Test are expressed as Bladder Cancer Index (BCI). BCI is calculated based on the DNA methylation level of three bladder cancer specific biomarkers. Elevated BCI correlates with the presence of bladder cancer DNA in the urine sample collected.

Negative Results:

Typical Bladder Cancer Index (BCI) values for negative patients are in the range of 0 to 2.4. Patients with negative results have an extremely low possibility to be affected by bladder cancer and do not require additional testing for bladder cancer. Eventual disorders (e.g. dysuria, frequent urination, cloudy urine) may be associated to other conditions like genitourinary tract infection and inflammation.

Urine samples with very high levels of hematuria may, however, result in false negative calls, therefore we recommend repeating the test for patients affected by high hematuria and with negative Bladder CARE™ results.

Patients with a history of bladder cancer have an increased risk for tumor recurrence, therefore we recommend repeating Bladder CARE™ test for these patients every 2-3 months even if the previous results were negative.

Although very unlikely, supplementation with S-adenosylmethionine (SAM), folate/folic acid, and HDAC inhibitors (e.g. Verinostat, Romidepsin, Belinostat, Sodium Butyrate, Valproic Acid, Lithium) may interfere with Bladder CARE™ test and may result in false negative calls.

High-Risk Results:

Typical Bladder Cancer Index (BCI) values for high-risk patients are in the range of 2.5 to 25. High-risk Bladder CARE™ results indicate that the patient has an elevated risk to have bladder cancer compared to a normal situation. The probability that a patient is affected by bladder cancer increases with the increase of the BCI value. Specifically, the probability to have bladder cancer is 65.4% for patients with BCI values between 2.5 and 4.5, 80% for BCI values between 4.6 and 7.5, and more than 90% for BCI values between 7.6 and 25. For all the patients classified as high-risk we strongly recommend repeating Bladder CARE™ test within one month from the date of the report. High-risk patients should consider the possibility of receiving a cystoscopic exam to confirm the presence of bladder cancer. Clinical studies demonstrate that Bladder CARE™ has the potential to detect cancer at early stages, when other tests may fail to do so (more than 88% of the low-grade bladder tumors cases are detected by Bladder CARE™).

Positive Results:

Typical Bladder Cancer Index (BCI) values for positive patients are greater than 25. In this case the chance that a patient is affected by bladder cancer is extremely high (more than 99%), and we strongly recommend performing a cystoscopic exam to confirm the presence of the tumor. To note, other malignancies (including prostate, endometrial, cervical, ovarian, kidney, hematological, and colorectal cancers) may be detected by Bladder CARE™ and may generate false positive results.

In general, we recommend a close monitoring of patients with BCI higher than 2.4, and patient management should be based on Bladder CARE™ Test results, clinical judgment, and shared decision making.

Pangea Laboratory, LLC. is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. The Bladder CARE™ test was developed and its performance characteristics determined by Pangea Laboratory, LLC. It has not been cleared or approved by the US Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. This test is intended for use as an aid to clinicians for patient diagnosis-related decisions. The test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician. Use outside of this indication has not been validated by Pangea Laboratory, LLC.