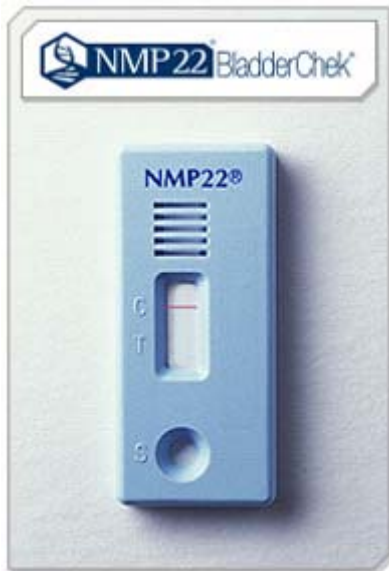




MATRITECH'S NMP22[®] BLADDERCHEK[®] TEST

Detecting More Cancers than Commonly Used Tests

The NMP22[®] BladderChek[®] Test is the only FDA approved in-office test for both the diagnosis and monitoring of bladder cancer. A painless and noninvasive assay that requires only four drops of urine, the NMP22 BladderChek Test detects in the urine elevated amounts of the Nuclear Mitotic Apparatus (NuMA) protein, which Matritech refers to as the NMP22 protein. Most healthy individuals have very small amounts of NMP22 protein in their urine, compared to the elevated amounts of NMP22 protein present in the urine of many individuals with bladder cancer, even at early stages of the disease.



The test can be performed in a physician's office, by the physician or a member of the staff. Results are available during the patient visit, allowing a rapid, accurate and cost-effective way to aid in the detection of bladder cancer. The NMP22 BladderChek Test is reimbursed by Medicare and most medical insurers and has an average cost of less than \$30.

The NMP22 BladderChek Test has been shown to detect cancers missed by currently used technologies. Independent clinicians have reported that when the test is used with cystoscopy (a visual examination of the interior of the bladder using a scope inserted through the urethra), the medical reference standard, the overall detection increases up to 99%. This includes cases missed by cystoscopy alone. The NMP22 BladderChek Test has also been shown to detect three times as many malignancies as those found by cytology, a commonly used laboratory based urine test.

In other clinical study analyses it was shown to detect 100% of the aggressive tumors, one of which was muscle invasive, in women with symptoms or risk factors for bladder cancer. It was also reported to detect all the transitional cell cancers that occurred in the upper urinary tract of patients with risk factors or symptoms of bladder cancer. Cystoscopy did not identify these tumors because they were outside the viewing area of the instrument.

In addition to published studies reporting that the NMP22 BladderChek Test identified many more cases of bladder cancer than urine cytology testing, other study results report that NMP22 BladderChek Test results are not hindered by the common presence of blood in urine samples. Other urine tests often report false-positives or do not provide a result when blood is present in the urine sample.

Featured in the *Journal of the American Medical Association (JAMA)* January 18, 2006 and February 16, 2005

Two studies – one on the diagnosis and one on the monitoring for recurrent bladder cancer – using the NMP22 BladderChek Test were published in the *Journal of the American Medical Association (JAMA)* in January 2006 and February 2005. The 2006 study reported on the use of the NMP22 BladderChek Test in combination with cystoscopy for the monitoring of recurrent bladder cancer. The 2005 study reported on its use in combination with cystoscopy in the initial diagnosis of bladder cancer.



In the January 18, 2006 issue of the *Journal of the American Medical Association (JAMA)*, the NMP22® BladderChek Test® was reported to significantly increase the detection of recurrent bladder cancer, finding 99% of the malignancies when used with cystoscopy. The NMP22 BladderChek Test was positive for 8 of 9 cancers not seen by cystoscopy, including eight tumors that were aggressive or advanced. The test also detected four times as many cancers as the commonly used laboratory based urine cytology test.

Bladder cancer has the highest rate of recurrence of any malignancy, with the cancer recurring in 50% to 90% of patients, depending on the aggressiveness and extent of the initial tumor. Patients are rigorously monitored throughout their lives for new malignancies. A combination of methods is used to monitor patients since no single method is 100% accurate in detecting the cancer.

According to Edward Messing M. D., Chairman of the Urology Department at the University of Rochester Medical Center, "Delay of diagnosis of an aggressive bladder cancer even by a few months can affect prognosis. The AUA guidelines for evaluation of patients with blood in the urine recommend using a urine test as back up to cystoscopy. We use the NMP22 test in our practice, and will include it in an upcoming National Cancer Institute (NCI) study for monitoring bladder cancer recurrence after treatment."

On February 16, 2005, an article in *JAMA* summarized the findings and conclusions of physicians who investigated the effectiveness of the NMP22 BladderChek Test in diagnosing cancer. In the study, NMP22 BladderChek Test detected cases of bladder cancer not seen by an initial cystoscopy, the medical reference standard for diagnosis. In this study, the NMP22 BladderChek Test detected nine out of ten life threatening tumors and the cystoscopic examinations found only six. Together the tests produced a combined detection of 94% of bladder cancers. Additionally, the point-of-care test detected over three times as many malignancies as cytology, the laboratory based urine test. The authors of the study determined the NMP22 BladderChek Test is a useful adjunctive tool in the evaluation of patients at risk for bladder cancer because it identified several malignancies missed by initial cystoscopy. The authors, who included physicians from M.D. Anderson Cancer Center, the University of Rochester Medical Center, and the University of Miami School of Medicine also cited the low cost of the test, about half that of cytology, its ability to detect cancer and ease of use, and mentioned that the NMP22 protein marker is the only one approved by the FDA as an aid in the detection of bladder cancer.

Cost Effective in Detecting Bladder Cancer

An article published in the American Cancer Society's journal *Cancer* (September 1, 2006), reported that screening for bladder cancer in high risk populations with the NMP22 BladderChek Test could save lives and reduce overall medical expenses. All other cancer screening programs save lives but increase expenses. Screening for bladder cancer with the NMP22 BladderChek Test could be less costly than not screening.

Yair Lotan, M.D., Assistant Professor, Department of Urology, University of Texas Southwestern Medical Center and his colleagues, created a decision analysis model to assess cost-effectiveness and life years saved from screening versus not screening for bladder cancer in high risk populations. They found that the urine-based NMP22 BladderChek Test could be cost effective for screening high risk populations based on its cost and accuracy in detecting bladder cancer.

High risk was defined as over 50 years of age with a smoking history and/or significant occupational exposure to toxins or dyes. The authors also took into consideration factors that limit the effectiveness of cancer screening, including survival benefit, disease prevalence, screening efficacy and cost.

In a separate and earlier analysis reported in the journal *Urologic Oncology*, Dr. Lotan and his colleagues evaluated the cost of screening individuals at high risk (based on risk factors such as long-term smoking or exposure to chemicals and dyes) with bladder tumor markers. They determined that for women undergoing mammography screening, the cost per breast cancer detected can be as high as \$14,000. Prostate cancer



screening with PSA leads to costs of nearly \$3,000 per cancer detected; colorectal cancer screening has a range of \$2,000-\$5,000 per cancer detected. For bladder cancer screening using the NMP22 BladderChek Test, the cost per cancer detected could be less than \$3,000 making it comparable to PSA and colon cancer screening. In the United States alone, it is estimated that the annual direct costs of bladder cancer management are \$4 billion.

Dr. Lotan suggests that bladder cancer is an ideal disease for screening a high risk population because the risk factors are well known. He emphasizes, "The best possibility for reducing bladder cancer mortality is early detection. The initial diagnosis of one out of four bladder malignancies currently occurs when the cancer is at an advanced stage, requiring expensive treatment and has reduced survival. Screening offers the potential for detecting cancers earlier, resulting in less extensive and less costly treatments, as well as improved survival."

Another recent study has proven that screening reduced bladder cancer mortality. Results of the long-term study were reported at the 2006 annual meeting of the American Urological Society (AUA) meeting by Edward Messing, M. D., Chairman of the Urology Department, University of Rochester Medical Center. His 14 year follow up of patients screened for bladder cancer showed that no patients who underwent screening died from bladder tumors, whereas 20% of unscreened patients did die from bladder cancer. The tumors found by screening were diagnosed at earlier stages, thereby improving outcomes. Overall mortality was significantly lower in screened patients (43%) compared to those whose were not screened (74 %). Dr. Messing is also a co-author of the two studies on the NMP22 BladderChek Test published in JAMA.

Bladder Cancer Screening in Communities across the Country

Firefighters and People "at risk" for Bladder Cancer Getting Tested

In communities in Colorado, Wisconsin, Texas, California, New Jersey, Massachusetts, and Rhode Island, physicians are offering screening programs for people at risk for bladder cancer. Screenings began in August, 2006 in Texas and have taken place in other states or are expected to take place. In Rhode Island, firefighters in Little Compton, Tiverton, Portsmouth, Middletown, and Jamestown were offered free screening for bladder cancer in a voluntary program paid for and sponsored by their local state representatives. The Rhode Island state representatives have filed legislation to create a statewide program, directed by the RI department of health, to test for, collect data on, and educate firefighters about bladder cancer and their risk for the disease. Screening programs for firefighters are also scheduled in other states including California and Massachusetts. Firefighters have an increased risk of bladder cancer.

About Bladder Cancer

There will be more than 63,000 new cases of bladder cancer diagnosed in the U.S. this year. Although it is the fifth most common cancer among men and women, it is also ranked as the second most common urologic malignancy in the U.S. after prostate cancer, and is almost as common in men as colon cancer. The prevalence of bladder cancer in the U.S. is higher than lung cancer. Bladder cancer has the highest rate of recurrence with 50 to 85 percent recurrence rates. Currently there are more than 500,000 Americans with a history of bladder cancer. The most common risk factor for bladder cancer is smoking. Occupational exposures to chemicals (aromatic amines) used in dry cleaning facilities and the production of dyes, paper, rope, apparel, rubber and petroleum products have been associated with increased risk for bladder cancer. Other industrial exposures implicated as risk factors for developing bladder cancer include combustion gases and soot from coal, chlorinated aliphatic hydrocarbons, and chlorination by-products in heated water.

If diagnosed in its early stages, bladder cancer has a five-year survival rate of 94%. If diagnosed at an advanced stage, however, the five-year survival rate can be less than 10%. It has been estimated that this year in the United States about 25% of bladder cancer patients will be diagnosed after their disease has become invasive or metastatic, significantly lowering the five year survival rate.



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About Bladder Cancer in Women

In the U.S., according to the most recent SEER data, the prevalence of bladder cancer in women (140,000) is comparable to the number of women with cervical (184,000) and ovarian (159,000) cancers. It is more common and has a higher mortality than cervical cancer. The five year survival rate of women is less than the ten year survival rate of men. It is postulated that diagnosis in women is delayed because symptoms are misinterpreted; this delay is correlated with a disproportionately higher death rate among women. In 2005 women were estimated to account for one in four new bladder cancer diagnoses, but one in three bladder cancer deaths.

One of the first signs of bladder cancer is blood in the urine (hematuria). Sometimes the urine appears normal and blood is detected only through a test. Other signs can include painful urination, increased frequency of urination, a feeling of needing to urinate but not being able to do so, and frequent urinary tract infection-like symptoms. While each of these symptoms might have benign causes, the possibility of bladder cancer should not be excluded.

About Matritech

Matritech is using its patented proteomics technology to develop diagnostics for the detection of a variety of cancers. The Company's first two products, the NMP22® Test Kit and NMP22® BladderChek® Test, have been FDA approved for the monitoring and diagnosis of bladder cancer. The NMP22 BladderChek Test is based on Matritech's proprietary nuclear matrix protein (NMP) technology, which correlates levels of NMPs in body fluids to the presence of cancer. Beginning with a patent portfolio licensed exclusively from the Massachusetts Institute of Technology (MIT), Matritech's patent portfolio has grown to 14 other U.S. patents. In addition to the NMP22 protein marker utilized in the NMP22 Test Kit and NMP22 BladderChek Test, the Company has discovered other proteins associated with cervical, breast, prostate, and colon cancer. The Company's goal is to utilize protein markers to develop, through its own research staff and through strategic alliances, clinical applications to detect cancer. More information about Matritech is available at www.matritech.com.

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