NMP22® BladderChek® Test & NMP22® Test EIA

Improving the early and rapid detection of bladder cancer

FDA tumour marker for monitoring and screening of patients at risk for Bladder Cancer

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The most common initial symptom of bladder cancer is haematuria (blood in the urine), often accompanied by pain on urination. However haematuria may arise from a number of non-malignant conditions such as a urinary tract infection or even recent strenuous exercise and therefore requires extensive differential diagnosis.

There has been no progress in the diagnosis of early bladder cancer for over 15 years until now. The gold standard for bladder cancer diagnosis is cystoscopy, which allows urologists to look at the inside of the bladder. However, cystoscopy does have limitations. It is unable to detect cancers in the upper urinary tract and is often unable to detect the more aggressive, life threatening form of bladder cancer, carcinoma in situ (CIS), which presents as a flat lesion. Additionally, poor visualisation may occur due to inflammatory conditions and folds in the bladder tissues. Finally, cystoscopy is an invasive procedure requiring an anaesthetic. There are several associated risks to general anaesthetic, whilst the cystoscopy procedure itself can often leave patients feeling uncomfortable afterwards.

New urine tests are now available for the non-invasive detection of bladder cancer using NMP22 as a urinary marker. NMP stands for Nuclear Matrix Protein and is a common protein found in the nucleus of all cells. NMPs have been identified in cancer cells, including bladder cancer. These cells release NMP22 into the urine where it can be detected using an NMP22 specific assay.

Most healthy people have a very small amount of NMP22 in their urine however this level is often elevated in people with transitional cell bladder cancer. Elevated levels of NMP22 are detectable even at early stages of the disease, making it an ideal marker for early diagnosis.
The NMP22 BladderChek Test and NMP22 Test EIA provide clinicians with the tools for an effective at-risk group screening and monitoring program in conjunction with cystoscopy. Not dependent on intact cells like cytology and with no interference from the presence of blood in the sample up to 100mg/dL, NMP22 is ideal for initial assessment of early stage bladder cancer.

When used as an adjunctive diagnostic tool over cytology, NMP22 BladderChek Test provides four-times the sensitivity of cytology at half the cost.

### NMP22 BladderChek Test
The NMP22 BladderCheck Test uses a lateral flow immunochromatographic strip to detect NMP22 in urine samples. The cartridge format is not only easy-to-use but clean with a large sample well. Requiring only four drops of urine, the test can be performed in a physician’s office with results delivered in just 30 minutes, allowing a rapid, accurate and cost-effective way to aid the detection of bladder cancer in at-risk patients.

### NMP22 Test EIA
The NMP22 test is also available as a quantitative microplate enzyme immunoassay, the NMP22 Test EIA.

### Features and Benefits
- **Results in 30 minutes**
- **Non invasive and painless**
- **Easy-to-use**
- **Can detect cancers in the upper urinary tract**
- **No interference with haematuria (up to 100mg/dL)**
- **Improves the sensitivity of cystoscopy**
- **FDA approved tumour marker**

### NMP22 BladderChek Test Features and Benefits
- **Positive NMP22, Positive Cystoscopy**: Increased risk of invasive cancer or CIS
- **Negative NMP22, Positive Cystoscopy**: More likely to be superficial cancer
- **Positive NMP22, Negative Cystoscopy**: Increased risk of upper tract cancer
- **Negative NMP22, Negative Cystoscopy**: 97% negative predictive value gives greater confidence in negative diagnosis

### Imaging
- **Ultrasound**
  - To detect renal tumours and calculi

### Cystoscopy
- **Cystoscopy**: All patients will undergo cystoscopy regardless of initial investigation results

### Results in a glance

### Urine Tests
- **Dipstick Test**
  - Performed before the NMP22 test to detect urinary tract infections such as cystitis and calculi. These require treatment first to avoid false positive results.

- **NMP22 BladderCheck Test**
  - To detect the bladder tumour marker NMP22
    - Void urine sample collected in plastic cup
    - Fresh test opened and four drops of urine placed into sample well
    - Avoid air bubbles
    - Test sample within 2 hours of collection
    - Read results 30-50 minutes later

  - **Positive**
    - The test line can be very faint
    - The control line must be present for valid result
    - Any smeared or incomplete line is an invalid result

  - **Negative**
    - The control line must be present for valid result

- **NMP22 Test EIA**
  - The quantitative microplate enzyme immunoassay, the NMP22 Test EIA.

- **Positive NMP22**
  - Increased risk of invasive cancer or CIS

- **Negative NMP22**
  - More likely to be superficial cancer

- **Positive NMP22, Negative Cystoscopy**: Increased risk of upper tract cancer
- **Negative NMP22, Negative Cystoscopy**: 97% negative predictive value gives greater confidence in negative diagnosis
Specifications

NMP22® BladderChek® Test

- Method: Lateral flow
- Time to result: 30 mins
- Storage: 2-30°C
- Shelf life: 12 months
- Sensitivity up to: 85% 6-11
- Specificity up to: 95% 6-11
- Sample type: Voided urine
- Kit size: 24 tests
- Product Code: D1200

NMP22® Test EIA

- Method: ELISA
- Storage: 2-8°C
- Shelf life: 14 months
- Sensitivity up to: 85% 6-11
- Specificity up to: 95% 6-11
- Sample type: Voided urine
- Kit size: 96 well plates
- Product Code: D1100

References

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