

Bladder Cancer - a neglected and serious disease

NMP22® BladderChek® Test



Bladder cancer can be present for many years without causing any symptoms. The NMP22® BladderChek® test is ideal for the early diagnosis and monitoring of bladder cancer, and offers the possibility for screening in defined high risk groups.

Up to 30% of the patients present at initial diagnosis with muscle invasive cancer, which dramatically reduces the 5 year survival rate for the patient as compared to those with superficial tumors. The early diagnosis is key for

better survival and allows effective local treatment as well as optimizing the success of surgical therapy.

NMP22 improving the early and rapid detection of bladder cancer

Risk groups for Bladder Cancer should be screened regularly with NMP22 and standard diagnostic procedures to detect the tumor in an early and more curable stage.

Who is at risk for Bladder Cancer?

- Patients with Hematuria.
- Smokers.
- People working with aromatic amines, dyes, tar, petrol, diesel fuel, paint.
- Occupational groups such as firemen, chemical workers,

roofers, painters, chimney sweeps, truck drivers, tanners and roadmen.

- Bladder cancer can develop in patients having had radiation therapy in the lower pelvis.

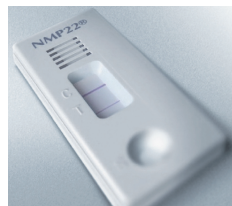
How to perform the NMP22 BladderChek Test:



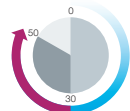
1. Collect a freshly voided urine sample into a cup. Then using the enclosed pipette transfer the sample to the sample well as soon as possible. N.B. Sample must be kept at room temperature. Do not refrigerate or freeze.

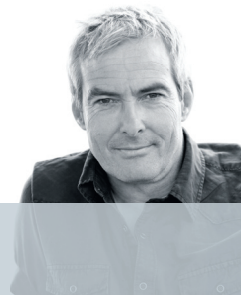


2. Add 4 full drops of urine sample into the well marked "S" on the test cassette.



3. Results may be read after only 30 minutes (but no later than 50 minutes). Even a very faint line in the test line marked "T" is considered positive.





Important hints - a checklist for the NMP22 BladderChek Test

All diagnostic procedures have their limitations and to ensure optimal performance of any test it is important to select suitable patient groups and to follow the correct test procedures.

Therefore, it is important to know:

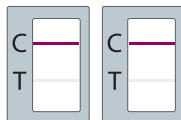
- the correct handling of pre-analytical procedures;
- the causes of interference and their potential to give false results.

Applying defined exclusion criteria, shown below, increases the tests specificity and positive predictive value thus enhancing its clinical use.

Exclusion criteria:

- Acute urinary tract infection, (UTI) inflammation, cystitis (treat & cure first).
- Renal calculi.
- Patients with a permanent catheter.
- Neobladder, Ileum-Conduits and using urine from bladder wash.
- The NMP22 test should not be performed any earlier than 14 days after any invasive procedure in the urinary tract.
- Intra-vesicle Chemo - or BCG therapy (wait 3 months for the first control cystoscopy).
- Radiation therapy.

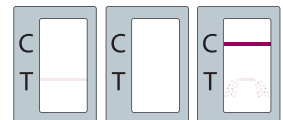
The Results



Positive Result



Negative Result



Invalid Result

Urine Collection Procedure:

- Urine needs to be collected in a plastic cup – no glass.
- Perform a urine dipstick test prior to the NMP22 testing, to look for UTI, calculi and inflammation.
- Use only fresh urine, no older than 2 hours - frozen or stabilized urine cannot be used.
- Ensure the urine has been in the bladder long enough for the NMP22 to be released from the cells.

When performing the NMP22 Test ensure:

- The test cassette is at room temperature and stays horizontal during the test run.
- The fresh urine sample is tested as soon as possible.
- Verify that 4 full drops of urine are used.
- Read the result within 30-50 minutes.

Reading the NMP22 test result:

Generally NMP22 is not present in large concentration in the nuclei of cells. *A very faint, weak test line is considered positive too*, reflecting concentration close to the cut-off.

