



NMP22™ BLADDERCHEK™ TEST

Ideal for early diagnosis and monitoring of bladder cancer with standard diagnostic procedures. It offers the possibility for early diagnosis in defined high risk groups.



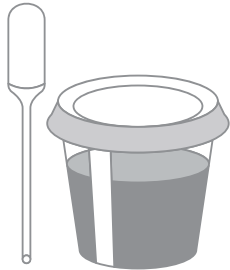
NMP22 improving the early and rapid detection of bladder cancer. Risk groups^{1,2,3} for bladder cancer should be tested regularly with NMP22 and standard diagnostic procedures to detect the tumor in an early and more curable stage.



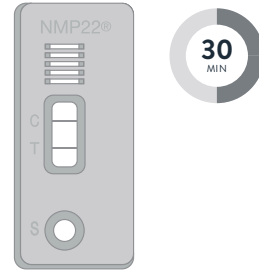
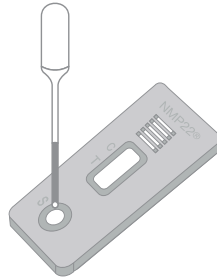
NMP22™ BladderChek™ Test

EASY TO USE

- 1 Collect a freshly voided urine sample into a plastic cup. Then fill the enclosed dropper with the patient's urine sample. 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 at 30 minutes (but no later than 50 minutes). Check the procedural Control (C) zone. A line must appear for the test to be valid. Carefully observe the Test (T) zone of the device. ANY complete line in the Test (T) zone is a POSITIVE result when a Control (C) line is present. Even a very faint line in the test line marked "T" is considered positive.



See the Product Insert for the complete assay procedure.



URINE COLLECTION PROCEDURE

Urine needs to be collected in a plastic cup – no glass.

Use only fresh urine, no older than 2 hours – frozen or stabilized urine cannot be used.

PERFORMING TEST

When performing the NMP22™ BladderChek™ 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.

EXCLUSION CRITERIA

Test should not be used on individuals with indwelling urinary tract devices (such as stents) or who have had a total cystectomy.

Intra-vesicle Chemo – or BCG therapy (wait 3 months for the first control cystoscopy).

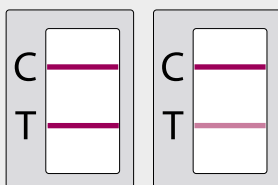
Renal calculi.

Patients with permanent catheter.

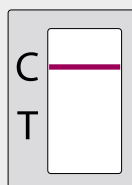
Neobladder, Ileum-Conduits and using urine from bladder wash.

Allow ample time for trauma recovery; the NMP22™ BladderChek™ Test should not be performed immediately after any invasive procedure in the urinary tract.

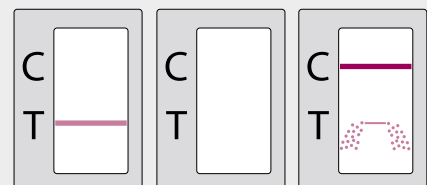
Radiation therapy.



POSITIVE RESULT



NEGATIVE RESULT



INVALID RESULT

FOR MORE INFORMATION VISIT GLOBALPOINTOF CARE.ABBOTT

EAU-Guidelines on Bladder Cancer Muscle-invasive and Metastatic A. Stenzl (chairman), J.A. Witjes (vice-chairman), E. Compérat, N.C. Cowan, M. De Santis, M. Kuczyk, T.Lebret, M.J. Ribal, A. Sherif European Association of Urology 2012

JAMA. 2005 Feb 16;293(7):810-6. Detection of bladder cancer using a point-of-care proteomic assay. Grossman HB, Messing E, Soloway M, Tomera K, Katz G, Berger Y, Shen Y. Source Department of Urology, M.D. Anderson Cancer Center, Houston, Tex 77030, USA.

Cancer. 2006 Sep 1;107(5):982-90. Should we screen for bladder cancer in a high-risk population?: A cost per life-year saved analysis. Lotan Y, Svatek RS, Sagalowsky AI. Source Department of Urology, University of Texas Southwestern Medical Center, Dallas, Texas 75390-9110, USA.