



**Matritech**

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### Product Information

NMP22<sup>®</sup> BladderChek<sup>®</sup> Control Kit  
Manufactured by Binax Inc.  
Scarborough, ME 04074 USA  
Phone: 321.441.7200, 877.444.7440  
Fax: 321.441.7440, 877.441.7441  
Catalog Number: D1250

### Intended Use

The Matritech NMP22<sup>®</sup> BladderChek<sup>®</sup> Control Kit is designed to provide the users of the Matritech NMP22 BladderChek Test with additional, optional, quality controls for operating the Test.

### Summary and Explanation

The NMP22 BladderChek Control Kit consists of a Negative and a Positive Control solution for use as an external control for the NMP22 BladderChek Test. External controls test for the functional reactivity of the capture and gold conjugated monoclonal antibodies in the test device. The NMP22 BladderChek Test Controls will not detect an error in the patient testing procedure.

The Positive Control solution ensures that NMP22 BladderChek devices will produce a visible line in the Test (T) window when testing patient samples containing concentrations of nuclear matrix proteins at or above the NMP22 BladderChek Test limit of detection. The Negative Control solution ensures that the NMP22 BladderChek devices produce negative results when testing patient samples containing concentrations of nuclear matrix proteins below the NMP22 BladderChek Test limit of detection. Refer to the NMP22 BladderChek Test package insert for additional information.

### Contraindications

- Do not use beyond the printed expiration date.
- Do not use if the vial or seal is damaged or opened.

### Warnings and Precautions

- For *in vitro* diagnostic use only.
- To avoid cross-contamination of controls, use a new dropper (not provided) for each control.
- Refer to local regulations for the disposal of medical waste when disposing of any remaining kit components.
- Prior to opening the NMP22 BladderChek Test Controls, inspect the vials for cracks, chips, or broken seals. Should you encounter any such damage to the packaging, DO NOT USE THE DEVICE.

### Devices and Reagents

#### MATERIALS PROVIDED IN KIT

#### NMP22 Bi-Level Controls 2 x 6 mL (lyophilized)

Contains NMP22 marker in a synthetic human urine solution containing human albumin, bovine proteins, and Fungizone<sup>™</sup> and gentamicin as preservatives.

Red-labeled Control: Negative Control  
Green-labeled Control: Positive Control

#### REAGENTS REQUIRED BUT NOT PROVIDED

- Matritech NMP22 BladderChek Test, catalogue number D1200

#### MATERIALS NOT PROVIDED

- Droppers to add water to the specified fill line (approximately 6 mL)

### Storage and Stability

- The **unopened** Matritech NMP22 BladderChek Test Control Kits are stable at 2-8°C until the printed expiration date. Do not freeze.
- The reconstituted Controls are stable for 48 hours at room temperature (18-25°C) or for 72 hours refrigerated at 2-8°C.

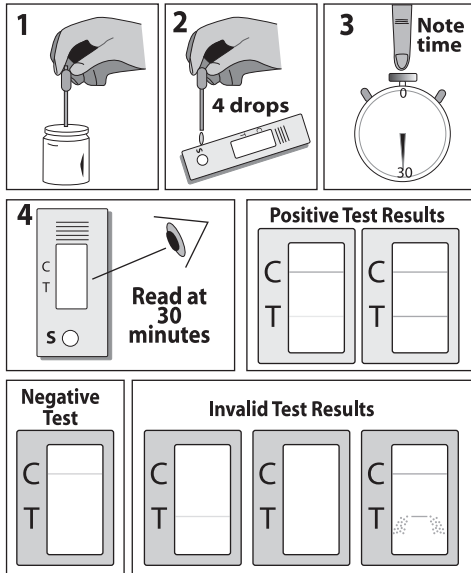
### Control Preparation

- Allow the Controls to equilibrate to room temperature (18-25°C) for 15 to 20 minutes before use.
- Reconstitute each Control by adding distilled or deionized water to the fill line specified on the label (approximately 6 mL). Recap and let stand at room temperature (18-25°C) for approximately 10 minutes. Invert and swirl gently to mix, do not vortex. Let stand an additional 10 minutes before use. Be sure the lyophilized material is completely dissolved before use.

### Assay Procedure

1. Obtain two (2) NMP22 BladderChek Test devices. Open the pouches.
2. Label one device "Negative", and the other "Positive".
3. Follow the directions outlined in the NMP22 BladderChek Test Package Insert, using the reconstituted Controls in place of the patient urine.
4. Add 4 FULL drops (without air bubbles) of the reconstituted Negative Control to the sample (S) well of the "Negative"-labeled device.
5. With a new dropper, add 4 FULL drops (without air bubbles) of the reconstituted Positive Control to the sample (S) well of the "Positive"-labeled device.
6. Read the test results at 30 minutes, but NO LATER THAN 50 minutes. Test results are not valid if read later than 50 minutes. Read the results as shown under "Interpretation of Results."
7. Discard used dropper and test device in a proper biohazard container.

## Interpretation of Results



1. Check the procedural Control (C) window. A line must appear for the test to be valid.
2. Positive Result: Carefully observe the Test (T) area of the device. **ANY complete** line in the Test (T) area is a POSITIVE result when a Control (C) line is present. Neither the intensity nor the color of the Test (T) line should be compared to that of the line in the procedural Control (C) area.
3. Negative Result: Carefully observe the Test (T) area of the device. The absence of any colored line in the Test (T) area is a NEGATIVE result if a Control (C) line is present.
4. Invalid Result: If no line appears in the procedural Control (C) area, or if the Test (T) line is smeared or incomplete, the test is INVALID and must be repeated with a new device. The most common reason for an invalid result is failure to add exactly 4 FULL drops, without air bubbles, of urine to the sample well.

## Quality Control

Good laboratory practices recommend the use of appropriate controls. There is an internal procedural control for the NMP22 BladderChek Test.

## Procedural Control

The procedural Control is found in the Control (C) zone of the test device. This control assures the operator that (1) sample addition and migration through the device has occurred, and that (2) the control goat anti-mouse antibody and the colloidal gold conjugated reporter monoclonal antibody are intact and functional. This control does not ensure that the Test (T) zone is accurately detecting the presence or absence of antigen in the sample.

## Expected Results

The Positive Control should produce a line in the Test (T) window of the NMP22 BladderChek Test device.

The Negative Control should not produce a line in the Test (T) window of the NMP22 BladderChek Test device.

If the Controls do not perform as expected, repeat the test or contact Inverness Medical Technical Service at 877-441-7440.