Alere™ Toxicology

DIAGNOSTIK NORD
IHR PARTNER FÜR IN VITRO DIAGNOSTIKA

# BT-K10

## BT Check

For professional use only

## » INTENDED USE

The One Step BT-Check® Bladder Tumor rapid test is a simple one step immuno-chromatographic assay for the rapid, detection of Bladder Cancer Marker (factor H related protein and hemoglobine) in urine. For professional use only

## » SUMMARY

Of all types of cancer, bladder cancer has an unusually high propensity for recurring after treatment. Bladder cancer has a recurrence rate of 50%-80%. The recurring cancer is usually, but not always, of the same type as the first (primary) cancer. It may be in the bladder or in another part of the urinary tract (kidneys or ureters). Bladder cancer is most common in industrialized countries. Bladder cancer affects three times as many men as women. Women, however, often have more advanced tumors than men at the time of diagnosis. Bladder cancer can occur at any age, but it is most common in people older than 50 years of age. The average age at the time of diagnosis is in the 60s. However, it clearly appears to be a disease of aging, with people in their 80s and 90s developing bladder cancer as well. Because of its high recurrence rate and the need for lifelong surveillance, bladder cancer is a highly expensive cancer to treat on a per patient basis. Risk Factors for bladder cancer are smoking, chemical exposures especially organic chemicals as aromatic amines, fried meats and animal fats. In addition: seniors are at the highest risk of developing bladder cancer, men are more likely than women to have bladder cancer, whites have a much higher risk of developing bladder cancer than other races and people with chronic bladder inflammation (frequent bladder infections, bladder stones, and other urinary tract problems) are at higher risk.

## » PRINCIPLE

The One Step BT-Check® Bladder Tumor rapid test employs a unique combination of monoclonal and polyclonal antibodies to selectively identify in test samples with a high degree of sensitivity. The targeted bladder cancer marker for the BCM test is the human factor H related protein, a well recognized marker for bladder cancer. The test sensitivity varies between 42.5% to 97.1 % depending on the stages and grades of the bladder tumor.

## » STORAGE AND STABILITY

The one step BCM combo test kit should be stored at room temperature or 2-30°C (35.6-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

## » WARNINGS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Clean up spills thoroughly using an appropriate disinfectant.
5. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
6. Do not use the test kit if the pouch is damaged or the seal is broken.

## » SPECIMEN PREPARATION

1. Specimen collection should not be performed during or within three days of a menstrual period for female, and if a positive result is obtained with a subject who is on aspirin, the test should be repeated after aspirin has been stopped for 7 days.

## » SPECIMEN COLLECTION

1. Only urine specimens should be used in this assay. Specimen should avoid contamination of toilet water.
2. Specimens collected, if not tested the same day, can be refrigerated and stored at 4 to 8 °C for testing up to 3 days after collection.

## » MATERIALS PROVIDED

The BT-Check® Bladder Tumor rapid test kit contains the following items to perform the test:

1. 10 BT-Check® Test Cassette
2. 10 Sample Dropper (1 within each pouch)
3. Instruction

## » MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer

## » PROCEDURE OF THE TEST

1. Remove the test panel from the foil pouch, and place it on a flat, dry surface.
2. If the specimen is refrigerated, then bring it to room temperature.
3. Transfer 2 to 3 drops of urine to each well of the test (Figure 1)
4. As the test panel begins to work, you will see purple color move across the respective Result Window in the center of the Test Panel.
5. Interpret test results at 9 minutes. Do not interpret test results after 10 minutes.

**Caution:** The above interpreting time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpreting time should be properly increased.

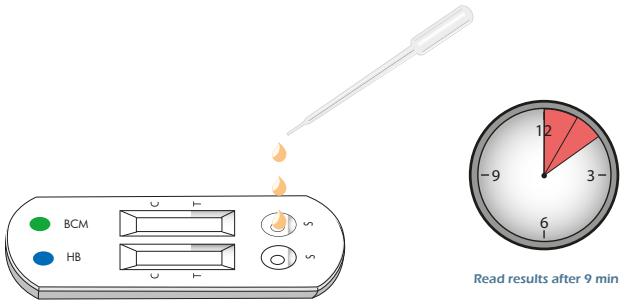
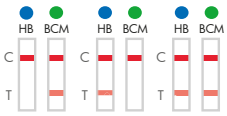



Fig. 1

## » INTERPRETATION OF THE TEST

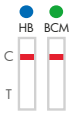
1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. A color band will appear at the test line "T" of the HB section (indicated by letters of "HB") section of the result window when hemoglobin level in a sample is 250 ng/ml or higher.
3. A color band will appear at the test line "T" of the Bladder Cancer Marker section (indicated by letter "BCM") section of the result window when BCM is detected in the urine. The absolute sensitivity could be determined at 100 ng/ml (distict visible T-Line) but to trained professional a T-Line might already be visible at concentrations of 25ng/ml.

**POSITIVE**



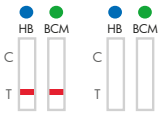

**If the "C" color band along with either or both visible test lines "T" of the HB and BCM sections** (no matter which band appears first) is present, then it indicates a positive result.

**NEGATIVE**




**If only the "C" color band within the result windows in both the HB and BCM sections is present, then it indicates a negative result.**

**INVALID**




**If after performing the test no color band or no "C" color band is visible within the result window, then the test is considered invalid.** The directions may not have been followed correctly or the test may have deteriorated. It is recommended to re-test the specimen.

**Note:** Once a positive result has been established (at 9 minutes), the result will not change. However, in order to prevent any incorrect results, the test result should not be interpreted after 10 minutes.

## » INTERPRETATION OF RESULT

1. A positive result in both HB and BCM indicates a likelihood of Bladder Cancer, however requires further confirmation.

2. A positive result in HB, other common causes of blood in urine need to be ruled out, such as bleeding from stones or enlarged prostate, and the subject need to be followed up with repeated testing.

3. Negative results do not exclude bladder cancer. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## » PERFORMANCE CHARACTERISTICS

**Clinical Study:**

A comparison study was performed with cytology (gold-standard, biopsy confirmed): A total of 225 patients with biopsy confirmed bladder cancer took part in this study, of the 225 patients, stages were determined on 223, and grades are determined on 210 patients. The age range of these 225 individuals was from 63 to 81 years, 86% were male. The collected specimens were tested with BT-check® rapid test and compared with cytology performed on the patient. A positive line from either hemoglobine (HB) or bladder cancer marker (BCM) on the BT-check® rapid test is considered as positive specimen. Of the 225 patients, a total of 37 never had bladder cancer previously. Of these 37 patients, none were stage 1, 11 were stage 2, and 26 were stage 3. BCM were positive on 24 of this group of 37 patients. Thus gives a sensitivity rate of 64.8%. All comparison studies were conducted blindly, i.e. the laboratory technician did not know which samples were hb/BCM positive or negative before testing.

Summarized relative sensitivities of the BT-check® rapid test in comparison with cytology test (n=225):

| Stage | n | Sensitivity (BCM) | n-Positive (BCM) | Sensitivity (BCM und HB) | n-Positive (BCM und HB) |
|---|---|---|---|---|---|
| Ta | 14 | 57% | 8 | 57% | 8 |
| T1 | 69 | 82,6% | 57 | 85,5% | 59 |
| T2, T3 | 140 | 86,4% | 121 | 94,2% | 132 |
| Total | 223 | 83,4% | 186 | 89,2% | 199 |
| Grade | N | | | | |
| 1 | 47 | 38,2% | 18 | 42,5% | 20 |
| 2 | 61 | 63,9% | 39 | 70,5% | 43 |
| 3 | 102 | 89,2% | 91 | 97,1% | 99 |
| | 210 | 70,5% | 148 | 77% | 162 |

**Relative Sensitivity:** The BT-ckeck® rapid test had an overall sensitivity varying from 77% to 89.2% (see above table , the test sensitivity range is between 42.5% to 97.1% depending on the stages and grades of the bladder tumor) . Of the subgroup who never had bladder cancer previously, the relative sensitivity is 64.8%.

To obtain clinical specificity data, urine from 38 healthy individuals with no known bladder tumors were tested:

| N | True Negative |
|---|---|
| BT-ckeck® rapid test positive | 4 |
| BT-ckeck® rapid test negative | 34 |
| Gesamt | 38 |

**Relative Specificity:** The BT-ckeck® rapid test had an overall Specificity of 89.5% (34/38)

## » INTERFERENCE AND CROSS-REACTIVITY

The following substances at the specified concentrations have not shown to interfere with the BT-ckeck® rapid test. Acetamiophen, 20 mg/dl; Acetyl salicylic Acid, 20 mg/dl; Ascorbic Acid, 20 mg/dl; Atropine, 20 mg/dl; Bilirubin, 60 mg/dl; Caffeine, 20 mg/dl; Creatinine, 20 mg/dl; Gentesic Acid, 20 mg/dl; Glucose, 2000 mg/dl; Hemoglobin, 500 mg/dl; Ketones, 40 mg/dl; Mestranol, 3 mg/dl; Nitrite, 20 mg/dl; Penicillin, 40,000 U/dl; Sodium Heparin, 3 mg/dl; Lithium Heparin, 3 mg/dl, LDL, 200 mg/dL, Triglyceride, 150 mg/dL.
The following organisms have not shown to interfere with the BT-ckeck® rapid test. Acinetobacter calcoaceticus, Proteus vulgaris, Salmonella typhi, Acinetobacter spp Staphylococcus aureus, Candida albicans Neisseria gonorrhae, Escherichia coli, Neisseria catarrhalis, Gardnerella vaginalis, Neisseria meningitidis, Streptococcus faecalis, Neisseria lactamica, Streptococcus faecium, Pseudomonas aeruginosa, Trichomonas vaginalis.

## » REFERENCES


*1) Badrinath R. Konety and Robert H. Getzenberg: Urine based markers of urological malignancy. The Journal of Urology, Vol. 165, 600-611, Feb, 2001*

*2) M-P Raitanen, E Kaasinen, E Rintala, E Hansson, P Nieminen, R Aine, TLJ Tammela1 and The Finn Bladder Group*: Prognostic utility of human complement factor H related protein test. British Journal of Cancer (2001) 85(4), 552–556*


## » SYMBOLS

| | |
|---|---|
| CE | Content |
| IVD For in-vitro diagnostic use only | LOT Lot number |
| For single use only | Expiry date |
| Carefully read package insert | Store at room temperature |

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## » PRODUCER


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