NADAL® BCA/HB Bladder Cancer – test

(test cassette)

Rapid Test for the Detection of Bladder Cancer Marker (hCFHrp) and Hemoglobin (HB) in Human Urine

Single Test Cassettes, separately sealed **Art. N° 562003**

INTENDED USE

The One Step NADAL® BCA/HB (Bladder Cancer Marker) combo test is a simple one step immuno-chromatographic assay for the rapid detection of Bladder Cancer Marker in urine.

PRINCIPLE

The One Step NADAL® BCA/HB combo 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 protein, a well recognized marker for bladder cancer. The test sensitivity for between 56% to 91% depending on the stages and grades of the bladder tumor.

STORAGE AND STABILITY

The one step NADAL® BCA/HB combo test kit should be stored at room temperature or 2°-30°C (35.6-86oF). The test device is sensitive to humidity and 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

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 are 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.

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 the each well of the bladder (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.

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 "BCA") section of the result window when BCM is detected in the urine.

Positive Result: If presence of the "C" color band along with either or both visible test lines "T" of the HB and BCA sections (no matter which band appears first), then it indicates a positive result. (Figures, 2, 3 and 4)

Negative Result: If presence of only the "C" color band within the result windows in both the HB and BCA sections, then it indicates a negative result. (Figure 5)

Invalid Result: 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 that the specimen be re-tested. (Figures 6 and 7)

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.

Figure 1

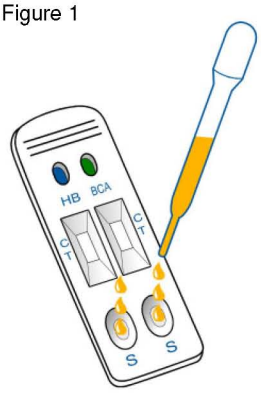


Figure 2

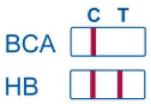


Figure 3

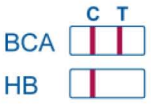


Figure 4

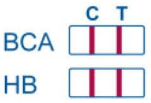


Figure 5

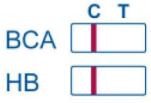


Figure 6

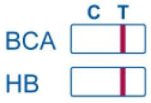
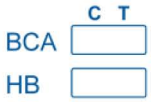


Figure 7



INTERPRETATION OF RESULT

1. A positive in both HB and BCA indicate a likelihood of Bladder Cancer, however requires further confirmation.
2. A positive 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.

CLINICAL STUDY

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.

Stage	N	Sensitivity (BCA only)	Sensitivity (BCA and HB)
Ta	14	57 %	57 %
T1	69	82,6 %	85,5 %
T2, T3	140	86,4 %	94,2 %
Grade	N		
G1	47	38,2 %	42,5 %
G2	61	63,9 %	70,5 %
G 3	102	89,2 %	97,1 %

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

GRAPHICAL SYMBOLS USED

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
REF	Catalogue number	CONT.	Contents
	Read instruction before use		Manufacturer

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