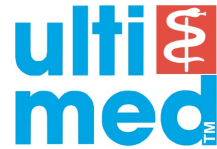


BCM - Test Cassette

004A215



ulti med BCM Combo test Bladder Cancer Marker and Haemoglobin in urine



Intended Use

The ulti med BCM (**B**ladder **C**ancer **M**arker) combo test is a simple one step immuno-chromatographic assay for the rapid, detection of Bladder Cancer Marker in urine (detection of hCFHrp: Human Complement Factor H-related protein). The test sensitivity of between 57% to 97% depends on the stadium and grade of the bladder tumour. In this combo test also haemoglobin (HB) is determined with a cut-off of 250 ng/ml.

Principle

The One Step BCM combo test employs a unique combination of monoclonal and polyclonal antibodies to selectively identify in test samples with a high degree of sensitivity.

Storage and Stability

The one step BCM combo test kit should be stored at room temperature or 2-30°C. 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

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 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

- Only urine specimens should be used in this assay. Specimen should avoid contamination of toilet water.
- Use fresh urine which preferably had had a retention period as long as possible.
- 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 cassette 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 colour move across the respective Result Window in the center of the test cassette.
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.

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Interpretation of the Test

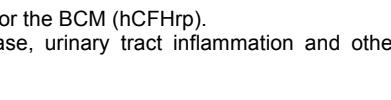
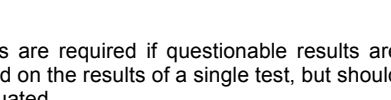
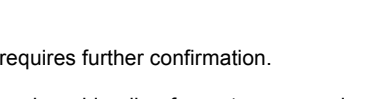
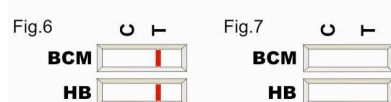
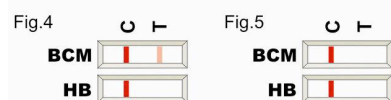
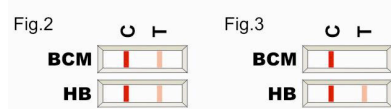
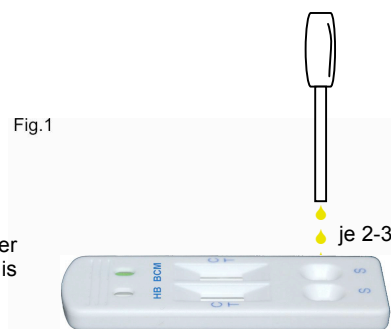
1. A coloured line will appear at the left section of the result window to show that the test is working properly. This line is the control line.
2. A coloured line will appear at the test line "T" of the HB section (indicated by letters of "HB") section of the result window when hemoglobin level in a sample is 250 ng/ml or higher.
3. A coloured line 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.

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

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

Invalid Result: If after performing the test no coloured line or no "C" coloured line 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 10 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:

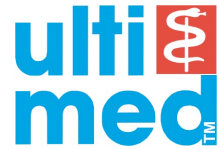
1. A positive in both HB and BCM indicate a likelihood of Bladder Cancer, however requires further confirmation.
2. A positive in HB, other common causes of blood in urine need to be ruled out, such as bleeding from stones or enlarged prostate, and the subject need to be followed up with repeated testing.
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.
4. Other diseases (benign), than bladder cancer may lead to false positive results for the BCM (hCFHrp). For example, recent genitourinary trauma (including cystoscopy), stone disease, urinary tract inflammation and other genitourinary malignancies.¹⁾

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. The test sensitivity for between 56% to 91% depending on the stages and grades of the bladder tumor.


Stadium	<n> patients	Sensitivity (BCM only)	Sensitivity (BCM and HB)
Ta	14	57%	57%
T1	69	82.6%	85.5%
T2, T3	140	86.4%	94.2%
Grade	<n> patients		
1	47	38.2%	42.5%
2	61	63.9%	70.5%
3	102	89.2%	97.1%

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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
- 3) Iman A.Abd el Gawad, M.D., Heba S.Moussa, M.D., Maha I. Nasr, M.D.: Comparative Study of NMP-22, Telomerase, and BTA in The Detection of Bladder Cancer. Journal of the Egyptian Nat. Cancer Inst., Vol. 17, No. 3, September: 193-202, 2005

 Manufacturer	 Contents sufficient for <n> tests
 For in vitro diagnostic use only	 Lot. no.
 For single use only	 Expiration date
 Read instructions for use	 Store at



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