

Status BTA

A Rapid Test For the Qualitative Detection of Bladder Tumor Associated Antigen in Human Urine of Patients Diagnosed with Bladder Cancer



- Indicated for use as an aid in the monitoring of bladder cancer patients in conjunction with cystoscopy²
- **CLIA Waived**
- Results in 5 minutes
- Simple procedure requires adding 3 drops of urine to test device; no sample preparation needed
- Accurate test results with superior sensitivity and specificity
- Detects early stage recurrence cancer that cytology¹ may miss

CPT CODE
86294QW

1: Cytology: a branch of pathology; the medical specialty that deals with making diagnoses of diseases and conditions through the examination of tissue or body fluid (blood, urine, etc) samples. In order for cytology examination to be carried out, the material to be examined is placed onto glass slides and stained. A physician then uses a microscope to examine the individual cells in the sample.

2: Cystoscopy: A procedure in which a lighted optical instrument called a cystoscope is inserted through the urethra to look at the bladder. A physician may perform a cystoscopy to explore the cause of many urinary conditions.

Procedure

1 Bring test materials and patient urine sample to room temperature (17 - 37°C, 63 - 99°F). Gently swirl to mix patient's urine sample.

2 Remove the test device and transfer pipette from foil package. Throw away small desiccant pouch. Place the device on a clean, well-lit, flat surface and label with the patient's identification.

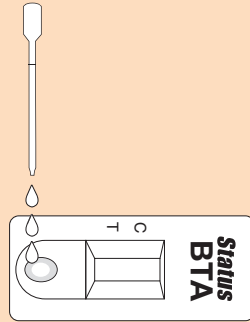
3 Fill the transfer pipette provided with the patient's urine sample and hold it upright above the sample well as shown.

4 Allow 3 FULL drops (without air bubbles) to fall into the sample well. Start timer.

5 When timer reaches 5 minutes, read results within 1 minute. Read results as shown under "Interpretation of Results."

Read at 5 minutes but NO LATER THAN 6 MINUTES. Test result is not valid if read after 6 minutes.

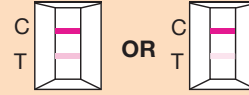
6 Discard used transfer pipette and test device in a proper biohazard container.



Interpretation of Results

1) Check the Control Position (C). A pink or reddish-brown line must appear for the test to be valid.

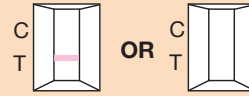
2) **Positive Result:** Carefully look at Test Position (T). ANY pink or reddish-brown colored line, **NO MATTER HOW FAINT**, in the Test Position (T) is a positive result. Neither the intensity nor the color should be compared to that seen in the Control Position (C).



3) **Negative Result:** Carefully look at Test Position (T). No colored line in the Test Position (T) is a negative result.



4) **Invalid Test Result:** If no line appears in the procedural Control Position (C), the test is invalid and must be repeated with a new device. The most common reason for an invalid test result is failure to add exactly 3 FULL drops.



Tumor markers are substances found in the blood, urine, stool, other body fluids, or tissues of some cancer patients. Tumor markers may be used to help diagnose cancer, predict a patient's response to certain cancer therapies, check a patient's response to treatment, or determine whether cancer has returned³. Because tumor markers can be used to assess the response of a tumor to treatment and for prognosis, rapid screening tests like the Status BTA product are very helpful in the treatment management of cancer patients.

The Status BTA test is an in vitro immunoassay intended for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer. The test is indicated for use as an aid in the management of bladder cancer patients in conjunction with cystoscopy. The simple urine sample collection also allows for improved patient comfort. Patients with previous diagnosis of bladder cancer have been routinely followed for recurrence by urine cytology and cystoscopy but both methods have their limitations.

3: National Cancer Institute at the National Institutes of Health
www.cancer.gov

ORDERING INFORMATION

PRODUCT	# OF TESTS	ITEM #
Status BTA	25	39025
CONTROL PRODUCT	# OF TESTS	ITEM #
Status BTA Control Kit	2 x 1.0 mL	200019

For more information or to place an order, contact:



A PBM Group Company

85 Orchard Road • Skillman • New Jersey • 08558
800.526.2125 • 732.246.3366 • Fax: 732.246.0570 • www.lifesignmed.com