

Status BTA

Instructions For Home Use

LifeSign, LLC

Doctor's Name _____ **Phone Number** _____

Patient's Name _____ **Phone Number** _____

Conduct a Status BTA test on (Date) _____

Caution: U.S.A. Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory, and use is restricted to, by or on the order of a physician.

Intended Use

Status BTA is to be used only under the guidance of a doctor and only by patients who have a history of bladder cancer. Your doctor will use the information from this test along with information from visual bladder examinations (Cystoscopy) to make decisions about your medical care.

Notes And Precautions

- Read this entire brochure before starting the test.
- Do not use after the expiration date on the label. The expiration date is located on the back of the test device pouch next to the hour glass symbol (⌚). The use of an expired device could cause a wrong answer.
- Store the **Status BTA** test device at room temperature (60 - 85°F). Do not freeze or refrigerate the device or store above 85°F as this could cause a wrong answer.
- For in vitro diagnostic use only (do not eat). Keep out of reach of children.
- Collect urine only in the plastic container provided by your doctor. Do not use paper or foam cups or any other container as this could cause a wrong answer.
- Do not reuse the test device. Throw away after using once.
- Do not use a test device if the package is damaged or opened.
- Touch only the plastic part of the device. Touching any other part of the device could damage the test device or cause a wrong answer.
- Use a new dropper (provided with each device) for each test. Reusing a dropper could cause a wrong answer.
- The test has been designed to work with 3 drops of urine. The test will not work correctly unless 3 fully formed drops of urine are added to the sample well.

Collection And Storage

Collect urine in the clean plastic container provided by your doctor. Do not use any other container for urine collection. **Do not collect your first morning urine sample.** Collect urine anytime of the day after your first morning urine. Test urine as soon after collection as possible. If testing can not be performed right after sample collection, cover the sample container and store urine at room temperature (60 - 85°F) until tested. Store urine sample covered up to 2 days if necessary.

Materials Required

Materials From Home



Stopwatch, clock, or watch that measures seconds

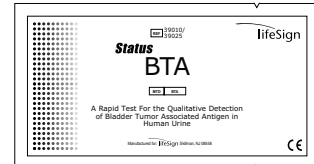


Pen or pencil

Materials From Doctor

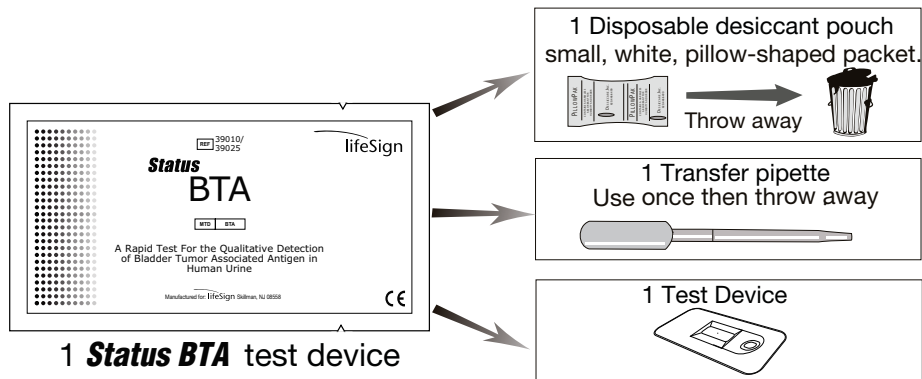


Collection cup (PLASTIC ONLY)

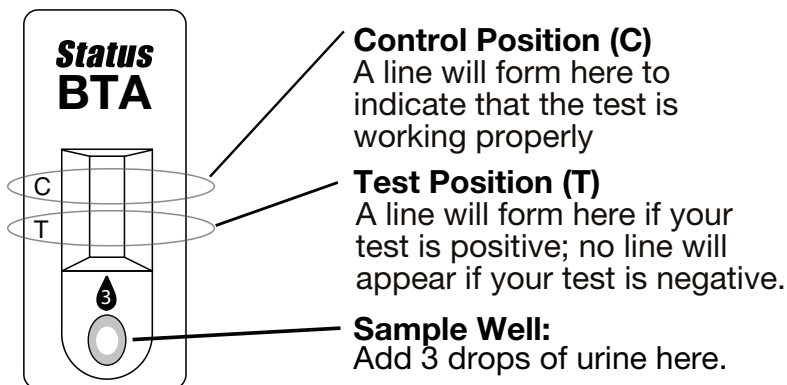


Status BTA test device

Content Of Status BTA Test Package



The Status BTA Test Device



Test Procedure

Before starting the test:

Write the lot number of the test device here.




Lot Number

The lot number is located on the back of the test device package next to the **LOT** symbol.

Write the expiration date of the test device here.



Expiration Date

The expiration date is located on the back of the test device package next to the () symbol. The expiration date is shown in year (Y) - month (M) format, YYYY-MM; 2012-10 indicates that the device may be used until the last day of October in the year 2012.

1. Collect urine sample in the cup provided by your doctor.



Date Urine Collected

Date Urine Tested

Plastic only

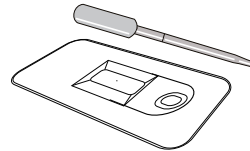


2. Open the test device package.

Remove the test device and dropper from the foil package.

Throw away the small white pillow-shaped desiccant pouch.

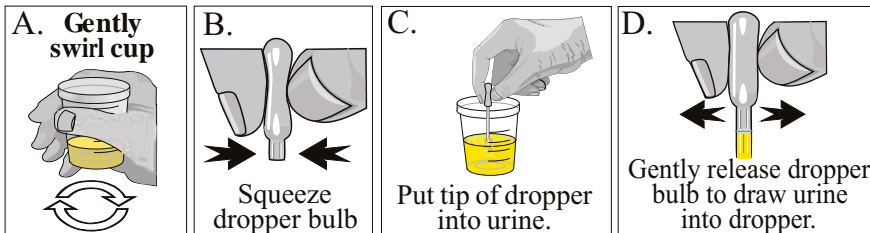
Place the device on a clean, well-lit, flat surface.



3. Prepare to time the test. Place stopwatch, clock or watch in front of you.



4. Mix the urine by **gently swirling** the sample cup. **Fill the dropper** with urine.

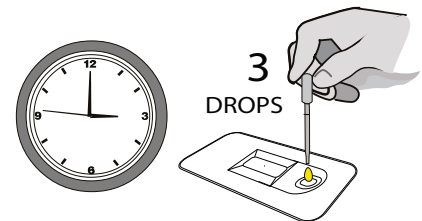


5. Hold the dropper **upright** above the sample well as shown.

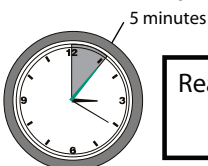
Allow **3 FULL** drops (without air bubbles) to fall into the sample well. **Dropper tip should not touch device.**

START TIMING

NOTE: The test will not work unless exactly **3 FULL** drops of urine are added to the sample well.



6. When 5 minutes have passed, read the answer within 1 more minute.

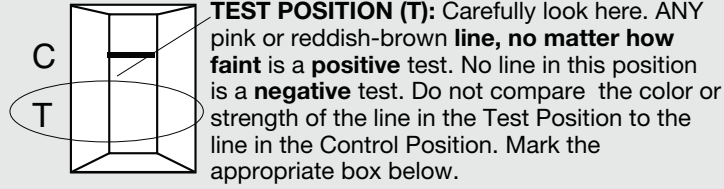


Read after 5 minutes but **NO LATER THAN 6 MINUTES.**
DONOT read after 6 minutes,
this may cause a wrong answer.

Turn the page and read about how to interpret the test result.

Interpret the Test Results

7. After 5 minutes but no later than 6 minutes, read and record the answer.



LINE

Example of a Positive Answer

C

T

NO LINE

Example of a Negative Answer

C

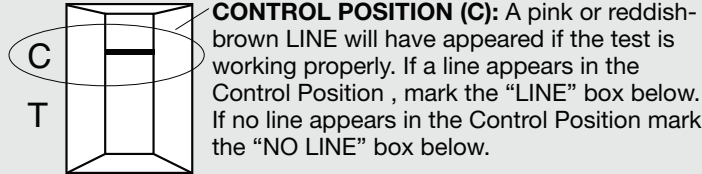
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ANSWER WAS READ AFTER 5 MINUTES BUT NOT LATER THAN 6 MINUTES:



YES

NO



LINE

NO LINE

If no line appeared in the Control Position the test did not work properly. Ask your doctor for further instructions.

Throw away used dropper and test device. Report to your doctor the information recorded:

- Lot number of test
- Expiration date of the test
- Date urine collected
- Date urine tested

- Was there a line in the test window? YES NO
- Was there a line in the control window? YES NO
- Was the test read after 5 minutes but no later than 6 minutes? YES NO

IMPORTANT: Positive results may be caused by conditions other than bladder cancer. Your doctor will consider all factors in your diagnosis. This test will not always detect bladder cancer, so continue your regular visits to your doctor.

For technical services contact Lifesign at 800-526-2125 or 732-246-3366

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