



INSTRUCTIONS FOR HOME USE

DOCTOR'S NAME _____ PHONE NUMBER _____

PATIENT'S NAME _____ PHONE NUMBER _____

CONDUCT A BTA *stat* 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

The BTA *stat* test 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.

WARNINGS 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 BTA *stat* 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.**

COLLECTING AND STORING URINE

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 YOUR DOCTOR

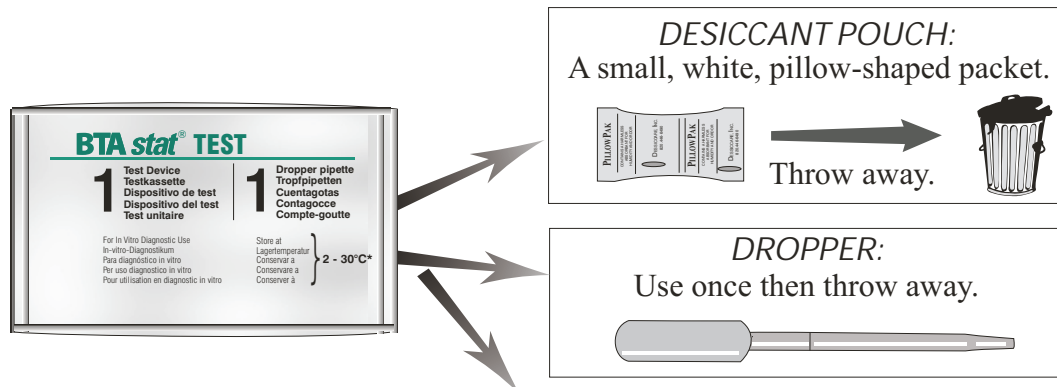


Collection cup (PLASTIC ONLY)



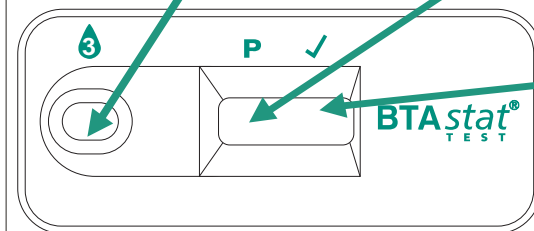
BTA *stat* Test Device

CONTENTS OF THE BTA *stat* TEST PACKAGE



THE BTA *stat* TEST DEVICE

SAMPLE WELL:
Add 3 drops of urine here.



PATIENT ZONE (P):
A line will form here if your test is positive; no line will appear if your test is negative.

CHECK ZONE (✓):
A line will form here to indicate that the test is working properly.

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.



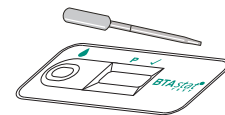
Date Urine Collected

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.



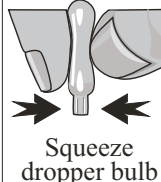
4 **Mix the urine by gently swirling** the sample cup.

Fill the dropper with urine.

A. Gently swirl cup



B.



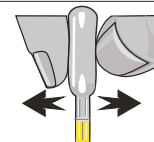
Squeeze dropper bulb

C.



Put tip of dropper into urine.

D.

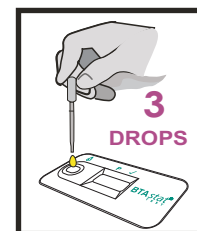


Gently release dropper bulb to draw urine into dropper.

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.

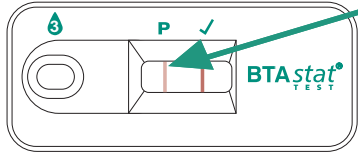


**Read after 5 minutes but NO LATER THAN 6 MINUTES.
DO NOT read after 6 minutes,
this may cause a wrong answer.**

Now turn the page and read about how to interpret the test results.

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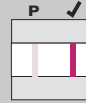
After 5 minutes but no later than 6 minutes, read and record the answer.



PATIENT ZONE (P): Carefully look here. ANY pink or reddish-brown **LINE, NO MATTER HOW FAINT** is a **positive** test. No line in this zone is a **negative** test. Do not compare the color or strength of the line in the Patient Zone to the line in the Check Zone. Mark the appropriate box below.



LINE
Example of a Positive Answer



NO LINE
Example of a Negative Answer

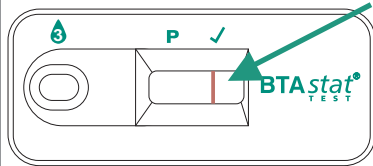


ANSWER WAS READ AFTER 5 MINUTES BUT NOT LATER THAN 6 MINUTES:



YES

NO



CHECK ZONE (✓): A pink or reddish-brown **LINE** will have appeared if the test is working properly. If a line appears in the Check Zone, mark the "LINE" box below.
If no line appears in the Check Zone mark the "NO LINE" box below.



LINE

NO LINE

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

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Throw away used dropper and test device.

Report to your doctor the information recorded on this booklet:

- Lot number of test
- Expiration date of the test
- Date urine collected
- Date urine tested
- Was there a line in the Patient window?
- Was there a line in the check window?
- Was the test read after 5 minutes but no later than 6 minutes?



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.

Manufactured for:



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510 Furnace Dock Road
Cortlandt Manor, NY 10567

To reorder or contact Technical Services:
800-431-2123 or 914-739-5400
www.polymedco.com www.btastat.com

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