BTA *stat*® Control Kit

15 Determinations - Cat. No. 661203

NTENDED USE

For use in the quality control of the BTA *stat* Test (Cat. Nos. 661230 and 661210).

UMMARY AND EXPLANATION

The BTA *stat* Test Control Kit consists of Negative and Positive Control solutions for use as external controls in the BTA *stat* Test. External controls test for the presence and reactivity of the capture and conjugated monoclonal antibodies in a test device. The BTA *stat* Test Negative and Positive Controls will not detect an error in performing the patient test procedure.

The Positive Control ensures that BTA *stat* devices will produce a visible line in the Patient (P) zone when testing patient samples containing concentrations of bladder tumor associated antigen at or above the BTA *stat* Test limit of detection. The Negative Control solution ensures that the BTA *stat* Test devices produce negative results when testing patient samples containing concentrations of bladder tumor associated antigen below the BTA *stat* Test limit of detection. Refer to the BTA *stat* Test package insert for additional information.

ONTRAINDICATIONS

- Do not use beyond the labeled expiration date.
- Do not use a Test Control Kit that is delivered damaged or that shows leakage from reagent vials.

ARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Control reagents contain 0.1% sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of control reagents, always flush with large volumes of water to prevent azide build-up.
- Treat controls and used devices as if they are potentially infectious. The BTA *stat* positive control contains material which has been purified from human sources. The source materials have been tested and found to be negative for Hepatitis B Surface Antigen (HBsAg) and antibodies to Human Immunodeficiency Virus Type 1 (HIV-1), Human Immunodeficiency Virus Type 2 (HIV-2) and Hepatitis C Virus (HCV). Since no test available can offer absolute assurance of the absence of infectious agents, handle these materials and all items coming in contact with them as potentially infectious.

OLUTIONS AND REAGENTS

- **Positive Control (+) Solution,** 2.0 mL in a dropper bottle. Human complement factor H, chromatographically purified from human sources, in a saline and Tris buffer with 2% bovine serum albumin. Contains 0.1% sodium azide as a preservative.
- **Negative Control (-) Solution,** 2.0 mL in a dropper bottle. Saline and Tris buffer with 2% bovine serum albumin. Contains 0.1% sodium azide as a preservative.

TORAGE AND HANDLING

- Store the BTA *stat* Test Control Kit at 2 - 8°C. The kit is stable when stored at these temperatures until the expiration date printed on the box label.
- Do not freeze the BTA *stat* Test Control Kit.
- Prior to use, allow a control to warm to room temperature (17 - 37°C, 63 - 99°F). Mix the control by gentle inversion for approximately 5 seconds. Do not shake.

NDICATIONS OF CONTROL DETERIORATION

The controls should be clear. They should be free of gross particulate matter. If turbidity is evident, the controls should not be used.

ONTENTS OF KITS

Cat. No. 661203

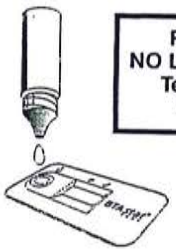
- Positive Control (+) Solution, 1 vial of 2.0 mL sufficient for 15 uses.
- Negative Control (-) Solution, 1 vial of 2.0 mL sufficient for 15 uses.
- 1 Package Insert.

ATERIALS REQUIRED BUT NOT PROVIDED

- BTA *stat* Test Kit - 30 test kit, Cat. No. 661230; 10 test kit, Cat. No. 661210
- Timer

QUALITY CONTROL TEST PROCEDURE

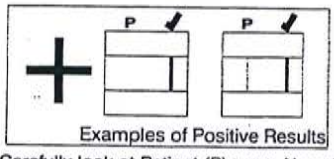
1. Follow these instructions for positive and negative control solutions. Use a separate device for each control solution.
2. Bring all materials to room temperature (17 - 37°C, 63 - 99°F).
3. Remove test device from foil pouch and place on a clean, well-lit, flat surface. Label appropriately. Set timer.
4. Hold the bottle upright above the sample well as shown. Allow 3 **FUL** 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 in "Interpretation of Results".
6. Discard used test device in a proper biohazard container.



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

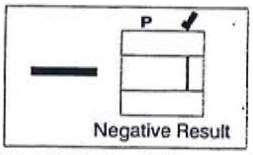
INTERPRETATION OF RESULTS

1. Check the procedural Control (✓) zone. A pink or reddish-brown line must appea for the test to be valid.
2. **Positive Result:** Carefully look at Patient (P) zone. **ANY** pink or reddish-brown colored line, **NO MATTER HOW FAINT,** in the Patient (P) zone is a positive result. Neither the intensity nor the color should be compared to that seen in the procedu Control (✓) zone.



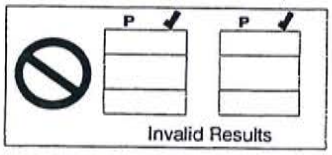
Examples of Positive Results

3. **Negative Result:** Carefully look at Patient (P) zone. No colored line in the Patient (P) zone is a negative result.



Negative Result

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



Invalid Results

EXPECTED RESULTS

The Positive Control should produce a line in the Patient (P) zone of a BTA *stat* Test device.

The Negative Control should not produce a line in the Patient (P) zone of a BTA *stat* Tes Device.

If controls do not perform as expected, do not use the test results. Repeat the test or contact Technical Service at 800-431-2123.

Manufactured by:

Polymedco Cancer Diagnostic Products, LLC
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