

BIOCARD™ TRICHOMONAS

Cat. no. 3-009-000

Test cards for rapid detection of Trichomonas antigen in vaginal swab specimens of symptomatic patients.

1. TEST PRINCIPLE

In the Biocard™ Trichomonas test, coloured latex particles are coated with antibodies against Trichomonas antigen. The reagent is dispensed as test doses and dried on the test card. The test is performed by adding one drop of diluted vaginal swab specimen onto the test latex dot. After mixing, the test card is tilted back and forth. If Trichomonas antigen is present in the sample it reacts with antibody-coated test latex particles, forming a blue agglutination that can be clearly demonstrated with the naked eye. If the sample is free of Trichomonas antigen the reaction mixture remains homogenous throughout the test. A control latex test is performed with each sample simultaneously with the test. The control latex test reveals those infrequent samples that spontaneously react with protein-coated latex particles.

2. MATERIALS PROVIDED

Biocard™ Trichomonas, 24 tests. Cat. no. 3-009-000

- 6 test cards packed individually in aluminium foil pouches. Each card contains 4 test circles with dried test latex and 4 control circles with dried control latex.
- Positive Control Reagent: 0,5 ml of diluted Trichomonas antigen.
- Specimen Dilution Buffer: 15 ml
- Sterile sample swabs 24 pcs.
- Stirrer-Pipettes: 24 pcs.
- Test tubes: 24 pcs.
- Instructions for use

Materials needed not provided

- Timer
- Scissors

3. SAMPLES

Using one sterile swab take a deep vaginal swab. Insert the swab into the test tube. Dispense about 10 drops (about 400 microliters) of Specimen Dilution Buffer into the tube so that the head of the swab is immersed in the buffer in the bottom of the test tube. Agitate the head of the swab in the buffer for 10 seconds. Finally rotate and squeeze the head of the swab against tube wall to recover as much fluid from the swab as possible. Discard the swab. The sample solution can be tested immediately or within 4 hours. Alternatively, the sample solution can be stored in a refrigerator for up to 48 hours before testing. Avoid sampling of mucus and blood. If mucous matter is in excess it will disturb the test reaction by causing a positive test and control latex reaction. The reading of the test result will become difficult if the specimen contains red blood cells in excess.

4. TEST PROCEDURE

- A. If Biocard™ Trichomonas reagents or any stored specimen eluates are stored in the refrigerator, allow them to reach room temperature. This will take from 5 to 15 minutes.
Open the Biocard™ Trichomonas test pouch by using scissors. If desired, cut the number of tests needed from test card.
- B. Mix the eluated sample thoroughly. Using disposable stirrer-pipette, pipet one free falling drop (30 microliters) of the sample eluate, first to one of the control latex dots and then to one of the test latex dots. (When pipetting, hold the pipet in a vertical position and avoid formation of bubbles on the test card.) Wait 10-20 seconds. Mix and spread the sample with the stirrer-pipette, first in the latex control circle and then in the test circle, to make two homogenous blue suspensions. Start the timer.
- C. Smoothly tilt and rock the test card so that the suspensions slowly rotate in their circles and examine for signs of agglutination.
- D. A positive reaction (Trichomonas antigen is present in the specimen) is indicated by a definite blue coloured agglutination in the test latex circle and the absence of definite agglutination in the control latex circle within 2 minutes reaction time.
A negative reaction is indicated by the absence of definite blue coloured agglutination in the test and control latex circles within 2 minutes reaction time.

If the test latex reaction is positive but agglutination is also observed in the control latex circle, the specimen includes components that aggregate protein-coated latex beads and the test result cannot be interpreted. In this case it is recommendable to repeat the test with a new specimen or to test the specimen with a culture method.

5. QUALITY CONTROLS

- A. Reagent control: Add one drop of Specimen Dilution Buffer to a test and control dots. Mix the moistened blue reagents with stirrer-pipette. Rotate the test card as described above and examine the signs of agglutination. If agglutination is observed then either the latex or the Specimen Dilution Buffer is giving non-specific agglutination and should be discarded.
- B. Positive control: Add one drop of Positive Control Reagent to a test and control dots. Mix the moistened blue reagents with stirrer-pipette. Rotate the test card as described above and examine the signs of agglutination. The agglutination should be obvious and clear within 2 minutes in the test circle. There should not be any agglutination in the control circle.

6. STORAGE

Test packages can be stored at ambient temperature +2...+27 °C. Positive Control Reagent in refrigerator +2...+8 °C.

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