T-5303-B

BioSign™ Chlamydia II

Direct *Chlamydia trachomatis* Antigen Test

For *In Vitro* Use Only

Immunoassay for the Qualitative Detection of
Chlamydia trachomatis Antigen
Directly from Endocervical Specimens

PBM

Catalog No. BSP-193-25 25 Test Kit

Intended Use

BioSign™ Chlamydia qualitatively detects *Chlamydia trachomatis* antigen directly from endocervical specimens. The test is intended for use in the rapid diagnosis of Chlamydial infection. Note: Use with male urethral or urine specimens has not been established.

Summary and Explanation

Chlamydia trachomatis is one of the most significant sexually transmitted human pathogens causing non-gonococcal urethritis, post-gonococcal urethritis, proctitis, cervicitis, infertility and endometritis[1,2]. If early diagnosis and treatment fail, these infections can result in acute epidymitis in the male, or pelvic inflammatory disease and ectopic pregnancy in the female[3]. Unlike classical culture methods for identification which require 48–72 hours to produce results, the **BioSign™ Chlamydia** test requires only 13–15 minutes.

Principle

The **BioSign™ Chlamydia** test involves the chemical extraction of the Chlamydia antigen (lipopolysaccaride, LPS) followed by solid-phase immunometric technology for the qualitative detection of extracted LPS. In the test procedure, an endocervical specimen is collected with a swab and Chlamydia antigens are extracted from the specimen with extraction reagents. The extract is added to the sample well using a dropper. If Chlamydia antigen is present in the specimen, it will react with the antibody coated on dye, which in turn will be captured by another antibody on the membrane to generate a colored line at the Test position of the result window. Presence of two colored lines, one at the Test position and the other at the Control position, indicates a positive result, while the absence of a line at the Test position indicates a negative result.

Reagents

Materials Provided

Each **BioSign™ Chlamydia** test kit contains enough reagents and materials for 25 tests.

- Test Devices (25)
- Each **BioSign™** test device contains a membrane strip coated with anti-LPS antibody and a pad impregnated with the antibody (anti-LPS)-dye conjugate in a protein matrix containing 0.1% sodium azide.
- Reagent A (12 mL)
- Reagent B (pink color) (1.5 mL)
- Swabs (25)
- Reaction Tubes (25)
- Transfer Pipettes (25)
- Droppers (25)
- Directions for Use

Materials Required but not Provided

- Timer
- Reaction tube rack

Precautions

- For *in vitro* diagnostic use only.
- Do not interchange materials from different product lots and do not use beyond the expiration date.
- Do not interchange caps between reagents.
- Use separate, clean Transfer Pipettes and Droppers for different specimens.
- Reagents A & B contain sodium azide, which on contact with lead and copper plumbing may react to form explosive metal azides. Use large volumes of water to flush reagents on disposal.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
- All patient samples should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.

- The **BioSign™ Chlamydia** device should remain in its original sealed pouch until ready for use.

Storage and Stability

The **BioSign™ Chlamydia** Reagents A & B should be stored refrigerated (2– 8 C). The **BioSign™ Chlamydia** test devices should be stored in their original sealed pouches at 2–30 C (36–86 F). The stability dating was established under these storage conditions.

Specimen Collection and Preparation

- Collect endocervical specimens using the swabs provided.
- Use a separate swab for each sample; remove excess mucus from the endocervical canal and discard. Insert a swab into the endocervix, rotate for 10–20 seconds and withdraw carefully. Avoid contamination of specimen from contacting with the vaginal surface.
- Swabs should be processed as soon as possible after collection. Otherwise, swabs can be stored up to 24 hours in a refrigerator.

Procedure

Procedural Notes

The instructions below must be followed precisely, to achieve optimal test reactivity with endocervical swab specimens. Follow the assay procedure and always perform the test under carefully standardized conditions.

- If specimens, kit reagents or the **BioSign™** device have been stored in a refrigerator, allow them to reach room temperature before use.
- Do not open the foil pouch until you are ready to perform the test.
- Several tests may be run at one time.
- To avoid cross contamination, use a new Transfer Pipette for each specimen.
- To avoid contamination of reagents, do not allow the tips of the reagent bottles to come in contact with the Reaction Tubes or Swabs.
- Label the test device with the patient name or control number.
- The special Transfer Pipette measures a precise volume of liquid in one pipette length. To use it properly, draw liquid into the pipette until it just flows into the reservoir. Empty one pipette-length (250 µL). The excess remains in the reservoir.
- To add Reagent A, fill the pipette so the reagent begins to enter the reservoir, then dispense the full amount in the vertical section of the pipette.
- To add Reagent B, hold the bottle in a vertical position above the reaction tube and dispense 1 large drop into the tube. Be careful to add only 1 drop.
- To add extract, allow the Transfer Pipette to fill with sample and add 4 drops (*less than one pipette full*) of extract into the sample well of the **BioSign™** test device in a vertical position.
- Handle all specimens as if capable of transmitting disease.
- After testing, dispose of the **BioSign™** device, endocervical swab, Reaction Tube and Transfer Pipette, following good laboratory practices. Consider each material that comes into contact with the specimen to be potentially infectious.

Test Protocol

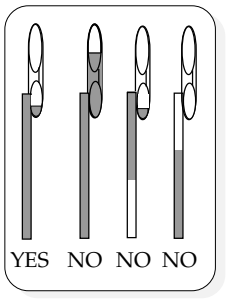
- Dispense a pipette full of Reagent A into a reaction tube (see illustration). Add the drops slowly.
- Place the swab in the reaction tube. Mix thoroughly and let the tube stand for 5 minutes at room temperature. Leave the swab in the tube.
- Dispense 1 drop (37 µL) of Reagent B (pink color) into the reaction tube and mix well with the swab. The solution should turn a yellow color. DO NOT add more than 1 drop.
- If the solution does not turn yellow, add 1 more drop of ***Reagent A*** to the tube, and mix well. Repeat this step, if necessary, until the solution turns yellow.
- Remove the swab from the tube, squeezing all excess liquid into the tube. Discard the swab.
- Add 4 drops of the extracted solution into the Sample well (S) using a dropper.
- Read the result in 8 minutes. Do not read after 10 minutes.

Interpretation of Results

Positive: Two colored lines in the result window: One colored line each at the Test position and at the Control position indicate that Chlamydia antigen has been detected.

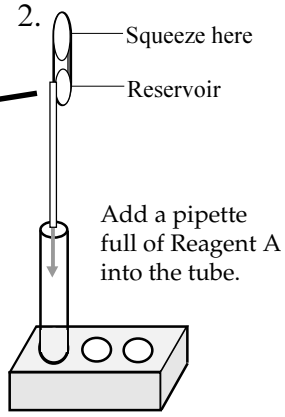
Note: *The test result can be read as soon as two distinct*

1.



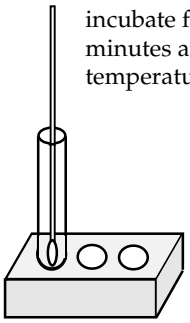
Make sure the stem of the Transfer Pipette is completely filled with Reagent A before dispensing.

2.

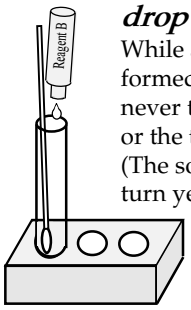


Add a pipette full of Reagent A into the tube.

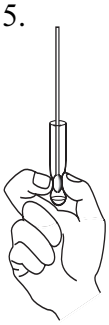
3. Place the swab in the tube. Mix and incubate for 5 minutes at room temperature.



4. Leaving the swab in the tube, add ***1 full drop of Reagent B***. While a full drop is formed, it should never touch the swab or the tube. Mix well. (The solution should turn yellow.)



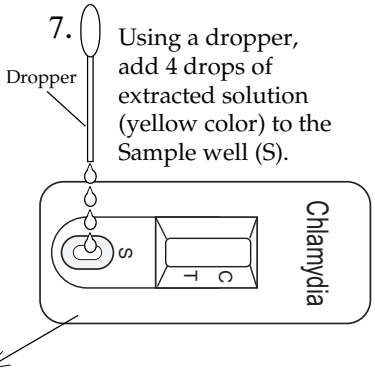
5.



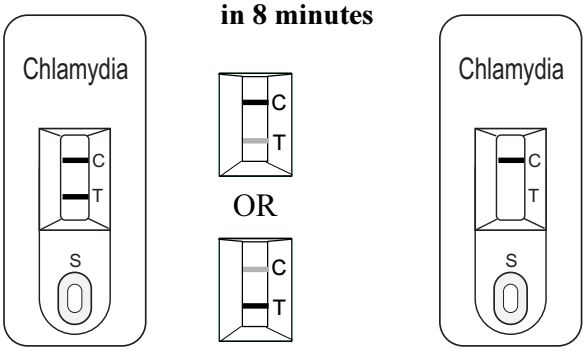
Squeeze out as much liquid as possible from the swab by pressing the swab firmly against the side of the tube.

6. Discard the swab.

7. Using a dropper, add 4 drops of extracted solution (yellow color) to the Sample well (S).



Read the Result in 8 minutes



2 Lines = Positive (+) **1 Line = Negative (–)**

pink-purple color lines appear—one at the Test position and one at the Control position. The test line will appear before the control line in most strong positive cases. The test line may appear after the control line in weak positive cases, and the control line may be darker than the test line. The three possible positive cases, therefore, are:

a. Two strong colored lines at both the Test (T) and Control (C) positions.

b. One strong colored line at the Test position (T) and one light colored line at the Control position (C).

c. One light colored line at the Test position (T) and one strong colored line at the Control position (C).

Negative: Only one colored line at the Control position (C), with no distinct colored line at the Test position other than the normal faint background color, indicates that Chlamydia antigen has not been detected.

Invalid: A distinct colored line at the Control position should always appear. The test is invalid if no line forms at the Control position.

Limitations

- The results obtained by this kit yield data that must be used only as adjunct to other information available to the physician.
- For best results, a proper endocervical specimen must be obtained using the swab provided.
- Though a patient may be at the onset of the disease, a negative result may be obtained due to low antigen level below the sensitivity of the test. If symptoms persist or intensify, the test should be repeated.

Quality Control

- A colored line at the Control position (C) can be considered a positive procedural control. If the reagents are added correctly and are performing properly, a distinct colored Control line will always appear. If no Control line appears, retest the specimen with a new test device. If problems persist, contact PBM Technical Services for assistance.
- A clear background in the result window is considered a negative procedural control. If the test is working properly and the procedure has been performed correctly, the background in the result window should be clear, providing a distinctly readable result.

- Positive and Negative Controls should be tested before using a new lot of tests to confirm the expected Q.C. results. The Positive Control will produce a moderate positive result. For information on how to obtain the Positive and Negative Controls, please contact PBM Technical Services.

Performance Characteristics

The performance of the **BioSign™ Chlamydia** was evaluated by the conventional culture techniques. Two endocervical specimens were collected from patients. One swab was used for the conventional culture method and the other was used for the **BioSign™ Chlamydia** test. The results are summarized below:

		BioSign™ Chlamydia		
		+	–	Total
Culture	+	39	5	44
	–	3	126	129
		42	**131**	**173**

Sensitivity: 88.6%
Specificity: 97.7%
Overall accuracy: 95.4%

To confirm the specificity of **BioSign™ Chlamydia**, the following organisms were tested at 1×10^7 cells/mL, yielding negative results:

Acinetobacter calcoaceticus	*Citrobacter freundii*
Candida albicans	*Corynebacterium glutamicum*
Enterobacter aerogenes	*Escherichia coli*
Gardnerella vaginalis	*Klebsiella pneumoniae*
Neisseria gonorrhoeae	*Neisseria lactamica*
Neisseria meningitidis	*Proteus vulgaris*
Pseudomonas aeroguinosa	*Salmonella typhi*
Staphylococcus epidermis	*Streptococcus faecalis*
Streptococcus pyogenes	

References

1. Schachter, J. *N. Engl. J. Med.* 298:428-435, and 540-549 (1978).
2. Department of Health and Human Services, DHHS Publication No. 81-2213. Washington, D.C., U.S. Government Patent Office, 1981.
3. Sweet, R. I. *Fertility and Sterility.* 38: 530-533 (1982).

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