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"See Now" Chlamydia CassetteTest

Secretory products

For in vitro Diagnosis Use
Product Code: SN 4.5

INTENDED USE

The *"See Now"* Chlamydia trachomatis Test is a lateral flow, immunochromatographic assay which utilizes a unique combination of monoclonal antibodies to selectively identify Chlamydia trachomatis antigen in endocervical or endourethral swab specimens with a high degree of sensitivity.

.PRINCIPLE

The antigens of Chlamydia trachomatis are extracted from the specimen with two reagents—one to lyse the cells and one to neutralize the solution. The extracted specimen is pipetted to the sample well (cassette) to begin the assay. During the assay, the extract is first allowed to react with colloidal gold reagents which have been labeled with anti-Chlamydia antibody. The extract then moves to a membrane precoated with anti-Chlamydia antibody at the test region. If Chlamydia trachomatis antigens are present in the specimen, a pink-colored band will develop on the membrane in proportion to the amount of antigen present. Absence of this pink-colored band in the test region suggests a negative result. To serve as a procedural control, a pink-colored band in the control region will always appear regardless the presence of Chlamydia trachomatis antigens.

MATERIALS SUPPLIED

- Pouch Contents: Cassette, Desiccant (store at 15 -25º C)
- Specimen Diluents A and B
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Clean and dry specimen extraction tube.
- 2 Sterile Swabs for female patients and 1 metal shafted sterile swab for male patients.
- Clock or timer.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 15-25ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN PREPARATION

A. Female Patients

Two sterile swabs with plastic shafts are required in the female collection procedure. One swab is used to prepare the sample site; the other is used for sample collection.

1.Remove any excess mucus from the potentially infected site with the first swab, then discard it.

2.Rub the second swab vigorously over the infected endourethral lining and endocervical cells in the canal wall. As gonorrhea are intracellular organisms, firm contact must be made with the canal wall for proper specimen collection. The rubbing action dislodges the endothelial cells and allows the swab to absorb the bacteria. Improper collection will result in poor visual readings and may cause invalid results. Vaginal specimens are not useful.

B. Male Patients

One metal-shafted sterile swab is needed for male penile sample collection. Do not use a plastic-shafted swab in this procedure.

1.Insert the swab into the urethra of the penis. Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotation.

2.Carefully remove the swab avoiding contact with any external surfaces.

PRECAUTIONS

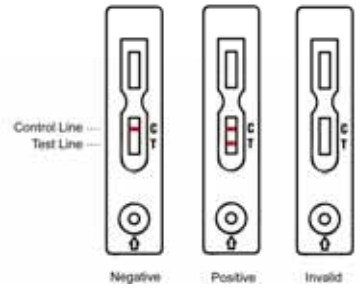
- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface. Label and extraction tube for each patient and place in a tube holder or rack.
- Place the swab into the microtube and add 5 drops specimen diluent A on the swab. Mix contents well with the swab and let stand for 2 minutes (but no longer than 10 minutes).
- Then add 5 drops diluent B into the microtube, Mix contents well with the swab and let stand for 2 minutes (no longer than 10 minutes). Remove liquid from the swab by pinching the rim of the extraction cup between thumb and finger and gently remove the swab from the cup.
- The extraction mixture can be tested immediately or at any time within the following 24 hours.
- Holding the Sample dropper vertically, adds 3 drops of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

- Read the result in 10 minutes. Ensure that the background of the test area is white before interpreting the result. Do not interpret the results after 30 minutes.

INTERPRETATION OF RESULTS



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

LIMITATION OF PROCEDURE

- The test is limited to the detection of Chlamydia trachomatis in swab specimens.
- The test does not differentiate between carriers and infected individuals.
- Pharyngitis may be caused by organisms other than Chlamydia trachomatis.
- .Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test. False negatives may result from improperly collected specimens. If negative or questionable results are obtained, the test should be repeated using a new swab specimen.
- The test only allows for the detection of Chlamydia as a presumptive indication of Chlamydia trachomatis infection. However cases in which patient swabs test negative while the patients' clinical symptoms are indicative of Chlamydia infection should be investigated further.
- .A test result read after 10 minutes may not be consistent with the original reading obtained within the 5 minute test period.

PERFORMANCE CHARACTERISTICS

Sensitivity Study

The analytical sensitivity of the *"See Now"* Chlamydia Rapid Screen Test was determined by testing serial dilutions of cultured specimens. The detection limit of the *"See Now"* Chlamydia Rapid Screen Test was determined to be 5 X 10^6 CFU/ml.

Specificity Study

To determine the specificity of the *"See Now"* Chlamydia Rapid Screen Test to C. trachomatis, 15 serovars were tested at different levels of organisms. Positive results obtained at the level of 5 X 10^6 CFU/ml for all C. trachomatis.

Cross Reactivity

Cross-reactivity studies with organisms likely to be found in the urogenital tract were also performed using the *"See Now"* Chlamydia Screen Rapid Test. Organisms tested at 1 X 10^8 Orgs/ml produced negative results in *"See Now"* Chlamydia Rapid Screen Test.

Group B Streptococcus	Neisseria lactima	Neisseria subflava
Pseudomonas aeruginosa	Neisseria gonorrhoeae	Klebsella pneumoniae
Staphylococcus aureus	Streptococcus pneumoniae	Garonerella vaginalis
Proteus vulgaris	Neisseria sicca	Saccharomyces cerevisiae
Streptococcus faecalis	Neisseria meningitidis	Neisseria lactamica
Escherichia coli	Candida albicans	