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Chlamydia Test Cassette (Swab)

Intended Use

The SMI Chlamydia Test Cassette is a rapid direct binding test for visual **detection of Chlamydia *trachomatis* antigen** in endocervical or endourethral swab specimens.

Summary

Chlamydia *trachomatis* is one of the most common sexually transmitted pathogens. It is a major cause of cervicitis, urethritis, endometritis and pelvic inflammatory disease in women. Serious complications can result in salpingitis, infertility and ectopic pregnancy. If transmitted to infants during birth, chlamydia can cause conjunctivitis and pneumonia. Fifty to seventy percent of infected women are asymptomatic, which makes diagnosis extremely important.

Chlamydia is related to gram-negative bacteria. They are intracellular in nature and are unable to synthesize adenosine triphosphate (ATP). The extracellular elementary body form is infectious while the intracellular reticulate form is metabolically active.

Epidemiological patterns indicate infections of Chlamydia *trachomatis* parallel or exceed those of Neisseria *gonorrhea* and the two often occur together. The disease cuts across the socio-economic spectrum. The primary method for detection of Chlamydia is growth of the organism in cell culture. Other methods include direct fluorescence assays (DFA), Enzyme Immunoassays (EIA) and nucleic acid probing.

Principle

The SMI Chlamydia Test Cassette (Swab) utilizes the chemical extraction of a carbohydrate antigen from chlamydia followed by the utilization of a double sandwich immunoassay for the qualitative detection of Chlamydia *trachomatis* antigen. The assay is conducted by adding pre-treated specimen to the sample well of the cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored dried conjugate of colloidal gold-monoclonal antibody. The sample reconstitutes the dried conjugate. If Chlamydia *trachomatis* antigen is present in the sample, it will react with the antibody to form a complex of colloidal gold-monoclonal antibody-Chlamydia. This complex migrates up the membrane strip chromatographically and through the band of immobilized antibody. Because the immobilized antibody is able to bind to the Chlamydia *trachomatis* antigen molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized antibody. If there is no Chlamydia *trachomatis* antigen present in the treated sample, the colloidal gold-monoclonal antibody conjugate will pass through the immobilized antibody band and no colored line will form – a negative test result.

Further up the membrane, passed the test region, is a control region. This band of antibody will bind only conjugate and form a colored line, regardless of whether Chlamydia *trachomatis* antigen is present in the sample or not. Appearance of the control line assures reagent integrity as well as correct testing procedure.

Reagents

The test contains anti–Chlamydia conjugated antibodies and anti-Chlamydia antibodies immobilized on the membrane.

Precautions

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

Storage & Stability

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials provided:

Test cassettes
Instructions
Extraction Buffer A
Extraction Buffer B
Extraction tube with dropper tip
Female Swabs: Plastic-shafted sterile swabs

Materials required but not provided:

Timer
Test tube rack

Specimen Collection & Preparation

Swab Sample

1.0 Use a swab to collect specimen in the following suggested method:

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.

a) Remove any excess mucus from potentially infected site with the first swab, and then discard the swab.
b) Rub the second swab vigorously over the infected endourethral lining and endocervical

cells in the canal wall. As Chlamydia is an intracellular organism, 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.

2.0 Place the swab into the extraction tube and add 10 drops (approximately 300µL) of extraction buffer A into the extraction tube. Compress the bottom of the tube between the thumb and the forefinger and twirl the swab 10 times.

3.0 Incubate at room temperature (15 to 30 °C) for 2 minutes. Compress the bottom of the tube between the thumb and forefinger and twirl the swab 10 times.

4.0 With the swab shaft to the side, add 20 drops (approximately 600 µL) of buffer B to the tube. Compress the bottom of the tube between the thumb and forefinger and twirl the swab 10 times.

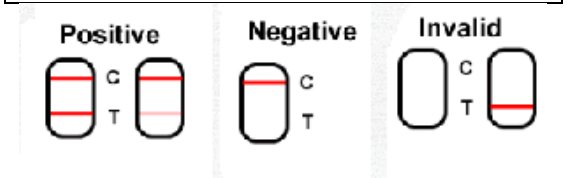
5.0 Squeeze out as much liquid as possible from the swab by compressing the middle of the tube and pulling the swab up through it. Discard the swab into an appropriate biohazard disposal container. Insert the dropper tip on the tube and mix the contents by gentle swirling. The swab extract must be tested immediately.

Directions for Use:

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Add 2 drops of the extracted sample (from the extraction tube) into the sample well of the test device (S), and then start the timer. Avoid trapping air bubbles in the specimen well.
3. Wait for the purplish line(s) to appear. The result should be read between 10-20 minutes. It is important that the background is clear before the result is read.

Note: Do not interpret the result after 30 minutes.

Interpretation of Results:



POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and contact Science with a Mission. **NOTE**: The intensity of the purplish color in the test line region (T) will vary depending on the concentration of Chlamydia antigen present in the specimen. However, the quantitative value cannot be determined by this qualitative test.

Quality Control

A procedural control is included in the test. A purple line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Limitations

1. This test provides a presumptive diagnosis for Chlamydia. A confirmed, infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. A specimen swab that contains too much blood may cause weak false positive results. Therefore, bloody swabs should be avoided.