



# **CHLAMYDIA**

*Rapid Chlamydia screen test*  
Cat.No. 101-0232  
Size 20 tests

## **PRINCIPLE:**

The Chlamydia screen test is a rapid qualitative one step immunoassay. The method employs a unique combination of monoclonal antibody-dye and polyclonal solid phase antibodies to selectively identify the LPS antigen of the Chlamydia trachomatis species with a high degree of sensitivity.

In this test, a specimen (endocervical or urethral swab) is first extracted with a buffer to isolate Chlamydia trachomatis, if present. Following the extraction of Chlamydia trachomatis antigen, the only step required is to add a quantity of the extract to the sample well of the test card.

As the sample extract flows through the absorbent pad, the labeled antibody-dye conjugate binds to the genus specific lipopolysaccharide (LPS) antigen of Chlamydia forming an antigen-antibody complex. The absorbent pad is in turn in contact with a chromatographic membrane which contains a region of immobilized polyclonal anti-Chlamydia antibody in the test well of the card.

The antibody-antigen complex moves by capillary forces along the strip. Upon contact with the polyclonal antibody in the test window a pink/purple colored line forms in the presence of Chlamydia antigen. If no antigen-antibody complex is formed due to the absence of Chlamydia, no colored line will appear in the test well of the card.

The test also provides an integral control feature. As the extract migrates across the control well, the appearance of a pink/purple colored line forms due to capture of the colloidal gold complex on immobilized antibody demonstrating proper performance of the test.

## **REAGENTS:**

1. Extraction solution: containing non-ionic buffer and 0.1% sodium azide as preservative (14 ml)
2. Chlamydia positive control swabs (2 swabs)
3. Chlamydia test cards (20 cards)
4. Sterile swabs (20 swabs)
5. Extraction tubes (20 tubes)
6. Pipettes (20 each)

Liquid reagents should be stored at +2 °C to +8 °C. They are stable up to the expiry date. The test cards can be stored at any temperature between +2 to +30°C.

## **PROCEDURES:**

Bring all reagents and samples, controls and reference materials to room temperature before use.

## **CLINICAL SIGNIFICANCE:**

Chlamydia are related gram-negative bacteria. However, they are intracellular in nature and are unable to synthesize adenosine triphosphate (ATP). The extra cellular elementary body form is infectious. The intracellular reticulate form is metabolically active.

Epidemiological patterns indicate infections of Chlamydia trachomatis parallel or exceed those of Neisserie gonorrhoea and the two often occur together. The primary method for chlamydeous detection is growth of the organism in cell culture. Other methods include Direct Fluorescence Assays (DFA), Enzyme immunoassays (EIA) and Nucleic Acid Probes.

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 complication can result in saipingitis, infertility, and ectopic pregnancy.

If transmitted to infants during birth, Chlamydia can cause conjunctivitis and/or pneumonia. It has been shown that 50 - 70% of infected women are asymptomatic, which makes diagnosis extremely important.

## **SPECIMEN COLLECTION AND STORAGE:**

### **A. For cervical specimens**

1. Use the swabs provided with the kit.
2. Remove excess mucous of the endocervical area with a separate swab or cotton ball and discard. Failure to remove mucous may result in a false positive test.
3. Insert a fresh sterile swab into the endocervical canal until most of the tip is no longer visible. Rotate the swab for 15-20 sec. Carefully withdraw the swab being careful not to touch the vaginal surface and place it in dry plastic tube and store refrigerated at +2 to +8°C for up to 72 hours if testing is not immediate.

### **B. For urethral specimens**

1. Standard wire shafted fiber tipped swabs, or cytology brushes (not provided) should be used for urethral specimens.
2. Insert the swab into the urethra about 2-4 cm, rotate for 3-5 sec. and withdraw. Place swab into collection tube (dry plastic tube, not provided) if the specimen is not being tested immediately.
3. Patient samples perform best if tested immediately after collection. If immediate testing is not possible, the sample should be placed in a dry plastic tube and stored at +2 to +8°C for up to 72 hours.

### **C. For male urine specimens**

1. Instruct the patient to collect at least 20-40 ml of first catch urine in a clean sterile container (not provided) without any preservatives.

First morning specimens are preferred to achieve the greatest probability of Chlamydia-antigen recovery. If the urine specimens are not to be tested on the day of collection, they can be stored refrigerated for up to 72 hours.

## **SAMPLE EXTRACTION:**

### **A. For swab specimens**

1. Use an extraction tube (provided) for each specimen to be tested, add 14 drops of extraction solution. Label each tube appropriately.
2. Immerse the swab into the tube containing the extraction reagent and swirl the contents thoroughly for 10 sec. to insure adequate mixing of the reagents with the swab specimen.
3. Place the extraction tube containing the swab into a test tube rack (not provided) and leave at room temperature for 5-10 min.
4. Swirl the swab 2-3 times for a few seconds during the extraction step, pressing it against the wall of the tube to express the liquid and insure through contact of reagents and specimen.
5. At the end of the 5-10 min. thoroughly remove as much extract from the swab as possible by raising it above the liquid level and squeezing the extraction tube. Remove swab from tube being careful not to insert it into the liquid again.
6. The swab extract can remain at room temperature for up to 30 min. without affecting the results.

### **B. Alternative procedure for male urine specimens**

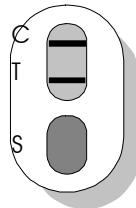
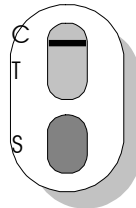
1. Collected urine specimens should be centrifuged in order to collect all particulate matter that may contain Chlamydia cells.
2. Centrifuge the urine at 10000 rpm for 10 min.
3. Carefully decant the supernatant and add 14 drops of the extraction solution to the sediment in the tube.
4. Resuspend the sediment by mixing and transfer the suspended sediment to an extraction tube (provided) using a disposable pipette.

### TEST PROCEDURE:

1. Remove as many test cards from the protective foil pouches as needed. Place on a flat surface. If test packs are stored at +2 to +8°C allow warming to room temperature before removing from foil pouch.
2. Using the pipettes supplied, carefully add 7 drops of the extract to the SAMPLE window of the test device card.
3. Allow reaction to take place - usually within 5-20 min.
4. Test results remain stable for at least 1 hour after addition of the extract to the test card.

### INTERPRETATION OF RESULTS:

1. **NEGATIVE:** Only one pink/purple colored band appears in the CONTROL (C) well of the test card demonstrating correct performance of the test. No clearly distinguishable pink/purple colored band in the TEST (T) well indicates no Chlamydia antigen was detected.
2. **POSITIVE:** In addition to the pink/purple colored band in the CONTROL (C) well of the card, a clearly distinguishable pink/purple colored band appears in the TEST (T) well of the card indicating the sample contains Chlamydia antigen.
3. **INCONCLUSIVE:** If no line appears in the CONTROL (C) well of the test card, the assay should be performed again with a fresh card.



### QUALITY CONTROL:

The Chlamydia rapid test contains highly stable positive control swab for use in determining the performance of the test. These swabs are used exactly as you would a patient sample.

A fresh sterile swab carried through the test procedure may be used as a negative control.

### USE OF CONTROL MATERIAL:

#### To run a positive control:

1. Remove one of the positive swabs from the protective foil pouch labeled POSITIVE CONTROL.
2. Add 15 drops of the extraction reagent to an extraction tube and place the swab into the reagent. Mix as directed for patient samples.
3. Allow the swab to remain in the extraction reagent the same amount of time as a patient sample.
4. Remove the swab from the extraction solution, squeezing as much extract off the swab as possible by pressing the swab onto the sides of the tube.
5. Add 6 drops of positive control extract using the droppers supplied to the SAMPLE well of the test card being used for the control test.
6. Results are interpreted as you would a patient sample. The POSITIVE control swab should produce a very clear pink/purple band in the TEST area of the card as well as in the CONTROL area. This indicates the test is performing properly.

### NOTE:

1. The Chlamydia screen test should be used for the detection of Chlamydia trachomatis antigen only and for specimens collected from endocervical, urethral regions and male urine. Specimens collected from other sites, such as the rectum or conjunctiva should not be used.
2. Specimens with an excessive amount of mucous or blood may give false positive results with this test.
3. Handle all specimens as if they contain infectious agents. When the assay is completed, dispose of swabs carefully after autoclaving for at least 1 hour. Alternatively, swabs can be treated with a 0.5% - 1.0% solution of sodium hypochlorite.
4. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves while collecting and testing samples.
5. Avoid any contact between hands and eyes and nose during specimen collection and testing.