

ONE STEP CHLAMYDIA DIPSTICK TEST

INTRODUCTION

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.

Chlamydia is related to gram-negative bacteria. The primary method for detection of Chlamydia is growth of the organism in cell culture. Other methods include direct fluorescence assays (DFA), enzyme immunoassay (EIA), and nucleic acid probing. The Chlamydia Rapid Test is a simple and rapid test, which can detect Chlamydia trachomatis antigen directly from swabs, allow physicians to diagnose and administer therapy immediately.

PRINCIPLE OF THE TEST

Chlamydia Dipstick Test is an 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. A swab specimen from a patient is treated with extraction buffer A and B to extract the antigen. The extracted specimen is pipetted to the sample well and it migrates through the absorbent area and along the membrane. If Chlamydia trachomatis antigen is present, the labeled antibody-dye conjugate binds to it forming an antibody-antigen complex. As the mixture flows along the membrane, the antibody immobilized in the test region (T) of the membrane captures the complex, producing a visible rose-pink color band proportion to the amount of antigens. 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 (C) will always appear regardless the presence of Chlamydia trachomatis antigens.

REAGENTS AND MATERIALS PROVIDED

1. Test Dipstick
2. Extraction Buffer A (8.0 ml/25 tests)
3. Extraction Buffer B (8.0 ml/25 tests)
4. Positive Control (0.6 ml/25 tests)
5. Test Cup (25 pieces/25 tests)
6. Cup Holder (25 pieces/25 tests)
7. Product Package Insert

Female Testing Kit Only:

8. Female swabs (50 pieces/25 tests)

Male Testing Kit Only:

9. Male swabs (25 pieces/25 tests)

STORAGE

Chlamydia Dipstick Test reagents (extraction buffers and positive controls) should be refrigerated at 2-8°C when not in

use. Other test components may be stored at room temperature (15-28°C). Refer to expiration date for stability.

PRECAUTIONS

1. The test is for *in vitro* diagnostic use only
2. Do not use beyond the expiration date.
3. Do not remove the device from pouch until just prior to use.
4. Do not allow a sample swab to come in contact with any reagent bottle tip. Reagent or bacterial contamination will invalidate test performance.
5. Do not touch the swab tip at any time. Wash hands after performing the test.
6. Use only the sterile swabs. Swabs from any other source may give faulty results.
7. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. Properly dispose of all contaminated waste such as swabs, test unites and extract.
8. Extraction buffers are slightly caustic. If these reagents contact the skin or eyes, flush with large volumes of water.

SPECIMEN COLLECTION

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.

Note: Use only the swabs provided with the kit.

1. Remove any excess mucus from the potentially infected site with the first swab, and then discard it.
2. Rub the second swab vigorously over the infected endourethral lining and endocervical cells in the canal wall. As Chlamydia is 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.

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.

Storage and Stability:

If a swab is not extracted immediately, store it refrigerated (2-8°C) for up to 5 days, preferably in transportation tube. Do not freeze. Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

ASSAY PROCEDURE

Procedural Note:

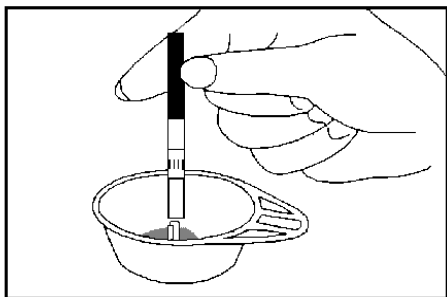
1. If specimen or reagent has been stored in the refrigerator, bring all specimens and reagents to room temperature (18-25°C) prior to testing.
2. Do not open the foil pouch until ready to perform the test.
3. Do not use commercial controls other than those provided with the test as they may contain additives that interfere with test performance.

Extraction:

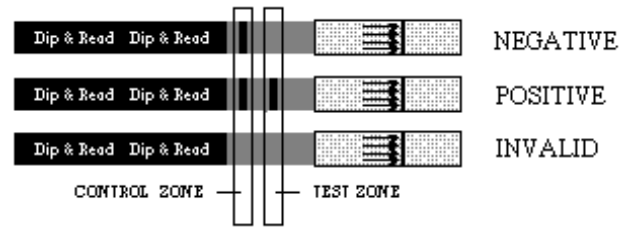
1. Label a test cup with patient's identification and place in cup holder.
2. Add 6 drops of extraction buffer A to test cup. Place specimen swab in the test cup and mix contents well with the swab and let stand for 5 minutes at room temperature.
3. Add 6 drops of extraction buffer B to test cup containing swab. Mix contents well with the swab for 10 seconds. Remove liquid from the swab by expunging. Discard the swab. The extraction mixture must be tested immediately.

Assay:

1. Bring test components and control to room temperature. Remove test strip from the foil pouch.
2. Place the test strip into the test cup containing the sample. The strip must be placed so that the words "dip" and "read" are in an upright position. Be careful not to submerge the test strip below the "↓↓↓ level" indicated on the strip. Rose-pink color will migrate across the membrane as the test progresses.
3. Read results at 15 minutes. *Do not interpret result after more than 15 minutes.*



INTERPRETATION OF RESULTS



Negative: At 15 minutes, only one rose-pink color band is visible indicating the result is negative for Chlamydia trichomatis antigen.

Positive: At 15 minutes, two horizontal rose-pink color bands appear indicating a positive result and that the sample contains Chlamydia trachomatis antigen.

Invalid: At 15 minutes, no bands appear, or a test band appears without a control band, disregard the result, indicating the test is invalid. It is recommended that the specimen be re-tested. The presence of a control band is necessary to validate proper test performance.

Note: There is no meaning attributed to line color intensity or width.

LIMITATIONS

1. The test is limited to the detection of Chlamydia trachomatis in swab specimens.
2. The test does not differentiate between carriers and infected individuals. Pharyngitis may be caused by other organisms besides Chlamydia trachomatis.
3. Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test. False negatives may result from improperly taken specimens. If negative or questionable results are obtained, the test should be repeated using a new swab specimen.
4. 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.

REFERENCES

1. Graystone, J.T. et al. Engl. J. Med. 315:161-8, 1986.
2. Chemesky M.A. et al., J. Infect. Dis. 154: 141-8, 1986.
3. Schachter J. Chlamydias P1045-53, Manual of clinical microbiology 5th ed. American Society Microbiology Washington D.C. 1991.