

HEALTH-CHEM DIAGNOSTICS LLC

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RAPIDTEST CHLAMYDIA TEST

NAME AND INTENDED USE

The **RapidTest Chlamydia Test** is a rapid diagnostic immunoassay for the direct qualitative 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. 50-70 percent of infected women are asymptomatic, which makes diagnosis extremely important(1). *Chlamydia* are related to gram-negative bacteria. They are intracellular in nature and are unable to synthesize adenosine triphosphate (ATP)(2). The extracellular elementary body form is infectious while the intracellular form is metabolically active.

Epidemiological patterns indicate that infections of *Chlamydia trachomatis* parallel or exceed those of *Neisseria gonorrhoeae* and the two often occur together(3). The disease cuts across the socioeconomic 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 [4,5].

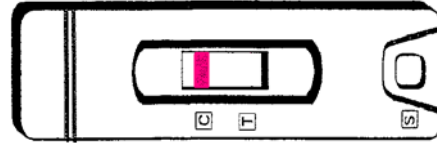
PRINCIPLE OF THE TEST

The **Rapid Chlamydia Test** utilizes a single step “sandwich” Immunochromatographic assay. Prior to the test, an endocervical clinical specimen is obtained and placed into a tube containing Reagent A (Extraction solution), After 2 minutes, Reagent B (Neutralization solution) is added to the tube and mixed well. Then 2 drops of extracted sample is added to the Sample well of the test device.

If Chlamydia is present in the sample in concentrations above the detection level, a labeled specific antibody-dye conjugate binds to it forming an antigen-antibody-dye complex. This complex migrates up, and is then captured by another specific antibody immobilized in the Test Zone (“T”) of the membrane, producing a visible reddish colored band on the membrane. A reddish line in the control zone indicates the test is working properly. When only a control line appears with no test line, *Chlamydia trachomatis* antigen has not been detected and the test result is considered negative.

The control line gives an added measure of quality control by demonstrating antibody recognition assuring that the procedure was performed correctly; and that the reagents are

chemically active. A desiccant is enclosed with the test device to stabilize the reactive agents.



REAGENTS AND MATERIALS PROVIDED

- Test Device Packaged in foil pouch.
- Extraction Reagent A (Acid) and B (Alkaline).
- Instruction manual.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock (watch) or timer.

WARNINGS AND PRECAUTIONS

1. Wear gloves while handling specimens.
2. Dispose of gloves and specimens using good microbiological practices.
3. Do not touch the swab tip at any time.
4. Wash hands after performing the test.
5. Use only the Sterile Dacron® swabs provided. Swabs from any other source may give erratic results.
6. Do not allow a sample swab to come in contact with any reagent vial dropper tip. Reagent or bacterial contamination can occur.
7. Do not use reagents after their expiration dates.

SPECIMEN COLLECTION

A. Female Patient:

Two Sterile Dacron® 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.(3) As Chlamydia 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 Patient:

One metal-shafted Sterile Dacron® swab is needed for male penile sample collection.*

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.

* optional

STORAGE AND STABILITY

If a test swab is not tested immediately, place it into a transportation tube *without media* and store refrigerated (2-8°C) for up to five days. Do not freeze. Swabs may be transported to the test site under ambient conditions.

TEST PROCEDURE

NOTE: *Read all test instructions before running patient samples or controls.*

PROCEDURE NOTES

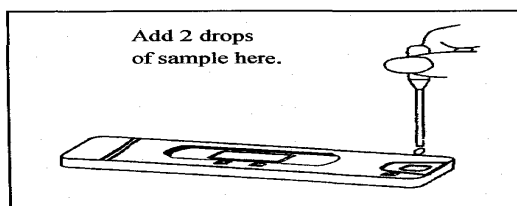
1. Bring all specimens and controls to room temperature (15-28°C) before testing.
2. Do not open the protective foil pouch until ready to perform the test.

A. Extraction

1. Label a Test Cup for each patient identification and place in the Cup Holder.
2. Add 9 drops of Extraction Buffer A to the Test Cup. Place the specimen swab in the Test Cup and twirl briefly to mix ingredients. Incubate at room temperature (15-28°C) for 5 minutes with the swab in the cup.
3. Add 9 drops of Extraction Buffer B to the Test Cup containing the swab.
4. Twirl the swab vigorously for 10 seconds, then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the cup. Discard the swab. Mix contents of the Test Cup by gently swirling. The swab extract can be tested immediately .

B. Immunoassay of the Extract

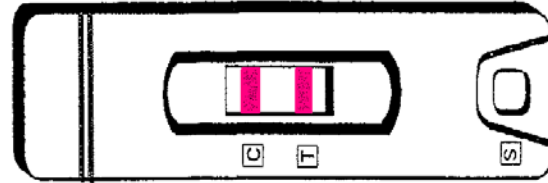
1. Remove the “Test Device” from the foil wrapper by tearing along the “splice”, and place it on a clean level surface. Discard the desiccant.
2. Add **2 drops** of the extracted sample from the tube to into the Sample Well (S) as shown in picture.
3. Read the results within 10 minutes.



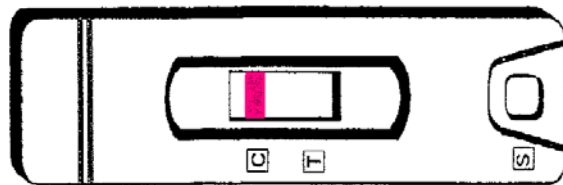
IMPORTANT: to avoid an incorrect reading or invalid results, do not interpret test results after more than 15 minutes.

INTERPRETATION OF RESULTS

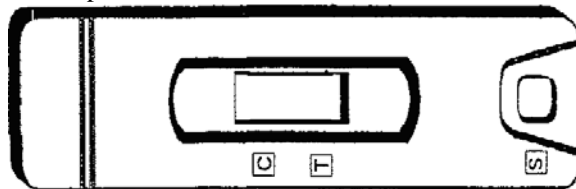
1. Positive. Two rose-pink bands are visible at the end of the assay: one in control zone and one in test zone. The sample should be considered positive for *Chlamydia trachomatis*.



2. Negative. One rose-pink band appears in the control zone, with no band in the test zone. *Chlamydia trachomatis* are not present in the test sample at the level of sensitivity of the test.



3. Invalid. There are no color bands on the membrane, or a band is visible in the test zone but not in the control zone. The test is invalid. The specimen should be re-tested using a new Test Dipstick.



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

1. Precision

A. Intra-Assay

Within-run precision was determined using the same 3 specimens containing negative, borderline positive, and positive values. The negative, borderline and positive values were correctly identified 100% of the time.

B. Inter-Assay

Between-run precision was determined using the same 3 specimens of negative, borderline positive control, and positive control of chlamydia antigen in 11 independent assays with 3 different lots of reagents over a 30-day period. Again, the negative, borderline and positive findings were correct 100% of the time.

LIMITATIONS OF THE TEST

1. The Assay is for *in vitro* diagnostic use only.
2. The test uses genus-specific monoclonal antibodies and will not specifically differentiate C.Trachomatis, C.Pneumonia or C.Psittaci.
3. Detection of chlamydia is dependent on the number of organisms present in the specimen. This may be affected by specimen collection procedure and patient's factors such as age, history of STD, presence of symptoms, etc.

PERFORMANCE CHARACTERISTICS

1. Specificity and Sensitivity

An evaluation of the **RapidTest Chlamydia Test** was performed to determine clinical performance in comparison to another commercially available immunoassay (a latex one step immunoassay). A total of 110 patients were included in the study, with two swabs collected from each patient. The results of the study were as follows:

		RapidTest Chlamydia Test	
		+	-
Latex One Step Immunoassay	+	36	1
	-	3	70

Compared with the latex one step immunoassay for detection of chlamydia from swab specimens, the **RapidTest Chlamydia Test** demonstrated 97.2% sensitivity (36 of 37) and 98.5% specificity (70 of 73). Overall agreement between the two tests is 96.3%.

REFERENCES

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5. Hipp, S.S., Y. Haun and D. Murphy. "Assessment of Enzyme Immunoassay and Immunofluorescence Tests for Detection of *Chlamydia Trachomatis*," *J. Clin. Microbiol.*, Vol. 25 (1987): 1938-1943.
6. Lennette, E. and Schachter, J. *Chlamydiae: Clinical Microbiology Manual*, Chapter 85, (American Society of Microbiology: 1985).

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