OnSite Chlamydia Rapid Test-Cassette (Swab)

REF

Catalog Number R0080C

IVD

In Vitro Diagnostic

INTENDED USE

The *OnSite* Chlamydia Rapid Test is a lateral flow immunoassay for the qualitative detection of *Chlamydia trachomatis (C. trachomatis)* antigen in endocervical or encourethral swab specimens. It is intended to be used as a screening test and as an aid in the diagnosis of the infection of *C. trachomatis*. Any reactive specimen with the *OnSite* Chlamydia Rapid Test must be confirmed with alternative testing method(s) such as antibody test, PCR and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

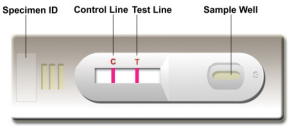
C. trachomatis is considered as the most common sexually transmitted bacterial pathogen[1]. At least 3 million new cases occur each year in the United States, with more than 80 million worldwide[2]. It is a major cause of cervicitis, urethritis, endometritis, and pelvic inflammatory disease in women. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and pneumonia. In men, complications of chlamydia infections include: urethritis and epididymitis. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic, which makes diagnosis extremely important.

The primary method for detection of chlamydia is growth of the organism in cell culture[3]. Other methods include direct fluorescence assays (DFA), enzyme immunoassays (EIA), and antigen test by nucleic acid probing, PCR or immunological antigen test[4-6].

The *OnSite* Chlamydia Rapid Test is an immunological antigen test, which provides an instant test result without special instrumentation or requirement of a skilled lab technician.

TEST PRINCIPLE

The *OnSite* Chlamydia Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique, which utilizes a unique pair of the mouse monoclonal antibody to selectively identify *C. trachomatis* antigen in the specimen. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse monoclonal anti-*C. trachomatis* antibody conjugated with colloid gold (antibody conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with another mouse monoclonal anti-*C. trachomatis* antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.



The *C. trachomatis* antigen is first extracted from the swab specimen with Reagent A. After neutralized by Reagent B, the antigen extracts are then dispensed into the sample well of the cassette. The extracts migrate by capillary action across the test cassette. *C. trachomatis* antigen if present in the extracts will bind to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a burgundy colored T band, indicating a *C. trachomatis* positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/antibody-gold conjugates regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Each kit contains 25 test devices, each sealed in a foil pouch with three items inside:
   a. One cassette device.
   b. One desiccant.
2. 1 vial of Extraction Buffer A (6 mL/vial)
3. 1 vial of Extraction Buffer B (6 mL/vial)
4. 25 sample extraction tubes
5. One package insert (instruction for use).

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Female swabs or male swabs for collecting swab specimen
2. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C -30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 15 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Swab specimen should be collected by standard male or female specimen collection methods.

Swabs should be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a dry, sterile, tightly capped tube or bottle and stored in refrigerator (2°C -8°C) for up to 5 days, preferably in a transportation tube.

A specimen swab which contains too much blood may cause weak false positive results. Therefore, bloody swabs should be avoided.

Do not freeze the swab.

Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

ASSAY PROCEDURE

1. Procedure Notes

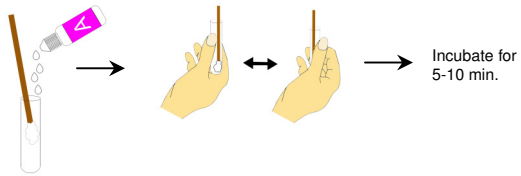
1.1 Bring all samples and controls to room temperature (15°C -30°C) prior to testing.

1.2 All drops must be free falling with the reagent bottles held vertically. In order to avoid contamination of reagents. Do not allow the tips of the bottles to come in contact with the extraction cups.

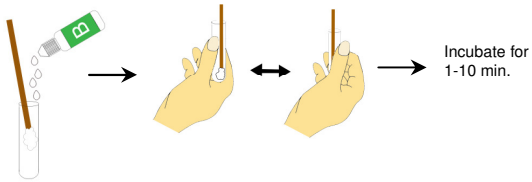
2. Extraction:

2.1 Label an extraction tube for each patient and place in a tube holder or rack.

2.2 Add 4 drops (200 µL) of **Extraction buffer A** to the extraction tube containing the specimen and twirl briefly to mix the reagent. Incubate at room temperature (15°C-30°C) for 5 minutes, but no longer than 10 minutes.



2.3 Add 4 drops (200 µL) of **Extraction buffer B** to extraction tube containing the swab. Twirl the swab vigorously for 10 seconds and incubate for 1 minute, but no longer than 10 minutes.



2.4 Then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab in a safety manner.

2.5 Cap the tube and mix contents by gentle swirling. The swab extract can be tested immediately or remain at room temperature for up to 3 hours without affecting test results.

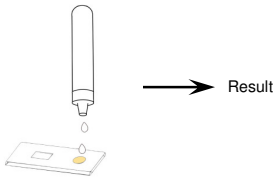
3. Perform Assay

3.1 Remove a Chlamydia Rapid Test device from its protective pouch. Place the test device on a clean, flat surface

3.2 Be sure to label the device with specimen's ID number.

3.3 Dispense 2 drops (100 µL) of liquid from the extraction tube to the sample pad. Don't

over load samples.



3.4 Set up timer.

3.5 Read the result within 15 minutes. Depending on the number of the *C. trachomatis* organisms on the swab, some positive results may be visible as soon as 1 minute. However, to confirm negative results the complete reaction time of 15 minutes is required.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

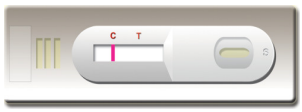
QUALITY CONTROL

Using individual *OnSite* Chlamydia Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

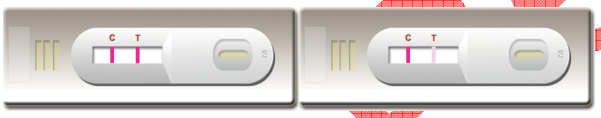
1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that no detectable *C. trachomatis* is present in the specimen. The result is negative or non-reactive.



2. **POSITIVE RESULT**: If both C and T bands are developed, the test indicates for the presence of *C. trachomatis* in the specimen. The result is positive or reactive.



Samples with positive results should be confirmed with alternative testing method(s) such as antibody test, PCR and clinical findings before a diagnostic decision is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 110 samples from susceptible subjects were tested by the *OnSite* Chlamydia Rapid Test and by a commercial latex rapid test. Comparisons for all subjects are shown in the following table:

	OnSite Chlamydia Rapid Test		
Latex rapid test	**Positive**	**Negative**	**Total**
Positive	32	2	34
Negative	2	74	76
Total	34	77	110

Relative Sensitivity: 94.1%, Relative Specificity: 97.4%, Overall Agreement: 96.4%

Cross-Reactivity

To confirm the specificity of *OnSite* Chlamydia Rapid Test, 15 serotypes were tested and demonstrated to yield Chlamydia-positive results. In addition *C. Pneumonia* and C. *psittaci* were tested with the *OnSite* Chlamydia Rapid Test and gave positive results.

Cross-reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml (CFU — colony forming unit) and demonstrated to yield Chlamydia-negative results. *Staphylococcus aureus* was tested at $1x10^6$ cells/test and also yielded negative results. The organisms tested are listed below:

Candida albicans	*Neisseria lactamica*	*Saccharomyces cerevisiae*
Escherichia coli	*Neisseria meningitides*	*Streptococcus faecalis*
Gardnerella vaginalis	*Neissera meningitidi*	*Streptococcus Group B*
Klebsiella pneumoniae	*Proteus vulgaris*	*Streptococcus pneumoniae*
Neisseria gonorrhoeae	*Pseudomonas aeruginosa*	

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of *C. trachomatis* antigen in the swab specimen from individual subjects. **For optimal test performance, proper sample collection and storage procedures are critical.** Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Chlamydia Rapid Test is limited to the qualitative detection of *C. trachomatis* antigen in human endocervical or encourethral swab specimens. The intensity of the test band does not correlate with antigen titer of the specimen.
3. The *OnSite* Chlamydia Rapid Test does not specifically differentiate between *C. Trachomatis*, *C. Pneumonia* or *C. Psittasi.* Detection of *Chlamydia* is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
4. A negative or non-reactive result for an individual subject indicates absence of detectable *C. trachomatis* antigen. However, a negative or non-reactive test result does not preclude the possibility of exposure to *C. trachomatis.*
5. A negative or non-reactive result can occur if the quantity of the *C. trachomatis* antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present in the swab specimen sampled, or improper sample treatment procedure.
6. If the symptom persists, while the result from *OnSite* Chlamydia Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device or alternative test methods.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Centers for Disease Control and Prevention. 1998 Guidelines from treatment of sexually transmitted disease. *MMWR* 1998;47:1-111
2. Gerbase AC, Rowley JT, Mertens TE. Global epidemiology of sexually transmitted disease. *Lancet* 1998; 351(Suppl 3): 2-4
3. Schachter J, Stamm WE. *Chlamydia.* In Murry PR, Baron EJ, Paller MA, Tenover FC, Yolken RH, eds: *Manual of clinical microbiology,* 7th ed. Washington DC: American Society for Microbiology, 1999: 795-806.
4. Chernesky, M.A. et al. "Detection of Chlamydia Trachomatis Antigens by Enzyme Immunoassay and Immunofluorescence in Genital Specimens from Symptomatic and Asymptomatic Men and Women," *J. Infect. Dis.*, Vol. 154 (1986): 141-148.
5. Hipp, S.S., Y. Haun and D. Murphy. "Assessment of Enzyme Immunoassay and Immunofluorescence Tests for Detection of Chlamydia Trachomatis," *J. Clin. Micriobiol.*, Vol. 25 (1987): 1938-1943.
6. Schachter J. NAATs to diagnose *Chlamydia trachomatis* genital infection: A promise still unfulfilled. *Exp. Rev. Mol. Diag* 2001; 1:137-144

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

PI-R0080C Rev. E
Effective date: 2011-05-10

For Export Only, Not For Resale In The USA