Chlamydia Trachomatis Test

Instructions for use

[Product Name] Chlamydia Trachomatis Test
[Packaging Specification] Cassette: 1T /bag; 10 T/box; 20 T/box; 30T/box; 50 T/box; 100T/box.
[Number] R16-112
[Intended Use]
Chlamydia Trachomatis (CT) Test adopts the colloidal gold method for the qualitative detection of CT in endocervical or endourethral swab specimens. The identification aids in the diagnosis of disease caused by Chlamydia Trachomatis.
Chlamydia Trachomatis is a type of microorganism that parasitizes cells. Human is its natural host. It primarily parasitizes mucous epithelial cells of the organism. Chlamydia trachomatis primarily invades young adults. The incubation period may vary from several days to several months after infection, generally 1-3 weeks. It is the main pathogen giving rise to non-gonococcal urethritis and approximately 40%-50% of non-gonococcal urethritis is caused by its infection. The manifestations are dominated by urethritis in males. Most of it will transform to chronic urethritis with aggravated periodicity if not cured. It may be complicated with epididymitis, proctitis etc. The manifestations are dominated by suppurative cervicitis, vaginitis and urethritis. In addition, ascending chlamydia trachomatis infection can also occur via the genital tract. It may cause acute or chronic pelvic cavity inflammations such as salpingitis, endometritis etc.

[Principle of The Test]
Chlamydia Trachomatis Test adopt the principle of double antibody sandwich method and are made of colloidal gold immunochromatography technology. The colloidal gold pad contains anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody I-Colloidal Gold Conjugate, the nitrocellulose membrane "T" band is coated with anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody II, and the "C" band is coated with goat anti mouse polyclonal antibody.
During detection, the processed sample is first mixed with anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody I-Colloidal Gold Conjugate, and the mixed solution is moved toward the "T" band by capillary action. If the sample contains Chlamydia trachomatis antigen, the Chlamydia trachomatis antigen will combine with the colloidal gold conjugate and the anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody II on the "T" band to form a double antibody sandwich complex, and gather on the "T" band to show a visible Red line, this is a positive result. No "T" band is a negative result.
Regardless of the presence of Chlamydia trachomatis antigen in the sample, the "C" band will be displayed. The appearance of the "C" band ribbon is a standard to judge whether there are enough samples and whether the immunochromatography process is normal.

[Major Components]
The CT test is made from solid base plate, sample pad, colloidal gold pad, and nitrocellulose membrane.
The colloidal gold pad is coated with anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody I- Colloidal Gold Conjugate.
The nitrocellulose membrane is coated with anti-chlamydia trachomatis lipopolysaccharide monoclonal antibody II and goat anti mouse polyclonal antibody.
Each box of product includes buffers (Buffer-A: NaOH solution (0.2M), Buffer-B: Tartaric Acid solution (0.2M)).

Item	Name
Material necessary for test that is provided	CT test reagent, desiccant, dropper, Buffer A and B, Female swab, sampling cup, stand
Material necessary for test that is not provided	Male swab, Stopwatch
Note: The components in the reagents of different batch numbers should not be interchanged for use to avoid any incorrect results.	

Female swab:

CE 0123

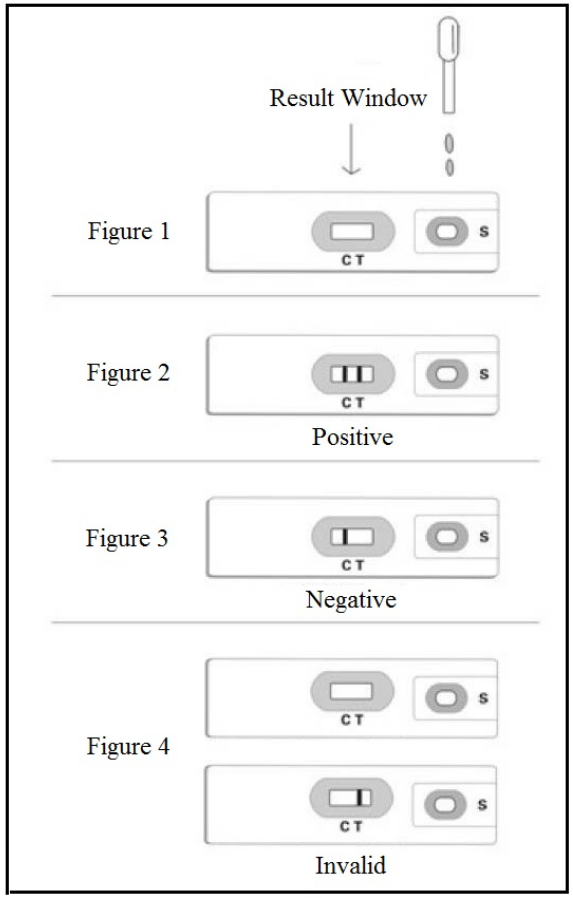
Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave, Huangyan, 318020 Taizhou, Zhejiang, China.

EC REP Shanghai International Holding Corp GmbH (Europe)
Eiffestrasse 80 20537 Hamburg, Germany.

[Storage Conditions and Expiration Date]
1. Storage Conditions: Chlamydia Trachomatis Test should be stored at room temperature 4℃-30℃. Be sure not to freeze the reagent. The test reagent should be used as soon as possible within 45 minutes after the aluminum foil bag is torn; it should be used immediately after the aluminum foil bag is torn particularly in an environment with the temperature over 30℃ or with a high humidity.
2. Expiration Date: 30 months. See the package for details.

[Specimen Requirements]
1. A correct sampling and collection technique is extremely important for detection of chlamydia trachomatis. Chlamydiae primarily parasitizes within the columnar epithelial cells of the cervical canals and urethra. To obtain proper specimens, the swab should be rubbed along the cervical canal or urethra. The following is the recommended sampling method during use of the product.
   A. Female cervical specimen:
      1) The swab provided should be used. A swab with flax or dacron head can also be used. Please do not use any swab containing cotton.
      2) The sticky sanies outside of the cervix should be removed by a tampon before sampling. A false positive result may occur if the specimen has a large amount of blood or sanies.
      3) Insert the swab into the cervical canal until most part of swab is invisible. Rotate the swab for 15-30 seconds. Please do not touch the vaginal wall when removing the swab.
   B. Male urethra specimen:
      1) Please do not urinate within 1 hour before sampling.
      2) Use a swab with a standard fiber head (not provided) to sample.
      3) Please insert the male swab into the urethra navicula (2-4cm) and rotate it for 3-5 seconds before removal.
2. The specimens collected should be tested as soon as possible. They should be stored in a sample collection tube (not provided) for consecutive 72 hours at 2-8℃ requiring no refrigeration if the specimens are not to be tested immediately.

[Test Method]
1. Add 6 drops of the Extraction Buffer A into the sampling cup. Place the specimen swab in the cup and twirl it vigorously to mix the reagents for about 15 seconds. Then incubate the mixture at room temperature for 3 minutes with the swab in the tube.
2. Add 6 drops of the Extraction Buffer B into the above sampling cup. Twirl the swab vigorously for 15 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.
3. The remaining mixed liquor can be tested immediately or remain at room temperature for at most 3 hours.
4. Place the product on a flat surface. Draw the mixed liquor with a sucker and drip 3 drops of the mixed liquor into the sample well (Figure 1). As the test kit begins to work, you will see purple color move across the Result Window in the center of the test disk.
5. Observe test results at 15 minutes. It is invalid interpret the result after 15 minutes.



[Judgment of Results]
POSITIVE RESULT: TWO COLOR BANDS
The presence of two purple bands ("T" band and "C" band). within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the stronger the "T" band color is and the quicker the coloration is. The higher the chlamydia trachomatis antigen level is in the specimen. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.
NEGATIVE RESULT: ONE COLOR BAND
If presence of only the "C" color band within the result windows, then it indicates a negative result (Figure 3).it means no chlamydia trachomatis antigen in the specimen.
INVALID RESULT:
If after performing the test no color band or no "C" color band is visible within the result window, then the test is considered invalid (Figure 4). The directions may not have been followed correctly or the test plate may have damaged. It is recommended that the specimen be re-tested with a new test plate after read the directions carefully again.

[Interpretation of the Test Results]
1. A false positive result may be obtained if the specimen contains a large amount of blood or sanies.
2. The Control Band (C) may be weak relatively when the Test Band (T) is very strong. It is a normal phenomenon.
3. Other clinical methods may be recommended for test if the test result is negative with clinical symptoms.

[Limitation of the Test]
1. The product is intended for qualitative detection of chlamydia trachomatis in secreta but not able to determine the content of chlamydia trachomatis in secreta.
2. The test results of the product can only serve as a reference for a doctor's synthetic judgment instead of the sole judgment criterion or clinical confirmation evidence. A further test should be conducted for confirmation.
3. The test result may be incorrect due to any possible technical or operational faults (Incorrect sampling, insufficient sample size, etc.) or potentially interfering substances that are not listed in the sample, please refer to the column of product performance indexes to check the list of interfering substances that may interfere with the detection.

[Reference Value (Range)]
The product sensitivity is determined to be 200ng/ml.

[Product Performance Indexes]
1. Specificity: The negative reference is tested negative using the CT test reagent.
2. Sensitivity: The 200ng/ml positive reference is tested positive using the CT test with sensitivity of 200ng/ml.
3. Reproducibility: The CT test for a dosage of 10 persons of the same batch number is tested with the positive reference of chlamydia trachomatis at a concentration of 500ng/ml and 200ng/ml. The reaction results are consistent (all are tested positive) and the color development is uniform.
4. Cross Reaction: The following microorganisms at the concentration of 1×10^6 CFU/ml would not have cross reactions with the test reagent.

Microorganism Type	Microorganism Concentration (CFU/ml)
Streptococcus Pneumoniae	1×10^6
Staphylococcus Aureus	1×10^6
Salmonella Typhimurium	1×10^6
Beta Hemolytic Streptococcus	1×10^6
Escherichia coli	1×10^6
Acinetobacter	1×10^6
Proteus vulgaris	1×10^6
Candida albicans	1×10^6
Neisseria gonorrhoeae	1×10^6
Pseudomonas	1×10^6

5. Interfering substances: Substances at the following concentrations will not interfere with the results of the reagents:
50ul/ml whole blood, 50ul/ml urine, 10mg/ml human albumin, 5mg/ml metronidazole (gel), 5mg/ml tinidazole (gel), 20ul/ml Jieeryin, 20ul/ ml Fuyinjie, chlorhexidine acetate 0.05%.

[Warnings]
1. For in vitro diagnostic use only.
2. The product is disposable. Please be sure not to reuse the product.
3. The product can be used only after recover to room temperature.
4. Please read the package insert carefully before use. Check the expiration date and the aluminum bag package. Please do not use the product if it expires or the aluminum bag is broken.
5. Buffer A contains sodium hydroxide and Buffer B contains tartaric acid. Flush the skin or eyes with copious amounts of water if either splashes onto the skin or into the eyes.
6. Wear a laboratory coat and protective gloves when collecting and testing specimens.
7. The specimens collected should be treated as a potential infection source. Eating and smoking are prohibited within the areas for specimen collection and testing.
8. The product should be disposed as specified by the hospital or environmental protection department after being used.

[References]

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4. Gupta PK, "Microbiology, Inflammation, and Viral Infection," Comprehensive Cytopathology, 1st ed, Bibbo M, ed, Philadelphia, PA: WB Saunders Co, 1991, 115-52.
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[GRAPHICAL SYMBOLS USED]

	Temperature limit
	In vitro diagnostic medical device
	Catalogue number
	Consult instructions for use
	Batch code
	Use-by date
	Manufacturer
	Authorized representative in the European Community
	Do not re-use
	Contains sufficient for <n> tests
	Skin corrosion and Serious eye damage

Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd.
K4-2 Science Technology Garden, Economic Development Zone, 314500
Tongxiang, Zhejiang, P.R. China
Tel.: 86-573-88111055
Fax: 86-573-88521527
www.ameritek.com.cn

Authorized representative in the European Community

CEpartner4U B.V.
Esdoornlaan 13, 3951 DB Maarn, The Netherlands
www.cepartner4u.com

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