One Step
Chlamydia Trachomatis (CT) Antigen Rapid Test
(Colloidal Gold)
(Swab)

Package Insert

(Catalog Number: H134)

A rapid, one step test for the qualitative detection of Chlamydia Trachomatis (CT) antigen in human swab.

For in vitro diagnostic use only.

PRODUCT NAME

One Step Chlamydia Trachomatis (CT) Antigen Rapid Test (Colloidal Gold)

PACK SIZE

Strip: 1 test/bag, 1 test/box, 20 tests/box, 40 tests/box, 50 tests/box, 100 tests/box

Cassette: 1 test/bag, 1 test/box, 20 tests/box, 40 tests/box, 50 tests/box, 100 tests/box

INTENDED USE

The reagent is used to detect the Chlamydia trachomatis antigen in female cervical swab and male urethral swab qualitatively.

Chlamydia trachomatis (Ct) is a kind of microorganism in the cell, which can infect the eye, the reproductive tract and other organs. Chlamydia is an important pathogen for causing urethritis and cervicitis. The ill population is mainly young adults. The incubation period of Ct is several days to several months, usually 1 to 3 weeks. In fact, 70% to 80% of women and 50% of men among the infected patients show no clinical symptoms, so that it is important to have a laboratory diagnosis. Immunochromatography detection of Chlamydia trachomatis is widely used in clinical diagnosis for its simple operation and quickness comparing to culture method and nucleic acid sequence-based amplification.

PRINCIPLE

The test utilizes antibodies including a goat anti-mouse IgG antibody and mouse anti-chlamydia lipopolysaccharide monoclonal antibody 2 on the nitrocellulose membrane with colloidal gold marked mouse anti-chlamydia lipopolysaccharide monoclonal antibody 1 as an mark tracer. The reagent is used to detect the chlamydia trachomatis antigen according to the principle of double antibody sandwich method and gold immunochromatography assay.

The specimen mixing up mouse anti-chlamydia lipopolysaccharide monoclonal antibody 1–marker move along the membrane to the T line, and form the T line with mouse anti-chlamydia lipopolysaccharide monoclonal antibody 2 when the specimen contains chlamydia trachomatis antigen, which a positive result. Conversely, it is a negative result.

MAIN COMPONENTS

1. The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mouse anti-chlamydia lipopolysaccharide monoclonal antibody, nitrocellulose membrane coated with mouse anti-chlamydia lipopolysaccharide monoclonal antibody， control line coated with goat anti mouse IgG antibody. The sample dilution A is made of 0.2M Na(OH), sample dilution B is made of 0.2M HCl.

2.

Pack size	Strip	Cassette	Sample Dilution	
			A	B
1 test/bag	1 test	1 test	1bottle	1 bottle
1 test/box	1 test	1 test	1bottle	1 bottle
20 tests/box	20 tests	20 tests	1 bottle	1 bottle
40 tests/box	40 tests	40 tests	2 bottles	2 bottles
50 tests/box	50 tests	50 tests	3 bottles	3 bottles
100 tests/box	100 tests	100 tests	5 bottles	5 bottles

3. Materials required but not provided: specimen tube, swab (depend on customer's requirement)

Description: different components of different batches cannot be used at the same time to avoid erroneous results

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity:20%~90%, Temp:10℃-50℃)

SAMPLE REQUIREMENTS

Quality of specimen is crucial. In order to ensure that there is sufficient amount of microorganisms to be tested in the swab, specimens must be collected from infected region (2-4cm inside the female cervical canal or male urethral orifice is the columnar epithelium, which is the most vulnerable area of Chlamydia.)

Female cervical sampling:

Use a cotton swab to clean the excess mucus outside the cervix before specimen collection. Put a swab 1-1.5 cm into the cervix, twist the swab several times and stay for 5-10 seconds before removal.

Male cervical sampling:

1. Use male urethral swab for collecting specimen. Be sure that there is no urination for at least 2 hours before specimen collection.

2. Put a swab 2-4 cm into the cervical, twist the swab several times and stay for 5-10 seconds before removal.

Put the swap into the specimen tube if the detection can be carry immediately. Specimens may be stored at 2-8℃ for 48h, and at -20 ℃ for 3 months. Frozen refrigerated samples should be recovered to room temperature before detection. Repeat freeze and thaw for only 1 time.

The samples that after adding into the tube may be stored at 2-8℃ for 48 hours or at - 20℃ for 3 months if it cannot be tested immediately.

The samples can be frozen and thawed for one time, and cannot be stored at - 20℃ again after thawing.

Please allow the samples to come to room temperature (Approximately 25℃) before being used.

TEST METHODS

1. *Instruction for Use* must be read carefully before taking the test. Allow the required test device to come to room temperature for 30 minutes (20℃-30℃) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened (Humidity:20%~90%, Temp:10℃-50℃)

2. Test Procedure

2.1 Specimen Preparation

(1) Drop 300 µL sample dilution A vertically into the specimen tube, put the swap with specimen on it into the tube immediately, squeeze the tube and twist the swab for 15 times, keep the swap stay inside for 2 minutes before removal.

(2) Drop 300 µL sample dilution B vertically into the specimen tube, squeeze the tube and twist the swab for 15 times, keep the swap stay inside for 1 minute before removal. Discard the swab and cover the lid of the tube.

2.2 Testing Steps

For Strip:

(1) Remove the test strip from the sealed pouch.

(2) Put the end of the test strip printed with arrows into the diluted specimen, the interface of liquid should not exceed the max line, take it out and place the test strip on a clean and level surface after 15 seconds.

(3) Observe the test results immediately within 15-20 minutes, the result is invalid over 25 minutes.

For Cassette：

(1) Remove the test cassette from the sealed pouch and place on a clean and level surface.

(2) Drop 3 drops of diluted specimen vertically into the specimen well (S) of the test cassette avoiding the formation of bubbles.

(3) Observe the test results immediately within 15-20 minutes, the result is invalid over 25 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. A red line in the control region (C), and another red line in the test region (T).

A pink to red line (T), even if it is very thin, indicates a positive result.

NEGATIVE: A red line appears in the control region(C). No line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons.

Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the kit and contact your local distributor.

POSITIVE NEGATIVE INVALID

LIMITATIONS

1. The results of the reagent only demonstrated the presence of Chlamydia trachomatis antigen in the specimen, which is not the only basis for clinical diagnosis and treatment. Chlamydia trachomatis antigen may still be retained a short term after the treatment.

2. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Limited by the detection method, the sensitivity was generally lower than that of the nucleic acid reagent. The experimental personnel should pay more attention to the negative results. If infection is still suspected, the specimen should be collected later and carry the detection with Nucleic acid detection or isolation and culture identification method.

4. False negative results may occur according to unreasonable specimen collection, transportation and sample preparation.

PERFORMANCE CHARACTERISTICS

1. Using enterprise quality control specimens:

Negative specificity: The results should all be negative when detecting 10 kits of Ct negative quality control specimens.

Positive specificity: The results should all be positive when detecting 10 kits of Ct positive quality control specimens. (Including strong, medium and weak positive specimens).

Limit of detection: Not less than 1×10^5 IFU/mL

Precision: The results should be consistent and the coloration degree should be consistent when detecting the precision control specimens by 10 kits of the same batch.

2. A clinical evaluation was conducted on 1000 specimens comparing the results obtained using the Diagnostic Kit for Chlamydia trachomatis Antigen and other commercially available Ct tests. The results demonstrated a 100% positive agreement.

3. Analytical sensitivity:

Jieeryin ≤20μL/mL, fuyinjie ≤20μL/mL, miconazole ≤5mg/mL, metronidazole ≤5mg/mL, tinidazole ≤5mg /mL has no effect on the detection result.

Staphylococcus aureus, candida albicans, escherichia coli, trichomonas vaginalis, S.faecium, S.faecalis, acinetobacter, alpha streptococcus, beta streptococcus, gamma streptococcus, human mycoplasma, bacillus proteus and neisseria gonorrhoeae (10^7 CFU/mL) showed no cross-reactivity.

4. Hook effect: the hook effect will not occur even the Ct concentration is as high as 9.64×10^7IFU/mL.

ATTENTIONS

1. For *IN VITRO* diagnose only.

2. Do not use after the expiration date.

3. The result is invalid over 25 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. There is no biological safety problem with the product itself, but the testing reagent and the specimen still should be treated as an infectious material after use.

BIBLIOGRAPHY

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[2] Yu Haiyan, Tao Yishun, Progress in Clinical Application of Immune Chromatography [J], Clinic Laboratory Information,1998, 4:118

[3] Valkirs GE, Barton R. Immunoconcentration-A New Format for Solid-phase Immunoassays. Clin chem, 1985,31:1427-1431.

INSTRUCTIONS OF SYMBOL

CE 0123	CE Mark, certified by TÜV SÜD		Keep dry
	Consult instruction for use	LOT	Batch number
	For single use	IVD	IVD product
	Store between		Date of manufacture
	Manufacturer		Contains sufficient for <n> tests
EC REP	European union representative		Expire date

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