IVD

Chlamydia trachomatis

Catalog No. M0102

25 tests

INTENDED USE

Autobio *Chlamydia trichomatis* test is a biochemical assay for the detection of *Chlamydia trichomatis* in clinical samples taken from the genital tract.

INTRODUCTION

Since the discovery of *Chlamydia trachomatis* inclusion body in 1907, along with technical development in examination, *C.trachomatis*, as a widely spread pathogen, is increasingly influential in sexually transmitted diseases (STD). It has exceeded gonorrhea as the STD with the most incidences, which accounts for 40 – 60% of non-gonococcal urethritis (NGU). *C.trachomatis* causes male urethritis, orchitis, epididymitis in men, causes urethritis, cervicitis, salpingitis in women, follicular conjunctivitis in newborns and staged pneumonia in young children. In addition, infertility and abortions can also be caused by *C. trachomatis. C. trachomatis* is a compulsory test item for the diagnosis of symptoms associated with urogenital tract infections.

C. trachomatis could be detected by many methods based on different technologies such as culture, immunofluorescence, PCR and colloidal gold, of which the colloidal gold method is the most commonly used. However, the colloidal gold method suffers a relatively poor sensitivity, which, to some extent, influences the clinical diagnosis of *C. trachomatis.*

BIOLOGICAL PRINCIPLE OF THE PROCEDURE

Invasion of C. trachomatis into the epithelial cells generates a glycogen structure, which reacts with anthrone under acidic conditions and the reaction can display a color change.

MATERIALS PROVIDED

1. Reaction Tube: test tube containing basal medium (25 tubes)
2. Chromogen Solution (2 vials, 5.5 mL/ea.)
3. Color Reference Card (1 piece)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Benchtop centrifuge
2. Heater capable of maintain a temperature at 80 ± 5 ℃.

STORAGE OF TEST KIT AND INSTRUMENTATION

Unopened test kits should be stored at 2 – 8℃ upon receipt. The test kit may be used throughout the expiry date of the kit (6 months from the date of manufacture). Refer to the package label for the expiry date.

SPECIMEN COLLECTION, PREPARATION, TRANSPORT AND STORAGE

1. Secretion is the recommended sample type for this assay.
2. Collect cervical secretions for female or urethral secretions for male with a sterile swab. Please note do not collect vaginal secretions for female.
3. Test samples on the same day of collection.

PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. This package insert must be fully understood prior to operation. The operation must be

stringently in accordance with the instruction for use.

3. This product is granted a state invention patent in P. R. China, patent No. ZL01133660.9., which is manufactured exclusively by Autobio.
4. Only use swabs made of synthetic material (e.g. polyester). Just stir the swab 3 – 5 times.
5. This product should be operated by a professional at room temperature (15 – 30℃) and with a relative humidity of 65% ± 20%, after operation, the rest of the reagent should be stored at 2 – 8℃.
6. It is important to ensure the epithelial cells are also collected, especially for the male specimen; for females, avoid collecting specimens in the menstruation period and pregnancy, taking the secretion from the cervix without touching the internal surface of the vagina.
7. When adding the Chromogenic Reagent, the bottle should be held upright. In case the Chromogen Solution is observed to have turned black, do not use it.
8. The reagents contain strong acid and alkaline, so pay attention to the corrosion.
9. Infected women would display slight ache, heaviness and distention, itching, pain in the waist, increased leucorrhea, along with other clinical symptoms after 2 - 3 weeks of infection. However, 30% carriers are asymptomatic.
10. Samples should be regarded as potentially infectious and be disposed of according to standard operating procedures for infectious diseases lab.

ASSAY PROCEDURE

1. Put the swab absorbed with secretion samples into the tube, stir 3 – 5 times, damp the swab. Centrifuge for 10 minutes at around 3000rpm. Remove the supernatant. Place the tube upside down on absorbent paper to dry.
2. Add 10 drops Chromogen Solution to the tube, mix thoroughly, incubate at 80 ± 5 ℃ for 10 minutes, then observe the color change.

INTERPRETATION OF RESULTS

Compare to the Color Reference Card

1. When the yellow color turns to green or blue, a positive result could be reported.
2. When the light yellow color does not change or turns to colors other than green or blue such as pink, a negative result could be reported.

LIMITATION

1. Secretions from women in the menstruation and pregnancy period have a increased level of glycogen. So samples taken under these conditions may generate false positive results. Sample collection should avoid menstruation and pregnancy period.
2. It is found by experiments that *Candida* may lead to false positive results; hence the samples must be cervical secretions.

SYMBOLS

LOT	**BATCH CODE**
	USE BY
	MANUFACTURER
Σ	**CONTAINS SUFFICIENT FOR <n> TESTS**
IVD	***IN VITRO* DIAGNOSTIC MEDICAL DEVICE**
	TEMPERATURE LIMITATION

REF	**CATALOGUE NUMBER**
	CONSULT INSTRUCTIONS FOR USE

REFERENCES

1. Chiappino M. L., Dawson C., Schachter J., et al. *J. Bacteriol.* **1995,** 177, 5358.
2. Yang C., Zhu D. *J. Clin. Microbiol.* **1998,** 36, 1081.

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