Gonorrhea+Chlamydia Antigen Combo Test Cassette

Specimens: Secretion
Version: 02 **Effective Date:** 2022-05

CE 0123 **For professional in vitro diagnostic use only**

INTENDED USE

Gonorrhea+Chlamydia Antigen Combo Test Cassette is a lateral flow immunoassay for the qualitative detection antigen of chlamydia and Gonorrhea in clinical specimens without other supporting instruments. It is used as an auxiliary diagnosis of clinical chlamydia and Gonorrhea.It is for in vitro diagnostic use only.

SUMMARY

Chlamydia trachomatics

Chlamydia trachomatics, an obligate intracellular human pathogen, is one of three bacterial species in the genus Chlamydia. Chlamydia trachomatics infection is one of the most common 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. trachomatics infection has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility. Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis and pneumonia. In men, C.trachomatics causes urethritis, orchitis, epididymitis.

Neisseria Gonorrhea

As one of most common sexually transmitted diseases, Gonorrhoea is caused by its pathogen is Nesseria Gonorrhea. Human body is sole host of N. Gonorrhea which usually adheres to columnar epithelial cells of mucosal surface. Pathogenic materials of N. Gonorrhea mainly contain flagella, membrane protein, protease, lipopolysaccharide, etc, which directly infect urogenital tract, oropharynx and rectal mucosa during sexual intercourse or newborn baby through birth canal to cause simple gonorrhea, pelvic inflammatory disease, oropharyngeal and anorectal disease, gonococcal conjunctivitis and disseminated gonorrhoea in clinical manifestation. Therefore, it is very important for early diagnosis and treatment of N.Gonorrhea.

TEST PRINCIPLE

Gonorrhea+Chlamydia Antigen Combo Test Cassette is a lateral flow chromatographic immunoassay. The Chlamydia antigen test strip consists of two parts.The first part of the cassette is a burgundy colored pad,which containing conjugates of mouse anti Chlamydia monoclonal antibody and colloidal gold.The other part of the cassette is a nitrocellulose membrane strip containing two test bands(T band and C band).The T band is pre-coated with mouse anti Chlamydia monoclonal antibody and the C band is pre-coated with goat anti mouse antibody.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. If Chlamydia antigen exists in the sample, it will combine with the conjugates of mouse anti Chlamydia monoclonal antibody and colloidal gold. The immune complex was captured on the membrane by the pre-coated mouse anti Chlamydia monoclonal antibody to form burgundy color of T band, indicating the positive result of Chlamydia test. The missing color of T band indicates the negative result of Chlamydia test.
The Gonorrhea antigen test strip consists of two parts.The first part of the cassette is a burgundy colored pad, which containing conjugates of mouse anti Gonorrhea monoclonal antibody and colloidal gold. The other part of the cassette is a nitrocellulose membrane strip containing two test bands(T band and C band).The T band is pre-coated with mouse anti Gonorrhea monoclonal antibody and the C band is pre-coated with goat anti mouse antibody.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. If Gonorrhea antigen exists in the sample, it will combine with the conjugates of mouse anti Gonorrhea monoclonal antibody and colloidal gold. The immune complex was captured on the membrane by the pre-coated mouse anti Gonorrhea monoclonal antibody to form burgundy color of T band, indicating the positive result of Gonorrhea test. The missing color of T band indicates the negative result of Gonorrhea test.
The test card also contains a quality control C band. The superfluous conjugates of mouse anti Chlamydia or Gonorrhea monoclonal antibody and colloidal gold migrates by capillary action across the cassette.The immune complex was captured on the membrane by the pre-coated goat anti mouse antibody to form burgundy color of C band.Regardless of the presence or absence of T band, the quality control C band should form burgundy color. If the quality control C band does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

KIT COMPONENTS

COMPONENTS	DETAIL	NUMBER
Individual packed combo test devices	Each device contains strip with colored conjugates and reactive reagents precoated at the corresponding position.	1/20 pcs
Buffer A	Main Ingedients: NaCl, NaOH, and purified water	1/7 ml
Buffer B	Main Ingredients: BSA, sodium Azide, and purified water	1/7 ml
Plastic Extraction Tube	For specimens preparation use	1/20 pcs
Disposable sterile swab	Disposable sterile swabs is used for specimen collection, which is CE certified	1/20 pcs
Package Insert	For operation instruction	1 pc

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND VALIDITY

- The kit should be stored at 2-30°C in a cool and dry place, protected from light.
- The test device is stable through the expiration date printed on the sealed pouch.
- Do not freeze.
- Do not use after the expiration date indicated on the package.
- The validity duration is 24 months.

SPECIMEN COLLECTION

The quality of specimen collected is extremely important. Detection of Chlamydia and Gonorrhea requires a rigorous and thorough collection technique which provides viable cellular tissues rather than just secretion. For female endocervical specimens, the specimens are invalid if the swab inserted into endocervical cannal is less than 1/2 deep or contaminated by exocervical or vaginal cells. For male urethral specimens, the specimens are invalid if the patient urinates within 1h or the swab inserted into urethra less than 2cm deep.
The operation of swab according to the instruction on swab labeling.

For female endocervical specimens:

- Use only dacron or polyester tipped sterile swabs. It is recommended to use the swab supplied by the kits manufacturer. Swabs with cotton tips are not recommended.
- Before specimen collection, remove excess mucus from the endocervical area with a separate swab or cotton ball and discard .The swab should be inserted into the endocervical cannal, past the squamocolumnar junction, until most of the tip is no longer visible. This will permit acquisition of columnar or cubical epithelial cells which are the main reservoir of CT and NG organisms. Firmly rotate (clockwise or anticlockwise) the swab in a circle and stay for 10 seconds without being contaminated with exocervical or vaginal cells.

For male urethral specimens:

- Standard Dacron tipped sterile swabs should be used for urethral specimen collection. Instruct the patients not to urinate at least one hour prior to specimen collection.
- Insert the swab into the urethra about 2-4cm; firmly rotate (clockwise or anticlockwise) a circle and stay for 10 seconds , withdraw it, and place it into the extraction tube, if the swab may be tested immediately. If not, place the specimen into a dry transport tube for transport and storage.

For male urine specimens

- Collect the first urine (approximately 15-30ml) in the morning. The maximum of C. trachomatics antigens can be detected from the first urine in the morning.
- Specimen should be stored 24 hours at 2-8°C, if immediate testing is not allowed.
- Shake and mix the specimen, 10ml specimen is drawn into centrifugal tube with 10ml distilled water, centrifugate the mixture at 3000rpm/s for 15-20 mins.
- Discard the supernatant carefully. Turn over the centrifugal tube, absorb the residual urine with absorbent paper.

Storage of specimens:

- The swabs maybe stored for 4-6 hours at room temperature (15-30°C) or 24- 72 hours at 2-8°C, freeze is forbidden. It is strongly recommended that test the specimen immediately after collection.
- All specimens should be brought back into room temperature of 15-30°C before testing.

PROCEDURE

- Read the entire procedure carefully prior to testing. Bring tests, specimen and buffer to room temperature (15-30°C) before use.
- Do not open the foil pouch until ready to perform the test.
- Place the tests on a clean and flat surface.
- Extract Chlamydia trachomatics and Neisseria Gonorrhea antigens according to different specimens.

Prepare endocervical or Urethral swab specimens:

- Add 5 drops of buffer A into the extraction tube vertically. Immerse the specimen swab into the extraction tube. Squeeze the tube and twirl the swab for 15 times. Then keep the swab into the extraction tube for 2 minutes.
- Add 5 drops of buffer B into the same extraction tube. Deposit may be produced in the mixture. Squeeze the tube and twirl the swab for 15 times. Then keep the swab into the extraction tube for one minute. The solution will be brown if the swab with blood. Squeeze and discard the swab. Finally, cover the extraction tube with dropper.
- Add 2 drops of extracted samples from extraction tube to both CT and NG sample well(S) on the test cassette.
- Read the result within 10-15 minutes. Positive result may be read within 10 minutes, negative result may be read within 15 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS

Chlamydia Trachomatics test strip:

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region(C) and another band appears in the test region (T). The result is positive for CT, This is indicates there has Chlamydia Trachomatics Antigen in the specimen.

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).The result is negative for CT, This is indicates there has no Chlamydia Trachomatics Antigen in the specimen.

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Neisseria Gonorrhea test strip:

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region(C) and another band appears in the test region (T).The result is positive for NG, This is indicates there has Neisseria Gonorrhea Antigen in the specimen.

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). The result is positive for NG, This is indicates there has Neisseria Gonorrhea Antigen in the specimen.

NVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But in the valid time, even the color band is very week, the result should be regarded as positive.

LIMITATIONS OF THE TEST

1. Read the entire procedure carefully prior to testing, incorrect performance may lead to incorrect results.
2. The Test Kit is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Chlamydia trachomatics and Neisseria Gonorrhea antigens.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be confirmed by the physician after all clinical and laboratory findings have been evaluated.
4. This kit is intended for an aid in the diagnosis of Chlamydia trachomatics and Neisseria Gonorrhea infection.
5. Only Dacron or Polyester swab can be used to collect endocervical samples, and the kit has Dacron swabs.

PERFORMANCE CHARACTERISTICS

1. 1025 cases were detected simultaneously with the Encode Chlamydia trachomatics antigen test kit and the same kind of product by blind method. The results were as follows.

		Contrast agents		
		positive	negative	total
Encode	positive	201	34	235
	negative	15	775	790
total		216	809	1025
Positive coincidence rate		93.1%		
Negative coincidence rate		95.8%		

2. 1000 cases were detected simultaneously with the Encode Neisseria Gonorrhea antigen test kit and the same kind of product by blind method. The results were as follows.

		Contrast agents		
		positive	negative	total
Encode	positive	219	6	255
	negative	10	765	775
total		229	771	1000
Positive coincidence rate		95.6%		
Negative coincidence rate		99.2%		

3, Analytical Sensitivity:

	Analytical Sensitivity	Type	Source
Chlamydia	$2x10^3$ IFU/ml	Inclusion body antigen	maxmed laboratories.inc
Gonorrhea	$3x10^4$ CFU/ml	ATCC 19424	GDMCC

4. Analytical Specificity: Compared with difference kinds infection factors and the test result are negative.

		Concentration	Source
Candida albicans	ATCC1023	$6*10^8$CFU/ml	GDMCC
Candida tropicali	ACCC20005	$6*10^8$CFU/ml	
Candida near smooth	ACCC20221	$6*10^8$CFU/ml	
Streptococcus fae cium	ATCC29212	$6*10^8$CFU/ml	
Proteus mirabilis	CMCC49005	$6*10^8$CFU/ml	
Staphylococcus a ureus	ATCC6538	$6*10^8$CFU/ml	
Escherichia coli	ATCC8739	$6*10^8$CFU/ml	
Pseudomonas aer uginosa	ATCC9027	$6*10^8$CFU/ml	
mycoplasma hominis	ATCC23114	$1×10^4$CCU/ml	Zhuhai Skin Disease Prevention and Control Institute
Ureaplasma urealyticum	ATCC2781	$1×10^4$CCU/ml	

5. Interference: After testing, the following interferences have no effect on the results. 50μl/ml whole blood, 5mg/ml mucoprotein, 50μl/ml urine, 5mg/ml nystatin, 5mg/ml miconazole, 5mg/ml tinidazole, 5mg/ml metronidazole (gels), 50μl/ml Jieeryin (lotion), 50μl/ml Fuyinjie(lotion).
6. Intra-batch Discrepancy: The test results are the same in one batch.
7. Inter-batch Discrepancy: The test results are the same in different batch.
8. Hook effect: No high dose hook effect was observed when tested with up to a concentration of 2.0×108 ifu/ml chlamydia positive reference, and 30×108 cfu/ml gonorrhea positive reference.

PRECAUTIONS

- For disposable use only.
- For professional in vitro diagnostic use only.
- The specimen dilution buffer contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. Do not drink or smell it.
- Do not use the devices when the package is damaged.
- Do not use the swab when the package is damaged.
- Do not interchange or mix reagents from different lots.
- Do not use after the expiration date indicated on the package.
- Do not touch membrane before performance.
- After the test procedure is completed, dispose of the test kit,tube and swab according to local regulations.
- Buffer A:Causes severe skin burns and eye damage.
- Buffer B:Fatal if swallowed.Very toxic to aquatic life.Contact with acids liberates very toxic gas.
- The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.

LITERATURE REFERENCES

1. Beggs M,Novotny M, Sampedro S,et al.A self-performing Chromatographic immunoassay for the qualitative determination of human chorionic gonadotrophic (HCG) in urine and serum ClinChem ,1990,36:1084
2. Valkirs G.E,Barton R, immunoconcentration A new format for solid- phase immunoassay Clinchem .,1985 31:1427
3. Knapp,J.S et al. Neisseria Gonorrhea, Manual of Clinical Microbiology, Sixth Edition, ASM press, Washington DC.,324-325(1995)
4. Centers for Disease Control and Prevention, Sexually Transmitted Diseases Treatment Guidelines 2002 Morbidity and Mortality Weekly Report(2002),51(rr-6)
5. Chlamydia trachomatis infection & female infertility Abida Malik, S.Jain. S.Hakim, I Shukla& M.Rizvi Indian J Med Res 123,June 2006.pp 770- 775.
6. Chlamydia trachomatis antibody titres by enzyme-liked immunosorbent assay are useful in predicting severity of adnexal adhesion M.Tanikawa. T.Harada,C. Katagiri. Y.Onohara,S.Yoshida and N.Terakawa Human Reproduction Vol 11 no 11 pp 2418-2421.1996.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		Guard against damp
	Keep out of the direct sun	EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		

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