Neisseria Gonorrheae (NGH) Antigen Rapid Test Strip (Colloidal Gold)

Strip

Instruction for Use

A rapid test for the qualitative detection of Gonorrhoea（GNH）antigen in the secretory specimen from human urogenital system

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) is a lateral flow immunochromatographic assay for the visual detection of Neisseria Gonorrheae (NGH) antigen in the secretory specimen from human urogenital system. It is used as an aid in the diagnosis of gonococcus infection. The test is recommended for professional use only. All results must be interpreted together with other clinical information or other diagnosis methods available to the physician.

SUMMARY

Sexual transmitted diseases (STDs) happen widely in the world nowadays. Among them the incidence of gonorrhea is the highest over 70% of all STDs. Specially in recent years, resistant strains of gonorrhea are appearing rapidly which make the disease more popular. Neisseria gonorrhoeae, also known as gonococci (plural), or gonococcus (singular), is a species of Gram-negative coffee bean-shaped diplococci bacteria responsible for the sexually transmitted infection gonorrhea.[1] N. gonorrhoeae is the causative agent of gonorrhea (also called "The Clap," which is derived from the French word "clapier," meaning "brothel") and is transmitted via sexual contact. Symptoms of infection with N. gonorrhoeae differ depending on the site of infection. Note also that 10% of infected males and 80% of infected females are asymptomatic. Infection of the genitals can result in a purulent (or pus-like) discharge from the genitals which may be foul smelling. Symptoms may include inflammation, redness, swelling, and dysuria N. gonorrhoeae can also cause conjunctivitis, pharyngitis, proctitis or urethritis, prostatitis and orchitis. Disseminated N. gonorrhoeae infections can occur, resulting in endocarditis, meningitis or gonococcal dermatitis-arthritis syndrome. Dermatitis-arthritis syndrome presents with arthralgia, tenosynovitis and painless non-pruritic (non-itchy) dermatitis. Infection of the genitals in females with N. gonorrhoeae can result in pelvic inflammatory disease if left untreated, which can result in infertility. Pelvic inflammatory disease results if N. gonorrhoeae travels into the pelvic peritoneum (via the cervix, endometrium and fallopian tubes). Infertility is caused by inflammation and scarring of the fallopian tube. Infertility is a risk to 10 to 20% of the females infected with N. gonorrhoeae.

Current diagnosis methods for N.Gonorrhea infection mainly are smear staining, isolated culture, the immunological method and probe hybridization. The sensitivity of smear staining is low of detection rate only around 50%. Isolated culture requires high laboratory conditions and long time, while probe hybridization has a higher requirement on laboratory equipment and cost. The Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) is a membrane based immunoassay for the qualitative detection of gonorrhea antigen in the secretory specimen from human urogenital system. Monoclonal and polyclonal antibodies are employed to identify gonorrhea specially. Both sensitivity and specificity of the test are higher than those of the present methods that often involved long hours of culturing collected specimen. Test results are not affected by medication that is being taken. Results are read visually without any instrumentation. This test is idea for screening specimen samples containing minimum $1*10^5$ bacteria per ml.

PRINCIPLE

The Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) is a qualitative, membrane based immunoassay for the qualitative detection of gonorrhea antigen in the secretory specimen from human urogenital system. The membrane of the test is pre-coated with monoclonal antibodies to Neisseria Gonorrhea (NGH). During testing, the specimen is added into the sample pad and NGH antigen if present will react with antibodies coated particles in the membrane strip. The mixture then migrates upwards by capillary action on the membrane and reacts with monoclonal antibodies on the membrane in the test line (T) region. If the specimen contains NGH antigen, a pink test line (T) will appear, indicating a positive result. If the specimen does not contain NGH antigen, the test line (T) will not appear, indicating a negative result. The test contains an internal control line (C) which should always exhibit a pink line regardless of the color in the test region. Otherwise, the test result is invalid and the specimen must be retested with a new test.

REAGENTS AND MATERIALS PROVIDED

Test devices. Each test strip is sealed in a foil pouch with a package of desiccant.
Specimen diluent 1
Specimen diluent 2

MATERIALS REQUIRED BUT NOT PROVIDED

1. Swab for male or female patients
2. A clean and dry microtube for holding specimen
3. Clock or Timer

PRECAUTIONS

1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use it after the expiration date.
4. All patient samples should be treated as if capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedure.

REAGENT STORAGE INSTRUCTIONS

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND HANDLING

1. Use the swab to collect specimen in the following suggested method:

a) **Male patients:** Swab discharge from the opening of the urinary tract. If no discharge is present, insert the swab 2-3 cm to the urinary tract, gently move a few turns and retrieve the swab.

b) **Female patients:** Swab discharge from the vaginal opening, then insert swab into vagina for half a minute and retrieve the swab.

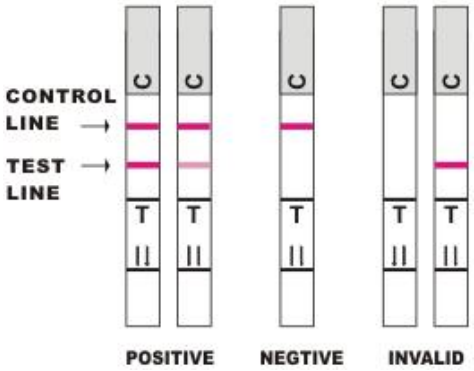
2. Place the swab into a microtube and add 6 drops (about 300uL) specimen diluent1 on the swab. Rotate the swab and squeeze. Discard the swab into an appropriate biohazard disposal container. Then add 2drops (about 100uL) diluent 2 into the microtube and mix well. Specimen collected in the diluent could be stored at 4-8℃ and tested within 24hours.
3. If specimens are to be shipped, they should be packed in compliance with government regulations covering the transportation of etiological agents.

ASSAY PROCEDURE

Test device, patient's samples, and controls should be brought to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test strip from the foil pouch and place it on a clean and level surface. Be sure to label the strip with specimen's ID number.
2. Dip the test strip with the arrow pointing down into the specimen for minimum 10-15 seconds. Do not immerse over the max line. Then take the strip out and lay it flat on a clean, dry and non-absorbent surface.
3. Start the timer. Read strong positive result at 5 minutes. Read weak positive and negative results at 30minutes. **Do not read results after 30 minutes.**

INTERPRETATION OF ASSAY RESULT



(Please refer to the illustration)

NEGATIVE RESULT: Only one colored band appears on the control(C) region, and no apparent band on the test (T) region.

POSITIVE RESULT: In addition to a pink colored C band, a distinct pink colored band will also appear on the test (T) region.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

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 test. If the problem persists, contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

Accuracy:

An overall agreement of 99.8% was found in the comparative testing work conducted on over 1000 tests of Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) and another well-known commercial Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold).

Sensitivity:

Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) has a sensitivity of detecting specimen samples containing minimum $1*10^5$ bacteria per ml

Interference:

No interference observed in the interference study of Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold). There is no cross-reaction with common pathogenic bacteria from human urogenital system such as Escherichia coli, enterococcus, Staphylococcus aureus, and Pseudomonas aeruginosa.

LIMITATIONS OF TEST

1. Failure to follow the procedures of assay and test result interpretation may give inaccurate results.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. A negative result for an individual subject indicates absence of detectable Neisseria Gonorrhea (NGH) antigen or the specimen samples containing Neisseria Gonorrhea (NGH) antigen lower than $1*10^5$ bacteria per ml, but does not preclude the possibility of exposure to or infection with NGH.
4. The Neisseria Gonorrheae（NGH） Antigen Rapid Test Strip (Colloidal Gold) is a qualitative screening test for the presence of Neisseria gonorrheae (NGH) antigen. If test results are negative but clinical symptoms are indicative of gonorrheal infection, further tests are recommended. Cell culture is the standard reference test method for the detection of Neisseria gonorrheae.

BIBLIOGRAPHY

1. Ryan KJ, Ray CG (editors) (2004). Sherris Medical Microbiology (4th ed.). McGraw Hill.
2. Genco, C; Wetzler, L (editors) (2010). Neisseria: Molecular Mechanisms of Pathogenesis. Caister Academic Press.
3. Stern, Anne; Brown, Nickel, Meyer (10). "Opacity genes in Neisseria gonorrhoeae: Control of phase and antigenic variation". Cell 47 (1).
4. Cahoon, Laty; Seifert (4). "Focusing homologous recombination: pilin antigenic variation in the pathogenic Neisseria". Mol. Microbiol. 81 (5): 1136–1143.
5. Michod RE, Bernstein H, Nedelcu AM (2008). Adaptive value of sex in microbial pathogens. Infect Genet Evol 8(3):267-285. Review.

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Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃-30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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