Gonorrhea Rapid Test

Cat. No.:DTS195
Pkg.Size:25 tests

Intended use

The Gonorrhoe Rapid Test is a rapid, direct binding test for the visual detection of gonorrhoea antigen, in the secretory specimen from urogenital system.
Test results are unambiguous and can be read in 10-20 minutes. The test kit is easy to operate and does not involve washing or comparison to standards.

General Description

Gonorrhea (colloquially known as the clap) is a common human sexually transmitted infection caused by the bacterium Neisseria gonorrhoeae. The usual symptoms in men are burning with urination and penile discharge. Women, on the other hand, are asymptomatic half the time or have vaginal discharge and pelvic pain. In both men and women if gonorrhea is left untreated, it may spread locally causing epididymitis or pelvic inflammatory disease or throughout the body, affecting joints and heart valves. Treatment is commonly with ceftriaxone as antibiotic resistance has developed to many previously used medications. This is typically given in combination with either azithromycin or doxycycline. There have been some strains of gonorrhea showing resistance to ceftriaxone.

Principle Of The Test

The Gonorrhoe Rapid Test is based on the principle of double sandwich immunoassay for the detection of gonorrhoea antigen in the secretory specimen. Monoclonal and polyclonal antibodies are employed to identify gonorrhoea specifically. Both sensitivity and specificity of the test are higher than those of the present methods, which often involve long hours of culturing the collected specimen. Test results are not affected by any medication that is being taken. Results are read visually without any instrumentation. This test is ideal for screening specimen samples containing at least 1 x10^5 bacteria per ml.
The assay is conducted by adding diluted swabbed discharge specimen to the test device and observing the formation of coloured lines. The specimen migrates via capillary action along the membrane to react with the coloured conjugate. Positive specimens react with the specific coloured antibody conjugates and form a coloured line at the test line region of the membrane. Absence of this coloured line suggests a negative result. To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

Reagents And Materials Provided

1. Gonorrhoea test cassette in foil pouch
2. Test tubes (25 per kit box)
3. Reagent 1 (1 per kit box)
4. Reagent 2 (1 per kit box)
5. Package insert (1 per kit box)

Materials Required But Not Supplied

Timer

Storage

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

The test kit can be stored at temperatures between 2 °C to 30 °C in the sealed pouch to the date of expiration.
The test kit must be kept away from direct sunlight, moisture and heat.
The expiration dating was established under these storage conditions.

Specimen Collection And Handling

Use only Dacron or Rayon tipped sterile swabs with plastic shafts. It is recommend to use the swab supplied by the kits manufacturer(The swab are not contained in this kit, for the ordering information, please contact the manufacturer or local distributor). Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.
1. Use a swab to collect specimen in the following suggested method:
a. Male sample specimens: Swab discharge from the opening of the urinary tract. If no discharge is present, insert the swab 2-4 cm into the urinary tract, gently move a few turns and retrieve the swab.
b. Female sample specimens: Swab discharge from the vaginal opening, then insert swab into vagina for half a minute and retrieve the swab.
Remark: Collect 20-30ml morning urine in the sterile container. Patient cannot drink water before collecting urine. Centrifuge the urine samples, discard the upper clear urine and take out the sediment for testing(Note: Although urine samples can work, secretion samples have high sensitivity.)
2. Place the swab into the test tube and add 6 drops (300 µl) of reagent 1 onto the swab, rotate swab at least 10 seconds.
Place the flocked swab in the test tube and rotate the flocked swab between two fingers for 10-15 seconds.
Discard the swab according to federal state and local regulations.
Then add 2 drops (100 µl) of reagent 2 into the test tube and mix well. Fit the dropper tip on top of the extraction tube.
Specimen collected in the solution should be stored at 4 °C to 8 °C and tested within 24 hours.

Assay Steps

Allow the test and the specimen to equilibrate to room temperature (15 °C to 30 °C) prior to testing.
1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test cassette from the pouch and use it as soon as possible.
2. Dispense 2 full drops into the sample well of the cassette.
3. Wait for the coloured lines to appear. Depending on the concentration of bacteria in the test specimen, positive results may be observed in as little as few seconds.
To confirm negative results, the test must be read again in 20 minutes.
Do not read results after more than 20 minutes.
Note: A low bacterial concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.

Quality Control

1. A coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
2. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.
3. External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly.
4. It is recommended that a control be tested at regular intervals as good laboratory testing process. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

Interpretation of Results

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NEGATIVE: Only one coloured line appears on the control region. No apparent line on the test region.
POSITIVE: Distinct colour lines appear on the control and test regions. The test result can be read as soon as the distinct coloured lines appear in the test region.
INVALID: No line appears in the control zone “C”, the test should be voided since an improper test procedure may have been performed or deterioration of reagents may have occurred. This is due to the internal control built in which a distinct control region (C) line should always appear. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Performance Characteristics

1. Expected Values: The Test is designed to show a positive result for Neisseria gonorrhoeae at a concentration of 1 x 10^5 bacteria/ml.
2. Accuracy: 150 patients were testd for gonorrhoeae infection and their swab specimens were tested in parallel using this Gonorrhea Test(Colloidal Gold) and a conventional culture test. Relative sensitivity is 97.9%. Relative Specificity is 97.5%.
3. Interfering Substances: The cross reactivity of product was evaluated using other bacterium strains. E. Coli, Salmonella Typhi, Staphyloccus Aureus, Pseudomonas Aeruginosa, Shigella and Proteus were added to samples and were tested for cross reactivity. No cross reactivity was observed.

Precautions

1. In research use only, For professional use only.
2. Do not use test kit beyond the expiry date.
3. The test device should not be reused.
4. Specimens may contain infectious agents and should be handled as though capable of transmitting disease.
5. Wear disposable gloves throughout the specimen collection and assay procedures.

REFERENCES

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