Science with a Mission, Inc. (SMI)
602 Massapoag Avenue
Sharon, MA 02067
Tel. or Fax (781) 784-6907
Web Address: www.sciencewithamission.org

Gonorrhea Test Cassette (Urine/Swab)

A rapid test for the diagnosis of gonorrhea by detection of gonorrhea antigen.

For professional in vitro diagnostic use only.

Intended Use

The SMI Gonorrhea Test Cassette (Urine/Swab) is a rapid and sensitive direct binding test for visual detection of gonorrhea in urine or a secretory specimen.

Summary

This Gonorrhea Test Cassette uses a rapid direct binding test that qualitatively detects the presence of gonorrhea antigen in urine or secretory specimens from urogenital system. The test utilizes monoclonal antibodies to selectively detect gonorrhea antigen in urine or a secretory specimen. This Gonorrhea Test shows no cross-reactivity interference from any medication that is being taken. The test is ideal for screening samples containing at least 1 X 10^5 bacteria per mL.

Principle

This Gonorrhea Test Device (Urine/Swab) is a rapid direct binding test based on the principle of a double sandwich immunoassay for the qualitative detection of gonorrhea antigen in urine and secretory specimen to aid in the early detection of gonococcus infection. The assay is conducted by adding pre-treated specimen to the sample well of the cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored dried conjugate of colloidal gold-monoclonal antibody. The sample reconstitutes the dried conjugate. If gonococcus antigen is present in the sample, it will react with the monoclonal antibody to form a complex of colloidal gold-monoclonal antibody-gonorrhea. This complex migrates up the membrane strip chromatographically and through the band of immobilized antibody. Because the immobilized antibody is able to bind to the gonococcus antigen molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized antibody. If there is no gonococcus antigen is present in the treated sample, the colloidal gold-monoclonal antibody conjugate will pass through the immobilized antibody band and no colored line will form – a negative test result.

Further up the membrane, past the test region, is a control region. This band of antibody will bind only conjugate and form a colored line, regardless of whether gonococcus antigen is present in the sample or not. Appearance of the control line assures reagent integrity as well as correct testing procedure.

Precautions

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as infectious agents. Wear disposable gloves throughout specimen collection and assay procedure.
- The test should be discarded in a proper biohazard container after testing.

Storage & Stability

Store as packaged in the sealed pouch at 4 -30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials provided:
- Test Cassette
- Instructions
- Extraction Buffer
- Extraction tube / dropper tip

Female Testing Kit Only
- Female Swabs: Plastic-shafted sterile swabs

Male Testing Kit Only
- Male Swabs: Metal-shafted sterile swabs

Materials required but not provided:
- Specimen collection container (for urine)
- Centrifuge (for urine samples)
- Timer
- External Controls

Specimen Collection & Preparation

Urine Specimen:
Please note: one individual found this test not to be senstive enough for urine samples. We advise you to use swab specimens if at all possible.
A urine specimen must be collected in a clean and dry container. Transfer the specimen to a centrifuge tube and centrifuge. Pour off the urine and treat the urine sediment as the sample.

Swab Sample:
1.0 Use a 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 into the urinary tract, gently move a few turns and retrieve the swab.
   b) Female patients: Swab discharge from the vaginal opening, then insert the swab into the vagina for half a minute and retrieve the swab.

2.0 Place the swab into a micro tube and add 8 drops (approximately 400µL) of extraction buffer to the tube. Compress the bottom of the tube between the thumb and the forefinger and twirl the swab 10 times.

3.0 Discard the swab into an appropriate biohazard disposal container.

4.0 Insert a tip on the tube and mix contents by gentle swirling. The swab extract must be tested immediately.

Directions for Use:

Allow the test device, urine/swab specimen and/or controls to equilibrate at room temperature (15-30°C) before testing.

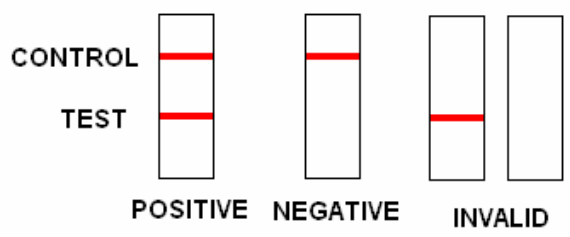
1. Bring the sealed pouch to room temperature

before opening it. Remove the test device from the pouch and use it as soon as possible.

2. Place the test cassette on a clean and level surface. Hold the extraction tube vertically and squeeze 1 full drop of extracted sample into the specimen well (S) of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.
3. Wait for the red line(s) to appear. The result should be read at 10-20 minutes. **If the membrane does not clear properly, one more drop of the extracted specimen may be added**. It is important that the background is clear before the result is read.
   Note: Do not interpret the result after 30 minutes.

Interpretation of Results:

(Please refer to the illustration)



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

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of gonorrhea antigen present in the specimen. However, the quantitative value cannot be determined by this qualitative test.

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

It is recommended that a positive Gonorrhea control and a negative Gonorrhea control be evaluated to verify proper test performance when a new shipment of test devices is received.

Users should follow their federal, state or local and laboratory guidelines concerning frequency for running external controls.

Limitations

This test provides a presumptive diagnosis for Gonorrhea. A confirmed, infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Expected Values

Negative results are expected in healthy non-infected women and men.

The Science with a Mission Gonorrhea Test Cassette (Urine/Swab) is capable of screening samples containing at least 1 X 10^{5} bacteria per mL.