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"See Now" Gonorrhea CassetteTest

Secretory products
For in vitro Diagnosis Use
Product Code: SN 4.4

INTENDED USE

The "See Now" Neisseria Gonorrhea (NGH) Test is a rapid and convenient immunochromatographic test for the visual detection of gonorrhea antigen in secretory specimens from urogenital system, as an aid in the diagnosis of gonococcus infection. The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for healthcare professional use only.

PRINCIPLE

Gonorrhea, caused by the bacterium Neisseria gonorrhoeae (NGH), is one of the most commonly occurring sexually transmitted disease (stds). It occurs simultaneously in around 50% of cases with Chlamydia or nongonococcal urethritis (NGU) depending on the sex of the individual infected. Gonorrhea is spread by sexual contact and can also be spread by vertical transmission from mother to newborn baby. Gonorrhea is treatable with some antibiotics, but antibiotic-resistant strains are now becoming more common.

"See Now" NGH Test is based on the principle of immunochromatographic assay. Monoclonal and polyclonal antibodies are employed to identify gonorrhea specifically. The test device has test line "T" and control line "C" on the membrane. The control line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control are working. A pink T line will be visible in the result window if enough NGH (equal to or more than 1×10^8 bacterial per ml) is present in the sample. The special NGH antibody is used in the test device as both capture and detector materials. The test results are not affected by the medication undertaken.

MATERIALS SUPPLIED

- Pouch Contents: Cassette, Desiccant (**store at 15 -25^o C**)
- Specimen Diluents A and B (**store at 2 -8^o C**)
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Clean and dry specimen extraction tube.
- 2 Sterile Swabs for female patients and 1 metal shafted sterile swab for male patients.
- Clock or timer.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 15-25°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN PREPARATION

A. Female Patients

Two sterile swabs with plastic shafts are required in the female collection procedure. One swab is used to prepare the sample site; the other is used for sample collection.

1. Remove any excess mucus from the potentially infected site with the first swab, then discard it.
2. Rub the second swab vigorously over the infected endourethral lining and endocervical cells in the canal wall. As gonorrhea are intracellular organisms, firm contact must be made with the canal wall for proper specimen collection. The rubbing action dislodges the endothelial cells and allows the swab to absorb the bacteria. Improper collection will result in poor visual readings and may cause invalid results. Vaginal specimens are not useful.

B. Male Patients

One metal-shafted sterile swab is needed for male penile sample collection. Do not use a plastic-shafted swab in this procedure.

1. Insert the swab into the urethra of the penis. Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotation.
2. Carefully remove the swab avoiding contact with any external surfaces.

PRECAUTIONS

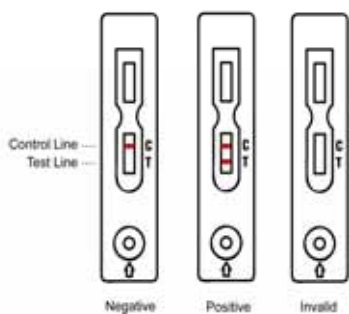
- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface. Label and extraction tube for each patient and place in a tube holder or rack.
- Place the swab into the microtube and add 6 drops (300µL) specimen diluent A on the swab, rotate swab and squeeze. Discard the swab into a disinfectant container..

- Then add 2 drops (100µL) diluent B into the microtube, and mix well. Specimen collected in the diluent should be stored at 4-8°C and tested within 24 hours.
- Holding the Sample dropper vertically, adds 5 drops (0.2ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.
- Read the result in 10-20 minutes. Ensure that the background of the test area is white before interpreting the result. Do not interpret the results after 30 minutes.

INTERPRETATION OF RESULTS



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

LIMITATION OF PROCEDURE

- The Gonorrhoea test is presumptive, screening test for the presence of *Neisseria gonorrhoea*. If test results are negative, but clinical symptoms are indicative of gonorrhoeal infection, further tests are recommended. Cell culture is the standard reference test method for the detection of *Neisseria gonorrhoea*.
- There is always a possibility that false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.