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Gonorrhea Swab Test

REF

Catalog No. R25-590 Female
Catalog No R25-591 Male

INTENDED USE

Immunospec Gonorrhea Swab Test is an enzyme detection system that screens for the presence of gonorrhea pathogen, (Neisseri gonorrhea), directly from patient specimens. It is a presumptive test intended for the use in physician's office, hospital laboratory, or STD clinic. The Test allows for immediate counseling and treatment of infected patients.

SUMMARY AND EXPLANATION OF THE TEST

Neisseria gonorrhea is one of the most common sexually transmitted pathogen.1,2 It is a major cause of cervicitis, urethritis, endometritis, and pelvic inflammatory disease in women.3. Serious complications can result in salpingitis, infertility, and entopic pregnancy. Large proportions of infect women and men are asymptomatic making diagnosis extremely important.4,5

The primary method for detection of gonococcus is growth of the organism in culture media. Other methods include direct fluorescence assays (DFA), enzyme immunoassay (EIA), and nucleic probing.

PRINCIPLE OF THE TEST

The Gonorrhea Rapid Swab Test is an enzyme detection system consisting of a synthetic substrate which in the presence of a specific Neisseria gonorrhoeae enzyme, causes a chemical reaction to occur. This reaction when coupled to a color developer causes a purple color to appear on the test swab.

REAGENTS AND MATERIALS PROVIDED

1. Reagent A, 1.0 ml	A dropper bottle containing synthetic substrate.
2. Reagent B, 1.0ml	A dropper bottle containing buffer solution
3. Reagent C 1.6ml	A dropper bottle containing color Developer solution.
4. Positive Control 0.25ml	A dropper bottle containing positive reagent control.
5. Color Interpretation Card	
6. Test Instruction, 1pc	

FEMALE TESTING KIT ONLY

7. Plastic swab. 20 pcs plastic-shafted sterile swab for testing female patients

MALE TESTING KIT ONLY

8. Metal swab 10pcs Metal-shafted sterile Swab for testing male patients.

STORAGE AND STABILITY

Store the kit between 2-8 degree Celsius upon receipt and when not in use. Refer to expiration date for stability.

WARNINGS AND PRECAUTIONS

1. Wear gloves while handling specimens.
2. Dispose of gloves and swabs using good microbiological practices.
3. Do not touch the swab tip at any time.
4. Wash hands after performing the test.
5. Reagent C will stain skin on contact. There is no danger, just a temporary cosmetic discoloration. Washing with soap and warm water may help.
6. Use only the sterile swabs provided. Swabs from any other source may give faulty results.
7. Do not allow a sample swab to one in contact with any reagent bottle tip. Reagent or bacterial contamination will invalidate test performance.
8. Do not use the reagents after their expiration dates.

QUALITY CONTROL

Note: If using a metal-shafted swab in the quality control procedure, use only one drop per reagent.

POSITIVE RAGETNCONTROL (PLASTIC-SHAFTED SWAB)

1. Add two drops of the Positive Control to a sterile plastic-shafted swab.
2. Add two drops of Reagent C to the swab.
3. Wait one minute.
4. Examine the swab for purple color development.
5. A positive test swab will turn a purple color similar to the positive control swab. However, an actual positive test result will only turn purpose where active Chlamydia bacteria are detected. It is not uncommon for a positive specimen swab to exhibit a purple pattern of spots in various shades.

NEGATIVE REAGENT CONTROL (PLASTIC-SHAFTED SWAB)

1. Add two drops of Reagent A to a clean swab (provided with the kit).
2. Add two drops of Reagent C to the swab
3. Wait one minute.
4. Examine the swab.
5. A negative result is indicated by a colorless, light yellow or pale Pink swab tip.

PERFORMANCE CHARACTERISTICS

DIRECTION LIMIT

Immunospec Gonorrhea Swab Test detects Neisseria gonorrhoeae at levels 10 colony forming units per ml and above.

SENSITIVITY AND SPECIFICITY

The sensitivity and specificity were determined in a mulitcenmeter comparison study using Gonorrhea and a culture recovery method. Though the culture recovery method is known to be 80-90 percent efficient, it was assumed to be 100% accurate for calculation purposes.

Two specimens using separate sterile Dacron"TM" swabs were collected from each of 166 adult patients. One swab was used in the Gonorrhea testing system and the other in the culture recovery. The result of the study are set forth in the table below:

CORRELATION STUDY

Culture method/ Gonorrhea rapid swab	
+/+	+/-
42	0
-/+	-/-
3	121

Relative Sensitiviity:100%
Relative Specificity 97.6%

The following ATCC strains were tested and found positive:
#9793 #9830 #11688 #19424 #21825
#27628 #27629 #27630 #27361 #27632
#27633 #31426 #31953 #35541 #35542

SPECIMENS STORAGE

SWAB STORAGE

1. Store a test swab as follows:
   a. For testing within twenty-four hours of collection, refrigerate the swab at 2-8degree Celsius in clean sterile container, i.e. test tube.

b. For testing between twenty-four hours and seven days after collection, use a transport system specified for gonococcus test swabs.
c. Samples should not be used after more than seven days.

2. Wear gloves and take general precautions when dealing with clinical material.

SPECIMEN COLLECTION AND TESTING

FEMALE PATIENT

A. Specimen collection- female patient

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

1. Remove any excess mucus from the potentially infected site with the first swab, and then discard it.
2. Rub the second swab vigorously over the infected endourethral lining and endocervical cells in the canal wall. 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

B. Testing procedure- female specimen swab

1. Add two drops of Reagent A and two drops of Reagent B to the swab tip.
2. Wait 10 minutes
3. Add two drops of Reagent C.
4. Wait one minute. Examine the swab for any visible purple color development. Compare it to the Color Interpretation Card to confirm the result. Any purple color development, regardless of its pattern or coverage on the swab, is a positive reading.

MALE PATIENT

A. Specimen Collection- Male Patient

One metal-shafted sterile Dacron"TM" 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 penus. 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

B. Testing procedure-Male Specimen Swab

1. Add one drop of Reagent A and one drop of Reagent B to the swab tips.
2. Wait 10 minutes
3. Add one drop of Reagent C.
4. Wait one minute. Examine the swab for any visible purple color development. Compare it to the Color Interpretation Card to confirm the result. Any purple color development, regardless of its pattern or coverage on the swab, is a positive reading.

LIMITATION OF THE TEST

1. Gonorrhea is a presumptive screening test for the presence of Neisseria Gonorrhoeae. The cases when patient swabs test negative while the patient's clinical symptom are indicative on gonorrhea should be investigated further. Cell culture is the standard reference test method for detection of gonococcus.
2. For optimal test performance, proper sample collection and storage procedures are crucial.

CROSS REATIVITY

Aeromonas spp Herpes simples virus Shigellosis spp
Bacteroides spp Klebsiella spp Staphylococcus (co ag neg.
Campylobacter spp Lactobacillus spp Staphylococcus spp(co-ag pos.)
Candida spp Listeria spp Steptococcus spp
Citrobacter spp Mycoplasma Trichomonas spp
Clostridium spp Neisseria Meningitidis
Enterobacter spp Peptococcus spp Ureaplasma urealyticum
Eschrichia coli proteus spp Veillenella spp
Gardnerella spp Pseudomonas spp Yersinia spp
Haemophilus influenzas Serratiaspp

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EC REP

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