Gonorrhea Rapid Test (Swab)

INTENDED USE

The Gonorrhea Rapid Test (Swab) is a rapid visual immunoassay for the qualitative presumptive detection of Neisseria gonorrhoeae in female cervical swab and male urethral swab specimens. This kit is intended for use as an aid in the diagnosis of Gonorrhea.

INTRODUCTION

Gonorrhea is a sexually transmitted disease caused by the bacterium Neisseria gonorrhoeae. Gonorrhea is one of the most common infectious bacterial diseases and is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. The causative organism can infect the throat, producing a severe sore throat. It can infect the anus and rectum, producing a condition called proctitis. With females, it can infect the vagina, causing irritation with drainage (vaginitis). Infection of the urethra may cause urethritis with burning, painful urination, and a discharge. When women have symptoms, they often note vaginal discharge, increased urinary frequency, and urinary discomfort. Spread of the organism to the fallopian tubes and abdomen may cause severe lower-abdominal pain and fever. The average incubation for Gonorrhea is approximately 2 to 5 days following sexual contact with an infected partner. However, symptoms may appear as late as 2 weeks. A preliminary diagnosis of Gonorrhea can be made at the time of examination. In women, Gonorrhea is a common cause of pelvic inflammatory disease (PID). PID can lead to internal abscesses and long-lasting, chronic pelvic pain. PID can damage the fallopian tubes enough to cause infertility or increase the risk of ectopic pregnancy. A smear or swab of urethral or cervical discharge may be taken and tested using a Gonorrhea Rapid Test Device (Swab).

PRINCIPLE

The Gonorrhea Rapid Test (Swab) detects Neisseria gonorrhoeae through visual interpretation of color development on the internal strip. Gonorrhea Antigen-specific monoclonal antibody is immobilized on the test region of the membrane. During testing, the specimen reacts with monoclonal anti-Gonorrhea antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient Gonorrhea antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Reagent A
- Package insert
- Workstation
- Extraction tubes & tips
- Reagent B
- Sterilized swabs

Materials Required but Not provided

- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Humidity and temperature can adversely affect results.
- When the assay procedure is complete, dispose of swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, swabs can be treated with 0.5% sodium hypochlorite (i.e., household bleach) for one hour before disposal.
- Used testing materials should be discarded according to local regulations.
- **Do not use cytology brushes with pregnant patients.**

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

The quality of specimen obtained is of extreme importance. Detection of gonorrhea antigen requires a vigorous and thorough collection technique that provides adequate amount of antigen. **Do not use 0.9% sodium chloride to treat swabs before collecting specimens.**

For female cervical specimens:

- Use the swab provided with the kit.
- Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the gonococcus organism. Firmly rotate the swab 360o in one direction (clockwise or counterclockwise) for 15 seconds, and then withdraw the swab. Avoid contamination from exocervical or vaginal cells. If the swab may be tested immediately, replace the swab into the extraction tube.

For male urethral specimens:

- Standard wire-shafted fiber-tipped swabs or cytology brushes (not provided) should be used for urethral specimen collection. Instruct the patients not to urinate at least one hour prior to specimen collection.
- Insert the swab 2-4 cm into the urea, rotate for 3-5 seconds and withdraw it. If the swab may be tested immediately, replace the swab into the extraction tube.

Do not place the swab in any transport device containing medium. Transport medium interferes with the assay, and viability of organisms is not required for the assay. If immediate testing is not possible, patient samples should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4 hours at room temperature (15-30°C) or 24 hours refrigerated (2-8°C). Do not freeze. All specimens should be allowed to reach a room temperature of 15-30°C before testing.

PROCEDURE

Allow the test, specimen, reagents, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Gonorrhea antigen according to the specimen type.
   - Hold the Reagent A bottle vertically and add 5 full drops of Reagent A (approximately 300 µL) to the extraction tube. Reagent A is colorless. Immediately insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes.
   - Hold the Reagent B bottle vertically and add 4 full drops of Reagent B (approximately 200 µL) to the extraction tube. The solution will turn turbid. Compress the bottom of tube and rotate the swab 15 times until the solution turns clear with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand for 1 minute.
   - Press the swab against the side of the tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of the extraction tube.
3. Place the test on a clean and level surface. Add 3 drops of the extracted solution (approximately 100 µL) to the specimen well (S) of the test, then start the timer. Avoid trapping air bubbles in the specimen well (S).
4. Wait for the colored line(s) to appear. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test, and cannot determine the concentrations of analytes in specimens.
2. Insufficient specimen volume, incorrect operation procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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.

LIMITATIONS OF THE TEST

1. The Gonorrhea Rapid Test (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Neisseria gonorrhoeae. No meaning should be inferred from the color intensity or width of any apparent bands.
2. This test will only indicate the presence of Gonorrhea antigen in specimens from both viable and non-viable Neisseria gonorrhoeae. Performance with other specimens has not been assessed.
3. Detection of Gonorrhea is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
4. 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.
5. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
6. Excessive blood (>20 µL in case of female swabs and >10 µL in case of male swabs) may cause false positive results. Endocervical samples from female patients should not be collected during menstrual period.

PERFORMANCE CHARACTERISTICS

Table: Gonorrhea Rapid Test vs. Culture

Female Cervical Specimens

Relative Sensitivity:
91.8% (80.4%-97.7%)*
Relative Specificity:
96.4% (87.7%-99.6%)*
Overall Agreement:
94.3% (88.0%-97.9%)*
***95% Confidence Interval**

		Gonorrhea Rapid Test +	Gonorrhea Rapid Test -	Total
Culture	+	45	4	49
	-	2	54	56
		47	58	105

Male Urethral Specimens

Relative Sensitivity:
91.7% (81.6%-97.2%)*
Relative Specificity:
95.8% (85.7%-99.5%)*
Overall Agreement:
93.5% (87.1%-97.4%)*
***95% Confidence Interval**

		Gonorrhea Rapid Test +	Gonorrhea Rapid Test -	Total
Culture	+	55	5	60
	-	2	46	48
		57	51	108

Specificity:
Cross reactivity with organisms has been studied using suspensions of 107 CFU/ml. The following organisms produced negative results with the test:

Acinetobacter calcoaceticus	*Pseudomona aeruginosa*	*Proteus mirabilis*
Acinetobacter spp	*Gardnerella vaginalis*	*Chlamydia trachomatis*
Enterococcus faecalis	*Salmonella choleraesius*	*Group B/C Streptococcus*
Enterococcus faecium	*Candida albicans*	*Hemophilus influenzae*
Staphylococcus aureus	*Proteus vulgaris*	*Klebsiella pneumoniae*
Branhamella catarrhalis	*Neisseria meningitides*	

LITERATURE REFERENCES

1. Knapp, J.S. et al. Neisseria gonorrhoeae. Manual of Clinical Microbiology, Sixth Edition, ASM Press, Washington DC., 324-325 (1995).
2. 2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines 2002. Morbidity and Mortality Weekly Report (2002), 51(RR-6)

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
µ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

µ

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