세로퀵

Seroquick

GONORRHEA ANTIGEN RAPID TEST DEVICE

INTENDED USE

Seroquick Gonorrhea Antigen Rapid Test Device is a lateral flow immunoassay intended for the qualitative detection of *Neisseria gonorrhoeae* antigens in female cervical and male urethral swab specimens. It serves as a screening tool to assist in the diagnosis of *Neisseria gonorrhoeae* infection, including in individuals who may be asymptomatic. This test may be used in clinical settings or for self-testing where permitted by local regulations. All results should be interpreted by a qualified healthcare professional in conjunction with the patient's symptoms, medical history, and, if necessary, additional laboratory findings to ensure appropriate medical follow-up and treatment.

PRINCIPLE

Seroquick Gonorrhea Antigen Rapid Test Device is a lateral flow immunoassay that detects *Neisseria gonorrhoeae* antigens using the colloidal gold method. The test employs a monoclonal antibody specific to *Neisseria gonorrhoeae* surface antigen, immobilized on a nitrocellulose membrane, along with a polyclonal IgG antibody positioned in the control region to ensure procedural integrity. A second monoclonal anti-gonococcal antibody is conjugated with colloidal gold particles and serves as the detection reagent.

When a clinical specimen from the female cervix or male urethra is introduced into the test device, any *Neisseria gonorrhoeae* antigens present will first bind to the gold-conjugated antibody. This antigen–antibody complex migrates along the strip by capillary action. If *Neisseria gonorrhoeae* antigen is present, it is captured by the immobilized antibody in the test region, forming a visible colored band. Absence of this band indicates that no detectable antigen is present in the sample. A separate control band must appear, regardless of the result, to confirm that the sample was applied correctly and that proper capillary flow occurred across the membrane. This built-in control helps ensure the test's validity and procedural reliability.

STORAGE

1. Store in a cool, dry place between 2°C and 30°C. Do not freeze.
2. Keep away from direct sunlight and excess humidity.
3. Do not open the sealed pouch until ready to use.
4. Use before the expiration date printed on the packaging.
5. Before use, allow all test components to gradually reach and stabilize at room temperature (15°C to 30°C) to ensure proper fluid migration.
6. For best results, test samples immediately after collection. Avoid using damaged or unsealed test devices.

PACKAGE CONTENTS

1. Instruction Manual
2. Gonorrhea Test Cassette
3. Buffer A Tube with Dropper Tip
4. Buffer B Tube with Dropper Tip
5. Sterile Swab

SPECIMEN COLLECTION

A. Female Cervical Swab Specimen:

1. Do not use creams, lubricants, or douche 24 hours before the test.
2. Ensure the individual is not menstruating at the time of collection.
3. Find a clean, private space with a mirror and adequate lighting.
4. Wash your hands thoroughly.
5. Use only the materials provided in this kit.
6. Open the Buffer A tube (see illustration ①) and place it on a flat, clean, and dry surface before starting specimen collection. This ensures it is ready to receive the swab immediately afterward. Avoid spilling or touching the inside of the tube. The solution is stable and will not spill, even if the tube is laid on its side.
7. Choose any of the following comfortable positions:
• Sit on the toilet with knees apart.
• Stand with one foot on a chair.
• Lie down with knees bent and legs apart.
8. Before collecting the specimen, gently remove any excess mucus from the endocervical area using a cotton ball, then discard it.
9. Open the swab without touching or contaminating the swab tip.
10. Insert the swab approximately 3 inches into the vaginal canal, or until slight resistance is felt, indicating contact with the cervix. Do not force the swab deeper if discomfort occurs.
11. Once contact is made, gently rotate the swab in a circular motion for 15 to 30 seconds. A slight pressure sensation is normal.
12. Withdraw the swab carefully, avoiding contact with external surfaces.
13. Insert the swab into the Buffer A tube immediately.

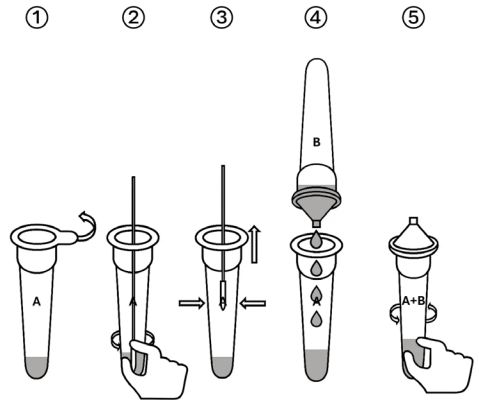
B. Male Urethral Swab Specimen:

1. Avoid urinating for at least one hour before collecting the sample.
2. Find a clean, private place with adequate lighting.
3. Wash your hands thoroughly.
4. Use only the materials provided in this kit.
5. Open the Buffer A tube (see illustration ①) and place it on a flat, clean, and dry surface before starting specimen collection. This ensures it is ready to receive the swab immediately afterward. Avoid spilling or touching the inside of the tube. The solution is stable and will not spill, even if the tube is laid on its side.
6. Open the swab without touching or contaminating the swab tip.
7. Insert the swab approximately 1 inch into the urethral meatus.
8. Rotate the swab gently for 5 to 10 seconds. A slight pressure sensation is normal.
9. Withdraw the swab carefully, avoiding contact with external surfaces.
10. Insert the swab into the Buffer A tube immediately.

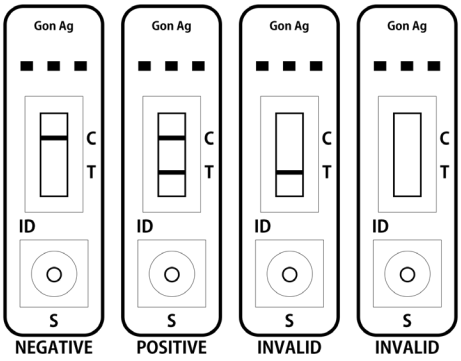
TEST PROCEDURE

1. Allow the test device, specimen, buffers, and/or controls to reach room temperature (15–30°C) before testing.
2. Remove the test device from the sealed foil pouch. Perform the test immediately after opening the pouch.
3. Hold Buffer A upright. Immediately insert the swab into the tube, then firmly squeeze the bottom of the tube while rotating the swab 15 times (see illustration ②). While continuing to squeeze the tube, move the swab up and down approximately 5 times to ensure thorough mixing of the specimen and buffer (see illustration ③). Let it stand for 2 minutes.
4. Hold Buffer B upright. Remove the foil seal and attach the dropper tip. Add the entire contents of Buffer B into the Buffer A tube (see illustration ④). While squeezing the bottom of the tube, rotate the swab 15 more times to mix thoroughly. Let it stand for 1 minute.
5. Press the swab firmly against the inside wall of the tube and withdraw it while continuing to squeeze to extract as much liquid as possible. Fit the

dropper tip securely onto the Buffer A tube, then gently rotate the tube about 10 times to mix the extracted solution (see illustration ⑤).
6. Place the test device on a flat, clean, and dry surface. Dispense 3 full drops (150 µL) of the extracted solution into the sample well, avoiding the formation of air bubbles. Immediately start the timer.
7. Wait for the colored band(s) to appear. Read the result exactly at 10 minutes. Do not read the result after 20 minutes. Discard the used cassette.



READING RESULT



Negative Result: If only the C band is visible and no band appears in the T region, this indicates that the specimen contains no gonorrhea antigen.
Positive Result: If a colored band appears in the T region along with the C band, this indicates the presence of gonorrhea antigen in the specimen.
Invalid Result: If the C band does not appear, the test is invalid regardless of a visible band in the T region. The test should be repeated using a new device.
Note: The intensity of the band in the T region may vary depending on the concentration of gonorrhea antigen present in the specimen. A darker band indicates a higher antigen concentration. Even a faint band in the T region should be considered positive if the C band is also present.

PERFORMANCE

A. Sensitivity

Seroquick Gonorrhea Antigen Rapid Test Device was evaluated using both cultured *Neisseria gonorrhoeae*-infected cells and clinical specimens obtained from patients at sexually transmitted disease (STD) clinics. The assay demonstrated the ability to detect *Neisseria gonorrhoeae* at concentrations as low as 10^5 organisms/mL. Polymerase chain reaction (PCR), regarded as the gold standard in molecular diagnostics, was employed as the reference method for comparison. Specimens were classified as positive or negative based on PCR results. Compared to PCR, Seroquick demonstrated a sensitivity of 96.1%, placing its diagnostic performance within approximately 2% of confirmatory PCR results. This makes it a highly reliable option for gonorrhea screening in non-laboratory settings.

B. Specificity

Seroquick Gonorrhea Antigen Rapid Test Device utilizes a detection method that is highly specific to *Neisseria gonorrhoeae* antigens. Based on comparative analysis with polymerase chain reaction (PCR) as the reference standard, the test demonstrated a specificity of 99.8%, indicating a low rate of false-positive results and high analytical precision. This high level of specificity ensures accurate identification of uninfected individuals, helping to prevent unnecessary treatment. The test's strong performance makes it well-suited for use in clinical, laboratory, and point-of-care settings where reliable and rapid diagnosis is essential for timely intervention.

C. Performance Summary

Parameter	Result	Notes
Total Samples	669	154 positive, 515 negative
Sensitivity	96.1% (148/154)	6 positives not detected
Specificity	99.8% (514/515)	1 false positive recorded
Overall Accuracy	98.7% (662/669)	Correctly identified samples
True Positives	148	Matched PCR-positive results
False Negatives	6	Missed confirmed infections
True Negatives	514	Accurately ruled out infection
False Positives	1	Incorrect positive result
Limit of Detection	~10^5 org/mL	Detection threshold
Time to Result	~15 minutes	Typical visual result time

D. Cross-reactivity

Seroquick Gonorrhea Antigen Rapid Test Device is validated to detect all clinically significant strains of *Neisseria gonorrhoeae*. Cross-reactivity testing was performed to confirm the assay's analytical specificity using a wide range of microorganisms commonly associated with urogenital, gastrointestinal, and oropharyngeal infections. Each organism was tested at a concentration of 10^7 organisms/mL to simulate high microbial load conditions. None of the tested organisms produced a false positive result, confirming that the assay does not cross-react with other pathogens. These findings demonstrate that Seroquick is highly specific for *Neisseria gonorrhoeae* antigens, even in the presence of closely related or co-infecting organisms.

Gram-positive bacteria	Gram-negative bacteria	Fungi/Other
Staphylococcus aureus	*Neisseria meningitidis*	*Candida albicans*
Streptococcus faecalis	*Escherichia coli*	*Trichomonas vaginalis*
Streptococcus faecium	*Pseudomonas aeruginosa*	*Mycoplasma hominis*
Group B Streptococcus	*Salmonella Typhi*	*Ureaplasma urealyticum*
Corynebacterium spp.	*Haemophilus influenzae*	*Chlamydia trachomatis*
	Klebsiella pneumoniae	*Treponema pallidum*
	Gardnerella vaginalis	
	Proteus mirabilis	

LIMITATIONS

1. This product is intended for in vitro diagnostic use only and should not be used for any other purpose.
2. Environmental factors such as excessive humidity, extreme temperatures, or improper storage may adversely affect performance.
3. Interfering substances in the specimen, as well as technical or procedural errors, may lead to false results. These are factors that may fall outside the manufacturer's control.
4. While the test demonstrates high accuracy and performance comparable to laboratory-based methods, a small possibility of false positive or false negative results still exists.
5. In cases of inconclusive or unexpected results, further evaluation with confirmatory laboratory testing is recommended. As with all diagnostic tools, results should be interpreted alongside the patient's clinical presentation, medical history, and other relevant laboratory findings.

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