Gonorrhea Rapid Test
Package Insert
For self-testing

REF	IGO-N502H-01/IGO-N502H-02/IGO-N502H-05/ IGO-N502FH-01/IGO-N502FH-02/IGO-N502FH-05/ IGO-N502MH-01/IGO-N502MH-02/IGO-N502MH-05	English

【INTENDED USE】

The Test is a rapid chromatographic immunoassay for the qualitative detection of *Neisseria gonorrhoeae* antigens in female cervical swab or male urethral swab specimens to aid in the diagnosis of Gonorrhea infection.

The Test is for self-testing use. The test is not automated. For *in vitro* diagnostic use only.

【SUMMARY】

Gonorrhea is a sexually transmitted disease caused by the bacterium *Neisseria gonorrhoeae*.[1] 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.[2] However, symptoms may appear as late as 2 weeks. A preliminary diagnosis of Gonorrhea can be made at the time of examination.[3] 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.[4]

【PRINCIPLE】

The Gonorrhea Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. The test contains an antibody to Gonorrhea that is conjugated with latex particles on the conjugate pad and antibody specific to the Gonorrhea antigen on the test line region. During testing, the extracted antigen solution reacts with an antibody to Gonorrhea conjugated with latex particles to form a antibody-antigen complex. The complex migrates up to react with the antibody to Gonorrhea on the membrane and generates a colored line in the test region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the test is working properly.

【REAGENTS】

The test contains Gonorrhea antibody conjugated latex particles on the conjugate pad and Gonorrhea antibody coated on the membrane.

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Do not use the test after expiration date. Do not reuse the test.
- Store in a dry place at 2-30°C (36-86°F). Do not use it if any of the test kit content or packaging is damaged or opened.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wash hands thoroughly before and after handling.
- Handle all specimens as if they contain infectious agents. The used tests and specimens may be infectious and should be place into plastic bag and tightly sealed, then dispose according to local regulation.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- This product is not intended for use with children.
- Carefully handle the buffer - do not ingest and avoid contact with skin or eyes. If contact does occur, immediately rinse with running water.
- Do not swallow Buffer 1, Buffer 2 or any other components in the box.
- The buffer 1 contains 0.6% NaOH. IF ON SKIN: Wash with plenty of soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin or eye irritation persists: Get medical advice/attention.
- It is important that the timings are strictly followed to ensure accurate results.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
- Components provided in the kit are approved for use in the Gonorrhea Rapid Test. Do not use any other commercial kit component.
- The test is not a substitute for professional medical advice. Do not take any decision of medical relevance without first consulting the appropriate healthcare professional



Warning

- The swab may be initially uncomfortable, but this is perfectly normal.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°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 after the expiration date.

Note: It is suggested to use test cassette within one hour after removing it from the foil pouch.

【MATERIALS】

Materials Provided

REF	Components						
	Test cassette	Package insert	Sterile female cervical swab	Sterile male urethral swab	Buffer 1	Buffer 2	Tube holder
IGO-N502H-01	1	1	1	1	1	1	On the box
IGO-N502H-02	2	1	2	2	2	2	
IGO-N502H-05	5	1	5	5	5	5	
IGO-N502FH-01	1	1	1	/	1	1	
IGO-N502FH-02	2	1	2	/	2	2	
IGO-N502FH-05	5	1	5	/	5	5	
IGO-N502MH-01	1	1	/	1	1	1	
IGO-N502MH-02	2	1	/	2	2	2	
IGO-N502MH-05	5	1	/	5	5	5	

***Note:**

Buffer 1	Buffer 2: Yellow
0.3 mL (0.6% NaOH)	0.24 mL (0.73% HCl)

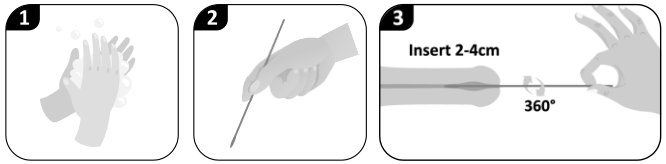
Materials Required But Not Provided

- Timer

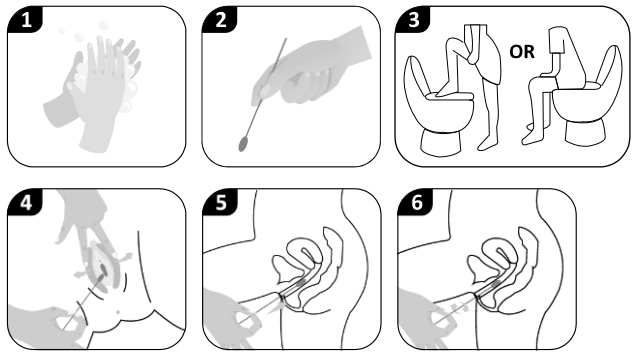
【COLLECTING THE SPECIMEN AND DIRECTIONS FOR USE】

Before performing the test, swab specimen must be collected following the instructions below.

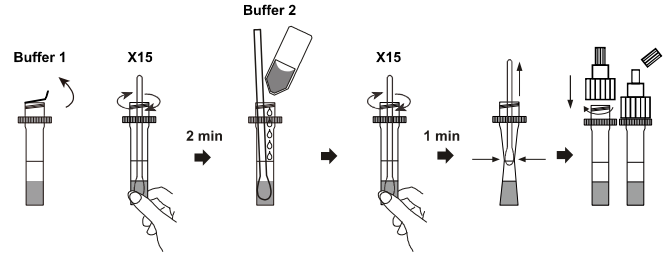
1. Wash your hands with soap and rinse with clean water.
   - To collect **Male Urethral Swab Specimens:**
     Please refrain from urinating for at least one hour before specimen collection.
     Remove the sterile male urethral swab from the pouch, insert the swab tip into the urethral about 2-4 cm, rotate the swab 360° in one direction (clockwise or counter clockwise), let stand for 10 seconds, and then withdraw. Carefully remove the swab avoiding contact with any external surfaces.



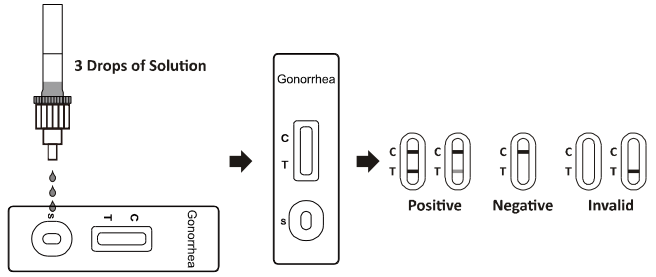
   - To collect **Female Cervical Swab Specimens:**
     Remove the sterile female cervical swab from the pouch. Insert the swab tip into vaginal, firmly rotate the swab 360°in one direction (clockwise or counter clockwise), let stand for 15 seconds, then withdraw the swab. Carefully remove the swab avoiding contact with any external surfaces.



   Note: Specimen should be tested immediately.
2. Allow the test and buffers to reach room temperature (15-30°C) (59-86°F). Remove the cover of the **Buffer 1 tube** and insert the tube into the tube holder on the packaging box, Buffer 1 is colorless. Immediately insert the swab into the tube with Buffer 1, compress the bottom of tube and rotate swab 15 times. Let stand for 2 minutes.
3. Break off the Buffer 2 at the breaking point (the narrowest place). Then add **entire Buffer 2** solution **(yellow liquid)** to the Buffer 1 tube. The solution would turn turbid. Compress the bottle of tube and rotate the swab 15 times until the solution turn clear with a slight green or blue tint. Let stand 1 minute.
4. Press the swab against the side of tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Close the cap onto the tube, then open the small cap.



5. Remove the test cassette from the sealed foil pouch and use it within one hour. Place the test cassette on a clean and level surface.
6. Invert the buffer tube and add **3 full drops of the extracted solution** to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. Do not move the test cassette during test developing.
7. Wait for the color to appear. **Read the result at 10 minutes**; do not interpret the result after 30 minutes.



【READING THE RESULTS】



POSITIVE:* **Two colored lines appear. Both T (Test) line and C (Control) line appear.**
A positive result indicates that Gonorrhea was detected in the specimen.
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of Gonorrhea present in the specimen.



NEGATIVE: **One colored line appears in the control line region (C). No line appears in the test line region (T).**
A negative result indicates that Gonorrhea antigens are not present in the specimen, or is present below the detectable level of the test.



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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms the test is working properly.

【PERFORMANCE CHARACTERISTICS】

Diagnostic Sensitivity	Diagnostic Specificity	Agreement Rate
96.0%	98.3%	97.3%

Performance data obtained by clinical study with 220 participants (including 110 male and 110 female) enrolled, including 50 positive urethral swab, 60 negative urethral swab, 50 positive cervical swab and 60 negative cervical swab. PCR has been utilized as reference method.

Analytical Sensitivity

The Gonorrhea Rapid Test can detect the level as low as 5E+06 CFU/mL (5E+04CFU/test) for Neisseria Gonorrhea.

Hook Effect

No high-dose hook effect was detected at the concentration up to 4.0E+09 CFU/mL for Neisseria Gonorrhea.

Precision-Repeatability

No difference was detected in intra lot. The results obtained are summarized in the following tables.

Sample	No. Negative/Total	No. Positive/Total	Agreement
Neisseria Gonorrhea Negative	25/25	0/25	100%
Neisseria Gonorrhea Positive	0/75	75/75	100%

Precision-Reproducibility

No difference was detected between days, sites, lots and operators. The results obtained are summarized in the following tables.

Sample	No. Negative/Total	No. Positive/Total	Agreement
Neisseria Gonorrhea Negative	225/225	0/225	100%
Neisseria Gonorrhea Positive	0/450	450/450	100%

Cross-Reactivity

No cross-reactivity was observed when tested with following organisms:

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

Interfering Substances

The following potentially interfering substances does not interfere with the test results.

Name	Name
Nifuratel and Nystatin Vaginal suppositories	Compound Metronidazole Vaginal Suppositories
Amphotericin B Vaginal Effervescent Tablets	Femfresh Daily Intimate Wash
Terbinafine Hydrochloride Vaginal	eve ™ Feminine Wash
Nifuratel Tablets	Miconazole Nitrate Vaginal Suppositories

【LIMITATIONS】

1. The Gonorrhea Rapid Test is for *in vitro* diagnostic use only. This test should be used for the detection of Gonorrhea antigens from female cervical swab or male urethral swab specimens. Neither the quantitative value nor the rate of increase in Gonorrhea antigens concentration can be determined by this qualitative test.
2. This test detects Gonorrhea antigens from Neisseria gonorrhoeae, regardless of bacterial viability. Performance has not been evaluated for specimen types other than male urethral swabs and female cervical swabs.
3. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
4. Excessive blood on the swab may cause false positive results.
5. Endocervical specimens from female should not be collected during menstrual period.

【EXTRA INFORMATION】

1. How does the Gonorrhea test cassette work?

Gonorrhea is a common human sexually transmitted infection caused by the bacterium *Neisseria gonorrhoeae*. The Gonorrhea Rapid Test detects specifically the antigens in vaginal discharge or urethral discharge to ascertain the presence of the bacterium.

2. When should the test be used?

Neisseria gonorrhoeae antigen can be detected from genital infections, and it is recommended to conduct tests in individuals with symptoms who meet the case definition (vaginitis, urethritis, or the following symptoms: dysuria, urethral discomfort, pain, swelling, and tenderness of the epididymis, erythema, redness, and edema of the scrotal skin, swelling, erythema, severe pain, and thickening of the vas deferens, lumbago, lower abdominal heaviness, bleeding, diarrhea, and mucoid discharge, abnormal vaginal discharge, bleeding outside of menstruation or after intercourse, and symptoms such as dysuria, frequent urination and urgency) and to test asymptomatic individuals limited to contacts of confirmed Gonorrhea cases or probable cases and to at-risk health workers.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if Gonorrhea Rapid Test gets wet before performing the test or if the quantity of specimens dispensed in the specimen well is too much or not sufficient, or if the number of extracted specimens drops are less than 3 or more than 4. Detection of gonococcus is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc. The minimum detection level of this test may vary according to serovar. Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the color and the intensity of the lines are different?

Color and intensity variations do not affect interpretation. The test is positive if both lines are visible, regardless of test line color strength.

5. What does the control line (C) indicate?

Appearance of the control line confirms the test is functioning properly. Its presence is required for valid result interpretation.

6. What do I have to do if the result is positive?

A positive result indicates that *Neisseria gonorrhoeae* has been detected in the specimen. Seek medical attention promptly and present your test result to a healthcare provider. They will determine if further testing or treatment is required.

7. What do I have to do if the result is negative?

A negative result means no gonorrhea antigens were detected in the specimen. However, consult a healthcare provider if symptoms persist or worsen, as this could indicate other conditions requiring evaluation.

【BIBLIOGRAPHY】

1. National Institute of Allergy and Infectious Diseases. Gonorrhea, NIAID Fact Sheet on Gonorrhea, 2015.
2. Groseclose S. L., Knowles C. M., Hall P. A., Adams, D. A., Anderson, W. J., et al. Summary of Notifiable Diseases, United States 1998. Morbidity and Mortality Weekly Report, 1999; 47(53): 1-93.
3. Kellogg, D. S., Cohen, I. R., Norins, L. C., Schroeter, A. L., & Reising, G. *Neisseria gonorrhoeae* II. Colonial Variation and Pathogenicity during 35 Months In Vitro. Journal of Bacteriology, 1968; 96(3): 596-605.
4. Kimberly A. Workowski, Stuart M. Berman. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines. Clinical Infectious Diseases, 2011; 53(S3): S59-63.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	*In vitro* diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Unique device identifier
	Warning		Importer		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 3018

EU REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Global Network Oy
Kalsiittikuja 6
20250 Turku, Finland

Swab:

Jiangsu Hanheng Medical Technology Co., Ltd.
#118 Xinyuan 3rd Road,
Xinbei District, Changzhou,
213031, Jiangsu P.R. China

CE 0197

Summary of safety and performance is available on website:
https://ec.europa.eu/tools/eudamed/

Number:14604131900
Revision Date:2026-08-24

Package Insert History Summary

Version	Date	Change Description