

inSTIcheck™ Gonorrhea

CE 2265

Rapid Immunoassay

Cassette Test Device

For the detection of

Neisseria Gonorrhoeae



See external label



2°C-30°C



Σ= 20, 40, 100 tests



Product Code: 85226400035

FOR IN VITRO USE ONLY

Warning: A positive result is not useful for establishing a diagnosis of Gonorrhea. In most situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of Gonorrhea except for incubating or early primary disease.

INTENDED USE

InSTIcheck™ Gonorrhea is a rapid chromatographic immunoassay for the qualitative detection of Neisseria Gonorrhoeae directly from endocervical swab or urine specimens to aid in the diagnosis of Gonorrhea infection.

SUMMARY

Neisseria gonorrhoeae species of gram negative, aerobic bacteria is primarily found in purulent venereal discharges; it is the causative agent of gonorrhea. It is spread from person to person by contact with infected secretions, most often by sexual contact. N. gonorrhoeae (GC) is a leading cause of sexually transmitted disease with over 300,000 cases reported annually in the United States. The genital site most commonly infected in women is the cervix. In men, the genital site most commonly infected is the urethra. For neonates, there is significant risk for developing gonococcal conjunctivitis from passage through an infected birth canal. Regardless of the anatomical site of infection, gonococcal disease left untreated may become disseminated throughout the body and lead to arthritis, carditis, and/or meningitis. Bacterial culture using a variety of selective media is considered the "gold standard" for detecting the presence of N. gonorrhoeae. These methods, however, may require up to 72 hours to obtain a result. The sensitivity and specificity of the InSTIcheck™ Gonorrhea test compared with the results of standard cultures were 92% and 99%, respectively. The predictive values of positive InSTIcheck™ and negative InSTIcheck™ were 93% and 97%, respectively. In contrast to standard cultures, gonococcal antigens in specimens were still detectable by this method up to 45 h of storage at either room temperature or 4°C. Considering the rapidity and ease of this method, the InSTIcheck™ Gonorrhea method is a useful and reliable diagnostic screening tool for gonococcal urethritis.

PRINCIPLE

The InSTIcheck™ Gonorrhea Rapid Test Device (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Gonorrhea antigen from cervical swabs and urine specimens. In this test, antibody specific to the Gonorrhea antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhea that is coated onto particles. The mixture migrates up to react with the antibody to Gonorrhea on the membrane and generates a colored line in the test line 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 proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Use separate, clean transfer pipettes for different specimens.
- The InSTIcheck™ Gonorrhea device should remain in its original sealed pouch until ready for use.

STORAGE AND STABILITY

- Store as packaged at room temperature or refrigerated in the sealed pouch at 4-30 °C.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

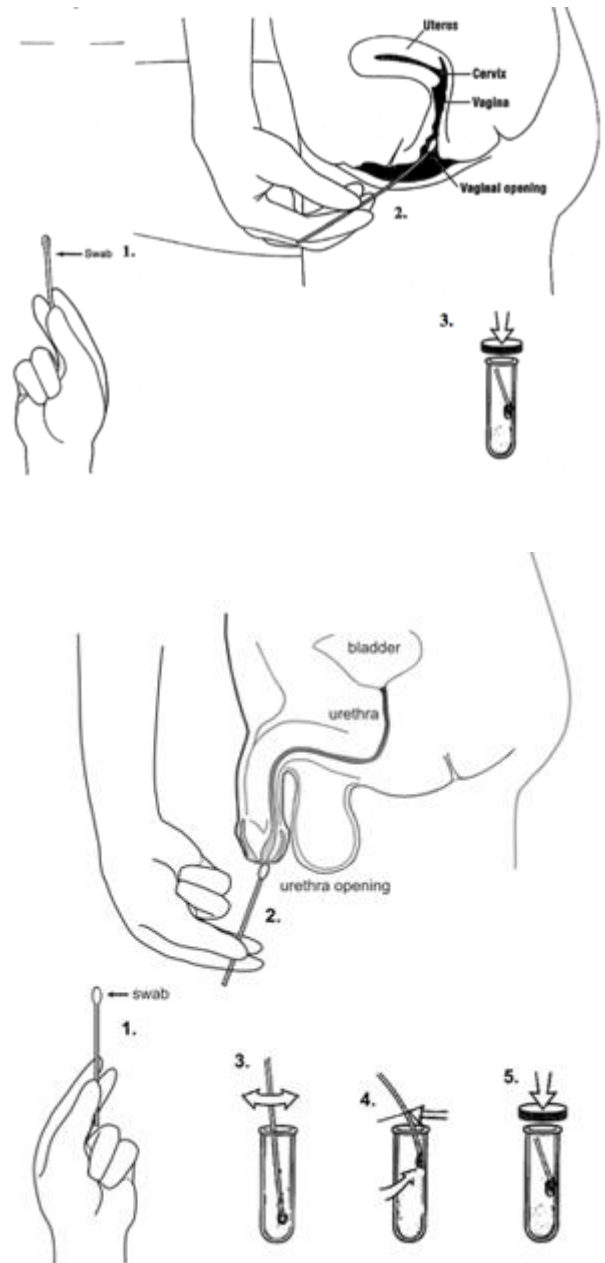
SPECIMEN COLLECTION AND PREPARATION

1. **Female Patient:** 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 end urethral lining and end cervical cells in the canal wall.
 3. As Gonorrhea is 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.
1. **Male Patient:** 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.

Urine specimen: Female patients should not cleanse the labial area prior to providing the specimen. First-void urine (patient should not have urinated for 1 hour prior to specimen collection) or endocervical/urethral swab specimen. Collect 15ml urine specimen; centrifuge the urine specimen at high speed (1,500-3,000 rpms) for 15 minutes. Discard the supernate. Use the precipitate for detection. Treat the urine sediment according to Direction for Use, if the test is to be conducted immediately.

Materials Provided

- Individually Pouched Test Devices & Pipettes
- 1 Buffer A/1 Bottle
- 1 Buffer B/2 Bottle



Urethral Swabs (sterile)

- 1 Positive control
- 1 Negative control
- 1 Package insert

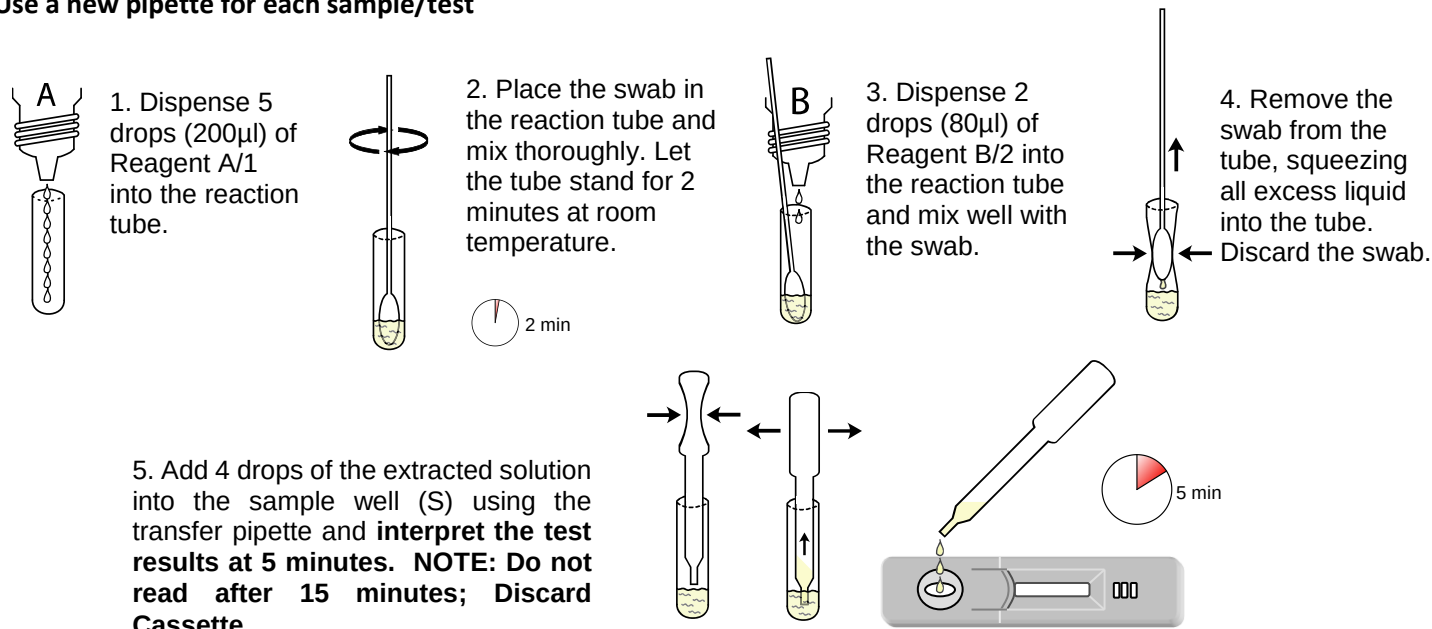
Materials May Be Required But Not Provided

Centrifuge tube (for urine specimens only)

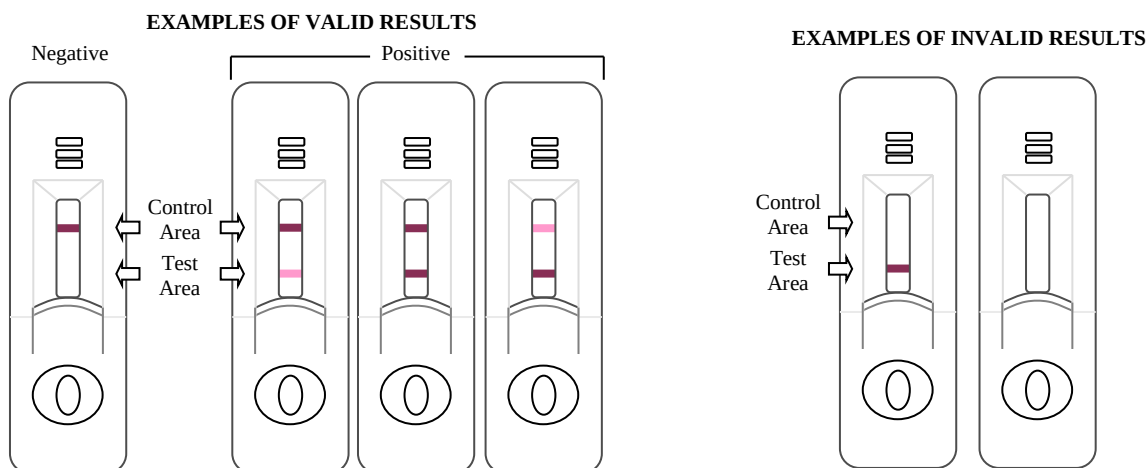
DIRECTIONS FOR USE

Allow test device, assay buffers, specimen, and/or controls to equilibrate to room temperature (18-30°C) prior to testing.

Use a new pipette for each sample/test



INTERPRETATION OF RESULTS



POSITIVE: RED bands will appear in the control and test areas, which indicate a positive result for Gonorrhea antigen.

NOTE: Low titers of Gonorrhea antigens might result in a faint line appearing in the test region. Therefore, any shade of RED (not grey) in the test region (T) should be considered positive.

NEGATIVE: One colored “RED” band will appear in the control area only, with no distinct colored line in the test window. This indicates a negative result.

INVALID: A distinct colored line in the Control area should always appear. The test is invalid if no line forms in the control window. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

NOTE: *The test result can be read as soon as a distinct pink-red color line appears in the test window. The test line will appear before the control line in most of the strong positive cases. The test line may appear after the control line in weak positive cases, and the control line may be darker than the test line.*

QUALITY CONTROL

Built-in Quality Control: A solid line appearing in the Control Area of the Result Window indicates that several of the built-in control features for the Gonorrhea test are working. Because the method of processing the built-in control and detecting features are identical, the appearance of a line in the Control Area ensures that the device’s functionality is preserved. In addition, the Control Area line is a sign that the seal on the foil storage pouch has not been breached and that the device has been protected from outside contaminants. Because capillary flow cannot be accomplished without a properly assembled device and the correct volume of fluid, the appearance of a line in the Control Area also means that the device’s components are accurately positioned and linked correctly and that the assay has been performed properly. Finally, if the Control Area line does not develop within 10 minutes, the test result should be considered invalid.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

As is the case with any other diagnostic procedure, the results obtained by this kit yield data that must be used only as adjunct to other information available to the physician.

- A proper endocervical specimen must be obtained using the swab provided, for best results. Though a patient may be at the onset of the disease, a negative result may be obtained due to low antigen level below the sensitivity of the test. If symptoms persist or intensify, the test should be repeated.
- The test is intended for use only with endocervical specimens collected on appropriate swabs and urine specimens collected in appropriate containers. Performance of the test with other clinical specimens has not been determined.
- Reliable results are dependent on adequate specimen collection. Detection of *N. gonorrhoeae* is dependent on the number of organisms present in specimens. This may be affected by specimen collection methods and patient factors such as age, history of STD, and presence of symptoms.
- The results are presumptive for all negative results. Negative results can occur from inadequate specimen collection, inappropriate specimen storage or levels of antigen which fall below the limits of detection of the test. Because many individuals infected with *N. gonorrhoeae* may have lower levels of antigen than detectable by InSTIcheck™, a negative result cannot be used to exclude infection with *N. gonorrhoeae*.
- The test results are presumptive for all positive results. Additional evidence should be used to identify *N. gonorrhoeae* infection.
- As with other non-culture methods, the test should not be used in the investigation of suspected sexual abuse or other medical-legal indications when identification of *N. gonorrhoeae* could lead to adverse psychosocial impact.
- Because antigen detection methods do not require organism viability, the test may produce a positive result in the absence of living organisms.
- Interpretation of positive results in a low risk or low prevalence population should be made with caution.
- Monoclonal antibodies may not detect all strains of *N. gonorrhoeae*.

PERFORMANCE CHARACTERISTICS

The performance of the InSTIcheck™ Gonorrhea was compared to that of conventional culture assay techniques. Two endocervical specimens were collected from 200 patients. One swab was used for the conventional culture method and the other was used for the InSTIcheck™ Gonorrhea test. The results are summarized below:

Swab Method:

Method		ELISA		Total
InSTIcheck™	Results	Positive	Negative	Results
Gonorrhea	Positive	31	1	32
Cassette	Negative	2	166	168
Total Results		33	167	200

Relative Sensitivity: >92.9%;

Relative Specificity: 99.3%;

Accuracy: 97.6%;

PPV: 93.5 %;

NPV: 97.8%

Urine Method:

Method		ELISA		Total
InSTIcheck™	Results	Positive	Negative	Results
Gonorrhea	Positive	48	2	50
Cassette	Negative	10	440	450
Total Results		58	442	500

Relative Sensitivity: >85.5%;

Relative Specificity: 99.5%;

Accuracy: 97.6%;

PPV: 95.5 %;

NPV: 97.8%

Cross-Reactivity

To confirm the specificity of InSTIcheck™ Gonorrhea, the following organisms were tested at 1×10^7 cells/mL, yielding negative results.

Acinetobacter calcoaceticus
Candida albicans
Chlamydia psitticii
Chlamydia pneumoniae
Chlamydia trachomatis
Enterococcus faecalis
Escherichia coli
Gardnerella vaginalis
Haemophilus influenzae
HSV-1
HSV-2
Klebsiella pneumoniae
Lactobacillus fermentum
Moraxella catarrhalis

Moraxella lacunata
Mycoplasma hominis: PG21
Mycoplasma hominis: W2
Neisseria armalis
Neisseria cinerea
Neisseria flavescens
Neisseria lactamica
Neisseria meningitidis
Neisseria mucosa
Neisseria perflaven
Neisseria sicca
Neisseria subflava
Peptostreptococcus productus
Proteus mirabilis
Pseudomonas aeruginosa

Salmonella choleraesuis
Subspecies: choleraesuis
Serotype: typhimurium
Salmonella choleraesuis
Subspecies: choleraesuis
Serotype: minnesota (R595) Salmonella
choleraesuis
Subspecies: choleraesuis
Serotype: minnesota
Staphylococcus aureus
Staphylococcus aureus
(Protein A Producer)
Staphylococcus epidermidis
Streptococcus Group A

References

1. Forbes BA, Sahm DF, Weissfeld AS. "Neisseria and Moraxella catarrhalis" in Bailey & Scott's Diagnostic Microbiology, Tenth Edition (Mosby, St. Louis) pp. 597-605 (1998).
2. "Summary of the Notifiable Diseases, United States, 1998." "Morbidity and Mortality Weekly Report 47(53): 1-93 (1999).
3. Morello JA, Janda WM, Doern GV. "Neisseria and Branhamella" in Manual of Clinical Microbiology (Balows A, Hausler WJ Jr., Herrmann KL, Isenberg HD, Shadomy HJ, edg.; American Society of Microbiology, Washington, DC), pp. 258-276 (1991).
4. Luer CA, Wong K-P "Conformation of Escherichia coli Ribosomal Protein L7/L12 in Solution: Hydrodynamic, Spectroscopic, and Conformational Prediction Studies." Biochemistry 18: 2019-2027 (1979).

ASSISTANCE

If you have any questions regarding the use of this product, contact your local distributor or First Diagnostic™ Corporation at sales@firstdiagnostic.com.

Lab Name:

Procedure #:

Procedure:

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

First Diagnostic provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

Lab Name:

LOG SHEET

Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient Name	Negative Procedural Control (Clear Bkgd)	Positive Procedural Control (Red Line)	Test Results At 10 minutes	Lot Number/Exp. Date	Technician
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

REF

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IVD



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Corporation

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Contact details updated October 2026

EC REP

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