

# InSTIcheck™ Gonorrhea

Rapid ImmunoAssay

Cassette Test Device

For the detection of

Neisseria Gonorrhoeae



**Product Code: ATF-129**

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 qualitatively detects Neisseria Gonorrhoeae antigen directly from endocervical or urine specimens. The test is intended for use in the rapid diagnosis of Gonorrheal 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 94.1% (32/34) and 95.8% (23/24), respectively. The predictive values of positive InSTIcheck™ and negative InSTIcheck™ were 96.9% (32/33) and 98.8% (23/25), 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 test involves the chemical extraction of the Gonorrhea antigen followed by solid-phase immunometric assay technology for the qualitative detection of extracted sample. In the test procedure, a specimen is collected with a swab and Gonorrhea antigens are extracted from the specimen with extraction reagents. The extract is

added to the sample well with the aid of a transfer pipette and allowed to soak in. If Gonorrhea antigen is present in the specimen, it will react with the conjugate dye, which binds to the antibody on the membrane to generate a colored line in the test window. The presence of two colored lines, one in the test window and the other in the control window, indicates a positive result, while the absence of a line in the test window indicates a negative result.

## PRECAUTIONS

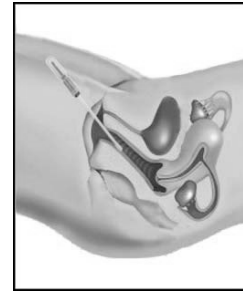
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- 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

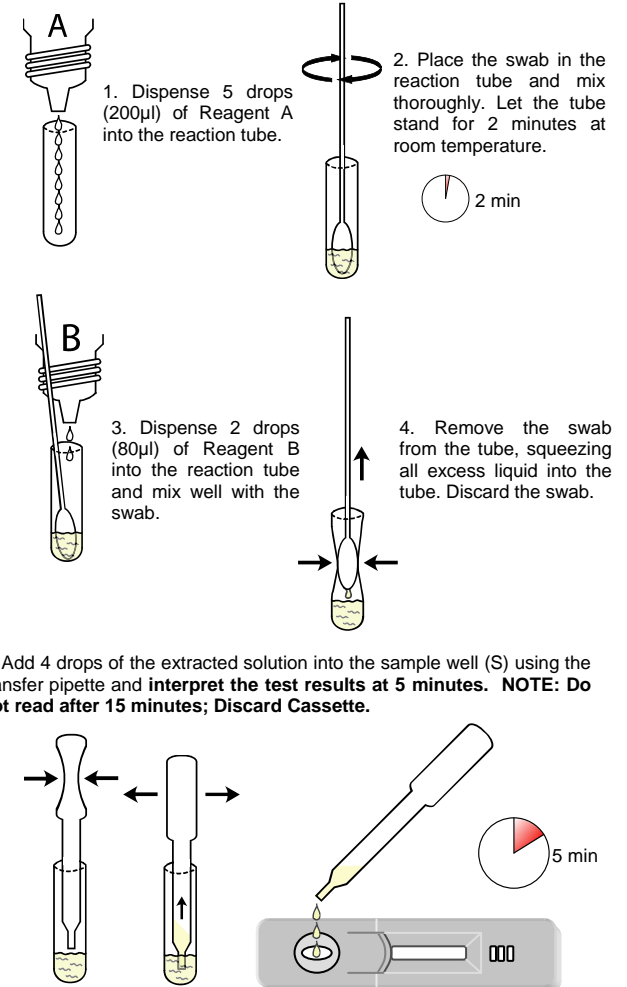
- 25 Individually Pouched Test Devices & Pipettes
- 1 Buffer A Bottle
- 1 Buffer B Bottle
- 1 Package insert

## Materials Required But Not Provided

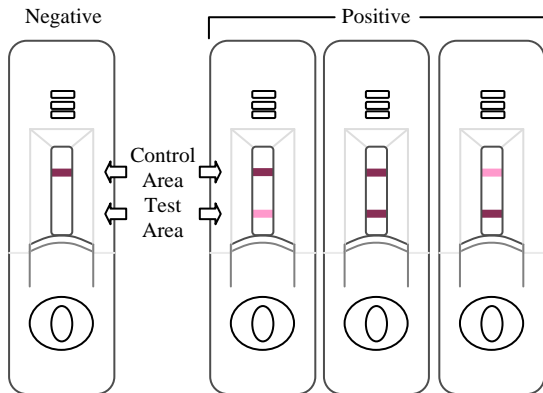
- Test Tubes
- Swabs

## DIRECTIONS FOR USE

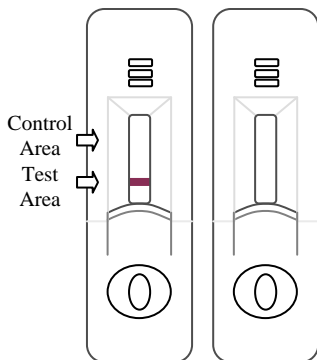
Allow test device, assay buffers, specimen, and/or controls to equilibrate to room temperature (18-30°C) prior to testing. Use a new pipette for each sample/test



## EXAMPLES OF VALID RESULTS



## EXAMPLES OF INVALID RESULTS



## INTERPRETATION OF RESULTS

**POSITIVE:** Two 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 in the test region (T) should be considered positive.

**NEGATIVE:** One color 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-purple 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 InSTIcheck™ 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 can not 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.

## 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 InSTIcheck™ test is intended for use only with endocervical specimens collected on appropriate swabs and urine specimens collected in appropriate containers. Performance of the InSTIcheck™ 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 InSTIcheck™ 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 InSTIcheck™ 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 InSTIcheck™ 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 InSTIcheck™ 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:

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

Relative Sensitivity: >96.9%

Relative Specificity: 98.8%

Accuracy: 97.8%

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

<i>Acinetobacter calcoaceticus</i>	<i>Neisseria armalis</i>	<i>Serotype: typhimurium</i>
<i>Candida albicans</i>	<i>Neisseria cinerea</i>	<i>Salmonella choleraesuis</i>
<i>Chlamydia psittaci</i>	<i>Neisseria flavescens</i>	Subspecies: <i>choleraesuis</i>
<i>Chlamydia pneumoniae</i>	<i>Neisseria lactamica</i>	Serotype: <i>minnesota</i>
<i>Chlamydia trachomatis</i>	<i>Neisseria meningitidis</i>	<i>Serotype: minnesota</i>
<i>Enterococcus faecalis</i>	<i>Neisseria mucosa</i>	(R595) <i>Salmonella choleraesuis</i>
<i>Escherichia coli</i>	<i>Neisseria perflaven</i>	Subspecies: <i>choleraesuis</i>
<i>Gardnerella vaginalis</i>	<i>Neisseria sicca</i>	Serotype: <i>minnesota</i>
<i>Haemophilus influenzae</i>	<i>Neisseria subflava</i>	<i>Staphylococcus aureus</i>
<i>HSV-1</i>	<i>Peptostreptococcus productus</i>	<i>Staphylococcus aureus</i>
<i>HSV-2</i>	<i>Proteus mirabilis</i>	(Protein A Producer)
<i>Klebsiella pneumoniae</i>	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus epidermidis</i>
<i>Lactobacillus fermentum</i>	<i>Moraxella catarrhalis</i>	<i>Streptococcus Group A</i>
<i>Moraxella lacunata</i>	<i>Moraxella lacunata</i>	
<i>Mycoplasma hominis: PG21</i>	<i>Salmonella choleraesuis</i>	
<i>Mycoplasma hominis: W2</i>	Subspecies: <i>choleraesuis</i>	

REF IVD

EC REP

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