# PreventID® Gonorrhoea

Manual (FOR PROFESSIONAL USE)



REF KSTIGO502GP

## Intended Use

The **PreventID® Gonorrhoea** is a rapid chromatographic immunoassay for the qualitative detection of Neisseria gonorrhoeae in female cervical swab and male urethral swab specimens to aid in the diagnosis of Gonorrhoea infection.

## Introduction

Gonorrhoea is a sexually transmitted disease caused by the bacterium Neisseria gonorrhoeae. Gonorrhoea 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 Gonorrhoea 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 Gonorrhoea can be made at the time of examination [1]. In women, Gonorrhoea 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[2]. A smear or swab of urethral or cervical discharge may be taken and tested using **PreventID® Gonorrhoea**.

## Test Principle

The **PreventID® Gonorrhoea** is a qualitative, lateral flow immunoassay for the detection of Gonorrhoea antigen from female cervical and male urethral. In the test, antibody specific to the Gonorrhoea antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhoea that is coated onto particles. The mixture migrates up to react with the antibody to Gonorrhoea on the membrane and generates a colour line in the test region. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## Reagents

The test contains Gonorrhoea antibody coated particles and Gonorrhoea antibodies coated on the membrane.

## Materials

**Materials provided**

- Test devices, individually packed TEST
- Extraction tubes
- Tube rack
- Extraction reagent 1 (0.15 M NaOH)
- Extraction reagent 2 (0.2 M HCl)
- Sterile female cervical swabs (individually packed with orange cap)
- Dropper tips
- Manual

**Materials Required but not Provided:** timer or stop watch, sterile male urethral swabs

## Storage and Stability

Store as packaged in the sealed pouch 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 beyond the expiration date.

## Precautions

1. For professional *in vitro* diagnostic use only. Do not use after the expiry date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.
8. Read the instruction carefully before performing the test.
9. Do not mix reagents from different lots.
10. If you have any questions please contact Preventis GmbH.

## Sample Collection and Sample Preparation

The **PreventID® Gonorrhoea** can be performed using female cervical swab and male urethral swab specimens. The quality of specimens obtained is of extreme importance. Detection of Gonorrhoea antigen requires a vigorous and thorough collection technique that provides adequate amount of antigen.

Female Cervical Swab Specimen:

- Use the swab provided in the kit. Alternatively, any shaft swab may be used.
- 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 Gonorrhoea organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens.
- If the test is to be conducted immediately, put the swab into the extraction tube.

Male Urethral Swab Specimens:

- Standard plastic-or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least 1 hour period to specimen collection.
- Insert the swab into the urethral about 2-4cm, rotate the swab 360°in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collection swab.
- If the test is to be conducted immediately, put the swab into the extraction tube.

It is recommended that specimens be processed as soon as possible after collection. If immediately testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swab may be stored for 4-6 hours at room temperature (15–30 °C) or refrigerated (2–8 °C) for 24 hours. Do not freeze. All specimens should be allowed to reach the room temperature (15–30 °C) before testing.

## Test Procedure

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

1. Remove the test device from the seal pouch and use it as soon as possible. Best result will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Gonorrhoea antigen according to the specimen type.
   - Hold the extraction reagent 1 bottle vertically and add **5 drops of extraction reagent 1** (approx. 300 µL) to the extraction tube. Extraction reagent 1 is colourless. Immediately insert the swab, compress the bottom of extraction tube and rotate swab 15 times. Let stand for 2 minutes.
   - Hold the extraction reagent 2 bottle vertically add **4 drops of extraction reagent 2** (approx. 200 µL) to the extraction tube. The solution would turn turbid. Compress the bottle of extraction tube and rotate the swab 15 times until the solution turn clear with a slight green or blue tint. If the swab is bloody, the colour will turn yellow or brown. Let stand 1 minute.
   - Press the swab against the side of extraction tube and withdraw the swab while squeezing the extraction tube. Keep as much liquid in the extraction tube as possible. Fit the dropper tip on top of extraction tube.
3. Place the test device on a clean and level surface *(Fig. 1)*. Add **3 full drops** of the extracted solution (approx. 100 µL) to the sample application window of the test device, then start the timer. Avoid trapping air bubbles in the sample application window.
4. Wait for the colour to appear. Read the result at **10 minutes**; do not interpret the result after 30 minutes.

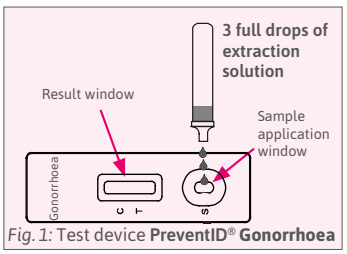


*Fig. 1:* Test device **PreventID® Gonorrhoea**

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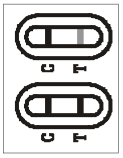
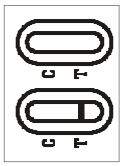
## Test Interpretation




**Positive: Two lines appear**. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). A positive result indicates that Gonorrhoea was detected in the specimen.
**Note:** The intensity of the colour in the test line region (T) will vary depending on the concentration of Gonorrhoea present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.


**Negative: One coloured line appears in the control line region (C).** No line appears in the test line region (T). A negative result indicates that Gonorrhoea antigen is 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 Preventis.

## Test Characteristics

### Expected Values

Gonorrhoea is a common adult disease around the world. With 351,852 Gonorrhoea cases reported in 2002 (125.0 cases per 100,000 person), Gonorrhoea is the second most frequently reported communicable disease in the United States. Gonorrhoea remains a frequently reported sexually transmitted disease, with an estimated more than 300,000 new infections occurring each year in the United States [2]. A significant proportion of those with infection are asymptomatic (up to 80% among women and 10% among men) and many victims will not go to see the doctor, making the prevalence higher than the report rate in fact. For example, in 1997, health care workers reported 324,901 cases of Gonorrhoea in the United States to the U.S. Centers for Disease Control and Prevention (CDC) while the Institute of Medicine, however, estimates that 650,000~800,000 cases of Gonorrhoea occur annually in the United States. Worldwide, an estimated 62 million new cases of Gonorrhoea occurred in 1997 [2, 3, 4]. A significant number of women may be asymptomatic and may be at risk for chronic or disseminated infection [4]. In the case of pregnant women, there is a potential risk of passage of Gonorrhoea to the newborn [5].

### Clinical Study

The **PreventID® Gonorrhoea** has been evaluated with specimens obtained from patients of STD clinics. Culture is used as the reference method for the **PreventID® Gonorrhoea**. Specimens were considered positive if culture indicated a positive result. Specimens were considered negative if culture indicated a negative result.

| | | Female Cervical Swab Specimens | | |
|---|---|---|---|---|
| **Method** | | **Culture** | | **Total Results** |
| **PreventID® Gonorrhoea** | Results | Postive | Negative | |
| | Positive | 67 | 3 | 70 |
| | Negative | 4 | 95 | 99 |
| Total Results | | 71 | 98 | 169 |

Relative sensitivity: 94.4% (95% CI*: 86.2% – 98.4%)
Relative specificity: 96.9% (95% CI*: 91.3% – 99.4%)
Accuracy: 95.9% (95% CI*: 91.7% – 98.3%) *Confidence Intervals

| | | Male Urethral Swab Specimens | | |
|---|---|---|---|---|
| **Method** | | **Culture** | | **Total Results** |
| **PreventID® Gonorrhoea** | Results | Postive | Negative | |
| | Positive | 98 | 3 | 101 |
| | Negative | 9 | 100 | 109 |
| Total Results | | 107 | 103 | 210 |

Relative sensitivity: 91.6% (95% CI*: 84.6% – 96.1%)
Relative specificity: 97.1% (95% CI*: 91.7% – 99.4%)
Accuracy: 94.3% (95% CI*: 90.2% – 97.0%) *Confidence Intervals

### Intra/Inter-assay

Within-run and Between-run precision have been determined with three different lots by using Gonorrhoea negative; low, middle and high positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

### Cross Reactivity

Cross reactivity with other organisms has been studied using suspensions of 107 Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the **PreventID® Gonorrhoea**:

| | | |
|---|---|---|
| Acinetobacter calcoaceticus | Pseudomonas aeruginosa | Proteus mirabilis |
| Acinetobacter spp | Gardnerella vaginalis | Chlamydia trachomatis |
| Enterococcus faecalis | Salmonella choleraesius | Group B/C Streptococcus |
| Enterococcus faecium | Candida albicans | Haemophilus influenzae |
| Staphylococcus aureus | Proteus vulgaris | Klebsiella pneumoniae |

## Quality Control

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. 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.

## Test Limitations

1. The **PreventID® Gonorrhoea** is for *in vitro* diagnostic use only. This test should be used for the detection of Gonorrhoea antigen from female cervical swab and male urethral swab specimens. Neither the quantitative value nor the rate of increase in Gonorrhoea antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Gonorrhoea antigen in specimens from both viable and non-viable Neisseria gonorrhoeae. Performance with specimens other than female cervical swabs and male urethral swabs has not been assessed.
3. 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. Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data available to the physician.
4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
5. Excessive blood on the swab may cause false positive results.
6. Endocervical samples from female patients should not be collected during menstrual period.

References:
1. Knapp, J.S. et al. Neisseria gonorrhoeae. Manual of Clinical Microbiology, Sixth Edition, ASM Press, Washington DC., 324-325 (1995).
2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines 2002. Morbidity and Mortality Weekly Report (2002), 51(RR-6)
3. Forbes B.A., Sahm D.F., Weissfeld A.S. Neisseria and Moraxella catarrhalis. Bailey & Scott's Diagnostic Microbiology, Tenth Edition, Mosby, St. Louis, 597-605 (1998).
4. Summary of the Notifiable Diseases, United States, 1998, Morbidity and Mortality Weekly Report (1999), 47(53): 1-93.
5. National Institute of Allergy and Infectious Diseases, National Institute of Health, US Department of Health and Human Services, NIAID Fact Sheet on Gonorrhea, October 2004.

*US: all products: Research Use Only. Not for use in diagnostic procedures.*

| | |
|---|---|
| Temperature limitation | Manufacturer |
| *In vitro* diagnostic device | Lot number |
| Catalogue number | Expiry date |
| Keep away from sunlight | Do not reuse |
| Read user instructions | Contains sufficient for <n> tests |

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