



## Rapid Test for Gonorrhea (Urine or Swab Specimens)

*A rapid, direct binding test for visual detection of gonorrhea.*

*For professional in vitro use only.  
Not for Sale in U.S.A.*

### INTENDED USE

The *ABI* Gonorrhea One-Step Test (Device or Cassette) is a rapid and sensitive direct binding test for visual detection of gonorrhea in urine and secretory specimen.

### SUMMARY AND EXPLANATION

The *ABI* One-Step Gonorrhea Test (Urine/Swab) is a rapid direct binding test that qualitatively detects the presence of gonorrhea antigen in urine and secretory specimen from urogenital system. The test utilizes monoclonal antibodies to selectively detect gonorrhea antigen in urine and secretory specimen. The *ABI* One-Step Gonorrhea Test (Urine/Swab) shows no cross-reactivity interference from any medication that is being taken. The test is ideal for screening samples containing at least  $1 \times 10^9$  bacteria per ml.

### PRINCIPLE OF THE PROCEDURE

The *ABI* One-Step Gonorrhea Test (Urine/Swab) is a rapid direct binding test based on the principle of a double sandwich immunoassay for the qualitative detection of gonorrhea antigen in urine and secretory specimen to aid in the early detection of gonococcus infection. The assay is conducted by adding pre-treated specimen to the sample well of the cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored dried conjugate of colloidal gold-monoclonal antibody. The sample reconstitutes the dried conjugate. If gonococcus antigen is present in the sample, it will react with the monoclonal antibody to form a complex of colloidal gold-monoclonal antibody-gonorrhea. This complex migrates up the membrane strip chromatographically and through the band of immobilized antibody. Because the immobilized antibody is able to bind to the gonococcus antigen molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized antibody. If there is no gonococcus antigen present in the treated sample, the colloidal gold-monoclonal antibody conjugate will pass through the immobilized antibody band and no colored line will form – a negative test result.

Further up the membrane, pass the test region, is a control region. This band of antibody will bind only conjugate and form a colored line, regardless of whether gonococcus antigen is present in the sample or not. Appearance of the control line assures reagent integrity as well as correct testing procedure.

### REAGENTS

The test contains monoclonal (murine) anti –gonorrhea coated particles and monoclonal anti-gonorrhea coated on the membrane.

### PRECAUTIONS

- For professional *in vitro* use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as infectious agents. Wear disposable gloves throughout specimen collection and assay procedure.
- The test should be discarded in a proper biohazard container after testing.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4 - 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.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Sample

A urine specimen must be collected in a clean and dry container. Transfer the specimen to a centrifuge tube and centrifuge. Pour off the urine and treat the urine sediment as the sample.

#### Swab Sample

Use a swab to collect a specimen in the following suggested method:

- 1) Male patients: Swab discharge from the opening of the urinary tract. If no discharge is present, insert the swab 2-3 cm into the urinary tract, gently move a few turns and retrieve the swab.
- 2) Female patients: Swab discharge from the vaginal opening, then insert the swab into the vagina for half a minute and retrieve the swab.
- 3) Place the swab into the extraction tube and add 600µL of extraction solution on the swab. Compress the bottom of the tube between the thumb and the forefinger and twirl the swab 10 times.
- 4) Incubate at room temperature (15 to 30 °C) for 5 to 10 minutes. Compress the bottom of the tube between the thumb and forefinger and twirl the swab 10 times.
- 5) Expunge as much liquid as possible from the swab by compressing the middle of the tube and pulling the swab up through it. Discard the swab into an appropriate biohazard disposal container. Insert a tip on the tube and mix contents by gentle swirling. The swab extract must be tested immediately.

#### Specimen Storage

Specimen collected in the diluent can be stored at 4 - 8°C and tested within 24 hrs.

### TEST PROCEDURE

#### Materials Provided

- Test devices
- Extraction Solution
- Disposable specimen droppers
- Package insert

#### Materials Required But Not Provided

- Specimen collection container
- Timer
- External Controls
- Centrifuge
- Pipette

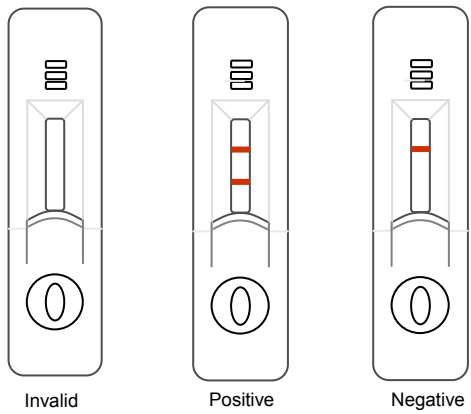
### DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 4 full drops of sample (approx. 200µL) into the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 10-20 minutes. It is important that the background is clear before the result is read.

Note: Do not interpret the result after 30 minutes.

## Interpretation of Test Results



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

**POSITIVE:** Two bands will appear in the control and test areas, which indicate a positive result for gonorrhea.

**NEGATIVE:** A color band will appear only in the control area, which indicates a negative result.

### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

It is recommended that a positive Gonorrhea control and a negative Gonorrhea control be evaluated to verify proper test performance when a new shipment of test devices is received.

Users should follow their federal, state or local and laboratory guidelines concerning frequency for running external controls.

### LIMITATIONS

This test provides a presumptive diagnosis for Gonorrhea. A confirmed, infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

### EXPECTED VALUES

Negative results are expected in healthy non-infected women and men.

The ABI Gonorrhea One-Step Test Device (Urine/Swab) is capable of screening samples containing at least  $1 \times 10^5$  bacteria per ml.