

# One Step Strip Style Gonorrhea Antigen Rapid Test

## INTRODUCTION

One Step Strip Style Gonorrhea Test is a rapid direct binding test for the visual detection of gonorrhea antigen, in the secretory specimen and urine from urogenital system, as an aid in the diagnosis of gonococcus infection. It is based on the principle of double sandwich immunoassay for detection of gonorrhea antigen in the secretory specimen or urine. Monoclonal and polyclonal antibodies are employed to identify gonorrhea specifically. Both sensitivity and specificity of the test are higher than those of the present methods that often involve long hours of culturing the collected specimen. Test results are not affected by medication that is being taken. Results are read visually without any instrumentation. This test is ideal for screening specimen samples containing at least  $1 \times 10^5$  bacteria per ml.

## SPECIAL FEATURES

- ✓ Test result is unambiguous and can be read in 10-20 minutes.
- ✓ Test kit is easy to operate and does not involve washing or comparison to standards.

## MATERIALS PROVIDED

1. Test strip
2. Specimen diluent 1
3. Specimen diluent 2

## SPECIMEN COLLECTION

1. Use a swab to collect specimen in the following suggested method:
  - a) Male patients: Swab discharge from the opening of the urinary tract. If no discharge is present, insert the swab 2-3cm into the urinary tract, gently move a few turns and retrieve the swab.
  - b) Female patients: Swab discharge from the vaginal opening, then insert swab into vagina for half a minute and retrieve the swab.
2. Place the swab into a microtube and add 6 drops (300 $\mu$ L) specimen diluent 1 on the swab, rotate swab and squeeze. Discard the swab into an appropriate biohazard disposal container. Then add 2 drops (100 $\mu$ L) diluent 2 into the microtube and mix well. Specimen collected in the diluent should be stored at 4-8°C and tested within 24 hours.

## TESTING PROCEDURE

Following the illustration, dip the test strip with the arrow pointing down into the specimen for about 5 seconds. Do not immerse past the MAX line. Wait 10-20 minutes and read results. Do not read results after 30 minutes.

## INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control region. No apparent band on the test region.
- **Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
- **Invalid:** A total absence of color in both regions is an indication of procedure error and/or test reagent deterioration.

## STORAGE AND STABILITY

The test kits can be stored at room temperature (2 to 30°C) or in a refrigerator (0 to 4°C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat. If the test kit package was refrigerated, allow it to reach room temperature first before usage.

## PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.
3. Do not use the test kit beyond the expiry date.
4. The test device should not be reused.

## MANUFACTURER

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