



REF

Catalog Number R0085S

IVD

In vitro Diagnostic

## INTENDED USE

The *OnSite* Gonorrhea Rapid Test is intended for the qualitative detection of the oxidase activity of *Neisseria gonorrhoeae* (*N. gonorrhoeae*) in the secretory specimen from urogenital system, as a screening test and as an aid in the diagnosis of infection with *N. gonorrhoeae*. Any reactive specimen with the *OnSite* Gonorrhea Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

## SUMMARY AND EXPLANATION OF THE TEST

Gonorrhea is the result of infection by *N. gonorrhoeae*, a gram-negative diplococcus that only infects human and causes a wide spectrum of clinical syndromes. The failure of clinicians to appreciate all possible manifestations of the disease, including the sub clinical ones, can result in missed diagnostic and therapeutic opportunities<sup>1</sup>.

Gram stain evaluation and culture isolation (especially in men) remain sensitive, specific, and inexpensive for gonococcus infection but the procedure is time consuming<sup>2</sup>. Nucleic acid amplification is superior to the traditional method<sup>3-4</sup>. However, this test is expensive and time consuming as well. Recently, rapid, non-culture tests became available to aim at instant diagnosis of gonococcus infection at a low cost<sup>5</sup>.

The *OnSite* Gonorrhea Rapid Test is a non-culture test and detects presumptive infection of *N. gonorrhoeae* in less than 1 min. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

## TEST PRINCIPLE

The *OnSite* Gonorrhea Rapid Test detects the activity of oxidase produced during gonococcus replication in the infected site<sup>6-10</sup>.

The test strip is pre-coated with the substrate of oxidase. The swab specimen if contains this enzyme, will react to the substrate, forming a color substance. The test result can be visually interpreted by color change.

## REAGENTS AND MATERIALS PROVIDED

- Each kit contains 50 test devices, each sealed in a foil pouch containing:
  - One test strip with swab
  - One desiccant.
- One package insert (instruction for use).

## MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or Timer

## WARNINGS AND PRECAUTIONS

## For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C -30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

## REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C -8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

- When ready to test, open the pouch at the notch and remove swab from the pouch.

## For Male:

Swab discharges from the opening of the urinary tract. If no discharge is present, insert the swab 2-3 cm into the urinary tract, gently rotate the swab and then retrieve the swab.

## For Female:

Swab discharges from the vaginal opening, or for more accurate results, insert swab into cervix or vagina for half a minute, rotate and retrieve the swab.

## Note:



- Soak the swab with saline first if discharge is too viscous.
- Don't apply blood, sperm, or other discharges from non- urogenital system.
- Collect cervical discharges without blood if in menstrual period.
- Don't take any vaginal medicine for 3 days prior to this test

Test the specimen immediately. Avoid drying out the specimen.

## ASSAY PROCEDURE

- Step 1: Take out the test strip from the pouch.
- Step 2: Apply the swab onto the orange strip.
- Step 3: Wait for 10 to 20 seconds to read result.

## INTERPRETATION OF ASSAY RESULT

Negative   
Positive 

**NEGATIVE:** Strip color remains orange or light green as demonstrated above.

**POSITIVE:** The color changes to dark green or dark blue as demonstrated above, suggesting the specimen presumptively contains *N. gonorrhoeae* oxidase. The test is positive.

**The positive test result should be confirmed by other confirmative tests.**

Note: Having Sex 3 days prior to testing may lead to false test result.

## PERFORMANCE CHARACTERISTICS

## Clinical Performance

A total of 200 samples from susceptible subjects were tested by the *OnSite* Gonorrhea Rapid Test and by a culture test.

## Comparison for all subjects

Culture	<i>OnSite</i> Gonorrhea Rapid Test		Total
	Positive	Negative	
Positive	48	2	50
Negative	3	147	150
Total	51	149	200

Relative Sensitivity: 96%, Relative Specificity: 98%, Overall Agreement: 97.5%

## LIMITATIONS OF TEST

- The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of *N. gonorrhoeae* oxidase in swab specimen from individual subjects. **For optimal test performance, proper sample collection and storage procedures are critical.** Failure to follow the procedure may give inaccurate results.
- The *OnSite* Gonorrhea Rapid Test is limited to the qualitative detection of *N. gonorrhoeae* oxidase in secretory specimen from urogenital system. The intensity of the test color does not correlate with the amount of the oxidase in the specimen.
- A negative result for an individual subject indicates absence of detectable *N. gonorrhoeae* oxidase. However, a negative test result does not preclude the possibility of exposure to or infection with *N. gonorrhoeae*.

4. A negative result can occur if the quantity of the oxidase present in the specimen is below the detection limits of the assay, or the oxidase that is detected are not present during the stage of disease in which a sample is collected.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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European Authorized Representative:



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**Index of CE Symbol**

	Attention, see instructions for use
	For <i>in vitro</i> diagnostic use only
<b>REF</b>	Catalog #
	Lot Number
	Use by
	Tests per kit
	Store between 2-30°C
	Do not reuse
	Manufacturer
	Date of manufacture