IVD

GONOCOCCUS DIAGNOSTIC KIT

Catalog No. B0101

25 tests

INTENDED USE

The Autobio gonococcus diagnostic kit is a biochemical assay designed for the rapid detection of gonococcus, aiding in the diagnosis of gonorrhea.

INTRODUCTION

Gonorrhea is a serious sexually transmitted disease (STD) caused by bacteria called *Neisseria gonorrhoeae*. At the beginning of adult infection, these bacteria can infect the genital tract, the mouth and the rectum. In women, the opening to the cervix is the first place of infection. However, the disease can be spread into the uterus and fallopian tubes, resulting in pelvic inflammatory disease (PID), and can cause infertility in as many as 10 percent of infected women and tubal (ectopic) pregnancy. Gonorrhea is spread during sexual intercourse. Infected women also can pass gonorrhea to their newborn infants during delivery, which causes eye infections in their babies and eventually leads to blindness.

Many methodologies could be used to test gonorrhea such as culturing method, immunological reactions, PCR, microscopy and biochemical enzyme method. The biochemical enzyme method, due to its advantages of no requirement for additional equipment, rapid and convenient and low price, is more and more favored by medical laboratory staff, being widely utilized in the screening of gonorrhea.

This assay is able to rapidly detect gonococcus, is not dependent upon special equipment, is highly sensitive, convenient and rapid, easy to distinguish the result and is painless to obtain specimens. It is well suited for use in hospitals of all levels, clinics and even individuals. It is especially good for assaying big volume specimens taken from physical examinations.

PRINCIPLE OF THE TEST

Gonococcus possesses a special kind of enzyme. If we add the reagent provided in the kit to the positive specimen, a reaction will occur, and a large quantity of bubbles would be generated from the reaction.

MATERIALS PROVIDED

1. Test Tube (25 tubes)
2. Reagent (1 bottle)

STORAGE OF TEST KIT AND INSTRUMENTATION

This assay should be stored at room temperature. The test kit may be used throughout the expiration date of the kit (1 year from the date of manufacture). Refer to the package label for the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Collect the first stream urine specimen with a disposable urine cup, or use a swab to sample cervical secretion (female) or urethra secretions (male), a specimen must be assayed within 1 hour.

PRECAUTIONS AND WARNINGS

1. This assay is supposed to be operated at room temperature (15 – 30℃) under a relative humidity of 65% ± 20%.
2. When dropping the reagent, the bottle must be held upright.
3. The clinical diagnosis is not supposed to be based only on the assay result. Because this assay is a rapid screening test with a relatively high sensitivity. Therefore, if the result is positive the sufferer's sexual contact (vaginal, oral, or anal) history and clinical symptoms should be taken into account in combination. It is recommended to carry out a bacterial culture on a gonococcus culture medium.
4. Wear disposable gloves during operation. Do not contact with skin or eyes. Once contacted, flush with copious amount of water.
5. Assure the tube opening is tightly plugged.
6. The result must be observed in 20 minutes; otherwise, the specimen must be re-assayed.

7. The urine specimen must be assayed within 1 hour; otherwise, another specimen must be taken.
8. Before disposing of a test tube where a positive reaction has occurred, the tube opening must be unplugged to prevent gas generated from the reaction from force opening the plug, which in turn contaminates the lab.
9. The specimen collected and the corresponding culture waste are supposed to be treated as potentially infectious, which have to be disposed according to standard working procedures set out for infectious disease laboratories.

ASSAY PROCEDURE

1. Obtain a test tube provided with the assay; add 2 mL of the specimen (approximately 1 mm below the mark on the tube. In the case of urine specimen, add directly; as to secretion specimen, flush the specimen absorbed within the swab with normal saline solution, into the test tube, then damp the swab.)
2. Hold the reagent bottle uprightly while adding 3 drops of the reagent. Plug the tube opening and mix gently.
3. After being placed for 5 minutes (for patients with mild symptoms, the time could be extended to 10 minutes), gently shake the tube another time (in case bubbles are already generated, do not shake), observe the generation of bubbles at the top of the liquid inside the tube. Results observed after 20 minutes are invalid.

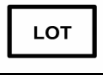
INTERPRETATION OF RESULTS

When a layer of or a circle of white air bubbles are observed at the top of the solution, the specimen is positive; in the case that no air bubbles are present or the bubbles are not sufficient to form a complete circle, the specimen is negative.

LIMITATION

Gonococcus assay relies on a specific enzyme possessed by gonococcus, which is not present in the most majority of interfering bacteria in the genital tract. Very few interfering bacteria, although possess this enzyme, are not able to generate false positive results due to low enzymatic activity, provided that the amount of the interfering bacteria lies within in the normal range. Under abnormal conditions, however, the amount of interfering bacteria or the enzymatic activity increases largely, which lead to false positive results. Consequently, the specificity of the assay is not guaranteed to be 100%, particularly for female patients, the specificity may be even lower. Cross reactions may occur on specimens collected from females in the menstruation period or those suffering from excessive leucorrhea. Hence, it is recommended to avoid the menstruation period when performing the assay. As for other types of specimens, in case the assay result is positive, the abovementioned conditions must be taken into account. Furthermore, a bacterial culture is supposed to be carried out on the surplus specimen. Then the conclusive diagnosis must be made considering patient history. A portion of the disease carriers, including children, are infected through contact with public facilities which are not hygiene, e.g. public bath, swimming pools, public toilets, etc., other than abusive sex activities. As a result, a positive result must be dealt with caution. When necessary, a bacterial culture should be carried out to confirm the result. Hematuric specimens or specimens with elevated urine proteins might generate false positive results, so these types of specimens are not permitted to be assayed.

SYMBOLS

	**BATCH CODE**
	**USE BY**
	**MANUFACTURER**
	**CONTAINS SUFFICIENT FOR <n> TESTS**

IVD	***IN VITRO* DIAGNOSTIC MEDICAL DEVICE**
	**TEMPERATURE LIMITATION**
REF	**CATALOGUE NUMBER**
	**CONSULT INSTRUCTIONS FOR USE**

REFERENCES

1. Tang X, Zhang W and Zhang Z, et. al. 1995. The Identification of Polymorphism as One of the Phenotypes of *Neisseria gonorrhoeae* with a Molecular Biology Method. Chinese Journal of Microecology. **9**: 39 – 41.
2. Yin X, Jiang P, Deng Y, et. al. 2004. The Separation and Identification of *Haemophilus parasuis*. Animal Husbandry & Veterinary Medicine. **36**: 6 – 8.

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