ULTI MED GONORRHOEA TEST
014B500-20

ulti med Gonorrhoea Test for body fluid specimens flocked swabs

SUMMARY
Gonorrhoea is a sexually transmitted disease. The presence of the bacteria *Neisseria gonorrhoeae* in body fluids indicates a possible infection.

INTENDED USE
ulti med Gonorrhoea Test is a rapid, direct binding test for the visual detection of gonorrhoea antigen, in the secretory specimen from urogenital system. It is used as an aid in the diagnosis of gonococcus infection. It is intended for professional use only and for in vitro diagnostic use only. Test results are unambiguous and can be read in 10-20 minutes. The test kit is easy to operate and does not involve washing or comparison to standards.

MATERIALS PROVIDED
- Gonorrhoea test cassette in foil pouch (20 per kit box)
- Flocked swabs (20 per kit box)
- Test tubes and dropper tips (20 per kit box)
- Workstation with extraction tubes and dropper caps (1 per kit box)
- Reagent 1 (1 per kit box)
- Reagent 2 (1 per kit box)
- Package insert (1 per kit box)

MATERIALS NEEDED BUT NOT PROVIDED
- Timer

PRINCIPLE OF TEST
ulti med Gonorrhoea Test is based on the principle of double sandwich immunoassay for the detection of gonorrhoea antigen in the secretory specimen. Monoclonal and polyclonal antibodies are employed to identify gonorrhoea specifically. Both sensitivity and specificity of the test are higher than those of the present methods, which often involve long hours of culturing the collected specimen. Test results are not affected by any medication that is being taken. Results are read visually without any instrumentation. This test is ideal for screening specimen samples containing at least 1 x 10^5 bacteria per ml.

The assay is conducted by adding diluted swabbed discharge specimen to the test device and observing the formation of coloured lines. The specimen migrates via capillary action along the membrane to react with the coloured conjugate. Positive specimens react with the specific coloured antibody conjugates and form a coloured line at the test line region of the membrane. Absence of this coloured line suggests a negative result. To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

REAGENTS
Coated Antibodies:
Control region: Goat anti-mouse (IgG) polyclonal antibody
Test region: Mouse monoclonal anti-gonococcus antibody A

Labeled Antibodies:
Colloidal gold conjugate of mouse monoclonal anti-gonococcus antibody B

WARNINGS & PRECAUTION
- In vitro diagnostic use for professional use only.
- Do not use test kit beyond the expiry date.
- The test device should not be reused.
- 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.

DIRECTIONS FOR USE
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 2-3 cm 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 the test tube and add 6 drops (300 µl) of Reagent 1 onto the swab. Place the flocked swab in the test tube and rotate the flocked swab between two fingers for 10-15 seconds. Discard the swab according to local regulations. Then add 2 drops (100 µl) of Reagent 2 into the test tube and mix well. Fit the dropper tip on top of the extraction tube. Specimen collected in the solution should be stored at 4-8ºC and tested within 24 hours.
3. Allow the test and the specimen to equilibrate to room temperature (15-30℃) prior to testing
4. To begin testing, open the sealed pouch by tearing along the notch. Remove the test cassette from the pouch and use it as soon as possible.
5. Dispense 4 drops (approx. 0.2 ml) from the extraction tube into the sample well of the cassette (see figure).
6. Wait for the coloured lines to appear. Depending on the concentration of bacteria in the test specimen, positive results may be observed in as little as few seconds. To confirm negative results, the test must be read again in 20 minutes. Do not read results after more than 20 minutes.

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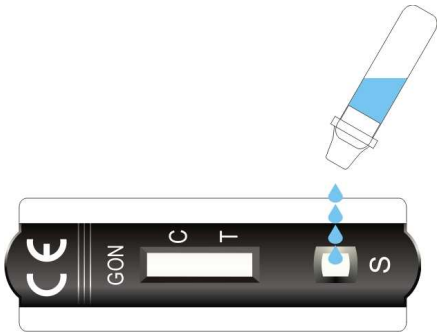


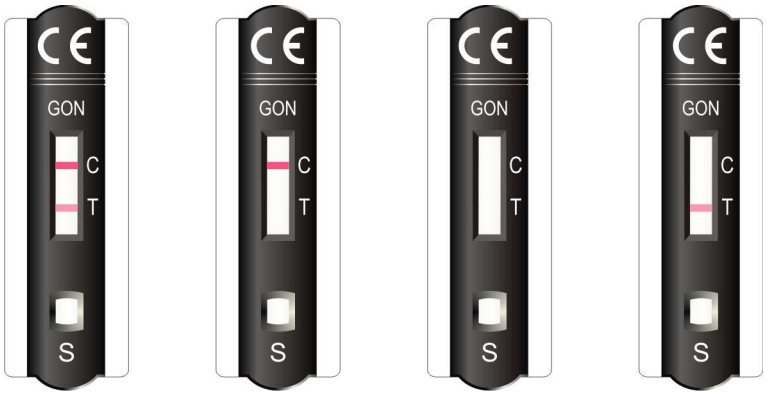
Note: A low bacterial concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: Only one coloured line appears on the control region. No apparent line on the test region.

Positive: Distinct colour lines appear on the control and test regions. The test result can be read as soon as the distinct coloured lines appear in the test region.

Invalid: No line appears in the control zone "C", the test should be voided since an improper test procedure may have been performed or deterioration of reagents may have occurred. This is due to the internal control built in which a distinct control region (C) line should always appear. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



positive **negative** **invalid** **Reproductions may vary from original!**

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit must be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

QUALITY CONTROL

A coloured 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 an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result. External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

LIMITATIONS

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other tests to diagnose gonorrhoea. A positive result would need a further confirmatory test.

2. The ulti med Gonorrhoea Test is a presumptive, screening test for the presence of *Neisseria gonorrhoeae*. If test results are negative but clinical symptoms are indicative of gonorrhoeal infection, further tests are recommended. Cell culture is the standard reference test method for the detection of *Neisseria gonorrhoeae*.

3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single laboratory test, but should only be made by the physician after all clinical and laboratory tests have been evaluated.

PERFORMANCE CHARACTERISTICS

Expected Values

Ulti med Gonorrhoea Test is designed to show a positive result for *Neisseria gonorrhoeae* at a concentration of 1×10^5 bacteria/ml.

Accuracy

To establish the sensitivity and specificity of ulti med gonorrhoea test kit relative to other rates of qualitative gonococcus tests, 205 clinical samples were studied. Another commercially qualitative test kit (PCR-gonorrhoea) was used to compare with ulti med Gonorrhoea test kit for relative sensitivity and specificity in 205 swab samples. Only 2 samples were discordant, the agreement is 99%. The detailed results are shown in Table 1.

Table 1 - Comparison of ulti med Gonorrhoea with PCR product for 205 cases

		Results of ulti med kits		Subtotal
		+	-	
Results of PCR kits	+	78	1	79
	-	1	125	126
Subtotal		79	126	205

Interfering Substances
The cross reactivity of product was evaluated using other bacterium strains. *E. Coli*, *Salmonella Typhi*, *Staphylococcus Aureus*, *Pseudomonas Aeruginosa*, *Shigella*, and *Proteus* were added to samples and were tested for cross reactivity. No cross reactivity was observed. The results are show in Table 2.

Table 2- Cross-reactivity study of ulti med Gonorrhoea test kit

	CROSS REACTIVITY
E.Coli	-
Salmonella Typhi	-
Staphylococcus Aureus	-
Pseudomonas Aeruginosa	-
Shigella	-
Proteus	-

References:

St John RK, Curran JW: Epidemiology of gonorrhoea. Sex Transm Dis. 1978 Apr-Jun;5(2):81-2. No abstract available.

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Woods GL: Update on laboratory diagnosis of sexually transmitted diseases. Clin Lab Med. 1995 Sep;15(3):665-84. Review.

Sherrard JS, Bingham JS: Gonorrhoea now. Int J STD AIDS. 1995 May-Jun;6(3):162-6. Review. No abstract available.

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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