KNOW.

IVD

REF: MSSH

Version No.: 2

Date: 2nd, April 2024

Know Rapid STD Screening Kit
(Sexual Transmitted Infection Self Rapid Urine Screening Kit)

Format: 4 in 1 combo test cassette
Specimen: Urine
Package Size: 1 Test / kit

[Intended Use]

The **Know Rapid STD Screening Kit** is intended for rapid chromatographyic immunoassay for the qualitative detection of 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae (NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG) antigen in human urine specimens from individuals for at home use. This device is not intended to be diagnostic and is instead intended to be used to aid in the diagnosis of disease.

[Summary]

Sexually transmitted infections (STIs) are among the most common causes of illness in the world and have far-reaching health, social and economic consequences for many countries[1]. STIs remain a public health problem of major significance in most parts of the world[1]. The incidence rate of acute STIs is believed to be high in many countries[1]. Failure to diagnose and treat STIs in an early stage may result in serious complications and sequelae, which includes infertility, fetal wastage, ectopic pregnancy, anogenital cancer and premature death, as well as neonatal and infant infections[2]. Females who have haemophilus infection may cause abnormal, foul-smelling, grayish vaginal discharges and sometimes redness or itching of vulva[3]. Males may harbor the germs that cause this infection in their bodies, but are usually asymptomatic[4]. Vaginitis, whether infectious or not, constitutes one of the most common problems in clinical medicine, and it is one of the main motives that lead women to seek out an obstetrician or gynecologist [5].

1. **Chlamydia trachomatis (CHT)** is known as the most common sexually transmitted bacterial pathogen[6]. It is a major cause of cervicitis, urethritis, endometritis and pelvic inflammatory disease in women and conjunctivitis and pneumonia in newborn [6] [7]. Men with symptoms typically have urethritis, with a mucoid or watery urethral discharge and dysuria.. Some men develop epididymitis (with or without symptomatic urethritis) with unilateral testicular pain, tenderness, and swelling. Chlamydia can infect the rectum in men and women[8].
2. **Neisseria gonorrhoeae (NGH*)*** is a common sexually transmitted infection caused by a type of bacteria Neisseria gonorrhoeae. It usually spreads through vaginal, oral and anal sex, it is one of the most common STIs[9]. It occurs simultaneously in around 50% of cases with Chlamydia or non-gonococcal urethritis (NGU) depending on the sex of the individual infected. It is spread by sexual contact and can also be spread by vertical transmission from mother to a newborn baby [9][10][11]. Neisseria Gonorrhoeae infection is treatable with some antibiotics, but antibiotic resistant strains are now becoming more common [10][11].
3. **Trichomonas vaginalis (TV)** is a preventable and curable sexually transmitted protozoan that infects the urogenital tract[12]. Although the majority of infections are asymptomatic, more than 50% of women with Trichomonas vaginalis infection have vaginal discharge and about 10% of men have urethritis.[12] The parasite is transmitted during oral, vaginal and anal sex, and in some rare instances during delivery[12]. Correct and consistent use of condoms during sex can prevent trichomoniasis[12]. Most infections in men and women are asymptomatic. Symptomatic women can have vaginal discharge (yellow in color), which may appear purulent. Other symptoms include a red and sore vagina. The person with the infection can also feel pain during intercourse and urination[12]. When T. vaginalis is present, a yellow or greenish and possibly frothy discharge can be observed in the vagina during a speculum examination by a health provider. Men are often asymptomatic, but some experience penile irritation and urethritis[13].
4. **Mycoplasma genitalium (MG):** It is now clear that Mycoplasma genitalium (MG) is the prime rather than secondary cause of many infections, including forms of bacterial vaginosis (BV) and non-gonococcal urethritis (NGU)[14]. Mycoplasma genitalium is an STD that can cause infection among people of any gender. Mycoplasma genitalium can infect the cervix (opening to the uterus), inside the penis (the urethra), or the rectum [14]. It has also been associated with pelvic inflammatory disease (PID) and implicated in other infections once attributed to other bacteria[14]. Most cases of MG are asymptomatic[14]. Mycoplasma genitalium symptoms also differ significantly in women and men: MG causes symptomatic and asymptomatic urethritis among men[14]. Women tend to experience vaginal itching, burning on urination, and pain during intercourse[14]. They may also find themselves bleeding between periods or after sex [14].[15] . MG is also associated with bacterial vaginosis, the symptoms of which can include a fishy odor after sex and changes in vaginal discharge. Men, on the other hand, may experience urethral discharge, burning on urination, and pain and swelling of the joints (arthritis). MG is the most common cause of non-chlamydial non-gonococcal urethritis in men [15.][16] .

Please refer to the reference section in this document to see the supporting literature.

[Principle]

The **Know Rapid STD Screening Kit** includes individual test strips for 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae

(NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG). Each test strip in the cassette is suitable for urine specimen screening. During screening test, if a specific antigen presented in the urine specimen reacts with each test cassette in the T reagent area, the conjugate antigens complex will be bound with the test cassette's antibody coated on the membrane in case of a positive result. This would show in a dark red colored line in the T line region of a positive result. In case of negative result, no conjugate would bind at the test cassette's antibody in the T line region and no line would form in the T line region of the test membrane. The C line serves as an internal qualitative control of the test system to indicate that an adequate volume of specimen has been applied and the flow occurred. The absence of the C line indicates an invalid test result.

[Components]

1. The test: 4 in 1 combo test cassette packed with desiccant and sealed in a foil pouch.
2. 1 set of sample accessories, each set is included the following items:
   a) 1 Sample tube included to 0.5ml buffer solution (content to: 0.5% Tween-80 0.01M PBS, PH 7.5, 0.01% NaN_3)
   b) 1 Sample dropper
   c) 1 Urine specimen collection cup
3. 1 "Quick Start Guide" with T line reaction color scale reference chart
4. 1 Package Insert

[Materials Required But NOT Provided]

1. Timer
2. Protective tools

[Storage and Stability]

The reagent kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date. The opened test cassette from the aluminum foil bag must be used within one hour.

[Shelf Life] 24 months, store at 2 – 30 ℃


[Precautions]

1. Read the package insert carefully before starting the tests. Follow the instructions to ensure accurate test results.
2. For in vitro diagnostic use only. Do not use it after the expiration date. Do not reuse.
3. **The Sample Buffer Solutions contain a saline solution with a bactericide (sodium azide) and a detergent at low concentrations. If the solution comes in touch with the skin or eyes, use a lot of water to flush it.**
4. Do not eat, drink or smoke in the area where the urine specimens or kits are handled.
5. **Store the test kit at room temperature and keep it in a dry place, away from direct sunlight. Avoid excessive heat (>30 °C).**
6. **Do not freeze the test kit.**
7. **Handle urine specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.**
8. **Discard the opened but not used test device when exposed to air for more than an hour.**

[Specimen Collection and Preparation]

The **Know Rapid STD Screening Kit** can be performed by using human urine. Morning urine will have better detection sensitivity. Do not add any preservatives in the urine sample. The urine can be stored at room temperature if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8°C for up to 14 days or at -10°C to -20°C for longer periods before testing. When necessary, urine specimens should be shipped in leak-proof containers at 2-8°C or frozen. Allow all specimens to equilateral to room temperature before screening test.

[Test Procedure]

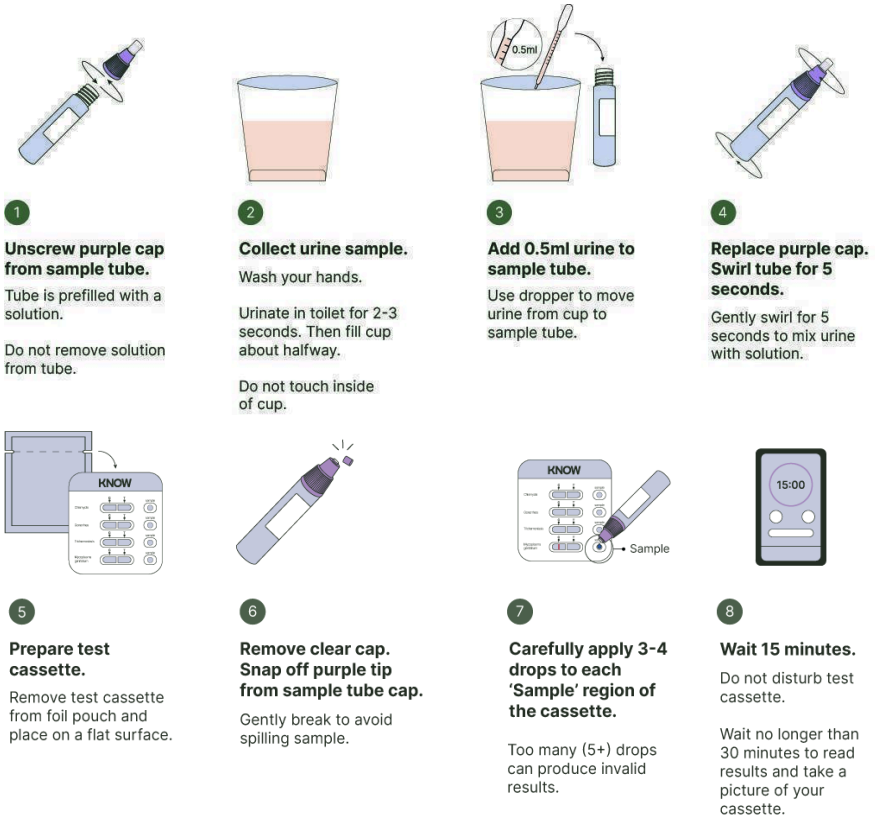
Allow the test, specimen, and test reagents to reach room temperature (15-30°C) prior to testing.

1. Unscrew purple cap from sample tube. Tube is prefilled with a solution. Do not remove the solution from the tube.
2. Collect urine samples. Wash your hands. Urinate in the toilet for 2-3 seconds. Then fill the cup about halfway. Do not touch

the inside of the cup.

3. Add 0.5ml urine to the sample tube. Use a dropper to move urine from cup to sample tube.
4. Replace purple cap. Swirl tube for 5 seconds. Gently swirl for 5 seconds to mix urine with solution.
5. Prepare a test cassette. Remove the test cassette from the foil pouch and place on a flat surface.
6. Remove the clear cap. Snap off purple tip from sample tube cap. Gently break to avoid spilling samples.
7. Carefully apply 3 to 4 drops to each 'Sample' region of the cassette. Too many (5+) drops can produce invalid results.
8. Wait 15 minutes to read the results. Do not disturb the test cassette. Wait no longer than 30 minutes to read results and take a picture of your cassette.

[Simple Operation Diagram]



[Result Interpretation]

- **Positive**: A red line appears on Control Line and a red line on Test Line.
  - Following the Reactive T line Color Scale Chart to interpret the positive T line reaction scale for Antigen reaction reference.
- **Negative**: A red line appears on the Control Line.
- **Invalid**: A total absence of color in both regions is an indication of procedure error and/or test reagent deterioration.

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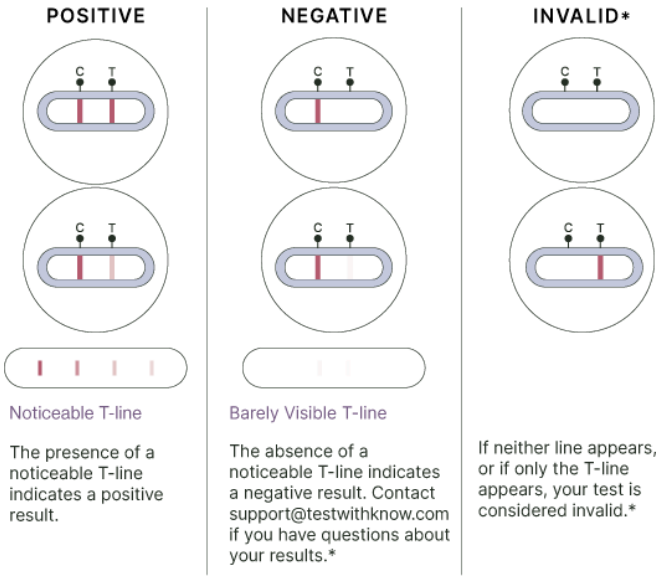

Important Note:

The results of the screening kit are not a substitute for professional medical advice or a diagnosis of infection or disease. We advise users to consult medical professionals or healthcare providers to seek medical advice, diagnosis, or treatment.

[Telehealth]

If the screening kit indicates a positive result for a STD, or the results are negative but you still have symptoms, you can request a Telehealth visit at https://testwithknow.com/products/telehealth-visit to connect with a doctor to discuss symptoms and potential treatment. Upon requesting the Telehealth visit, you will receive an email that links to a medical intake questionnaire. After you submit the form (note: you will need a photo Id and picture of your test results), a board-certified doctor will reach out to begin the Telehealth visit.

[Sensitivity and Specificity]

The **Know Rapid STD Screening Kit** is manufactured by MobiLab Medical Innovative Inc. MobiLab conducted a validation study for detecting 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae (NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG), antigen in human urine specimens. The results are seen below.

Performance Result		1. Chlamydia trachomatis (CHT)	2. Neisseria gonorrhoeae (NGH)	3. Trichomonas vaginalis (TV)	4. Mycoplasmagenitalium (MG)
Sensitivity	MobiLab Brand	87%	93%	100%	90%
	Market brand	82%	87%	92%	100%*
Specificity	MobiLab Brand	88%	90%	99%	88%
	Market brand	98%	80%	92.2%	100%

Note: Confirmation with Culture Method – Culture method is growing bacteria in the controlled setting (lab) to identify MG bacteria in a sample, to confirm our screening test sensitivity and specificity

[Cross Reaction]

The Other common causative agents of infectious diseases were evaluated for cross reactivity with the screening kit. Some pathogenic specimens of other common infectious diseases were spiked into each test item positive and negative specimen and tested separately. No cross reactivity was observed with specimens from below items.

Cross factor test	Code Number	1. Chlamydia trachomatis (CHT)	2. Neisseria gonorrhoeae (NGH)	3. Trichomonas vaginalis (TV)	4. Mycoplasma Genitalium (MG)
Escherichia coli	133264	Negative	Negative	Negative	Negative

Staphylococcus epidermidis	102555	Negative	Negative	Negative	Negative
Streptococcus hemolyticus-α	353758	Negative	Negative	Negative	Negative
Streptococcus hemolyticus -β	102660	Negative	Negative	Negative	Negative
Proteus vulgaris Hauser	336633	Negative	Negative	Negative	Negative
Garnerella vaginalis	337545	Negative	Negative	Negative	Negative
Trichomonas Vaginial	JD-TVPC	N/A	Negative	Positive	Negative
Candida Albican (wild)	74710	Negative	Negative	Negative	Negative

[Interference Test]

We simulated interference factor detection, which was divided into endogenous factors from patient diseases and exogenous factors such as vaginal ointment, cleaning agent. All the tests 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae (NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG) gave negative results.

Exogenous Factors		Endogenous Factors	
pH value	8.5	Glucose	55 mmol/L
Amoxicillin	200 mmol/L	Albumin	60 mg/mL
Acetaminophen	200 umol/L	Hemoglobin	200mg/mL
ibuprofen	250 umol/L	pH value	3.5
Metronidazole	700 mmol/L		
Fluconazole	250 umol/L		
Ethinyl estradiol	4.5nmol/L		
$NaHCO_3$	2%		

[Detection Limitation]

For the Antigen detected limitation test, the **Know Rapid STD Screening Kit** used BCA protein quantitative method (Bradford protein quantitative assay) to measure the positive standard protein concentration of internal 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae (NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG) antigen protein which was diluted from 500 ng / ml to 1ng / ml. The detected limitation is 1. Chlamydia trachomatis (CHT), 2. Neisseria gonorrhoeae (NGH), 3. Trichomonas vaginalis (TV), 4. Mycoplasma genitalium (MG) antigen on the 4ng/ml dilution unit of in-house test protein concentration was seen as a light clear T line appeared. Therefore, the minimum detection concentration was set as 4ng / ml as in house specification.

[Kit Contents]

The **Know Rapid STD Screening Kit** contains the following contents: 1 test cassette, 1 paper cup, 1 tube of buffer solution, 1 dropper, 1 bag of desiccant, instructions for use, and quick start guide.

[References]

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Symbols Glossary

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Caution

Consult instructions for use

Temperature limitation

Date of manufacture

Use-by date

Contains sufficient for
< n > tests

Manufacturer

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Distributed by: Know, LLC
Address: 301 E. Archer St., Tulsa, OK, 741200
Email: support@testwithknow.com

Manufactured by: MobiLab Medical Innovative Inc
Address: 807 Altaire Walk, Palo Alto, CA 94303
Email: Info@mobilabstore.com