JDBIOTECH Mycoplasma *genitalium* Antigen Rapid Test

Cat No: JMGAG

Package Size: 25 Tests/ kit

For In Vitro Diagnostics Use only

[Introduction]

Sexually transmitted infectious (STIs) are among the most common cause of illness in the world and have far-reaching health, social and economic consequences for many countries. STDs remain a public health problem of major significance in most parts of the world. The incidence of acute STDs is believed to be high in many countries. Failure to diagnose and treat STIs at an early stage may result in serious complications and sequelae, including infertility, fetal wastage, ectopic pregnancy, anogenital cancer and premature death, as well as neonatal and infant infections. Females who have hamephilius infection may cause an abnormal, foul-smelling, greyish vaginal discharges and sometimes redness or itching of vulva. Males may harbor the germs that causes this infection in their bodies, but usually asymptomatic. 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. Bacterial vaginosis, candidiasis and trichomoniasis are responsible for 90% of the case of infectious origin. Mycoplasma *genitalium* (MG) is the prime rather than secondary cause of many infections, including forms of bacterial vaginosis (BV) and non-gonococcal urethritis (NGU). It has also been associated with pelvic inflammatory disease (PID) and implicated in other infections once attributed to other bacteria. Most cases of MG are asymptomatic. If symptoms do appear, they are largely nonspecific and easily mistaken for other STIs such as chlamydia and gonorrhea. Testing for MG can be cumbersome for time consuming because M. *genitalium* is a slow growing organism. Isolating and culturing M. genitalium not feasible when there is a need to institute antimicrobial therapy. The PCR test method is preferred technique to test M. genitalium. It can be performed on multiple sample types, including urethral, vaginal, and cervical swabs, urine and endometrial biopsies. However, PCR assays for diagnostics were developed for the research, the result is only available in reference labs or usually at large university hospitals. For the M. *genitalium* Rapid Test diagnosis is a progress and breakthrough that can be expected for a simple and convenient method to detect MG.

[Intended Use] JDBIOTECH Mycoplasma *genitalium* Antigen Rapid Test is intended for the qualitative detection of **M.*genitalium***, antigens from urine or swab sample. For professional use only.

[Principle]

The individual test strip in card includes:(1) a burgundy-colored conjugate pad containing colloidal gold coupled with M. *genitalium* secreted protein of antibodies, and (2) the nitrocellulose membrane containing a test line (T-line) and control line (C-line). The T line is coated with each test item's antibodies and the C-line is coated with second antibody to gold conjugation of antibodies. When patient antigens to each test item present in the specimen, the T line will become a burgundy-colored band. If antigen to above test item is not present are below the detectable level, it is no T line develop. The C line should always appear as a burgundy-colored band regardless of the present of secreted protein of antigen to each test item. 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.

[Components]

1. The test: 25 cassettes / Kit, each sealed with a test strip and a desiccant in the pouch.
2. Sample Buffer: 30 ml/bottle, 1 bottle (content to: 0.5% Triton X -100, 0.01M PBS, PH 7.5, 0.05% NaN3)
3. Dropper: 25 droppers
4. Test Tube: 25 tubes
5. 3ml/dropper: 1 pc
6. Urine Cup: 25 cups
7. Package Insert

[Materials is required but NOT provided]

1. Timer
2. Protective tools
3. Sterilized swabs

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

[Precautions]

1. Read the package insert carefully prior to testing the kit and follow the instruction to obtain accurate results.
2. For in vitro diagnostic use.
3. This test is one time use only.
4. Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage, disposal of patient specimens, and all items exposed to patient specimens.

5. 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.
6. Do not use sample diluent buffer or positive control reagent with turbidity. The reagent may be contaminated with microorganism.
7. Solutions that contain sodium azide may react with lead or copper plumbing to form potentially explosive metal azide. Flush it with large amount of water and discarding solutions into a sink.
8. Store the sealed test Cassette at room temperature, keep it in a dry place and away from direct sunlight. Avoid excessive heat (>30 °C).
9. Do not freeze. Do not use tests and reagents after expiration date.
10. Use a timer and wait exactly 30 minutes to read result.
11. Discard opened-unused tests after 1 hour.
12. Do not read the test result after 1 hour.

[Specimen collection and preparation]

For urine sample

1. Collect a urine specimen in a clean glass, plastic, or wax coated container.
2. Please do not use any preservatives.
3. If the test is not run immediately after sample collection, please take the equal volume of sample buffer of kit into a test tube and mix well with sample. The diluent sample should be stored at 2-8°C and brought back to room temperature (15-28°C) before testing. If testing is delayed more than 48 hours, the specimen should be frozen at -20°C or lower.
4. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed in room temperature.

For Swab sample

1. Collect specimen with a sterile swab from vaginal cavity or Glans. Process the swab as soon as possible after collecting specimen. Place sample swab into sample collection tube (with 1.0ml of sample buffer) and mix well.
2. You may store and desiccated swabs in a dry form during this Test does not require live organisms for processing,
3. If you cannot desiccate the swabs or perform test immediately, extract the swabs in Sample Buffer as per protocol and store the aqueous extracted specimen at 2–8°C for up to 24 hours.
4. Desiccated swabs can be stored at 2-8°C for up to 24 hours prior to extraction and testing.

[Assay Procedure]

1. Dispense 3 to 4 drops (~ 80μL) of sample buffer into a test tube.
2. Pipette equal volume 3~4 drops (~ 80μL) of urine sample into test tube and mix well in 10 seconds.
3. Remove the test cassette from its foil pouch.
4. Pipette 3 to 4 drops (~ 80μL) of diluted sample into “S” region.
5. Wait for 15 minutes.
6. Interpretation of result by eyes.

[Result Interpretation]

- **Positive**: A red line appears on Control Line and a red line on Test Line.
- **Negative**: A red line appears on Control Line.
- **Invalid**: A total absence of color in both regions is an indication of procedure error and/or test reagent deterioration.

[Sensitivity and Specificity]

Group 1 :

The group I was for M. genitalium test to compare with culture media test. We collected 50 samples of vaginal secretion swabs. Which was positive result in Culture media.

M. genitalium test performance of JDBIOTECH M.genitalium Antigen Rapid Test and culture media.

JDBIOTECH Test	specimen (50 cases)		
	Culture Media (Positive)	Culture Media (Negative)	Total
Ag (Positive)	44	5	41
Ag (Negative)	6	45	46
Total	50	50	100

Result: Compared performance of M. genitalium test result between culture media method: Sensitivity: 88%, Specificity:90%, Accuracy: 99%

[Cross Reaction]

The pathogenic cross reaction test was done to Negative result, the test item information is below tabel:

Name	Code Number
Escherichia coli	133264
Staphylococcus epidemrmidis	102555
Streptococcis hemolytis-α	353758
Streptococcis hemolytis -β	102660
Proteus vulgaris Hauser	336633
Garnerella vaginalis	337545
Trichomonas Vaginial	JD-TVPC
Candida Albican (wild)	74710

[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 were negative.

exogenous factors		Endogenous factors	
pH value	8.5	Glucose	55mmol/L
Amoxicillin	200mmol/L	Albumin	60mg/mL
Acetaminophen	200umol/L	Hemoglobin	200mg/mL
Ibuprofen	250umol/L	pH value	3.5
Metronidazole	700ummol/L		
Fluconazole	250umol/L		
Ethinyl estradiol	4.5nmol/L		
NaHCo3	2%		

[Detection limitation]

According to the above experimental test results, JDBIOTECH M.*genitalium* Antigen Rapid Test uses BCA protein quantitative method **(Bradford protein quantitative assay)** to measure the positive standard protein concentration of M.genitalium , which is diluted from 500ng / ml to 1ng / ml. The detected limitation is M.genitalium Ag 4ng/ml. Those test protein concentration in 4ng/ml was seen a light clear T-line appeared. Therefore, the minimum detection concentration was set as 4ng / ml.

[References]

1. Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR3):1-137.
2. Unemo M, Jensen JS. Antimicrobial-resistant sexually transmitted infections: gonorrhoea and *Mycoplasma genitalium*. *Nat Rev Urol*. 2017;14(3):139-152.
3. Munoz JL, Goje OJ. Mycoplasma genitalium: An Emerging Sexually Transmitted Infection. Scientifica (Cairo). 2016;2016:7537318. doi: 10.1155/2016/7537318. Epub 2016 Feb 29. PMID: 27034904; PMCID: PMC4789526.
4. Marie C Le Roux, Maanda Mafunise, Barbara E de Villiers, Ramalau Mm Ditsele. (2018) Antimicrobial susceptibility of Mycoplasma genitalium isolates from Pretoria, South Africa in 2012 and 2016. Southern African Journal of Infectious Diseases 33:2, pages 46-49.
5. World Health Organization (WHO). Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Switzerland: World Health Organization 2013
6. Taylor-Robinson D, Horner PJ. The role of Mycoplasma genitalium in non-gonococcal urethritis. *Sex Transm Infect*. 2001;77(4):229-231. doi:10.1136/sti.77.4.229
7. Mycoplasma genitalium - an up-date. *International Journal of STD & AIDS*. 2002;13(3):145-151. doi:10.1258/0956462021924776

CE Marketing
Contains sufficient for < n > tests
IVD In vitro diagnostic medical device
Manufacturer
REF Catalog Number
Use-by date
Caution
LOT Batch code
Consult instructions for use
Do not re-use
Temperature limitation
EC REP Authorized Repre the European Community
Date of manufacture

EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

JD Biotech 杏恩®
Manufactured by : Jei Daniel (JD) Biotech Corp.
Address: A201, Building 1, No. 69 Hua Yang Road, Jinan, Shandong 250100 China
Tel: +86 531 8237 3551 Email: business@jdbiotech.com
www.jdbiotech.com www.jeidanielbiotech.com

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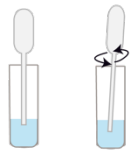
* Urine sample

1 Collect a urine specimen.

2

Dispense 3 to 4 drops (~ 80μL) of sample buffer into a test tube.

3



Pipette equal volume 3~4 drops (~ 80μL) of urine sample into test tube and mix well in 10 seconds.

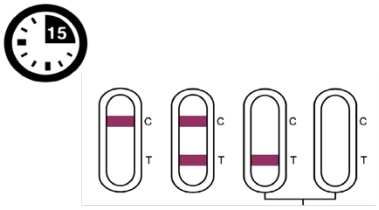
4

Remove a test card from its foil pouch.

5

Pipette 3 to 4 drops (~ 80μL) of diluted sample into “S” region.

6 Wait for 15 minutes to read the result.



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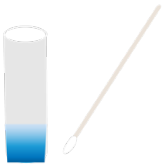
Swab Sample

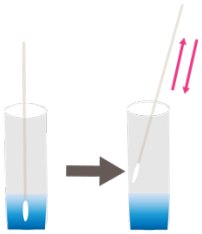
1 Dispense 1ml of sample buffer into a test tube.

2



Place the collected swab sample into the tube and mix the sample buffer by rotating the swab vigorously in the tube.

3



Allow the swab to soak in sample buffer for 30-60 seconds,.pressing against the side of the tube to extract liquid. Remove the swab.

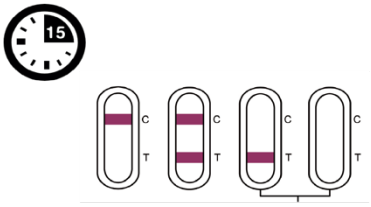
4

Remove the test card from its foil pouch.

5

Pipette 3 to 4 drops (~ 80μL) of diluted sample into “S” region of TV, CA and GV Ag.

6 Wait for 15 minutes to read the result.



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