Humasis

Chlamydia Test

Please read the instructions carefully before use!

For professional use

[INTENDED USE]

The Humasis Chlamydia test is a rapid and sensitive direct binding test for visual detection of Chlamydia trachomatis antigen in endocervical swab specimens.

[SUMMARY AND EXPLANATION]

Chlamydia Trachomatis is the most common cause of sexually transmitted veneral infection in the world, with an incidence estimated at 3~4 million cases per year in the United States. Chlamydia are composed of elementary bodies(the infectious form) and reticulate or inclusion bodies(the replication form) and comprise 15 known servars.

It is a major cause of cervicitis, urethritis, endometritis, and pelvic inflammatory disease in women. Serious complications can result in salpingitis, infertility, and ectopic pregnancy. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and pneumonia. 50~70% of infected women are asymptomatic, which makes diagnosis extremely important.

Chlamydia are related to gram-negative bacteria. They are intracellular in nature and are unable to synthesize adenosine triphosphate(ATP). The extracellular elementary body form is infectious while the intracellular reticulate form is metabolically active.

Various methods are available for the diagnosis of Chlamydia infection. Conventional isolation of Chlamydia Trachomatis involves culturing the organism in a suitable cell line. Other methods include direct fluorescence assay(DFA), enzyme immunoassays (EIA), and nucleic acid probing and polymerase chain reaction(PCR).

The Humasis Chlamydia Test is a solid phase immunochromatographic assay for the rapid, qualitative detection of Chlamydia antigen directly from endocervical swab. This test is intended for professional use as an aid in the presumptive diagnosis of Chlamydia infection.

Humasis Chlamydia Test detects the Chlamydia genus specific lipopolysaccharide (LPS) antigen. The method employs a unigue combination of monoclonal-dye conjugate and solid phase antibodies to identify the Chlamydia antigen in the swab sample with a high specificity and sensitivity.

In this test, the specimen is first treated with an extraction buffer to isolate Chlamydia LPS antigen when present and the extracted sample is then added in the device sample well.

As the extract flows through the absorbent device, the labeled antibody-dye conjugate binds to the Chlamydia antigen forming an antibody antigen complex. This complex binds to the antibody in the positive reaction zone (Test) and produces an color band when the Chlamydia antigen concentration is present in the sample.

In the absence of Chlamydia antigen, there is no line in the positive reaction zone (Test). The reaction mixture continues flowing through the absorbent device, past the positive reaction zone and control zone. Unbound conjugate binds to the reagents in the control zone producing a color band, demonstrating that the reagents are functioning correctly.

[REAGENT AND MATERIAL SUPPLIED]

The Humasis Chlamydia Test kit contains following items to perform the assay.

1. Humasis Chlamydia Test device individually foil pouched with desiccant. (25 Tests)
2. Extraction solution in plastic dropper bottles containing buffer. (25 bottles)
3. Sterile swabs and Transport tubes.
4. Instruction for use.

[STORAGE AND STABILITY]

1. All Humasis Chlamydia Test kit components should be stored at room temperature (4˚C to 30˚C)
2. Do not Freeze the test kit.
3. Humasis Chlamydia Test is stable until the expiry date stated on the package label.

[PRECAUTIONS]

1. To obtain accurate results, you must follow the instruction for use.
2. For in vitro diagnostic use and professional use only.
3. Do not use kit contents after the expiration date printed on the outside of the kit.
4. Use appropriate precaution in the collection, storage, handling and disposal of patient samples and used kit contents.
5. Use of Nitrile or Latex glove is recommended when handling patient samples.
6. The Humasis Chlamydia Test device must remain sealed in the protective foil pouch until just prior to use. All kit components must be at room temperature prior to use.
7. The Humasis Chlamydia Test device is sensitive to humidity and as well as to heat. Perform the test immediately after removing the test device from the pouch.
8. Use only the sterile swabs supplied in the kit.
9. Do not use the test kit if the pouch is damaged or the seal is broken.
10. When the assay procedure is completed, dispose of swabs carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.

[SPECIMEN COLLECTION AND PREPARATION]

1. Use a swab to remove excess mucus from the exocervix. Take another swab to insert into the cervix past the squamo columnar junction until the tip of the swab is no longer visible. Firmly rotate the swab for 15-30 seconds to collect samples. Remove the swab carefully to avoid any contamination from cervical or vaginal cells.
2. Test the sample immediately after collection, otherwise store the sample in a dry transport tube.
3. Collected samples may be stored at 2-8C for up to 72 hours. Do not freeze the samples.

[TEST PROCEDURE]

1. Test prepration

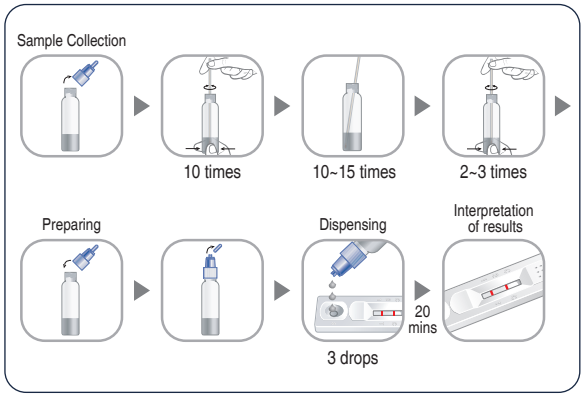
1) Leave the sample and test device in ambient environment for them to reach room temperature (20-30˚C) before testing.
2) Place the test device on level surface.
3) Unscrew the cap of the extraction buffer tube.

2. Sample extraction procedure

1) Insert the collected swab into the extraction buffer tube.
2) Swirl the swab 10 times firmly against the tube wall while squeezing the tube for sufficient sample extraction.
3) Leave the tube with swab inside in room temperature for 10-15 minutes. While waiting, swirl the swab 2-3 times firmly against the tube wall while squeezing the tube for sufficient sample extraction.
4) Dispose of the swab and screw attach the cap on the tube. Break the tip of the screw cap.

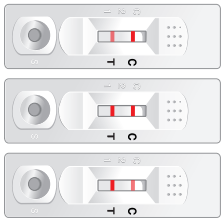
3. Test procedure

1) Label the device with patient's name or control number.
2) Apply 3 drops (100uL) of the extraction buffer into the sample well of the device. Allow each drop to absorb before adding the next drop to avoid forming bubbles on the sample well.
3) Read results at 20 minutes after release of the sample.



[INTERPRETATION OF RESULTS]

1. Positive



The presence of two color bands within the result window, no matter which band appears first, indicates a positive result. A positive result indicates that the specimen is presumptive for the presence of Chlamydial antigen.

2. Negative

The presence of only one purple color band within the result window indicates a negative result. A negative result indicates that specimen is presumptive negative for the presence of chlamydial antigen.

3. Invalid

If the purple color band is not visible within the result window after performing the test, the test result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

[LIMITATIONS OF THE TEST]

1. The Humasis Chlamydia Test has been tested using endocervical swab clinical specimen for the qualitative detection of Chlamydia antigen. Performance with other specimens has not been assessed.
2. Detection of Chlamydia is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
3. Test results should be interpreted in conjunction with other laboratory and clinical data available to the physician. Standard chlamydial cell culture methods should be used in the available to suspected sexual abuse and the other medicolegal cases where diagnosis could lead to adverse psychosocial impact.

[PERFORMANCE CHARACTERISTICS]

1. Comparison with Polymerase Chain Reaction(PCR) method

The accuracy of Humasis Chlamydia Test was evaluated in comparison to PCR positive/ negative result of endocervical specimens. Of the 51 positive specimens, Humasis Chlamydia Test correctly identified 100% (51/51) and of the specimens, Humasis Chlamydia Test correctly identified 100% (85/85)

Humasis Chlamydia Test	PCR		Total
	Positive	Negative	
Positive	51	0	51
Negative	0	85	85
Total	51	85	136

- Relative sensitivity : 100% (51/51)
- Relative specificity : 100% (85/85)
- Accuracy : 100% (136/136)

2. Comparison study with a commercially available Rapid Chlamydia Test

The accuracy of Humasis Chlamydia Test was also evaluated against a commercially available rapid Chlamydia test using endocervical specimens. The used specimens were tested and confirmed with culture and DFA method as positive(51)/ negative(85). Of the 51 positive specimens and 85 negative specimens, Humasis Chlamydia Test correctly identified 100%.

Humasis Chlamydia Test	Chlamydia Test		Total
	Positive	Negative	
Positive	51	0	51
Negative	0	85	85
Total	51	85	136

- Relative sensitivity : 100% (51/51)
- Relative specificity : 100% (85/85)
- Accuracy : 100% (136/136)

[PRECISION]

The within-run, between-run, between-site performance of the Humasis Chlamydia test was evaluated by following methods. The specimens contained a negative, a low positive, moderately positive, strong positive. Testing was performed by the laboratory personnel three times per day in replicates of three each level over three days. All qualitative result was 100% agreement with the expected results.

[CROSS-REACTIVITY]

Specimens positive for 36 pathogenic microbe have been tested. No cross-ractivity was observed, indicating that the Huamsis Chlamydia test has a high degree of specificity for Chlamydia antigen.

Bacteria (10 CFU/mL)	Viruse (10^5~10^6PFU/mL)	Fungi (10^7CFU/mL)
Campylobacter jejuni	HIV PRZ204-05 (type1)	Candida glabrata
Serratia marcescens	HIV PRZ204-03 (type2)	Candida schatavii
Shigella flexneri	HIV PRZ204-14 (type3)	
Staphylococcus aureus	Anti-HBs	
Staphylococcus epidermidis	Human hepesvirus 1 HF	
Enterococcus faecalis	Coxsackievirus A9 P.B	
Escherichia coli	Coxsackievirus B5 Faulkner	
Gardnerella vaginalis	Echovirus 6 D'Amori	
Haemophilus aphrophilus	Echovirus 6 Harris	
Klebsiella pneumoniae	Human Respiratory syncytial virus Long	
Lactobacillus casei	Human adenovirus 1	
Listeria monocytogenes	Adenovirus Type 18	
Neisseria sp.	Adenovirus Type 23	
Proteus mirabilis	Human Coronavirus OC43	
Shigella flexneri	Rubella virus	
Shigella sonnei	Dengue virus type 4	
Streptococcus sp.		
Vibrio parahaemolyticus		

[REFERENCES]

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: Manufacturer | : Do not reuse | : Consult instructions for use

REF : Catalogue number | LOT : Lot number | IVD : *In vitro* diagnostic medical device

: Temperature limit | : Use by | : Contains sufficient for <n> tests

: Keep away from sunlight | : Keep dry | : Do not use if package is damaged

Humasis Co., Ltd.

Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02, 88, Jeonpa-ro,
Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
TEL: +82-31-8085-6200, FAX: +82-31-8085-6249
Email: question@humasis.com
www.humasis.com

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