IVD

Asan Easy Test® Chlamydia

ASAN

Diagnostic kit for Chlamydia antigen

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test® Chlamydia, a rapid, visual immunochromatographic test, was designed to detect *Chlamydia trachomatis* from cervix or penis through visual interpretation of color development. The test contains pre-coated membrane strip which has anti-Chlamydia antibody on the test line ("T") and goat anti-mouse antibody on the control line ("C"). Gold colloidal reagents are labeled with anti-Chlamydia antibody. When Chlamydia antigen is present in the extracts of specimen, the mixture of colloidal gold conjugate and extracts of Chlamydia chromatographically moves along the membrane by capillary action. At first, Chlamydia antigen in the extracts of specimen reacts with anti-Chlamydia antibody and forms a complex of Chlamydia antigen and colloidal gold conjugates. As this mixture migrates to the test line ("T"), the Chlamydia antigen and colloidal gold conjugates complex is captured by another anti-Chlamydia antibody pre-coated in test line, and forms a visible line. When Chlamydia antigen is absent in the extracts of specimen, no visible colored line in the test line. The control line ("C") should always appear if the test procedure is performed properly.

MATERIALS PROVIDED

Asan Easy Test® Chlamydia kit contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Reagent A (Extraction solution 10㎖/vial).
3. Reagent B (Neutralization solution 20㎖/vial).
4. Disposable droppers and transport tubes.
5. Sample collection swabs.
6. Instruction manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. Use only sterile swabs provided in the kit, or cytology brushes to obtain endocervical specimens.
6. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
7. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
8. Reagent A contains sodium hydroxide; Reagent B contains hydrochloric acid. If either of the reagents contact the skin or eye, flush with large volumes of water.
9. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

A. Endocervical swab :

1. A first swab should be taken to remove excess mucus from exocervix.
2. The second swab should be inserted into the endocervical canal, past the squamocolumnar junction, until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells which are the main reservoir of the Chlamydia organism.
3. Firmly rotate the swab for 10~20seconds.
4. The swab should be withdrawn without contamination with exocervical or vaginal cells.
5. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 24hours.

B. Cytology brush :

1. After cleaning the exocervix with the swab provided in the kit, insert the cytology brush into the endocervical canal, past the squamocolumnar junction.
   (NOTE : Do not use cytology brush with pregnant patient)
2. Leave it in the place for 2~3 seconds.
3. Rotate the cytology brush two full turns and withdraw the brush without touching any vagunal surface.
4. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 15~27℃ for up to 4hours, 2~8℃ for up to 3days .

TEST PROCEDURE

A. Extraction procedure

1. All materials should be equilibrated to room temperature (2~30℃) before performing the test.
2. Prepare disposable droppers and sample extraction tubes as you need.
3. Add 4 drops (300㎕) of reagent A to the transport tube.
4. Immerse the patient swab or brush into the tube containg reagent A for 2 minutes. During extraction, compress the bottom of the tube between the thumb and forefinger and swirl the swab at least 10 times.
5. Fill a disposable dropper to the bottom of the bulb with reagent B (600㎕).
6. With the swab shaft to the side, add reagent B to the tube. Discard the dropper.
7. Swirl the swab at least 10 times.
8. Discard the swab squeezing against the wall of tube.

B. Assay procedure

1. Remove the test strip from the its protective pouch.
2. Dispense 3drops of the extracted sample from the tube into sample well(S) of the test device.
3. Interpret test results within 10minutes. Do not interpret after 15 minutes.

INTERPRETATION OF THE TEST

A. NEGATIVE RESULTS:

The presence of only one purple color band (control band) within the window indicates a negative result.

B. POSITIVE RESULTS:

The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.

C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

STORAGE & EXPIRATION

1. Asan Easy Test® Chlamydia should be stored at 2 to 30℃ (35.6 - 86 ℉).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 316 specimens. Each specimen was tested with Asan Easy Test® Chlamydia and Chlamydia MEIA. The results are summarized in the following tables.

n= 316		Chlamydia MEIA		Total
		Positive	Negative	
Asan Easy Test® Chlamydia	Positive	135	2	137
	Negative	10	169	179
Total		145	171	316

※ Relative Sensitivity : 93.1%, Relative Specificity : 98.8%
※ Detection limit : $2x10^7$EB/ml

SPECIFICITY

Chlamydia pittachi and *Chlamydia pneumonia* strains have been tested with Chlamydia antigen test and gave a positive result. Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml. The following organisms were not detected using Asan Easy Test® Chlamydia.
Acinetobacter calcoaceticus, Bacillus subtilis, Candida albicans, Candida tropicalis, Escherichia coli, Escherichia faecalis, Gardnerella vaginalis, Mycobacterium kansasii, Neisseria gonorrhoeae, Neisseria lactamica, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella typhimurium, Shigella sonnei, Streptococcus pneumoniae, Staphylococcus saprophyticus, Trichomonas vaginalis.

LIMITATIONS OF THE RESULTS

1. Asan Easy Test® Chlamydia is designed for the qualitative detection of Chlamydia antigen in endocervical swab and cytology brush clinical specimens
2. Detection of Chlamydia is dependent on the number of organisms present in the specimen collection methods and patient factors such as age, history of STD, present of symptoms, etc.

REFERENCES

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2. Brunham RC, Maclean IW, Binns B and Peeling RW. *Chlamydia trachomatis*: It's role in tubal infertility. Journal Infectious Disease, 1985, 152:1275-1282.
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