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REF

Catalog No. R25-515

IVD

For In Vitro Research Use Only

INTENDED USE

The Immunospec Chlamydia Test is a rapid immunoassay for direct qualitative detection of Chlamydia trachomatis antigen in endocervical or endourethral swab specimens.

SUMMARY AND EXPLANATION OF THE TEST

Chlamydia trachomatis is one of the most common sexually transmitted pathogens. It is amajor cause of cervicitis,urethritis, endometritis, andpelvic 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. 1
Chlamydia are related to gramnegativebacteria . They are intracellular in nature and are unable to synthesize adenosine etriphosphate(ATP). The extracellular elementary body form is infectious while the intracellular reticulate form is metabolically active. Epidemiological patterns indicate infections of Chlamydia trachomatis parallel or exceed those of Neisseria gonorrhoeae and the two often occur together. The disease cuts across the socioeconomic spectrum. The primary method for detection of chlamydia is growth of the organism in cell culture. Other methods include direct fluorescence assays(DFA),enzymeimmuno assays (EIA), and nucleic acid probing.

PRINCIPLEOFTHETEST

The Immunospec Chlamydia Test utilizes the chemical extraction of acarbohydrate antigen from Chlamydia followed by the utilization of migratory color immunoassay technology for the qualitative detection of Chlamydia trachomatis.
In the test procedure,a unique set of polyclonal and monoclonal antibodies are employed.One antibody is immobilized on a porous membrane while the other antibody is conjugated to dye particles as signaling component. A swab specimen from apatient is treated with extraction reagent A and B to extract the antigen. The test dipstick is then immersed in the extraction sample. The liquid migrates through the absorbent area and along the membrane. If Chlamydia trachomatis antigen is present,the labeled antibody-dye conjugate binds to it,forming an antibody-antigen complex. As the mixture flows along the membrane, the complex is captured by the antibody immobilized in the test zone(T)of the membrane, producing a visible rose-pink color band.Another dye-conjugated reagent is captured by the antibody immobilized in the control zone(C) of the membrane.
A rose-pink line in the test zone(T) indicates the presence of Chlamydia trachomatis antigen.A rose-pink line in the control zone(C) indicates the test is working properly. When only a control line appears with no test line, Chlamydia trachomatis antigen has not been detected and the test result is considered negative.
The control line gives an added measure of quality control by demonstrating antibody recognition;assuring that the procedure was performed correctly; and that the reagents are chemically active. A desiccant is enclosed with the test device to stabilize the reactive agents.

REAGENTSANDMATERIALSPROVIDED
NOTE:This test kit does not contain any viable infectious agents.

1. Testing Devices: Contains dye-conjugated and immobilized anti-chlamydial antibody. Sealed individually in protective foil pouches

2. Extraction Buffer A (10.0ml) : 0.05 N Sodium hydroxide solution, in a dropper , in a dropper vial.
3. Extraction Buffer B (10.0ml): TrisHClbufferpH9.0with0.02%sodium azide,inadropper vial.

4. Positive Control (1.0ml) : Contains non infective chlamydial antigen derived from in vitro culture, with 0.1%sodium azide.

5. Extraction Tube.

6. Test Instructions

Female Testing Kit Only

7. Female Swab, 50pcs/25tests. Plastic shafted sterile swab for testing female patients.

Male Testing Kit Only

8. Male Swab, 25pcs/25tests. Metal shafted sterile swab for testing male patients.

In addition to the materials provided, a watch or timer and test tube rack are also required.

STORAGEANDSTABILITY

All Immunospec ChlamydiaTest reagents (extraction buffers and positive controls) should be refrigerated at28°C when not in use. Other test components may be stored at room temperature (15-28°C). Refer to expiration dates for stability.

WARNINGSANDPRECAUTIONS

1. Wear gloves while handling specimens.
2. Dispose of gloves and swabs using good microbiological practices.
3. Do not touch the swab tip at any time.
4. Wash hands after performing the test.
5. Use only the sterile swabs provided.Swabs from any other source may give faulty results.
6. Do not allow a sample swab to come in contact with any reagen tbottle tip. Reagent or bacterial contamination wil linvalidate test performance.
7. Do not use the reagents after their expiration dates.

SPECIMENCOLLECTIONANDPREPARATION

A. Female Patients

Two sterile swabs with plastic shafts are required in the female collection procedure. One swab is used to prepare the sample site; the other is used for sample collection.

NOTE: Use only the swabs provided with the kit.

1. Remove any excess mucus from the potentially infected site with the first swab,then discard it.
2. Rub the second swab vigorously over the infected endourethral lining an dendocervical cells in the canal wall. As Chlamydia are intracellular organisms, firm contact must be made with the canal wall for proper specimen collection. The rubbing action dislodges the endothelial cells and allows the swab to absorb the bacteria.Improper collection will result in poor visual readings and may cause in valid results. Vaginal specimens are not useful.

B. Male Patient

One metal –shafted sterile swab is needed for male penile sample collection. Do not use a plastic shafted swab in this procedure.

1. Insert the swab in to the urethra of the penis .Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotation.
2. Carefully remove the swab avoiding contact with any external surfaces.

STORAGE AND STABILITY

If a swab is not extracted immediately, store it refrigerated (2°-8°C) for up to 5 days, preferably in a transportation tube. Do not freeze. Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

TEST PROCEDURE

NOTE: Read all test instructions before running patient samples or controls

Procedure Notes

1. Bring all samples and controls to room temperature (15°-28°C) prior to testing.
2. Do not open the foil pouch until ready to perform the test.
3. Do not use commercial controls other than those provided with the test as they may contain additives which interfere with test performance.

A. Extraction

1. Label an extraction tube for each patient and place in a tube holder or rack.
2. Add 6 drops of Extraction Buffer A to the extraction tube. Mix liquids by gently swirling the tube. Place the specimen swab in the tube and twirl briefly to mix the reagent Incubate at room temperature (15°-28°C) for 5 minutes, with the swab in the tube.

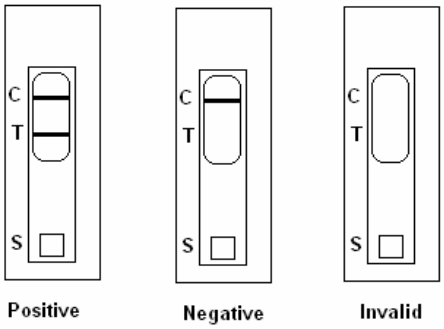
3. Add 6 drops of Extraction Buffer B to the extraction tube containing the swab.
4. Twirl the swab vigorously for 10 seconds, then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab. Cap the tube and mix contents by gentle swirling. The swab extract must be tested immediately.

B. **Immunoassay of the Extract**

1. Remove the test cassette from its sealed foil pouch by tearing a long the notch. Dispense 7drops of liquid from the extraction tube in to the sample well (“S”) of the test device by inverting and squeezing the tube.
2. Read the test results at 15 minutes.

IMPORTANT:To avoid incorrect readings or invalid results, do not interpret test results after more than 15 minutes

INTERPRETATIONOFRESULTS



1. Positive: Two rose-pink bands appear—one in the control zone (“C”) and one in the test zone(“T”). The sample should be considered positive for the presence of Chlamydia trachomatis.
2. Negative: One rose-pink band appears in the control zone (“C”) with no apparent band in the test zone (“T”). The sample should be considered negative for Chlamydia trachomatis.
3. Invalid:If no rose-pink band appears in the control zone (“C”), or if a band appears in the test zone (“T”) but not in the control zone, then the test is invalid. It is recommended to retest the specimen using a new Testing Device.

Note: There is no meaning attributed to line color intensity or width.

QUALITYCONTROL

A. Internal Controls:

The Immunospec Chlamydia Test contains built-in quality control features. The development of a rose-pink band in the control zone indicates that the sample has been absorbed in to the device, that capillary flow has occurred, and that antibody reactivity is at normal level. If the test device is working properly the back ground in the reaction area will clear, providing a distinct result.

B. External Controls:

Good laboratory practice recommends the use of quality controls to ensure proper test performance. A Positive Control containing non-viable Chlamydia trachomatis antigen is provided with each kit to verify test performance.

Add 4 drops of Extraction Buffer A to an extraction tube. Add one drop of Positive Control to the tube. Shake the tube to mix the solution well and incubate at room temperature (15°-28°C) for 5 minutes.

Add 4drops of Extraction Buffer B to the tube. Cap the tube and thoroughly

Mix the contents by gentle swirling. Complete the test according to the procedures described above. A positive result is indicated by the appearance of two rose-pink colored lines on the membrane.

LIMITATIONS OF THE TEST

1. The test is limited to the detection of Chlamydia trachomatis in swab specimens.
2. For in vitro diagnostic use only.
3. A specimen swab which contains too much blood may cause weak false positive results. Therefore, bloody swabs should be avoided.
4. Although the test is very accurate, a low incidence of false results may occur.
5. If negative or questionable results are obtained, the test should be repeated using a new swab specimen.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. The test only allows for the detection of Chlamydia as a presumptive indication of Chlamydia trachomatis infection. However, cases in which patient swabs test negative while the patients' clinical symptoms are indicative of Chlamydia infection should be investigated further.
8. For optimal test performance, proper sample collection and storage procedures are critical.

PERFORMANCE CHARACTERISTICS

1. Specificity and Sensitivity

A) An evaluation of the Immunospec Chlamydia Test kit was run to determine clinical performance characteristics for the test relative to an available latex immunoassay. A total of 110 patients were tested, with two swabs collected for each patient. The results of the study were as follows.

		Immunospec	
		+	–
(37)	+	36	1
(73)	–	3	70

Compared with a latex immunoassay for detection of Chlamydia from swab specimens, the Immunospec Chlamydia Test demonstrated a relative sensitivity of 97.2% (36/37). The Immunospec test also demonstrated a relative specificity of 95.8% (70/73) and an overall agreement with latex immunoassay of 96.3%.

B) An additional evaluation of Immunospec Chlamydia test was conducted to determine the diagnostic specificity and sensitivity of the test compared with the established PCR method. Patients who were classified as positive (100%sensitivityandspecificity) showed a positive result with the PCR test. Two tests were conducted in parallel: Immunospec Chlamydia Test vs. PCR test method (manufacturer: BECTONDICKINSON, Heidelberg; name of test: BDP robetecETSystem®) The results of the study were as follows:

	Immunospec Negative	Immuospec Positive	
PCRNegative	572	10	582
PCRPositive	2	12	14
	574	22	596

Diagnostic Sensitivity= Immunospec Pos./PCR(=correct)Pos.
Diagnostic Specificity=Immunospec correct Neg. /PCR(=correct)Neg.

Sensitivity: Immunospec Chlamydia Test 85.7%
Specificity: Immunospec Chlamydia Test 98.3%
Conclusions: Immunospec Chlamydia test shows compared with the PCR Test sensitivity of 85.7% and specificity of 98.3% for diagnosis of a Chlamydia infection. Immunospec Chlamydia Test is shown to be a meaningful test for point of care diagnosis of a chlamydia infection.

2. Precision

A. Intra-Assay: Within-run precision was determined using the same 3 specimens containing negative, border line positive, and positive values. The negative, order line and positive values were correctly identified in 100% of the tests.

B. Inter-Assay: Between-run precision was determined using the same 3 specimens of negative, border line positive control, and positive control of Chlamydia antigen in 11 independent assays with 3 different lots of reagents overa30day period. Again, the negative, border line and positive findings were correct in 100% of the tests.

3. Cross Reactivity

To confirm the specificity of the Immunospec Chlamydia Test, 15 serotypes were tested and demonstrated to yield Chlamydia positive results. Cross reactivity with other organisms has been studied using suspensions of 107 CFU/ml (CFU—colony forming unit) and demonstrated to yield Chlamydia-negative results. Staphylococcus aureus was test at 1x106 cells/test and also yielded negative results. The organisms tested are listed below:

Streptococcus pneumoniae
Aeromonas spp
Bacteroides spp
Campylobacter spp
Candidaspp
Citrobacterspp
Clostridium spp
Enterobacter spp
Escherichia coli
Gardnerella spp
Haemophilus coli
Herpes simplex virus
Klebsiella spp
Lactobacillus spp Listeriaspp
Mycoplasma spp
Neisseriagonorrhoea
Neisseriameningitis
Peptococcusspp
Proteus spp
Pseudomonas spp
Salmonellaspp
Serratiaspp
Shigellaspp
Streptococcus spp
Staphylococcus spp(coag. neg)
Staphylococcus spp(coag. pos)
Trichomonas spp
Ureaplasmaurealyticum
Veillonellaspp
Yersiniaspp

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PIR25-515
Revision 8
Revision Date 11-10-2006