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CLEARVIEW CHLAMYDIA

For the direct qualitative detection of Chlamydia trachomatis antigen in endocervical swab specimens

INTENDED USE

Clearview Chlamydia is a rapid immunoassay for the direct qualitative detection of Chlamydia trachomatis antigen in endocervical swab specimens.

INTRODUCTION

The Chlamydiae are a group of obligate intracellular parasites. There are four known species of chlamydia: Chlamydia trachomatis, a human pathogen, Chlamydia psittaci, an animal and human pathogen, Chlamydia pneumoniae (TWAR) which is pathogenic only for humans, and the recently discovered Chlamydia pecorum which is pathogenic only for animals (cattle and sheep). C. trachomatis is the etiological agent in a number of sexually transmitted diseases, including non-gonococcal urethritis, post-gonococcal urethritis, proctitis, cervicitis, infertility and Reiter's Syndrome in adults; inclusion conjunctivitis and pneumonia in neonates¹.

In cases where the infection goes untreated, the organism can result in epididymitis in males, or can reach the fallopian tubes causing the development of complications such as pelvic inflammatory disease and ectopic pregnancy² in females.

Various methods are available for the diagnosis of chlamydial infections. The traditional method is the inoculation of monolayer cell cultures with clinical specimens, followed by staining and visual examination after 48-72 hrs.³ Direct tests such as enzyme immunoassays and immunofluorescence assays are regarded as easier to perform and require less time and labor than culturing the organism. Immunofluorescence requires specialised equipment and a skilled

operator to read the result, which can limit the number of samples that can be screened in a day.

Clearview Chlamydia provides a simple direct detection assay for chlamydial antigen in endocervical swab specimens, which is sensitive, specific and rapid, making the test suitable for either single testing or batch use.

TEST PRINCIPLE

Chlamydial antigen is extracted from the specimen by heating the swabs at 80°C with the Extraction Buffer.

Following extraction of the Chlamydia trachomatis antigen, the only step required is to add the extract to the Sample Window of the Clearview Chlamydia Test Unit. The appearance of a line in the Result Window indicates the presence of chlamydial antigen. The absorbent pad in the Sample Window contains a latex-labeled monoclonal antibody directed against a genus-specific lipopolysaccharide epitope of Chlamydia.

The swab extract rehydrates the labeled antibody and the extracted antigen reacts with this to form a complex.

The pad is in contact with a test strip which contains a region of immobilised monoclonal anti-chlamydia antibody in the Result Window.

The extract-latex mixture moves by capillary action along the strip.

The formation of a line in the Result Window indi-

cates the presence of chlamydial antigen in the extract.

The line is formed due to the binding of the chlamydial antigen to the latex-labeled antibody and the subsequent immobilisation of this complex by the zone of antibody located in the Result Window. If no antigen is present, the Result Window will remain clear.

Clearview Chlamydia also provides an integral control feature. The appearance of a line in the Control Window shows the test has been carried out correctly.

PRECAUTIONS

For in vitro diagnostic use. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures.

It is recommended that disposable gloves should be worn during the handling of patient specimens.

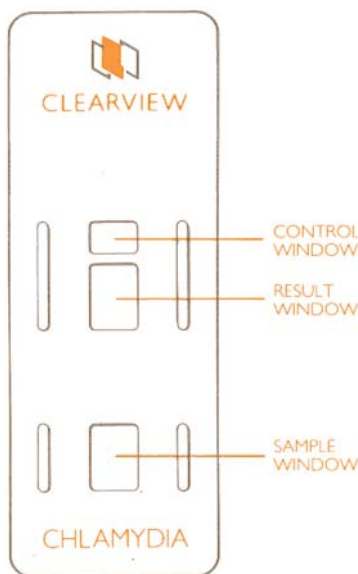
Do not mix kit components from different lots. Do not use after the stated expiration date.

Do not mix bottle caps.

The Positive Control contains sodium azide which on contact with lead and copper plumbing may react to form explosive metal azides. Use large volumes of water to flush reagents on disposal.

Properly dispose of all contaminated waste such as swabs, Chlamydia Test Units, and extract.

Chlamydia in the Positive Control have been shown to be non-infectious in cell culture; however the



control must still be handled and disposed of as though potentially infectious.

Do not smoke, drink or eat while handling specimens.

For specimen collection, use only the Clearview Chlamydia Female Specimen Collection Kit (Product Code # 135315).

KIT CONTENTS

Each Clearview Chlamydia kit contains sufficient reagents for 20 tests.

Extraction Buffer with 0.1% sodium azide 3 x 5.0ml

Positive Control containing non-infective chlamydial antigen derived from in-vitro culture, with 0.1% sodium azide. 1 x 1.0ml

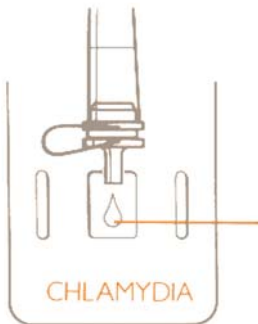
Clearview Chlamydia Test Unit: containing separate regions of murine monoclonal anti-chlamydial antibody, rabbit anti-mouse antibody and latex labeled murine monoclonal anti-chlamydia antibody. 20

Extraction Tubes: 20

Product Insert

STORAGE

Clearview Chlamydia reagents should be stored refrigerated (2°-8°C).



SPECIMEN COLLECTION AND STORAGE

For specimen collection, use only the Clearview Chlamydia Female Specimen Collection Kit (Product Code # 135315).

The correct specimen collection technique is very important. Chlamydia are intracellular organisms that infect columnar epithelial cells of the cervix. To ensure an adequate specimen, rotate the swab against the surface of the cervical canal. The following technique is recommended:

Recommended Procedure

Remove excess mucus from the exocervix with a separate swab or cotton ball and discard.

Insert the swab into the endocervix and rotate for 10 to 30 seconds.

Avoid touching any vaginal surface when withdrawing the swab. If the swab is not to be extracted immediately, return to the transportation tube.

Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

If the specimen is not to be tested within 1 day, store refrigerated (2°-8°C) for up to 5 days. Do not freeze.

ASSAY PROCEDURE

Materials provided:
20 Clearview Chlamydia tests
20 extraction tubes

Materials required but not provided:
80°C (±2°C) Heating source, eg
Clearview WorkStation: 120 volt (Product Code # 130035)

Clearview Chlamydia Female Specimen Collection Kit (Product Code # 135315)

Timer.

Ensure that all reagents, Test Units and swabs are at room temperature before beginning the assay (by allowing 30 minutes after removal from 2°-8°C).

EXTRACTION

Ensure heating apparatus is at 80°C ± 2°C.

Fill extraction tube to the line on the tube (0.6ml) with Extraction Buffer.

Immerse the swab into the extraction tube and agitate.

Place extraction tube, containing swab, into the heating apparatus and leave for 10-12 minutes.

Remove the extraction tube from the heating apparatus. Rotate the swab in the extraction tube.

Thoroughly remove liquid from the swab by pinching the rim of the extraction tube between thumb and finger and gently removing the swab from the tube.

CAUTION: The bottom half of the tube will be hot.

Discard the swab.

Allow the sample to cool for at least five minutes at room temperature.

The swab extract can remain at room temperature for up to 3 hours without affecting the result of the Clearview test.

TEST PROCEDURE

Remove a Test Unit from the foil and place on a level surface.

Cap the extraction tube with the attached dropper and apply five drops of extract to the Sample Window of the Test Unit.

The test should be read 15 minutes after adding the extract suspension to the Sample Window. Test results should remain stable for up to 20 minutes after addition of extract to the Test Unit.

INTERPRETATION OF RESULTS

A line in the Control Window shows the test has worked correctly.

A line in the Result Window (see diagram) indicates a positive result and that the sample contains chlamydial antigen. If no line appears in the Result Window, the test is negative for chlamydial antigen.

A difference of intensity may occur between the lines in the Result and the Control Windows but this does not affect the interpretation of the results.

If no line appears in the Control Window the test should be repeated using a fresh Test Unit. The remaining extraction mixture can be used for this purpose, provided it has been prepared for less than 3 hours. Alternatively, a fresh specimen may be collected.

It is possible for a strong positive sample to form a line in the Result Window before 15 minutes have elapsed. This is indicative of a positive result and the correct functioning of the test is confirmed by the subsequent formation of a line in the Control Window.

QUALITY CONTROL

Good laboratory practice recommends the use of external control material to ensure proper kit performance. Two levels of controls should be run periodically to verify proper performance of all kit components.

A positive antigen control is provided as a means of quality control testing.

Add 5 drops of the Positive Control to an extraction tube and fill to the line with the Extraction Buffer.

Mix the reagents by swirling and place in the heating apparatus, (pre-heated to 80°C ± 2°C) for 10-12 minutes.

Allow to cool for 5 minutes at room temperature (18° to 30°C).

Cap the tube with the attached dropper and complete the test procedure as for an extracted specimen.

Lines in the Result and Control Windows show that the test is working correctly.

The built-in control line provides an assurance of proper performance of the test reagents.

Note: A negative control can be performed by following the Extraction and Test procedure using Reagent I but without the addition of a swab.

LIMITATIONS OF THE PROCEDURE

1. Clearview Chlamydia is for use only with endocervical swab specimens. The performance of the test with swabs taken from other sites has not been established.
2. The test does not differentiate between carriers and infected individuals, nor viable and non-viable organisms.
3. Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test.
4. False negatives may result from improperly taken samples (see Specimen Collection section).
5. Additional follow-up testing using a culture method is required if the Clearview Chlamydia result is negative and clinical symptoms persist.
6. It is not advisable to use any direct antigen detection test for Chlamydia (including Clearview Chlamydia) in the investigation of suspected child sexual abuse.

EXPECTED RESULTS

For women attending STD (Sexually Transmitted Disease) clinics, and other high risk populations, the prevalence of Chlamydia infection has been reported to be between 20% and 30%. In a low-risk population, such as those patients attending obstetrics and gynaecology clinics the prevalence is approximately 5% or less.

Normal carriage rates of Chlamydia in asymptomatic men is less than 5%.

PERFORMANCE CHARACTERISTICS

The performance of Clearview Chlamydia has been determined in a multi-centre clinical evaluation of female patients.

A total of 875 endocervical swab specimens were obtained from patients attending STD and Genito-Urinary Medicine clinics. Two swabs were taken from each patient, one being used for conventional tissue culture and the other for the Clearview Chlamydia assay. Of the total specimens tested 643 were evaluated against primary culture with iodine staining and 232 against immunofluorescent antibody staining.

The prevalence of Chlamydia infections in women at these sites ranged from 8.3% to 19.7%

The results are summarised below:

| Culture | Clearview Chlamydia | | Total |
|---------|---------------------|-----|-------|
| | + | - | |
| + | 100 | 15 | 115 |
| - | 9 | 751 | 760 |

Of the 760 specimens confirmed as negative by culture, 751 produced negative results in the Clearview Chlamydia assay. Of the 115 culture positive results, 100 produced positive results with

Clearview Chlamydia. The sensitivity of Clearview Chlamydia was determined to be 87.0%, the specificity 98.8%, and the overall agreement with culture 97.3%. These results together with assay performance in various prevalence settings are summarised below.

| Prevalence | Sensitivity | Specificity | PPV | NPV |
|------------|-------------|-------------|--------|-------|
| 8.3% | 86.1% | 98.7% | 86.1% | 98.7% |
| 19.7% | 82.9% | 97.6% | 89.5% | 95.9% |
| 16.4% | 92.1% | 100.0% | 100.0% | 98.5% |
| Overall | 87.0% | 98.8% | 91.7% | 98.0% |

Of the 9 specimens initially found positive by

Clearview Chlamydia and negative by culture, a commercially available direct immunofluorescence test of the swab prior to testing with Clearview Chlamydia confirmed 4 specimens to be antigen positive. The resolved sensitivity and specificity were 87.4% and 99.3% respectively.

In a high risk female population (20% prevalence), the predictive value of a positive test is 94.8%, while that of a negative test is 96.8%.

In a low risk female population (5% prevalence), the predictive value of a positive result is 79.2%, while that of a negative test is 99.3%.

These values were calculated using Clearview Chlamydia's sensitivity of 87.0% and specificity of 98.8%.

SPECIFICITY:

The antibody used in Clearview Chlamydia has been shown to detect all 15 Chlamydia serovars. In addition Chlamydia psittaci has been tested with Clearview Chlamydia and gave a positive result.

Cross reactivity with other organisms has been studied using suspensions of 10⁷ CFU/ml. The following organisms were not detected using Clearview Chlamydia:

Acinetobacter calcoaceticus, Salmonella typhi, Staphylococcus aureus, Neisseria gonorrhoeae, Neisseria catarrhalis, Neisseria meningitidis, Neisseria lactamica, Pseudomonas aeruginosa, Proteus vulgaris, Acinetobacter spp, Candida albicans, Escherichia coli, Gardnerella vaginalis, Streptococcus faecalis, Streptococcus faecium and Trichomonas vaginalis.

ADVICE LINE

If there are any questions concerning any aspects of

the test, please call Wampole Laboratories Technical Services at 1-800-257-9525.

REFERENCES

1. Genital Infection by *Chlamydia trachomatis*. Oriel, J. D. and Ridgway, G. L. (1982). Edward Arnold, London.
2. Sweet, R. L. Chlamydial Salpingitis and Infertility. Fertility and Sterility, 38, 530-533 (1982).
3. Schachter, J. Sexually transmitted *Chlamydia trachomatis* infection. Postgraduate Medicine, 72, 60-69 (1982).

Test System Code and Name: 64001

Analyte Code and Name: 1016 Chlamydi

CLIA Complexity: Moderate

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Product Code / 135301 20 Test Kit



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WAMPOLE LABORATORIES, Dist.
Div. of Carter-Wallace, Inc.
Cranbury, New Jersey 08512
Tel: 1-800-257-9525