EVALUATION THE ENZYME IMMUNOSORBENT ASSAY IDEIA™ TEST DETECTING *CHLAMYDIA TRACHOMATIS* IN CERVIX

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Abstract. A total of 87 cervical specimens of unselected female sex workers in massage parlors were tested by an enzyme amplified immunoassay IDEIA™ Chlamydia test and cell culture for the presence of *Chlamydia trachomatis*. The prevalence of *C. trachomatis* was 28 (32%) cases and 34 (39%) cases by the cell culture and the IDEIA™ Chlamydia test respectively. The IDEIA™ Chlamydia test demonstrated the sensitivity and specificity of 85.7% and 83% respectively, positive and negative predictive values of 70.5% and 92.4% respectively.

INTRODUCTION

The standard method of the cell culture technique is generally used to detect the *Chlamydia trachomatis* in the clinical specimens. However, the test is inconvenient in most laboratories since it requires a complicated and costly facility, is time consuming and requires the transportation of the specimens (Kallings and Mardh, 1982). Therefore non culture methods to detect chlamydial antigen using a commercial kit were introduced, in order that they can be performed in the clinic and can obtain the results within minutes to a few hours (Mahony *et al*, 1989; Hammerschlag *et al*, 1990).

The IDEIA™ Chlamydia test (Novo Biolabs) is the amplified enzyme-linked immunoassay, using a genus-specific monoclonal antibody to detect *C. trachomatis* from the genital specimens. This test was not commonly used until recently. Therefore we evaluated a commercial IDEIA™ Chlamydia test in the detection of *C. trachomatis* compared to the cell culture technique in female genital tract specimens.

MATERIALS AND METHODS

Study population

A total of 87 cases of unselected female sex workers in massage parlors in Bangkok during June, 1990, having the routine check up for genital tract infection were the cases studied. The endocervical specimens were collected for the antigen detection using the IDEIA™ Chlamydia test and for the cell cultures. The exocervix was cleaned with cotton swab to remove the mucus and exudate before the sample taking.

The IDEIA™ test

The IDEIA™ transportation kit for the IDEIA™ Chlamydia test is composed of the vial of transport media and 2 swabs, for collecting urethral and cervical samples respectively. The cervical swab, which is larger than the urethral swab, was inserted into endocervical canal and rotated. The swab was then put into the IDEIA transport medium. In the laboratory the specimens were kept in the refrigerator at +4°C and tested within a week according to the instructions described by the manufacturer. The results were read by eye and by ELISA reader.

The color intensity of the reaction was graded by the same reader according to the following criteria :

negative	–	the same color produced by negative control test
1+	–	pale pink but pinker than the negative control
2+ → 3+	–	the color compared to 1 + and 2 + respectively
4+	–	purple

The results obtained by the ELISA reader were calculated according to the instructions.

Cultured *C. trachomatis*

Isolation of *C. trachomatis* by cell culture method was performed. The specimen from the endocervix was collected in the same way as previously described by using an ENT swab (Medical Wire and Equipment Co, Ltd, Corsham Wilts, England). The swab then was placed in 2SP transport medium in an ice box, and kept at -20°C (Kallings and Mardh, 1982). The cell culture was performed within 3 days by following the method for *C. trachomatis* in cycloheximide treated McCoy cells as described by Ripa and Mardh (1977) and then stained with iodine. The number of the inclusions was counted using the following criterial.

1+ = 1-10 inclusions/slide
2+ ≥ 10-100 inclusions / slide
3+ ≥ 100-1,000 inclusions / slide
4+ ≥ 1,000 inclusions / slide

RESULTS

Of the total 87 cases, *C. trachomatis* were isolated in 28 (32%) cases and the IDEIA™ Chlamydia test was positive in 34 cases (39%), while 24 cases were culture positive. In the group of 53 cases which had negative results by the IDEIA™ Chlamydia test, 4 cases were positive for *C. trachomatis* by cell culture (Table 1). The sensitivity and specificity were 85.7% and 83% respectively. The positive predictive value and negative predictive value were calculated as 70.5% and 92.4% respectively. In Table 2, of 4 cases of false negative results by the IDEIA™ Chlamydia test had less than 10 inclusions (1+) in cell culture, and in the false positive group the color intensity varied from 3+ to 1+.

Table 1

The result of IDEIA™ Chlamydia test compared to the cell culture technique.

Result of IDEIA™ test	Results of *Chlamydia* cell culture		
	Positive	Negative	Total
Positive	24	10	34
Negative	4	49	53
Total	28	59	87

DISCUSSION

Previous studies of IDEIA™ Chlamydia test in cervical specimens reported the sensitivity varied from 74 to 97 percent and the specificity varied from 97 to 99 percent (Mahony *et al*, 1989; Thomas *et al*, 1989). The present study gave lower values of both sensitivity and specificity, possibly because of the method of collection of the specimen.

Table 2

The correlation of *C. trachomatis* inclusion count and the color intensity of IDEIA™ Chlamydia test of 87 cases.

Inclusion count of *C. trachomatis*	Total no.	Color intensity of IDEIA™ test				
		4+	3+	2+	1+	Neg
4+	16	6	6	3	1	0
3+	2	1	1	0	0	0
2+	4	1	0	3	0	0
1	6	1	0	0	1	4
0	59	–	1	3	6	49

There was a suggestion from previous studies that increasing the sensitivity of the test was possible by taking up to 3 swabs for a transport medium vial (Thomas *et al*, 1989; Bygdeman *et al*, 1989) or using the cytobrush (Moncada *et al*, 1989). We also compared the variation in taking the specimen from the endocervix with 2 swabs in the same subject and separated each pair of swabs for each transport medium in pilot study. Of 98 cases in the pilot study, there were 94 cases or 95.9 percent who had agreement of the results. Of 4 cases with disagreement, 3 cases were positive by IDEIA™ Chlamydia test in the second swab and one case was positive in the first swab. It was suggested that the second swab took up the infected cells more adequately than the first one. It was possible because the first swab removed mucus from the site of the endocervix that made the second swab collect a more adequate specimen. We suggested that the clinician carefully remove the mucus from endocervix before the specimen was collected by swab in the clinical practice.

The number of the chlamydial inclusions also affected on the IDEIA™ Chlamydia test. A small number of inclusions is likely to give a false negative result by the IDEIA™ test (Ostergaard *et al*, 1990) as was confirmed by the present study.

Compared to the tissue culture technique, the IDEIA™ Chlamydia test can detect *C. trachomatis* even if they have lost their infectivity (Ostergaard *et al*, 1990). The study of Ripa estimated the sensitivity of the cell culture between 75% and 90% (Ripa, 1982). The transportation of the specimens is one of the factors to affect the isolation of *C. trachomatis* (William *et al*, 1985). We collected the cervical specimens in the STD clinic in massage parlors, the specimens were in ice box about 3 hours, therefore *C. trachomatis* may have lost infectivity during the transportation. On the other hand the sex worker usually washed out the cervical canal after having sexual intercourse, therefore it may suggest that the organism lost infectivity and caused the cell culture to be negative, which affected the low specificity in the present study.

In the laboratory where there is no ELISA reader, it is possible to determine the color developing result by eye. In comparison to the negative control, the color of the positive test was distinct and all agreed with the ELISA reader.

From the present study, the IDEIA™ Chlamydia test is a good commercial test for clinical use. It is easy to perform, less time-consuming. The sensitivity, specificity, positive predictive value and negative predictive value are within acceptable limits. The authors suggest that the specimen collection should be appropriate and adequate in order to make the result more sensitive and specific.

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