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Evaluation of a Monoclonal Antibody Test to Detect Chlamydia in Cervical and Urethral Specimens

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The MicroTrak *Chlamydia trachomatis* Direct Specimen Test (MT; Syva Co., Palo Alto, Calif.) was compared with cell culture in two patient populations. The sensitivity of the MT for a low-prevalence group was significantly lower (59.6%) than that for a high-prevalence group (84.4%). The results underscored the need to run the MT in parallel with culture initially if the prevalence of chlamydial infections is unknown and questioned the usefulness of the MT as a screening test for chlamydia in low-prevalence populations.

Recently, the MicroTrak *Chlamydia trachomatis* Direct Specimen Test (MT; Syva Co., Palo Alto, Calif.) became commercially available to detect *C. trachomatis* in urethral and endocervical swab specimens. To date, several studies have compared the results of the MT with those of cell culture. Tam et al. (6) and Foulkes et al. (3) reported sensitivities and specificities which were greater than 90% for the MT. Patients tested were those attending a clinic for sexually transmitted diseases. Similar results were described by Stamm et al. (5) and Quinn et al. (4) in a multicenter trial and an inner-city population, respectively. Uyeda and coworkers (8) reported a comparable sensitivity and specificity for the MT in asymptomatic women who were either pre- or postabortal patients. In this report, we describe our results and experience with the MT fluorescein-labeled monoclonal antibody for the detection of *C. trachomatis* directly in clinical specimens in two patient populations with significantly different prevalence rates for chlamydial infections.

(Results of this study were presented in part at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy, Minneapolis, Minn., 29 September to 2 October 1985 [B. A. Forbes, N. Bartholoma, J. McMillan, M. Roefaro, L. Weiner, and L. Welych, Program Abstr. 25th Intersci. Conf. Antimicrob. Agents Chemother., abstr. no. 728, 1985].)

Specimens were collected from patients attending obstetrical-gynecological clinics at the Upstate Medical Center. The prevalence rate of chlamydial infection for this particular population over the last 3 years was 6.7%. In addition, specimens were obtained through a university health service from a population of students (72 males, 78 females) with a prevalence rate of greater than 20% for chlamydial infections.

Two specimens were collected from each patient. Swabs for culture were subsequently inoculated into McCoy cell monolayers. The isolation procedure for chlamydia followed the recommendations of the Centers for Disease Control (1, 2). After collection, the MT kit swab was rolled onto the collection kit slide and processed. Patient and control slides were stained according to the instructions of the manufacturer with the monoclonal antibody to *C. trachomatis*. Slides were examined under ×400 magnification. Morphology was confirmed by using ×1,000 magnification. A smear with visible cells and more than or equal to 10 characteristically fluorescing elementary bodies was considered positive. All discrepancies between the MT and cell culture were reexamined. Negative MT slides for which the corresponding culture was positive were examined under ×1,000 magnification.

Of the 792 urogenital specimens included for study, 10.1% (80/792) were positive by culture for *C. trachomatis*. The prevalence of chlamydial infections in the low-prevalence patient group for this study was 7.3% (47/642). In contrast, 22.0% (33/150) of the specimens obtained from patients attending the university health service were positive for *C. trachomatis*. The results of the MT and cell culture are shown in Table 1. There was an overall agreement between the MT and culture of 94.9% (752/792). The overall sensitivity and specificity of the MT when compared with cell culture was 70.0% (56/80) and 97.8% (696/712), respectively. With respect to the 16 false-positive MT smears, the number of organisms observed ranged from 10 to more than 100 organisms per smear. Only one of the 16 corresponding cultures revealed one inclusion after blind cell passage. The predictive values for positive and negative tests were 77.8 and 96.5%, respectively. The comparison of MT and cell culture results by study population is shown in Table 2.

A second reading was performed under ×1,000 magnification when MT results were discrepant with those of cell culture. The results of readings 1 and 2 are compared in Table 2. After reading 2 at ×1,000 magnification, the overall sensitivity for the MT significantly increased from 70.0 to 88.8%. When these data are examined by study group (Table 2), the sensitivity increases to 80.9% for the low-prevalence population, with the specificity remaining unchanged. Simi-

TABLE 1. Comparison of the MT with cell culture

MT result	Cell culture result	No.
Negative	Negative	696
Positive	Positive	56
Positive	Negative	16
Negative	Positve	24

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TABLE 2. Results of the MT by patient population

Study population	Sensitivity (%)	Specificity (%)	Predictive value (%)	
			Positive	Negative
Reading 1				
Overall	70.0	97.8	77.8	96.5
Low prevalence	59.6	98.3	73.7	96.8
High prevalence	84.4	94.1	82.4	95.7
Reading 2				
Overall	88.8	97.8	81.6	99.0
Low prevalence	80.9	98.3	79.1	98.5
High prevalence	100.0	94.1	84.6	100.0

larly, the MT sensitivity increases in the high-prevalence population to 100%.

The number of elementary bodies observed on reading 2 for the MT slides which were negative on reading 1 but which had a corresponding positive culture is shown in Table 3. Forty percent (6/15) of the false-negative MT results had fewer than 10 elementary bodies in the entire smear. In addition, another 40% (6/15) of these false-negative MT smears demonstrated 0 to 5 organisms per oil immersion field, with more than 10 but fewer than 25 elementary bodies per smear. Cell culture results were quantitated for the nine patients for whom the MT was negative after reading 2 under oil immersion. Quantitation revealed that two-thirds had few-to-rare *C. trachomatis* inclusions. All nine patients were from the low-prevalence population.

In conclusion, an overall sensitivity and specificity of 70 and 97.8%, respectively, was obtained for the MT. The sensitivity of the MT was significantly improved by changing the manufacturer's criteria for positivity from more than or equal to 10 organisms per smear to 3 or more organisms per smear and examining the smears under oil. These findings are similar to those of Thomas et al. (7), who reported that 44% of their smears with corresponding positive cultures would have been read as negative, owing to fewer than 10 organisms per smear. It is of concern that reexamination of false-negative MT smears by using ×1,000 magnification revealed 10 to 25 organisms in eight patients, suggesting the ×400 screening could miss positive smears, particularly if the microscopist is inexperienced or relatively small numbers of organisms are present.

TABLE 3. Quantitation of elementary bodies on MT smears which were negative on reading 1 but positive after reading 2

No. of elementary bodies	No. of smears positive after reading 2
>25/smear	1
>10 but <25/smear (0–5/oil immersion field	6
10/smear	2
3–5/smear	6

The overall results for sensitivity and specificity appear to differ significantly from those obtained by other investigators (5–8). However, when the data were analyzed by population, a close correlation between culture and MT results was observed in the population with a high prevalence for chlamydial infections, again confirming the utility of the MT in patient populations with high chlamydial infection rates. In contrast, data obtained on specimens from the low-prevalence group differed significantly from those of the high-prevalence group as well as from reports of previous investigators. A possible explanation for the decreased sensitivity of the MT compared with cell culture in the evaluation of specimens from the low-prevalence population is that more of these patients are infected with fewer organisms.

In conclusion, the results of the MT correlated well with cell culture results in a patient population with a high prevalence of infection. However, based on sensitivity in a population with a lower rate of infection, it is unlikely that this screening test will be useful on a routine basis in lieu of cell culture. It is recommended that when the prevalence of chlamydial infections is unknown the MT be run in parallel with cell culture before the decision is made to use the test on a routine basis.

LITERATURE CITED

1. **Bird, B. R., and F. T. Forrester.** 1980. Laboratory diagnosis of *Chlamydia trachomatis* infections, p. 41–79. Centers for Disease Control, Atlanta.
2. **Centers for Disease Control.** 1982. *Chlamydia trachomatis* infections. Morbid. Mortal. Weekly Rep. **31**:35S–36S.
3. **Foulkes, S. J., R. Deighton, A. R. B. Feeney, K. C. Mohanty, and C. W. Freeman.** 1985. Comparison of direct immunofluorescence and cell culture for detecting *Chlamydia trachomatis*. Genitourin. Med. **61**:252–254.
4. **Quinn, T. C., P. Warfield, E. Kappus, M. Barbacci, and M. Spence.** 1985. Screening of *Chlamydia trachomatis* infection in an inner-city population: a comparison of diagnostic methods. J. Infect. Dis. **152**:419–423.
5. **Stamm, W. E., H. R. Harrison, E. R. Alexander, L. D. Cles, M. R. Spence, and T. C. Quinn.** 1984. Diagnosis of *Chlamydia trachomatis* infections by direct immunofluorescence staining of genital secretions—a multicenter trial. Ann. Intern. Med. **101**:638–641.
6. **Tam, M. R., W. E. Stamm, H. H. Handsfield, R. Stephens, C. Kuo, K. Holmes, K. Ditzenberger, M. Krieger, and R. Nowinski.** 1984. Culture-independent diagnosis of *Chlamydia trachomatis* using monoclonal antibodies. N. Engl. J. Med. **310**:1146–1150.
7. **Thomas, B., R. T. Evans, D. A. Hawkins, and D. Taylor-Robinson.** 1984. Sensitivity of detecting *Chlamydia trachomatis* elementary bodies in smears by use of a fluorescein labelled monoclonal antibody: comparison with conventional chlamydial isolation. J. Clin. Pathol. **37**:812–816.
8. **Uyeda, C. T., P. Welborn, N. Ellison-Birang, K. Shunk, and B. Tsaouse.** 1984. Rapid diagnosis of chlamydial infections with the MicroTrak direct test. J. Clin. Microbiol. **20**:948–950.