## Improved Syva MicroTrak Chlamydia trachomatis Direct Test Method

BARBARA A. JUDSON\* AND PAMELA P. LAMBERT

Infectious Diseases Division, Syva Company, 900 Arastradero Road, Palo Alto, California 94304

Received 5 July 1988/Accepted 7 September 1988

Recent changes in the MicroTrak Chlamydia trachomatis Direct Specimen Test (Syva Company, Palo Alto, Calif.) have led to improved product performance. The use of the recommended cervical cytology brush can significantly increase the number of endocervical cells collected, and fixation with methanol increases the intensity of elementary-body staining in many specimens.

Recent articles (1, 2) have compared the MicroTrak Chlamydia trachomatis Direct Specimen Test (Syva Company, Palo Alto, Calif.) to other C. trachomatis detection methods. Since these comparison studies were done, changes have been made in both the collection procedure for endocervical specimens and the fixation procedure used in the Syva test. These changes have significantly improved test performance

Until August 1987, the recommended collection devices for all specimen types were the Dacron swabs provided in the collection kit, and the recommended fixative was acetone. Studies performed at Syva and by outside investigators have shown that the cytology brush is superior to the Dacron swab for the collection of endocervical specimens and that methanol fixation results in increased elementary-body (EB) fluorescence intensity in most specimens. We briefly present these data and describe the effect of these product changes on product performance.

Endocervical specimen collection. Paired endocervical specimens were collected at two trial sites by using a cytology brush and a Dacron swab. Specimens were collected in alternate order with the two devices, deposited on two separate 8-mm slide wells, and stained with the Syva reagent. The results, as shown in Table 1, demonstrated a greater than 70% increase in the number of samples containing 20 or more endocervical cells when a cytology brush was used for sample collection.

Also, significantly more chlamydia-positive specimens were detected among cytology brush samples (n = 81) than among swab samples (n = 71) (R. Boughton et al., manuscript in preparation).

**Fixation.** (i) Fixation studies done at Syva compared fluorescence intensities of all 15 *C. trachomatis* serovars. Both American Type Culture Collection strains and patient isolates of known serovars were propagated in cell culture. EBs were spotted in duplicate slide wells and allowed to air dry. One well was fixed with acetone, and the other was fixed with methanol, by flooding the slide with 0.5 ml of fixative and allowing it to air dry. Each preparation was then stained with the Syva reagent according to the package insert procedure. Fluorescence intensity of EBs was determined by using a Zeiss 50-W mercury bulb epifluorescence microscope and a 100× oil objective. A scale of +/- (very dull green, faint staining) to 4+ (very bright, intense applegreen) was used to rate intensity of fluorescence. For all serovars, fluorescence intensity increased significantly (a

change of 1+ or greater) with methanol fixation, with the exception of certain H, K, and L2 serovars, which stained at 3+ to 4+ when fixed with either acetone or methanol.

(ii) Fixation studies on paired endocervical smears were done at two different field trial sites. At a sexually transmitted diseases clinic, 110 paired smears were evaluated for chlamydiae by using the Syva reagent after methanol or acetone fixation. Nineteen of these paired specimens were positive for chlamydiae. Increased fluorescence intensity of EBs was noted in 14 (74%) of these positive specimens. At an obstetrics-gynecology clinic, 240 paired smears fixed with methanol or acetone were evaluated. Fifty-nine specimens were chlamydia positive with the Syva reagent. Forty-five percent of these positive specimens showed increased EB fluorescence with methanol fixation.

At both field trial sites, readers were able to detect greater numbers of EBs on 30 to 50% of the methanol-fixed slides than on the paired acetone-fixed slides. This increased number of EBs was probably the result of brighter fluorescence and, thus, easier detectability, although sampling variability may also have contributed to the difference.

(iii) In a study on detection of chlamydial infections in children with trachoma, the sensitivity of the MicroTrak test relative to that of culture, Chlamydiazyme, or a DNA probe increased from 51 to 78% when slides were refixed with methanol, restained, and reread (J. Schachter, J. Moncada, C. R. Dawson, J. Sheppard, P. Courtright, M. E. Said, S. Zaki, S. F. Hafez, and A. Lorincz, J. Infect. Dis., in press).

In light of these data, we believe that studies reporting fixation with acetone or the collection of endocervical specimens with a Dacron swab may not accurately reflect the

TABLE 1. Comparison of Dacron swab and cytology brush for collection of endocervical cells

Trial site and method	% of samples with:	
	≥1 EC"	≥20 ECs
1		
Swab	98.6	48.2
Cytology brush	99.6	82.4 <sup>b</sup>
2		
Swab	83.1	38.7
Cytology brush	95.9	72.4°

<sup>&</sup>quot; EC, Endocervical cell.

<sup>\*</sup> Corresponding author.

<sup>&</sup>lt;sup>b</sup> Seventy-one percent increase over swab.

<sup>&</sup>lt;sup>c</sup> Eighty-seven percent increase over swab.

2658 NOTES J. CLIN. MICROBIOL

performance of the Syva MicroTrak Chlamydia trachomatis Direct Specimen Test.

## LITERATURE CITED

Lefebvre, J., H. Laperrière, H. Rousseau, and R. Massé. 1988.
 Comparison of three techniques for detection of Chlamydia

trachomatis in endocervical specimens from asymptomatic women. J. Clin. Microbiol. 26:726-731.

Tilton, R. C., F. N. Judson, B. C. Barnes, R. P. Gruninger, R. W. Ryan, and O. Steingrimsson. 1988. Multicenter comparative evaluation of two rapid microscopic methods and culture for detection of *Chlamydia trachomatis* in patient specimens. J. Clin. Microbiol. 26:167-170.