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Rapid Antigen Detection Assay for Identification of *Chlamydia trachomatis* Infection

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A rapid antigen detection test was compared with direct fluorescent-antibody staining and with tissue culture isolation for the detection of *Chlamydia trachomatis* infections in 507 women. The sensitivities observed were 75, 76, and 84%, respectively, with specificities of >99%.

Chlamydia trachomatis infections are the most common bacterial sexually transmitted disease, and they have potentially serious sequelae (1). Tissue culture for the diagnosis of active infection has been the standard against which other tests have been measured because of its relatively high sensitivity and specificity (7). However, there are many situations in which accessibility of culture is limited or in which the need for rapid results outweighs the advantages of diagnosis by culture (4). To assess the sensitivity and specificity of a commercially available rapid antigen detection assay, we compared results obtained by Sure-Cell (Kodak, Rochester, N.Y.) with those obtained by tissue culture and by a direct fluorescent-antibody (DFA) assay, MicroTrak (Syva, San Jose, Calif.).

Endocervical specimens were collected in triplicate from unselected women attending a sexually transmitted disease clinic after swab specimens had been collected for gonorrhea culture. One Dacron swab was placed in transport medium containing sucrose, phosphate, and glutamic acid for culture, and another swab specimen for antigen detection was obtained in accordance with the manufacturer's (Kodak) instructions. The order of collection of these two specimens was random. The last specimen collected was a cervical sample collected with a cytobrush for DFA analysis. Specimens for culture and antigen detection were held at 4°C until their arrival at the laboratory. Cultures were inoculated within 24 h of collection, and antigen detection assays were run within 12 h of collection.

The specimens for DFA assays were fixed, incubated for 30 min with staining reagent, and read according to the manufacturer's (Syva) instructions. Culture was performed as previously described (6) by inoculation of triplicate McCoy cell monolayers with 0.1 ml of specimen which had been vortexed and sonicated. Monolayers were then overlaid with 0.2 ml of minimum essential medium, centrifuged at 1,700 × *g* for 1 h, incubated at 37°C for 48 h, fixed with methanol, and stained with a genus-specific monoclonal antibody. The rapid antigen assay was also performed according to the manufacturer's instructions. Briefly, the specimens were extracted, filtered, and placed in wells of a cassette to which enzyme-conjugated solutions were added. Positive and negative control wells were tested with each well containing a sample from a patient. A colorimetric change on the cassette filter indicated a positive reaction; negative wells had no color development.

Specimens were obtained from 507 women over a 5-month period. Fifteen patients from whom the DFA assay specimens were judged to be inadequate (those specimens with fewer than 10 columnar epithelial cells per slide) were excluded, leaving specimens from 492 women for further analysis. An infection was considered to be present if the culture was positive, if both nonculture assays were positive, or if only one assay was positive but was confirmed. Confirmation was performed by centrifuging 0.1 ml of the culture transport medium and staining the pelleted material with a species-specific monoclonal antibody (2). The visualization of three or more chlamydial elementary bodies was required for confirmation. Infections in a total of 63 women were identified according to these criteria (Table 1). Culture identified 53 infections, while the rapid antigen detection assay identified 47 infections and the DFA assay identified 50 infections. Three infections were identified by the rapid antigen detection assay only, and all three were confirmed. The DFA assay identified as positive five specimens which were not identified by the other two methods. Two of these could not be confirmed. The number of inclusion-forming units per well was determined for all culture-positive specimens. The number of inclusion-forming units per well for culture-positive specimens from individuals for whom all three assays were positive did not differ from that for culture-positive specimens from individuals with negative Sure-Cell or MicroTrak results (Table 2). There were, however, fewer elementary bodies found in positive direct-smear specimens for patients whose samples were negative by either culture or the rapid antigen detection assay.

In this relatively small study, Sure-Cell and MicroTrak were both marginally less sensitive than culture, although the differences were not statistically significant (all P values were >0.1) and they were not different from each other. The observed sensitivity of Sure-Cell with cervical specimens was comparable to that reported for women in a similar study (8), although we observed fewer false-positive results and thus a higher specificity. The reason for this discrepancy is not readily apparent.

TABLE 1. Performance characteristics of *Chlamydia* assays

Assay	Sensitivity[a]	Specificity[b]	Positive predictive value (%)	Negative predictive value (%)
Sure-Cell	47/63 (75)	429/429 (100)	100	96.4
Culture	53/63 (84)	429/429 (100)	100	97.7
MicroTrak DFA	48/63 (76)	427/429 (99.5)	96	97.1

[a] Number testing positive/number infected (percentages given in parentheses).
[b] Number testing negative/number uninfected (percentages given in parentheses).

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TABLE 2. Numbers of elementary bodies and inclusion-forming units

Specimen group	No. of patients	No. of:	
		EB for DFA-positive specimens[a]	IFU/well for culture-positive specimens[b]
Positive by all three methods	37	62.8 ± 46.4	621 ± 1,837
Sure-Cell negative	16	21.5[c] ± 6.5	562 ± 1,546
Culture negative	10	20.9[d] ± 10.0	NA[e]
MicroTrak negative	15	NA	590 ± 1,606

[a] Values are means ± standard deviations. EB, elementary bodies.
[b] Values are means ± standard deviations. IFU, inclusion-forming units.
[c] Compared with specimens with all three tests positive, $P = 0.049$.
[d] Compared with specimens with all three tests positive, $P = 0.031$.
[e] NA, not applicable (result was negative for these samples).

Also, in the previous study the reported sensitivity of Sure-Cell was lower for men, perhaps reflecting the lower average number of organisms which are shed from an infected male urethra compared with the average number of organisms shed from an infected endocervix (5). Another report indicated that Sure-Cell performed well with neonatal ocular specimens (3). The MicroTrak DFA assay is inexpensive (approximately $1 per test) and can be performed in 30 min. However, it requires both specialized equipment and a highly trained technician to read and interpret the slides. This makes MicroTrak impractical in many clinical settings. Sure-Cell is more expensive per unit test (approximately $9), but the total time required for performance is only 15 min and clinicians can easily perform the assay and interpret the results. Thus, it is a potentially useful test in situations in which access to a specialized laboratory is limited or in which results need to be obtained while the patient is waiting.

Kodak donated Sure-Cell kits.

REFERENCES

1. **Centers for Disease Control and Prevention.** 1993. Recommendations for the prevention and management of *Chlamydia trachomatis* infections, 1993. Morbid. Mortal. Weekly Rep. **42:**1–39.
2. **Gaydos, C. A., C. A. Reichart, J. M. Long, L. E. Welsh, T. M. Neumann, E. W. Hook III, and T. C. Quinn.** 1990. Evaluation of Syva enzyme immunoassay for detection of *Chlamydia trachomatis* in genital specimens. J. Clin. Microbiol. **28:**1541–1544.
3. **Hammerschlag, M. R., M. Gelling, W. Dumornay, P. Roblin, and M. Worku.** 1991. Office diagnosis of neonatal chlamydial conjunctivitis. Pediatr. Infect. Dis. J. **10:**540–541.
4. **Hook, E. W., C. Spitters, C. A. Reichart, T. M. Neumann, and T. C. Quinn.** 1994. Use of cell culture and a rapid diagnostic assay for *Chlamydia trachomatis* screening. JAMA **272:**867–870.
5. **Jones, R. B., B. P. Katz, B. Van Der Pol, V. A. Caine, B. E. Batteiger, and W. J. Newhall V.** 1986. Effect of blind passage and multiple sampling on recovery of *Chlamydia trachomatis* from urogenital specimens. J. Clin. Microbiol. **24:** 1029–1033.
6. **Jones, R. B., B. Van Der Pol, and B. P. Katz.** 1989. Effect of differences in specimen processing and passage technique on recovery of *Chlamydia trachomatis*. J. Clin. Microbiol. **27:**894–898.
7. **Schachter, J.** 1994. Diagnosis of *Chlamydia trachomatis* infection, p. 293–302. *In* J. Orfila, G. I. Byrne, M. A. Chernesky, J. T. Grayston, R. B. Jones, G. L. Ridgway, P. Saikku, J. Schachter, W. E. Stamm, and R. S. Stephens (ed.), Chlamydial infections: proceedings of the Eighth International Symposium on Human Chlamydial Infections. Società Editrice Esculapio, Bologna, Italy.
8. **Schubiner, H. H., W. D. LeBar, S. Joseph, C. Taylor, and C. Jemal.** 1992. Evaluation of two rapid tests for the diagnosis of *Chlamydia trachomatis* genital infections. Eur. J. Clin. Microbiol. Infect. Dis. **11:**553–556. (Erratum, **11:**872.)