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Comparison of IDEIA III and Cell Culture for the Detection of *Chlamydia trachomatis* in Endocervical Specimens

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A total of 803 endocervical samples were obtained from females with clinical or epidemiological histories suggesting chlamydia infection. These specimens were tested by IDEIA III and cell culture for the presence of *Chlamydia trachomatis*. After resolution of discrepant results by direct fluorescent-antibody staining of pelleted cell culture transport materials, IDEIA III demonstrated sensitivity, specificity, and positive and negative predictive values of 93.8, 99, 92.9, and 99.1%, respectively.

The introduction of nonculture methods for the diagnosis of genital *Chlamydia trachomatis* infections, such as immunofluorescence, enzyme immunoassay, and DNA probes, has provided an alternative to cell culture in laboratories lacking culture capability and in which the initiation of a new diagnostic service is desired. In addition, nonculture assays have replaced cell culture in many facilities because of their ease of performance, ability to automate, labor savings, and objective result interpretation.

The IDEIA Chlamydia Test (Novo BioLabs, formerly Celltech Diagnostics) uses a genus-specific monoclonal antibody and an alkaline phosphatase substrate with an alcohol oxidoreductase-diaphorase amplification system for the detection of *C. trachomatis* from genital sources (1, 6). The performance of this assay has been evaluated in human genital infections (1, 2, 4–7, 9–11) as well as in a mouse model of genital infection (8). In this study, we evaluate the performance of the revised IDEIA, IDEIA III, in the detection of *C. trachomatis* in female genital tract specimens.

A total of 803 patients were tested in this study. Endocervical specimens were collected from 400 females seen in the Providence Hospital (Southfield, Mich.) emergency department or gynecology clinic and 403 females seen in an inner-city adolescent health care clinic who had urogenital complaints or epidemiological histories suggesting chlamydial infection.

The exocervix was cleansed with a cotton swab to remove excess mucus and exudate. Cultures were obtained by inserting a Dacron-tipped swab into the endocervical canal and rotating it. All specimens were placed into 2-sucrose phosphate transport medium. Both cell culture and IDEIA III were performed with material obtained from the transport as follows. Specimens were transported to the laboratory where they were processed or were stored at 2 to 4°C for no longer than 24 h. Sample (200 μl) was added to each of two 1-dram (1 dram = 3.888 g) shell vials containing cycloheximide-treated McCoy cells. Cultures were incubated for 48 h, and one vial was stained with monoclonal antibody to *C. trachomatis*. If no inclusions were demonstrated, the second vial was passaged. The cell culture and passage technique have been described previously (3).

To perform IDEIA III, all specimens were collected in 2-sucrose phosphate transport medium. Upon receipt, transports were vortexed and 200 μl of specimen was withdrawn and placed into a vial containing 1.0 ml of Novo chlamydial transport medium. Because specimens were collected initially in 2-sucrose phosphate, an additional 50 μl of concentrated transport medium was then added (per the instructions of the manufacturer). Specimens were stored at 2 to 4°C and tested within 72 h of receipt. The IDEIA III procedure was performed according to the instructions of the manufacturer. The absorbance of each specimen was read at 492 nm by using a Bio-Tek EL 307 spectrophotometer (Bio-Tek Instruments, Inc., Winooski, Vt.). The cutoff value was calculated by adding 0.05 to the negative control mean.

Direct immunofluorescence staining (DFA) was performed for resolution on samples with discrepant IDEIA-positive and cell culture-negative results. Material from the 2-sucrose phosphate transports was centrifuged at 3,000 × *g* for 10 min. The supernatant was removed, and two smears were prepared for DFA (Kallestad Diagnostics, Austin, Tex.). Specimens were considered true positives if at least four elementary bodies were seen. Since this was a procedure to resolve discrepant positive IDEIAs and negative cell cultures, testing was not performed in a blinded fashion.

A total of 803 women from an emergency department, gynecology clinic, or adolescent health care center were tested for *C. trachomatis* by culture and IDEIA III. The combined prevalence of infection by culture was 9.8% (36 of 400 women from the emergency department and gynecology clinic and 45 of 403 women from the adolescent health center).

Of 87 specimens positive by culture, 81 were positive in IDEIA III, with a resulting sensitivity of 93.1% and a positive predictive value of 81.8%. The specificity of the assay was 97.4%, with a negative predictive value of 99.1%. Six of the cultures were positive on passage only, and IDEIA III identified four of the six.

There were a total of 18 discordant IDEIA III-positive samples. Elementary bodies were identified in 11 of 18 of these samples by our procedure for resolution of discrepant results. The adjusted sensitivity, specificity, and positive predictive value for IDEIA III were 93.8, 99, and 92.9%. In this study, a new version of IDEIA, IDEIA III, was compared with cell culture for the detection of *C. trachomatis* in female endocervical specimens. This version of the assay differs from previous versions in its use of Fab fragments rather than whole monoclonal immunoglobulin G as the capture antibodies coating the microdilution wells.

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Previous studies have shown a significant variation in the sensitivity of IDEIA. For male urethral specimens, the assay has demonstrated a range of sensitivity from 44 to 95.6% (2, 4–7, 9, 10), with the best correlation seen in symptomatic patients. For female endocervical samples, the sensitivity has ranged from 40 to 100%, with the lowest sensitivity seen in specimens with 0 to 10 leukocytes observed on gram-stained smears (1, 2, 4–6, 9–11). Tjiam et al. demonstrated a better performance of the assay in symptomatic patients (10); however, Mahony et al. noted that the presence of symptoms was not associated with positivity in this assay (4).

Thomas et al. were able to show an increased sensitivity of the assay by testing three cervical swabs from the same patients and placing the material into a single transport vial (9). Testing multiple swabs in this manner had no effect on the specificity of the assay.

IDEIA III demonstrated a sensitivity of 97.1% and a specificity of 98% in an earlier study (3). However, that study was performed on a smaller number of patients (n = 201) that were at high risk for disease. In this study, IDEIA III demonstrated acceptable sensitivity (93.8%), specificity (99%), and agreement (97%) when compared with diagnosis using cell culture and one blind passage in a patient population at moderate risk for infection. In summary, IDEIA III provides a reliable alternative to cell culture for the diagnosis of *C. trachomatis* infection in endocervical specimens. Further testing is needed to assess the performance of this assay for asymptomatic females and male urethral specimens.

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