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Comparison of Kodak Surecell Chlamydia Test Kit with Culture for the Diagnosis of Chlamydial Conjunctivitis in Infants

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The accuracy of the Surecell Chlamydia Test Kit (Kodak Clinical Products, Rochester, N.Y.) in detecting neonatal conjunctival infection caused by *Chlamydia trachomatis* was determined by comparison of this enzyme immunoassay with the isolation of *C. trachomatis* in tissue culture. Kodak Surecell is a rapid monoclonal antibody-based membrane capture enzyme immunoassay which can be processed in the office of a physician. The sensitivity and specificity compared to culture in detecting *C. trachomatis* in conjunctival specimens from infants with conjunctivitis were 93 and 96%, respectively. The test does not require specialized equipment or trained personnel and would be ideal for physicians who see low numbers of infants with possible chlamydial conjunctivitis in their offices.

The Surecell Chlamydia Test Kit (Kodak Clinical Products, Rochester, N.Y.) is a rapid self-contained monoclonal antibody-based membrane antigen capture enzyme immunoassay (EIA) that can detect chlamydial antigen in patient specimens within 30 min. Surecell represents a major new direction in chlamydial antigen detection tests in that this test can be processed in the office of a physician and does not require specialized equipment since color change can be read with the naked eye.

Previous studies have demonstrated that both the direct fluorescent-antibody test (MicroTrak, Syva, and others) and EIAs such as Chlamydiazyme (Abbott Diagnostics, Abbott Park, Ill.) perform very well for the evaluation of conjunctival specimens from infants with conjunctivitis and nasopharyngeal specimens (swab or aspirate) from infants with suspected chlamydial pneumonia (2–5). However, neither type of test is designed for doctors' offices as they both require specialized equipment, i.e., a spectrophotometer, a fluorescence microscope, and highly trained personnel to run and interpret the tests.

The purpose of this study was to compare the Kodak Surecell with culture for the diagnosis of chlamydial conjunctivitis in infants. Infants (<6 weeks old) with conjunctivitis were enrolled in the study. These infants were seen in the emergency room or by neonatal services at Kings County Hospital Center, Brooklyn, N.Y. Samples for *Chlamydia trachomatis* culturing were collected with wire-shafted, cotton-tipped swabs (cotton swab type 1; Spectrum, Houston, Tex.) from the conjunctivae. The swabs were immersed in 2 ml of transport medium containing a sucrose phosphate buffer with 10% fetal bovine serum–10 μg of gentamicin per ml–10 μg of vancomycin per ml–1 μg of amphotericin B per ml and refrigerated for up to 24 h or frozen at −80°C if not cultured within that period. For the Surecell test, specimens were collected with wire-shafted Dacron swabs (Dacroswab type 1; Spectrum, Houston, Tex.) which were placed in sterile plastic tubes and frozen at −80°C until processing. Isolation of *C. trachomatis* was performed with cycloheximide-treated McCoy cells grown in 96-well microdilution plates (2). After 48 to 72 h of incubation, the wells were fixed and stained with fluorescein-conjugated monoclonal antibody (Pathfinder Culture Confirmation system; Kallestad Diagnostics, Chaska, Minn.). The EIA (Kodak Surecell Chlamydia Test) was performed according to the instructions of the manufacturer; reagents were supplied by Kodak. The test cell is divided into three separate reaction compartments or test wells that have built-in negative and positive controls as well as one for the patient sample.

The test begins with a three-step procedure to extract the chlamydia lipopolysaccharide antigen, if present, from the specimen swab of the patient. This procedure takes 9 min. Any extracted antigen is filtered directly into the reaction compartments of the test cell, where it adheres to the membrane; nonspecifically bound material is washed away. Specific anti-chlamydia lipopolysaccharide monoclonal antibody is added and binds to antigen if any is present. Unbound antibody is washed away. Next, horseradish peroxidase-labeled anti-mouse antibody is added. A wash step follows to separate bound from free reactants. Finally, a dye solution (enzyme substrate) is added to each well, causing a colorless-to-red reaction in the presence of peroxidase. When the sample well (well 2) is compared with that of the negative control (well 1), the appearance of substantial red in the sample well indicates the presence of chlamydial antigen. The positive control (well 3) should also give a red reaction.

Clinical samples which were EIA positive but culture negative were reevaluated by fluorescent-antibody staining of the original culture specimen. A 1-ml fraction of the discordant specimen was added to 1 ml of phosphate-buffered saline and centrifuged at 3,000 × *g* for 1 h. The supernatant was discarded, and the pellet was suspended to a volume of 100 to 200 μl with phosphate-buffered saline. One drop of this suspension was spotted onto a glass slide, air dried, and fixed with acetone. The specimen was stained with a fluorescein-conjugated anti-chlamydia monoclonal antibody (Pathfinder Direct Specimen Antigen Detection system; Kallestad) and examined for the presence of apple green fluorescing elementary bodies. Positive and negative controls were examined at the same time.

Paired ocular specimens for culture and EIAs were obtained from 38 infants with conjunctivitis. Fourteen (37%) of the 38 infants with conjunctivitis had positive conjunctival cultures for *C. trachomatis*. Thirteen of the conjunctival

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TABLE 1. Comparison of *C. trachomatis* detection by culture and EIA in conjunctival specimens from infants with conjunctivitis

EIA result	No. of culture results[a]		
	Positive	Negative	Total
Positive	13	1	14
Negative	1	23	24
Total	14	24	38

[a] Sensitivity was 93%, specificity was 96%, and the predictive values of the positive and negative tests were 93 and 96%, respectively.

specimens tested were both Surecell and culture positive, one specimen was EIA negative and culture positive, and one was EIA positive and culture negative (Table 1). The original culture specimen of the EIA-positive, culture-negative sample was examined by fluorescent-antibody staining and was found to contain typical fluorescing elementary bodies on the smear of the pellet.

Kodak Surecell demonstrated a sensitivity of 93% and a specificity of 96% for conjunctival specimens when compared with cell culture. The predictive values of positive and negative tests were 93 and 96%, respectively.

The results of this preliminary study demonstrate that the Kodak Surecell Chlamydia Test Kit is both a sensitive and a specific assay for the detection of *C. trachomatis* in conjunctival specimens from infants with chlamydial conjunctivitis. The sensitivity and specificity are comparable to those previously reported for Chlamydiazyme and MicroTrak (2–5). The one discordant EIA-positive, culture-negative eye specimen was positive by fluorescent-antibody staining and thus was probably not a false positive. The organisms may have been nonviable because of previous antibiotic therapy.

Recently, Coleman et al. (1) reported their experience with a similar rapid EIA kit, TestPack Chlamydia (Abbott Laboratories, Abbott Park, Ill.), for the detection of *C. trachomatis* in endocervical specimens. The sensitivity compared to culture averaged 72.9%, with an overall specificity of 97.4%. The performance of the Surecell Chlamydia Test Kit for conjunctival specimens was superior, but the eye is an easier site to sample and infants with chlamydial conjunctivitis also tend to have very high titers of organism present.

The Kodak Surecell Chlamydia Test Kit does not require any special equipment, and the endpoints are clear and unambiguous. The manufacturer states that specimens can be safely stored at room temperature for 24 h or refrigerated for 48 h before being processed. This would be very convenient for the physician who sees a small number of infants with possible chlamydial conjunctivitis per week. The test takes 20 min and can be performed by a nurse or other personnel easily. All of the EIAs were performed by a research nurse (M.G.). The use of this test will make it possible for many physicians or small hospital laboratories to rapidly diagnose chlamydial conjunctivitis and institute specific therapy.

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