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NOTES

Evaluation of Two Commercial Procedures for Rapid Identification of *Neisseria gonorrhoeae* Using a Reference Panel of Antigenically Diverse Gonococci

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Two commercial tests for the rapid identification of *Neisseria gonorrhoeae* were evaluated. Two hundred seventy-nine organisms were tested, including 202 strains of *N. gonorrhoeae*. The Syva MicroTrak test results were less subjective but required a fluorescence microscope. The Phadebact Monoclonal GC OMNI Test required modification of the manufacturer's interpretive instructions in order to avoid cross-reactions, but it was a practical test. Specificities of both tests were 100%. Sensitivities of the Phadebact Monoclonal GC OMNI and Syva MicroTrak tests were 100% and approximately 100%, respectively.

Differentiation of *Neisseria gonorrhoeae* from other oxidase-positive diplococci has been accomplished by detection of acid production from sugars incorporated in cysteine tryptic digest agar (4). However, this procedure requires incubation for 24 h before a definitive identification can be made.

Serologic tests for the identification of isolates of *N. gonorrhoeae* include a fluorescent-antibody method, the Syva MicroTrak *N. gonorrhoeae* culture confirmation test (Syva Co., Palo Alto, Calif.), and a coagglutination method, the Phadebact Monoclonal GC OMNI Test (Pharmacia Diagnostics, Piscataway, N.J.). We evaluated the Syva MicroTrak and the Phadebact OMNI tests for their ability to identify *N. gonorrhoeae*.

A total of 279 strains were evaluated by both procedures. These included 202 isolates of *N. gonorrhoeae*, of which 29 were penicillinase-producing *N. gonorrhoeae* (PPNG). One hundred thirty *N. gonorrhoeae* strains, including 7 PPNG, were obtained from the Wisconsin State Laboratory of Hygiene from 1987 to 1989. Forty-two strains of *N. gonorrhoeae*, including 20 PPNG, were obtained from the Centers for Disease Control, Atlanta, Ga. We also tested 30 strains of *N. gonorrhoeae* (2 PPNG) that were part of an antigenically diverse panel of worldwide origin. These strains were designated NRL (*Neisseria* Reference Laboratory) strains and are numbered 1567, 1859, 1955, 4286, 5001, 5016, 5288, 5766, 5767, 6611, 7122, 7786, 7870, 8035, 8658, 8660, 30010, 32775, 32777, 32778, 32779, 32780, 32781, 32783, 32786, 32787, 32789, 32790, 33520, and 33525. The NRL strains represent 90% of the primary panel and 28% of the secondary panel of strains recommended for evaluation of diagnostic reagents (7, 8). In addition, we tested 19 strains of *Neisseria cinerea*, 32 strains of *Neisseria meningitidis*, 5 strains of *Neisseria lactamica*, 1 strain of *Neisseria sicca*, 9 strains of *Neisseria subflava*, and 11 strains of *Branhamella catarrhalis*. Most of the strains were stored at −70°C and subcultured twice before testing. Fresh strains were also subcultured to chocolate agar to provide a sufficient amount of growth. All strains of *Neisseria* species and *B. catarrhalis* were identified on the basis of the ability to grow on modified Martin-Lewis agar, typical colony morphology, positive oxidase reaction, Gram stain reaction, and typical cell morphology. Specific identification was made by using cysteine tryptic agar sugars and the *o*-nitrophenyl-β-D-galactopyranoside test, which were heavily inoculated and read at 4 and 24 h after incubation. When necessary, other appropriate tests were performed (4). Commercial tests were run according to the manufacturers' instructions, with the exception of interpretation of the Phadebact Monoclonal GC OMNI Test agglutination reactions, as noted below. All testing was performed by using a blinded regimen.

Of the two commercial tests evaluated, the results of the Syva MicroTrak test were more readily interpreted. All strains of *N. gonorrhoeae* showed bright fluorescent diplococci, while the nongonococcal strains failed to fluoresce. The sensitivity and specificity were both 100%. These findings confirm previous reports (5, 10, 12). Recently, Walton (11) reported a single strain of fluorescent-antibody-negative PPNG. All 29 strains of the PPNG that we tested were fluorescent antibody positive. However, after completion of this evaluation, we found a β-lactamase-negative strain of *N. gonorrhoeae* that was negative in the Syva MicroTrak test. This cervical isolate was originally negative in cysteine tryptic digest agar medium containing glucose, sucrose, or maltose. Nevertheless, we suspected that it was an atypical *N. gonorrhoeae* strain on the basis of its source, Gram stain reaction, cell morphology, colony morphology, and positive oxidase reaction. Upon subculture, it did metabolize glucose only. The strain was, however, positive by the Phadebact Monoclonal GC OMNI Test. Since it was not part of our study population, it was not included in our statistical evaluation. However, it does indicate that the sensitivity of the Syva MicroTrak test is slightly less than 100%.

As with other fluorescent-antibody procedures, technician

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time per specimen was considerably reduced when organisms were evaluated within the same run. Batching of tests makes this procedure practical for laboratories having a relatively high volume of positive specimens. It is also potentially useful for examining multiple colonies or a sweep of confluent growth containing multiple organisms from anal and oral cultures. This is important because the sensitivity of a culture method for anal and oral specimens is low owing to frequent overgrowth of normal flora bacteria. The reliability of the test for these body sites, however, remains to be documented.

The Phadebact Monoclonal GC OMNI Test was easier to perform. However, optimal results were obtained only after the manufacturer's instructions for interpretation of reactions were modified. The Phadebact OMNI test states that a positive test is any degree of agglutination in the absence of agglutination in the control reagent. By using this interpretive criteria, we observed a specificity of only 29%. This low specificity was primarily the result of weak agglutination of the test reagent with some strains of *N. meningitidis*, *N. lactamica*, other *Neisseria* spp., and *B. catarrhalis*. Specifically, we detected weak to moderate (1+ to 2+) agglutination with 23 of 32 *N. meningitidis* strains (72%), 5 of 19 *N. cinerea* strains (26%), 5 of 5 *N. lactamica* strains (100%), 6 of 9 *N. subflava* strains (66%), and 7 of 11 *B. catarrhalis* strains (64%). These results confirm previous reports (1, 5). In contrast, all strains of *N. gonorrhoeae* produced a strong (3+) agglutination reaction with an obvious clearing of the blue background (1, 3, 5). By ignoring weak-to-moderate agglutination reactions, 100% sensitivity and specificity were achieved. In all cases, the negative control failed to agglutinate. Carlson et al. (3) have reported that weak-to-moderate agglutination reactions could be avoided by using fresh 0.9% NaCl for preparing suspensions of test organisms. By ignoring the weak-to-moderate reactions, we were able to obtain reliable results by using 0.9% NaCl solutions that were several weeks old. We also performed the Phadebact OMNI test, substituting Todd-Hewitt medium for saline to prepare the test organism suspension as recommended by Anand et al. (1). Although this technique uniformly diminished weak false-positive reactions, it proved inconvenient. We recommend that only strong agglutination reactions be interpreted as positive. Weak-to-moderate agglutination reactions should be interpreted as negative.

Most importantly, no false-positive tests occurred when we tested 19 strains of *N. cinerea* by using the Syva MicroTrak and Phadebact OMNI tests. This contrasts with other reports, which state that *N. cinerea* strains can be misidentified as *N. gonorrhoeae* by using other commercial identification methods (2, 6) and interpreting Phadebact OMNI test weak-agglutination reactions as being positive (5).

The costs of reagents per test with the Syva MicroTrak and Phadebact OMNI tests were approximately $2.29 and $1.76, respectively. Interpretation of the Syva MicroTrak test is less subjective, but it does require a fluorescence light microscope. The Phadebact OMNI test is moderately subjective and can be used by most small laboratories. It is critical, however, that users be familiar with typical positive and negative agglutination reactions. Although none of the strains of *N. gonorrhoeae* that we tested yielded weak or moderate agglutination reactions, other workers have observed strains that do (1, 9). As a result, the identity of any isolate yielding a weak reaction should be confirmed. Finally, all isolates that are suspected of being *N. gonorrhoeae* but that are Syva MicroTrak negative should be confirmed by detection of acid production from sugars contained in cysteine tryptic medium (11).

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