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Evaluation of Culture and the Gen-Probe PACE 2 Assay for Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in Endocervical Specimens Transported to a State Health Laboratory

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The Gen-Probe PACE 2 assay (Gen-Probe Inc., San Diego, Calif.) was compared with culture for the detection of *Neisseria gonorrhoeae* in endocervical specimens that were mailed to the laboratory. During mail transport, the specimens were exposed to extremes of hot and cold weather for several days before arriving in the laboratory. Specimens on culture plates deteriorated during transport, as evidenced by many dead gonococcus-like colonies. The manufacturer's recommendation for reporting PACE 2 assay-positive results was modified to create a suspicious category for samples with relative light units near the positive cutoff value. Of a total of 4,869 specimens tested, 30 were positive by both methods and 102 were positive only by the PACE 2 assay. These additional 102 positive specimens were likely to be true positives, as indicated by several lines of indirect evidence, including detailed probe competition analysis, patient history, and the lack of false-positive results in hand-delivered specimens. Although Gen-Probe Inc. indicates that specimens are stable for up to 7 days, *N. gonorrhoeae* was easily detectable by the PACE 2 assay after 1 month of incubation at room temperature in the PACE 2 transport buffer. We also compared the Gen-Probe PACE 2 assay for *Chlamydia trachomatis* with culture on endocervical specimens delivered by same-day courier. Of 398 endocervical specimens tested, the PACE 2 assay detected 19 of 20 culture-positive samples. Although the assay failed to detect one culture-positive sample, it was able to detect two very weak culture-suspicious samples. Finally, PACE 2 assays for *N. gonorrhoeae* and *C. trachomatis* performed on the same samples indicated that the coinfection rate was 40% for women attending five family planning clinics. We concluded that the Gen-Probe PACE 2 assay system should be considered for use in testing those specimens that are transported to the laboratory through the mail.

The Gonorrhea Screening Laboratory of the New York State Department of Health processes specimens mailed from throughout New York State for the detection of *Neisseria gonorrhoeae*. The system involves specimen collection and inoculation onto modified Thayer-Martin plates (JEMBEC system; Remel Co., Kansas City, Mo.) (11) at the clinic site. After 12 to 24 h of incubation, the samples are mailed to the New York State Department of Health via the regular U.S. mail system, and the specimens usually arrive at the laboratory within 2 to 3 days. Owing to mail delays, it is not unusual for the laboratory to receive specimens 4 days or longer after collection. These older specimens are often overgrown with various contaminating microorganisms or contain gonococcus-like colonies that are nonviable and that cannot be subcultured for identification. In addition, extreme weather conditions can damage the media in the plates, rendering many specimens unsatisfactory for processing. Thus, harsh transport conditions and delayed transport times can have detrimental effects on a diagnostic laboratory's ability to obtain in vitro growth of the gonococcus, which poses problems for those clinics that do not have convenient access to a diagnostic laboratory.

The problems associated with mailing culture specimens to the laboratory prompted us to evaluate alternate transport and detection systems that would be stable yet that would maintain or improve our ability to detect *N. gonorrhoeae* after prolonged transport. A system reported to be stable and accurate for detecting both *N. gonorrhoeae* and *Chlamydia trachomatis* based on DNA probes complementary to rRNA is the Gen-Probe PACE 2 assay (Gen-Probe Inc., San Diego, Calif.). This assay, which is based on a chemiluminescence detection system, has been shown to perform comparably to culture for *N. gonorrhoeae* and *C. trachomatis* detection on the basis of parallel testing of duplicate samples (4, 6, 8). However, prior studies involved the testing of limited numbers of specimens from local sites and did not involve significant specimen transport time. One of our aims was to determine whether the PACE 2 assay has a stable transport system and whether this stability would translate into the improved detection of *N. gonorrhoeae* compared with that of culture for specimens mailed to the laboratory. In addition, because fewer data were available for assessing the reliability of the Gen-Probe PACE 2 assay for *C. trachomatis*, we also evaluated this system in comparison with culture in a smaller separate study that did not involve mailing of the specimens.

MATERIALS AND METHODS

Clinic sites and handling of specimens for culture of *N. gonorrhoeae*. Five family planning clinics from Brooklyn, N.Y., and the surrounding area were selected for the study aimed at determining whether the Gen-Probe PACE 2 assay system offers any advantages over culture for the detection of *N. gonorrhoeae* from endocervical specimens collected

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off site. We estimated that specimens would be in the U.S. mail system for a minimum of 2 days in transit from clinics in Brooklyn to the laboratory at the Wadsworth Center in Albany, N.Y. In addition, one sexually transmitted disease (STD) clinic in Schenectady, N.Y., that delivered specimens by same-day courier was selected to participate in the study. The study extended from August 1990 to May 1991, which subjected the specimens to extremes of both hot and cold weather during transit.

At the clinic sites, two swabs were used to collect endocervical specimens from each patient; one swab was streaked onto a modified Thayer-Martin plate (JEMBEC system; Remel Co.), and a Gen-Probe swab was placed in the Gen-Probe transport buffer. The order of collection was random. The culture plate was incubated for 12 to 24 h at 37°C at the clinic. The Gen-Probe tube was left at room temperature and was then mailed with the culture plate on the following day.

Culture for *N. gonorrhoeae*. Upon receipt in the laboratory, culture plates were screened for gonococcus-like colonies and were then incubated at 36°C with 5% CO_2 and reexamined for growth, usually after 24 and 48 h. Potential gonococcal colonies were Gram stained, tested for oxidase, stained with a fluorescent antibody (FA; Syva Corp., Palo Alto, Calif.) (7), and for isolation, streaked onto New York City medium plates (1). On the next day, the colonies were tested for specific sugar fermentation by using the quadFERM+ system (Analytab Products Inc., Plainview, N.Y.) (5), as directed by the manufacturer, or on rare occasions, the colonies were subcultured onto New York City plates containing glucose or maltose, and the color change was noted after 24 or 48 h of incubation. Specimens that were FA positive, glucose positive, and maltose negative were reported as positive for *N. gonorrhoeae*. If the colonies were positive by FA but were nonviable and could not be subcultured for sugar fermentation testing, they were reported as suspicious for *N. gonorrhoeae*.

Gen-Probe PACE 2 testing for *N. gonorrhoeae*. Upon arrival at the laboratory, the Gen-Probe specimen tubes were mixed by using a Multi-Tube vortex mixer (VWR, Rochester, N.Y.), the swabs were pressed out and discarded, and the specimens were frozen at −20°C until they were tested (usually 1 to 2 days later). The Gen-Probe specimens were tested and were reported according to the manufacturer's instructions, with the following exception. The Gen-Probe system reports any specimen with 300 relative light units (RLUs) above the background as being positive for *N. gonorrhoeae*. During preliminary testing, we found that specimens with RLUs of between 300 and 500 above the background did not yield consistently reproducible results. Therefore, we designated those specimens with RLUs of between 300 and 500 above the background as being suspicious for *N. gonorrhoeae*. Assay of the suspicious samples was repeated to confirm the RLU value, and if the sample was <300 RLU above the background after the assay was repeated, the results were reported as negative. If the repeat result was >500 RLUs above the background, the sample was tested a third time, and the two consistent results were reported. Samples with initial RLUs 500 above the background were reported as positive for *N. gonorrhoeae*.

Discrepant sample analysis. Specimens that were positive for *N. gonorrhoeae* by the PACE 2 assay but that were negative or suspicious by culture were further analyzed in an attempt to resolve the discrepancy. First, the JEMBEC plates were examined for dead gonococcus-like colonies or overgrowth of contaminating bacteria or fungi that would cause a false-negative culture result. Second, selected discrepant samples were further analyzed by a probe competition analysis (PCA) performed by Gen-Probe. PCA involved testing of a sample by three different probe systems. The first system was a repeat of the PACE 2 assay by using the standard probes. The second system included the addition of unlabeled homologous *N. gonorrhoeae* probe to the standard assay, which should result in a 90% drop in RLUs because of probe competition. The third system involved the addition of an unlabeled heterologous *Mycoplasma* probe to the standard assay and should result in no greater than a 10% drop in RLU because of the lack of competition between probes. Finally, we analyzed the results of the PACE 2 assay versus those of culture for specimens from the local clinic that delivered specimens on the same day of collection. Specimens from that clinic served as a reference for the culture system, because they were handled under optimal conditions and there should have been no false-negative results by culture because of improper transport.

Determination of coinfection rates. Because the Gen-Probe assay can detect both *N. gonorrhoeae* and *C. trachomatis* in the same sample, we were able to determine the coinfection rate, i.e., those samples that were positive for *N. gonorrhoeae* that were also positive for *C. trachomatis*. Thus, every Gen-Probe specimen that was tested for *N. gonorrhoeae* was also tested for *C. trachomatis* by the Gen-Probe PACE 2 assay, and the coinfection rate was calculated from the test results for those samples.

Stability of the specimens tested by the Gen-Probe PACE 2 assay. The Gen-Probe PACE 2 product information sheet indicates that specimens should be tested within 7 days after collection (or should be frozen until they are tested). Because mail delays may result in specimens that remain in transit longer than 7 days after collection, we wanted to determine whether there was any drop in RLUs after the specimens were stored for a prolonged time at room temperature. We also wanted to determine whether Gen-Probe specimens containing many *N. gonorrhoeae* organisms were as stable as specimens containing few organisms. Several colonies from a fresh clinical isolate of *N. gonorrhoeae* were suspended in 0.85% saline and were serially diluted in 10-fold increments, and 0.1 ml from each dilution was spread onto a New York City plate and incubated for 48 h. In addition, 0.1 ml was placed into a Gen-Probe transport tube and was incubated at room temperature. After 48 h, the colonies on the plates were enumerated. The Gen-Probe samples were tested on the day of inoculation and then at weekly intervals for 4 weeks.

Clinic sites and specimen handling of *C. trachomatis* specimens. Three local clinics (one STD, one family planning, and one student health clinic) submitted parallel specimens for *Chlamydia* culture and for testing by the Gen-Probe PACE 2 assay. Two endocervical specimens were collected from each patient; one was placed in a tube of 2SP medium (13) and the other was placed in the Gen-Probe transport buffer. The order of collection was random, and the specimens were delivered to the laboratory on wet ice on the day of collection.

Culture for *C. trachomatis*. Specimens for culture were received in the laboratory on the same day that they were collected and were either processed immediately or were frozen on dry ice until the following day. Specimens were inoculated onto cycloheximide-treated, 2-day-old McCoy cell monolayers and were stained with *C. trachomatis*-specific FA (Syva) as described previously (2, 3, 9, 10, 13).

TABLE 1. Comparison of the Gen-Probe PACE 2 assay with culture for the detection of *N. gonorrhoeae*

Culture result	No. of specimens with the following Gen-Probe PACE 2 assay result:		
	Positive	Negative	Suspicious[a]
Positive	30	1	0
Negative	79	4,727	9
Suspicious[b]	23	0	0

[a] RLUs of 300 to 500 above the background level.
[b] Nonviable colonies that were positive with FA only.

Specimens were reported as positive for *C. trachomatis* if three or more inclusion bodies were noted. If one or two inclusion bodies were noted, then the specimen was reported as suspicious for *C. trachomatis*.

Gen-Probe PACE 2 testing for *C. trachomatis*. Upon arrival at the laboratory, the Gen-Probe specimen tubes were mixed by using a Multi-Tube vortex mixer, the swabs were pressed out and discarded, and the specimens were frozen at −20°C until they were tested (usually 1 to 2 days later). As with the *N. gonorrhoeae* evaluation, the Gen-Probe PACE 2 specimens were tested according to the manufacturer's instructions, with the following change in interpretation. Gen-Probe indicates that an RLU of 350 above the background is considered positive, but we established a minimum positive value at 550 RLU above the background. Therefore, specimens with RLUs of between 350 and 550 above the background were considered suspicious, and testing of these samples was repeated to confirm the RLUs, similar to the procedure described above for reporting the *N. gonorrhoeae* results.

RESULTS

Direct comparison of the Gen-Probe PACE 2 assay versus culture for the detection of *N. gonorrhoeae* in specimens transported by mail. A total of 4,869 specimens were tested for the detection of *N. gonorrhoeae* by both culture and the Gen-Probe PACE 2 assay. Most of the specimens arrived in the laboratory 2 to 6 days after collection. On the basis of prior testing of the PACE 2 system compared with that of culture, we determined that specimens with RLUs of between 300 and 500 above the background should not be reported as positive because of the variability in the RLU after repeat testing (data not shown) and because the clinical significance of these low RLUs was not clear. Thus, specimens were reported as suspicious for *N. gonorrhoeae* if the RLUs were in this range. The results of parallel testing are given in Table 1 and indicate that all but one of the culture-positive specimens were detected by the PACE 2 assay. The colonies from the one discrepant sample were positive by the Gen-Probe Accuprobe culture confirmation assay (data not shown). Therefore, it is likely that a clinical error contributed to the false-negative result. The Gen-Probe PACE 2 assay detected an additional 102 positive specimens that were negative or suspicious by culture. Therefore, the culture positivity rate was calculated to be 0.6% and the Gen-Probe positivity rate was calculated to be 2.7%.

Discrepant sample analysis. Because the Gen-Probe assay for *N. gonorrhoeae* detected 102 additional positive specimens that were culture negative or suspicious, we attempted to obtain additional evidence to help determine whether these were true positives.

TABLE 2. Use of PCA to confirm PACE 2 assay results for selected discrepant samples

Gen-Probe PACE 2 assay result	No. of specimens with the following PCA result:		
	Positive[a]	Negative[b]	Probable positive[c]
Positive	15	0	1
Negative	0	5	0
Suspicious[d]	3	1	0

[a] Competition from an unlabeled homologous probe was >90%.
[b] Competition from an unlabeled homologous probe was <70%.
[c] Competition from an unlabeled homologous probe was between 70 and 90%.
[d] RLUs of 300 to 500 above the background level.

First, the culture plates were analyzed for the presence of contaminating bacteria or fungi that may have precluded the isolation of *N. gonorrhoeae*. Analysis of the 102 culture plates indicated that 14% were overgrown with other microorganisms and 42% had nonviable gonococcus-like colonies. It was impossible to make a definitive identification of *N. gonorrhoeae* from these plates, although 23 of the plates with nonviable gonococcus-like colonies were reported as suspicious on the basis of the positive FA result. The remainder of the plates from the discrepant samples had no growth (30%) or were not examined (14%).

We also analyzed the correlation between the results of culture and the Gen-Probe PACE 2 assay for specimens from the local clinic that were delivered by same-day courier. Although the total was only 46 samples, with 5 culture-positive samples, there was an exact correlation with the PACE 2 assay.

We sent 20 randomly selected discrepant samples and 5 negative control samples to Gen-Probe in a blind study for confirmation and a PCA. As shown in Table 2, the results confirmed the original assay results. However, one sample that was reported as suspicious by the PACE 2 assay in our laboratory was determined to be negative by PCA.

The clinical histories of 63 Gen-Probe-positive, culture-negative patients were analyzed for STDs and the presence of clinical symptoms, and we identified whether any repeat cultures were performed. The results indicated that 56 of 63 patients had a confirmed history of STDs, had contact with an infected partner, or had a second test for *N. gonorrhoeae* that was positive (data not shown).

Finally, the positivity rate for specimens from the five family planning clinics was compared with their culture positivity rate from the previous 12 months before this study was initiated. During this period, the cultures were processed soon after collection and did not involve significant transport time. These results indicated a past positivity of 3.0% compared with positivity rates of 0.6% for culture and 2.7% for Gen-Probe in the study described here.

Coinfection rates. To determine the percentage of patients infected with *N. gonorrhoeae* who were also infected with *C. trachomatis*, i.e., coinfection rate, a Gen-Probe PACE 2 *Chlamydia* test was done on all 4,869 samples. Of the *N. gonorrhoeae* Gen-Probe-positive specimens, 40% were also positive for *C. trachomatis*.

Stability of the Gen-Probe PACE 2 assay for *N. gonorrhoeae*. A fresh clinical isolate of *N. gonorrhoeae* was serially diluted and plated onto culture medium to determine the viable cell count. Samples from each dilution were also placed in a Gen-Probe PACE 2 transport tube and tested by the PACE 2 assay every week for 4 weeks. As shown in

TABLE 3. Stability of PACE 2 assay samples for the detection of *N. gonorrhoeae*

Viable cell count[a]	RLU at:					Result
	Wk 0	Wk 1	Wk 2	Wk 3	Wk 4	
4×10^7	477,873	541,841	571,844	675,920	611,288	Positive
4×10^6	497,467	553,299	548,354	657,321	568,476	Positive
4×10^5	117,659	86,037	110,826	145,275	112,205	Positive
4×10^4	8,204	5,364	9,557	21,877	9,480	Positive
4×10^3	581	551	939	1,522	1,187	Positive
4×10^2	99	123	126	236	180	Negative

[a] Cells were diluted and were then plated onto New York City plates and also placed in a Gen-Probe transport tube. A 100-μl sample of one specimen resulted in approximately 400 colonies on the plate. The approximate viable cell count in the other tubes was calculated from these results.

Table 3, after incubation of the PACE 2 assay specimens at room temperature for 4 weeks, there was no apparent significant drop in RLUs, i.e., no change in the number of positive or negative test results. Table 3 also shows that specimens containing low numbers of *N. gonorrhoeae* were stable for the entire 4 weeks of testing, which indicates that the number of viable cells in the Gen-Probe sample was not an important factor in specimen stability. The results of this experiment also suggest that the approximate detection limit of the Gen-Probe PACE 2 assay is about 4,000 organisms in 1 ml of transport buffer.

Evaluation of the Gen-Probe PACE 2 assay compared with culture for detection of *C. trachomatis*. As shown in Table 4, of the 398 samples tested, the Gen-Probe PACE 2 assay for *C. trachomatis* correlated exactly with culture results except for 1 false-negative sample. There were two culture specimens reported as suspicious because of the low numbers of inclusion bodies, but these samples were positive by the Gen-Probe PACE 2 assay. The positivity rate for *C. trachomatis* in the study was 4.8%. In contrast to the lengthy transport time for specimens in the *N. gonorrhoeae* study, the *C. trachomatis*-containing specimens were delivered directly to the laboratory shortly after collection, and thus, the culture results were more reliable. The sensitivity and specificity of this assay were calculated to be 95 and 100%, respectively. The positive predictive value was 100%, and the negative predictive value was 99.7%.

DISCUSSION

Although culture of microorganisms is considered the definitive method of detection and identification, many specimens for culture must be processed carefully under optimal conditions. Certain fastidious organisms such as *N. gonorrhoeae* and *C. trachomatis* are especially difficult to grow in culture when a laboratory is not readily available to process the specimen. The period of time that the specimen is in transport and the transport conditions are important factors in determining whether the culture system will be successful. The results of this study indicated that the success rate for culture of *N. gonorrhoeae* is markedly reduced for specimens that are delayed in transport to the laboratory. Therefore, it was difficult to consider culture as a "gold standard" in this situation. Although we expected a reduction in the number of culture-positive specimens because of transport conditions, the magnitude of the drop was surprising.

TABLE 4. Comparison of the Gen-Probe PACE 2 assay with culture for the detection of *C. trachomatis*

Culture result	No. of specimens with the following Gen-Probe PACE 2 assay result:		
	Positive	Negative	Suspicious[a]
Positive	19	1	0
Negative	0	376	0
Suspicious[b]	2	0	0

[a] RLUs of 350 to 550 above the background level.
[b] Culture specimens with only one to two inclusions seen after staining.

Unfortunately, many patient clinic facilities rely on an off-site laboratory and must use the U.S. mail system to transport specimens. The possibility of being unable to culture *N. gonorrhoeae* because of harsh transport conditions led us to investigate the Gen-Probe system as an alternative to culture for specimens that are mailed in to the laboratory. Previous studies by Panke et al. (8) have indicated the Gen-Probe test for *N. gonorrhoeae* is comparable to culture when specimens are processed and tested under optimal conditions for both assays. We also found that the Gen-Probe PACE 2 assay system is reliable, but the assay has the advantage of detecting many more additional positive specimens than culture does for specimens that are mailed in to the laboratory. The primary factor behind the increased sensitivity of the Gen-Probe PACE 2 assay appears to be the ability of the transport buffer to stabilize the specimen. Therefore, transport conditions that were detrimental to the culture did not affect the PACE 2 assay. During the course of this study, we noted that many of the PACE 2-positive specimens had corresponding culture plates that contained gonococcus-like colonies that apparently were rendered nonviable during transport to the laboratory.

Because the number of Gen-Probe-positive specimens was much greater than the number of culture-positive specimens for the detection of *N. gonorrhoeae*, we sought to determine whether the PACE 2 assay or the culture results were true. Several lines of indirect evidence led us to conclude that the specimens positive by the PACE 2 assay were most likely true positives. The test results obtained by the Gen-Probe assay correlated exactly with culture results for those specimens that were procured locally and delivered on the day of collection. We concluded that the culture results of the Gen-Probe-positive, culture-negative discrepant samples were false-negative results. This conclusion was based on the fact that transport conditions affected our ability to recover viable microorganisms. In addition to the PCA, which indicated that these discrepant specimens were true positives, the clinical histories of the patients also suggested that the positive specimens were true positives. Finally the Gen-Probe positivity rate (2.7% versus a culture positivity rate of 0.6%) was consistent with the past positivity rate of 3% for patients who attend these clinics. Thus, the available evidence supports the conclusion that the Gen-Probe PACE

2 assay system performs better than culture for specimens in transit for a significant period of time and should be considered as an alternative to culture. This study did not address whether the system would offer any advantages over culture for on-site laboratories.

The stability study data indicated that the RNA of *N. gonorrhoeae* is stable at room temperature for at least 1 month in the Gen-Probe transport buffer. Although the RLUs did vary during the month, the qualitative (positive or negative) results were stable. However, it is prudent to follow the manufacturer's recommendation of 7-day stability until further detailed studies are done to define precisely the stability of the Gen-Probe specimens.

To avoid the uncertainties and inconsistencies associated with borderline values, we established a range of RLUs for which samples would be reported as suspicious. This gray zone is essential until the significance of these specimens with low RLUs is determined. Most often, specimen results in the suspicious range on initial testing were negative after repeat testing. In one case, a specimen result was in the suspicious range for the initial and repeat testing, but it was determined to be negative by the Gen-Probe PCA. The significance of these borderline positive values by the Gen-Probe PACE 2 assay is not yet clear, especially owing to the variability in RLUs at this low level. Although we feel that this modification is extremely important, relatively few test results were in this suspicious category, because most of the positives samples had very high RLUs (data not shown).

The Gen-Probe PACE 2 assay was also comparable to culture for the detection of *C. trachomatis*. Of the 398 samples directly tested by using both culture and the Gen-Probe PACE 2 assay, we noted only one false-negative result with the Gen-Probe system. As noted by Iwen et al. (4) and Kluytmans et al. (6), the system is simpler and cheaper than culture and can be considered a good alternative to culture.

Two additional advantages of the Gen-Probe system are that (i) specimens can be frozen indefinitely and retested at a later date if needed, and (ii) one can test for both *N. gonorrhoeae* and *C. trachomatis* in the same specimen. This system offers significant advantages for both patients and laboratories. Because of this flexibility, we were able to determine that the coinfection rate of *N. gonorrhoeae* and *C. trachomatis* was 40% in this study, which is within the estimated range of 40 to 50% for coinfection with these two microorganisms in heterosexual women (12).

There are several potential disadvantages to the Gen-Probe PACE 2 assay system. One disadvantage is that it is currently approved only for endocervical and urethral specimens. Another disadvantage is that epidemiological tracking of antibiotic resistance trends for *N. gonorrhoeae* is not possible. Although it is not a significant problem owing to the lack of resistance of *N. gonorrhoeae* to ceftriaxone, tracking may be important in the future. The final disadvantage is that the cost of testing for *N. gonorrhoeae* alone by the PACE 2 assay may exceed the cost of culture. However, the advantage of detecting many additional positive results (in a mail-based system) may outweigh the additional cost.

In summary, the Gen-Probe PACE 2 assay system can offer a marked improvement over culture for the detection of *N. gonorrhoeae* in specimens that are transported to the laboratory by mail. In addition, the rate of detection of *C. trachomatis* by the Gen-Probe PACE 2 assay system is comparable to that of culture and can be considered an alternative to culture, to avoid the labor-intensive techniques and specialized equipment necessary for culturing *C. trachomatis*.

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REFERENCES

1. **Granato, P. A., C. Schneible-Smith, and L. B. Weiner.** 1981. Use of New York City medium for improved recovery of *Neisseria gonorrhoeae* from clinical specimens. J. Clin. Microbiol. **13:** 963–968.
2. **Hipp, S. S.** 1986. Laboratory technique for identification of *Chlamydia trachomatis*, p. 161–171. *In* T. Sun (ed.), Sexually related infectious disease. Year Book Medical Publishers, Inc., New York.
3. **Hipp, S. S., Y. Han, and D. Murphy.** 1987. Assessment of enzyme immunoassay and immunofluorescence tests for detection of *Chlamydia trachomatis*. J. Clin. Microbiol. **25:**1938–1943.
4. **Iwen, P. C., M. S. Tina, M. H. Blair, and G. L. Woods.** 1990. Comparison of the Gen-Probe PACE 2 system, direct fluorescent-antibody, and cell culture for detecting *Chlamydia trachomatis* in cervical specimens. Clin. Microbiol. Clin. Chem. **95:**578–582.
5. **Janda, W. M., K. L. Zigler, and J. J. Bradna.** 1987. API QuadFERM+ with rapid DNase for identification of *Neisseria* spp. and *Branhamella catarrhalis*. J. Clin. Microbiol. **25:**203–206.
6. **Kluytmans, J. A. J. W., H. G. M. Niesters, J. W. Mouton, W. G. V. Quint, J. A. J. Ijpelaar, J. H. van Rijsoort-Vos, L. Habbema, E. Stolz, M. F. Michel, and J. H. T. Wagenvoort.** 1991. Performance of a nonisotopic DNA probe for detection of *Chlamydia trachomatis* in urogenital specimens. J. Clin. Microbiol. **29:**2685–2689.
7. **Laughon, B. E., J. M. Ehret, T. T. Tanino, B. A. van der Pol, H. H. Handsfield, R. B. Jones, F. N. Judson, and E. W. Hook III.** 1987. Fluorescent monoclonal antibody for confirmation of *Neisseria gonorrhoeae* cultures. J. Clin. Microbiol. **25:**2388–2390.
8. **Panke, E. S., L. I. Yang, P. A. Leist, P. Magevney, R. J. Fry, and R. F. Lee.** 1991. Comparison of Gen-Probe DNA probe test and culture for the detection of *Neisseria gonorrhoeae* in endocervical specimens. J. Clin. Microbiol. **29:**883–888.
9. **Ripa, K. T., and P.-A. Mardh.** 1977. Cultivation of *Chlamydia trachomatis* in cycloheximide-treated McCoy cells. J. Clin. Microbiol. **6:**328–331.
10. **Sompolinsky, D., and S. Richmond.** 1974. Growth of *Chlamydia trachomatis* in McCoy cells treated with cytochalasin B. Appl. Microbiol. **28:**912–914.
11. **Symington, D. A.** 1975. Improved transport system for *Neisseria gonorrhoeae* in clinical specimens. J. Clin. Microbiol. **2:**498–503.
12. **Thomson, S. E., and A. E. Washington.** 1983. Epidemiology of sexually transmitted *Chlamydia trachomatis* infections. Epidemiol. Rev. **5:**96–123.
13. **World Health Organization.** 1975. Guide to laboratory diagnosis of trachoma, p. 25. World Health Organization, Geneva.