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Comparison of the APTIMA CT and GC Assays with the APTIMA Combo 2 Assay, the Abbott LCx Assay, and Direct Fluorescent-Antibody and Culture Assays for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

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The Gen-Probe APTIMA Combo 2 (AC2) is a Food and Drug Administration-cleared nucleic acid amplification test (NAAT) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from urine and urogenital swab specimens. The Centers for Disease Control and Prevention have recommended confirmation of positive NAAT results in low-prevalence populations. APTIMA CT (ACT) and APTIMA GC (AGC) are two discrete NAATs for *C. trachomatis* and *N. gonorrhoeae* detection that are suitable for confirming AC2-positive results because they target different nucleic acid sequences. Our objective was to determine if ACT and AGC could be used as confirmatory tests for AC2 and to correlate the APTIMA assays with culture, direct fluorescent-antibody (DFA), and LCx CT and GC assays. Urine and swab specimens (1,304) were initially tested with either culture, DFA, or LCx, followed by AC2. A subset (675) was then tested with ACT and AGC. There was absolute concordance between ACT-AGC and AC2. LCx did not detect 1 of 14 AC2-ACT- and 1 of 6 AC2-AGC-positive urine samples, and it yielded one *C. trachomatis*- and one *N. gonorrhoeae*-positive swab result that were not detected by AC2 and ACT-AGC. Culture failed to detect 5 of 20 AC2-ACT and 3 of 4 AC2-AGC positives, and DFA missed 4 of 4 AC2-ACT positives. Thus, ACT and AGC relative sensitivity compared to that of AC2 was 100%. All APTIMA assays detected more confirmed positive results than culture, DFA, and LCx. The performance of APTIMA assays was not altered by the use of various swab types and by long-term storage of specimens. All APTIMA assays are highly sensitive and rapid. ACT and AGC can be recommended for confirmation of positive results from other NAATs, such as AC2 and LCx.

Chlamydia trachomatis and *Neisseria gonorrhoeae* are among the most prevalent sexually transmitted pathogens worldwide. Diagnosis of infection through laboratory testing using nucleic acid amplification tests (NAATs) has been integrated into clinical practice and has improved the accuracy of detection due to the higher sensitivity of the tests (1, 4, 6, 7, 9, 14, 22, 24–26). Screening programs and diagnostic testing for these infections are now in place in most of the United States (12, 13).

C. trachomatis infections are often asymptomatic and can cause pelvic inflammatory disease (PID), cervicitis, salpingitis, urethritis, and postpartum endometritis (3, 18, 27, 29). Infertility and ectopic pregnancy are complications of untreated PID leading to billions of dollars in direct and indirect healthcare costs (10). Substantial rates of *C. trachomatis* and *N. gonorrhoeae* infections are found among postpartum women, most of whom had negative results on the last prenatal test (15). Among men, urethritis is the most common illness resulting from *C. trachomatis* infection.

In 2001, *N. gonorrhoeae* was second in frequency among reportable transmittable infections in the United States (30). *N. gonorrhoeae* infections, like *C. trachomatis*, are often asymptomatic in women and can lead to PID, tubal infertility, ectopic pregnancy, and chronic pelvic pain if left untreated (11). *N. gonorrhoeae* often causes symptomatic urethritis among men and occasionally results in epididymitis.

Treatments for both *C. trachomatis* and *N. gonorrhoeae* are effective and relatively inexpensive. Because the majority of individuals with *C. trachomatis* and *N. gonorrhoeae* infections are asymptomatic, routine laboratory screening of sexually active, asymptomatic individuals at high risk for infection has been recommended by the Centers for Disease Control and Prevention (CDC) (30).

NAATs are critical new tools to diagnose *C. trachomatis* and *N. gonorrhoeae* infections. Commercially available NAATs, by using methods such as PCR, ligase chain reaction (LCR), strand displacement amplification, and transcription-mediated amplification (TMA) are now the "gold standard" tests for genital chlamydial infection and are increasingly used in screening for gonococcal infection. While PCR, LCR, and strand displacement amplification methods amplify bacterial DNA, TMA amplifies bacterial rRNA. The increased application of NAATs for detection has revealed that a large proportion of all genital infections are asymptomatic, with up to 75% asymptomatic infections among women and 50% among men (21).

NAATs are theoretically capable of detecting as little as one organism in a sample (20). However, in practice, this sensitivity is rarely achieved because of sample inhibition, due to factors such as beta-human chorionic gonadotropin, crystals, nitrites, and hemoglobin, as well as loss of DNA during extraction (2),

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which can hinder the amplification reaction and yield false-negative results (5, 16). Mishandling of urine specimens may also lead to false-negative results (5, 19). It has been shown that ensuring the quality of testing and using confirmatory tests are highly desirable for preventing outbreaks of genital infections (8).

The prevalence of *C. trachomatis* infection in populations that are screened typically ranges from 2 to 10%. Both the prevalence of infection and the specificity of the screening test strongly influence the proportion of true positive results (the positive predictive value [PPV]) (28). Recently, revised CDC guidelines for *C. trachomatis* and *N. gonorrhoeae* testing recommend that a confirmatory NAAT be performed following a positive screening test in order to improve the specificity of testing, especially in low-prevalence populations (12).

As with *C. trachomatis*, test specificities and prevalence in populations screened for *N. gonorrhoeae* are key determinants of the rate of positive screening test results. Reported clinical specificities of *N. gonorrhoeae* screening tests are similar to those for *C. trachomatis*. However, unlike *C. trachomatis* tests, some NAATs for *N. gonorrhoeae* cross-react with other pathogenic and nonpathogenic *Neisseria* species, which results in lower analytical and diagnostic specificities (17, 23). This cross-reactivity has not been reported for the Abbott LCx, Gen-Probe APTIMA Combo 2 (AC2), and PACE 2 assays (12).

All positive *C. trachomatis* or *N. gonorrhoeae* screening tests should be considered as presumptive evidence of *C. trachomatis* or *N. gonorrhoeae* infection (12). The prevalence of *N. gonorrhoeae* is usually lower than that of *C. trachomatis*; therefore, PPVs for *N. gonorrhoeae* are usually low as well. Thus, laboratories should consider routine confirmatory testing for persons with positive *C. trachomatis* or *N. gonorrhoeae* screening tests when risk factor information or actual surveys indicate that the prevalence is sufficiently low to produce PPVs of <90%. The CDC has recommended that *C. trachomatis* and *N. gonorrhoeae* NAATs be confirmed with other NAATs. Since very few laboratories have access to a second NAAT platform, it has been suggested that a more appropriate solution to confirmatory NAAT testing would be to use the same NAAT technology targeting alternate *C. trachomatis* and *N. gonorrhoeae* nucleic acid sequences (12).

Gen-Probe's Food and Drug Administration-cleared AC2 is a second-generation NAAT using target capture specimen processing, TMA technology, and dual kinetic assay technology for the simultaneous detection of *C. trachomatis* and *N. gonorrhoeae* in endocervical or male urethral swabs, vaginal swabs, and urine specimens. APTIMA CT (ACT) and APTIMA GC (AGC) are based on the same technology as AC2, but they target different *C. trachomatis* and *N. gonorrhoeae* rRNA sequences than AC2 (ACT and AGC are currently under review by the Food and Drug Administration). Thus, they can effectively be used as confirmatory assays for AC2 or other NAATs, as well as primary tests for *C. trachomatis* or *N. gonorrhoeae* detection.

The purpose of this study was to evaluate the performance of AC2, ACT, and AGC and assess whether ACT and AGC are suitable tests to confirm AC2-positive results. The study was also designed to determine whether the APTIMA assays performed equally well when using alternate swab types including LCx, culture, and direct fluorescent-antibody (DFA) specimen collection swabs.

MATERIALS AND METHODS

A total of 1,304 specimens consisting of first-catch urine and urogenital swab specimens were collected from male and female patients for detection of *C. trachomatis* and *N. gonorrhoeae*. Swab specimens were tested using culture, DFA, or LCx assays, while urine specimens were only tested using the LCx assay. Specimen collection was performed with the appropriate swab type (i.e., LCx, culture, M4 media, or DFA swab) for each assay. Specimens were stored at 4°C for an average time of 2 weeks in their original storage medium before they were retested with AC2 for the simultaneous detection of *C. trachomatis* and *N. gonorrhoeae*. Specimens were transferred into AC2 specimen collection tubes, which releases the rRNA targets and protects the rRNA from degradation during storage (2002 AC2 package insert; Gen-Probe). LCx, DFA, and culture swabs were also tested by transferring swab media or the swab itself to AC2 swab transport media. All swab and urine specimens were tested according to Gen-Probe AC2 kit insert and Specialty Laboratories, Inc., protocol for different swab samples. AC2-positive specimens were tested twice. AC2 samples were stored at 4°C for further testing with ACT and AGC (storage time was up to 60 days). Of the 1,304 samples tested with AC2, a subset of 675 specimens (253 urine specimens and 422 urogenital swabs, both negative and positive) was further tested by ACT and AGC as confirmatory assays for the detection of *C. trachomatis* and *N. gonorrhoeae*, respectively. The subset was chosen based on sufficient sample volume availability after the initial AC2, LCx, DFA, or culture testing.

The ACT, AGC, and AC2 assays are NAATs utilizing target capture specimen processing, TMA technology, and dual kinetic assay detection technology allowing the qualitative detection and differentiation of rRNA from *C. trachomatis* and *N. gonorrhoeae* in endocervical and male urethral swabs, vaginal swabs, and urine specimens. AC2 amplifies a specific region from the 23S rRNA for *C. trachomatis* and 16S rRNA for *N. gonorrhoeae*. ACT and AGC amplify regions located within the 16S rRNA of *C. trachomatis* and *N. gonorrhoeae*, which are different from AC2's target sequences. The AC2 assay was performed as described in the package insert. ACT and AGC assays were performed identically to AC2, except that the chemiluminescent signal cutoff was determined to be 50,000 relative light units (RLU). The LCx CT and LCx GC assays use the LCR method to amplify *C. trachomatis* or *N. gonorrhoeae* plasmid DNA, and the signal emitted by the LCR reaction product is detected by the Abbott LCx analyzer. The assay was performed according to the package insert. DFA was performed by Bartels chlamydiae fluorescent monoclonal antibody test. Cultures for *C. trachomatis* and *N. gonorrhoeae* were performed according to the Specialty Laboratories standard operating procedures.

RESULTS

A total of 1,304 clinical specimens were tested for the detection of *C. trachomatis* and *N. gonorrhoeae* by using various methods. A total of 710 clinical specimens were analyzed for *C. trachomatis*, of which 516 were analyzed with LCx, 109 with DFA, and 85 with culture (Table 1). All specimens (710) were retested with AC2 during a second round of testing. AC2 positives were tested twice, and all repeat AC2 results were concordant. Of the 710 specimens, 79 were found positive by AC2 (*C. trachomatis* prevalence of 11.1%), while the first round of testing (culture, DFA, and LCx combined) only found 61 positives (*C. trachomatis* prevalence of 8.6%) (Table 1).

For *N. gonorrhoeae*, 594 specimens were analyzed, of which 510 were analyzed with LCx and 84 with culture (Table 1). All specimens (594) were retested with AC2 during a second round of testing. AC2 positives were tested twice, and all repeat AC2 results were concordant. Of the 594 specimens, 23 were found positive by AC2 (*N. gonorrhoeae* prevalence of 3.9%), while the first round of testing (culture and LCx combined) only found 19 positives (*N. gonorrhoeae* prevalence of 3.2%) (Table 1).

A subset of 675 specimens (both positive and negative) was

TABLE 1. Detection of *C. trachomatis* and *N. gonorrhoeae* in a total of 1,304 urine and swab specimens during initial testing with culture, DFA, and LCx and during retesting with AC2

Specimen and result	No. detected by:			
	Initial testing			AC2 retesting
	Culture	DFA	LCx	
C. trachomatis				
Positive	16	0	45	79
Negative	69	109	471	631
Total	85	109	516	710
N. gonorrhoeae				
Positive	1	NA[a]	18	23
Negative	83	NA	492	571
Total	84	NA	510	594

[a] NA, not applicable.

further tested with the ACT or AGC assays in order to determine the correlation between the various testing methods. Of the 710 specimens previously analyzed for *C. trachomatis* by AC2 and by LCx, culture, or DFA, 361 were further tested with the ACT assay, and of the 594 specimens previously tested for *N. gonorrhoeae* by AC2 and by LCx or culture, 314 were further tested with the AGC assay.

There was absolute concordance between the results obtained with AC2 and ACT and AGC for both *C. trachomatis* and *N. gonorrhoeae* detection and for all swab and urine specimens (Tables 2 to 5). LCx did not detect 1 out of 14 AC2-ACT-positive and 1 out of 6 AC2-AGC-positive urine specimens (Table 2), and it yielded one *C. trachomatis*- and one *N. gonorrhoeae*-positive result for swab specimens (Table 3) that were not confirmed by a corresponding positive AC2 or ACT-AGC result. Culture did not detect 6 out of 21 AC2-ACT-positive and 3 out of 4 AC2-AGC-positive specimens (Table 4). DFA failed to detect any of the four AC2-ACT-positive specimens (Table 5).

The same swabs initially tested using the culture, DFA, or LCx assays were subsequently tested with AC2, ACT, and AGC. As described above, the correlation between all three APTIMA assays was found to be 100%, indicating that performance of the three assays was not altered by the use of various swab types such as LCx, culture, M4 medium, and DFA swabs.

TABLE 2. Concordance between ACT-AGC, AC2, and LCx assays for the detection of *C. trachomatis* and *N. gonorrhoeae* in urine specimens

Specimen and result	No. detected by:			
	ACT	AGC	AC2	LCx
C. trachomatis (n = 129)				
Positive	14		14	13
Negative	115		115	116
N. gonorrhoeae (n = 124)				
Positive		6	6	5
Negative		118	118	119

TABLE 3. Concordance between ACT-AGC, AC2, and LCx assays for the detection of *C. trachomatis* and *N. gonorrhoeae* in swab specimens

Specimen and result	No. detected by:			
	ACT	AGC	AC2	LCx
C. trachomatis (n = 171)				
Positive	11		11	12
Negative	160		160	159
N. gonorrhoeae (n = 164)				
Positive		8	8	9
Negative		156	156	155

This study also investigated whether prolonged refrigerated storage of samples influenced the results obtained with ACT and ACG assays. In the present study, swab and urine specimens that had been tested with AC2 were stored in their original collection tube or media for up to 2 months at 4°C before they were further tested with ACT and AGC. Both *C. trachomatis* and *N. gonorrhoeae* target sequences were successfully amplified by ACT-AGC from all 50 *C. trachomatis* and 18 *N. gonorrhoeae* specimens that had been found positive by AC2. This demonstrates that, if kept properly refrigerated, samples could be stored up to 60 days before further testing with ACT or ACG without affecting the results obtained with the assays.

DISCUSSION

This study compared the performance of the ACT and AGC analyte-specific reagent assays with the AC2, LCx, DFA, and culture assays for the detection of *C. trachomatis* and *N. gonorrhoeae* in urine and urogenital swab specimens. ACT and AGC are sensitive and specific tests for detection of *C. trachomatis* and *N. gonorrhoeae* infections. Results of these assays demonstrated absolute concordance with the AC2 screening test for the detection of *C. trachomatis* and *N. gonorrhoeae* infection in urine and swab samples.

Correlation of the APTIMA assays with LCx was generally quite good. However, there were a few discrepancies between the assays. As shown in Tables 2 and 3, there were four discrepancies between LCx and APTIMA for *C. trachomatis* and *N. gonorrhoeae* detection in urine and swab samples. For urine specimens, the APTIMA tests (AC2, ACT, and AGC) revealed one additional positive for *C. trachomatis* and *N. gon-*

TABLE 4. Concordance between ACT-AGC, AC2, and culture assays for the detection of *C. trachomatis* and *N. gonorrhoeae* in swab specimens

Specimen (n) and result	No. detected by:			
	ACT	AGC	AC2	Culture
C. trachomatis (33)				
Positive	21		21	15
Negative	12		12	18
N. gonorrhoeae (26)				
Positive		4	4	1
Negative		22	22	25

TABLE 5. Concordance between ACT, AC2, and DFA assays for the detection of *C. trachomatis* in swab specimens

Result	No. detected by[a]:		
	ACT	AC2	DFA
Positive	4	4	0
Negative	24	24	28

[a] $n = 28$.

orrhoeae compared to LCx. For the swab samples it was the opposite; LCx detected one more positive *C. trachomatis* and *N. gonorrhoeae* than the APTIMA tests. We did not perform additional resolution on these discrepant samples. However, several recent publications on *C. trachomatis* and *N. gonorrhoeae* NAAT testing have adopted a patient infected standard convention which defines a positive patient by two or more positive results when three different NAATs are used on samples from the same patient (for example, see reference 7). This convention considers only one NAAT positive on a patient as inconclusive. If the patient infected standard is applied to these discrepant samples, then the infection status of the two APTIMA-positive, LCx-negative patients in Table 2 is positive and the LCx is a false-negative result for both patients. The two LCx-positive, APTIMA-negative patient results in Table 3 are inconclusive, since only the LCx was positive out of the three NAATs run on the sample.

As expected, the sensitivity of culture and DFA was significantly lower, since many positive samples were not detected by these assays (28% positives missed by culture and 100% by DFA).

The present study also demonstrated that AC2, ACT, and AGC performance was not altered when using LCx, culture, or DFA swabs rather than the specific swabs provided by Gen-Probe in APTIMA assay kits (unisex specimen collection kit for endocervical and urethral swab specimens). Moreover, the APTIMA assays could be performed using specimens that were stored in their original transport medium (specific to LCx, culture, or DFA assays) and transferred after 2 weeks to the APTIMA-specific transport tubes without any apparent loss of diagnostic sensitivity. These results show the versatility of the APTIMA assays. Furthermore, the compatibility of APTIMA assays with LCx specimen collection methods and storage media conveniently allows the use of APTIMA assays as confirmatory tests of LCx-positive screening results using the same specimen.

The CDC recently published guidelines for *C. trachomatis* and *N. gonorrhoeae* testing recommending that a confirmatory NAAT be performed following a positive screening test (12). Confirmatory testing is particularly recommended when the prevalence is low, resulting in a low PPV (<90%). For instance, it was calculated that when prevalence drops from 15 to 5%, the apparent PPV for *C. trachomatis* detection by AC2 drops from 90.4 to 73.7% (AC2 package insert). Confirmatory testing is needed to help prevent false-positive results that can lead to adverse medical, social, and psychological impacts on the patient. False positives can also increase health care costs as a result of unnecessary antibiotic treatment, potential antibiotic-related adverse events, and unnecessary counseling sessions. Although the costs of false positives are not well defined, preventing false positives by performing a confirmatory test would presumably outweigh the cost of the test itself.

False positives may occur as a result of contamination, human error, cross-reaction, or inherent assay malfunction. Good laboratory practices can virtually eliminate problems related to contamination, and automation tends to reduce human error. ACT and AGC, which utilize the TMA technology, could potentially function as confirmatory assays for other NAATs. Moreover, even though ACT, AGC, and AC2 all use the TMA technology, the fact that ACT and AGC target *C. trachomatis* and *N. gonorrhoeae* rRNA sequences different from AC2 makes them very suitable for confirming positive results obtained with the AC2 assay.

The APTIMA assays are robust, easy to perform, and rapid. As demonstrated here, different swab types (e.g., LCx, culture, and DFA swabs) can be conveniently used in all three of the APTIMA assays, even after long-term storage of the specimens. The AC2 assay may also be cost-effective for screening in the setting of public health programs, since it can detect both *C. trachomatis* and *N. gonorrhoeae* simultaneously. The ACT and AGC tests can be used as stand-alone *C. trachomatis* or *N. gonorrhoeae* tests or as confirmatory tests for AC2-positive samples. Since AC2, ACT, and AGC use identical specimen storage buffers and conditions, similar procedures, and the same equipment, confirmatory testing with ACT-AGC following AC2 is a very convenient and easy approach to implement in a clinical laboratory setting.

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