Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

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Sexually transmitted diseases (STDs) constitute an epidemic with an estimated 15 million persons in the United States acquiring a new STD each year. Infections with *Chlamydia trachomatis* and /or *Neisseria gonorrhoeae* (C/GC) were the first and second most common STDs in the United States reported to the Centers for Disease Control and Prevention (CDC) in the year 2000 and accounted for 80% of all notifiable diseases *(1)*.

The array of technologies now available for the laboratory diagnosis of Chlamydia and gonorrhea has expanded greatly over the last few years with the addition of molecular assays. The first FDA-cleared assays to detect for the presence of specific nucleotides in clinical specimens were probe-based. Prior to February 2002, the NPHL utilized the Gen-Probe PACE 2C probe-based assay (Gen-Probe, Incorporated, San Diego, CA) to detect both *C. trachomatis* and *N. gonorrhoeae* from genital specimens. Recently, the NPHL switched to a nucleic acid amplification test (NAAT) as a more sensitive approach to detection chlamydia and gonorrhea. Numerous commercial NAATs have been developed and marketed which differ substantially in amplification methodology and their target nucleic acid sequences . The assay, chosen for use at NPHL called the BD ProbeTec™ET (Becton, Dickinson, Franklin Lakes, NJ), has the ability (found among all NAATs) to amplify as few as a single copy of the target DNA or RNA specific for the organisms being detected. This leads to increased sensitivity for these tests and allows for the testing of direct specimens such as urine. One of the most important advantages of NAAT is to reduce the dependence on invasive swab procedures to collect specimens.

The NPHL has been monitoring the percentage of positive screens to compare current amplification test results to prior non-amplification testing. **Table 1** shows a comparison of the non-amplified Gen-Probe assay results to BD ProbeTec assay for the detection of chlamydia at various state program sites. The incidence of chlamydia detected in endocervical specimens by NAAT showed a 1.2% to 3% increase over non-amplified depend ing on which clinic site was tallied. The sites with the highest number of positives were the County Health Department (CHD) clinics at 10.3% and 13.3% for the non-amplified and amplified tests, respectively. In male urethral specimens, the greatest increase in chlamydia positives was also seen in the CHD clinics where the increase between non-amplified and amplified testing was 4.8%.

Less significant improvement was seen in the detection of gonorrhea, between the Gen-Probe and BD ProbeTec tests. The highest incidence of gonorrhea was observed in the CHD clinics for female endovervical testing at 6.4% using the amplified test and for the testing of male urethra at 10.7% using the non-amplified test (**Table 2**). The number of males tested reflects only those associated with known exposure to an infected female partner or those who present to the clinic with symptoms of disease. Therefore, as expected, the number of screens performed in males is lower.

The testing of urine specimens has only recently been developed as an alternative to invasive specimen collection techniques. Generally, the testing of urine is performed as a screening tool for clinics associated with the correctional facilities and the youth detention centers. The increase in chlamydia positivity between the Gen-Probe assay and the BDProbeTec assay when testing urine was 4.2% and 8.2% in males and females, respectively (**Table 3**). It is unknown why a difference was seen between these assays however, increased training for collection and more selective testing may have played a role in this difference. An FDA-cleared test for urine was not available for use from Gen-Probe to detect for *N. gonorrhoeae*, therefore no comparison was possible.

As expected, a substantial increase in the number of specimens positive for chlamydia and gonorrhea resulted from changing to an amplified method. Although amplification

testing requires more attention to procedural details than the non-amplified nucleic acid hybridization
probe assay, the cost per positive result is actually lower due to the increase in
the number of positive patients. Selective testing of high-risk target groups will add to the cost effectiveness of amplification assays.

ReferenceReferences

1. Workowski, K. A.; Levine, W. C.; Wasserheit, J. N. *Ann Intern Med* **2002**, *137*, 255-62.
2. Centers for Disease Control and Prevention. Screening test to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections - 2002. MMWR 2002: 51 (RR-5).

Table 1. Comparison between the Gen-Probe PACE 2C and the BD ProbeTec assays for the detection of *C. trachomatis* at various state program testing sites. [a]

	Family Planning clinics			CHD clinics			Other STD clinics		
Specimen type (Test)	Total tests	Pos	%	Total tests	Pos	%	Total tests	Pos	%
Endocervix									
(GP)	17772	638	3.6	1189	122	10.3	8410	361	4.3
(BD)	11433	510	4.5	1097	146	13.3	5103	284	5.6
Male urethra									
(GP)	608	70	11.5	2114	182	8.6	764	95	12.4
(BD)	423	67	15.8	1546	207	13.4	333	57	17.1

[a] Nebraska, January 2000 through September 2002.
Abbreviation: CHD, county health department (Lancaster and Douglas)

Table 2. Comparison between the Gen-Probe PACE 2C and the BD ProbeTec assays for the detection of *N. gonorrhoeae* at various state program testing sites.[a]

	Family Planning clinics			CHD clinics			Other STD clinic		
Specimen type (Test)	Total tests	Pos	%	Total tests	Pos	%	Total tests	Pos	%
Endocervix									
(GP)	17772	98	0.6	1311	70	5.3	8349	60	0.7
(BD)	11433	51	0.4	1097	70	6.4	5103	34	0.7
Male Urethra									
(GP)	678	25	3.7	2114	226	10.7	704	60	8.5
(BD)	423	20	4.7	1546	142	9.2	333	30	9.0

[a]Nebraska, January 2000 through September 2002.
Abbreviation: CHD, county health department (Lancaster and Douglas)

Table 3. Comparison between the amplified Gen-Probe PACE 2C and the BD ProbeTec assays for the detection of *C. trachomatis* and *N. gonorrhoeae* from urine.[a]

		Chlamydia			Gonorrhea		
Gender	(Test)	Total tests	Pos	%	Total tests	Pos	%
Female							
	(AGP)	122	8	6.6	*	*	*
	(BD)	485	69	14.8	485	24	4.9
Male							
	(AGP)	2155	53	2.5	*	*	*
	(BD)	2233	150	6.7	2233	25	1.1

[a]Nebraska, January 2000 through September 2002.
[b]Gen-Probe amplification test used at the NPHL was not FDA-cleared to detect for *N. gonorrhoeae*.