

Testing for Sexually Transmitted Diseases in U.S. Public Health Laboratories in 2004

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Objective: Appropriate laboratory testing practices are a critical part of sexually transmitted disease (STD) control.

Goal: The goal of this study was to describe the type and volume of STD tests performed in public health laboratories in the United States in 2004.

Study Design: A web-based survey was made available to 144 members of the Association of Public Health Laboratories.

Results: One hundred fourteen laboratories responded (79%). Overall, 3,553,196 chlamydia tests and 3,461,151 gonorrhea tests were performed; 64.4% of chlamydia tests and 60.8% of gonorrhea tests were nucleic acid amplification tests. Ninety-four percent of laboratories performed syphilis testing. Few laboratories used type-specific tests for herpes simplex virus or used new tests for trichomoniasis, bacterial vaginosis, or human papillomavirus.

Conclusions: This survey collected important data that can be used to monitor trends in STD testing practices in public health laboratories.

RECENT ESTIMATES SUGGEST THAT 18.9 million new cases of sexually transmitted diseases (STDs) occur each year in the United States, with 48% of new infections occurring among young persons aged 15 to 24 years.¹ Chlamydia, human papillomavirus (HPV), and trichomoniasis account for 88% of all new cases in this young age group. These 3 STDs, along with gonorrhea and genital herpes, are often asymptomatic or have nonspecific symptoms and require laboratory testing for detection.^{2–6}

Appropriate laboratory testing practices are a critical part of the efforts to reduce the prevalence and consequences of STDs in the United States; however, little information is available on the volume and type of laboratory testing performed for STDs. Only one state regularly surveys their public health and private laboratories about their STD testing practices.⁷ A national survey of STD

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testing practices in public health laboratories in 2000 was conducted by the Centers for Disease Control and Prevention (CDC) in collaboration with the Association of Public Health Laboratories (APHL).⁸ To assess current volume and type of laboratory testing for STDs, the CDC and the APHL conducted a follow-up national survey of public health laboratories in February 2005. The purpose of this analysis is to describe the types and volume of laboratory testing performed for chlamydia, gonorrhea, syphilis, herpes simplex virus (HSV), human papillomavirus, bacterial vaginosis (BV), and trichomoniasis in public health laboratories in the United States in 2004 and to identify any changes in testing practices for these STDs since the 2000 survey.

Methods

Laboratory Survey

A total of 144 public health laboratories that were members of the APHL were asked to participate in the survey. A web-based survey was developed and included questions on the volume and type of testing for chlamydia, gonorrhea, syphilis, HSV, human papillomavirus, BV, trichomoniasis, and the number of Pap tests in the United States for calendar year 2004. An e-mail that included a request from CDC and APHL for participation, background information about the survey, and a direct link to the web-based survey was sent to the laboratory directors. If there were any problems with the e-mail delivery, a fax was sent to the laboratory director with the same information and the web link.

The laboratory directors were asked to respond within 2 weeks. Follow-up reminders were sent by e-mail to the directors who had not responded at the end of 1 week and again at the end of the 2-week deadline. Additional reminders were given by e-mails or telephone calls to nonresponders after 3 weeks.

We examined the number and percent of laboratories that reported performing each of the laboratory tests listed in the survey. We calculated the percent of chlamydia and gonorrhea tests that were nucleic acid amplification tests (i.e., NAATs, which include BDProbeTec ET *Chlamydia trachomatis* Amplified DNA assay, BDProbeTec ET *Neisseria gonorrhoeae* Amplified DNA assay, Gen-Probe Transcription Mediated Amplified DNA assay, Gen-Probe APTIMA Combo 2 assay, Roche COBAS AMPLICOR Test for *C. trachomatis* [automated and microwell], and Roche

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Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention.

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COBAS AMPLICOR Test for *N. gonorrhoeae* [automated and microwell]) or nonnucleic acid amplification tests (i.e., non-NAATs, which include culture, Gen-Probe Pace 2 *C. trachomatis* test, Gen-Probe Pace 2 *N. gonorrhoeae* test, Gen-Probe Pace 2C *C. trachomatis* and *N. gonorrhoeae* test, Trinity Biotech MicroTrak Chlamydia DFA Direct Specimen kit, Trinity Biotech MicroTrak Chlamydia EIA Test kit, and Digene Hybrid Capture 2 assay). We compared the results from this survey with those from the 2000 survey.

Manufacturer Survey

The national account managers from the 4 test manufacturers that supply the majority of chlamydia and gonorrhea test kits to U.S. laboratories were contacted and asked to provide the total number of test kits sold in the United States in 2004 and the approximate number or percent of those kits sold to public health laboratories. The manufacturers included Becton, Dickinson, and Co., Sparks, Maryland; Gen-Probe, Inc., San Diego, California; Roche Diagnostics Corp., Indianapolis, Indiana; and Trinity Biotech USA, Berkeley Heights, New Jersey.

The manufacturers provided data adjusted for the number of tests used for controls. Using these data from the manufacturers, we estimated the total number of chlamydia and gonorrhea tests sold in the United States in 2004 as well as the total number of tests sold by test type (culture, non-NAAT, NAAT) and by type of facility (public health vs. nonpublic health). We compared this information with results from the 2000 survey.

Results

Laboratory Survey Response

Survey responses were received from 114 of the 144 public health laboratories contacted for an overall response rate of

79%. Of the laboratories that responded, 53.5% were state laboratories, 36% were county laboratories, and 10.5% were city laboratories. The responding laboratories represented 49 states.

Chlamydia Testing Data From the Laboratory Survey

Of the 114 responding laboratories, 108 performed chlamydia testing in 2004, and they reported performing a total of 3,553,196 tests (Table 1). The most frequently performed chlamydia tests were BDProbeTec ET *C. trachomatis* Amplified DNA assay (31% of all tests done) and Gen-Probe APTIMA Combo 2 assay (30.4% of all tests done). Eighty-seven percent of the public health laboratories reported performing at least one NAAT; a total of 2,289,254 NAATs were performed (64.4% of all chlamydia tests done). Approximately 48% of laboratories reported performing at least one non-NAAT; a total of 1,263,942 non-NAATs were performed for chlamydia (35.6% of all tests done).

Gonorrhea Testing Data From the Laboratory Survey

Of the 114 responding laboratories, 108 performed gonorrhea testing in 2004, and they reported performing a total of 3,461,151 tests (Table 2). The most frequently performed gonorrhea tests were Gen-Probe Aptima Combo 2 assay (32.4% of all tests done) and BDProbeTec ET *N. gonorrhoeae* Amplified DNA assay (28.4% of all tests done). Almost 79% of the public health laboratories reported performing at least one NAAT for gonorrhea; a total of 2,106,055 NAATs were performed (60.8% of all tests done). Approximately 85% of the laboratories reported performing at least one non-NAAT; a total of 1,355,096 non-NAATs were performed for gonorrhea (39.2% of all tests done). Although almost 78% of the responding laboratories

TABLE 1. Types and Number of Chlamydia Tests Performed by Public Health Laboratories in 2004

Type of Test	Laboratories That Reported Doing Test* (N = 108 labs)		Tests Done (N = 3,553,196 tests)	
	No.	Percent	No.	Percent
Nonnucleic acid amplification tests	52	48.2	1,263,942	35.6
Culture	15	13.9	2937	0.1
Enzyme immunoassay [†]	6	5.6	112,247	3.2
Gen-Probe Pace 2 <i>Chlamydia trachomatis</i> test	24	22.2	683,700	19.2
Gen-Probe Pace 2C <i>C. trachomatis</i> and <i>Neisseria gonorrhoeae</i> test	17	15.7	414,264	11.7
Trinity Biotech Micro Trak Chlamydia DFA Direct Specimen kit	9	8.3	2041	0.1
Digene Hybrid Capture 2 assay	1	0.9	48,753	1.4
Nucleic acid amplification tests	94	87.0	2,289,254	64.4
BDProbeTec ET <i>C. trachomatis</i> Amplified DNA assay	47	43.5	1,101,838	31.0
Gen-Probe Transcription Mediated Amplified DNA assay	3	2.8	73,390	2.1
Gen-Probe APTIMA Combo 2 assay	42	38.9	1,081,518	30.4
Roche PCR [‡]	5	4.6	32,508	0.9

*Laboratories could perform more than one chlamydia test.

[†]Includes Trinity Biotech MicroTrak Chlamydia EIA Test kit and Bio-Rad Laboratories Pathfinder Chlamydia EIA Microplate.

[‡]Includes COBAS AMPLICOR Test for *C. trachomatis* (automated) and Amplicor Test for *C. trachomatis* (microwell).

TABLE 2. Types and Number of Gonorrhea Tests Performed by Public Health Laboratories in 2004

Type of Test	Laboratories That Reported Doing Test* (N = 108 labs)		Tests Done (N = 3,461,151 tests)	
	No.	Percent	No.	Percent
Nonnucleic acid amplification tests	92	85.2	1,355,096	39.2
Culture	84	77.8	293,006	8.5
Gen-Probe Pace 2 <i>Neisseria gonorrhoeae</i> test	24	22.2	532,417	15.4
Gen-Probe Pace 2C <i>Chlamydia trachomatis</i> and <i>N. gonorrhoeae</i> test	17	15.7	404,938	11.7
Other†	6	5.6	124,735	3.6
Nucleic acid amplification tests	85	78.7	2,106,055	60.8
BDProbeTec ET <i>N. gonorrhoeae</i> Amplified DNA assay	43	39.8	978,362	28.3
Gen-Probe Aptima Combo 2 assay	42	38.9	1,122,609	32.4
Roche PCR‡	2	1.9	5084	0.1

*Laboratories could perform more than one gonorrhea test.

†Other tests include Gonostat-Sierra Diagnostics, Gram stain, and Gen-Probe Accu-Probe.

‡Includes COBAS AMPLICOR Test for *N. gonorrhoeae* (automated) and Amplicor Test for *N. gonorrhoeae* (microwell).

reported doing gonorrhea culture, culture represented only 8.5% of all gonorrhea tests done in public health laboratories in 2004.

Manufacturer Survey Data

All 4 manufacturers contacted provided the requested information. An estimated 25,914,270 tests for chlamydia were sold in the United States in 2004 (Table 3). Overall, 56.9% of the tests sold were NAATs (14,750,482 tests) and 43.1% were non-NAATs (11,163,788 tests). Approximately 19% of all chlamydia tests were sold to public health facilities in 2004.

An estimated 29,416,670 tests for gonorrhea were sold in the United States in 2004 (Table 3). Overall, 49.2% were NAATs (14,458,160); 34.2% were non-NAATs (10,068,500 tests), and 16.6% were culture (4,890,010 tests). Approximately 19% of all gonorrhea non-NAATs and NAATs were sold to public health facilities.

Syphilis

Ninety-four percent of the responding public health laboratories reported performing syphilis testing in 2004 (Table 4). Ninety-one

TABLE 3. Estimated Volume of Chlamydia and Gonorrhea Testing in the United States, Survey of Chlamydia and Gonorrhea Test Manufacturers, 2004

Type of Test	Total Volume		Public Health Facilities		Nonpublic Health Facilities	
	No. of Tests	Percent	No. of Tests	Percent of Type of Test Sold to Public Health Facilities	No. of Tests	Percent of Type of Test Sold to Nonpublic Health Facilities
Chlamydia*	25,914,270	100.0	5,025,754	19.4	20,888,516	80.6
Non-NAAT†	11,163,788	43.1	2,180,376	19.5	8,983,412	80.5
NAAT‡	14,750,482	56.9	2,845,378	19.3	11,905,104	80.7
Gonorrhea	29,416,670	100.0				
Culture§	4,890,010	16.6	Not available		Not available	
Non-NAAT¶	10,068,500	34.2	1,951,600	19.4	8,116,900	80.6
NAAT	14,458,160	49.2	2,817,748	19.5	11,640,412	80.5

*No information available on chlamydia culture.

†Nonnucleic acid amplification tests which include Gen-Probe Pace 2 *Chlamydia trachomatis* test, Gen-Probe Pace 2C *C. trachomatis* and *Neisseria gonorrhoeae* test, Trinity Biotech Micro Trak Chlamydia DFA Direct Specimen kit, Trinity Biotech MicroTrak Chlamydia EIA Test kit, and Digene Hybrid Capture 2 assay.

‡Nucleic acid amplification tests, which include BDProbeTec ET *C. trachomatis* Amplified DNA assay, Gen-Probe Transcription Mediated Amplified DNA assay, Gen-Probe APTIMA Combo 2 assay, Roche COBAS AMPLICOR Test for *C. trachomatis* (automated), and Roche Amplicor Test for *C. trachomatis* (microwell).

§Includes Gonorrhea Selective Media, e.g., Thayer-Martin and Martin-Lewis plates.

¶Non-NAATs include Gen-Probe Pace 2 *N. gonorrhoeae* test and Gen-Probe Pace 2C *C. trachomatis* and *N. gonorrhoeae* test.

||NAATs include BDProbeTec ET *N. gonorrhoeae* Amplified DNA assay, Gen-Probe Aptima Combo 2 assay, and Roche COBAS AMPLICOR Test for *N. gonorrhoeae* (automated) and Amplicor Test for *N. gonorrhoeae* (microwell).

percent of the laboratories reported performing at least one nontreponemal test; 63.2% reported doing quantitative rapid plasma regain (RPR) and 43.9% reported doing Venereal Disease Research Laboratory (VDRL) tests. Treponemal tests were performed in 75.4% of all public health laboratories, and direct detection of syphilis was performed in 27.2% of the laboratories.

Herpes Simplex Virus

Testing for HSV was available in 47.4% of the public health laboratories in 2004 (Table 5). Approximately 44% of the laboratories performed culture and 15.8% used direct detection methods. Almost 15% of the laboratories reported performing HSV serologic tests, but only 6% performed type-specific HSV serologic tests.

Trichomoniasis and Bacterial Vaginosis

Only 4 public health laboratories reported performing any tests for trichomoniasis in 2004; 2 laboratories reported using the Affirm VP test, one the In-Pouch TV (BioMed Diagnostics), and one Diamond's media culture (Table 5). The majority of the tests performed were Affirm VP.

Twenty-one public health laboratories used Gram stain to test for BV in 2004; 2 of those laboratories also used the Affirm VP test (Table 5).

Cervical Cytology and Human Papillomavirus

Three laboratories reported doing HPV testing in 2004; one laboratory used the Hybrid Capture II high-risk probe test, one used PCR, and one used an in situ hybridization test (Table 5). No laboratories used the Hybrid Capture II low-risk probe test for HPV. Six public health laboratories reported performing Pap tests;

3 used the conventional method only, one used ThinPrep (Cytoc) only, and 2 laboratories reported using both.

Discussion

Comparing the results of this follow-up survey with our survey in 2000 indicated significant increases in the use of NAATs for chlamydia and gonorrhea in U.S. public health laboratories.⁸ The percentage of laboratories that reported performing NAATs for chlamydia increased from 58% in 2000 to 87% in 2004. The increase in the use of NAATs was even more dramatic for gonorrhea; 38.4% of laboratories performed NAATs in 2000 compared with 78.7% in 2004. Although DNA probes were the most frequently performed tests for both chlamydia and gonorrhea in 2000, NAATs were the most frequently performed tests in 2004. The overall percentage of public health laboratories that performed gonorrhea culture remained relatively stable from 2000 (79.8%) to 2004 (77.8%). However, the percentage of gonorrhea tests that were culture decreased from 18% in 2000 to 8.5% in 2004. This decrease could have represented a shift toward the use of NAATs for genitourinary testing for gonorrhea. Unfortunately, no data were collected on anatomic sites tested for gonorrhea or chlamydia.

A similar shift from the use of non-NAATs to NAATs for both chlamydia and gonorrhea testing was seen in the data from the manufacturer survey.⁸ In 2001, 30.1% of all chlamydia tests sold in the United States were NAATs compared with 56.9% in 2004. For gonorrhea, 22.1% of all tests sold in 2001 were NAATs compared with 36.9% in 2004.

In 1994, it was estimated that 41% of all chlamydia testing and 35% of all gonorrhea testing was done in public health laboratories.⁹ Approximately one fourth of all chlamydia and gonorrhea testing was done in public health laboratories in 2000.⁸ The 2004

TABLE 4. Types and Number of Syphilis Tests Performed by Public Health Laboratories in 2004

Type of Syphilis Test	Laboratories That Reported Doing Test (N = 114 labs)		No. of Laboratories That Reported Volume of Tests Done	No. of Tests Done
	No.	Percent		
Any syphilis test	107	93.9		
Nontreponemal tests				
Any nontreponemal test	104	91.2		
VDRL	50	43.9	46	399,202
RPR-qualitative	83	72.8	80	1,554,698
RPR-quantitative	72	63.2	69	86,824
USR	4	3.5	4	27,886
Stat RPR	15	13.2	15	20,895
Trust (New Horizon Diagnostics, Inc.)	2	1.8	2	98,270
Treponemal tests				
Any treponemal test	86	75.4		
Captia Syphilis G EIA (Trinity Biotech)	3	2.6	3	20,789
FTA-ABS	29	25.4	29	23,958
FTA-ABS DS	16	14.0	16	15,776
Serodia TP-PA (Fujirebio, Inc.)	49	43.0	48	59,322
TREP-CHEK Anti-Treponemal EIA (Phoenix Biotech Corp.)	8	7.0	8	22,282
Direct detection tests				
Any direct detection test	31	27.2		
Darkfield	19	16.7	17	1203
DFA-TP	12	10.5	10	458

VDRL indicates Venereal Disease Research Laboratory; RPR = rapid plasma reagin.

TABLE 5. Types and Number of Herpes Simplex Virus, Trichomoniasis, Bacterial Vaginosis, Human Papillomavirus, and Pap Tests Performed by Public Health Laboratories in 2004

Type of Test	Laboratories That Reported Doing Test (N = 114 labs)		No. of Laboratories That Reported Volume of Tests Done	No. of Tests Done
	No.	Percent		
Herpes simplex virus				
Any herpes test	54	47.4		
Culture	50	43.9		
Standard cell culture	40	35.1	40	33,387
Shell vials	12	10.5	12	9320
Direct detection	18	15.8		
Direct fluorescent antibody	14	12.3	14	7151
Enzyme immunoassay	2	1.8	1	151
Polymerase chain reaction	4	3.5	4	2654
Serology	17	14.9		
Type-specific	7	6.1		
HerpeSelect (Focus Technologies)	7	6.1	7	13,263
Western blot	1	0.9	1	913
Not type-specific	10	8.8	10	2505
Trichomoniasis				
Affirm VP	2	1.8	2	6604
In-Pouch TV (BioMed Diagnostics)	1	0.9	0	—
Culture (Diamond's)	1	0.9	1	407
Bacterial vaginosis				
Affirm VP	2	1.8	2	265
Gram stain	21	18.4	21	55,887
Human papillomavirus				
Hybrid Capture II low-risk probe	0	0.0	—	—
Hybrid Capture II high-risk probe	1	0.9	1	824
Other*	2	1.8	2	1022
Cervical cytology				
Conventional Pap tests	5	4.4	5	312,569
ThinPrep (Cytyc)	3	2.6	3	138,882

*Other tests include polymerase chain reaction and in situ hybridization.

manufacturer survey suggested that only 19% of chlamydia and gonorrhea testing was done in public health laboratories. Nonetheless, public health laboratories continue to play an important role in providing reference and confirmatory testing for the private sector.¹⁰ Overall, the manufacturer data indicated increases in the total number of chlamydia and gonorrhea tests sold in the United States in 2004 compared with 2000.⁸ These increases, coupled with the decreased proportion of testing in public health laboratories, could suggest increasingly widespread chlamydia and gonorrhea screening in the United States in 2004.

Most public health laboratories had the capability to perform syphilis testing. The majority of tests performed for syphilis were RPR tests or VDRL tests. The percent of laboratories that reported performing stat RPR tests increased from 5% in 2000 to 15% in 2004, resulting in more than a 30-fold increase in the number of tests performed. Although approximately 16% of public health laboratories reported performing dark-field tests for syphilis in both 2000 and 2004, the number of tests performed doubled between those years. All of these increases suggest that providers are trying to more quickly diagnose and treat patients for syphilis during a clinic visit.

Both culture and type-specific serologic tests should be available to confirm a clinical diagnosis of HSV.^{11,12} This survey found that only 45.6% of public health laboratories performed cultures in 2004 compared with 54% in 2000. Although some laboratories were using serologic tests for HSV, the majority of those labora-

tories were not using type-specific serologic assays in either 2000 or 2004. Five percent of public health laboratories used type-specific serologic assays in 2000 compared with 6.1% in 2004. Only 4.4% of the reporting laboratories performed culture and type-specific serologic tests for HSV in 2004. Continued use of serologic assays that are not type-specific is not helpful for clinical diagnosis.

Three laboratories reported performing tests for HPV in 2004 compared with none in 2000. HPV testing is a useful option for the management of women with certain Pap test abnormalities (i.e., atypical squamous cell of undetermined significance) and for use along with a Pap test for screening women age 30 years and older; however, HPV screening of all women is not recommended.¹²⁻¹⁷ In both 2000 and 2004, the number of cervical cytology tests performed in public health laboratories was low.

The number of chlamydia and gonorrhea tests sold to public health facilities based on the manufacturer survey was slightly higher than the number of tests public health laboratories reported performing in 2004. Although the data from the manufacturers were adjusted for the number of tests used for controls, the data from the manufacturer survey could have included tests used for purposes other than patient testing (e.g., research, proficiency testing, laboratory verification and validation). We did not adjust the manufacturer data to account for tests used for patient retesting (e.g., repeat testing of positive or indeterminate results and a repeat of runs with out-of-range controls). In addition, the number of tests sold to public health facilities included tests performed in nonpub-

lic health laboratories for public health clinics; the nonpublic health laboratories were not included in this survey. We suspect that the larger difference between the number of public health non-NAATs sold and the reported number of non-NAATs performed by public health laboratories was the result of an increase in the use of non-NAATs for verification studies when public health laboratories were switching from non-NAATs to NAATs.

The volume and type of testing for STDs reported by the public health laboratories did not necessarily reflect the amount of testing done in public health clinics in 2004. As the manufacturer data suggested, some public health clinics send their chlamydia and gonorrhea tests to nonpublic health laboratories. This is likely to be true for other STDs as well. This implies the volume of testing for STDs reported by the public health laboratories in this survey is an underestimate of the overall frequency of testing for STDs in public health clinics.

Appropriate testing practices for STDs are a crucial part of the efforts to control and prevent these diseases, but testing patterns can also affect our ability to monitor trends in the prevalence of STDs. For example, the continuing decline in the number of gonorrhea tests that are cultures could affect our ability to monitor trends in antimicrobial resistance. The use of the more sensitive but more expensive NAATs for the detection of chlamydia and gonorrhea could affect the number of tests that public screening programs are able to fund. On the other hand, the use of urine NAATs for chlamydia and gonorrhea provides the opportunity to increase screening among high-risk groups of women who are not receiving a pelvic examination in a clinic setting or for men not seeking routine care in a healthcare setting. Although continued monitoring of STD testing practices in public health laboratories is important, the percent of chlamydia and gonorrhea tests performed by public health laboratories has been steadily decreasing over the last decade. Future surveys of the volume and type of testing for STDs need to include private laboratories to monitor testing practices in the broader community and to enhance continued surveillance efforts for these diseases.

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