VOLUME AND TYPE OF LABORATORY TESTING METHODS FOR SEXUALLY TRANSMITTED DISEASES IN PUBLIC HEALTH LABORATORIES 2007

SUMMARY REPORT
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EXECUTIVE SUMMARY

This report provides a summary of the responses received from a web-based survey conducted among public health laboratories on the volume and type of testing for sexually transmitted diseases in the United States in 2007. The survey was conducted in January 2008, and responses were received from 61.4% (94 of 153) of all invited participants.

Overall in 2007, 3,290,390 chlamydia tests and 3,157,827gonorrhea tests were performed in surveyed laboratories; 89.7% of chlamydia tests and 84.4% of gonorrhea tests were nucleic acid amplification tests (NAATs).

Of the 90 labs reporting any gonorrhea testing, 52.1% reported performing gonorrhea culture. Among the surveyed laboratories that reported doing gonorrhea testing, but reported having no culture capacity, 33.3% had access to gonorrhea culture for medical-legal purposes.

Over 90% of surveyed laboratories reported conducting syphilis testing. Of the 49 public health laboratories that reported doing herpes testing (79,614 total tests), 71.4% reported doing standard cell culture, and 30.6% of labs performed the HerpesSelect test (type-specific serology). Only 14 labs reported performing any trichomonas testing, and the majority of tests were culture based. Only 10 labs reported performing any bacterial vaginosis testing. Three labs performed 3,315 human papillomavirus tests and 5 labs reported doing pap smears, of which the majority was using liquid-based cytology.

INTRODUCTION

In the United States, about 18.9 million people become infected with one or more sexually transmitted infections each year, often causing severe consequences and adding substantially to healthcare costs. Sexually transmitted diseases (STDs) are one of the most under-recognized health problems.

Laboratory technology to detect STDs is ever evolving. To better understand current laboratory test usage and procedures, the Centers for Diseases Control and Prevention, Division of STD Prevention, with assistance from the Association of Public Health Laboratories (APHL), surveyed public health laboratories throughout the U.S. in January 2008. The purpose of the survey was to collect information about the volume and type of testing for STDs in the U.S. in 2007. A similar survey was conducted in February 2005 and in February 2001 (*Dicker LW, Mosure DJ, Steece R, Stone KM. Testing for Sexually Transmitted Diseases in U.S. Public Health Laboratories in 2004. Sex Transm Dis 2007;34(1):41-46* and *Dicker LW, Mosure DJ, Steece R, Stone KM. Laboratory Tests Used in US Public Health Laboratories for Sexually Transmitted Diseases, 2000. Sex Transm Dis 2004;31(5):259-264*). This summary report presents information gathered from the 2007 survey from all the public health laboratories that responded.

METHODOLOGY

Sample

State and local members of the Association of Public Health Laboratories (APHL), members of the California Association of Public Health Laboratory Directors (CAPHLD), and laboratories participating in the Infertility Prevention Project (IPP) were included in this survey.

Construction of Survey Instrument

A web-based survey was developed using the previous 2004 survey instrument as a template. Questions were designed to allow for comparisons with those data previously collected. The survey received OMB clearance (PRA 0920-0677). In addition, the survey was considered non-research and exempt from IRB.

Survey Administration

An email was sent to the laboratory directors that included a letter of introduction and a direct link to the web-based survey with a unique userID and password to access the survey. If there was any difficulty transmitting the email, then a fax or scanned version of the survey questions was sent to the laboratory director. The laboratories were asked initially to respond in 4 weeks. Due to several technical problems with the survey instrument, completed surveys were accepted up to 8 weeks after release. Follow-up reminders were sent via email to non-responders at weeks 3, 5, and 7.

Data Analysis

This survey and analysis focused on the types of STD testing used and testing volumes in the U.S. in laboratories that participated in this survey. Tables were produced describing the number of laboratories that reported performing each of the laboratory tests listed in the survey, as well as summarizing the quantity of the tests conducted.

Survey Limitations

The questions for this survey were modeled after questionnaires from previous surveys in an effort to increase the utility of the data and add considerably to the general body of knowledge about STD testing. This survey was also updated to reflect current market availability of STD test technology. Laboratories were asked to provide testing and volume information for the prior year (2007). Some laboratories were unable to provide specific test volume details from the prior year. In addition, for laboratories that reported performing “other” tests, we did not have any additional information on the specific type of tests. Some laboratories reported tests that had not been FDA- cleared for specific use for specimens from different anatomical sites; however, we assumed that each laboratory conducted their own verification study and had CLIA-approval to perform these tests.

RESULTS

Response Rate

153 public health laboratories were invited to participate in this survey. The survey was completed by 94 of 153 public health laboratories, for an overall response rate of 61.4%.

Description of Respondents

Of the laboratories that responded to the survey, 71% were members of APHL, 19% were members of CAPHLD, and 23% were laboratories participating in IPP. The percentages can add up to more than 100% since respondents could have more than one affiliation.The responding laboratories were from 45 states.

Table 1. Type and Number of Chlamydia Tests Performed in Public Health Laboratories, 2007

Type of Test	Labs Reporting Testing (%)	Total Tests Reported(%)	Urine Tests† (%)	Vaginal Swab Tests† (%)
Any CT testing	**87 of 94 (92.6)**	**3,290,390**	**582,265 (17.7)**	**424,316 (12.9)**
Non-NAAT*		**524,947 (16.0)**	**30 (0.0)**	**108,550 (25.6)**
Culture	10 (11.5)	2,379 (0.1)	---	2 (0.0)
DFA	3 (3.4)	245 (0.0)	---	---
EIA	2 (2.3)	62,420 (1.9)	30 (0.0)	---
Hybrid Capture 2 (Digene)	1 (1.1)	47,402 (1.4)	---	---
PACE 2 (Gen-Probe)	13 (14.9)	109,681 (3.3)	---	17,510 (4.1)
PACE 2C (Gen-Probe)	11 (12.6)	302,820 (9.2)	---	91,038 (21.4)
NAAT**		**2,684,278 (81.6)**	**578,882 (99.4)**	**312,284 (73.6)**
SDA (Becton Dickinson)	28 (32.2)	844,093 (25.7)	242,422 (41.6)	265,684 (62.6)
Aptima Combo 2 (Gen-Probe)	51 (58.6)	1,747,651 (53.1)	303,558 (52.1)	45,074 (10.6)
Aptima CT(Gen-Probe)	8 (9.2)	46,643 (1.4)	13,813 (2.4)	1,526 (0.4)
PCR COBAS Amplicor (Roche)	2 (2.3)	34,802 (1.1)	8,000 (1.4)	---
PCR Amplicor MWP (Roche)	1 (1.1)	11,089 (0.3)	11,089 (1.9)	---
Serology		**84 (0.0)**		
CF	0 (0.0)	0 (0.0)		
IFA	2 (2.3)	67 (0.0)		
MIF	1 (1.1)	7 0.0)		
Serology-Other	1 (1.1)	10 (0.0)		
Other Antigen Tests	**5 (5.7)**	**81,081 (2.4)**	**3,353 (0.6)**	**3,482 (0.8)**

Access to CT Culture for Med-legal Purposes	
Yes	18 (20.7)
No/Did Not Answer/Missing	69 (79.3)

CT=Chlamydia
NAAT=Nucleic acid amplification test
* 27 labs reported doing at least 1 type of non-NAAT.
** 78 labs reported doing at least 1 type of NAAT; 67 labs reported only performing 1 type of NAAT; 11 labs reported performing >1 type of NAAT. Labs may have reported both non-NAATs and NAATs.
† Some urine and vaginal swab tests may have been reported erroneously. Cells shaded in gray represent test and specimen combinations not explicitly FDA-cleared. Participating labs may have performed independent verification. Data shown in this table are as reported.

Table 2. Type and Number of Gonorrhea Tests Performed in Public Health Laboratories, 2007

Type of Test	Labs Reporting Testing (%)	Total Tests Reported (%)	Urine Tests† (%)	Vaginal Swab Tests† (%)
Any GC testing	**90 of 94 (95.7)**	**3,157,827**	**556,337 (18.6)**	**406,653 (12.7)**
Non-NAAT*		**560,128 (17.7)**	**12,538 (2.1)**	**91,159 (22.4)**
Culture	49 (54.4)	157,294 (4.9)	10 (0.0)	659 (0.2)
Hybrid Capture 2 (Digene)	0 (0.0)	0 (0.0)		
PACE 2 (Gen-Probe)	13 (14.4)	89,894 (2.8)	---	2,395 (0.6)
PACE 2C (Gen-Probe)	11 (12.2)	312,940 (9.7)	12,528 (2.1)	88,105 (21.7)
NAAT**		**2,524,382 (80.0)**	**540,446 (97.1)**	**312,012 (76.7)**
SDA (Becton Dickinson)	26 (28.9)	755,958 (23.4)	218,227 (39.2)	260,944 (64.2)
Aptima Combo 2 (Gen-Probe)	53 (58.9)	1,733,430 (53.8)	312,924 (56.2)	51,067 (12.6)
Aptima GC (Gen-Probe)	4 (4.4)	12,414 (0.4)	15 (0.0)	1 (0.0)
PCR COBAS Amplicor (Roche)	1 (1.1)	18,300 (0.6)	5,000 (0.9)	---
PCR Amplicor MWP (Roche)	1 (1.1)	4,280 (0.1)	4,280 (0.8)	---
Other Antigen Tests	**4 (4.4)**	**73,317 (2.3)**	**3,353 (0.6)**	**3,482 (0.9)**

Anatomical Culture Sites‡	Total Labs (%)	Total Tests
Cervical	41 (83.7)	11,739
Urethral	41 (83.7)	14,235
Rectal	42 (85.7)	12,220
Pharyngeal	42 (85.7)	28,255
Other	14 (28.6)	258
Total	**49**	**66,707**

Access to GC Culture for Med-legal Purposes	
Yes	33 (36.7)
No/NA	57 (63.3)

GC=Gonorrhea
NAAT=Nucleic acid amplification test
* 55 labs reported doing at least 1 type of non-NAAT.
** 76 labs reported doing at least 1 type of NAAT; 67 labs reported only performing 1 type of NAAT; 9 labs reported performing >1 type of NAAT.
† Some urine and vaginal swab tests may have been reported erroneously. Cells shaded in gray represent test and specimen combinations not explicitly FDA-cleared. Participating labs may have performed independent verification. Data shown in this table are as reported.
‡Anatomical culture site was only reported for 66,707 tests out of 157,294 total culture tests (42.4%).

Table 3. Type and Number of Gonococcal Antimicrobial Susceptibility Tests Performed in Public Health Laboratories, 2007

	Labs Reporting Testing (%)	Total Tests Reported (%)
Any AST	29 of 49 (59.2)	
Agar Dilution	1 (3.4)	107 (0.4)
Disk Diffusion	20 (69.0)	14,668 (53.5)
E-Test	11 (37.9)	2,760 (10.1)
β-lactamase	7 (24.1)	9,861 (36.0)
Other	0 (0.0)	0 (0.0)
Total AST Tests		**27,396**

Antibiotic Tested	Labs Reporting Testing (%) (n=29)
Azithromycin	10 (34.5)
Cefixime	7 (24.1)
Cefpodoxime	5 (17.2)
Ceftriaxone	22 (75.9)
Cefuroxime	0 (0.0)
Ciprofloxacin	22 (75.9)
Erythromycin	2 (6.9)
Levofloxacin	1 (3.4)
Ofloxacin	5 (17.2)
Penicillin	10 (34.5)
Spectinomycin	11 (37.9)
Tetracycline	10 (34.5)
Other	6 (20.7)

AST=Antimicrobial susceptibility testing

Table 4. Type and Number of Syphilis Tests Performed in Public Health Laboratories, 2007

	Labs Reporting Testing (%)	Total Tests Reported (%)
Any Syphilis Test	88 of 94 (93.6)	**1,978,172**
Direct Detection		**1,358 (0.1)**
Dark-field	15 (17.0)	1,176 (0.1)
DFA-TP	5 (5.7)	167 (0.0)
PCR	1 (1.1)	15 (0.0)
Non-Treponemal		**1,785,000 (90.2)**
VDRL	37 (42.0)	131,349 (6.6)
RPR-qualitative	62 (70.5)	1,251,866 (63.3)
RPR-quantitative	65 (73.9)	260,432 (13.2)
USR	3 (3.4)	24,180 (1.2)
Stat RPR	9 (10.2)	14,345 (0.7)
Trust	2 (2.3)	102,792 (5.2)
Other Non-Treponemal	2 (2.3)	36 (0.0)
Treponemal		**191,814 (9.7)**
Captia Syphilis G (EIA)	6 (6.8)	57,624 (2.9)
FTA-ABS	27 (30.7)	44,469 (2.2)
FTA-ABS DS	14 (15.9)	15,450 (0.8)
Inno-LIA (Immunoblot)	2 (2.3)	10 (0.0)
TP-PA	49 (55.7)	50,790 (2.6)
Trep-Chek IgG (EIA)	4 (4.5)	8,752 (0.4)
Trep-Sure (EIA)	3 (3.4)	5,117 (0.3)
Western Blot	3 (3.4)	76 (0.0)
Other Treponemal	3 (3.4)	9,526 (0.5)

DFA=Direct fluorescent antibody
TP=*Treponema pallidum*
PCR=Polymerase chain reaction
VDRL=Venereal Disease Research Laboratory
RPR=Rapid plasma reagin
USR=Unheated serum reagin
EIA=Enzyme immunoassay
FTA-ABS=Fluorescent treponemal antibody-absorption
DS=Double stain
LIA=Line immunoassay
TP-PA=*Treponema pallidium* particle agglutination

Table 5. Type and Number of Other STD tests Performed in Public Health Laboratories, 2007

	Labs Reporting Testing (%)	Total Tests Reported (%)
Herpes Simplex Virus (HSV)	**49 of 94 (52.1)**	**79,614**
Culture		
Standard cell Culture	35 (71.4)	26,817 (33.7)
Shell Vials	13 (26.5)	5,836 (7.3)
Direct Detection		
DFA	18 (36.7)	6,787 (8.5)
Roche Lightcycler (PCR)	9 (18.4)	4,268 (5.4)
Tzanck	0 (0.0)	0 (0.0)
Other (Specify)	5 (10.2)	0 (0.0)
Serology		
Type-Specific		
HerpesSelect (Focus Technology)	15 (30.6)	22,085 (27.8)
Fisher SureVue Bioki-HSV-2	1 (2.0)	575 (0.7)
Western Blot	1 (2.0)	105 (0.1)
Other	8 (16.3)	13,141 (16.5)
Trichomonas	**14 of 94 (4.8)**	**22,115**
Affirm VP		
DFA	0 (0.0)	0 (0.0)
PCR	0 (0.0)	0 (0.0)
Xenostrip-TV	0 (0.0)	0 (0.0)
Culture	0 (0.0)	0 (0.0)
In Pouch	2 (14.3)	646 (2.9)
Other	12 (85.7)	21,469 (97.1)
Bacterial Vaginosis (BV)	**10 of 94 (10.6)**	**22,177**
Affirm VP	0 (0.0)	0 (0.0)
Gram Stain	10 (100.0)	22,177 (100.0)
Human Papillomavirus (HPV)	**3 of 94 (3.2)**	**3,315**
Hybrid Capture 2 High-Risk Probe	2 (66.7)	1,529 (46.1)
Hybrid Capture 2 Low-Risk Probe	1 (33.3)	100 (3.0)
Other HPV test	1 (33.3)	1,686 (50.9)
Pap Smears	**5 of 94 (5.3)**	**190,301**
Conventional	2 (40.0)	37,436 (19.7)
Liquid-based Cytology		
ThinPrep	4 (80.0)	127,996 (67.3)
SurePath	2 (40.0)	24,869 (13.0)
Other	0 (0.0)	0 (0.0)

DFA= Direct fluorescent antibody
PCR=Polymerase chain reaction
TV=*Trichomonas vaginalis*

CONCLUSION

This survey documented the types and number of sexually transmitted disease tests performed in public health laboratories in the United States in 2007. Further analysis will be performed to compare testing practices from similar surveys done in 2000 and 2004. It is important to continue to monitor the capacity of public health laboratories to appropriately test for STDs, and ongoing monitoring of testing practices should be an important part of our efforts to reduce the prevalence and consequences of these diseases.