2012 California Clinical Laboratory Survey: STD/ HIV/ Hepatitis Testing

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California Association of Public Health Laboratory Directors
Annual Institute Partners Day-October 5, 2015
Overview

• Background
  – STD Epidemiologic Context and Role of Laboratory Survey

• 2012 Clinical Laboratory Survey

• STD Program Partnerships with and Resources for Laboratories
Chlamydia, Gonorrhea, and Early Syphilis

- **Chlamydia**: 453.4 (N=174,557)
- **Gonorrhea**: 116.8 (N=44,974)
- **Early Syphilis**: 18.7 (N=7,191)
Gonococcal Isolate Surveillance Project (GISP), Percent of Neisseria Gonorrhoeae Isolates with CDC "Alert" Values for Selected Cephalosporins in Five California STD Clinics, 1992–Sept. 2015

- Cefixime susceptibility was not run in 2007-2008.
- * Cefixime alerts have MICs ≥ 0.25 μg/mL. Ceftriaxone alerts have MICs ≥ 0.125 μg/mL.

STD Clinic Sites: Long Beach (ended participation in 2007), Los Angeles (added in 2003), Orange, San Diego, San Francisco
Multi-faceted STD Surveillance Strategies
(chlamydia, gonorrhea, syphilis, chancroid, PID)

System Component:
- Case-based Surveillance
- Prevalence Monitoring
- Enhanced Surveillance
- Population Behavioral Surveillance (BRFSS, CHIS, CWHS)
- Gonococcal Isolate Surveillance Project (GISP)
- Clinical Laboratory Survey

Data Needed:
- Disease/Infection Patterns and Trends
- Treatment / Clinical Factors
- Risk Behaviors / Other Characteristics
- Antibiotic Resistance
- Trends in Diagnostic Tests
CA STD Program Questions

• Assessment
  – What are current laboratory testing practices that might impact case detection?
  – Are laboratories transitioning to Electronic Laboratory Reporting?

• Assurance
  – What is the capacity of laboratories to maintain and/or increase access to tests necessary for effective STD control?
Trends in the Use of Sexually Transmitted Disease Diagnostic Technologies in California, 1996–2003

KATHERINE AHRENS, MPH,* K. JAYNE BRADBURY, MPH,* HEIDI M. BAUER, MD, MPH,* MICHAEL C. SAMUEL, DRPH,* GAIL GOULD,§ GIANNINA DONATONI, PHD,† CHANDRA HIGGINS, MPH,† PETER KERNDT, MD, MPH,† AND GAIL BOLAN, MD, MPH*

Repeating Low-Positive Nucleic Acid Amplification Test Results for Chlamydia trachomatis and Neisseria gonorrhoeae: Assessment of Current Practice in Selected California Public- and Private-Sector Laboratories

2012 California Clinical Laboratory Survey Methods

- Conducted every 2-3 years (1996-2009*)
  - Collaborated with Los Angeles STD Program
- CDPH Laboratory Field Services list of all 1663 CA licensed laboratories in 2012
- Surveys mailed Jan 2014; follow-up through Jan 2015
- Survey instrument (paper = 11pp. and Qualtrics online) collected laboratory data for 2012
  - Laboratory identifiers, type (PHL, HMO, free-standing private, hospital, etc.)
  - Test types (chlamydia, gonorrhea, syphilis, HIV, hepatitis B/C, HSV1-2, HPV, cervical and anal cytology/histology), volume, % positive
  - Quality assurance, reflex testing
  - DCDC programs collaborated for additional questions on TB and enteric pathogens

CALIFORNIA CLINICAL LABORATORY SURVEY

AFFIX LABEL HERE
(CA LICENSE NUMBER
LAB DIRECTOR NAME
LABORATORY NAME
ADDRESS

USE SPACE BELOW TO
CORRECT ADDRESS

CLIA NUMBER: ____________________________
NAME OF PERSON(S) COMPLETING SURVEY: ____________________________
Title: ____________________________ Phone #: __/__-_________ FAX #: __/__/_________
Email address: ____________________________

LABORATORY INFORMATION

1. Which of the following categories best describes your laboratory? (Check one)
   - Private Hospital
   - Community Clinic
   - Free-standing Private
   - County/District Hospital
   - Physician’s Office/Group Practice
   - Health Maintenance Organization
   - VA/Military Hospital
   - Student Health Services
   - Public Health
   - University Hospital
   - Custody/Correctional Facility
   - Other (specify): ____________________________
   - Free-standing Blood Bank/Plasma Center

2. Is this facility a draw station only?
   - Yes If yes, for which laboratory (name)? ____________________________
   - No Continue below

3. For which of the following conditions did your laboratory perform tests or process specimens in 2012?
   - Sexually transmitted diseases (STD)—Go to #4
   - Hepatitis
   - Human immunodeficiency virus (HIV)
   - Cervical cytology and/or human papillomavirus (HPV)
   - Tuberculosis
   - Enteric pathogens

END OF SURVEY

California State STD Control Branch
STD Test Volume Performed by All and Top 20 Laboratories, 1996-2012

N=257 laboratories reporting STD testing
30 of 36 PHL respondents
STD Test Volume by Laboratory Type, 2012

Free-Standing Private
Health Maintenance Organization
Community Clinic
Public Health
Private Hospital
Physician's Office/Group Practice
County/District Hospital
University Hospital
Student Health Services
Custody/Correctional Facility

STD Test Volume (millions)
Percent of Chlamydia Tests by Test Type, non-Public Health Labs, 1996-2012
Percent of Chlamydia Tests by Test Type, Public Health Labs, 1996-2012

- NAAT
- DNA Probe
- Culture


Percent of Tests: 0%, 20%, 40%, 60%, 80%, 100%
Percentage of Laboratories Accepting Specimen Types for Chlamydia Testing (of those performing NAAT), 2012

- Urine: 80%
- Cervical: 80%
- Urethral: 60%
- Vaginal: 60%
- Liquid Cytology/Pap: 30%
- Rectal: Not FDA-cleared
- Pharyngeal: 20%
- Other: <10%
Gonorrhea Test Volume and Statewide Case Rate, 1996-2012

- **Test Volume**
  - Year of STD Clinical Laboratory Survey:
    - 1996: 2.0
    - 1997: 2.5
    - 1999: 2.8
    - 2000: 3.0
    - 2001: 3.2
    - 2003: 3.4
    - 2005: 3.6
    - 2007: 3.8
    - 2009: 4.0
    - 2012: 4.2

- **Case Rate**
  - Year of STD Clinical Laboratory Survey:
    - 1996: 10
    - 1997: 10
    - 1999: 10
    - 2000: 10
    - 2001: 10
    - 2003: 10
    - 2005: 10
    - 2007: 10
    - 2009: 10
    - 2012: 10

- **Case Rate per 100,000 Population**
  - Year of STD Clinical Laboratory Survey:
    - 1996: 10
    - 1997: 10
    - 1999: 10
    - 2000: 10
    - 2001: 10
    - 2003: 10
    - 2005: 10
    - 2007: 10
    - 2009: 10
    - 2012: 10
Percentage of Gonorrhea Tests by Test Type, 1996-2012

- NAATs
- DNA Probe
- Culture
- Gram Stain

Year of STD Clinical Laboratory Survey
Percent of Gonorrhea Tests by Test Type, PHL, 1996-2012

- **NAAT**
- **Culture**
- **DNA Probe**
Percent of Gonorrhea Tests by Test Type, non-PHL, 1996-2012

- **Culture**
- **NAAT**
- **DNA Probe**
Percentage of Laboratories Accepting Specimen Types for Gonorrhea Testing (of those performing NAAT), 2012

- Urine
- Cervical
- Urethral
- Vaginal
- Liquid Cytology/Pap
- Rectal
- Pharyngeal
- Other

Not FDA-cleared
Percent of Public Health and non-Public Health Laboratories Accepting Specimen Types, 2012

NOTE: Categories not mutually exclusive
Gonorrhea Culture Capacity and Antimicrobial Susceptibility Testing

182 Labs GC Testing

91 Labs GC Culture

13 PHL GC Culture

2 PHL AST

13 non-PHL GC Culture

78 non-PHL GC Culture

13 non-PHL AST

Syphilis Test Types
(N=2.15 million tests)

Direct Detection and Non-treponemal

- Dark field
- RPR Qual
- RPR Titer
- VDRL Qual
- VDRL Titer

N= 1,586,502 tests
92% RPR

Treponemal

- FTAABS
- TPPA
- EIA
- CIA

N= 563,833 tests
89% EIA/CIA/MBIA
HIV Test Types
(N=2.45 million tests)

EIA

- Oral
- Serum EIA
- Rapid oral EIA
- Rapid serum EIA

N = 1,921,444 tests
96% Serum EIA

- 65,737 4th generation p24 tests performed
- Half of these tests done by PHL
# STD/HIV Positivity

Public vs. Private Labs, 2012

<table>
<thead>
<tr>
<th>Test</th>
<th>Public Health Labs</th>
<th>Non Public Health Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia NAAT</td>
<td>5.4 - 6.7%</td>
<td>2.8 – 4.1%</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td>18.4%</td>
<td>2.3%</td>
</tr>
<tr>
<td>NAAT</td>
<td>1.7% - 4.8%</td>
<td>0.7 – 2.5%</td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral EIA</td>
<td>4.0%</td>
<td>-</td>
</tr>
<tr>
<td>Serum/Plasma EIA</td>
<td>2.8%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>
Electronic Laboratory Reporting

- Awareness of state regulation* mandating ELR <1 year state ELR implementation
  - 90% (27/30) PHL versus 58% (161/278) non-PHL
- Can send HL7 ELR message
  - 42% (13/31) PHL versus 23% (62/372) of non-PHL
- 75% do not use CalREDIE ELR
  - But labs using CalREDIE ELR account for 11M of 18M STD test volume
- Barriers to ELR
  - Financial
  - Lack sufficient technical resources

*Commencing July 1, 2009, or within one year of the establishment of a state electronic laboratory reporting system, whichever is later, a report generated pursuant to this section, or Section 121022, by a laboratory shall be submitted electronically in a manner specified by the department.
STD Program Use of Laboratory Survey Data

Declining gonorrhea culture volume and limited capacity for AST:

• **Create and disseminate a statewide directory** of laboratories performing GC culture and AST.
• **Provide TA** to maintain and build capacity for GC AST.

Limited number of labs accepting extragenital specimens for CT/GC NAAT:

• **Provide validation protocols and suggested sources of specimen panels** to high volume laboratories that use NAATs but do not conduct extra-genital testing.

Need to increase labs using ELR for reporting:

• **Collaboration with CalREDI E ELR** to work with high volume non-ELR laboratories
STD Program Resources for Laboratories

Use of Treponemal Immunoassays for Screening and Diagnosis of Syphilis

Guidance for Medical Providers and Laboratories in California

These guidelines were developed by the California Department of Public Health (CDPH) Sexually Transmitted Diseases (STD) Control Branch in conjunction with the California STD Controllers Association and the California STD/HIV Prevention Training Center

Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014
STD Program Partnerships with Laboratories

- Survey dissemination to and feedback from labs on test menus and QA, reference networks
  - 2009 Clinical Laboratory survey report:
- CDPH Microbial Disease Laboratory partnership on CDC GISP testing (2015)
- SFPHL collaboration on evaluation of InTray NG transport device
- Kaiser northern/southern CA Regional Laboratory
  - Public Health Improvement Project quarterly videoconference calls
  - CDC head-head evaluation of automated and rapid treponemal assays
  - Assessment of extragenital STD testing in HIV care settings
- How can we help YOU?
  - What should the next lab survey look like?
Thank You

STDCB:  
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Heidi Bauer  
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Ina Park  
Stella Morris  
Emily Stoops  
Jason Otow  
Joanna Wong  
Lavidus Walton

Office of AIDS:  
Jessica Brown  
Deanna Sykes

TB Control:  
Christy Pak  
Gianna Peralta

Infectious Disease  
Janice Kim  
Hilary Rosen

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Percent of Chlamydia Tests by Test Type, PHL versus non-PHL, 1996-2012
Percent of Gonorrhea Tests by Test Type, PHL versus non-PHL, 1996-2012
### Syphilis Test Types

<table>
<thead>
<tr>
<th>Syphilis Test Type</th>
<th>Number Labs</th>
<th>Number Tests</th>
<th>Percentage of Tests</th>
<th>Number Positive</th>
<th>Percentage Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct Detection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darkfield</td>
<td>9</td>
<td>684</td>
<td>&lt;0.1%</td>
<td>67</td>
<td>9.8%</td>
</tr>
<tr>
<td>DFA-TP</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Other Direct Detection</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>9</td>
<td>684</td>
<td>&lt;0.1%</td>
<td>67</td>
<td>9.8%</td>
</tr>
<tr>
<td><strong>Non-Treponemal Serology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR (Qualitative)</td>
<td>129</td>
<td>1,466,324</td>
<td>58.9%</td>
<td>47,621</td>
<td>3.2%</td>
</tr>
<tr>
<td>RPR Titer (Quantitative)</td>
<td>73</td>
<td>69,999</td>
<td>2.8%</td>
<td>41,685</td>
<td>59.6%</td>
</tr>
<tr>
<td>VDRL (Qualitative)</td>
<td>18</td>
<td>46,383</td>
<td>1.9%</td>
<td>2,890</td>
<td>6.2%</td>
</tr>
<tr>
<td>VDRL Titer (Quantitative)</td>
<td>17</td>
<td>3,796</td>
<td>0.2%</td>
<td>2,281</td>
<td>60.1%</td>
</tr>
<tr>
<td>Other Non-Treponemal Serology</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>137</td>
<td>1,586,502</td>
<td>63.7%</td>
<td></td>
<td></td>
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<tr>
<td><strong>Treponemal Serology</strong></td>
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<td></td>
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</tr>
<tr>
<td>FTA-ABS</td>
<td>15</td>
<td>21,288</td>
<td>0.9%</td>
<td>9,807</td>
<td>46.1%</td>
</tr>
<tr>
<td>TP-PA</td>
<td>35</td>
<td>39,115</td>
<td>1.6%</td>
<td>19,387</td>
<td>49.6%</td>
</tr>
<tr>
<td>EIA(IgG/IgM)</td>
<td>11</td>
<td>309,224</td>
<td>12.4%</td>
<td>21,435</td>
<td>6.9%</td>
</tr>
<tr>
<td>CIA</td>
<td>5</td>
<td>186,120</td>
<td>7.5%</td>
<td>3,757</td>
<td>2.0%</td>
</tr>
<tr>
<td>MBIA</td>
<td>1</td>
<td>8,000</td>
<td>0.3%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Other Treponemal Serology</td>
<td>1</td>
<td>86</td>
<td>&lt;0.1%</td>
<td>61</td>
<td>70.9%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>55</td>
<td>563,833</td>
<td>22.6%</td>
<td></td>
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<tr>
<td><strong>Blood Bank Screening</strong></td>
<td>9</td>
<td>339,556</td>
<td>13.6%</td>
<td>345</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>143</td>
<td>2,490,575</td>
<td>100.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## HIV Test Types

<table>
<thead>
<tr>
<th>HIV Test Type</th>
<th>Number Labs</th>
<th>Number Tests</th>
<th>Percentage of Tests</th>
<th>Number Positive</th>
<th>Percentage Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EIA Tests</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral EIA</td>
<td>11</td>
<td>9,083</td>
<td>0.3%</td>
<td>359</td>
<td>4.0%</td>
</tr>
<tr>
<td>Serum/Plasma EIA</td>
<td>72</td>
<td>1,843,259</td>
<td>66.2%</td>
<td>12,596</td>
<td>0.7%</td>
</tr>
<tr>
<td>Urine EIA</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Rapid Oral (EIA)</td>
<td>3</td>
<td>11,240</td>
<td>0.4%</td>
<td>15</td>
<td>0.1%</td>
</tr>
<tr>
<td>Rapid Serum/Plasma (EIA)</td>
<td>72</td>
<td>57,862</td>
<td>2.1%</td>
<td>415</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>139</td>
<td>1,921,444</td>
<td>69.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other Tests</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Western Blot</td>
<td>10</td>
<td>903</td>
<td>&lt;0.1%</td>
<td>636</td>
<td>70.4%</td>
</tr>
<tr>
<td>Serum Western Blot</td>
<td>21</td>
<td>29,067</td>
<td>1.0%</td>
<td>14,354</td>
<td>49.4%</td>
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<tr>
<td>Qualitative RNA</td>
<td>5</td>
<td>13,526</td>
<td>0.5%</td>
<td>111</td>
<td>0.8%</td>
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<tr>
<td>RT-PCR</td>
<td>6</td>
<td>23,931</td>
<td>0.9%</td>
<td>7,065</td>
<td>29.5%</td>
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<tr>
<td>Serum IFA</td>
<td>10</td>
<td>2,036</td>
<td>&lt;0.1%</td>
<td>1,074</td>
<td>52.8%</td>
</tr>
<tr>
<td>Pooled RNA Screening</td>
<td>4</td>
<td>82,739</td>
<td>3.0%</td>
<td>638</td>
<td>0.8%</td>
</tr>
<tr>
<td><strong>4th Generation Antibody/Antigen (p24) Assay</strong></td>
<td>10</td>
<td>65,737</td>
<td>2.4%</td>
<td>714</td>
<td>1.1%</td>
</tr>
<tr>
<td>Viral Load (Quantitative)</td>
<td>25</td>
<td>170,841</td>
<td>6.1%</td>
<td>47,602</td>
<td>27.9%</td>
</tr>
<tr>
<td>Genotypic Drug Resistance Testing</td>
<td>6</td>
<td>2,236</td>
<td>&lt;0.1%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>CD4 Counts</td>
<td>18</td>
<td>120,671</td>
<td>4.3%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Other Non-EIA</td>
<td>9</td>
<td>16,843</td>
<td>0.6%</td>
<td>279</td>
<td>1.7%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>58</td>
<td>528,530</td>
<td>19.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Bank Screening</td>
<td>7</td>
<td>334,788</td>
<td>12.0%</td>
<td>156</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>160</td>
<td>2,784,762</td>
<td>100.0%</td>
<td></td>
<td></td>
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