HIV Testing in Public Health Labs
Results from the 2009 APHL HIV Testing Practices Survey

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Survey of Public Health Laboratory HIV Testing Practices

- Conducted in July 2009
- Covered testing from July 1, 2008 through June 30, 2009
- Used MRInterview to obtain responses
- Sent to 88 Labs
  - 50 state labs
  - 38 local labs

Survey Response

- Response from 42 states (84%) and 27 (71%) local labs receiving the survey

- 61 labs reported conducting HIV testing
  - 42 state and 19 local labs

Specimen Types Received by Reporting Laboratories

- 88% serum or plasma
- 9% oral fluid specimens
- 0.25% DBS
- Remainder, “other”

- Total specimens – almost 1.7 million

Subset Responding in 2006 & 2009

- 38 state and 12 local labs completed the 2006 survey as well as the 2009 survey
  - These labs reported 83% (~1.4M/~1.7M) of the specimens submitted to responding labs in 2009
- For these 50 labs, total specimens decreased 22% but oral fluid submissions decreased 54%
  - Ten labs stopped receiving oral fluid specimens
  - Some labs requested serum follow up to rapid test reactive specimens
  - Positivity rate increased from 1.4 to 1.7%

Oral Fluid Specimens

- Laboratory testing for confirmation of rapid test reactive specimens
  - Oral fluid submissions more apt to have **indeterminate** results (3.5%) compared to serum/plasma specimens (2.4%)
    - EIA+/WB Indeterminate
  - Oral fluid submissions also more apt to have **inconclusive** results (4.1% vs. 1.1%)
    - EIA+/WB-

Algorithms in Use

- 52/61 (85%) use one screening test
- 9/61 (15%) use an alternative algorithm
  - 3 use 2 assays in tandem
  - 6 use multiple assays sequentially

- All labs performing confirmatory testing use WB (51) or IFA (6)

NAAT Usage

- HIV detection 19 labs (31%)
- Viral load 13 labs (21%)
- Resistance testing 5 labs (8.3%)
- Resolution of results 10 (16%)
  - Indet. or Inconcl.
- Acute infection 10 (16%)
  - On request
- All seronegatives 7 (11.5%)
  - Pooled testing

HIV-2 Testing

- Initial testing
  - Over 90% use an HIV1/2 assay
- Confirmation
  - Only 5 labs reported in house capability
  - Over half send specimens to CDC
  - Over a quarter use a discriminatory assay to resolve indeterminate or inconclusive results
  - The majority request follow up specimens to help resolve indeterminate results

Barriers to Change Cited in Survey

- Concerns about
  - Funding (43%)
  - Workforce (28%)
  - Physical laboratory space (8%)
  - Regulatory issues (5%)

Survey Limitations

- Data from one to two years ago
  - For instance, status of oral fluid testing has changed; FDA approved assay for oral fluid again available
- Not easy to compare data over time
  - Differences in questions
  - Differences in participating laboratories
  - Lack of information in some labs about prior testing, e.g.., which specimens were rapid test reactive and if so, what test was used

Summary of 2009 Survey Findings

- Testing volume in public health labs has decreased, especially oral fluid specimens
- Initial testing was performed generally with 3rd generation assays; majority of labs now screening for HIV-2
  - In 2004 and 2005, ~2/3 labs screened only for HIV-1 with a lst generation assay
- Most labs continue to use WB or IFA supplemental assays to confirm following the traditional 1980's algorithm
- NAAT use has increased but is still limited

HIV Testing Algorithm Activities

- HIV Testing Algorithms: A Status Report http://www.aphl.org/hiv/statusreport
  - Corrections including serum indication for NAAT
  - Draft of additional algorithm utilizing a 4th generation initial assay for screening
  - Draft of algorithm for bridging POC and laboratory testing

- APHL PH Lab Issues Brief Detailing Survey Responses http://www.aphl.org/aphlprograms/infectious/hiv/Documents/HIV_2009_Survey.pdf

HIV Testing Algorithm Activities

- 2010 HIV Diagnostics Conference, including presentations of data identified as needs for algorithms in the status report http://www.hivtestingconference.org

- CLSI document in preparation
  - "Criteria for Laboratory Testing and Diagnosis of HIV-1 Infection"
    - Includes algorithms utilizing assays available outside the US as well as those FDA approved

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