Confirmatory Testing Practices among Participants in the CDC's Model Performance Evaluation Program for HIV Rapid Testing

Laurina O. Williams,[1] Leigh I. Vaughan,[1] G. David Cross,1 Courtney L. Rodi[2]

[1]Centers for Disease Control and Prevention(CDC), Atlanta, Georgia • [2]Constella Group, Inc., Atlanta, Georgia

MPEP

Use of trade names is for identification only and does not constitute endorsement by the U.S. Department of Health and Human Services

Abstract

BACKGROUND: Current CDC initiatives for HIV/AIDS prevention are aimed at reducing barriers to early diagnosis of HIV infection and increasing access to health services by encouraging the use of HIV rapid tests. Recommendations for confirming reactive HIV rapid test results have been published and we sought to learn if they are being followed. (http://www.phppo.cdc.gov/mpep)

METHODS: Univariate and bivariate analyses were performed on survey responses from a convenience sample comprised of all testing sites that participated in the CDC's Model Performance Evaluation Program (MPEP) for HIV rapid testing in August 2004. Participants in the event tested a set of six challenge samples and also answered questions about their laboratory testing practices.

RESULTS: Of the 384 participants, U.S. testing sites predominated (327; 85.2%). Of U.S. respondents most were hospital testing sites (227/327; 69%); 42 (18%) self-identified as "independent" or "other"; and 12 sites (3%) as community based organizations, sexually transmitted disease clinics, or drug treatment centers. There were 338 unique responses regarding confirmatory testing practices reported by U.S. testing sites. Testing sites using more than one type of rapid test could report more than once. A variety of confirmatory testing practices were observed. Three testing sites reported that no confirmatory testing was required. Two hundred seven (61%) respondents indicated referring specimens to another facility for confirmation. Of the 126 respondents indicating doing onsite confirmation testing, 60 (48%) of them appeared to have followed published recommendations to perform WB or IFA1,2,3; 19% (24/126) indicated using only EIA testing; 22 of those were hospital laboratories. Three percent (4/126) used EIA in combination with a second rapid test (same kit); 14% (18/126) of respondents indicated that they used a second rapid test with no other type of confirmatory testing. Overall, 17% (56/338) of total U.S. respondents indicated confirmatory testing practices that did not include either WB, IFA, or referring tests out.

CONCLUSIONS: U.S. testing sites reported using a variety of confirmatory testing practices, some of which are not in compliance with current recommendations that either WB or IFA testing be used to confirm a preliminary positive HIV rapid test result. Follow up is needed to confirm these findings and to improve adherence to published recommendations. (www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm; www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm)

E-mail address for Laurina Williams: low1@cdc.gov

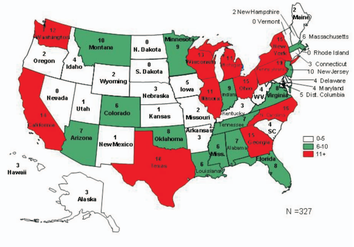
Response Rate

The HIV rapid testing sample shipment and response survey were sent to 436 testing sites within and outside of the United States. Responses were received from 384 of the testing sites (88.1%). Of those who responded:

- 327 (85%) were from U.S. testing sites, and
- 57 (15%) were from non-U.S. testing sites.

Note:
Twelve testing sites submitted multiple responses, indicating the use of from 1 to 7 different test kits.

Number of MPEP HIV Rapid Testing Sites Returning Results in the United States and Territories

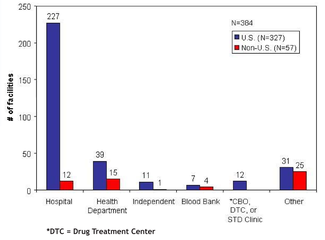


Non-U.S. Participants - List of Countries (Number of Participant Laboratories in Each Country)

Country	Number	Country	Number
Argentina	1	Indonesia	1
Australia	1	Kenya	1
Bahamas	1	Liberia	1
Bangladesh	1	Malawi	1
Belgium	1	Malaysia	1
Botswana	3	Myanmar	1
Burkina Faso	1	Niger	1
Burundi	1	Nigeria	2
Canada	1	Panama	1
Congo	1	Peru	1
Cote d'Ivoire	2	Philippines	3
Dominican Republic	1	Republic of Singapore	1
Egypt	1	Republic of Yemen	1
El Salvador	1	Slovakia	1
Eritrea	1	South Korea	1
Ethiopia	1	Taiwan	1
Ghana	1	Tanzania	4
Guyana	1	Thailand	6
Honduras	1	Uganda	1
Hungary	1	Zambia	1
India	2	Zimbabwe	1

N=57

Type of Testing Sites by U.S. and Non-U.S.



*DTC = Drug Treatment Center

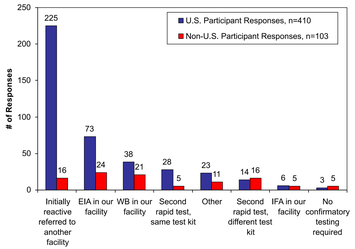
Survey of Confirmatory Testing Practices

The survey included the following question regarding confirmatory testing:

Question:
"For the rapid HIV test kit you specified in question #1, what confirmatory test(s) does your facility require to confirm a preliminary positive (REACTIVE) HIV Rapid Test result?" (Multiple responses were accepted.)

- The intent of this question was to evaluate whether or not the testing sites required that confirmatory testing be done on preliminary positive (reactive) samples before reporting a final "positive" result, and if so, what process they followed for confirmatory testing.
- Testing sites using more than one kit could submit more than one response.

Types of Confirmatory Testing Reported By MPEP Testing Sites - Total Responses

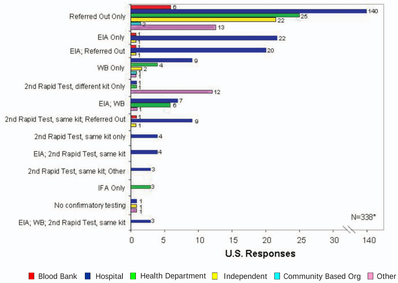


Note: Respondents could indicate more than one answer.

Confirmatory Testing Practices (U.S. and Non-U.S. Responses)

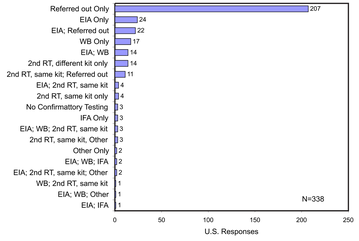
- Many respondents (338/513; 65.9%) reported either
  - sending the reactive (preliminary positive) specimens to another facility (241/513; 47.0%), or
  - performing EIA alone or in combination with other tests (18.9%;97/513).
- Several respondents (63/513; 12.3%) reported using a second rapid test for confirmatory testing.
  - Of these, 27/63 (42.9%) reported using a second rapid test with no other type of confirmatory testing.
- 3 U.S. respondents and 5 non-U.S. respondents reported that no confirmatory testing was required prior to reporting a positive result.

Patterns of Confirmatory Testing U.S. Testing Sites by Lab Type

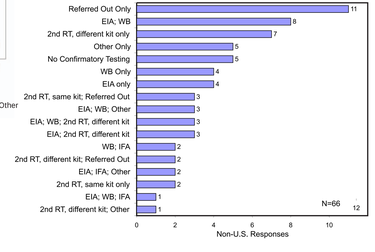


*Testing patterns for which there were less than three answers not depicted.

Patterns of Confirmatory Testing U.S. Respondents



Patterns of Confirmatory Testing Non-U.S. Respondents



Conclusions

- Participants reported a variety of schemes for doing confirmatory testing.
- Some U.S. testing sites are using confirmatory testing algorithms other than WB or IFA as recommended by CDC
- 3 U.S. testing sites reported: "No confirmatory testing required"
  - Of U.S. respondents doing onsite confirmatory testing:
  - 19% (24/126) did only EIA testing
  - 3% (4/126) used EIA in combination with a 2nd rapid test only
  - 14% (18/126) used a 2nd rapid test with no other confirmatory testing
- The reasons for U.S. testing sites using alternative confirmatory testing patterns, other than those currently recommended by CDC are unclear.
- Follow-up is needed to confirm these findings, to determine why U.S. testing sites are not using recommended confirmatory testing practices, and to encourage compliance with current recommendations.

Recommendations

- U.S. testing sites are reminded that HIV rapid tests are screening tests and reactive results are considered to be "preliminary positives" that must be confirmed by either a Western blot or IFA test.
- U.S. testing sites should become familiar with following the current CDC recommendations regarding confirmatory testing:

1. Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV Antibody Test. Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services. 2003. http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm

2. Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests. MMWR 2004; 53(10): 221-222. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm

3. CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001; 50(No. RR-19):1-57. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm