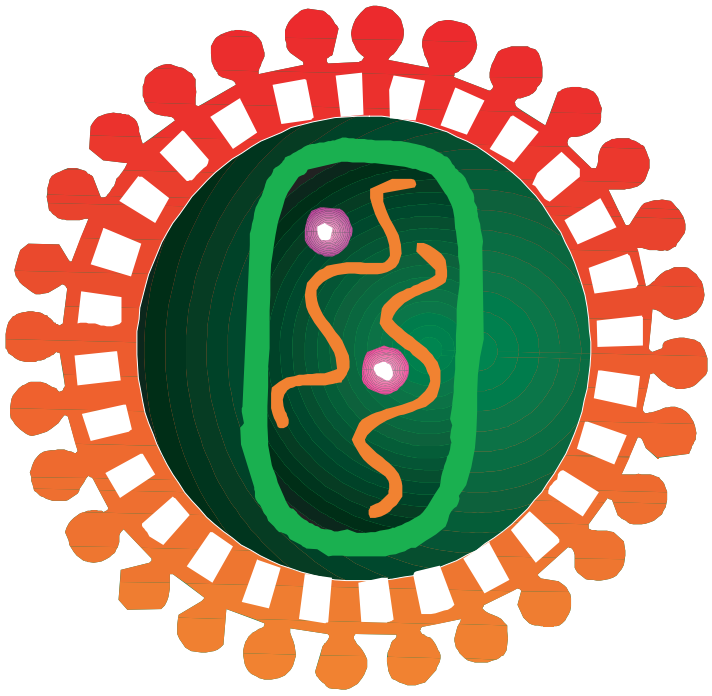
MPEP

HIV Rapid Testing

Report of Sample Shipment Results, December 2006



DEPARTMENT OF HEALTH & HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV-1 Rapid Testing MPEP December 2006 Report of Results

Report of the December 2006 Human Immunodeficiency Virus Type 1 (HIV-1) Rapid Testing (RT) Performance Evaluation Sample Results Provided by Participant Facilities in the Model Performance Evaluation Program (MPEP), Centers for Disease Control and Prevention (CDC).

Coordination of report production

The production of this report was coordinated in CDC by:

Division of Laboratory Systems ……..... D. Joe Boone, Ph.D., Acting Director

Laboratory Practice Evaluation and
Genomics Branch..... Julie Taylor, Ph.D., Acting Chief

Report content

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP)…… G. David Cross, M.S., Manager

MPEP HIV-1 Rapid Testing Performance Evaluation..... Leigh Inge Vaughan, B.A.,
HIV Rapid Testing Project Coordinator

MPEP acknowledges the contributions of Daline Derival, M.P.H., of Constella Group, LLC and Pam Robinson of CDC for their help in preparing this report.

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

Contact information

Comments and inquiries regarding this report should be directed to:

Ms. Leigh Vaughan: telephone (404) 718-1005 email LVaughan@cdc.gov

Table of Contents **page**

Donor Report

HIV Rapid Testing MPEP December 2006

Panel and Vial Designations, CDC Donor Bulk Numbers, CDC HIV Rapid Test Results and Donor HIV Status

Panel Letter	Vial Label	CDC Donor Bulk Number	CDC Test Result[1,3]	Donor HIV Status	Laboratory Interpretation[2] and/or Results	
					Test Result	Interpretation
A	A1	6	Negative (N)	Uninfected	_____	_____
	A2	21	Positive (W)	Infected	_____	_____
	A3	12	Positive (S)	Infected	_____	_____
	A4	20	Positive (W)	Infected	_____	_____
	A5	6 *	Negative (N)	Uninfected	_____	_____
	A6	20*	Positive (W)	Infected	_____	_____
B	B1	6	Negative (N)	Uninfected	_____	_____
	B2	6 *	Negative (N)	Uninfected	_____	_____
	B3	20	Positive (W)	Infected	_____	_____
	B4	21	Positive (W)	Infected	_____	_____
	B5	20*	Positive (W)	Infected	_____	_____
	B6	12	Positive (S)	Infected	_____	_____
C	C1	21	Positive (W)	Infected	_____	_____
	C2	6	Negative (N)	Uninfected	_____	_____
	C3	12	Positive (S)	Infected	_____	_____
	C4	20	Positive (W)	Infected	_____	_____
	C5	20*	Positive (W)	Infected	_____	_____
	C6	6 *	Negative (N)	Uninfected	_____	_____
D	D1	6	Negative (N)	Uninfected	_____	_____
	D2	20	Positive (W)	Infected	_____	_____
	D3	6 *	Negative (N)	Uninfected	_____	_____
	D4	21	Positive (W)	Infected	_____	_____
	D5	12	Positive (S)	Infected	_____	_____
	D6	20*	Positive (W)	Infected	_____	_____

* Duplicate of previous sample

[1] The CDC result was obtained after pre-shipment testing for the presence of HIV-1 antibody with all commercially available HIV rapid testing kits licensed by the Food and Drug Administration (FDA) and with selected FDA-licensed Enzyme Immunoassay (EIA) kits. The CDC result is consistent with the manufacturers' criteria for interpretation of results.

[2] Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

[3] Strong (S) and Weak (W) designations are based on qualitative observations of the colorimetric test results for reactive samples.

Report of Results: Overview

Purpose

This report describes the results of the ninth HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) shipment survey. It represents a collection of results reported by a variety of testing sites using different HIV rapid test kits on six samples.

The six survey samples were derived from four individual donors and included two duplicate samples.

The major findings are summarized below.

Response rate

The survey shipment was sent to 607 testing sites within and outside of the United States. Responses were received from 528 (87.0%) of the testing sites. Of those responding:

- 461 (87.3%) were U.S. testing sites, and
- 67 (12.7%) were non-U.S. testing sites.

Notes:

1) Sixteen testing sites submitted multiple result forms, indicating the use of from two to four different test kits, so that the total number of responses was 548.
2) Four sites reported results for an incorrect panel designation; these results were not included in the analyses.

Overall performance

Overall accuracy (percent of correct results) for all samples, by all sites with all kit types, was 94.3% (3063/3248). "Indeterminate" result interpretations were considered to be incorrect, and "Invalid" result interpretations were not included in the analyses. (Forty invalid results were reported by twenty-eight testing sites. These tended to be related to the use of flow-through testing devices, e.g. absorption difficulties.)

A summary of results for all challenges is shown in the following table:

Table 2: Percentages of positive and negative results by donor type

		Positive Donors			Negative Donors			
Total # of facilities	Total # of Results	Positive/ Reactive Results	Ind*	False Negative (% False Neg.)	Negative/ Non-Reactive Results	Ind	False Positives (% False Pos.)	Overall Performance (TP + TN/Total # of Results)
528	3248	2015	16 (0.7%)	153 (7.0%)	1048	8 (0.8%)	8 (0.8%)	94.3%

* Ind= Indeterminate

Continued on next page

Report of Results: Overview, Continued

MPEP plasma samples, summary results

- The MPEP plasma **positive challenges** included one strong-positive sample (donor 12) and two weak-positive samples (Donors 20 and 21).
- The 153 false-negative and 16 indeterminate results represent a higher rate of error than in previous surveys; of these 169 incorrect results reported for positive challenges:
    - 5 (3.0%) were reported for Donor 12,
    - 130 (76.9%) were reported for Donor 20 and
    - 34 (20.1%) were reported for Donor 21.
    - Overall accuracy for MPEP plasma positive samples was 92.3% (2015/2184).
    - Accuracy varied with test kit used (83.3% - 100%).
    - The kit types used by participants reporting the errors were as follows:

Rapid HIV kit type	# false-negatives (n=153)	# indeterminates (n=16)
OraQuick ADVANCE	101	5
Trinity Biotech Unigold Recombigen	30	3
MedMira Reveal G2 or G3	10	0

- Eight false positive and eight indeterminate results were reported on the **negative challenge** (Donor 6).
    - Overall accuracy was 98.5% (1048/1064).
    - Five out of the eight false positive results were associated with use of the OraSure OraQuick ADVANCE Rapid HIV 1/2 Ab Test.

Changes in specimen type

- **Oral fluid (oral mucosal transudate) as a specimen type:**
    - was indicated in 103 responses by sites using the OraSure OraQuick Advance Rapid HIV-1/2 test kit,
    - showed an increase in usage from the 88 responses reported to MPEP in the June 2006 survey,
    - was used primarily in the U.S. (101/103, 98.1%) by sites identified as:
        - health department (52/101, 51.5%),
        - counseling and testing (16/101, 15.8%)
        - community based organization (CBO) (12/101, 11.9%) or
        - Hospital (7/101, 6.9%).

Confirmatory testing practices

Twenty-seven U.S. testing sites indicated that only EIA (in-house or sent out) was done for confirmation of a preliminary positive (reactive) rapid test result.

CDC guidelines state that reactive rapid HIV tests should be confirmed with Western blot (WB) or indirect immunofluorescence assay (IFA), even if a subsequent EIA is nonreactive. ***It is the responsibility of each testing site to ensure that appropriate guidelines are being followed*** regardless of where the confirmatory tests are performed.

Challenge Samples

Sample description

The plasma samples for this challenge shipment of the HIV-RT MPEP were shipped in December 2006.

The six samples for this shipment were from four donors:

- one strong HIV-1 antibody positive,
- two weak HIV-1 antibody positive (one in duplicate), and
- one HIV-1 antibody negative, in duplicate.

Description of challenge samples

All sample plasma were single bleeds drawn from individual donors. The resulting plasma for all samples was tested to determine HIV-1 antibody reactivity.

The samples for the December 2006 HIV Rapid Testing MPEP survey were processed as follows:

- All donor samples were clarified prior to dispensing and tested to ensure they were free of bacterial contamination.
- HIV-1 antibody-positive plasma samples were heat-treated at 56ºC for 60 minutes to inactivate infectious agents, whereas HIV-antibody-negative samples were not heat-treated.
- The serostatus of both positive and negative samples was confirmed by all FDA-approved rapid HIV antibody tests, as well as selected FDA-approved EIA and Western blot kits.
- Negative samples were negative for HIV-1 antigen using an FDA-approved monoclonal antibody-based p24 antigen test.
- Positive samples were selected using the following criteria:
    - reactive by the Genetic Systems rLAV enzyme immunoassay kit at a signal-to-cutoff ratio between 3 and 5 for the weak-positive seroconverter samples and greater than 5 for the strong-positive samples, and
    - positive by the APHL/CDC interpretive criteria for Western blot (WB) patterns.

The negative sample and one of the weak-positive samples were included in the shipment in duplicate.

Demographics

Overview

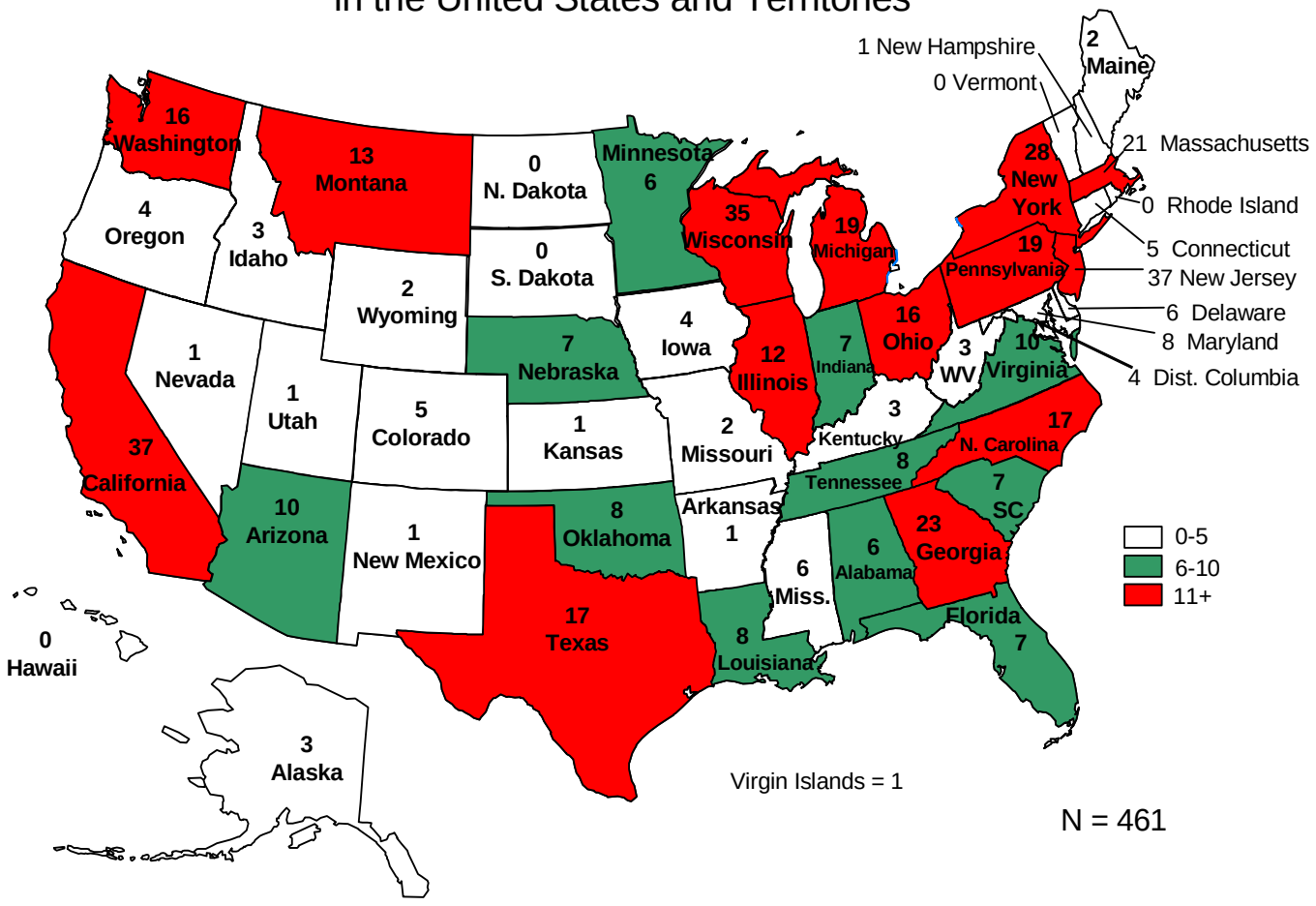
A total number of 528 different testing sites (foreign and domestic) submitted results. Of these:

- the 461 domestic testing sites are depicted in ***Figure 1***, and
- the 67 non-U.S. testing sites are listed in ***Table 3***.

The types of testing site participants responding are depicted in ***Figure 2***:

- The number of non-U.S. participants in the current survey (67) was similar to the previous survey (June 2006, n = 61).
- Non-U.S. participants included over 1/3 of the countries in the Global AIDS Program (GAP).
- The number of U.S. participants in the current survey (461) was greater by 9.2% from that of the previous survey (422).
- In the U.S., hospital testing sites predominated.

Figure 1



Continued on next page

Demographics, Continued

The following table shows the breakdown of participants outside the United States.

Table 3

Country	Number	Country	Number
Argentina	0	India	3
Australia	2	Indonesia	1
Bahamas	1	Kenya	1
Bangladesh	1	Liberia	1
Belgium	1	Malawi	1
Botswana	3	Malaysia	1
Brazil	1	Mali	1
Burkina Faso	2	Niger	1
Burundi	1	Nigeria	2
Cameroon	1	Panama	1
Canada	2	Peru	1
Central African Republic	1	Philippines	3
Congo	1	Republic of Yemen	1
Cote d'Ivoire	1	Senegal	2
Dominican Republic	1	Slovakia	1
Egypt	1	South Korea	1
El Salvador	1	Suriname	1
Eritrea	1	Taiwan	1
Ethiopia	1	Tanzania	8
Germany	1	Thailand	5
Guyana	1	Uganda	1
Honduras	2	Zambia	2

N = 67

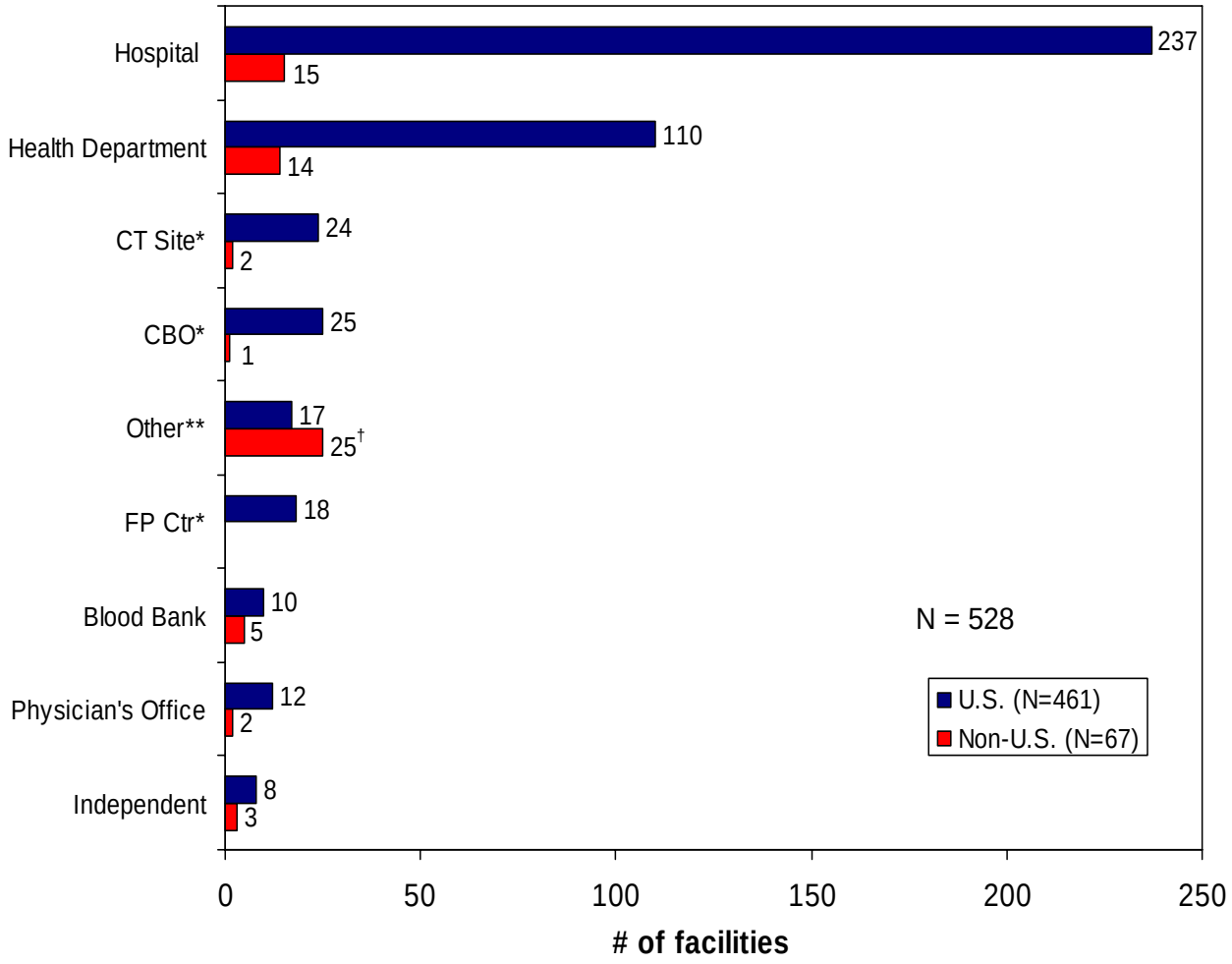
Continued on next page

Demographics, Continued

The types of testing sites for all participants in the current survey are shown in Figure 2, by U.S. and non-U.S. participants.

Figure 2:

Type of Testing sites, by U.S. & non-U.S.



*Abbreviations:

CBO = community based organization
CT Site = counseling and testing site
FP Ctr = family planning center

** "Other" facility type includes:
health maintenance organization (HMO)
Medical Examiner
sexually transmitted disease (STD) clinic
correctional facility
drug treatment center

(†) 15/25 of the Non-U.S. "Other" type of testing sites were laboratories or medical units associated with U.S. embassies.

Detailed Performance Results

Table 4 below gives the reactivity results by donor.

Table 4

	Reactivity					
Donor Number	**# of Participants**	**# of Results**	**# Pos.**	**# Neg.**	**# Indeter**	**% Correct**
6 (Negative)	528	1064	8	1048	8	98.5%
12 (Stong Pos)	528	546	541	3	2	99.1%
20 (Weak Pos	528	1090	960	118	12	88.1%
21 (Weak Pos)	528	548	514	32	2	93.8%

MPEP plasma samples, detailed performance results

MPEP Negative Sample (Donor 6):

- Eight false-positive results were reported; six by U.S. sites, and two by non-U.S. sites.
- Eight indeterminate results were reported.

MPEP Positive Samples:

- There were 169 incorrect results on the MPEP HIV-positive samples. Of these:
  - One-hundred and fifty-three were false negative errors (143 by U.S. and 10 by non-U.S. sites), with
    - One-hundred and eighteen errors reported for weak-positive Donor 20,
    - Three errors reported for strong-positive Donor 12, and
    - Thirty-two errors reported for weak-positive Donor 21.
  - Sixteen were indeterminate results.

Continued on next page

Table 5: Results by test kit

Kit Type (manufacturer)	Reactive/Positive						Non-Reactive/Negative						Totals		
	# of Sites	# of Results	# Reactive	# Non-Reactive	# Indeter	% Correct	# of Sites	# of Results	# Reactive	# Non-Reactive	# Indeter	% Correct	Total # of Results	# Correct	% Correct
Oraquick ADVANCE Rapid HIV-1/2 Ab Test (OraSure)	312	1241	1135	101	5	91.5%	312	622	5	617	0	99.2%	1863	1752	94.0%
Reveal G2 Rapid HIV-1 Antibody Test (MedMira)	57	228	221	7	0	96.9%	47	90	1	84	5	93.3%	318	305	95.9%
Reveal G3 Rapid HIV-1 Antibody Test (MedMira)	21	84	81	3	0	96.4%	19	37	0	34	3	91.9%	121	115	95.0%
Determine HIV-1/2 (Abbott)	42	168	160	5	3	95.2%	42	84	0	84	0	100.0%	252	244	96.8%
Biotech Uni-Gold Recombigen HIV (Trinity)	67	268	235	30	3	87.7%	67	134	0	134	0	100.0%	402	369	91.8%
Biotech Uni-Gold (Trinity)	7	28	24	4	0	85.7%	7	14	0	14	0	100.0%	42	38	90.5%
Biotech Capillus (Trinity)	9	36	36	0	0	100.0%	9	18	0	18	0	100.0%	54	54	100.0%
Multispot HIV-1/HIV-2 (Bio-Rad)	6	24	20	0	4	83.3%	6	12	0	12	0	100.0%	36	32	88.9%
Genie II HIV-1/HIV-2 (BioRad)	2	8	8	0	0	100.0%	2	4	0	4	0	100.0%	12	12	100.0%
Serodia HIV (Fujirebio)	1	4	4	0	0	100.0%	1	2	2	0	0	0.0%	6	4	66.7%
Serodia HIV 1/2 (Fujirebio)	3	12	12	0	0	100.0%	3	6	0	6	0	100.0%	18	18	100.0%
HIV 1/2 Stat-Pack (CASSETTE)	2	8	8	0	0	100.0%	2	4	0	4	0	100.0%	12	12	100.0%
Other	19	75	71	3	1	94.7%	19	37	0	37	0	100.0%	112	108	96.4%

Table 5 gives the accuracy for all samples by kit type

Kit Types Used By Participants

Overview This section describes the kit types used by participants.

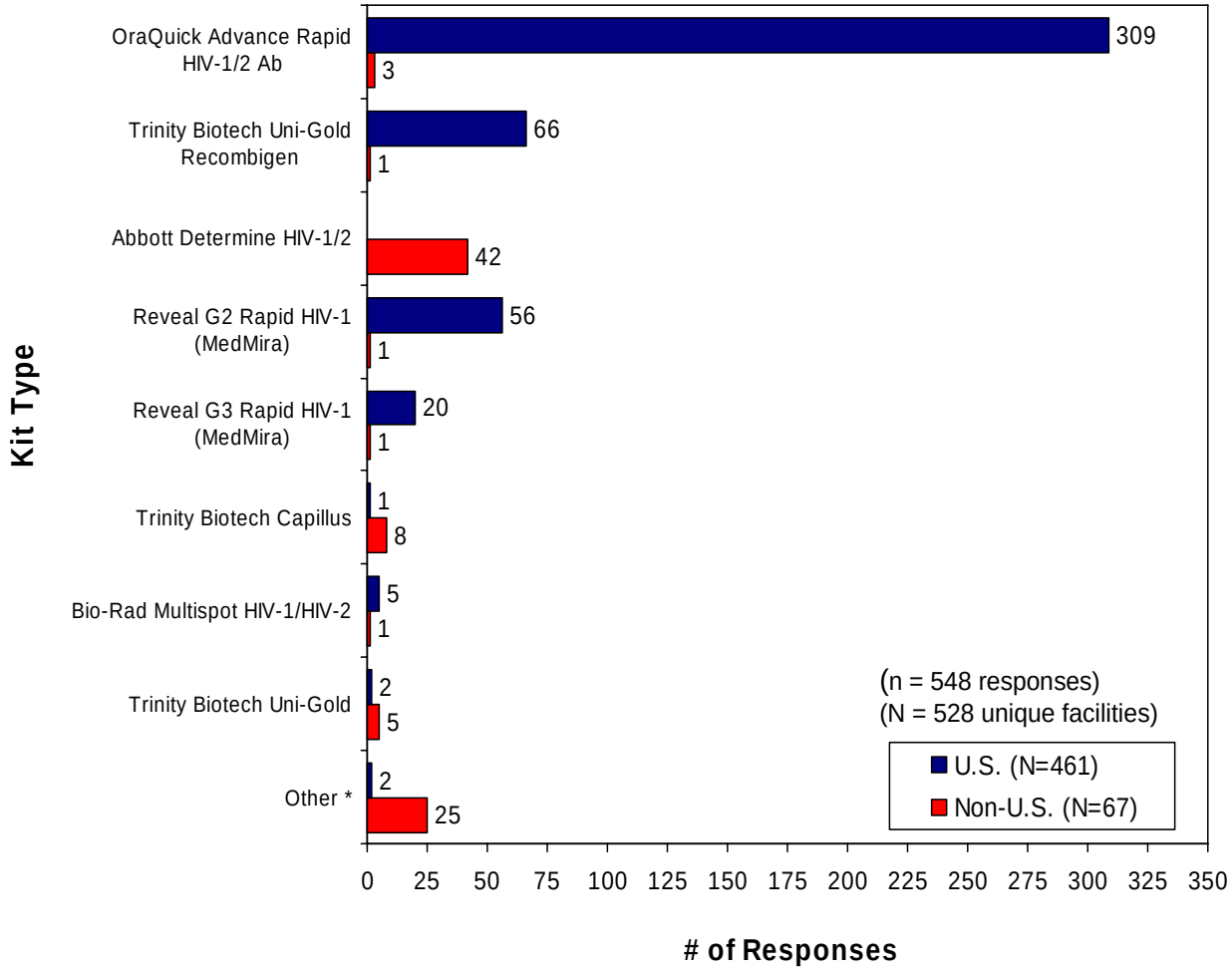
- The predominant kit type used in the U.S. was OraQuick ADVANCE Rapid HIV 1/2 Ab test (67.0%; 309/461), as shown in ***Figure 3***:

- The predominant kit type used in non-U.S. testing sites was Abbott Determine HIV-1/2 (48.3%; 42/87).

- Kit usage by lab type is shown in ***Figure 4.***

Figure 3:

Kit types



* "Other" kit types include: Bio-Rad Genie II HIV-1/HIV-2
HIV 1/2 Stat-Pak (Cassette)
Fujirebio Serodia HIV-1/2

Continued on next page

Kit Types Used By Participants, Continued

The following figure illustrates the usage of the kit types by type of testing site. The methods for which there were twelve or less results are included in the "other kit type" category.

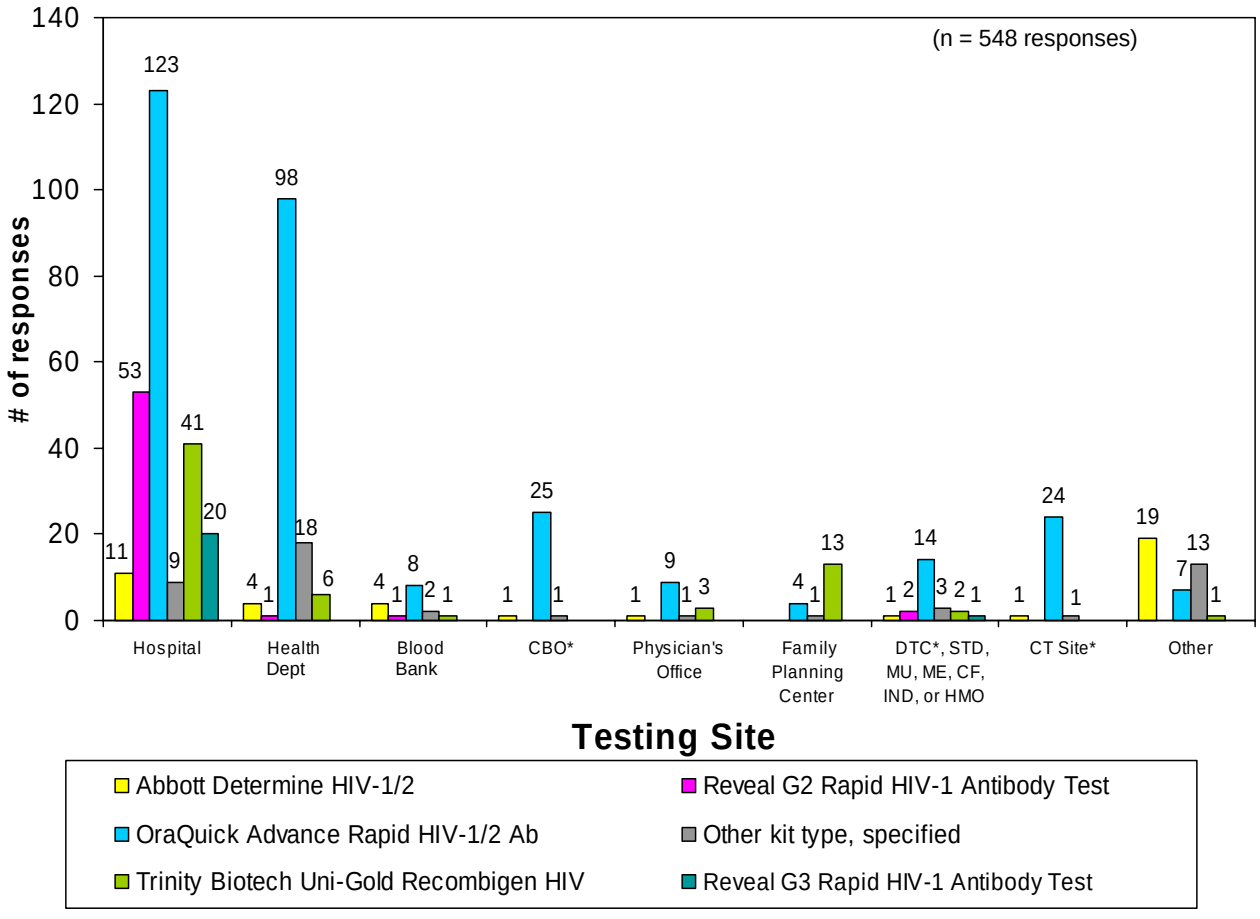
The predominate test kit used was OraQuick ADVANCE Rapid HIV 1/2 Ab Test. The percent of sites using this kit, by type of facility, is as follows:

- hospitals, 47.9%
- health departments, 77.2%
- outreach sites (DTCs, STD clinics, CT sites, family planning centers, mobile units)*, 62.7%
- CBOs*, 92.6%
- blood banks, 50.0%
- physician offices, 64.3%

Note: Some testing sites used more than one type of testing kit.

Figure 4:

Testing site by kit type



*Abbreviations:

CBO = community based organization
DTC = drug treatment center
STD = sexually transmitted disease clinic
IND = independent
CT Site = counseling and testing site
CF = correctional facility
ME = Medical Examiner
MU = mobile unit
HMO = health maintenance organization

Specimen Types Used By Participants

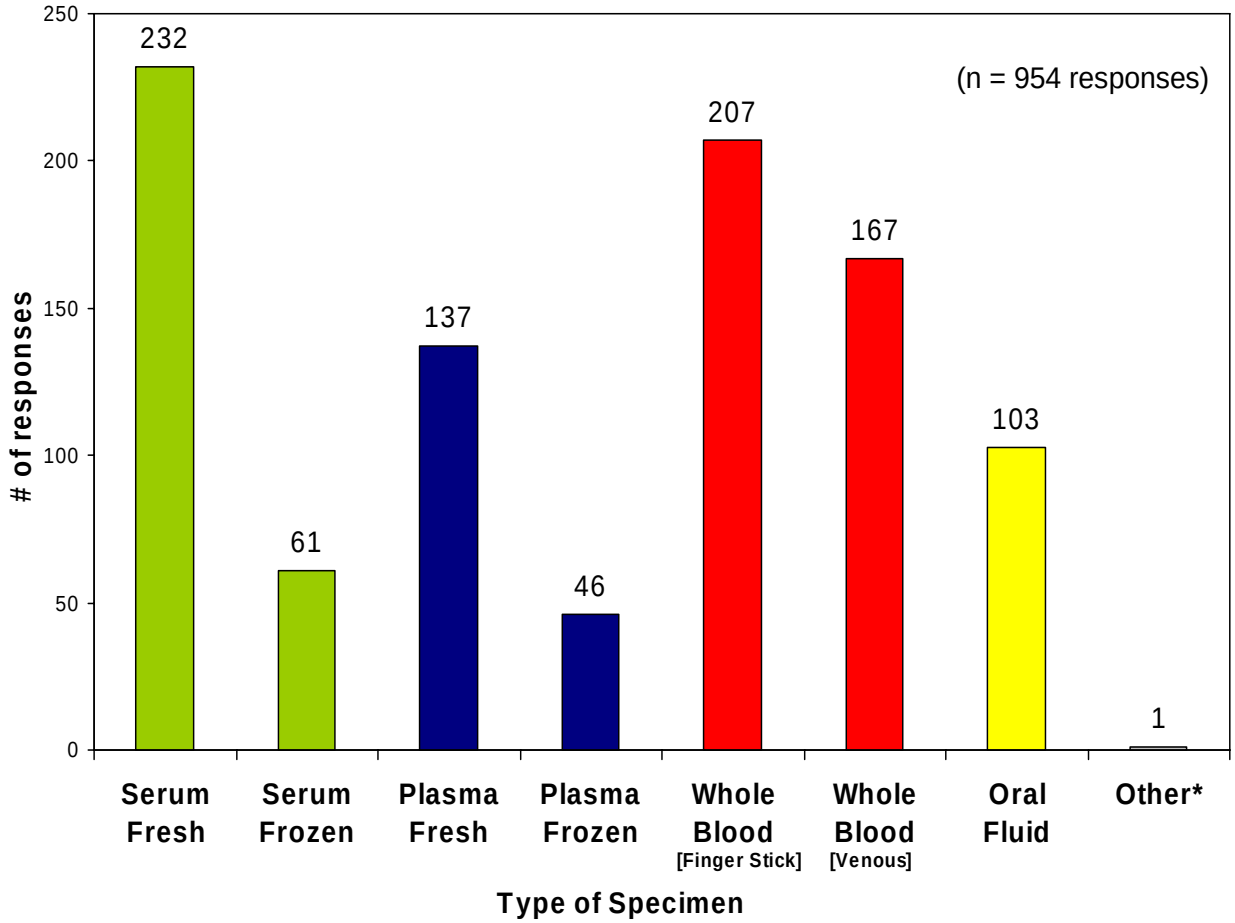
Overview

Participants were asked what type of specimens they normally use for HIV rapid tests.

- The breakdown in specimen types reported is shown in ***Figure 5***.
- Testing sites could report using more than one specimen type.

Figure 5:

Specimen types



* One facility indicated the "Other" specimen type as dried blood spot.

The type of specimen(s) used in performing HIV rapid testing varied by the type of facility and the method of rapid testing (kit type).

The number of reports indicating oral fluid use increased slightly, with respect to the previous survey, from 88 (18.2%) to 103 (19.5%).

Quality Control (QC)

Overview

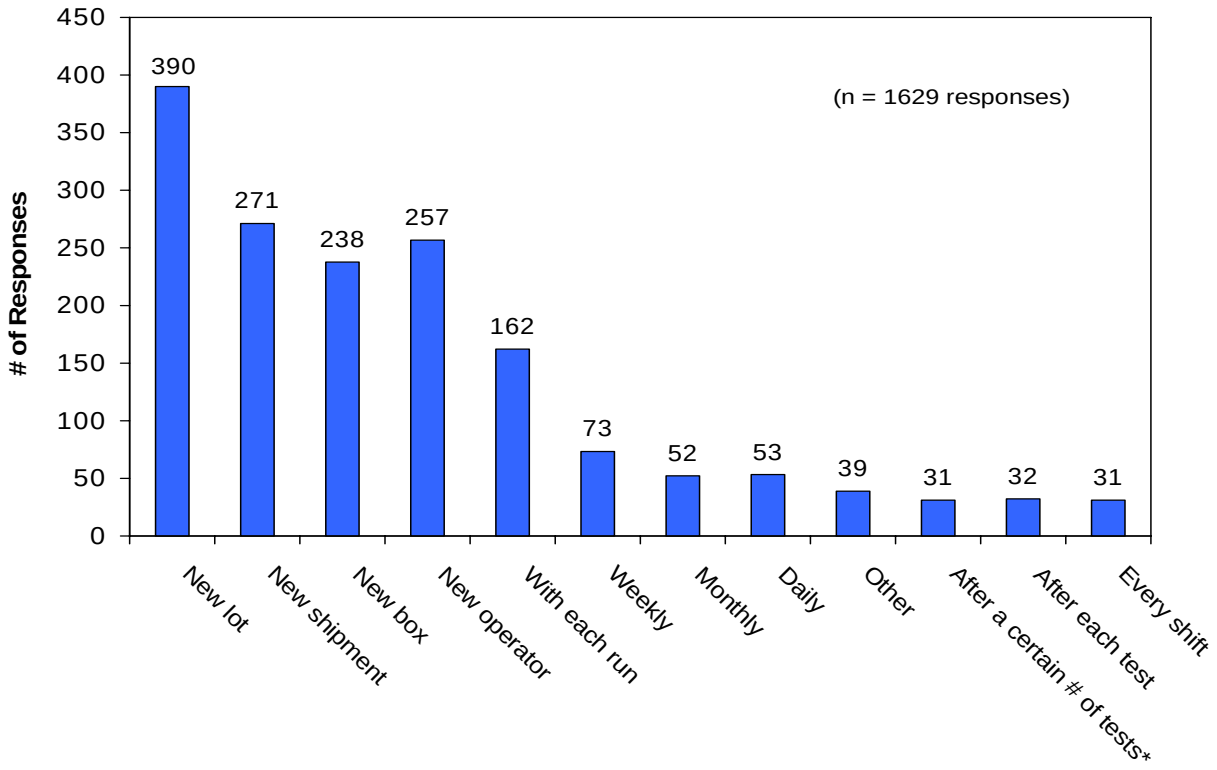
Testing sites were asked if they used quality control (QC) samples, either positive or negative, when performing HIV rapid tests. The frequency of use of quality control materials is shown in ***Figure 6***.

- All of the 528 facilities that returned responses answered the question regarding use of quality control samples (question #5).
- Most of these facilities (93.2%, 492/528) indicated the use of QC samples for at least one of the kit types they use at their testing site.
- Of the 1378 responses indicating the source(s) from which the QC samples (positive and/or negative) were obtained, the sources identified were as follows:
  - controls obtained from the same manufacturer as the test kit (89.6%, 1235/1378),
    - 39.5% (488/1235) were included in the test kit, and
    - 60.5% (747/1235) were purchased from the kit manufacturer separately.
  - in-house controls (6.7%, 93/1378).
  - "Other" manufacturer (manufacturer not the same as for the test kit) controls (3.6%, 50/1378).

Notes: 1. Testing sites could provide more than one answer.
2. Testing sites reporting the use of multiple kit types answered the question separately for each kit type.

Figure 6:

Frequency of use of quality controls



* The most frequent response was 25 tests (Range 20-100)

Confirmatory Testing

Overview

The types of confirmatory testing reported by laboratories varied (as shown in ***Figure 7)***. ***Note:*** Testing sites could answer by indicating more than one confirmatory test.

- Most responses given (494/ 843; 58.6%) indicated that reactive (preliminary positive) specimens were sent to another facility.

- In several cases, EIA was performed alone (35/843; 4.2%) or in combination with other testing (135/843; 16.0%).

- Some responses given (130/843; 15.4%) indicated using a second rapid test for confirmatory testing. Of these, 23/130 (17.7%) indicated using a second rapid test with no other type of confirmatory testing.

Nineteen respondents indicated that no confirmatory testing was required to confirm a positive result for the HIV rapid testing kit listed on at least one form. Of these:

- fifteen sites did not indicate the use of confirmatory testing with any HIV rapid test kit;

  - eight were U.S. facilities, with the purpose for using the specified kit being
    - HIV initial testing (e.g. for patients/clients, needlestick and/or source patient): five testing sites.
    - non-clinical testing (e.g. research, training, etc.) and determination of HIV-1 vs. HIV-2 reactivity: one testing site.
    - no purpose specified: two testing sites.

  - seven were non-U.S. facilities, with the purpose for using the specified kit being
    - HIV initial testing: three testing sites.
    - non-clinical HIV testing: four testing sites.

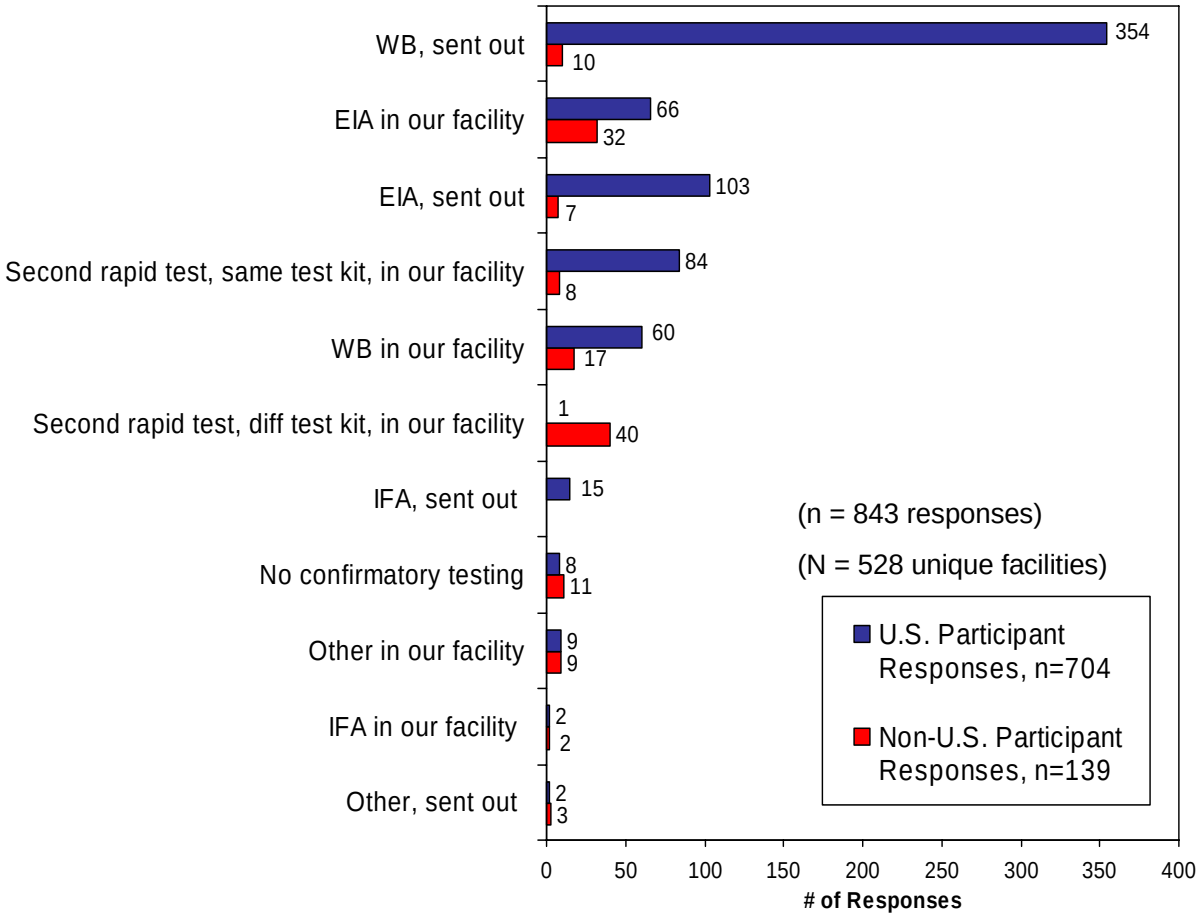
- four non-U.S. sites indicated that confirmatory testing was performed for another HIV rapid testing kit used in their facility. ***Note***: For three of these sites, the HIV rapid test for which confirmation was *not* required was reported as the confirmatory test for the other kit used.

Continued on next page

Confirmatory Testing, continued

Figure 7:

Types of confirmatory testing



Conclusions and Discussion

Overall performance

Overall accuracy in this shipment was 94.3%:

- 92.3% for the positive samples;
    - 99.1% for Donor 12 (strong positive),
    - 93.8% for Donor 21 (weak positive), and
    - 88.1% for Donor 20 (weak positive).

- 98.5% for the negative samples (Donor 6).

Specimen types

The number of testing sites reporting the use of oral fluid increased from 88 to 103 responses. Of these, 101 were U.S. testing sites that tended to be health departments (53/101), counseling and testing sites (16/101), or community based organizations (12/101).

In this survey, 37 U.S. testing sites reported using serum and/or frozen plasma as specimen types for the OraQuick ADVANCE HIV-1/2 Antibody test kits. This is a decrease from the 46 U.S. testing sites who reported using serum and/or frozen plasma as specimen types for the same kits in the June 2006 shipment. It should be noted that:

- The OraQuick test is not FDA approved for serum (fresh or frozen) or for frozen plasma specimens.

Use of non-FDA approved specimen types for either of these test kits is considered a modification of the OraQuick testing procedure and makes these non-waived under the Clinical Laboratory Improvement Amendments (CLIA). U.S. facilities should be aware of the CLIA regulations requiring the establishment of performance specifications when modifying an FDA-approved test (Sec. 493.1253).[5]

Errors on positive samples

The results from the current survey show an unusually high number of errors on the positive challenge plasma samples (169/2184, 7.7%), as compared to recent previous surveys:

- 21/1489 (1.4%) for the June 2006 survey,
- 4/1464 (0.3%) for the December 2005 survey, and
- 27/2414 (1.1%) for the June 2005 survey.

The majority of these errors (130/169, 77%) were reported for the weak Donor 20 samples, which were present as duplicates in the performance evaluation panels.

To rule out a possible sample/shipping issue, extensive post-shipment testing was performed. The post-survey re-validation analyses included:

- ruling out bacterial contamination,
- testing one or more examples of each donor's sample aliquots with all FDA-approved HIV rapid testing kit types (i.e. repeating the preshipment testing for sample panel validation), and
- re-testing one participant's Donor 20 samples which were reported as negative.

After analyzing these results we have concluded that all positive samples unquestionably come from HIV-positive individuals.

Continued on next page

Conclusions and Discussion, Continued

Errors on positive samples (continued)

The Western blot results for the weak positive samples (Donors 20 and 21) showed highly reactive gp41 and p24 bands, while the gp120 bands were absent. This pattern indicates that these sera come from donors in the early stages of HIV infection (i.e. the donors are seroconverters). The reason for such an unusually large number of false-negatives for the Donor 20 samples remains unclear.

The errors on the Donor 20 samples may reflect that the concentration of antibody in this donor's plasma was at the limit of detectability for these test kits. In this case, within the acceptable bounds of quality control variability for sensitivity, a particular lot number for a rapid test kit could have a sensitivity just below that required to detect the antibodies in such a weak sample.

Alternatively, this very weakly-reactive positive challenge sample might have been missed more frequently due to testing technique or the testing/interpretation conditions at the testing site. An extremely light-colored "reactive" test line (or dot) can be so difficult to detect that it requires a particularly high level of confidence by the person interpreting the test to report a "reactive" result. In addition to this confidence, which comes from training and experience, good lighting in the testing area is necessary to correctly interpret a result from a very faint reaction.

Further investigation is indicated in order to identify the reason(s) for the unusual error rate for results submitted for the weak positive Donor 20 samples.

Confirmatory testing

Some U.S. testing sites that use HIV rapid tests for HIV initial testing purposes (i.e. screening) continue to use confirmatory testing algorithms that do not include Western blot (WB) or indirect immunofluorescence assay (IFA) as recommended by the CDC.

U.S. participants are reminded that:

1) HIV rapid tests (RT) are screening tests and reactive results are considered to be "preliminary positives" that must be confirmed by either a WB or IFA test.[1,3]

2) EIA tests for HIV are also considered to be screening, not confirmatory, tests. Some RT reactive specimens confirmed positive by WB or IFA produce negative results using EIAs.

3) CDC Guidelines recommend that preliminary positive (reactive) HIV rapid tests be confirmed with WB or IFA, even if a subsequent EIA test is nonreactive.[3]

Continued on next page

Conclusions and Discussion, Continued

Guidelines

Testing sites are advised to follow appropriate guidelines with respect to performing HIV rapid tests and reporting results.[1,2,3] Attention to recognized guidelines and good testing practices is crucial to patient safety and to the delivery of accurate test results.

For example, the CDC has published quality assurance guidelines for testing using the OraQuick rapid test.[1] These guidelines can be applied to other HIV rapid tests performed in U.S. sites.

The guidelines:

- stress that a testing site must have an adequate quality assurance (QA) program in place before offering rapid HIV testing,
- provide recommendations for a comprehensive QA program,
- include recommendations regarding test verification to ensure that the test kits work as expected in a given testing environment,
- encourage participation in an external quality assessment program, such as the MPEP, and address the logistics for providing confirmatory testing for preliminary positive (reactive) results.[1,3]

References

1. Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 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. 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

3. 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

4. Notice to Readers: Approval of a New Rapid Test for HIV Antibody. MMWR 2002; 51(46): 1051-1052. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5146a5.htm

5. Code of Federal Regulations: Laboratory Requirements, 42 C.F.R. Chapter IV, Part 493 (2003). http://www.phppo.cdc.gov/clia/regs/toc.aspx

Topical Issues in HIV Rapid Testing

Introduction

The HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) strives to be a resource for facilities using HIV rapid testing kits. This section of the HIV-RT MPEP Report of Results, "Topical Issues in HIV Rapid Testing," is intended to address that part of our mission. We are including:

- ***Frequently Asked Questions (FAQs)*** by HIV RT MPEP participants to share with all participants our responses to some recent queries,
- ***CDC websites*** to provide participants with access to timely relevant material published online by the CDC, and
- ***HIV Rapid Testing Resources*** as a link to long-term references.

FAQs: December 2006 survey

This section provides answers to some of our participants' frequently asked questions (FAQs).

Q: Can I use an expired kit to do my MPEP sample panel (or patients) if the device control (the control line/dot) within the testing device develops properly?

A: No.

The expiration dates set by the manufacturers reflect the ability of the test kits to produce a valid result for all samples over a specific time frame; while proper development of the device control must occur for a valid test, a valid test result also depends on the tester adhering to ALL of the manufacturer's instructions–including using a non-expired test kit.

Highlights of previous FAQs

Q: May we use as QC material the positive and/or negative MPEP samples left over from the panels you send us?

A: No, this is an inappropriate use of MPEP samples.

Our samples are validated only for the purpose of performance evaluation (PE) in HIV rapid testing. While we recognize that extra sample volume (i.e. not used to do the test for the survey shipment) in our panels has been, and will continue to be used effectively for training/practice purposes, the "left-over" sample material is not designed to be used in the very important role of Quality Control (QC) samples. Appropriate QC material can be purchased from a number of commercial sources.

For more information on proper specimen labeling and other good laboratory testing practices, please see *Good Laboratory Practices for Waived Testing Sites*, [MMWR 54(RR13):1-25] at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm

Continued on next page

Topical Issues in HIV Rapid Testing, Continued

Highlights of previous FAQs (continued)

Q: What types of specimens can be used in performing HIV rapid testing?
A: The type(s) of specimens (e.g. whole blood, serum, plasma, oral fluid, etc.) that are appropriate to use for HIV rapid testing depends on the test kit used. Each manufacturer includes information regarding approved specimen type(s) in the package insert for their HIV rapid testing kit.

Q: Can I read my HIV rapid test results as soon as the control line/spot appears?
A: You need to wait the minimum time as specified in the directions given by the manufacturer (as found in the package insert) before reading the result for a client/patient. Even if the within-device control line/spot can be seen, positive specimens may need the full minimum time for the color to develop properly. Please note that you should not read results after the specified maximum time limit.

To view other FAQs in previous HIV RT MPEP reports, please visit our website at:
http://www.phppo.cdc.gov/mpep/HIV-1rt.aspx

CDC websites

Quick Facts: Rapid Testing April 2003 - April 2004
http://www.cdc.gov/hiv/rapid_testing/materials/QuickFact_April2004.htm

MMWR: Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm

Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test
http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm

International Laboratory-related Resource and Activity Directory
http://www.phppo.cdc.gov/dls/ila/default.aspx

MMWR: Good Laboratory Practices for Waived Testing Sites
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm

HIV rapid testing resources

HIV Rapid Testing MPEP website: http://www.phppo.cdc.gov/mpep/HIV-1rt.aspx

Model Performance Evaluation Program (MPEP) Home page: http://www.phppo.cdc.gov/mpep/

Food and Drug Administration (FDA) Licensed / Approved HIV, HTLV and Hepatitis Tests
http://www.fda.gov/cber/products/testkits.htm

The National Center for HIV, STD, and TB Prevention (NCHSTP)
Divisions of HIV/AIDS Prevention (DHAP) website: http://www.cdc.gov/hiv/dhap.htm

The National Center for HIV, STD, and TB Prevention (NCHSTP) Home page
http://www.cdc.gov/nchstp/od/nchstp.html

The World Health Organization: http://www.who.int/en/