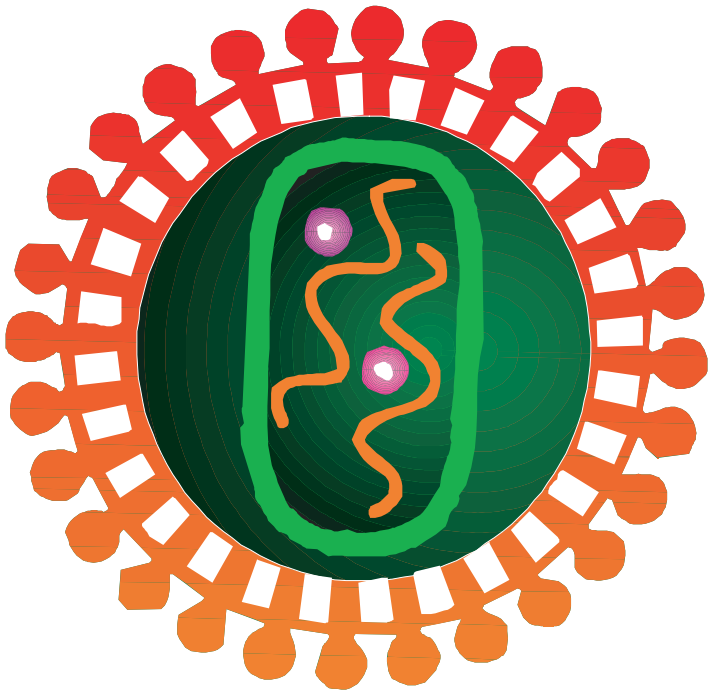
MPEP

HIV Rapid Testing

Report of Sample Shipment Results, December 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV-1 Rapid Testing MPEP December 2007 Report of Results

Report of the December 2007 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).

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Donor Report

HIV Rapid Testing MPEP December 2007

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	27	Negative (N)	Uninfected	_____	_____
	A2	13	Positive (S)	Infected	_____	_____
	A3	23	Positive (W)	Infected	_____	_____
	A4	13*	Positive (S)	Infected	_____	_____
	A5	23*	Positive (W)	Infected	_____	_____
	A6	24	Positive (W)	Infected	_____	_____
B	B1	13	Positive (S)	Infected	_____	_____
	B2	27	Negative (N)	Uninfected	_____	_____
	B3	23	Positive (W)	Infected	_____	_____
	B4	23*	Positive (W)	Infected	_____	_____
	B5	24	Positive (W)	Infected	_____	_____
	B6	13*	Positive (S)	Infected	_____	_____
C	C1	23	Positive (W)	Infected	_____	_____
	C2	24	Positive (W)	Infected	_____	_____
	C3	27	Negative (N)	Uninfected	_____	_____
	C4	13	Positive (S)	Infected	_____	_____
	C5	13*	Positive (S)	Infected	_____	_____
	C6	23*	Positive (W)	Infected	_____	_____
D	D1	23	Positive (W)	Infected	_____	_____
	D2	13	Positive (S)	Infected	_____	_____
	D3	13*	Positive (S)	Infected	_____	_____
	D4	27	Negative (N)	Uninfected	_____	_____
	D5	23*	Positive (W)	Infected	_____	_____
	D6	24	Positive (W)	Infected	_____	_____

* Duplicate donors

[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

Introduction

This report describes the results of the eleventh 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 684 testing sites within and outside of the United States. Responses were received from 622 (90.9%) of the testing sites. Of those responding:

- 557 (89.5%) were U.S. testing sites, and
- 65 (10.5%) were non-U.S. testing sites.

Note:
Fourteen testing sites submitted two result forms, indicating the use of two different test kits, so that the total number of responses was 636.

Overall performance

Overall accuracy (percent of correct results) for all samples, by all sites with all kit types, was 98.4% (3724/3783). "Indeterminate" result interpretations were considered to be incorrect, and "Invalid" result interpretations were not included in the analyses. (Eight invalid results were reported by seven testing sites. These tended to be related to the use of flow-through testing devices, e.g. possible 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)
618	3783	3099	12 (0.3%)	41 (1.1%)	625	0 (0.0%)	6 (0.16%)	98.4%

* Ind= Indeterminate

** Note: Four sites returning responses were not included in the testing result analyses, although the other laboratory practice information they supplied was included in the data. One of the sites gave no sample panel testing results; the other three sites reported rapid testing results for which the sample code did not match the sample panel they were shipped and their answers were inconsistent with the sample code they reported.

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Report of Results: Overview, Continued

MPEP plasma samples, summary results

- The MPEP plasma **positive challenges** included one strong-positive sample (donor 13) and two weak-positive samples (Donors 23 and 24).
- The 41 false-negative and 12 indeterminate results represent a rate of error less than that of the June 2007 and December 2006 surveys, both of which had notably higher error rates than in previous surveys. The current survey's error rate was similar to surveys conducted prior to December 2006.
- Of the 53 incorrect results reported for positive challenges:
  - 6 (11.3%) were reported for Donor 13 (strong positive),
  - 33 (62.3%) were reported for Donor 23 (weak positive) and
  - 14 (26.4%) were reported for Donor 24 (weak positive).
  - Overall accuracy for MPEP plasma positive samples was 98.3% (3099/3152).
  - Accuracy varied with test kit used (88.9% - 100%).
  - The three (3) most frequently used kit types were as follows:

Rapid HIV kit type	# sites	# false-negatives (n=41)	# indeterminates (n=12)
OraQuick ADVANCE	316	36	7
Trinity Biotech Unigold Recombigen	122	1	1
MedMira Reveal G3	63	1	0

- Six false positive and no indeterminate results were reported on the **negative challenge** (Donor 27).
  - Overall accuracy was 99.0% (625/631).
  - Five out of the six 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 normally used specimen type:**
  - was indicated in 140 responses, by 138 U.S. sites* using OraQuick Advance Rapid HIV-1/2 and by two non-U.S. sites using Determine HIV-1/2.
  - was similar in usage to the 142 responses reported to MPEP in the June 2007 survey,
  - was used primarily in the U.S. (138/140, 98.6%) by sites identified as:
    - health department (37/138, 26.8%),
    - community based organization (CBO) (33/138, 23.9%)
    - counseling and testing (28/138, 20.3%)
    - family planning center (10/138, 7.2%)
    - hospital (7/138, 5.1%) or
    - sexually transmitted disease (STD) clinic (6/138, 4.3%).

*Note: 43.3% (138/319) of U.S. sites that reported using OraQuick ADVANCE Rapid HIV-1/2 indicated use of oral fluid as a specimen type.

Confirmatory testing practices

Twenty-four 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 2007.

The six samples for this shipment were from four donors:

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

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 2007 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.
- The Western blot results for the weak positive samples (e.g. highly reactive gp41 and p24, weak or absent gp120 bands) indicated that the sera came from donors in the early stages of HIV infection (i.e. these donors are seroconverters).
- Negative samples were negative for HIV-1 antigen using an FDA-approved monoclonal antibody-based p24 antigen test. These samples were also HIV-negative by the FDA-approved HIV rapid testing kits that detect both HIV-1 and HIV-2 antibodies.
- 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 strong-positive and one of the weak-positive samples were included in the shipment in duplicate.

Demographics

Overview

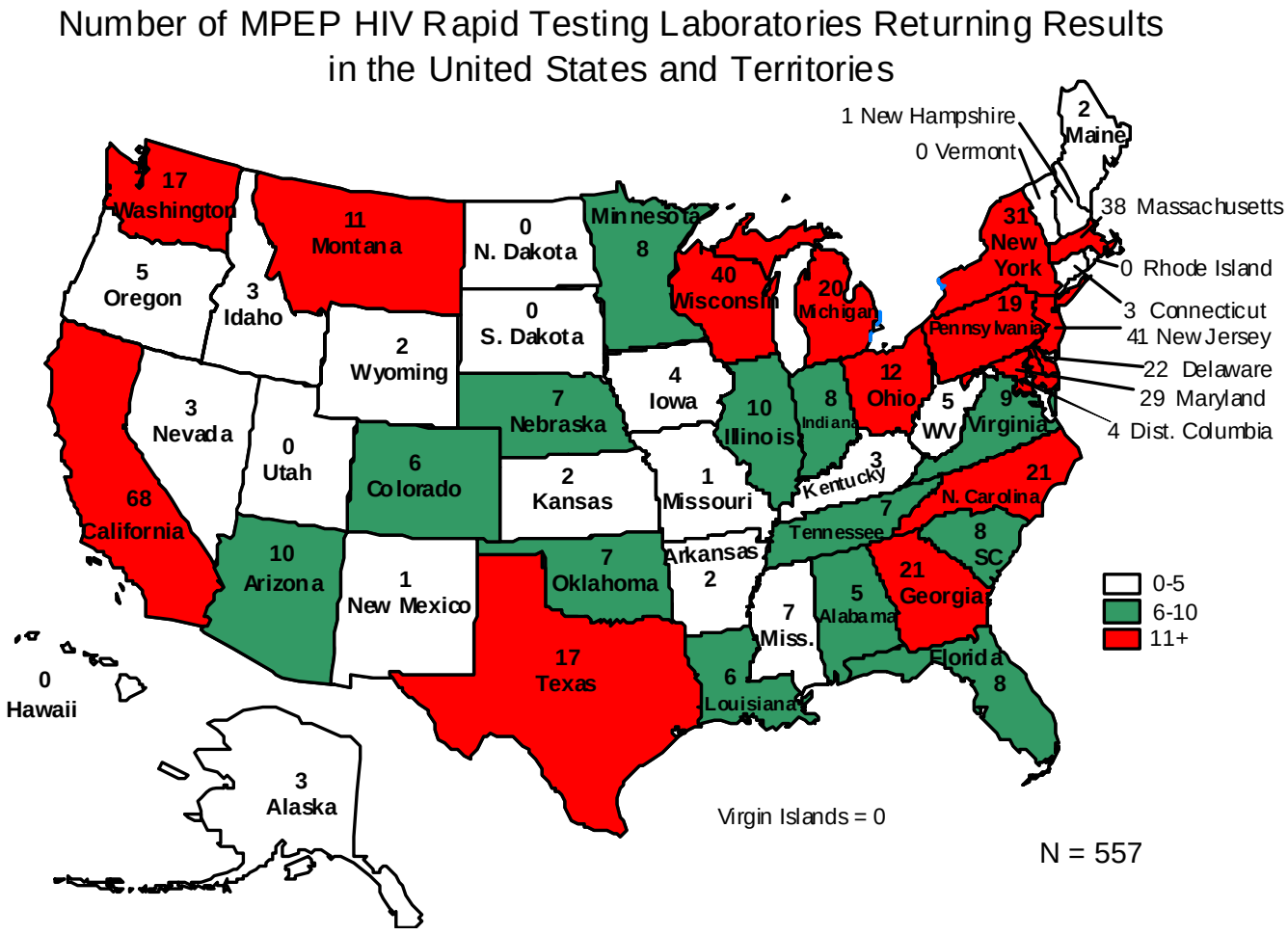
A total number of 622 different testing sites (foreign and domestic) submitted result forms. Of these:

- the 557 domestic testing sites are depicted in ***Figure 1***, and
- the 65 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 (65) was similar to the previous survey (June 2007, n = 69).
- Of the 65 non-U.S. participants, 53 (81.5%) are located in countries which are part of the President's Emergency Plan for AIDS Relief (PEPFAR).
- The number of U.S. participants in the current survey (557) was greater by 9.0% from that of the previous survey (511), primarily due to 44 new enrollees from California and Maryland.
- In the U.S., hospital testing sites predominated.

Figure 1



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Demographics, Continued

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

Table 3

Country	Number	Country	Number
Albania	1	Kenya	1
Australia	2	Liberia	1
Bahamas	1	Malawi	1
Belgium	1	Malaysia	1
Botswana	3	Mali	1
Brazil	1	Nepal	1
Burkina Faso	1	Niger	1
Burundi	1	Nigeria	1
Cameroon	2	Panama	1
Canada	2	Peru	1
Columbia	1	Philippines	3
Congo	1	Republic of Yemen	1
Cote d'Ivoire	1	Senegal	1
Dominican Republic	1	Slovakia	1
El Salvador	1	South Korea	1
Eritrea	1	Suriname	1
Ethiopia	2	Taiwan	1
Ghana	1	Tanzania	6
Guyana	1	Thailand	6
Honduras	1	Zambia	2
India	3	Zimbabwe	2
Indonesia	1		

N = 65

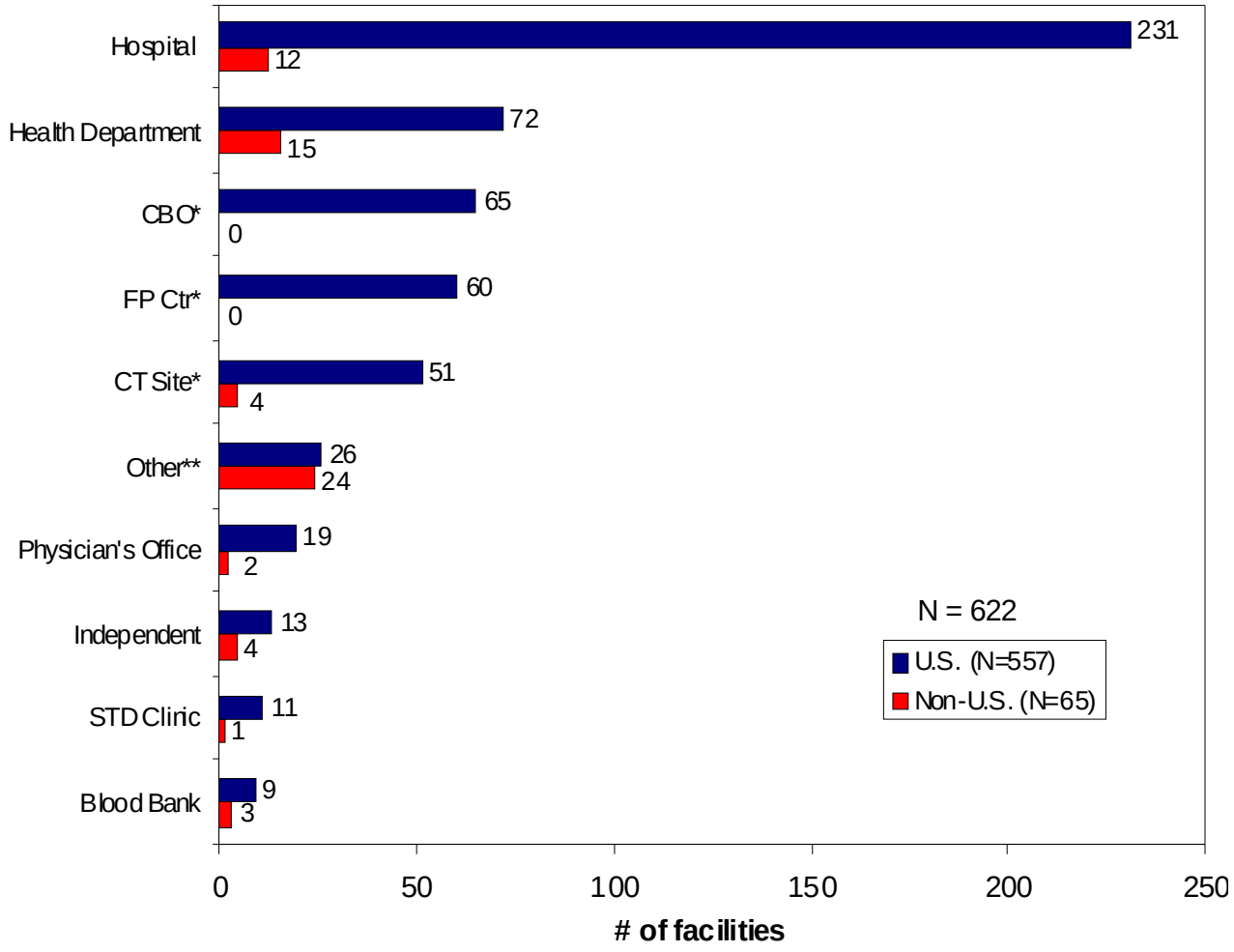
Continued on next page

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
STD clinic = sexually transmitted disease clinic

** "Other" facility type includes:
health maintenance organization (HMO)
correctional facility
drug use treatment center (DTC)
mobile unit (other than blood donation)

Table 4 below gives the reactivity results by donor.

Table 4

Donor Number	Reactivity					
	# of Participants	# of Results*	# Pos.	# Neg.	# Ind	% Correct
27 (Negative)	618**	631	6	625	0	99.0%
13 (Strong Pos)	618	1262	1256	4	2	99.5%
23 (Weak Pos)	618	1262	1229	28	5	97.4%
24 (Weak Pos)	618	628	614	9	5	97.8%

***** Some testing sites used more than one type of testing kit, therefore, the total number of results may exceed the total number of participants.

** Note: Four sites returning responses did not have their MPEP sample testing results included in the analyses. One of the sites gave no testing results; the other three sites reported rapid testing results for which the sample code did not match the sample panel they were shipped and their answers were inconsistent with the sample code they reported.

MPEP plasma samples, detailed performance results

MPEP Negative Sample (Donor 27):

- Six false-positive results were reported; five by U.S. sites, and one by a non-U.S. site.
- No indeterminate results were reported.

MPEP Positive Samples:

- 53 incorrect results were reported on the MPEP HIV-positive samples. Of these:
  - 41 were false negative errors (39 by U.S. and 2 by non-U.S. sites), with
    - 28 errors reported for weak-positive Donor 23,
    - 9 errors reported for weak-positive Donor 24, and
    - 4 errors reported for strong-positive Donor 13.
  - 12 were indeterminate results.
  - Of these positive sample errors, 39/53 (74%) were made as multiple errors by 13 testing sites.

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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)	316	1577	1534	36	7	97.3%	316	316	5	311	0	98.4%	1893	1845	97.5%
Reveal G3 Rapid HIV-1 Antibody Test (MedMira)	63	311	310	1	0	99.7%	63	63	0	63	0	100.0%	374	373	99.7%
Determine HIV-1/2 (Abbott)	42	210	209	1	0	99.5%	42	42	0	42	0	100.0%	252	251	99.6%
Clearview HIV 1/2 Stat-Pak (Inverness Medical)	41	205	205	0	0	100.0%	41	41	0	41	0	100.0%	246	246	100.0%
Uni-Gold Recombigen HIV (Trinity Biotech)	122	610	608	1	1	99.7%	121	121	0	121	0	100.0%	731	729	99.7%
Uni-Gold HIV (Trinity Biotech)	9	45	45	0	0	100.0%	9	9	0	9	0	100.0%	54	54	100.0%
Capillus HIV (Trinity Biotech)	5	25	25	0	0	100.0%	5	5	0	5	0	100.0%	30	30	100.0%
Multispot HIV-1/HIV-2 (Bio-Rad)	9	45	40	1	4	88.9%	9	9	0	9	0	100.0%	54	49	90.7%
Genie II HIV-1/HIV-2 (Bio-Rad)	1	4	4	0	0	100.0%	1	1	0	1	0	100.0%	5	5	100.0%
Serodia HIV (Fujirebio)	2	10	10	0	0	100.0%	2	2	1	1	0	50.0%	12	11	91.7%
Serodia HIV 1/2 (Fujirebio)	4	20	20	0	0	100.0%	4	4	0	4	0	100.0%	24	24	100.0%
HIV 1/2 Stat-Pack (CASSETTE)	2	10	10	0	0	100.0%	2	2	0	2	0	100.0%	12	12	100.0%
Other*	16	80	79	1	0	98.8%	16	16	0	16	0	100.0%	96	95	99.0%

*Other kit types included:

Bioline HIV 1/2 3.0 (Standard Diagnostics); 4 sites;
Doublecheck II (Orgenics), 3 sites;
Hexagon HIV (Human), 3 sites, and one site each reported using:
HIV Cadispots (Cadila Pharm.), Biolytical, NEVA (Cadila Pharm.),
Retrocheck HIV (QualPro Diag.)**, ImmunoComb II HIV 1/2 (Biospot Orgenics), & CombAIDS RS Advantage (Span Diagnostics)

**The site using this kit reported the one false negative in the “Other” category

Kit Types Used By Participants

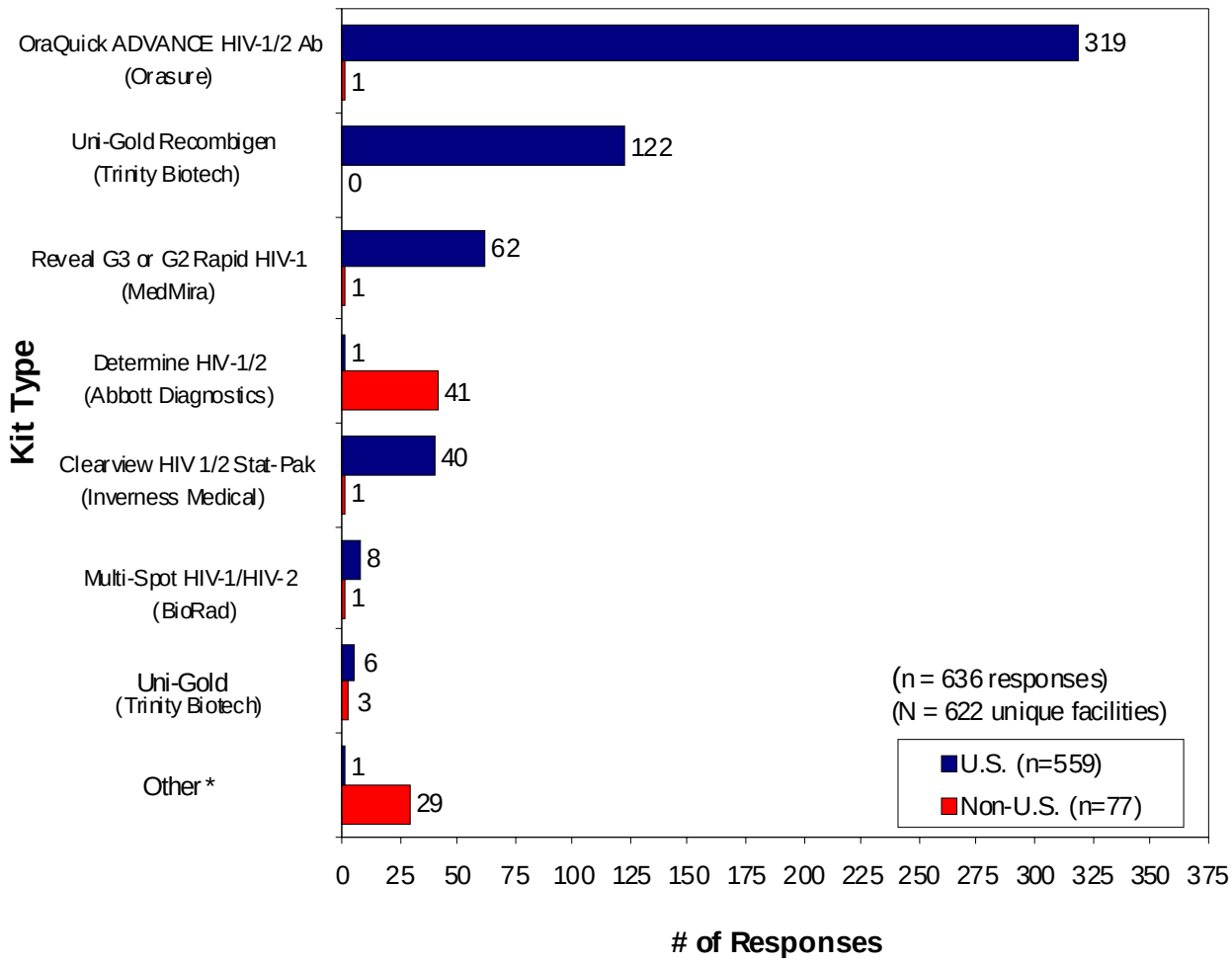
Overview

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 (57.1%, 319/559), as shown in ***Figure 3***:
- The predominant kit type used in non-U.S. testing sites was Abbott Determine HIV-1/2 (53.2%; 41/77).
- Kit usage by lab type is shown in ***Figure 4.***

Figure 3:

Kit types



* "Other" kit types include:

HIV 1/2 Stat-Pak (Cassette) (2 non-US, 0 US responses)
Capillus (Trinity Biotech) (5 non-US, 0 US responses)
Serodia HIV-1/2 (Fujirebio) (4 non-US, 0 US responses)
Serodia HIV (Fujirebio) (2 non-US, 0 US responses)
Genie II HIV-1/HIV-2 (BioRad) (0 non-US, 1 US responses)
Other kit type, specified (16 non-US, 0 US responses); see Table 5 for complete list.

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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 seventeen or less results are included in the "other kit type" category.

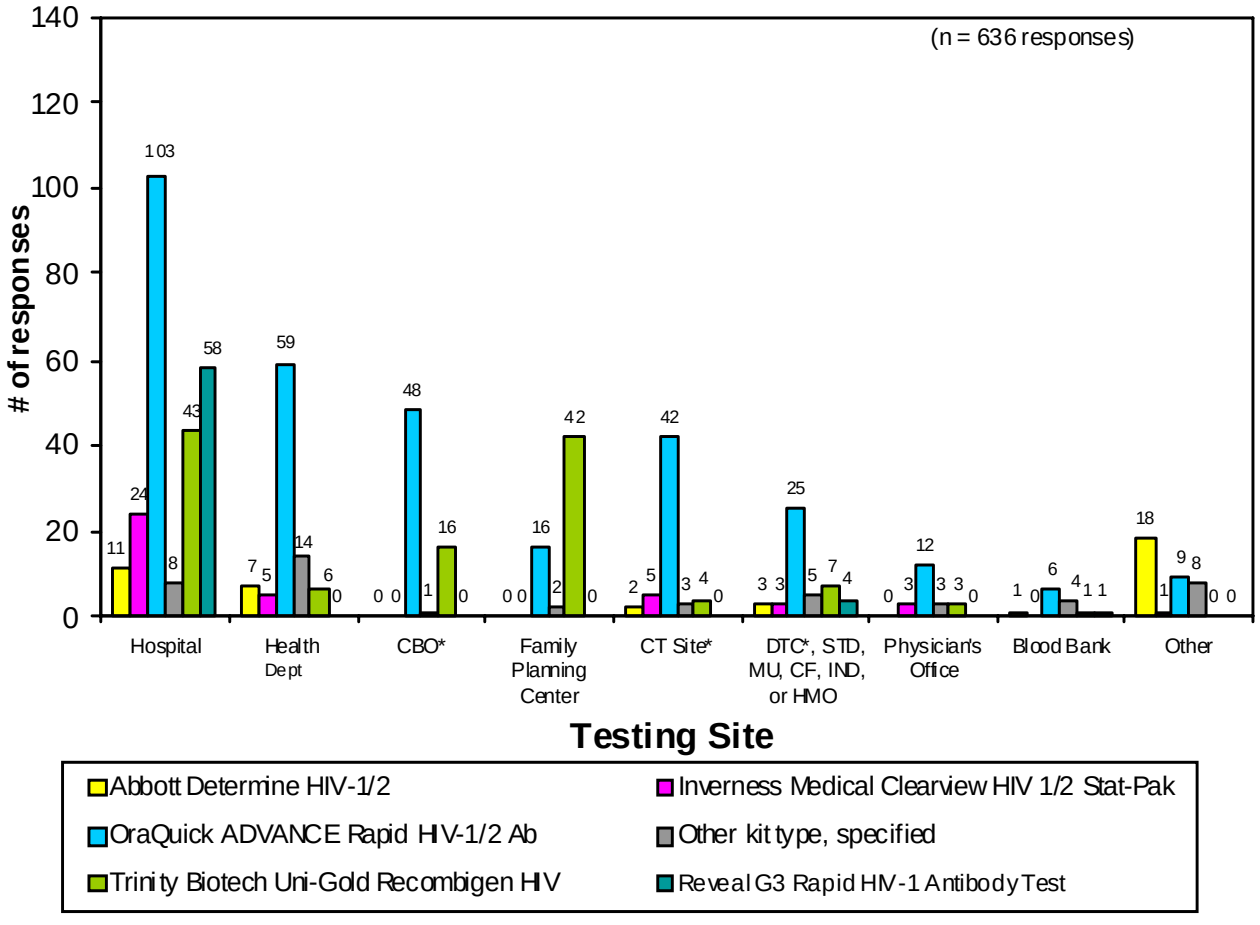
The predominate test kit used was OraQuick ADVANCE Rapid HIV 1/2 Ab Test. The percent of sites using this kit, by type of facility, is as follows:

- hospitals, 41.7%
- health departments, 64.8%
- outreach sites (family planning centers, CT sites, DUTCs, STD clinics, mobile units, correctional facilities, independent sites, and HMOs)*, 50.9%
- CBOs*, 73.8%
- blood banks, 46.2%
- physician offices, 57.1%

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
MU = mobile unit
HMO = health maintenance organization

Specimen Types Used By Participants

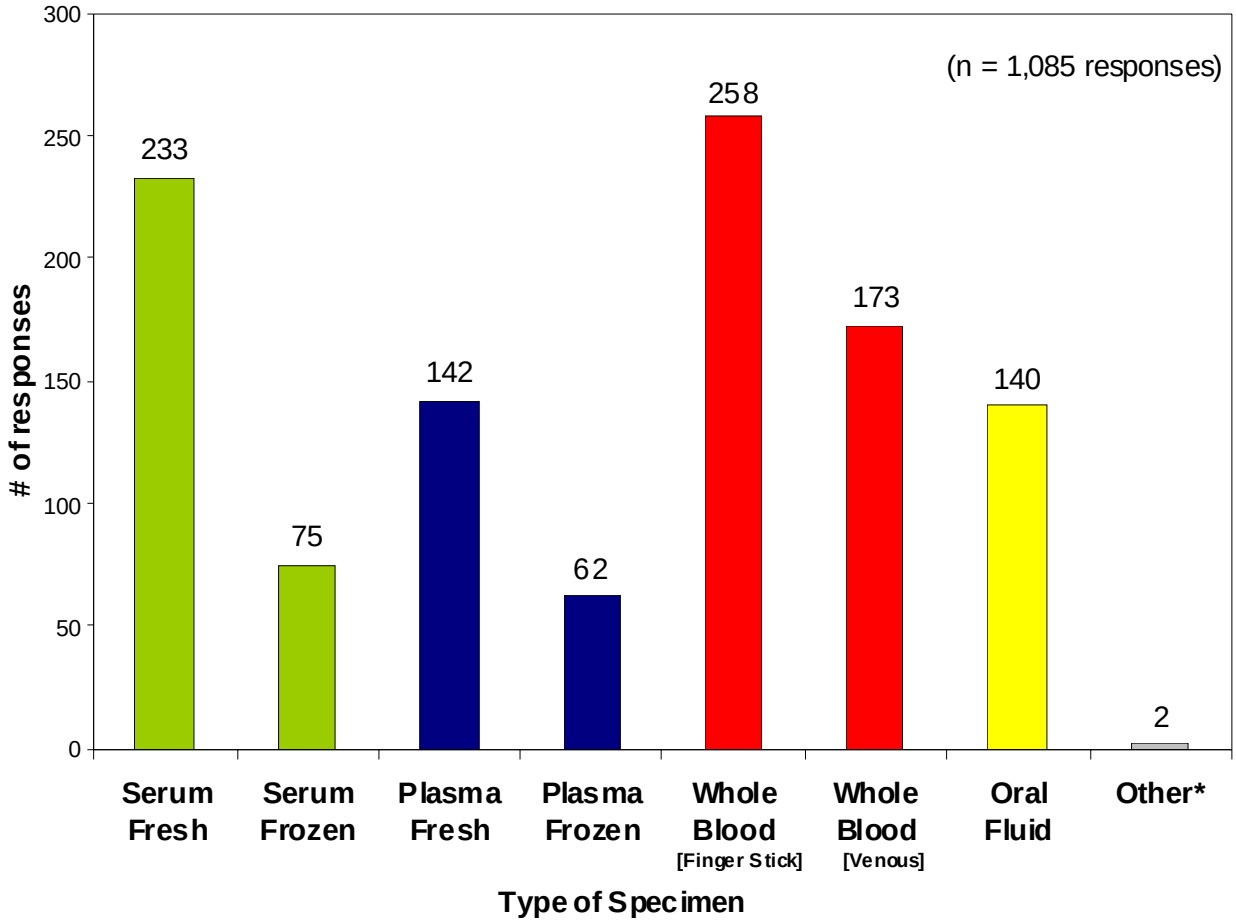
Overview

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



* Both “Other” specimen types were indicated as dried blood spots

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 and percentage of reports indicating use of oral fluid (140/1085, 12.9%) was similar to the previous survey (142/1036, 13.7%).

Quality Control (QC)

Overview

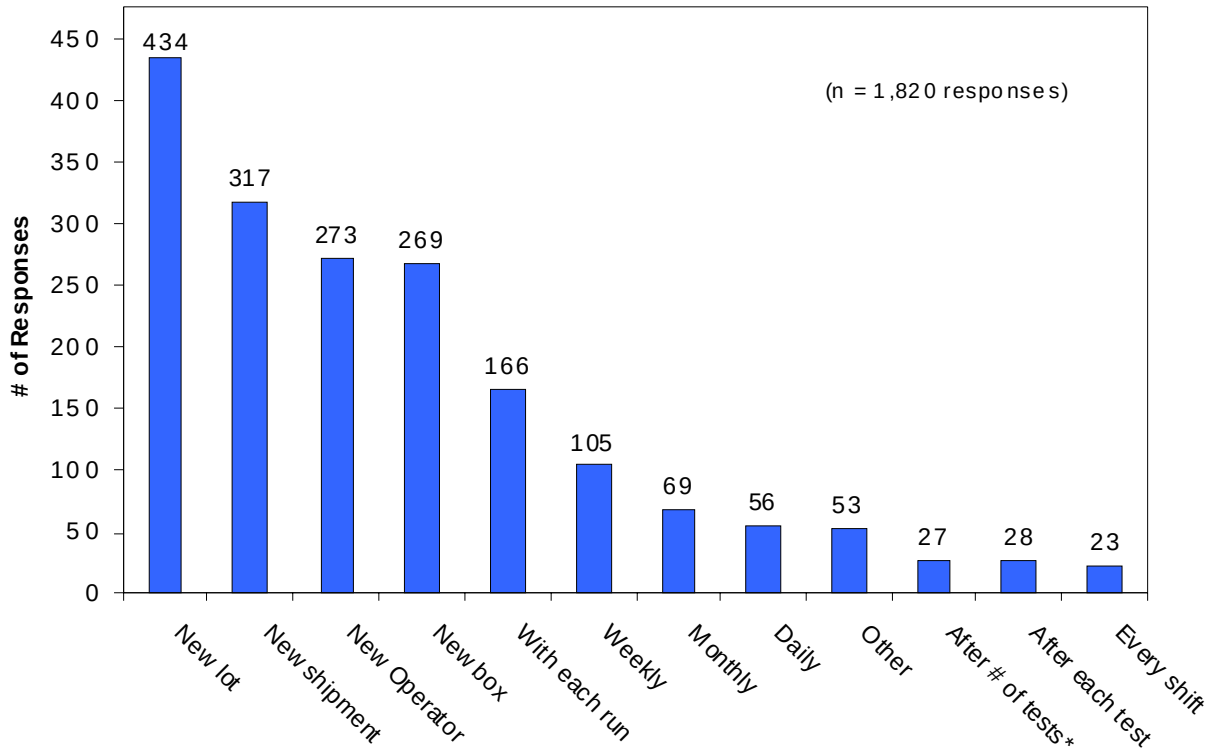
Testing sites were asked if they used quality control (QC) samples, either positive or negative, when performing HIV rapid tests. The frequency of use of quality control materials is shown in ***Figure 6***.

- 621 of the 622 facilities that returned responses answered the question regarding use of quality control samples (question #5).
- Most of these facilities (94.7%, 588/621) indicated the use of QC samples for at least one of the kit types they use at their testing site.
- Of the 1,566 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 (91.2%, 1428/1566),
    - 33.3% (476/1428) were included in the test kit, and
    - 66.7% (952/1428) were purchased from the kit manufacturer separately.
  - in-house controls (6.4%, 100/1566).
  - "Other" manufacturer (manufacturer not the same as for the test kit) controls (2.4%, 38/1566).

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 'after 25 tests' (Range 10-250)

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 (644/988; 65.2%) indicated that reactive (preliminary positive) specimens were sent to another facility.

- In several cases, EIA was performed alone (29/988; 2.9%) or in combination with other testing (203/988; 20.5%).

- Some responses given (140/988; 14.2%) indicated using a second rapid test for confirmatory testing. Of these, 21/140 (15.0%) indicated using a second rapid test with no other type of confirmatory testing.

Twenty-four 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:

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

  - eleven 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): six testing sites.
    - non-clinical testing (e.g. research, training, etc.) and/or determination of HIV-1 vs. HIV-2 reactivity: four testing sites.
    - used for confirmatory testing and determination of HIV-1 vs. HIV-2 reactivity: one testing site.

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

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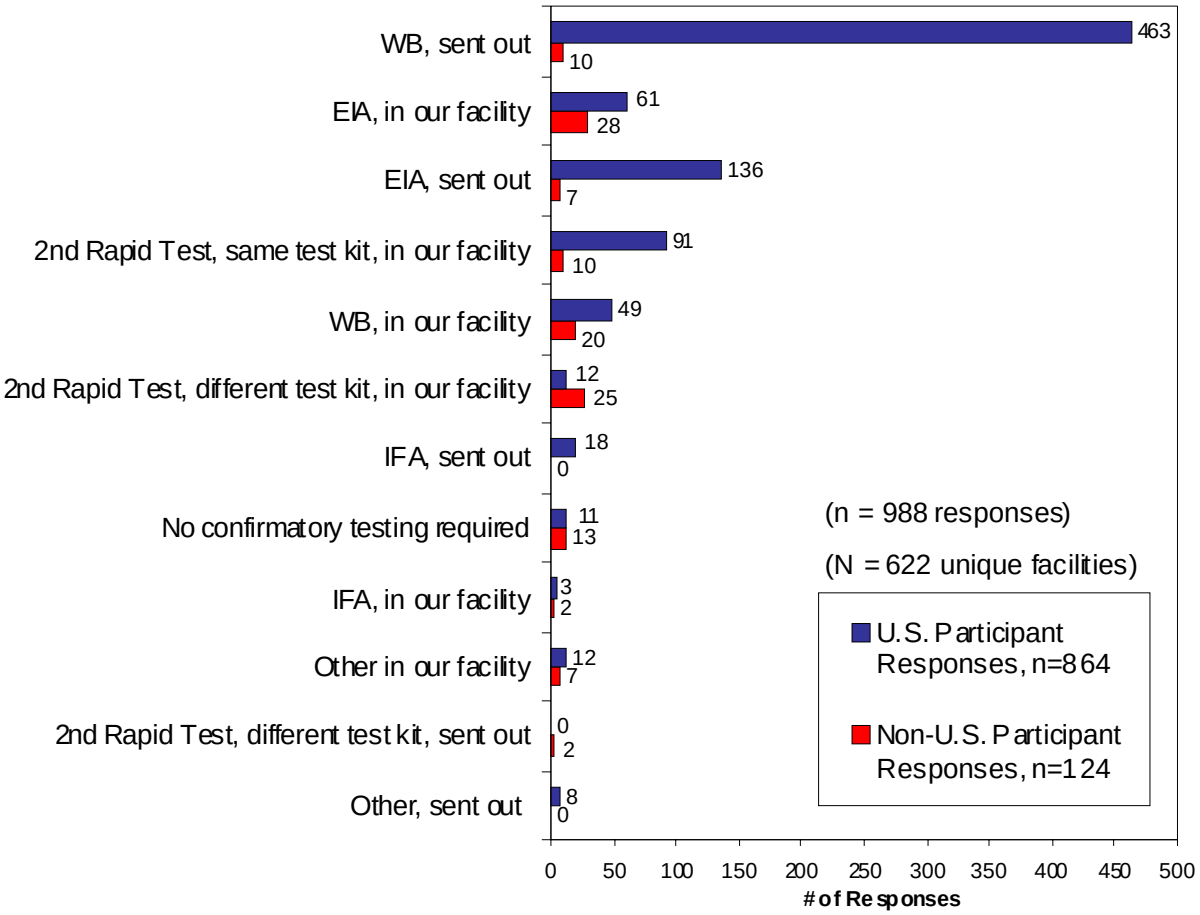
Confirmatory Testing, continued

Figure 7:

Types of confirmatory testing



Conclusions and Discussion

Overall performance

Overall accuracy in this shipment was 98.4%:

- 98.3% for the positive samples;
    - 99.5% for Donor 13 (strong positive),
    - 97.4% for Donor 23 (weak positive), and
    - 97.8% for Donor 24 (weak positive).

- 99.0% for the negative sample (Donor 27).

Specimen types

The number of testing sites reporting the use of oral fluid as one of their normal specimen types (140 responses) remained approximately the same as the previous survey (142 responses). Of these, 138 were U.S. testing sites that tended to be health departments (37/138), community based organizations (CBO) (33/138), counseling and testing sites (28/138), or family planning centers (10/138). The 138 U.S. sites reporting oral fluid use represented 43.3% (138/319) of U.S. sites using the OraQuick ADVANCE HIV-1/2 Antibody test kits.

In this survey, 56 U.S. testing sites reported using serum and/or frozen plasma as specimen types for the OraQuick ADVANCE HIV-1/2 Antibody test kits. 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 a low number of errors on the positive challenge plasma samples (53/3152, 1.7%), lower than the previous two surveys (December 2007 and June 2007), but similar to the June 2006 survey and other previous surveys. The unusually high error rate in the June 2007 & December 2006 surveys has been previously discussed in their respective reports (http://wwwn.cdc.gov/mpep/hiv-1rt.aspx).

A summary of error rates for the past five HIV Rapid Testing MPEP sample surveys is shown below:

- 216/3043 (7.1%) for the June 2007 survey
- 169/2184 (7.7%) for the December 2006 survey
- 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 the false-negative errors in the current survey (28/41; 68.3%) were reported for the weak Donor 23 samples in the performance evaluation panels.

It should be emphasized that all donor material undergoes extensive validation testing prior to inclusion in an HIV Rapid Testing MPEP survey panel.

Continued on next page

Conclusions and Discussion, Continued

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.[1,2]

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]

Guidelines

Testing sites are advised to follow appropriate guidelines with respect to performing HIV rapid tests and reporting results.[1,2] 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 waived HIV rapid tests[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.[1,2]

Continued on next page

Conclusions and Discussion, Continued

References

1. Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988. Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services. July 24, 2007. http://www.cdc.gov/hiv/topics/testing/resources/guidelines/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 2007 survey

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

Q: Will we be getting an individual report (or grade) from the MPEP?

A: No. The MPEP provides a "Donor Report", which is mailed one to two weeks after the submission deadline, for our participants to self-grade. The Donor Report (see Table 1, pg 3) provides the correct results for each donor and panel shipped for the current survey.

Highlights of previous FAQs

Q: (from U.S. testing sites) If we participate in your program, will we be satisfying the legal requirements for performing HIV rapid testing on client/patient samples?

A: Not necessarily. The MPEP is not part of any regulatory body; we maintain the confidentiality of our participants' results. You should check with your state department of health for specific information regarding legal approval for performing HIV rapid testing on clinical specimens.

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.

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

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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://wwwn.cdc.gov/mpep/hiv-1rt.aspx

CDC websites

Quick Facts: Rapid Testing
http://www.cdc.gov/hiv/topics/testing/index.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 Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988. Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services. July 24, 2007.
http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa_guide.htm

International Laboratory-related Resource and Activity Directory
http://wwwn.cdc.gov/dls/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://wwwn.cdc.gov/mpep/hiv-1rt.aspx

Model Performance Evaluation Program (MPEP) Home page: http://wwwn.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/default.htm

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

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