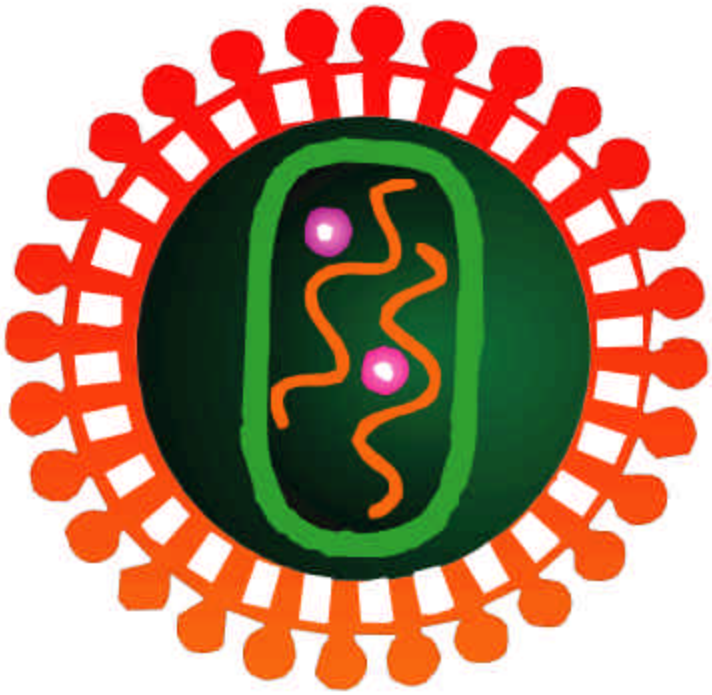
MPEP

HIV Rapid Testing

Report of Sample Shipment Results, August 2004



DEPARTMENT OF HEALTH & HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV-1 Rapid Testing MPEP August 2004 Report of Results

Report of the August 2004 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

Table 1 **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	7	Positive (S)	Infected	_____	_____
	A2	15	Positive (W)	Infected	_____	_____
	A3	3	Negative	Uninfected	_____	_____
	A4	2	Positive (W)	Infected	_____	_____
	A5	3	Negative	Uninfected	_____	_____
	A6	15	Positive (W)	Infected	_____	_____
B	B1	15	Positive (W)	Infected	_____	_____
	B2	2	Positive (W)	Infected	_____	_____
	B3	15	Positive (W)	Infected	_____	_____
	B4	3	Negative	Uninfected	_____	_____
	B5	7	Positive (S)	Infected	_____	_____
	B6	3	Negative	Uninfected	_____	_____
C	C1	15	Positive (W)	Infected	_____	_____
	C2	3	Negative	Uninfected	_____	_____
	C3	3	Negative	Uninfected	_____	_____
	C4	15	Positive (W)	Infected	_____	_____
	C5	2	Positive (W)	Infected	_____	_____
	C6	7	Positive (S)	Infected	_____	_____
D	D1	7	Positive (S)	Infected	_____	_____
	D2	15	Positive (W)	Infected	_____	_____
	D3	3	Negative	Uninfected	_____	_____
	D4	3	Negative	Uninfected	_____	_____
	D5	15	Positive (W)	Infected	_____	_____
	D6	2	Positive (W)	Infected	_____	_____

[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), as well as with selected FDA-licensed Enzyme Immunoassay (EIA) and Western Blot (WB) kits. All reactive samples were confirmed positive by WB. 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 third HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) shipment. It represents a collection of results reported by a variety of testing sites using different HIV rapid test kits on six plasma samples from four donors.

Sample shipment description

The plasma samples for this challenge shipment of the HIV-RT MPEP were shipped in August 2004.

The six plasma samples from four donors included:
- a strong HIV-antibody positive sample,
- two HIV-antibody negative samples from one donor sent in duplicate, and
- three weak positive samples derived from two seroconverter donors, with one of the donors sent in duplicate.

Response rate

The survey shipment was 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 (85.2%) were from U.S. testing sites, and
- 57 (14.8%) were from non-U.S. testing sites.

Notes:
1. Twelve testing sites submitted multiple forms, indicating the use of from one to seven different test kits, so that the total number of responses was 406.
2. Four sites reported results for the wrong panel and these results were therefore excluded from the analyses.

Description of challenge samples

All plasma samples were single bleeds drawn from individual donors. The resulting plasma was tested to determine HIV-1 reactivity. The samples for the August 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 56°C 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.

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Description of challenge samples (continued)

- Positive samples were selected using the following criteria:
  - reactive by the Genetic Systems rLAV enzyme immunoassay (EIA) kit at a signal-to-cutoff ratio between 3 and 5 for the 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 seroconverter samples were included in the shipment in duplicate.

Summary of findings

The major findings described in this report include the following:

1. Performance results grouped by positive, weak positive, negative and all samples are summarized below:

Sample Type	Overall Accuracy*	Range (by kit)
Positive (strong + weak)	99.4% (1597/1606)	97.1% - 100%
Positive (weak only)	99.3% (1195/1204)	96.1% - 100%
Negative	99.5% (795/799)	99.2% - 100%
All samples	99.5% (2392/2405)	98.1% - 100%

* Accuracy is defined as the percentage of correct results

2. All of the nine incorrect results on positive challenge samples were false negative interpretations that were reported for weak positive samples:
   - Eight out of nine of these (88.9%) were reported for donor 15; the other false negative was reported for donor 2 (see Tables 4 and 5 for complete results).
   - Of the nine false negative reported results:
     - five were reported using the OraQuick test,
     - two were reported using the Reveal Rapid HIV-1 Antibody test and
     - two were reported using an “other” test kit.
3. There were four incorrect results on the negative challenge (donor 3):
   - The three false positive results were reported by three different sites using the OraQuick test.
   - The one “indeterminate” result was reported for the MedMira Reveal Rapid HIV-1 test.

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Summary of findings (continued)

4. There were seven results reported as "invalid" by several sites. The table below summarizes the results:

# Sites	# Results	Test Kit	Donor # (Target Value)
1	1	OraQuick Rapid HIV-1 Antibody Test	3 (Neg)
1	1	MedMira Rapid HIV Antibody Test	3 (Neg)
2	3	Reveal Rapid HIV-1 Antibody Test (MedMira)	3 (Neg)
1	2	Reveal Rapid HIV-1 Antibody Test (MedMira)	15 (Pos)

- The site using the OraQuick Rapid HIV-1 Antibody Test reported one "invalid" result with no other comment,
- The sites using the Reveal Rapid HIV-1 Antibody Test and MedMira Rapid HIV Antibody Test reported the six "invalid" results and provided comments indicating absorption difficulties with the specimens.

5. A total of 59% (226/383) of respondents reported normally running some type of external quality control when performing HIV rapid tests; one facility did not answer the question.

Demographics

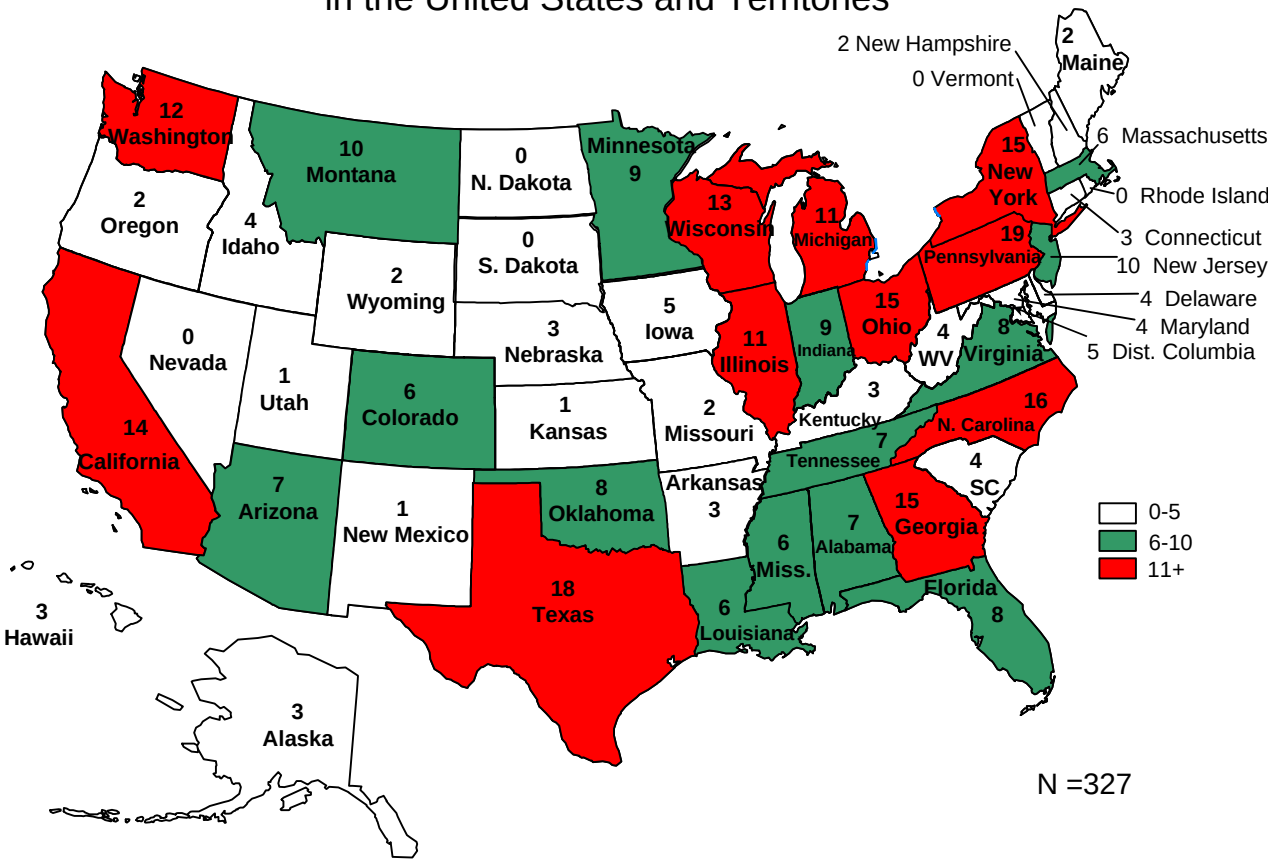
Overview

The total number of different testing sites (foreign and domestic) submitting results was 384. Of these:

- The 327 United States (domestic) testing sites are depicted in ***Figure 1***.
- The 57 foreign testing sites are listed in ***Table 2***.
- The types of testing site participants responding are depicted in ***Figure 2***:
  - in the U.S., hospital testing sites predominated.
  - the number of U.S. participants increased from the May 2004 survey.
  - generally, the number of participants in most non-U.S. sites was similar to the May 2004 survey.

Figure 1

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



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Demographics, Continued

The following table shows the breakdown of participants outside the United States, for this MPEP shipment.

Table 2

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

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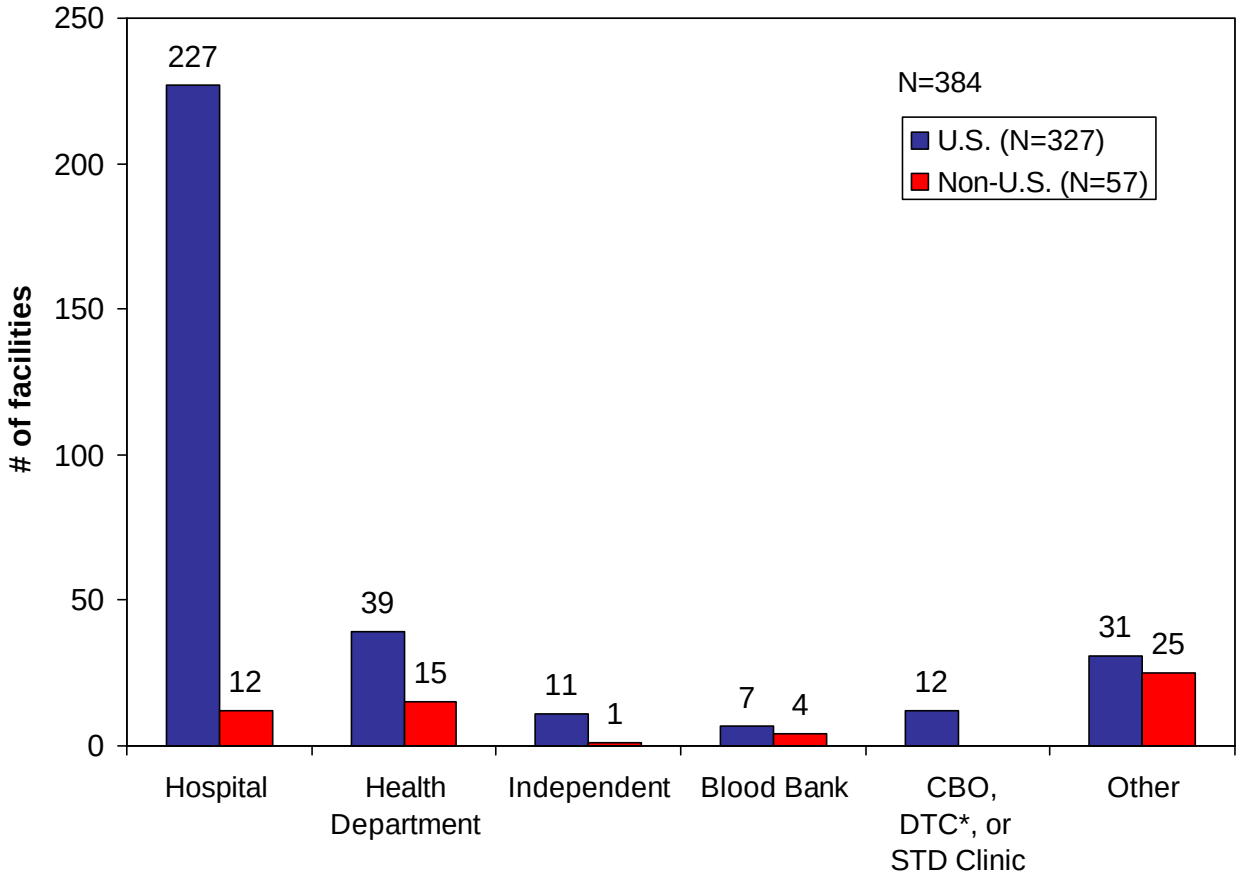
Demographics, Continued

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. and non-U.S.



*DTC = Drug Treatment Center

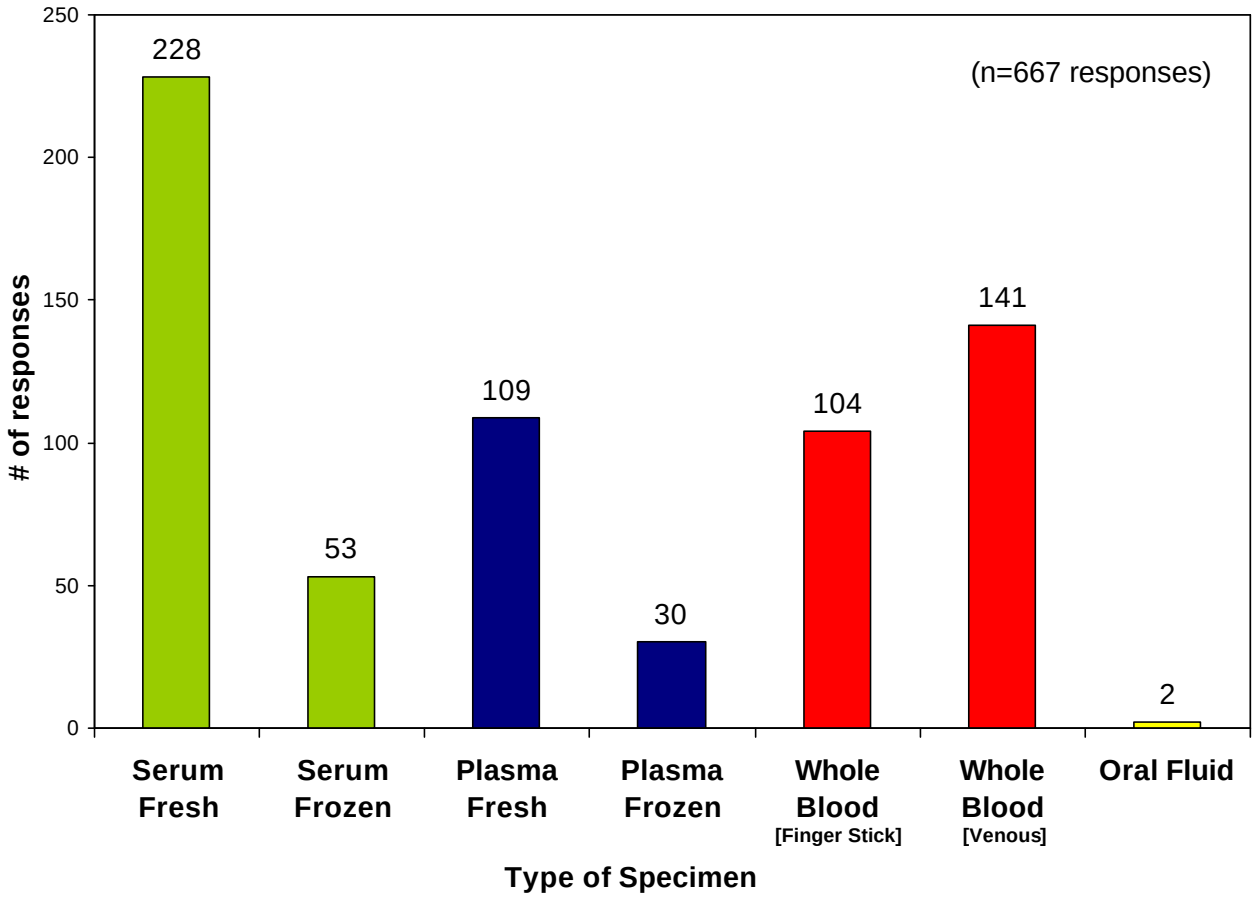
Specimen Types Used by Participants

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

Overview

- Most specimens typically used for HIV rapid testing were either serum or plasma, as shown in ***Figure 3***.
- Testing sites could report using more than one specimen type.
- Testing sites that used the whole-blood finger stick specimens typically used the OraQuick Rapid HIV-1 Antibody Test testing method (91/104).
- Two U.S. labs reported using oral fluid specimens with the OraQuick test.

Figure 3: specimen types



Kit Types Used by Participants

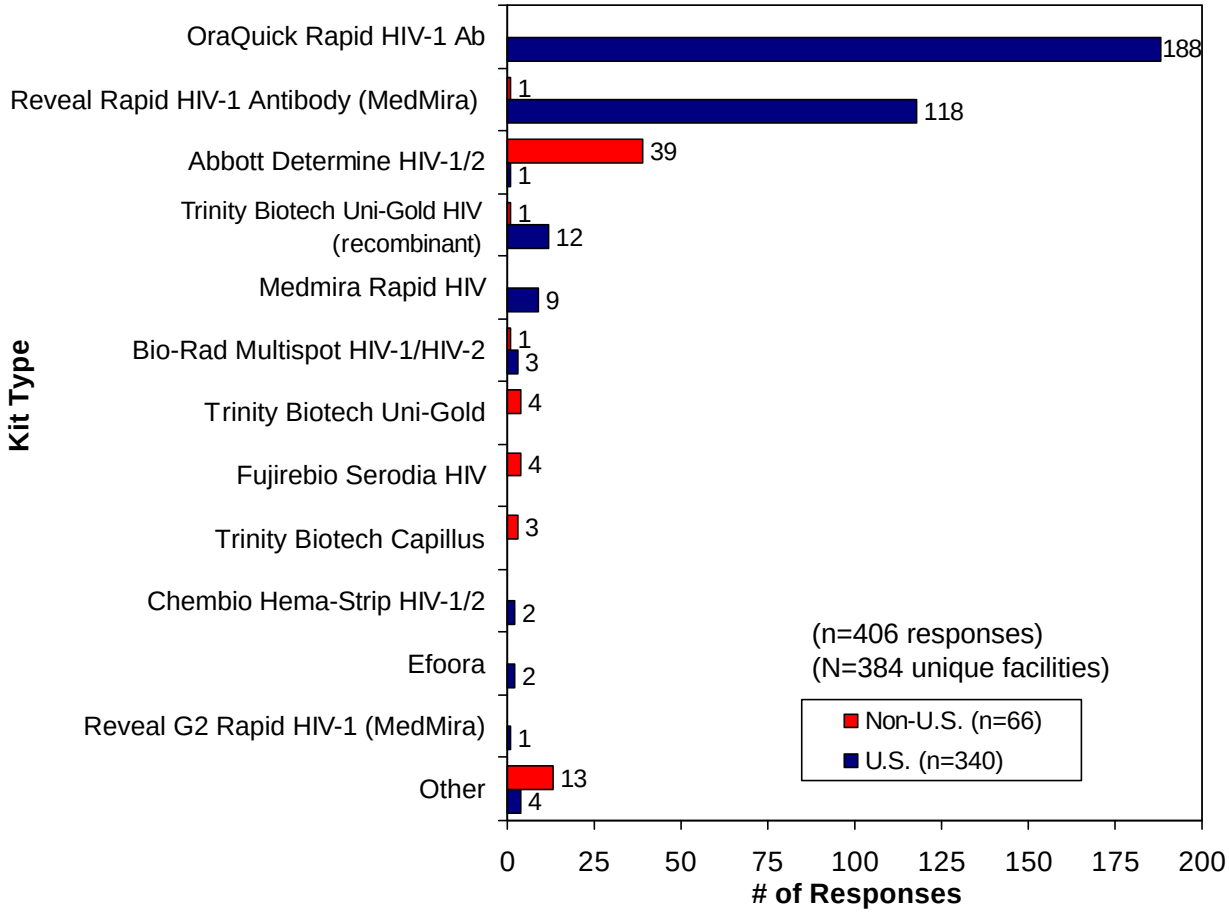
Overview

This section describes the kit types used by participants. The predominant kit types used were:

- OraQuick Rapid HIV-1 Ab (46.3%, 188/406),
- All MedMira HIV rapid tests (31.8%, 129/406), and
- Abbott Determine HIV-1/2 (9.9%, 40/406) as shown in ***Figure 4***.
- Kit usage by lab type is shown in ***Figure 5.***
- U.S. laboratories typically used the following FDA-approved kit types (93.5%, 319/340). These kits are:
  - OraSure OraQuick Rapid HIV-1 Antibody Test,
  - MedMira Reveal or Reveal G2 Rapid HIV-1 Antibody Test, and
  - Trinity Biotech Uni-Gold Recombigen HIV test.

Note:
Test kits for which less than three interpretations were reported were included in the "other" category.

Figure 4: Kit types



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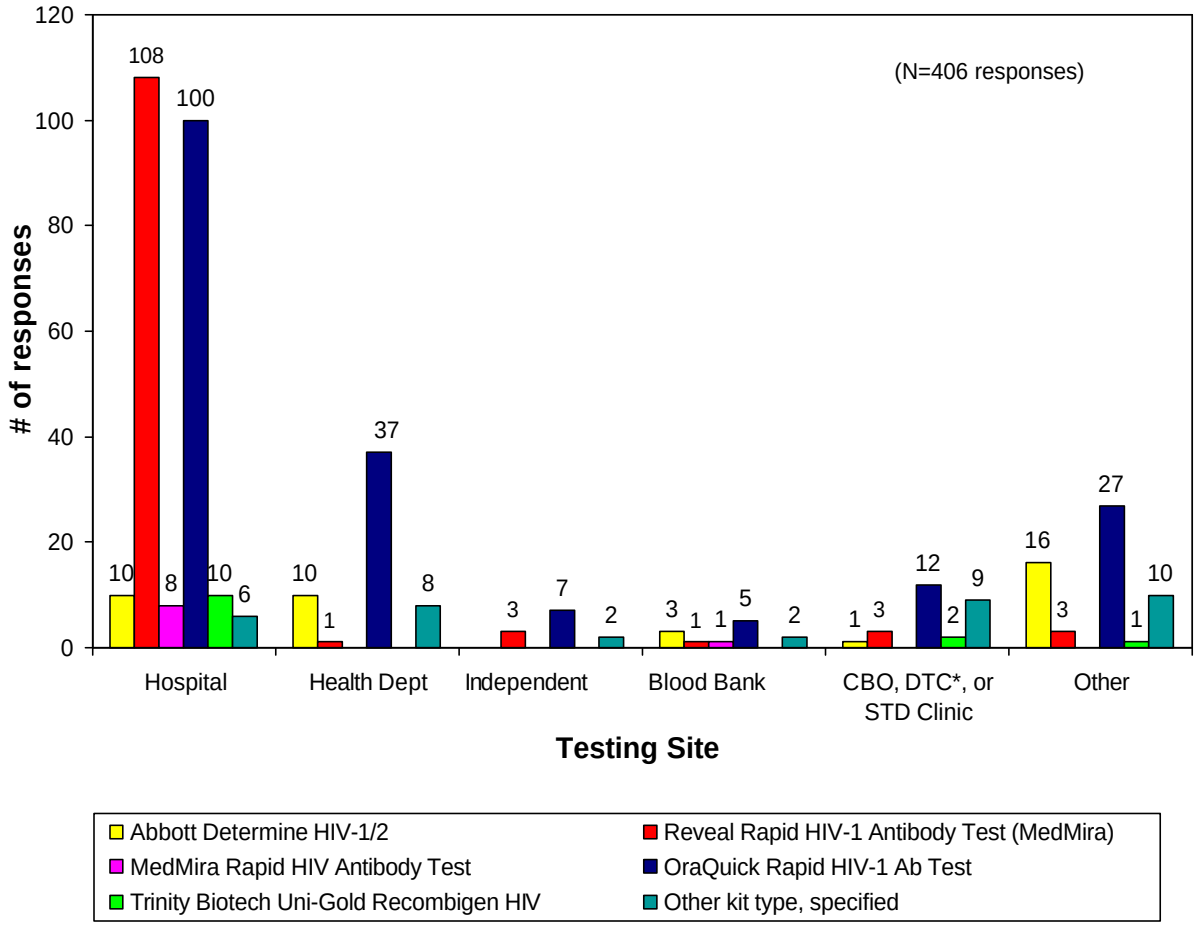
Kit Types Used by Participants, Continued

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

Figure 5:

Testing site by kit type



*DTC = Drug Treatment Center

Performance Results

Overview

The following figures and tables refer to the accuracy (% of correct responses out of the total number of responses) for this HIV-RT shipment.

- The overall accuracy for HIV-antibody positive samples was 99.4% (range 97.1% to 100%).
- The percentages of all reported positive and negative results are shown, by donor, in ***Table 3***.
- The results for all participants by kit type are shown in ***Table 4***.
- The overall accuracy for the weak positive donors (Donors 2, 15, and donor 15 duplicate) was 99.3% (96.1-100%) as shown in ***Table 5.***
- Eight out of the nine false negative results were reported for donor 15; the other false negative was reported for donor 2.
- Out of three false positive results, one was reported by a hospital testing site, and one each by a health department and an "other" testing site using FDA-approved test kits.

Table 3: Percentages of positive/ negative results by donor

The following table gives the percent of positive reported results for donors 2, 7, and 15 (the positive donors) and the percent of negative reported results for donor 3 (the negative donor).

	Reactive/Positive			Non-Reactive/Negative		
Donor Number	**# of Participants**	**# of Results**	**% Positive**	**# of Participants**	**# of Results**	**% Negative**
2	380	402	99.8%	n/a	n/a	n/a
3	n/a	n/a	n/a	379	799	99.5%
7	380	402	100.0%	n/a	n/a	n/a
15	379	802	99.0%	n/a	n/a	n/a

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Performance Results, Continued

Table 4: Results for all samples (Donors 2, 3, 7 and 15)

Kit Type	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 Rapid HIV-1 Ab	187	752	747	5		99.3%	187	375	3	372		99.2%	1127	1119	99.3%
Reveal Rapid HIV-1 Test (MedMira)	118	470	468	2		99.6%	117	233		232	1	99.6%	703	700	99.6%
Abbott Determine HIV-1/2	39	156	156			100.0%	39	78		78		100.0%	234	234	100.0%
Other	15	68	66	2		97.1%	15	34		34		100.0%	102	100	98.0%
Trinity Biotech Uni-Gold Recombigen HIV	13	52	52			100.0%	13	26		26		100.0%	78	78	100.0%
MedMira Rapid HIV	9	36	36			100.0%	9	17		17		100.0%	53	53	100.0%
Bio-Rad Multispot HIV-1/HIV-2	4	16	16			100.0%	4	8		8		100.0%	24	24	100.0%
Fujirebio Serodia HIV	4	16	16			100.0%	4	8		8		100.0%	24	24	100.0%
Trinity Biotech Uni-Gold	3	12	12			100.0%	3	6		6		100.0%	18	18	100.0%
Efoora HIV Rapid Test	2	8	8			100.0%	2	4		4		100.0%	12	12	100.0%
Chembio Hema-Strip HIV-1/2	2	8	8			100.0%	2	4		4		100.0%	12	12	100.0%
Trinity Biotech Capillus	2	8	8			100.0%	2	4		4		100.0%	12	12	100.0%
Reveal G2 Rapid HIV-1 Antibody Test (MedMira)	1	4	4			100.0%	1	2		2		100.0%	6	6	100.0%

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Performance Results, Continued

Table 5: Results for weak positives (Donors 2 and 15)

Kit Type	Reactive/Positive					
	# of Sites	# of Results	# Reactive	#Non-Reactive	# Indeter	% Correct
OraQuick Rapid HIV-1 Ab	187	564	559	5		99.1%
Reveal Rapid HIV-1 Test (MedMira)	118	352	350	2		99.4%
Abbott Determine HIV-1/2	39	117	117			100.0%
Other	15	51	49	2		96.1%
Trinity Biotech Uni-Gold Recombigen HIV	13	39	39			100.0%
MedMira Rapid HIV Ab	9	27	27			100.0%
Bio-Rad Multispot HIV-1/HIV-2	4	12	12			100.0%
Fujirebio Serodia HIV	4	12	12			100.0%
Trinity Biotech Uni-Gold	3	9	9			100.0%
Efoora HIV Rapid Test	2	6	6			100.0%
Chembio Hema-Strip HIV-1/2	2	6	6			100.0%
Trinity Biotech Capillus	2	6	6			100.0%
Reveal G2 Rapid HIV-1 Antibody Test (MedMira)	1	3	3			100.0%

Quality Control

Overview

Testing sites were asked if they used external quality control, i.e., controls not included in the test kit, when performing HIV rapid tests.

- 383 out of 384 facilities that returned responses answered the question regarding use of external quality controls (question #6).
  – Over half (59%, 226/383) indicated the use of external quality control.

- The sources of the external controls tended to be either:
  – controls obtained from the same manufacturer (76.5%, 173/226) or
  – in-house controls (14.6%, 33/226).

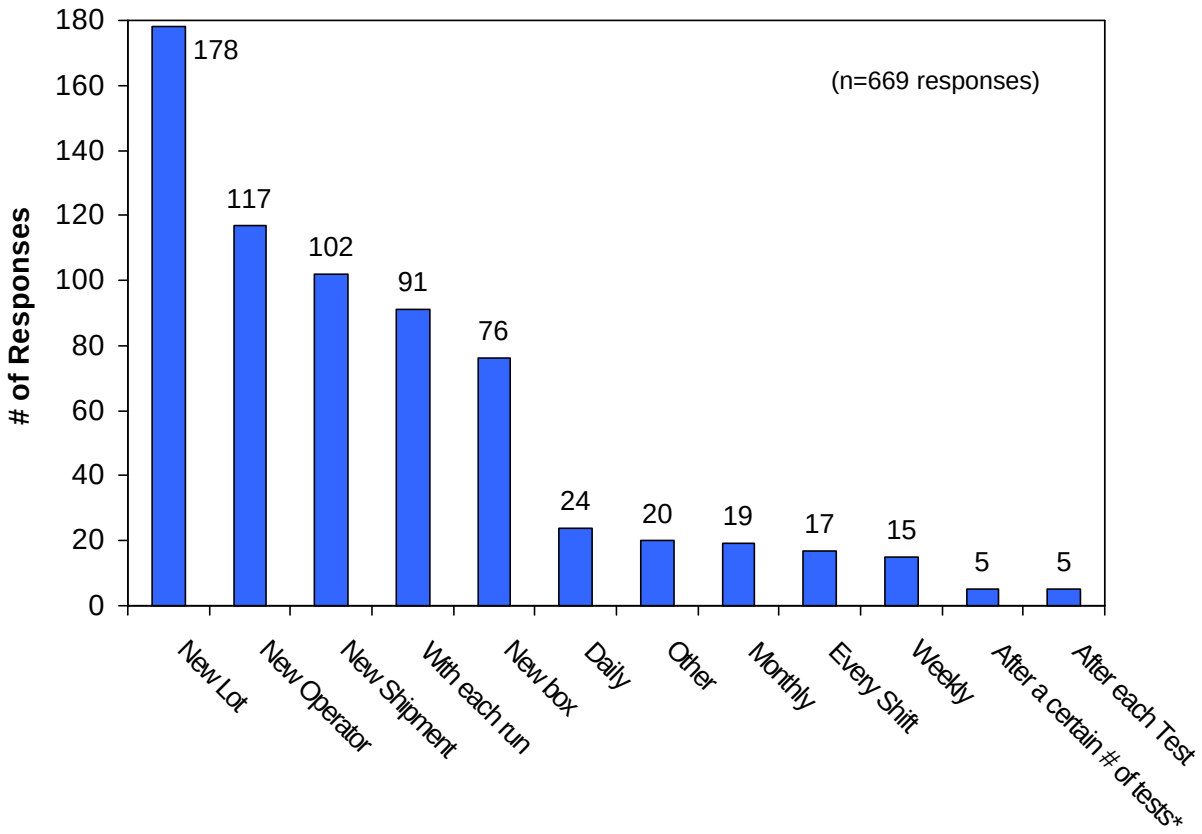
- The frequency of use of external quality control materials is shown in ***Figure 6***.

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 external controls



* The most frequent response was 25 tests (Range 1-60)

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.

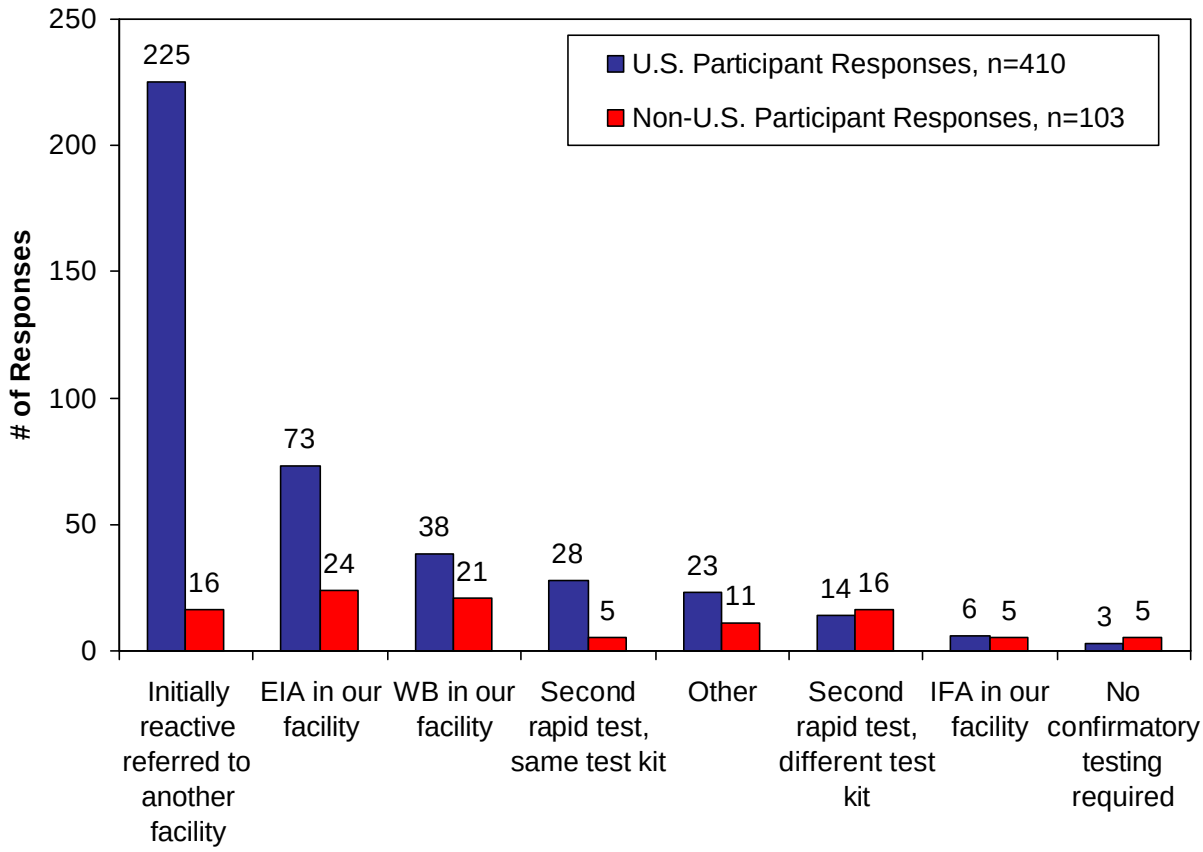
- Many participants (338/513; 65.9%) reported either
  - sending the reactive (preliminary positive) specimens to another facility (241/513; 47.0%), or
  - performing EIA alone or in combination with other tests (18.9%; 97/513).

- Several participants (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.

Eight participants reported that no confirmatory testing was required prior to reporting a positive result. The circumstances surrounding the use of HIV rapid tests without confirmatory testing are unclear.

Figure 7:

Types of confirmatory testing



Conclusions and Discussion

Overall performance

Overall, testing sites performed well in this MPEP shipment.

- Overall accuracy (% of correct results) for all samples, by all sites with all kit types, was 99.5% (2392/2405).
- Most of the incorrect results were reported by multiple sites on one of the weak positive challenges.
- All incorrect results were reported by testing sites using the two predominant kit types, except for one site using an "other" kit type. This could be due to
  - the fact that many more results were reported by sites using these kits than for sites using any other kit types, thus increasing the chances of observing errors with the predominant kits,
  - varying conditions in sites using these kits, or
  - other factors that were not measured in this survey.

Confirmatory testing

This survey included a question regarding confirmatory testing.

- The intent was to measure whether or not the testing sites require that confirmatory testing be done on preliminary positive (reactive) samples before reporting a final "positive" result.
- Participants reported a variety of schemes for doing confirmatory testing.
- Some U.S. labs are apparently using algorithms other than the WB or IFA as recommended by CDC.

U.S. participants 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 (1,3) .

Quality control

The proportion of facilities that reported normally running external quality control material when performing HIV rapid testing (59%) is similar to that observed in the May 2004 shipment (56.5%).

The question on frequency of use of external quality control material allowed more than one answer to be given, i.e. facilities may indicate they use this material in a variety of circumstances. Of the 669 responses received:

- 435 (65%) reported only one type of occasion for use,
- 234 (35%) reported using external QC for two or more types of occasions.

Other types of errors

There were some errors made by some participants that impact Quality Assurance (QA) for HIV Rapid Testing, including:

1. Incorrect reporting of the panel letter (A, B, C or D).

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Conclusions and Discussion, Continued

Other types of errors (continued)

2. Testing the wrong panel for the current survey, e.g. pulling an old survey from storage and mistakenly using it instead of the current panel.

Performance evaluation data with these types of errors are not included in MPEP analyses.

It should be noted that these types of errors could be analogous to testing and/or reporting the results of the wrong patient or client. It is very important for testing personnel to consistently practice the careful examination of all specimen labels in order to ensure that the correct specimen is tested.

Guidelines

Testing sites should 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).

Discussion 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

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: August survey

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

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, positives samples 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.

Previous FAQs

Q: The MPEP letter that came with the HIV rapid testing samples says that your samples are previously frozen plasma, but we use whole blood for our HIV rapid testing. Can we use your samples?
A: Our samples have been validated (i.e. checked to make sure they can be used) for all FDA[3] approved HIV rapid testing kits, including those that use whole blood. If your kit requires special steps for using previously frozen plasma (see your kit's package insert) then these steps should be taken prior to using our samples.

Q: What protocol should we follow for testing MPEP HIV rapid testing samples?
A: Our samples should be tested according to the methodology described by the manufacturer in your HIV rapid testing kit's package insert. Specific questions about technique should be addressed to the manufacturer's technical support area.

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Topical Issues in HIV Rapid Testing ,Continued

Previous FAQs (continued)

Q: We need more control sample material for training purposes. Can you supply us with extra sample material so we can practice with it?
A: No. While we recognize that extra sample volume (i.e. not used to do the test for the survey shipment) in our current panels has been, and will be, used effectively as material for training/practice purposes, we do not have sufficient "left-over" sample material to distribute specifically for those purposes. However, similar material is available from commercial sources.

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

HIV rapid testing resources

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

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

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

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

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

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