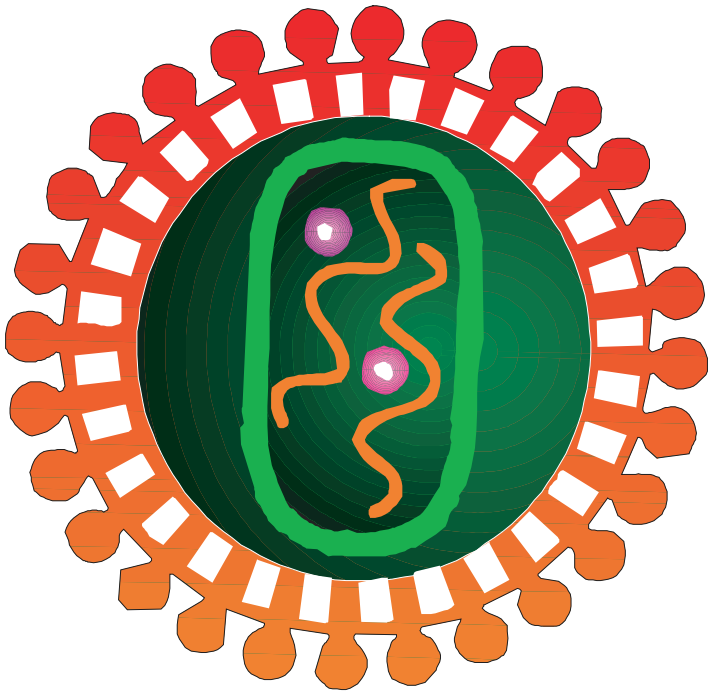
MPEP

HIV Rapid Testing

Report of Sample Shipment Results, June 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HIV-1 Rapid Testing MPEP June 2005 Report of Results

Report of the June 2005 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	11	Positive (S)	Infected	_____	_____
	A2	1	Positive (W)	Infected	_____	_____
	A3	11	Positive (S)	Infected	_____	_____
	A4	9	Positive (W)	Infected	_____	_____
	A5	9	Positive (W)	Infected	_____	_____
	A6	4	Negative	Uninfected	_____	_____
B	B1	1	Positive (W)	Infected	_____	_____
	B2	11	Positive (S)	Infected	_____	_____
	B3	9	Positive (W)	Infected	_____	_____
	B4	11	Positive (S)	Infected	_____	_____
	B5	4	Negative	Uninfected	_____	_____
	B6	9	Positive (W)	Infected	_____	_____
C	C1	9	Positive (W)	Infected	_____	_____
	C2	9	Positive (W)	Infected	_____	_____
	C3	11	Positive (S)	Infected	_____	_____
	C4	4	Negative	Uninfected	_____	_____
	C5	11	Positive (S)	Infected	_____	_____
	C6	1	Positive (W)	Infected	_____	_____
D	D1	9	Positive (W)	Infected	_____	_____
	D2	9	Positive (W)	Infected	_____	_____
	D3	4	Negative	Uninfected	_____	_____
	D4	11	Positive (S)	Infected	_____	_____
	D5	1	Positive (W)	Infected	_____	_____
	D6	11	Positive (S)	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) 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 sixth 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 plasma samples from four donors.

The major findings are summarized below.

Response rate

The shipment survey was sent to 493 testing sites within and outside of the United States. Responses were received from 459 of the testing sites (93.1%). Of those responding:

- 391 (85.2%) were U.S. testing sites, and
- 68 (14.8%) were non-U.S. testing sites.

Note:

Eighteen testing sites submitted multiple result forms, indicating the use of from one to six different test kits, so that the total number of responses was 486.

Overall Performance

Overall accuracy (percent of correct results) for all samples, by all sites with all kit types, was 98.9% (2864/2897). "Indeterminate" result interpretations were considered to be incorrect and "Invalid" result interpretations were not included in the analyses. (Twelve invalid results were reported by eight testing sites. These tended to be related to the use of flow-through testing devices or technical problems such as spills).

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

Table 2: Percentages of positive/ negative results by donor

		Positive Donors			Negative Donors			
Total # of facilities	Total # of Results	Positive/ Reactive Results	Indeterminate	False Negative (% False Neg.)	Negative/ Non-Reactive Results	Indeterminate	False Positives (% False Pos.)	Overall Performance (TP + TN/Total # of Results)
459	2897	2387	8	19 (0.8%)	477	2	4 (0.8%)	98.9%

- The **positive challenges** included one strong positive donor in duplicate (Donor 11, Donor 11 duplicate) and two weak positives, one in duplicate (Donor 1, Donor 9, and Donor 9 duplicate). Twenty-seven incorrect results were reported on these samples (8 for strong positive samples and 19 for weak positive samples.
  - o Overall Accuracy for all testing sites was 98.9% (2387/2414)
  - o Accuracy varied with test kit used (96.6% to 100%).*

    *Note: This range excludes incorrect interpretations reported for test kits in the "Other" category because those errors were clustered among 3 testing sites, each using one of 3 different test kits (Core HIV 1 & 2, Acon HIV Ultra Rapid Test Device, Fujirebio Serodia HIV-1).
  - o 10/19 false negative results were reported by testing sites using the MedMira Reveal G2 Rapid HIV-1 Antibody Test. (9/10 of these were reported for weak positive samples; 1/10 was reported for a strong positive sample.)
- Six incorrect results were reported on the **negative challenge** (Donor 4).
  - o Overall Accuracy was 98.8% (477/483).
  - o Incorrect results appeared to be random.

Report of Results: Overview, Continued

Overall Performance (continued)

- The number of testing sites reporting using oral fluid as a specimen type increased to 58 from 11 reported in January 2005. These were primarily counseling and testing centers and community based organizations in the U.S. using the new Oraquick Advance Rapid HIV-1/2 test kit.

- Several U.S. testing sites reported testing specimen types which are not FDA approved for the test kit used: 44 used either serum or frozen plasma with OraQuick Rapid HIV-1 or Advance HIV-1/2 Antibody test kits; 7 used oral fluid with the OraQuick Rapid HIV-1 kit. This is a modification of the manufacturer's procedure and makes the tests non-waived under CLIA.

- Some U.S. testing sites indicated that only EIA was done for confirmation of a preliminary positive (reactive) rapid test result or that further confirmatory tests were done only if the EIA was positive. CDC guidelines require that reactive rapid HIV tests must 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 whether the confirmatory tests are done in-house or sent out to an external facility.

Challenge Samples

Sample description

The plasma samples for this challenge shipment of the HIV-RT MPEP were shipped in June 2005.

The six plasma samples from four donors included:

- two strong HIV-antibody positive samples from one donor sent in duplicate, and
- one HIV-antibody-negative sample from one donor, and
- three weak positive samples derived from two seroconverter donors, with one of the donors sent in duplicate.

Description of challenge samples

All plasma samples were single bleeds drawn from individual donors. The resulting plasma was tested to determine HIV-1 antibody reactivity. The samples for the June 2005 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 (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.

One positive sample and one of the seroconverter samples were included in the shipment in duplicate.

Demographics

Overview

A total number of 459 different testing sites (foreign and domestic) submitted results. Of these:

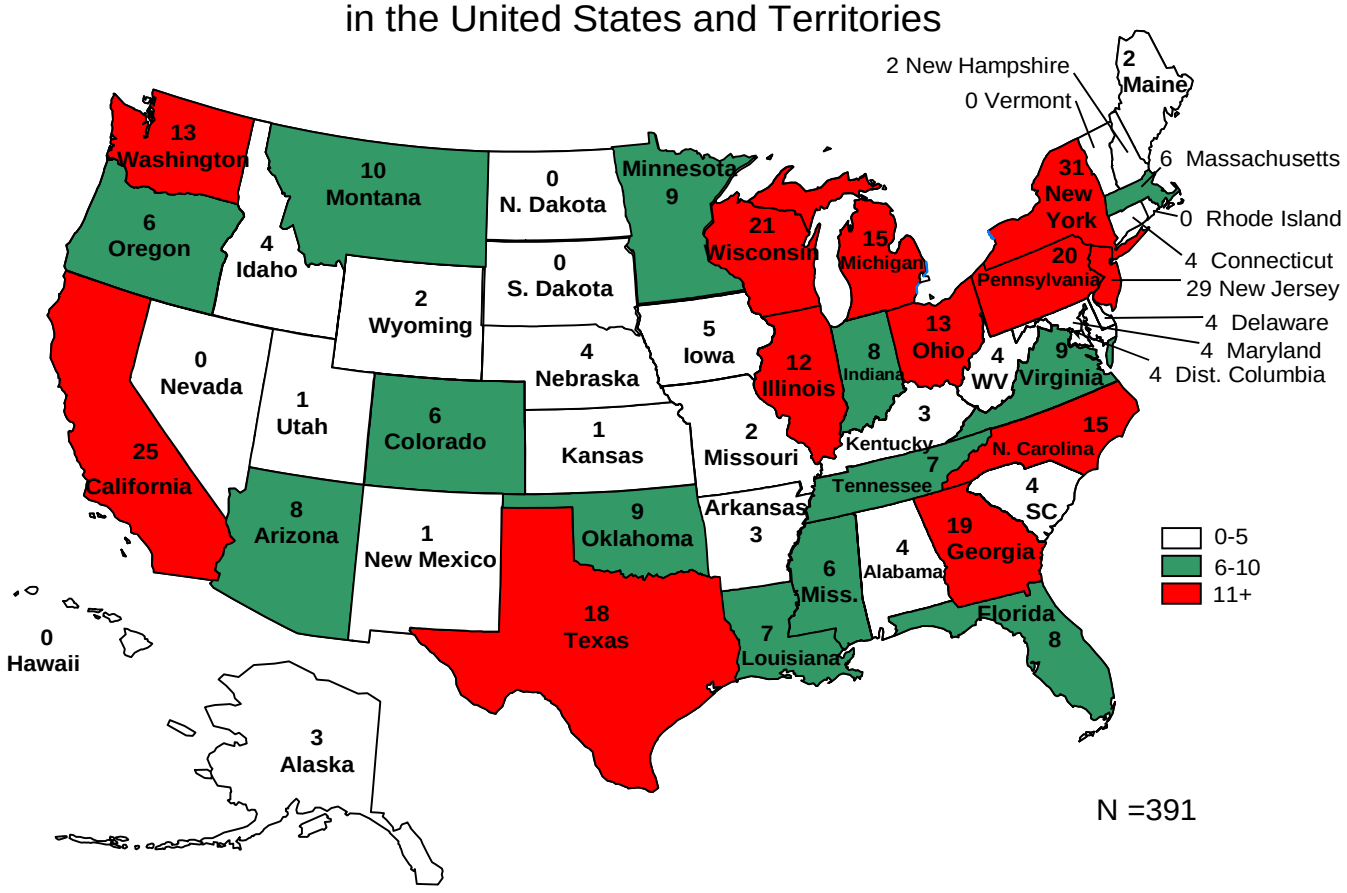
- the 391 U.S. (domestic) testing sites are depicted in ***Figure 1***, and
- the 68 foreign testing sites are listed in ***Table 3***.

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

- The number of foreign participants in the current survey (68) reflected an increase of ~11% from the previous survey (January 2005, n=61).
- Non-U.S. participants included over 2/3 of the countries in the Global AIDS Program (GAP).
- The number of U.S. participants in the current survey (391) was greater by ~16% than that of the previous survey (329). This increase primarily reflects the enrollment of additional facilities with a core/satellite site relationship.
- In the U.S., hospital testing sites predominated.

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.

Table 3

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

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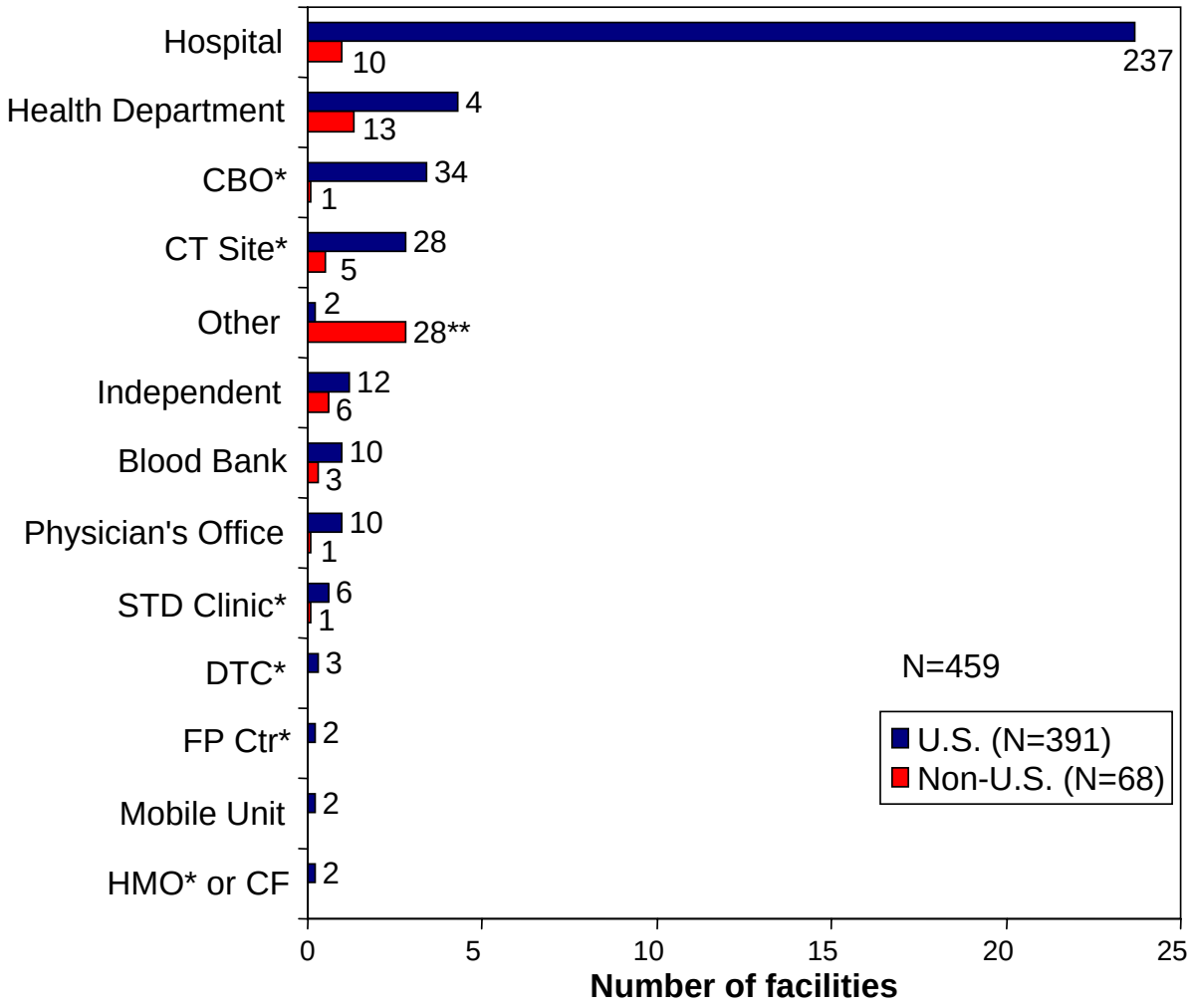
Demographics, Continued

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. & non-U.S.



Abbreviations (*):

CBO = Community Based Organization
CT Site = Counseling and Testing site
STD Clinic = Sexually Transmitted Disease Clinic
DTC = Drug Treatment Center
FP Ctr = Family Planning Center
HMO = Health Maintenance Organization
CF = Correctional Facility

(**) 19/28 were laboratories or medical units associated with U.S. embassies.

Detailed Performance Results

Table 4 gives the results by donor for the percent of reactive/positive reported results for Donors 1, 9 and 11 (positive donors) and the percent of non-reactive/negative reported results for Donor 4 (the negative donor).

	Reactive/Positive						Non-Reactive/Negative					
Donor Number	**# of Participants**	**# of Results**	**# Pos.**	**# Neg.**	**# Indeter**	**% Pos.**	**# of Participants**	**# of Results**	**# Pos.**	**# Neg.**	**# Indeter**	**% Neg.**
1 (Weak Pos)	456	482	480	2		99.6%	n/a	n/a	n/a	n/a	n/a	n/a
4 (Negative)	n/a	n/a	n/a	n/a	n/a	n/a	457	483	4	477	2	98.8%
9/9-dup (Weak Pos)	459	966	949	12	5	98.2%	n/a	n/a	n/a	n/a	n/a	n/a
11/11-dup (Strong Pos)	458	966	958	5	3	99.2%	n/a	n/a	n/a	n/a	n/a	n/a

The results varied with respect to the donor as follows:

- The 19 false-negative results were reported by 12 testing sites;
  - Of these 12 sites,
    - nine were U.S. facilities:
      - eight hospitals and
      - one blood bank
    - three were non-U.S. facilities
      - one hospital,
      - one Other (Embassy Health Unit) and
      - one Independent.
    - 14/19 false-negative results were reported for the weak positive samples:
      - 9/12 were reported by 5 testing sites using the Reveal G2 Rapid HIV-1 Antibody test kit (MedMira).
      - Four sites reported false-negative results for both Donor 9 samples (Donor 9 and Donor 9 duplicate)

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Detailed Performance Results, Continued

Table 5 gives the accuracy by kit type.

Table 5: Results for all samples 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 Rapid HIV-1 Ab (OraSure)	140	699	696	1	2	99.6%	140	140		140		100.0%	839	836	99.6%
Oraquick Advance Rapid HIV-1/2 Ab Test (OraSure)	116	578	575	3		99.5%	115	115	1	114		99.1%	693	689	99.4%
Reveal G2 Rapid HIV-1 Antibody Test (MedMira)	110	547	537	10		98.2%	109	109		108	1	99.1%	656	645	98.3%
Determine HIV-1/2 (Abbott)	43	213	210	1	2	98.6%	43	43		42	1	97.7%	256	252	98.4%
Biotech Uni-Gold Recombigen HIV (Trinity)	29	145	145			100.0%	29	29	1	28		96.6%	174	173	99.4%
Multispot HIV-1/HIV-2 (Bio-Rad)	7	35	35			100.0%	7	7		7		100.0%	42	42	100.0%
Biotech Capillus (Trinity)	6	29	28		1	96.6%	6	6		6		100.0%	35	34	97.1%
Serodia HIV 1/2 (Fujirebio)	4	18	18			100.0%	4	4		4		100.0%	22	22	100.0%
Biotech Uni-Gold (Trinity)	3	15	15			100.0%	3	3		3		100.0%	18	18	100.0%
Reveal Rapid HIV-1 Test (MedMira)	2	10	10			100.0%	2	2		2		100.0%	12	12	100.0%
Hema-Strip HIV-1/2 (Chembio)	1	5	5			100.0%	1	1		1		100.0%	6	6	100.0%
HIV-TRIDOT (J.Mitra & Co, Ltd)	1	5	5			100.0%	1	1		1		100.0%	6	6	100.0%
HIV Rapid Test (Efoora)	1	5	5			100.0%	1	1		1		100.0%	6	6	100.0%
Other	22	110	103	4	3	93.6%	22	22	2	20		90.9%	132	123	93.2%

Kit Types Used By Participants

Overview

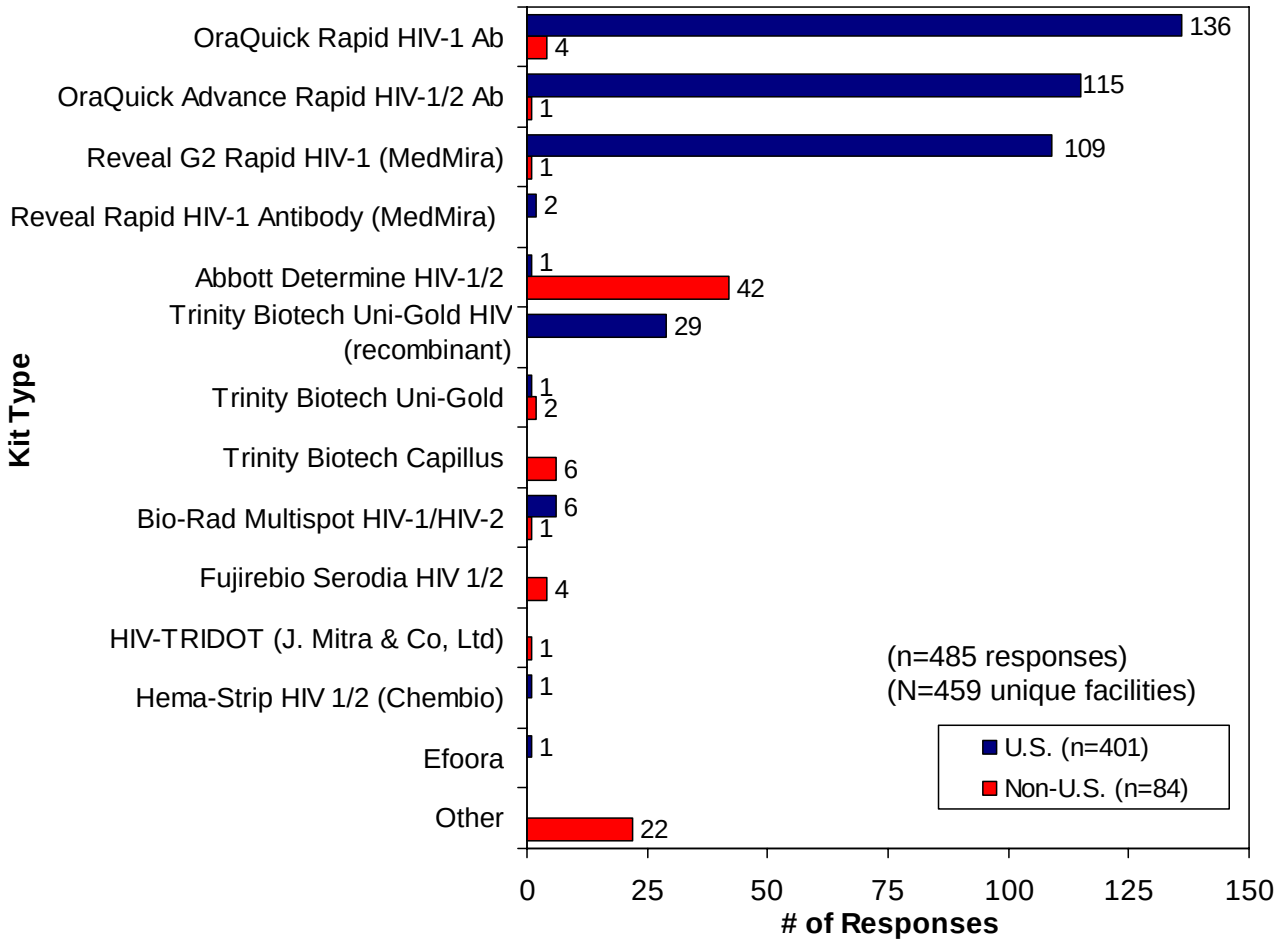
This section describes the kit types used by participants.

- The predominant kit types, as shown in ***Figure 3***, were:
  - OraQuick Rapid HIV-1 or ADVANCE HIV 1/2 Ab tests (52.8%, 256/485),
  - MedMira Reveal or Reveal G2 HIV rapid tests (23.1%, 112/485), and
  - Abbott Determine HIV-1/2 (8.9%, 43/485).

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

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

Figure 3: Kit types



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Kit Types Used By Participants, Continued

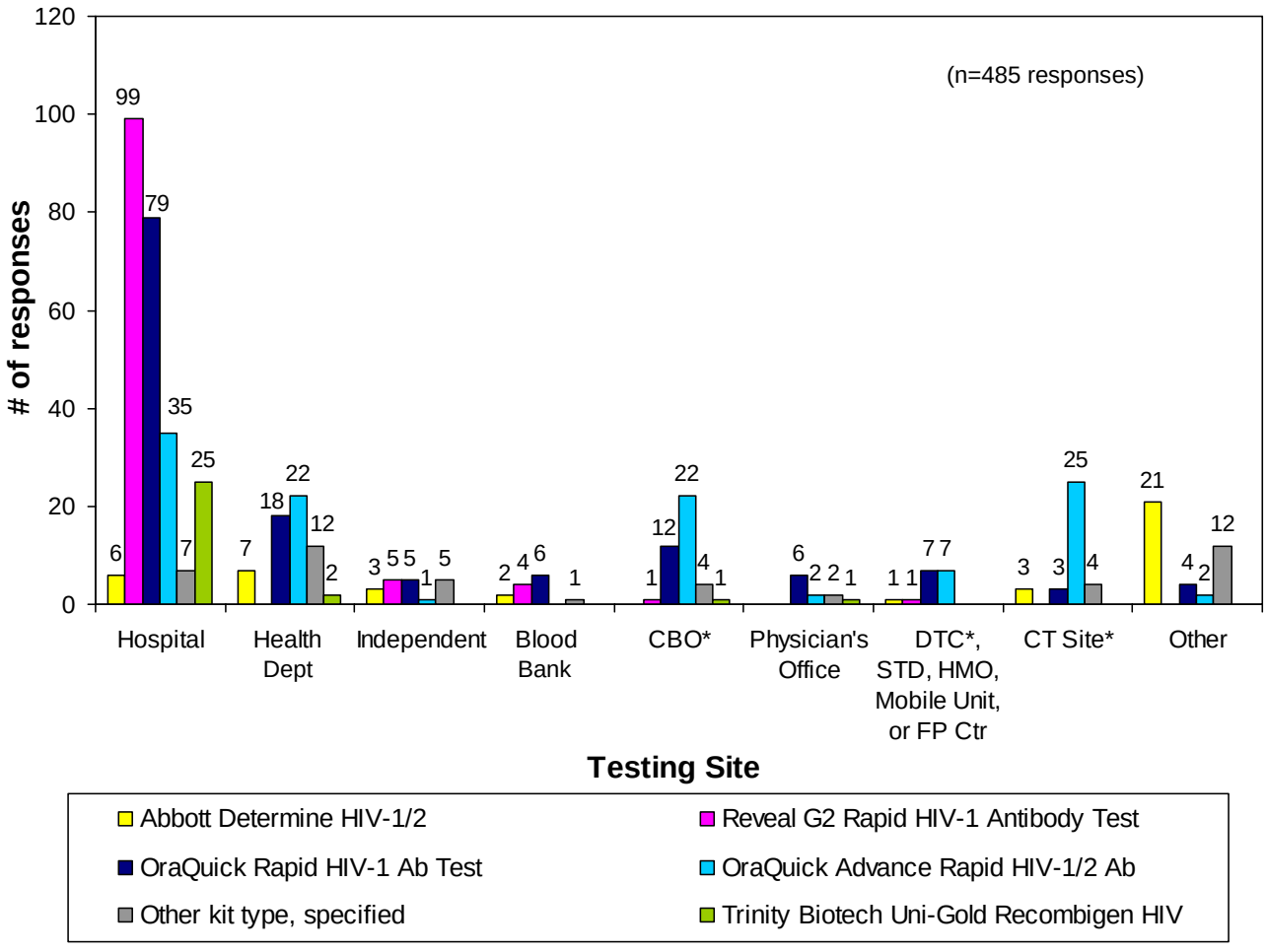
The following figure illustrates the usage of the kit types by type of testing site. The methods for which there were seven or less results are included in the "other kit type" category.

Outreach sites in the United States (CBO's, DTC's, STD clinics, CT sites) and physician's offices tended to use rapid tests that are waived tests under the Clinical Laboratory Improvement Amendments (CLIA).

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
FP Ctr = Family Planning Center
CT Site = Counseling and Testing site

Specimen Types Used By Participants

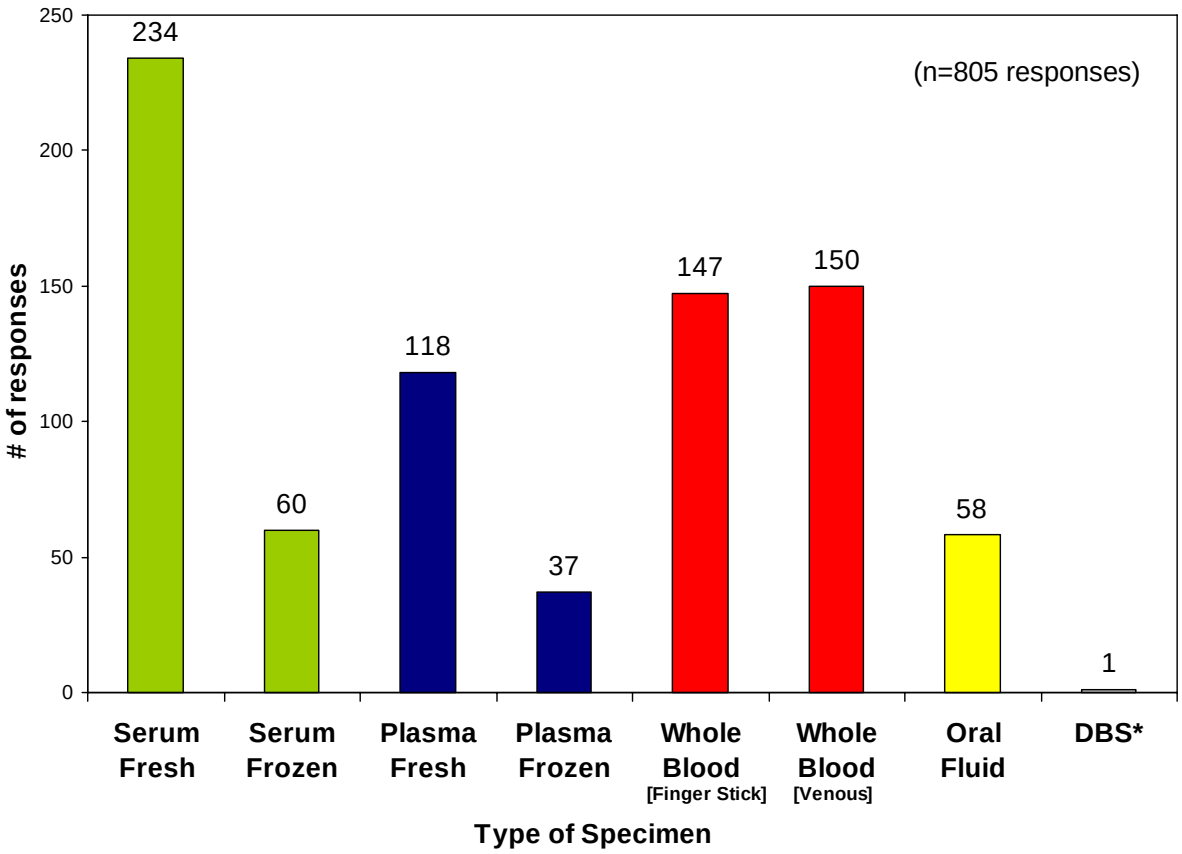
Overview

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



*DBS: 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, with respect to the previous survey, from 11 to 58. This increase reflects the availability of the new OraQuick Advance Rapid HIV- 1/2 Ab test kit which is FDA approved for both oral fluid and whole blood.

Quality Control (QC)

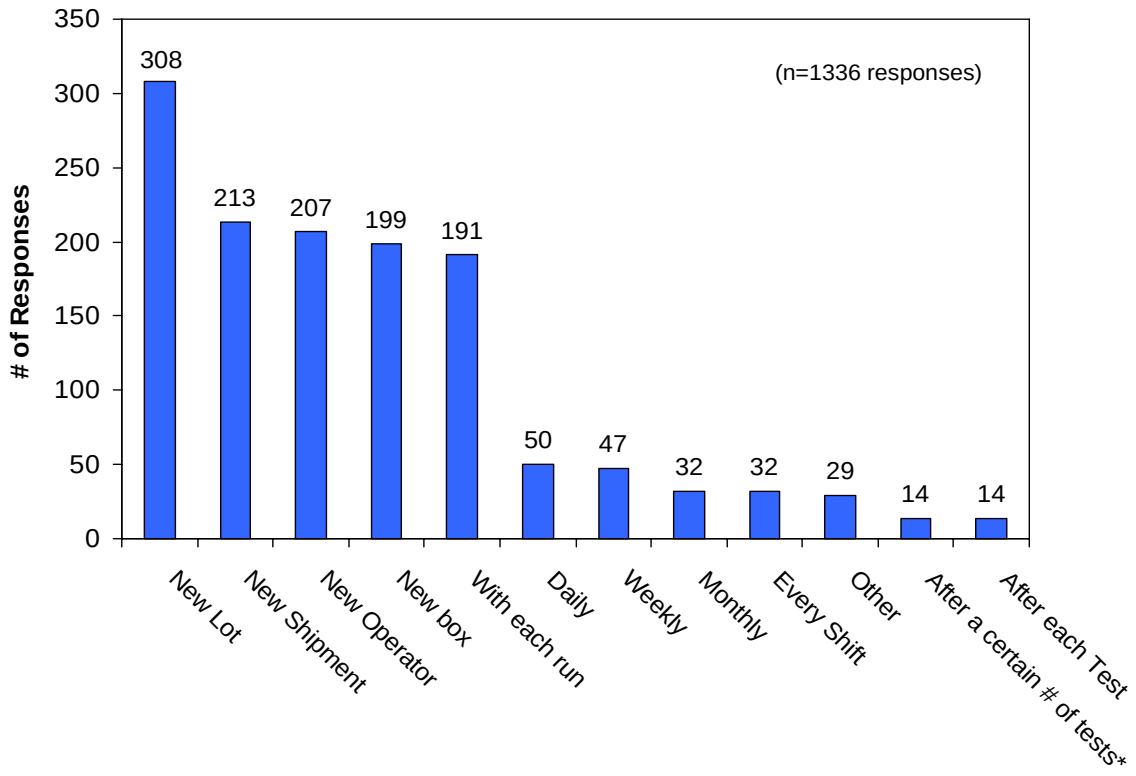
Overview

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 459 facilities that returned responses answered the question regarding use of quality control samples (question #5).
- Most facilities (92.8%, 426/459) indicated the use of QC samples for at least one of the kit types they use at their testing site.
- Of the 921 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 (86.3%, 795/921),
    - 42.4% (337/795) were included in the test kit, and
    - 57.6% (458/795) were purchased from the kit manufacturer separately.
  - in-house controls (8.6%, 79/921).
  - "Other" manufacturer (manufacturer not the same as for the test kit) controls (5.1%, 47/921).

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 10-60)

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.

- Most responses (546/762; 71.7%) indicated either
  - reactive (preliminary positive) specimens were sent to another facility (433/762; 56.8%), or
  - EIA was performed alone (16/762; 2.1%) or in combination with other testing (97/762; 12.7%) in their facility

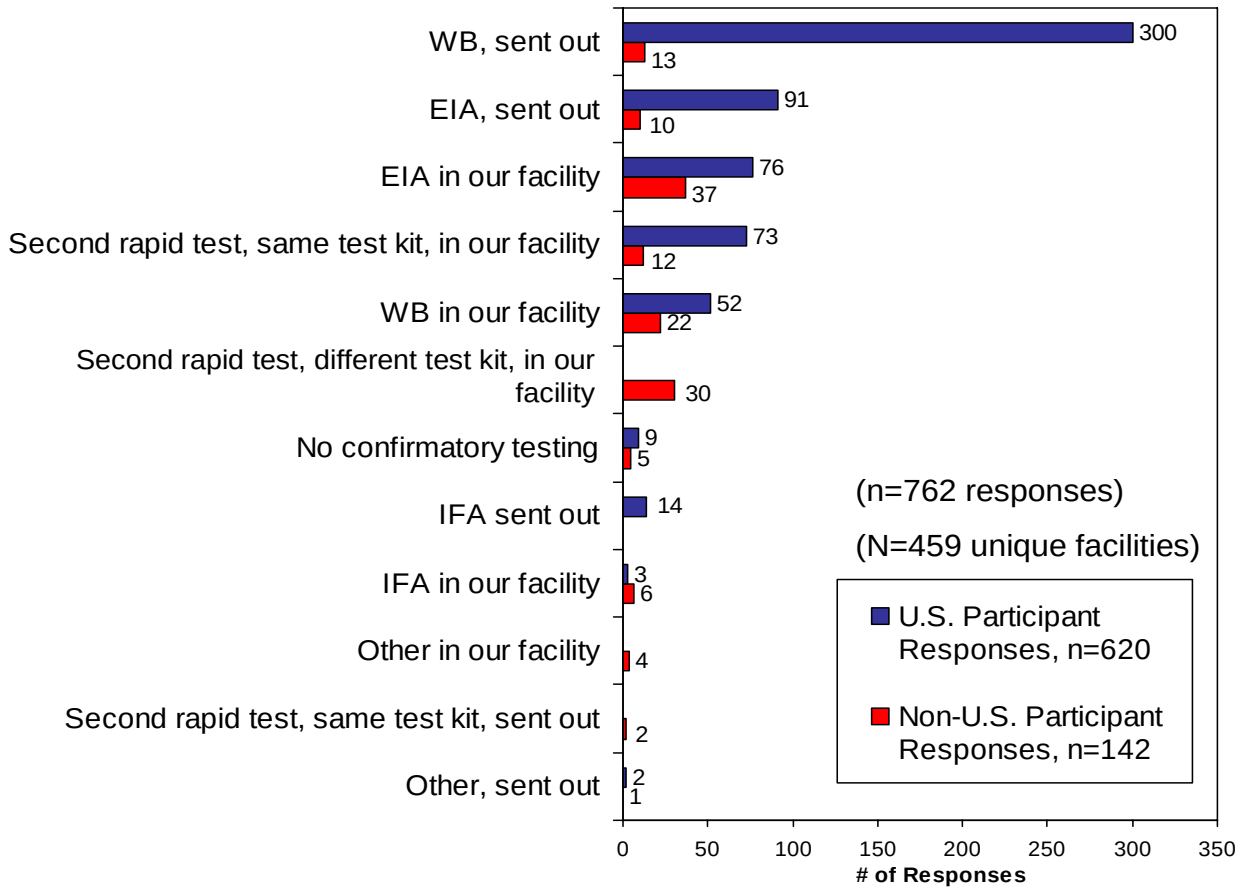
- Several responses (117/762; 15.4%) indicated using a second rapid test for confirmatory testing. Of these, 18/117 (15.4%) indicated using a second rapid test with no other type of confirmatory testing.

Fourteen responses indicated that no confirmatory testing was required prior to reporting a positive result for the HIV rapid testing kit listed. ***Note***: Separate report forms are required for each different HIV rapid testing kit used, and participants could have reported different confirmatory testing information on each form.

Twelve of these 14 responses were reported by sites not using confirmatory testing for ***any*** kit type:
- Eight were from U.S. sites.
- Four were from non-U.S. sites

The circumstances surrounding the use of HIV rapid tests without confirmatory testing are unclear.

Figure 7: Types of confirmatory testing



Conclusions and Discussions

Overall performance

Testing sites performed well in this MPEP shipment survey (98.9% correct results). Overall accuracy when testing positive samples was 98.9%. Overall accuracy for negative samples was (98.8%).

Incorrect results reported for positive samples varied with kit type. Most of the incorrect results were reported for the weak positive samples, especially donor 9, the weakest positive. The nineteen false-negative results were reported by twelve different testing sites.

The six incorrect results reported for negative samples were apparently random.

Specimen types

The number of testing sites reporting the use of oral fluid increased from 11 to 58 sites. Of these, 54 were U.S. testing sites that tended to be community-based organizations (18/54), counseling and testing centers (16/54), or health departments (14/54). The change in specimen types used reflects the availability of the new OraQuick Advance Rapid HIV-1/2 Ab test which is FDA approved for oral fluid. At least 21 of these testing sites that also participated in the January 2005 survey changed from the OraQuick Rapid HIV-1 Ab test to the new test kit. This trend is likely to continue.

In this survey, 38 U.S. testing sites and six non-U.S. sites reported using serum and/or frozen plasma as specimen types for the OraQuick Rapid HIV-1 or ADVANCE HIV-1/2 Antibody test kits. In addition, 7 U.S. testing sites indicated the use of oral fluid for the OraQuick Rapid HIV-1 test. It should be noted that:

- The OraQuick tests are not FDA approved for serum (fresh or frozen) or for frozen plasma specimens
- The OraQuick Rapid HIV-1 test is not FDA approved for oral fluid use, only the ADVANCE HIV-1/2 test is FDA approved for both oral fluid and whole blood.

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 CLIA. U.S. facilities should be aware of the Clinical Laboratory Improvement Amendments (CLIA) regulations requiring the establishment of performance specifications when modifying an FDA-approved test (Sec. 493.1253).[5] In addition, as the package insert for the OraQuick tests states: "**Any modification by the laboratory to the test system or FDA-approved test system instructions will result in the test no longer meeting the requirements for waived category**."

Confirmatory testing

Some U.S. testing sites 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 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.

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

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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

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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: June 2005 survey

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

Q: Are we following CDC guidelines when we send out a specimen to a reference lab for the confirmation of a reactive (preliminary positive) HIV rapid test?

A: Before referring specimens, testing sites in the U.S. should confer with the reference laboratory to ensure that either a WB or IFA will be done to confirm all preliminary positive (reactive) HIV rapid test results. CDC emphasizes that reactive rapid HIV tests must be confirmed with either WB or IFA, even if a subsequent EIA is nonreactive.[3]

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Topical Issues in HIV Rapid Testing, Continued

Highlights of previous FAQs

Q: What types of specimens can be used in performing HIV rapid testing?
A: The type(s) of specimen (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

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/