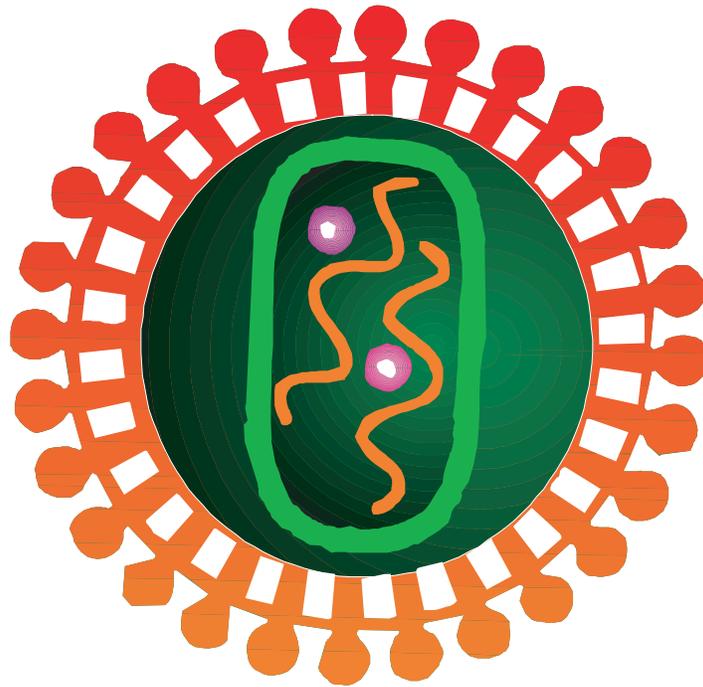




HIV Rapid Testing

Report of Sample Shipment Results, September 2009



DEPARTMENT OF HEALTH & HUMAN SERVICES



HIV-1 Rapid Testing MPEP September 2009 Report of Results

Purpose Report of the September 2009 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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Report of Results Overview

Introduction This report describes the results of the 11th HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) shipment survey. It represents the aggregate results submitted by the testing sites currently enrolled. The testing sites used various HIV rapid test kits to test six challenge samples.

The challenge panels for this HIV-RT MPEP challenge samples surveys were shipped in September 2009.

The major findings are summarized below.

Challenge samples: description The six challenge samples were derived from five individual donors. One duplicate sample was included in this survey.

The six challenge samples were plasma samples derived from five individual donors:

- three weakly reactive HIV-1 antibody positive plasma samples; from Donor 1 (in duplicate) and Donor 2,
 - two strongly reactive HIV-1 antibody positive plasma samples; from Donors 3 and 4, and
 - one HIV-1 antibody negative plasma sample from Donor 5.
-

Challenge sample selection Samples for this MPEP challenge were purchased from SeraCare Life Sciences, Inc., where they were pre-tested prior to shipment to participating laboratories.

These challenge samples were:

- pre-tested to ensure they were free of bacterial contamination,
 - heat-treated at 56°C for 60 minutes to inactivate infectious agents such as bacteria and viruses,
 - stability tested to ensure appropriate antibody reactivity over the period of storage (frozen at -20°C for six months between matched sample surveys) and during shipment to survey participants (a minimum of one week at ambient temperature) and
 - tested with all FDA-approved rapid HIV antibody tests (see Figure 3) as well as selected FDA-approved EIA and Western blot assays to confirm the serostatus.
-

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Report of Results Overview, Continued

Challenge sample selection (continued)

Positive samples were selected using the following criteria:

- Reactive by the Genetic Systems rLAV enzyme immunoassay kit at signal-to-cutoff ratios
 - between 3 and 5 for the weakly positive seroconverter samples and
 - greater than 5 for the strongly positive samples.
- The strongly positive samples have WB results that demonstrate antibody reactivity to all major HIV-1 viral proteins (gag, pol, and env), and specifically, to p24, p31, gp41, p51, p66, gp120, and gp160 proteins.
- The weakly positive samples have WB results that demonstrate reactivity to at least two of the following major HIV-1 viral proteins: gp41, gp120, gp160.

Negative samples were non-reactive by all FDA-approved EIA kits, including the HIV-1/HIV-2 combination kits and negative with all FDA-approved HIV-1 Western Blot (WB) kits with no bands on the WB strips.

Response rate

Of the 563 challenge panels that were shipped to the currently enrolled HIV rapid testing sites,

- 482 (87.5%) submitted results
- 8 declined to participate in the survey and
- 4 panels were returned.

The remaining 69 nonresponders had either discontinued HIV rapid testing at their facility, decided to cancel enrollment in the MPEP, were unable to perform HIV rapid testing during the period of result submission for the September HIV-RT MPEP sample survey, or were no longer in operation.

Overall performance

Overall accuracy (percent of correct results) for all samples (see Table 3), by all testing sites with all kit types is 99.0% (2969/3000). In this survey, six results were reported by five testing sites as invalid, i.e. the result could not be determined as either “reactive” or “nonreactive.” No comments were made with respect to the invalid results regarding testing difficulties.

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Report of Results Overview, Continued

Overall performance (continued)

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

Table 1: Results summary

Total # of sites	Total # of Results	Positive Donors			Negative Donors			Overall Performance (TP +TN)/ Total # of Results
		Positive/ Reactive	Invalid	False-Negatives (% False Neg.)	Negative/ Non-Reactive	Invalid **	False-Positives (% False Pos.)	
482	3000	2475	5 (0.2%)	20 (0.8%)	494	1 (0.2%)	5 (1.0%)	99.0%

* Some laboratories (n=18) evaluated the samples with more than one method and submitted separate results for each method

** Invalid result interpretations are considered to be incorrect results.

Results summary

Accuracy of the testing facilities varied with between 98.4% and 100% depending on the donor samples.

Overall accuracy for the **positive challenge samples** was 99.0% (2475/2500). These included

- two weakly positive samples (Donors 1 and 2) and
- two strongly positive samples (Donors 3 and 4).

Participants reported 20 false negatives and 5 invalid results. Since invalid results are considered to be incorrect, the error rate is calculated to be 1.0% (25/2500).

Of the 25 incorrect results reported for positive challenges:

- 4 (16.0%) were reported for Donor 1 (weakly positive)
- 9 (36.0%) were reported for Donor 2 (weakly positive)
- 11 (44.0%) were reported for Donor 3 (strongly positive) and
- 1 (4.0%) was reported for Donor 4 (strongly positive).

Overall accuracy for the **negative challenge samples** from Donor 5 was 98.8% (494/500).

Donor Report

The following worksheet (**Table 2: Donor Report**) is provided to participating testing sites one to two weeks after the result submission deadline. The Donor Report worksheet:

- gives the correct result values for each challenge panel sent out by MPEP,
- is designed as a visual convenience for participants to record their results side-by-side with the correct values, and
- is an optional means for self-evaluation of participants' results.

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Report of Results Overview, Continued

Donor Report (continued)

Table 2: Results worksheet

Panel Letter	Vial Label	CDC Donor Number	Expected Results ^{1,2}	Donor HIV Status	Your Laboratory Results ³	
					Test Results	Interpretation
A	A1	1*	Positive(W)	Infected		
	A2	2	Positive(W)	Infected		
	A3	3	Positive(S)	Infected		
	A4	1*	Positive(W)	Infected		
	A5	4	Positive(S)	Infected		
	A6	5	Negative	Uninfected		
B	B1	2	Positive	Infected		
	B2	3	Positive	Infected		
	B3	1*	Positive	Infected		
	B4	4	Positive	Infected		
	B5	5	Negative	Uninfected		
	B6	1*	Positive	Infected		
C	C1	3	Positive	Infected		
	C2	1*	Positive	Infected		
	C3	4	Positive	Infected		
	C4	5	Negative	Uninfected		
	C5	1*	Positive	Infected		
	C6	2	Positive	Infected		
D	D1	1*	Positive	Infected		
	D2	4	Positive	Infected		
	D3	5	Negative	Uninfected		
	D4	1*	Positive	Infected		
	D5	2	Positive	Infected		
	D6	3	Positive	Infected		

* Duplicate donors

1. The CDC results were obtained from the vendor SeraCare after they performed composite testing with all six commercially available HIV Rapid Testing kits licensed by the Food and Drug Administration (FDA). All CDC results are consistent with the manufacturer's criteria for interpretation of the results.
2. Strong (S) and Weak (W) designations for reactive samples are based on qualitative observations of the HIV rapid test colorimetric results, EIA test signal-to-cut off ratios of OD values, and WB test band patterns.
3. Laboratory Interpretation space is to be completed by participant laboratories to facilitate comparison of their result with CDC result.

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Report of Results Overview, Continued

**Confirmatory
testing
practices**

Sixteen testing sites performed only EIA (in-house or sent out) for confirmation of a preliminary positive (reactive) rapid test result.

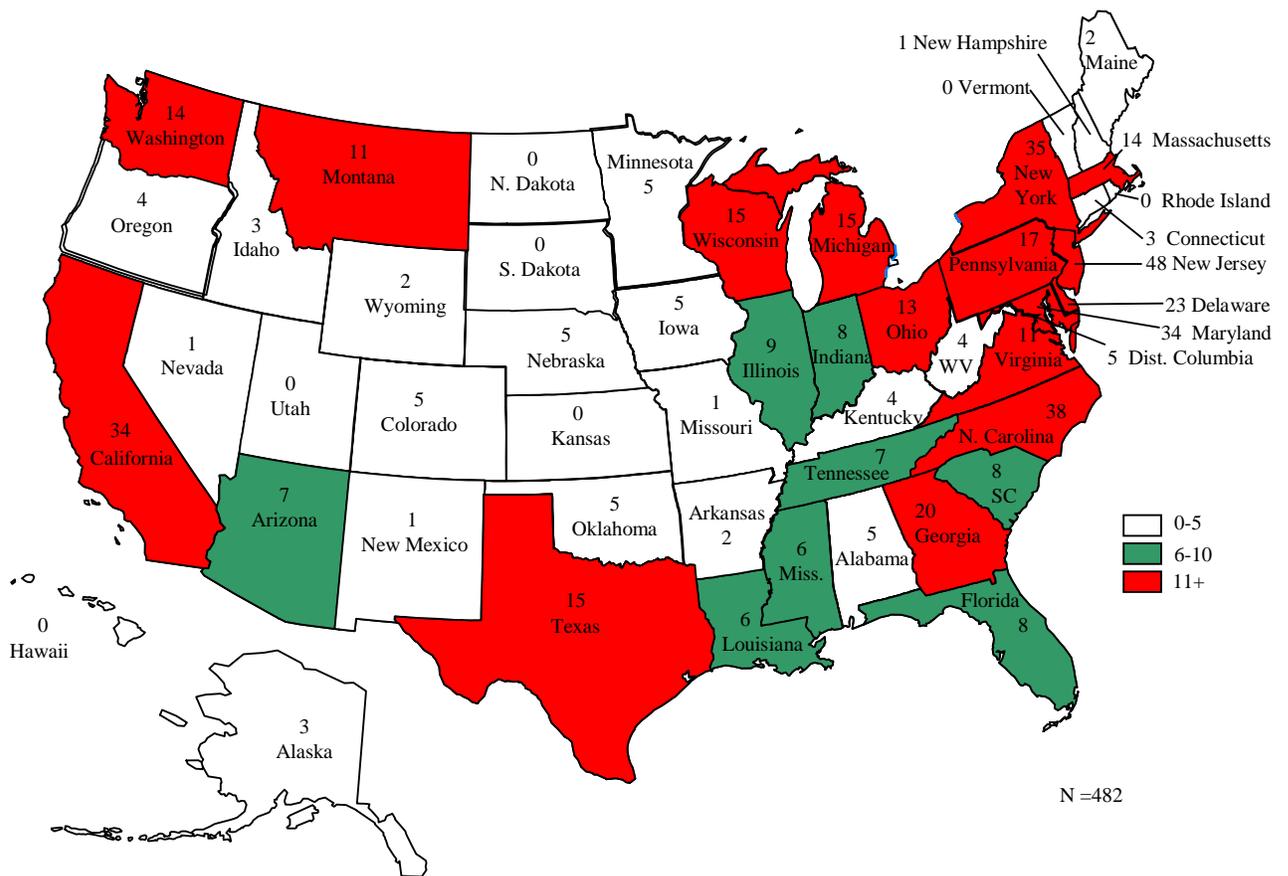
Current CDC guidelines state that reactive rapid HIV tests should be confirmed with Western blot (WB) or indirect immunofluorescence assay (IFA), even if a subsequent EIA is nonreactive. See the link below:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm>

Demographics

Overview

A total of 482 testing sites submitted results, as shown in *Figure 1*.

Figure 1: The number and location of the MPEP HIV-RT participants



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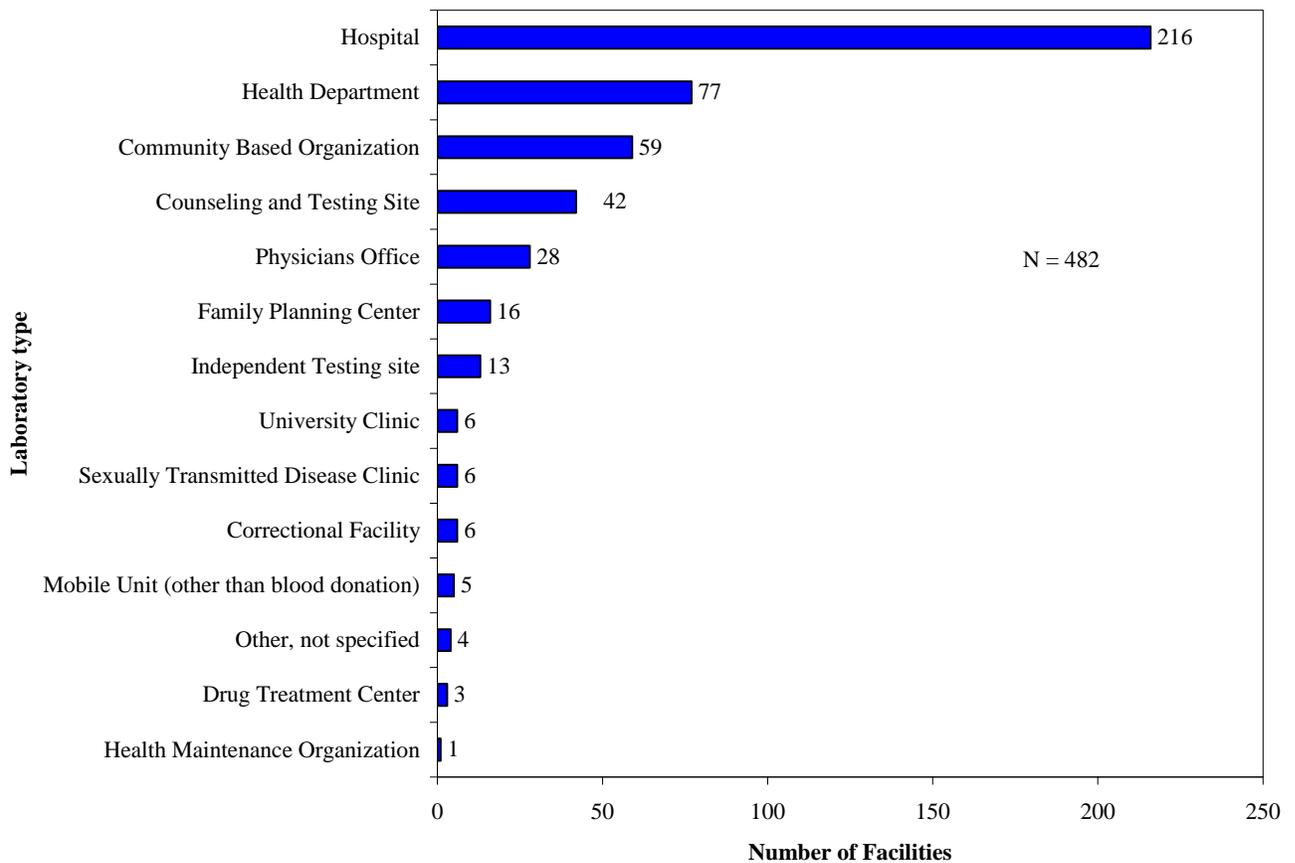
Demographics, Continued

Type of testing sites

At this time, only U.S. sites participated in this survey. The types of testing sites reported by participants are shown in *Figure 2*. In this survey, the predominate types were:

- hospitals, 216 (44.8%)
- health department, 77 (16.0%)
- community-based organizations, 59 (12.2%), and
- counseling and testing sites, 42 (8.7%).

Figure 2: The number and types of testing facilities



Detailed Performance Results

Results by donor

Some of the participants used more than one type of test kit and submitted more than one form. Therefore, the total number of results exceeds the total number of participants (482). *Table 3*, below, shows the reactivity by donor.

Table 3: Results and percent correct response by donor

Donor Number	# of participants	# of results	Reactivity			% Correct
			# Pos.	# Neg.	# Invalid	
1 (Weak Pos)	482	1000	996	1	3	99.6%
2 (Weak Pos)	482	500	491	7	2	98.2%
3 (Strong Pos)	482	500	489	11	0	97.8%
4 (Strong Pos)	482	500	499	1	0	99.8%
5 (Negative)	482	500	5	494	1	98.8%

Of the 25 incorrect results reported for the **HIV-positive samples** by 17 testing sites, there were:

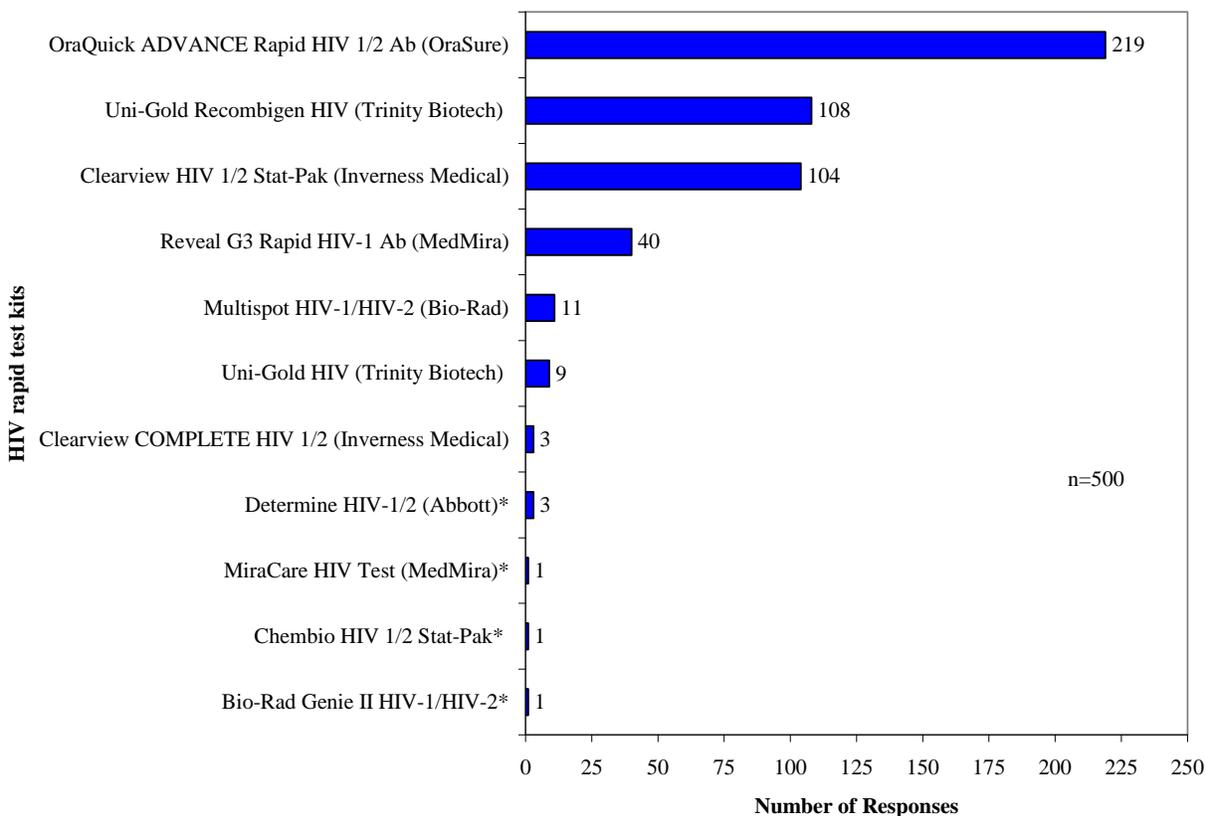
- 20 false-negative results and
- 5 invalid results.

Kit types used by participants

Overview

Figure 3 shows the type and number of test kits used by participants. Presently, there are 6 FDA-approved rapid HIV antibody screening tests. Some testing sites reported using test kits that are not FDA-approved.

Figure 3: Kit types by the number of responses



* Rapid test kits that are not yet FDA-approved; 1.2 % of results were reported using these kits

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Kit types used by participants, Continued

Detailed kit performance

The table below shows the accuracy of the testing facility by kit manufacturer.

Table 4: Results by test kit

Kit Type (manufacturer)	# of Sites	Positive Donors					Negative Donor					Totals		
		# of Results	Reactive	Non-Reactive	Invalid	% Correct	# of Results	Reactive	Non-Reactive	Invalid	% Correct	Total # of Results	# Correct	% Correct
Oraquick ADVANCE Rapid HIV-1/2 Ab Test (OraSure)	219	1095	1078	13	4	98.4%	219	5	214	0	97.7%	1314	1292	98.3%
Uni-Gold Recombigen HIV (Trinity Biotech)	108	540	540	0	0	100.0%	108	0	108	0	100.0%	648	648	100.0%
Clearview HIV 1/2 Stat-Pak (Inverness)	104	520	515	4	1	99.0%	104	0	104	0	100.0%	624	619	99.2%
Reveal G3 Rapid HIV-1 Antibody Test (MedMira)	40	200	197	3	0	98.5%	40	0	39	1	97.5%	240	236	98.3%
Multispot HIV-1/HIV-2 (Bio-Rad)	11	55	55	0	0	100.0%	11	0	11	0	100.0%	66	66	100.0%
Unigold HIV (Trinity Biotech)	9	45	45	0	0	100.0%	9	0	9	0	100.0%	54	54	100.0%
Determine HIV-1/2 (Abbott)	3	15	15	0	0	100.0%	3	0	3	0	100.0%	18	18	100.0%
Clearview Complete HIV 1/2 (Inverness)	3	15	15	0	0	100.0%	3	0	3	0	100.0%	18	18	100.0%
Genie II HIV-1/HIV-2 (BioRad)	1	5	5	0	0	100.0%	1	0	1	0	100.0%	6	6	100.0%
Chembio HIV 1/2 Stat-Pak (CASSETTE)	1	5	5	0	0	100.0%	1	0	1	0	100.0%	6	6	100.0%
MiraCare HIV test (MedMira)	1	5	5	0	0	100.0%	1	0	1	0	100.0%	6	6	100.0%

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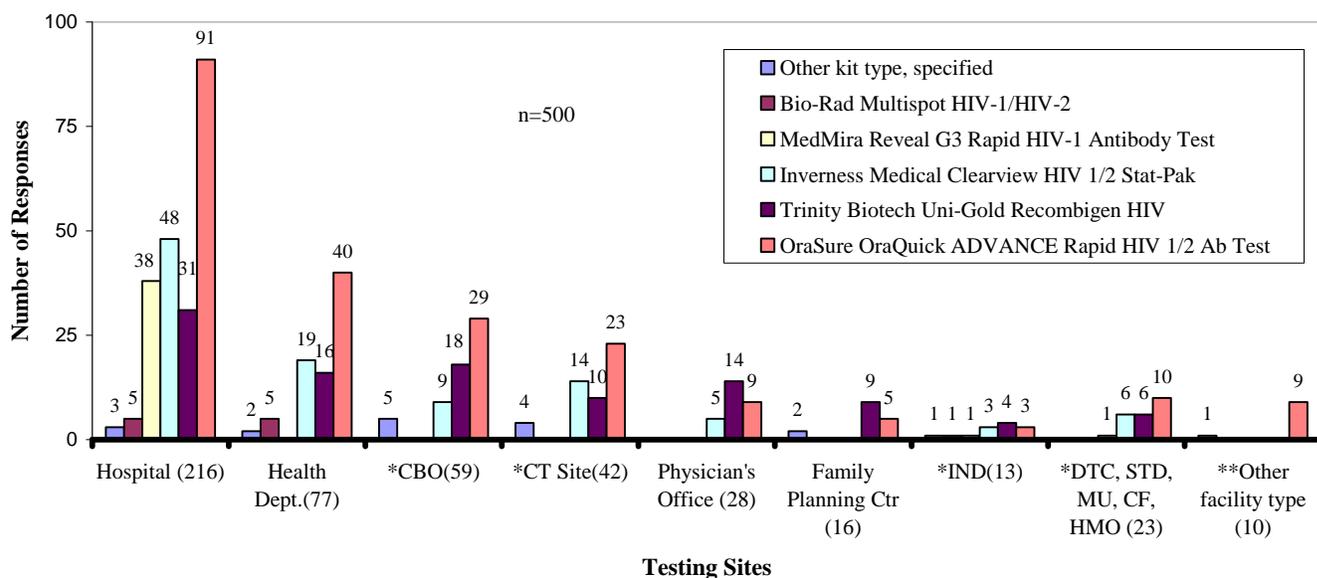
Kit types used by participants, Continued

Testing sites by kit type

Figure 4 shows the usage of test kit types by the type of testing facility. The methods for which there were ten or less results are included in the “other kit type” category.

Four hundred and eighty-two testing facilities reported results. However, 18 facilities submitted two test kits. Therefore, the total number of responses is 500.

Figure 4: Test kits by facility type



*Abbreviations:

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

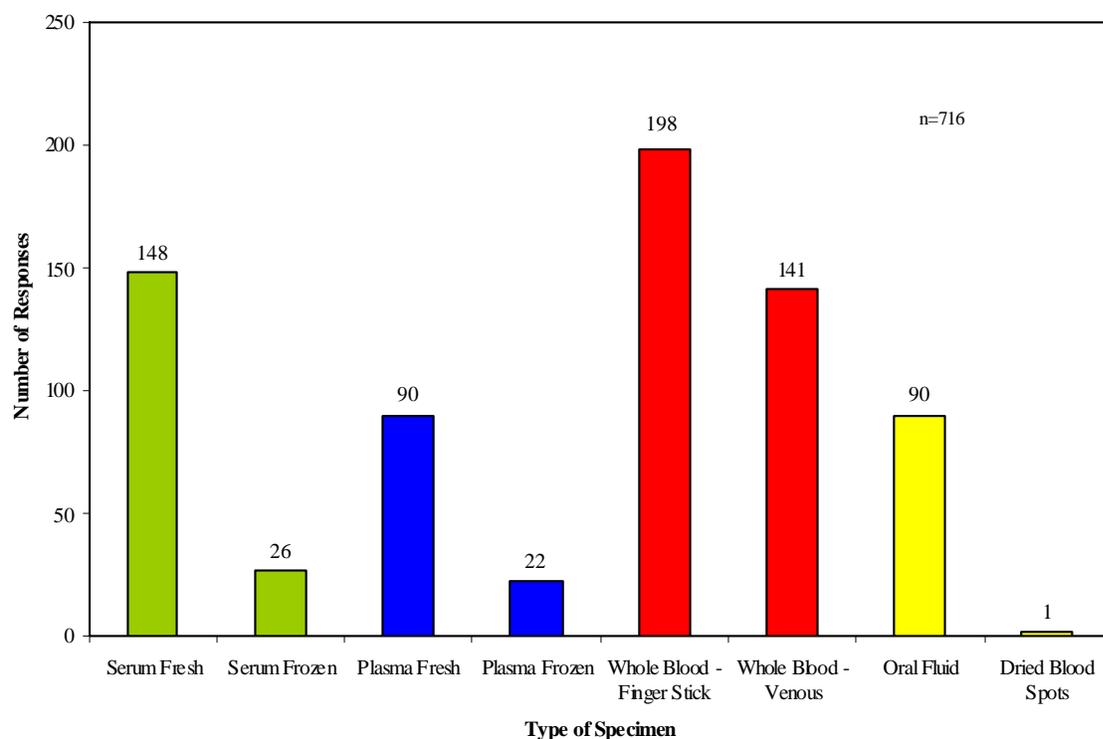
** The “Other” facility types were six University clinics and four not further specified

Specimen types normally used by participants

Overview

Participants were asked what type of specimens they *normally* use for HIV rapid tests. **Figure 5** shows the participants responses. Some testing sites reported using more than one specimen type.

Figure 5: Specimen types used by participants



Specimen types

Testing facilities were asked to report the specimen types *normally* received in their facilities:

- 339 (70.3 %) reported whole blood (finger stick or venous)
- 174 (36.1%) reported serum (fresh or frozen)
- 112 (23.2 %) reported plasma, (fresh or frozen)
- 90 (18.7%) reported that they usually receive oral fluid (oral mucosal transudate), and
- 1 (0.2 %) reported dried blood spot.

Some testing facilities receive or test more than one specimen type. Therefore, the total number of specimen types and reported results is greater than the total number (482) of facilities submitting results.

Quality Control (QC) Testing

Overview

Testing sites were asked if they used quality control (QC) samples, either positive or negative, when performing HIV rapid tests.

Most, 96.7% (466/482), of the facilities indicated the use of QC materials for at least one of the kit types used. Of the sites using QC materials:

- 98.1%, (457/466) indicated that they obtained controls obtained from the same manufacturer as the test kit, of which
 - 30.6%,(140/457) were *included* in the test kit, and
 - 69.4% (317/457) were purchased separately from the same manufacturer.
- 2.1% (10/466) used in-house controls
- 3.2% (15/466) used purchase control from another manufacturer (not the same as the test kit manufacturer).

Note: 16 sites selected QC materials from two different sources.

Frequency of use of QC materials

The frequency of use of quality control materials is shown in *Table 5*. Most facilities selected more than one response since the intervals and reasons for performing QC varied within institutions and testing sites.

Table 5: Frequency of QC by the type of facility

Facility Type	QC Use										
	Each Run	New Operator	New Lot	New Box	Each Shipment	Each Shift	Daily	Weekly	Monthly	After # of tests	Other
Hospital	60	88	146	72	117	15	15	15	28	0	9
Health department	22	39	55	28	41	0	5	37	11	8	10
Counseling & testing site	4	14	27	19	37	0	3	23	7	5	9
Community based org	4	20	39	22	33	0	6	28	5	4	6
Physician's office	4	7	12	14	13	0	1	2	3	0	0
Independent testing site	7	4	6	4	6	2	2	0	1	0	0
Family planning center	1	5	12	7	3	0	1	0	0	1	0
Correctional Facility	1	3	5	3	6	0	2	3	0	0	0
Sexually Transmitted Disease Clinic	1	2	4	2	3	0	1	3	2	1	1
Mobile unit	0	0	4	3	5	0	0	3	0	0	1
Drug Treatment Center	0	1	1	1	2	0	0	2	1	0	0
Health maintenance org	0	0	1	0	1	0	0	0	0	0	0
Other facility type	2	5	6	6	5	0	0	5	1	1	2
Totals (%)	106 (8%)	188 (14%)	318 (24%)	181 (13%)	272 (20%)	17 (1%)	36 (3%)	121 (9%)	59 (4%)	20 (2%)	38 (3%)

Confirmatory testing

Overview

Participants were asked what confirmatory test(s) their facilities required to confirm reactive (preliminary positive) HIV rapid testing results.

468 (97.1%) of the testing facilities submitted a total of 771 responses. Some facilities indicated the use of more than one algorithm for confirmatory testing.

Current CDC guidelines^{1-2,3} for confirmatory testing of reactive (preliminary positive) rapid test results, recommended testing algorithms are as follows:

- All reactive (preliminary positive) rapid test results must be followed up with an approved supplemental test, such as a Western blot, an immunofluorescence assay (IFA) or an RNA nucleic acid amplification test (NAAT), for confirmation.
- Confirmatory testing may be performed on blood (plasma, serum, or dried blood spots) or oral fluid specimens, though blood specimens have higher accuracy than oral fluid specimens. Urine should not be used for confirmatory testing because of its lower sensitivity.

Most participants indicated that their facilities follow the current CDC guidelines:

- 430 (91.9%) indicated the use of WB either in-house or send-out
- 24 (5.1%) indicated IFA in-house or send-out.

However, 14 responses indicated that no confirmatory testing was required by their facility to confirm a reactive HIV rapid testing result.

Performing an enzyme immunoassay (EIA/ELISA) test after a reactive HIV rapid test and prior to a confirmatory test is optional at the present time, since currently the specimen must be confirmed by a Western blot, IFA, or RNA test regardless of the EIA result.

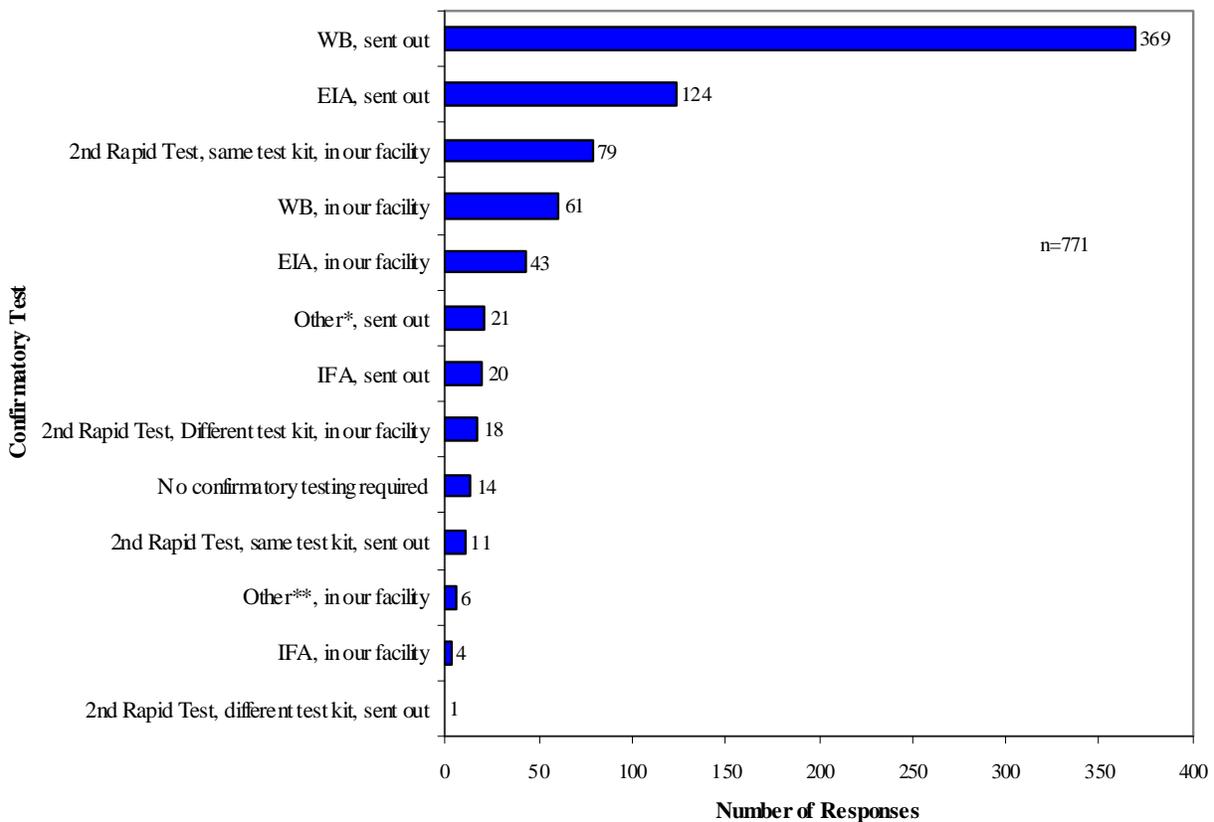
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Confirmatory testing, Continued

Types of confirmatory testing

The figure below shows the responses regarding confirmatory testing practices. Four hundred and eighty-two testing facilities submitted responses. Some facilities submitted more than one response. This may indicate that the person responding to this survey may not be familiar with the testing or confirmatory algorithm used by their facility. This could also indicate that the facility has different criteria for different specimen types.

Figure 6: Confirmatory testing patterns used by participants



*Other, sent out: PCR/viral load, n=9; Not specified: n=6; Conditional: if EIA is pos. & WB is neg. do Multispot testing, n=5; Conditional: Immunoblot if HIV-2, n=1

**Other, in our facility: Chemiluminescence, n=3; Conditional: if sample is Oral Fluid do 2nd rapid test (same test kit), n=1; ECiQ HIV 1/2, n=1; Not specified: n=1

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Confirmatory testing, Continued

Confirmatory testing and quality assurance guidelines

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

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 observance of 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, and
- 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}

Conclusions and Discussion

Overall Performance Overall accuracy of the laboratory results for all samples by all testing sites and including all test kits used in this shipment is 99.0%:

- 99.0% for the positive samples;
 - 99.6% for Donor 1 (weak positive),
 - 98.2% for Donor 2 (weak positive),
 - 97.8% for Donor 3 (strong positive),
 - 99.8% for Donor 4 (strong positive), and
- 98.8% for the negative sample (Donor 5)

The majority (90%, 18/20) of the false-negative errors in this survey were reported for weak Donor 2 and strong Donor 3 (7 and 11 false negatives, respectively).

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(RR-19):1-58.
<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>
-

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 educational goal 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:
September
2009 survey**

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

Q: When will we be receiving our next HIV Rapid Testing sample survey from the MPEP?

A: The MPEP is scheduled to ship the next challenge panel in March, 2010. Enrollees will receive email notification approximately 6 weeks before the shipment.

**Highlights of
previous
FAQs**

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

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

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.

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Topical Issues in HIV Rapid Testing, Continued

Highlights of previous FAQs (continued)

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\]](#)

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 from previous HIV RT MPEP reports, please visit our website at: <http://wwwn.cdc.gov/mpep/hiv-1rt.aspx>

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Topical Issues in HIV Rapid Testing, Continued

CDC websites *Quick Facts: HIV 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

Centers for Disease Control and Prevention: Division of Laboratory Systems <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) Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays

<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/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Home page: <http://www.cdc.gov/nchhstp/>

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

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Acknowledgments

Special thanks to Jagdeep Bedi and Ryan McCormick CDC/Atlanta (Northrop Grumman Contractors) for creating the website for data collection and for assisting the MPEP HIV-RT team with the data analysis for this report.