

HIV-1 Rapid Testing MPEP March 2010 Report of Results

Purpose Report of the March 2010 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 12th HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) shipment survey. It represents the aggregate results submitted by 532 of the testing sites currently enrolled. The testing sites used various HIV rapid test kits to test six challenge samples.

The challenge sample panels for this HIV-RT MPEP survey were shipped in March 2010. The major findings are summarized below.

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

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

Challenge sample selection Bulk plasma for the MPEP challenge samples was purchased from SeraCare Life Sciences, Inc. The sample material was pre-tested both at SeraCare Life Sciences and at CDC 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 enzyme immunoassay (EIA) and Western blot (WB) 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, and gp160.

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

Response rate

Of the 567 challenge panels that were shipped to the currently enrolled HIV rapid testing sites, 532 (93.8%) submitted results.

The remaining 35 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 March HIV-RT MPEP sample survey, or were no longer in operation.

Overall performance

Overall accuracy (percent of correct results) for all samples (see Table 1), by all testing sites with all kit types is 98.2% (3244/3305). In this survey, nine results were reported by different testing sites as invalid, (i.e., the result could not be determined as either “reactive” or “nonreactive”). For five of these “invalid” results, no comments were made with respect to the reason for that result, (e.g., testing difficulties). Four comments were given that described “faint” lines, either for the control line, test line, or both.

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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 Responses	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.)	
551	3305 **	2705 (98.2%)	8 (0.3%)	41 (1.5%)	539 (97.8%)	1 (0.2%)	11 (2.0%)	98.2%

* Some laboratories (n=19) evaluated the samples with more than one method and submitted separate responses for each method

** One result (for positive Donor 3) was reported as “QNS” (quantity not sufficient for testing) and therefore not included in the analyses

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

Results summary

Accuracy of the reported results varied between 95.8% and 99.6% depending on the donor samples (see Table 3).

Overall accuracy for the **positive challenge samples** was 98.2% (2705/2754). These included

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

Participants reported 41 false negatives and 8 invalid results. Since invalid results are considered to be incorrect, the error rate is calculated to be 1.8% (49/2754).

Of the 49 incorrect results reported for positive challenges:

- 23 (46.9%) were reported for Donor 1 (weakly positive)
- 13 (26.5%) were reported for Donor 2 (weakly positive)
- 11 (22.4%) were reported for Donor 3 (strongly positive) and
- 2 (4.1%) were reported for Donor 4 (strongly positive).

Overall accuracy for the **negative challenge samples** from Donor 5 was 97.8% (539/551).

Donor Report

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

- gives the expected result values for each challenge panel;
- is designed as a visual convenience for participants to record their results side-by-side with the expected 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	4	Positive(S)	Infected		
	A5	5	Negative)	Uninfected		
	A6	3*	Positive(S)	Infected		
B	B1	2	Positive	Infected		
	B2	3	Positive	Infected		
	B3	4	Positive	Infected		
	B4	5	Negative	Uninfected		
	B5	3*	Positive	Infected		
	B6	1	Positive	Infected		
C	C1	3	Positive	Infected		
	C2	4	Positive	Infected		
	C3	5	Negative	Uninfected		
	C4	3*	Positive	Infected		
	C5	1	Positive	Infected		
	C6	2	Positive	Infected		
D	D1	4	Positive	Infected		
	D2	5	Negative	Uninfected		
	D3	3	Positive	Infected		
	D4	1	Positive	Infected		
	D5	2	Positive	Infected		
	D6	3*	Positive	Infected		

* Duplicate donors

1. The CDC results were obtained after composite testing with all 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 for voluntary completion by participant laboratories to facilitate comparison of their result with the expected results.

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Report of Results Overview, Continued

**Confirmatory
testing
practices**

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

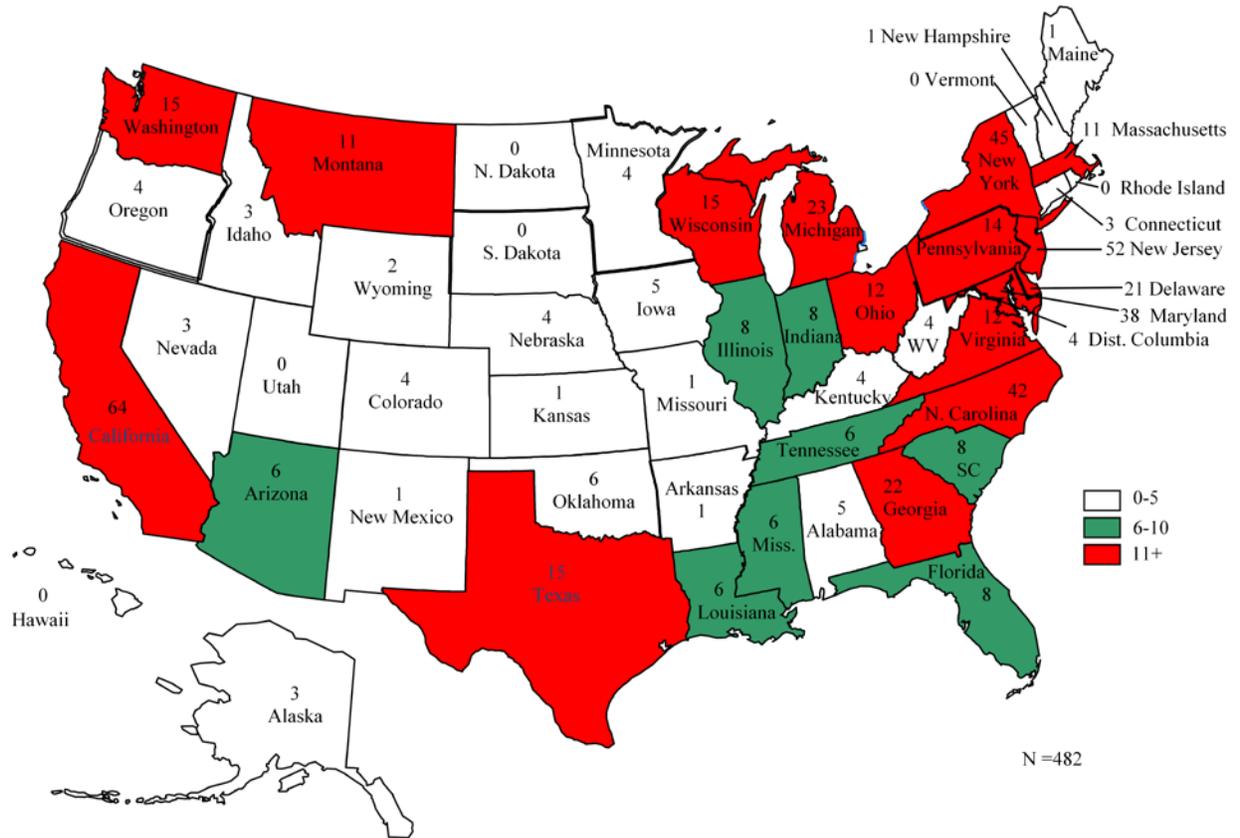
Current CDC guidelines state that reactive rapid HIV tests should be confirmed with Western blot (WB) or indirect immunofluorescence assay (IFA), even if a subsequent EIA is nonreactive. See the link below:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm>

Demographics

Overview

A total of 532 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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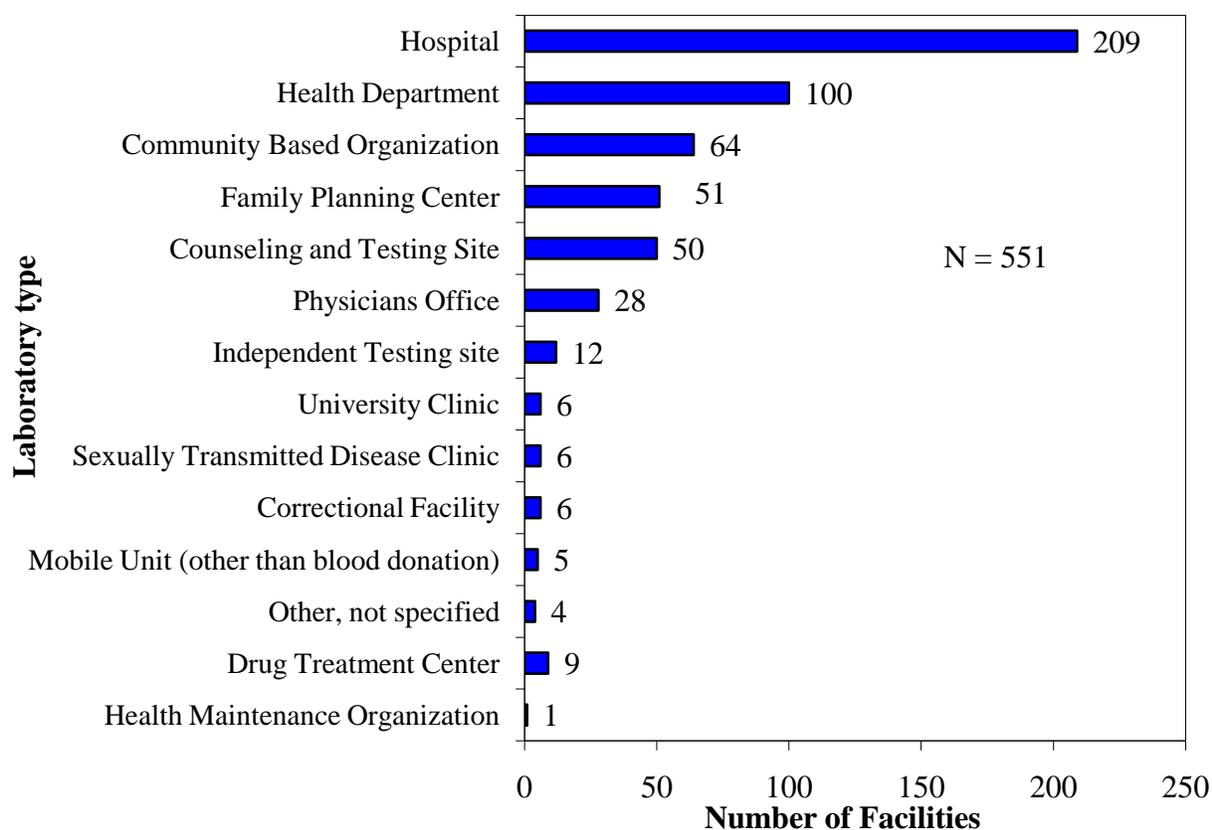
Demographics, Continued

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, 209 (37.9%)
- health department, 100 (18.1%)
- community-based organizations, 64 (11.6%),
- family planning centers, 51 (9.3%), and
- counseling and testing sites, 50 (9.1%).

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' responses (551). **Table 3**, below, shows the reactivity by donor.

Table 3: Results and percent correct response by donor

Donor Number	# of responses by participants	# of results	Reactivity			
			# Pos.	# Neg.	# Invalid	% Correct
5 (Negative)	551	551	11	539	1	97.8%
4 (Strong Pos)	551	551	549	2	0	99.6%
3 (Strong Pos)	551	1101*	1090	7	4	99.0%
2 (Weak Pos)	551	551	538	13	0	97.6%
1 (Weak Pos)	551	551	528	19	4	95.8%

Of the 49 incorrect results reported for the **HIV-positive samples** by 28 testing sites, there were:

- 41 false-negative results and
- 8 invalid results.

17/28 sites reported multiple errors, of these:

- 14 sites had 2 errors
- 2 sites had 3 errors, and
- 1 site had 6 errors (all results were incorrect).

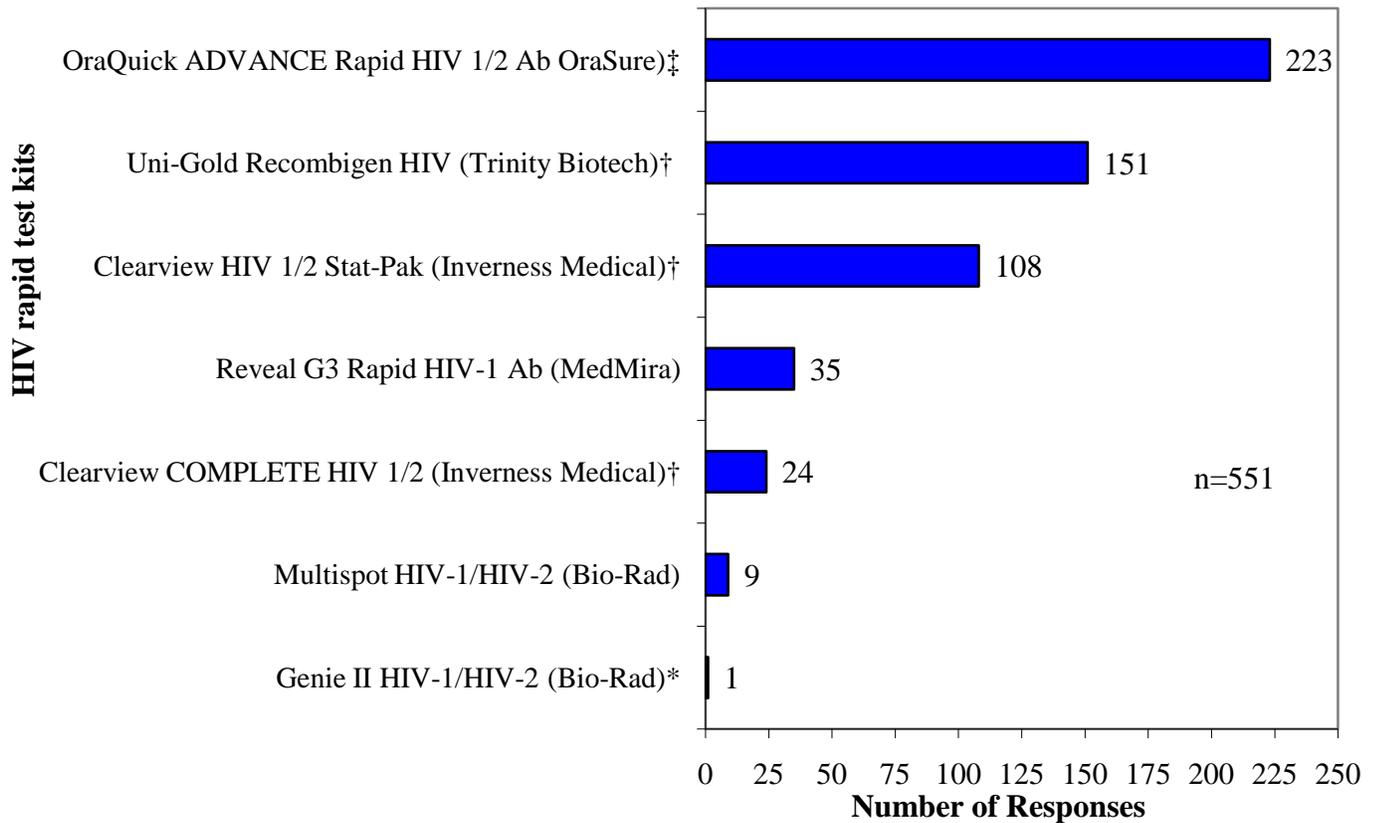
* One result (for positive Donor 3) was reported as "QNS" (quantity not sufficient for testing) and therefore not included in the analyses

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; 4 of these are categorized for some sample types as waived under the Clinical Laboratory Improvement Amendments (CLIA). Some testing sites reported using test kits that are not FDA-approved.

Figure 3: Kit types by the number of responses



* This rapid test kit is not yet FDA-approved

† These rapid test kits are CLIA-waived for fingerstick whole blood samples

‡ This rapid test kit is CLIA-waived for fingerstick whole blood and oral fluid samples

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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)	223	1114	1091	20	3	97.9%	223	5	218	0	97.8%	1337	1309	97.9%
Uni-Gold Recombigen HIV (Trinity Biotech)	151	755	751	2	2	99.5%	151	2	148	1	98.0%	906	899	99.2%
Clearview HIV 1/2 Stat-Pak (Inverness)	108	540	527	11	2	97.6%	108	2	106	0	98.1%	648	633	97.7%
Reveal G3 Rapid HIV-1 Antibody Test (MedMira)	35	175	172	2	1	98.3%	35	1	34	0	97.1%	210	206	98.1%
Clearview Complete HIV 1/2 (Inverness)	24	120	114	6	0	95.0%	24	1	23	0	95.8%	144	137	95.1%
Multispot HIV-1/HIV-2 (Bio-Rad)	9	45	45	0	0	100.0%	9	0	9	0	100.0%	54	54	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%

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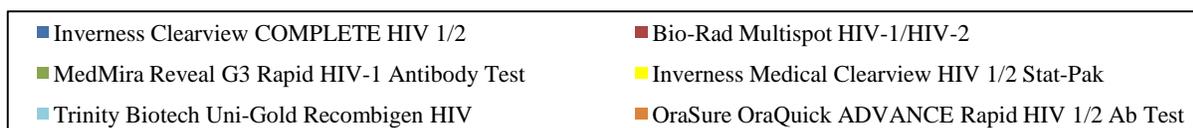
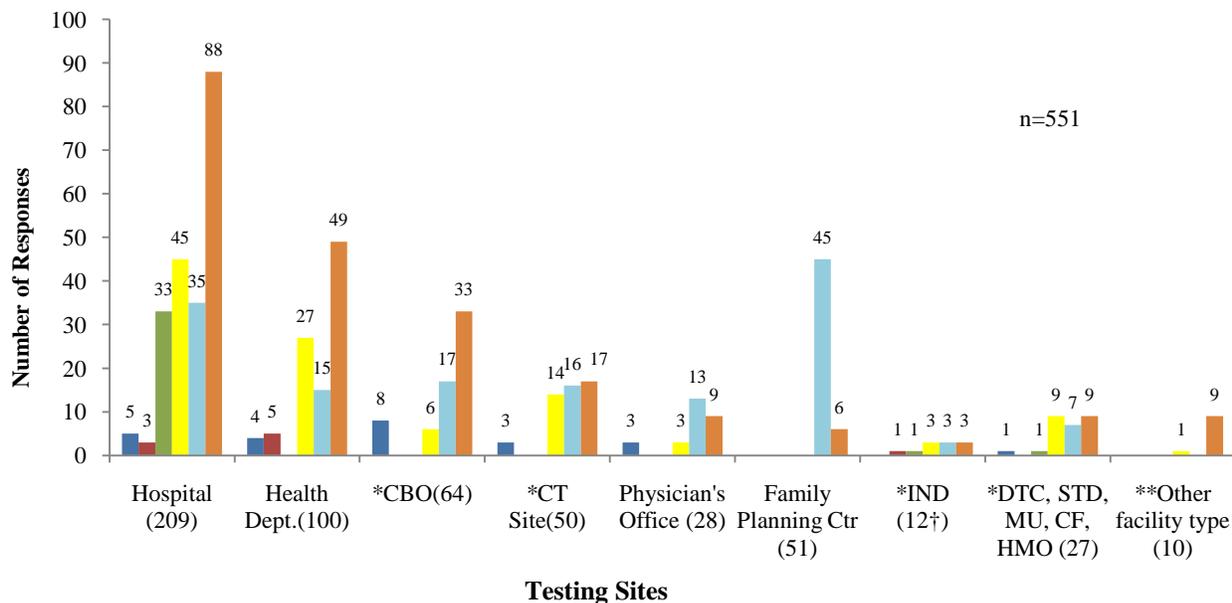
Kit types used by participants, Continued

Testing sites by kit type

Figure 4 shows the usage of test kit types by the type of testing facility.

Five hundred and thirty-two (532) testing facilities reported results. However, 19 facilities submitted two test kits. Therefore, the total number of responses is 551.

Figure 4: Test kits by facility type



* Abbreviations:

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

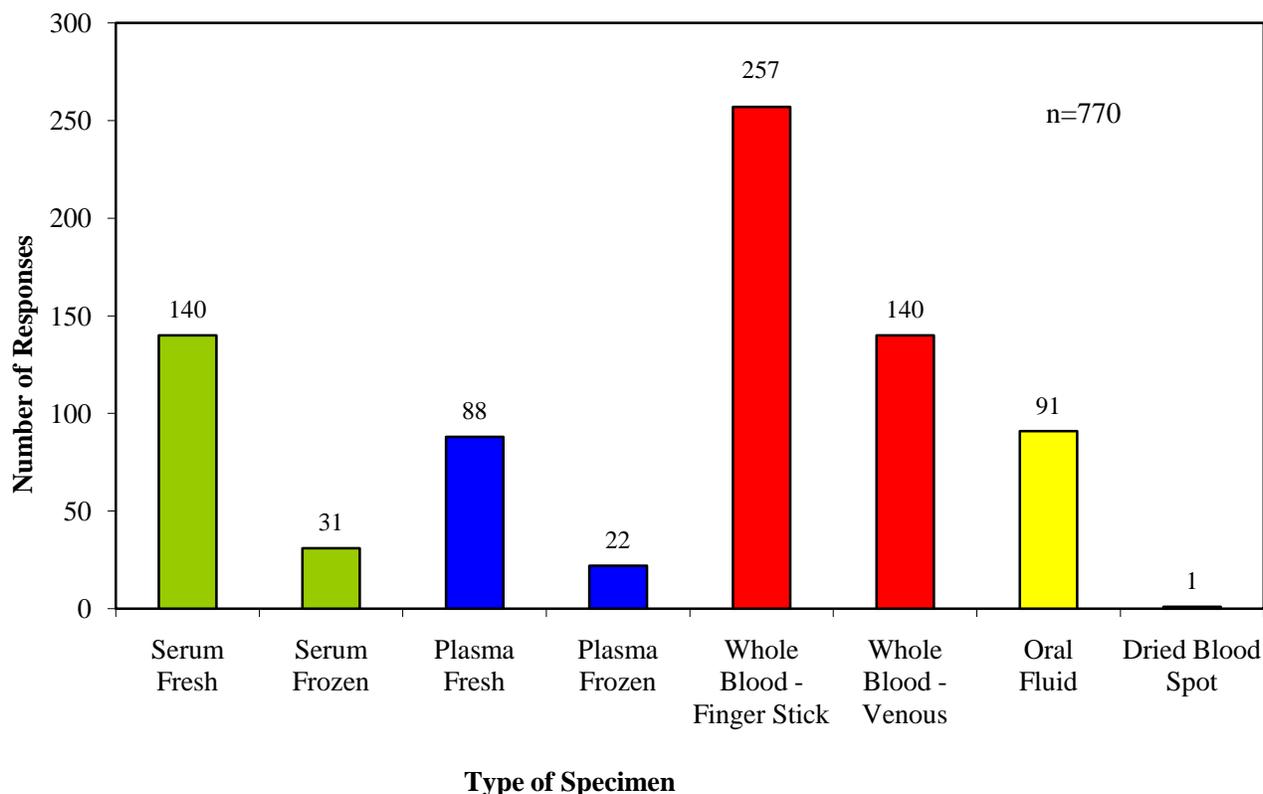
† One site reported using Bio-Rad Genie II HIV-1/HIV-2, a kit currently without FDA approval

**The "Other" facility types were six (6) University clinics and four (4) 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.

Figure 5: Specimen types used by participants



Specimen types

A variety of specimen types were reported:

- 397 (51.6 %) reported whole blood (finger stick or venous)
- 171 (22.2%) reported serum (fresh or frozen)
- 110 (14.3 %) reported plasma, (fresh or frozen)
- 91 (11.8%) reported oral fluid (oral mucosal transudate), and
- 1 (0.1 %) reported dried blood spot.

Some testing facilities receive or test more than one specimen type. Therefore, the total number of specimen types reported is greater than the total number (532) of facilities submitting results. When more than one type of rapid testing kit was reported used, the above results were based on the first reported kit type.

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. The following results were based on the first reported kit type.

Most, 97.6% (519/532), of the facilities indicated the use of QC materials for all kit types. Of the sites using QC materials:

- 99.4%, (516/519) indicated that they obtained controls from the same manufacturer as the test kit, of which
 - 27.9%,(144/516) were *included* in the test kit, and
 - 72.1% (372/516) were purchased separately from the same manufacturer.
- 2.1% (11/519) used in-house controls
- 2.1% (11/519) purchased control from another manufacturer (not the same as the test kit manufacturer).

Note: Sites could select QC materials from multiple 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

LabType	QC Use										
	Each Run	New Operator	New Lot	New Box	Each Shipment	Each Shift	Daily	Weekly	Monthly	After # of tests	Other
Blood Bank	0	0	0	0	0	0	0	0	0	0	0
Hospital	60	85	142	76	121	12	12	15	26	0	7
Health Dept.	30	52	78	35	56	0	16	44	8	10	10
Independent	7	4	5	2	4	1	2	0	0	0	0
Family Planning Ctr	3	22	40	9	31	0	1	0	7	1	0
HMO	0	0	0	0	1	0	0	0	0	0	0
Med Examiner/Coroner	0	0	0	0	0	0	0	0	0	0	0
Physicians Office	2	7	17	14	14	0	0	2	3	0	1
STD Clinic	0	4	5	3	3	0	1	3	2	0	1
Correctional Facility	1	2	4	2	3	0	1	2	1	0	1
Counseling & Testing Site	2	9	27	21	27	1	1	24	8	1	10
Drug Treatment Center	3	3	4	3	4	0	0	7	2	0	1
Military (not blood donation)	0	0	0	0	0	0	0	0	0	0	0
Mobile Unit (not blood donation)	0	0	3	2	3	0	0	3	0	0	0
Community Based Org (CBO)	8	23	47	25	29	0	8	25	4	3	6
Other	2	6	8	6	7	0	0	5	1	0	3
Totals	118 (7.8%)	217 (14.3%)	380 (25.0%)	198 (13.0%)	303 (19.9%)	14 (0.9%)	42 (2.8%)	130 (8.6%)	62 (4.1%)	15 (1.0%)	40 (2.6%)

Confirmatory testing

Overview

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

512 (96.2%) of the testing facilities that submitted results indicated that they require one or more confirmatory tests, for a total of 832 responses.

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 (WB), an immunofluorescence assay (IFA), or an RNA nucleic acid amplification test (NAAT), for confirmation. If the NAAT is used for confirmation and has a negative result, it should be followed by either a WB or IFA.
- 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 (485/532, 91.2%) indicated that their facilities follow the current CDC guidelines; of these:

- 476 indicated the use of WB either in-house or send-out;
- 9 did not use WB (with or without other testing), of these
 - 4 indicated IFA in-house or send-out, and
 - 5 indicated the use of viral load/RNA testing

Twenty-two sites indicated using either EIA alone (n=17) or a second rapid HIV test alone (n=5) for their confirmatory testing algorithm; the reason for this is unclear.

Twenty sites responded that confirmatory testing is not required to confirm a reactive (preliminary positive) HIV rapid test result. Of these, 15 indicated that these rapid testing kits were used for HIV initial testing (e.g., for patients/clients, needlestick, or source patient).

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. It is expected that in the future there will be an updated approved, primary (Unified) algorithm for HIV-1 and HIV-2 screening and confirmation. Work is ongoing regarding the process of evaluating and validating proposed algorithm recommendations.

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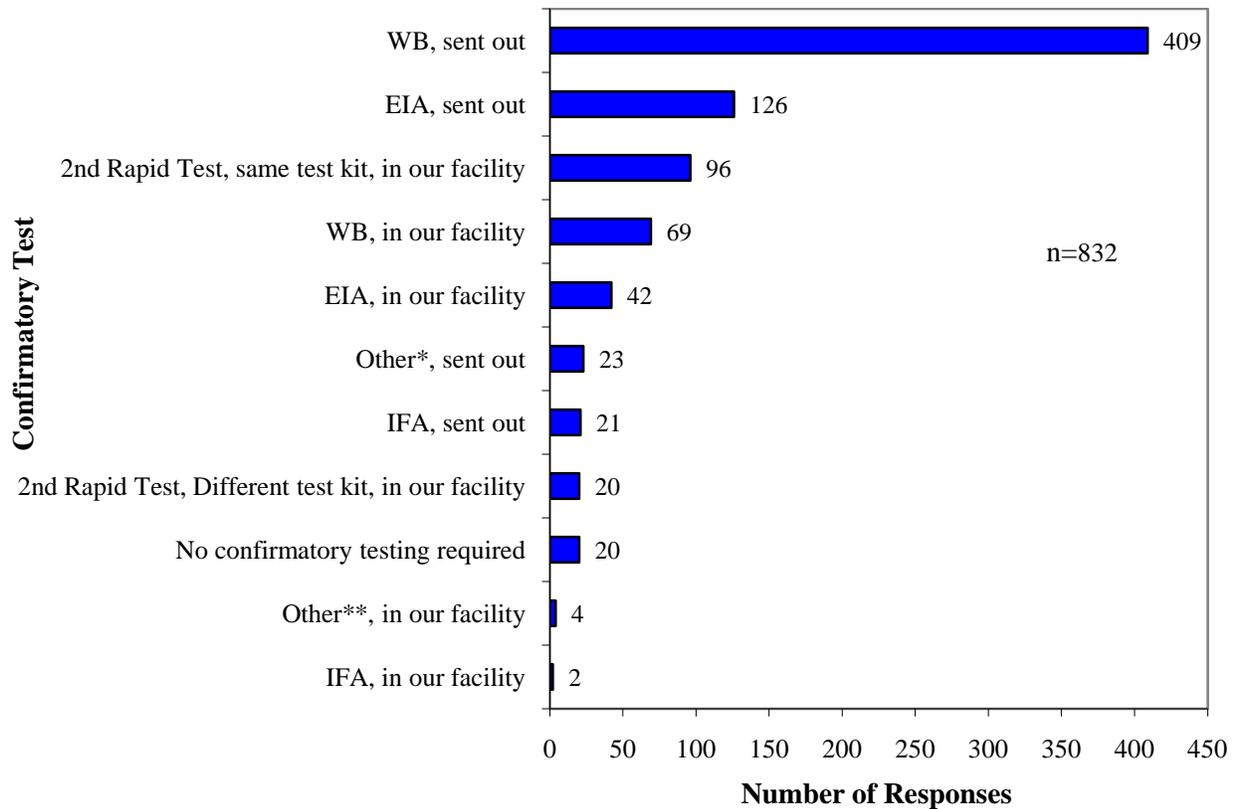
Confirmatory testing, Continued

Types of confirmatory testing

The figure below shows the responses regarding confirmatory testing practices. Five hundred and thirty-two testing facilities submitted responses.

Note: sites could indicate more than one type of confirmatory test

Figure 6: Confirmatory testing patterns used by participants



*Other, sent out: PCR/viral load, n=14; Conditional: if EIA & WB results don't match, do Multispot testing, n=5; Not specified: n=2; Conditional: Immunoblot for HIV-2 only upon request by physician, n=1; HIV-2 Elisa with reflex HIV-2 WB, n=1

**Other, in our facility: Chemiluminescence, n=3; Immunometric assay, 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, IFA, or NAAT test, with a negative confirmatory NAAT requiring further follow-up testing by WB or IFA.^{1,2,4}
- 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, 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}

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 98.2%:

- 98.2% for the positive samples:
 - 95.8% for Donor 1 (weak positive);
 - 97.6% for Donor 2 (weak positive);
 - 99.0% for Donor 3 (strong positive); and
 - 99.6% for Donor 4 (strong positive).

- 97.8% for the negative sample (Donor 5).

The majority (78%, 32/41) of the false-negative errors in this survey were reported for weak Donors 1 & 2 (19 and 13 false negatives, respectively).

Comments provided for four of the nine “invalid” results indicated that the result was due to the faintness of the test line, control line or both. For example, the comment with the invalid result for Donor 5 stated “Test line did not appear... Faint control line”. The comments with the two invalid results for Donor 1 stated “Very faint” and “Both lines are faint lines...can’t determine results”. The last comment with an invalid result was for Donor 3: “T[est] line is very faint”. These comments may reflect a reluctance to submit a result when the color development is reduced, rather than indicating a problem with the testing itself, as would be the case if the test device did not show a valid outcome. For example, if the test device’s internal control line/dot did not appear, this would generally be considered to reflect either a problem with the test device or indicate that sufficient sample was not used, and would be reported as a legitimate “invalid” result.

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Appendix-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 the educational goal of our mission. We are including:

- *The current survey’s most frequently asked question (FAQ)* by HIV RT MPEP participants;
- *Highlights of Previous FAQs*;
- *CDC websites* to provide participants with access to timely relevant material published online by CDC; and
- *HIV Rapid Testing Resources as a link to long-term references.*

FAQ: March 2010 survey This section responds to the current survey’s most frequently asked question.

Q: If we notify the MPEP that our reported values for the MPEP sample panel included one or more results that were accidentally switched (e.g., if we reported sample#1’s result in the space for sample#2, and visa versa) can this be corrected?

A: Any mislabeling of sample results may be corrected for your own records, depending on the policy of your testing site, but we do not alter the resported result data. Transcription mistakes of this type are appropriately noted as errors in the testing process, just as mixing up and incorrectly reporting the results of two patient/clients’ tests would be considered an error. Having a good system for ensuring that reported results correctly match the corresponding sample’s “name” (in our case the sample code) is a very important part of quality assurance (QA) in the HIV rapid testing process.

Highlights of previous FAQs This section provides the answers to some of our participants’ frequently asked questions (FAQs) from previous surveys.

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 [2]) 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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Appendix-Appendix-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 [reliably] 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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Appendix-Appendix-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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