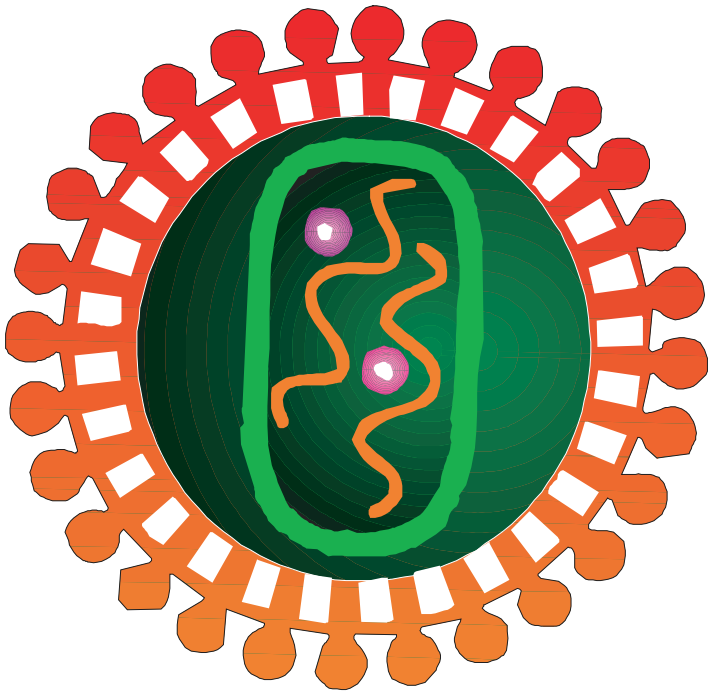
# MPEP

# HIV Rapid Testing

## Report of Sample Shipment Results, January 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

# HIV-1 Rapid Testing MPEP January 2005 Report of Results

Report of the January 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).

**Coordination of report production**

The production of this report was coordinated in CDC by:

Coordinating Center
for Health Information and Service..... Ed Sondik, Ph.D.,
Blake Caldwell, M.D., M.P.H., Directors

National Center for Health Marketing..... Steve Solomon, M.D., Director

Division of Public Health Partnerships..... Robert Martin, M.P.H., Dr. P.H., Director

Laboratory Practice Evaluation and
Genomics Branch..... Devery Howerton, Ph.D., Chief

**Report content**

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP)..... Laurina O. Williams, Ph.D., M.P.H.,
Co-Manager

..... G. David Cross, M.S., Co-Manager

MPEP HIV-1 Rapid Testing Performance Evaluation..... Leigh Inge Vaughan, B.A.,
HIV Rapid Testing Project Coordinator

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**Contact information**

Inquiries should be directed to the Model Performance Evaluation Program by calling Leigh Vaughan at (770) 488-8095 or Dr. Laurina Williams at (770) 488-8130.

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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 | 4 | Negative | Uninfected | _____ | _____ |
| | A2 | 9 | Positive (W) | Infected | _____ | _____ |
| | A3 | 11 | Positive (S) | Infected | _____ | _____ |
| | A4 | 1 | Positive (W) | Infected | _____ | _____ |
| | A5 | 4 | Negative | Uninfected | _____ | _____ |
| | A6 | 1 | Positive (W) | Infected | _____ | _____ |
| B | B1 | 4 | Negative | Uninfected | _____ | _____ |
| | B2 | 4 | Negative | Uninfected | _____ | _____ |
| | B3 | 1 | Positive (W) | Infected | _____ | _____ |
| | B4 | 9 | Positive (W) | Infected | _____ | _____ |
| | B5 | 1 | Positive (W) | Infected | _____ | _____ |
| | B6 | 11 | Positive (S) | Infected | _____ | _____ |
| C | C1 | 9 | Positive (W) | Infected | _____ | _____ |
| | C2 | 4 | Negative | Uninfected | _____ | _____ |
| | C3 | 11 | Positive (S) | Infected | _____ | _____ |
| | C4 | 1 | Positive (W) | Infected | _____ | _____ |
| | C5 | 1 | Positive (W) | Infected | _____ | _____ |
| | C6 | 4 | Negative | Uninfected | _____ | _____ |
| D | D1 | 4 | Negative | Uninfected | _____ | _____ |
| | D2 | 1 | Positive (W) | Infected | _____ | _____ |
| | D3 | 4 | Negative | Uninfected | _____ | _____ |
| | D4 | 9 | Positive (W) | Infected | _____ | _____ |
| | D5 | 11 | Positive (S) | Infected | _____ | _____ |
| | D6 | 1 | 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) 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 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 January 2005.

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 435 testing sites within and outside of the United States. Responses were received from 390 of the testing sites (89.7%). Of those responding:

- 329 (84.4%) were from U.S. testing sites, and
- 61 (15.6%) were from non-U.S. testing sites.

*Notes*:
1. Sixteen 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 412.
2. One site 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 January 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.

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 are summarized below.

**Overall performance**

Overall accuracy (percent of correct results) for all samples, by all sites with all kit types, was 99.2% (2417/2436). "Indeterminate" result interpretations were considered to be incorrect and "Invalid" result interpretations were not included in the analyses.

A summary of results for all positive and negative 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 Neg (% False Neg) | Negative/Non-Reactive Results | Indeterminates | False Positives (% False Pos) | Overall Performance (TP + TN/Total # of Results) |
| 390 | 2436 | 1624 | 1 | 5 (0.3%) | 793 | 5 | 8 (1.0%) | 99.20% |

- The **positive challenges** included one strong positive (Donor 11) and two weak positives, one in duplicate (Donor 1, Donor 1 duplicate, and Donor 9). There were six incorrect results on these samples (three for strong positive samples and three for weak positive samples).
    - Overall Accuracy was 99.6%% (1624/1630).
    - Accuracy varied with test kit used (98.8% to 100%).

- The **negative challenge** (Donor 4) was included in the panel in duplicate. There were 13 incorrect results on these samples:
    - Overall Accuracy was 98.4% (793/806).
    - Accuracy varied with test kit used (89.1% to 100%).

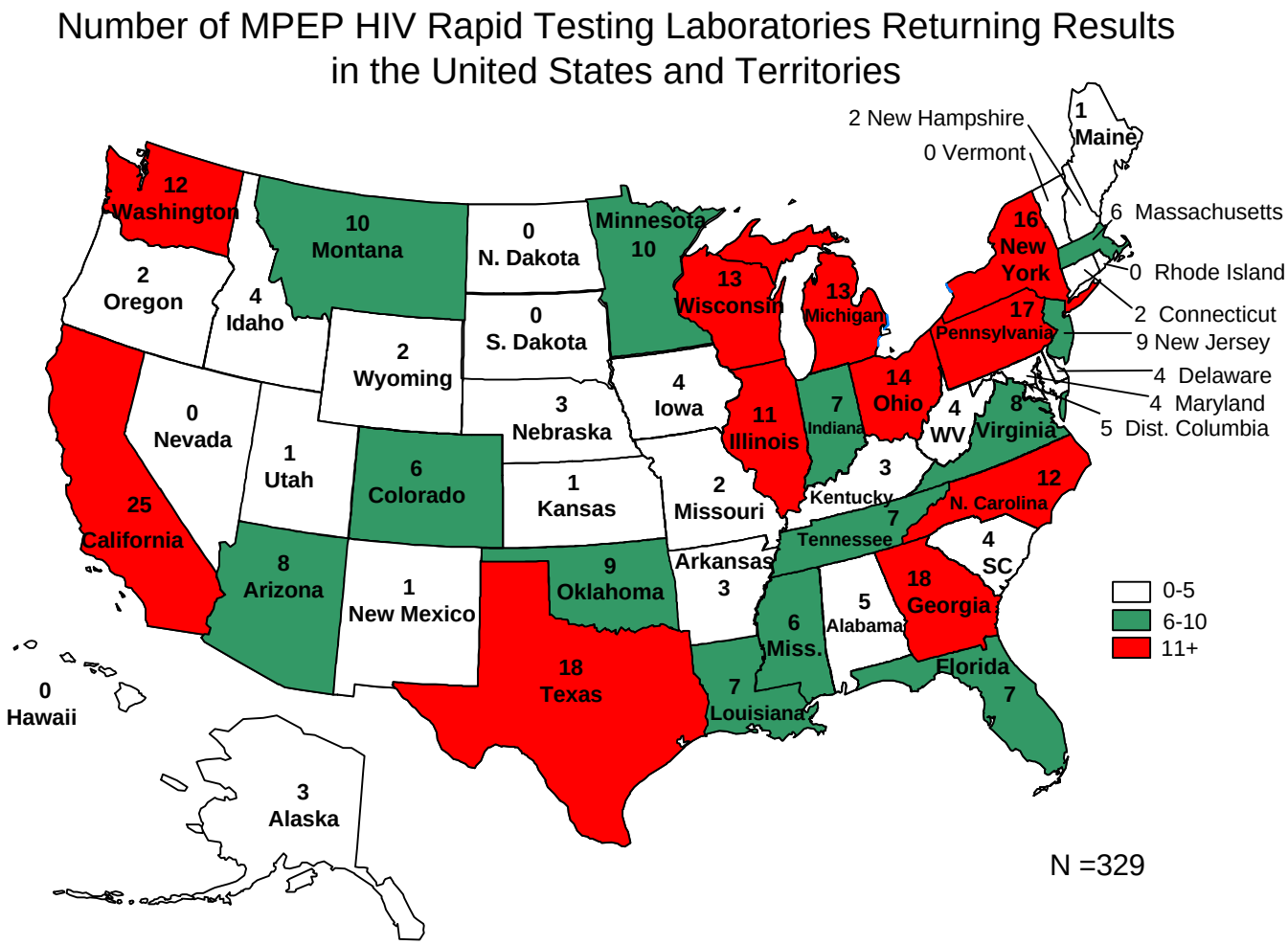
# Demographics

**Overview**

The total number of different testing sites (foreign and domestic) submitting results was 390. Of these:

- the 329 U.S. (domestic) testing sites are depicted in ***Figure 1***, and
- the 61 foreign testing sites are listed in ***Table 3***.
- 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 in the current survey (329) was similar to that of the August 2004 survey (327).

**Figure 1**

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

**Table 3**

| 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 | Mali | 1 |
| Brazil | 1 | Myanmar | 1 |
| Burkina Faso | 1 | Nepal | 1 |
| Burundi | 1 | Niger | 1 |
| Cameroon | 1 | Nigeria | 1 |
| Canada | 1 | Pakistan | 1 |
| Congo | 1 | Panama | 1 |
| Cote d'Ivoire | 1 | Peru | 1 |
| Dominican Republic | 1 | Philippines | 3 |
| Egypt | 2 | Republic of Yemen | 1 |
| El Salvador | 1 | Senegal | 1 |
| Eritrea | 1 | Slovakia | 1 |
| Ethiopia | 1 | Taiwan | 1 |
| Ghana | 1 | Tanzania | 3 |
| Guyana | 1 | Thailand | 6 |
| Honduras | 2 | Uganda | 1 |
| Hungary | 1 | Zambia | 1 |
| India | 2 | Zimbabwe | 2 |

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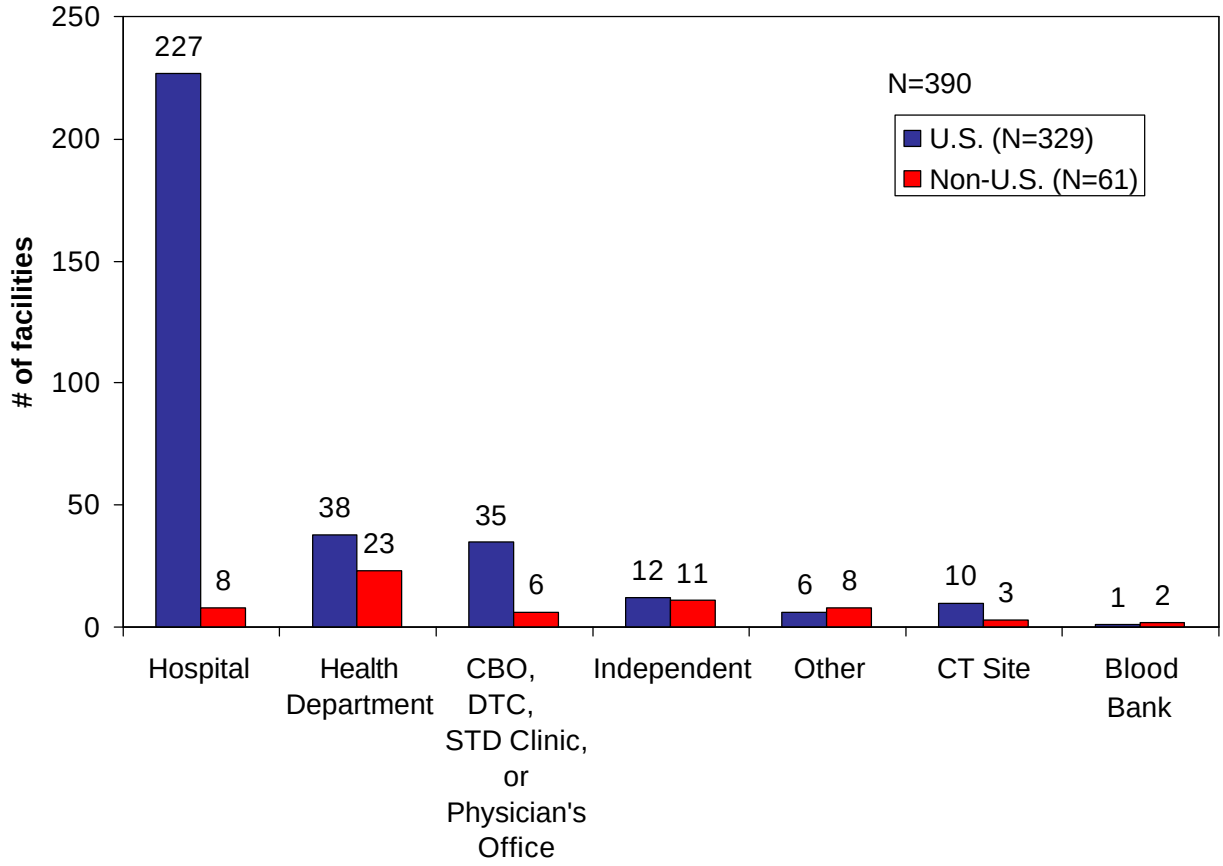
## Demographics, Continued

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

DTC = Drug Treatment Center

CT Site = Counseling and Testing site

# Detailed Performance Results

***Table 4*** gives 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** | **% Positive** | **# of Participants** | **# of Results** | **% Negative** |
| **1 (Weak Positive)** | 388 | 815 | 99.9% | n/a | n/a | n/a |
| **4 (Negative)** | n/a | n/a | n/a | 384 | 806 | 98.4% |
| **9 (Weak Positive)** | 388 | 409 | 99.5% | n/a | n/a | n/a |
| **11 (Strong Positive)** | 385 | 406 | 99.3% | n/a | n/a | n/a |

The results varied with respect to the donor:

- Of the five false-negative results:
    - three were reported for the weak positive samples:
        - Donor 9 (2/5), and
        - Donor 1 (1/5).
    - two were reported for the strong positive sample (Donor 11).
- Of the eight false-positive results, three were reported by two different U.S. health department testing sites, and five were reported by three non-U.S. testing sites classified as “other”.
- The six indeterminate results were reported for the following donor samples:
    - Donor 11 (strong positive sample), one result, and
    - Donor 4 (negative sample), five results.

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## 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) | 188 | 751 | 749 | 2 | | 99.7% | 188 | 376 | 3 | 373 | | 99.2% | 1127 | 1122 | 99.6% |
| Oraquick Advance Rapid HIV-1/2 Ab Test (OraSure) | 11 | 44 | 44 | | | 100.0% | 11 | 22 | | 22 | | 100.0% | 66 | 66 | 100.0% |
| Reveal Rapid HIV-1 Test (MedMira) | 27 | 108 | 108 | | | 100.0% | 25 | 50 | | 50 | | 100.0% | 158 | 158 | 100.0% |
| Reveal G2 Rapid HIV-1 Antibody Test (MedMira) | 84 | 335 | 331 | 3 | 1 | 98.8% | 82 | 160 | | 159 | 1 | 99.4% | 495 | 490 | 99.0% |
| Determine HIV-1/2 (Abbott) | 39 | 156 | 156 | | | 100.0% | 39 | 78 | 2 | 74 | 2 | 94.9% | 234 | 230 | 98.3% |
| Biotech Uni-Gold Recombigen HIV (Trinity) | 20 | 79 | 79 | | | 100.0% | 20 | 40 | | 40 | | 100.0% | 119 | 119 | 100.0% |
| Biotech Uni-Gold (Trinity) | 7 | 28 | 28 | | | 100.0% | 7 | 14 | | 14 | | 100.0% | 42 | 42 | 100.0% |
| Biotech Capillus (Trinity) | 4 | 15 | 15 | | | 100.0% | 4 | 8 | | 8 | | 100.0% | 23 | 23 | 100.0% |
| Multispot HIV-1/HIV-2 (Bio-Rad) | 2 | 8 | 8 | | | 100.0% | 2 | 4 | | 4 | | 100.0% | 12 | 12 | 100.0% |
| Serodia HIV (Fujirebio) | 3 | 12 | 12 | | | 100.0% | 3 | 6 | | 6 | | 100.0% | 18 | 18 | 100.0% |
| HIV Rapid Test (Efoora) | 1 | 4 | 4 | | | 100.0% | 1 | 2 | | 2 | | 100.0% | 6 | 6 | 100.0% |
| Other | 19 | 90 | 90 | | | 100.0% | 19 | 46 | 3 | 41 | 2 | 89.1% | 136 | 131 | 96.3% |



***Table 5*** gives the accuracy, by kit type for this HIV-RT shipment.

# Kit Types Used By Participants

**Overview**

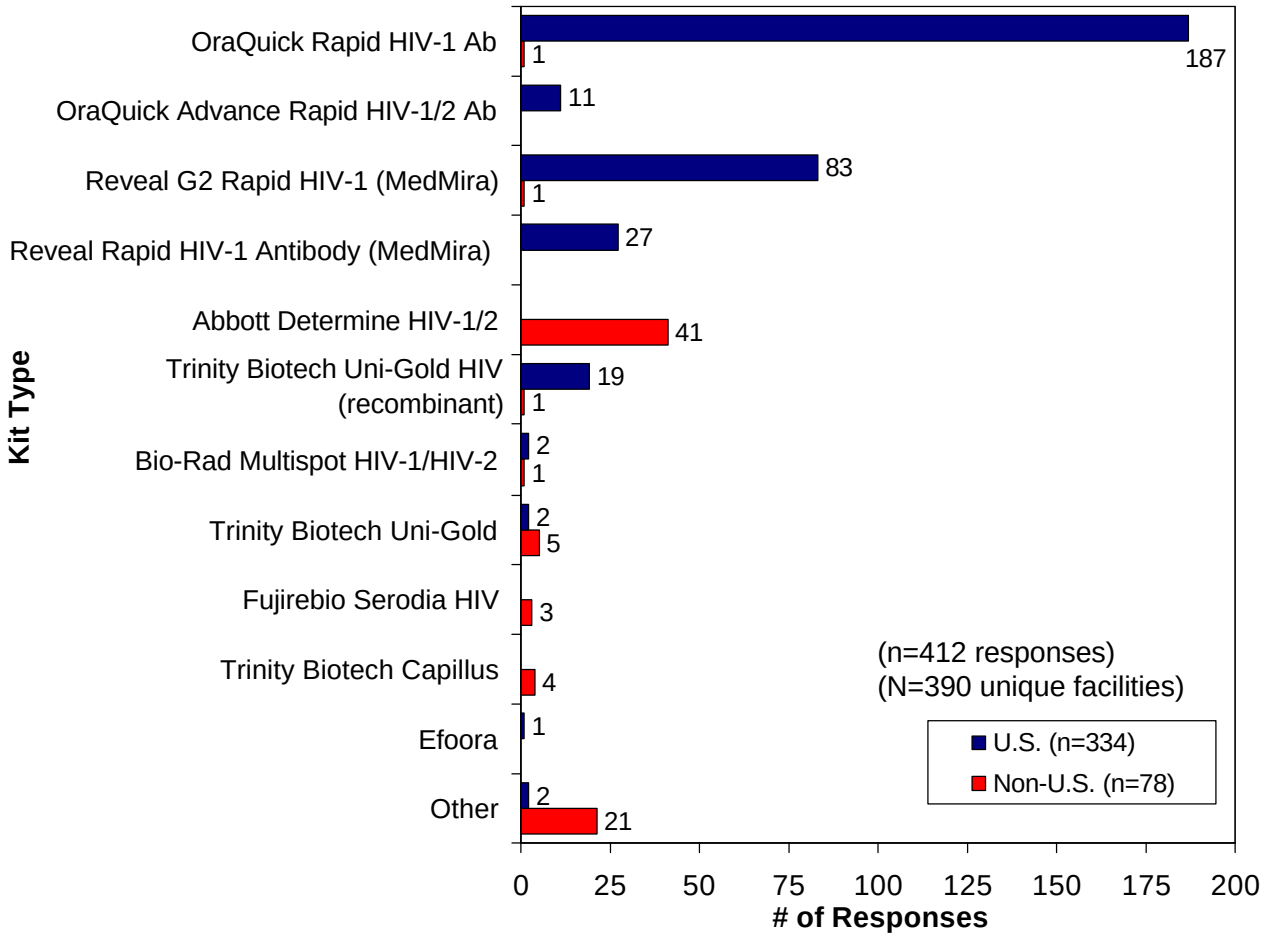
This section describes the kit types used by participants.

- The predominant kit types, as shown in ***Figure 3***, were:
  – OraQuick Rapid HIV-1 or ADVANCE HIV 1/2 Ab (48.3%, 199/412),
  – MedMira Reveal or Reveal G2 HIV rapid tests (26.9%, 111/412), and
  – Abbott Determine HIV-1/2 (10.0%, 41/412).

- 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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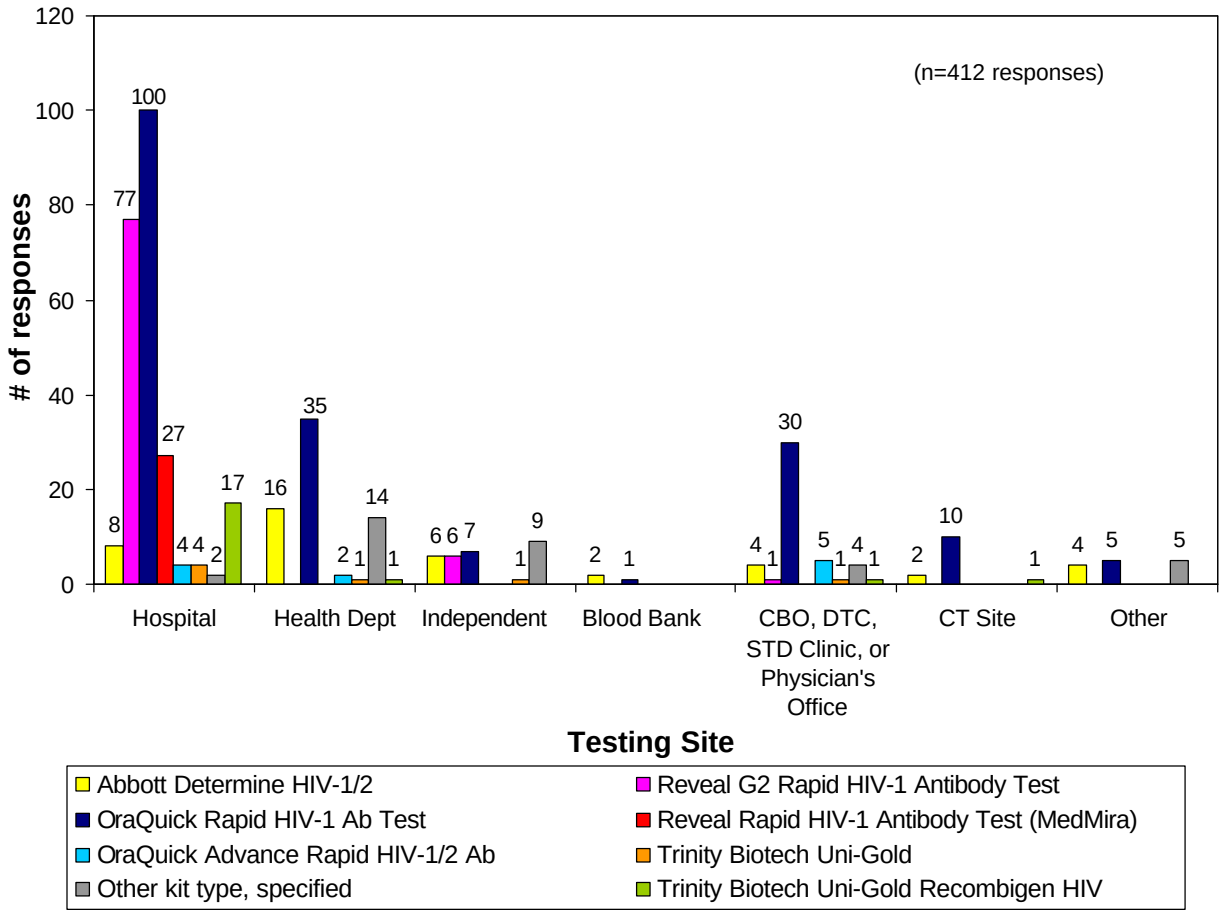
# Kit Types Used By Participants, Continued

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.

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
CT Site = Counseling and Testing site

# Specimen Types Used by Participants

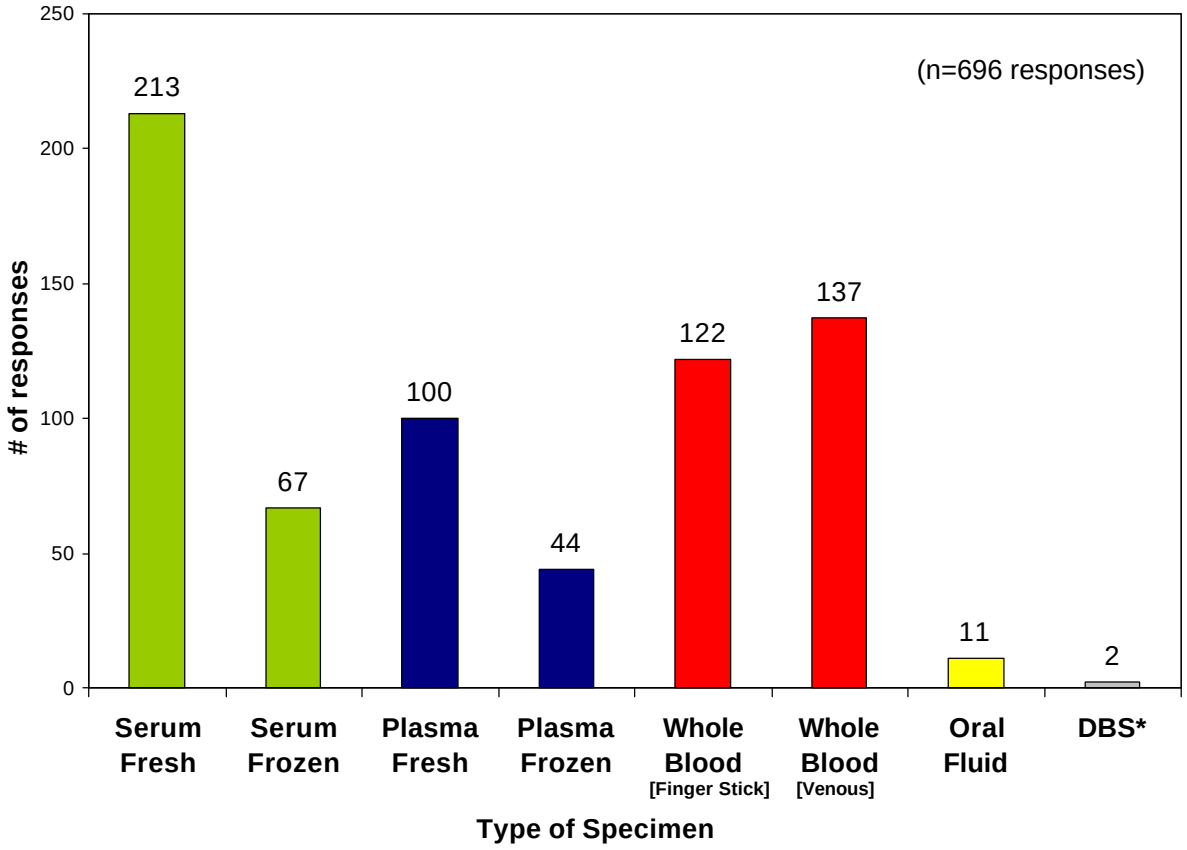
**Overview**

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

- Most specimens typically used for HIV rapid testing were either serum or plasma, as 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 two to 11.

# Quality Control (QC)

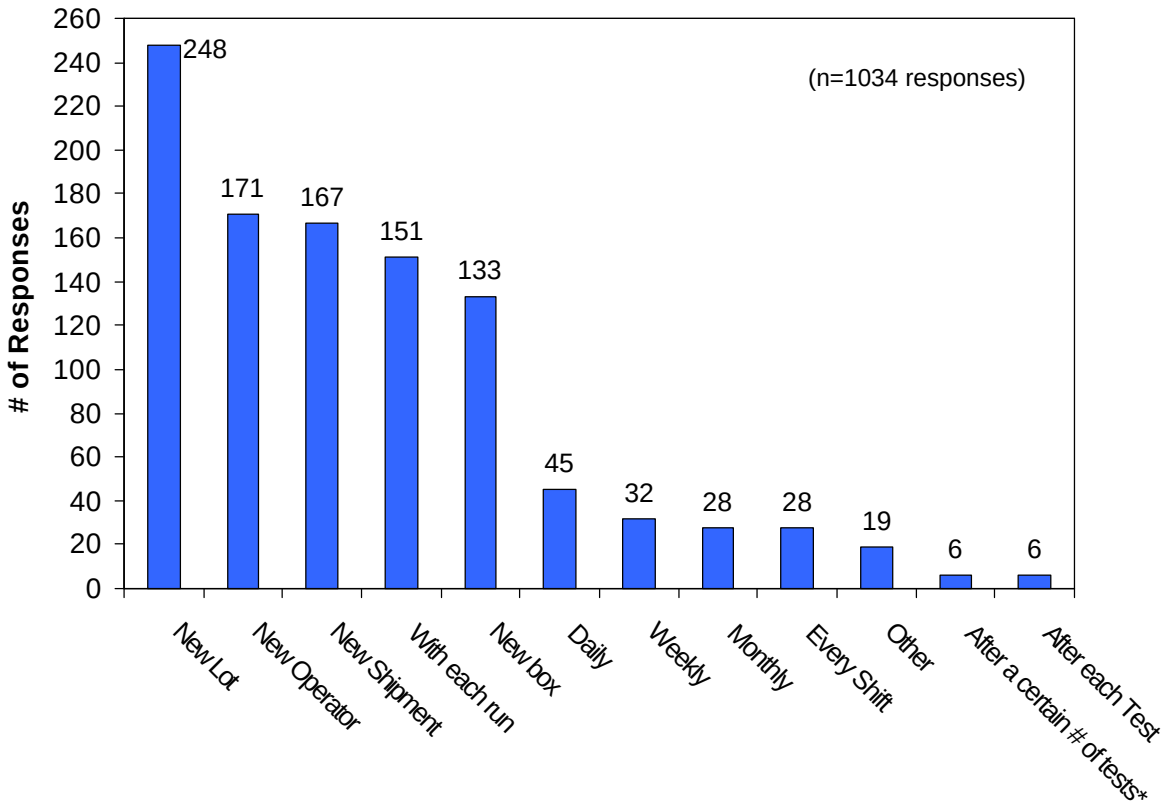
**Overview**

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***.

- 389 out of 390 facilities that returned responses answered the question regarding use of quality control samples (question #5).
  - Most facilities (92.3%, 359/389) indicated the use of QC samples.
- 453 responses indicated the source from which the QC samples were obtained. The sources of the control samples were as follows:
  - controls obtained from the same manufacturer as the test kit (79.5%, 360/453),
    - 46.4% (167/360) of these QC samples were included in the test kit, and
    - 53.6% (193/360) were purchased from the kit manufacturer separately.
  - in-house controls (13.0%, 59/453).
  - "Other" manufacturer controls (manufacturer not the same as for the test kit) (7.5%, 34/453).

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 20-60)

# 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 participants (376/544; 69.1%) reported either
  – sending the reactive (preliminary positive) specimens to another facility (274/544; 50.4%), or
  – performing EIA alone (23/544, 4.2%) or in combination with other tests (79/544; 14.5%).

- Several participants (65/544; 11.9%) reported using a second rapid test for confirmatory testing. Of these, 15/65 (23.1%) reported using a second rapid test with no other type of confirmatory testing.

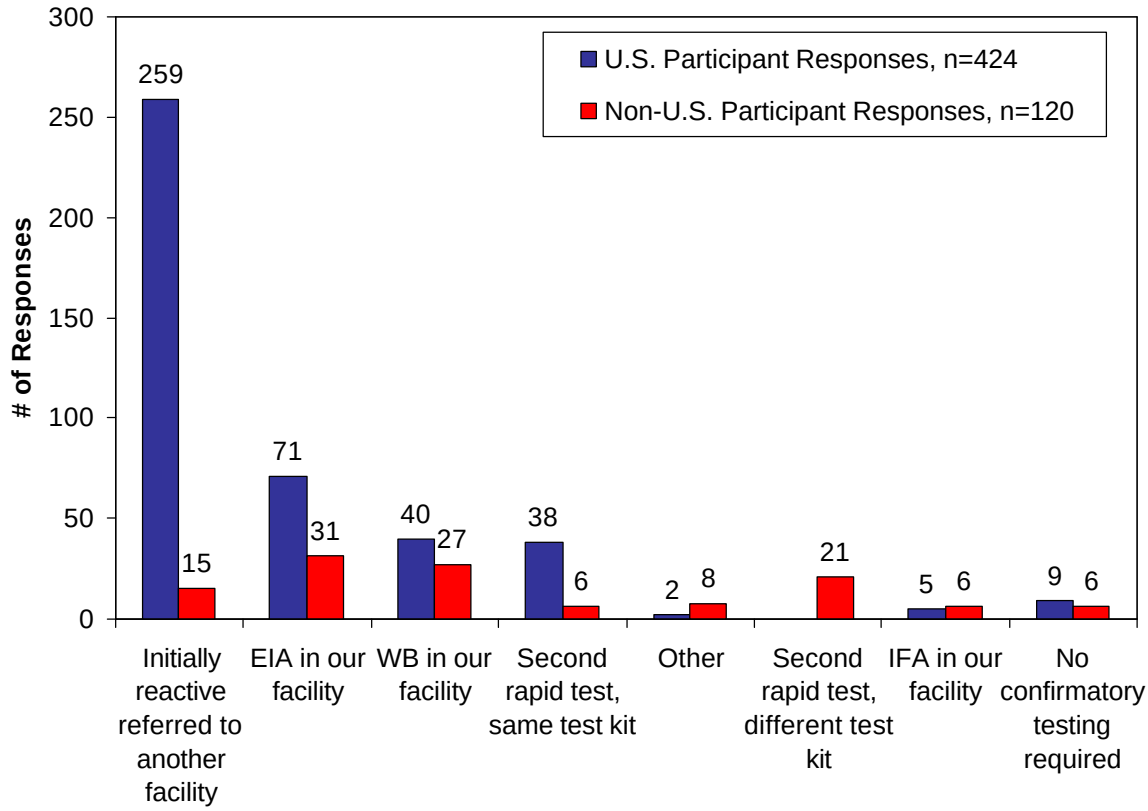
Fifteen responses indicated that no confirmatory testing was required prior to reporting a positive result for the HIV rapid testing kit listed. ***Note***: Separate report forms are required for each different HIV rapid testing kit used, and participants could have reported different confirmatory testing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

Eight of these 15 responses were reported by sites not using confirmatory testing for ***any*** kit type:
- four were U.S. sites, and
- three were non-U.S. sites, one of which submitted two forms (two kit types).

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

**Figure7:**

**Types of confirmatory testing**



# Conclusions and Discussion

**Overall performance**

Overall, testing sites performed well in this MPEP shipment.

Accuracy when testing positive samples (99.6%) was better than accuracy when testing negative samples (98.4%).

Incorrect results reported for positive samples varied with kit type, but otherwise appeared to be random.

Incorrect results reported for negative samples varied with kit type and by donor. All of the indeterminate results for negative samples were reported for Donor 4. The reasons for this are unclear. The eight false-positive results were reported by five different testing sites.

Most of the errors were reported using one of the three predominant kit types. Thus, the apparent variations in accuracy with kit type may simply be explained by the fact that there was more opportunity to observe errors using these kit types.

**Specimen types**

The number of testing sites reporting the use of oral fluid increased from two to 11 sites. Of these, nine were U.S. testing sites that tended to be either community-based organizations (4/9) or health departments (3/9).

In this survey, 26 U.S. testing sites and one non-U.S. site reported using serum and/or frozen plasma as specimen types for the OraQuick Rapid HIV-1 or ADVANCE HIV-1/2 Antibody test kits. It should be noted that the OraQuick tests are not FDA approved for serum (fresh or frozen) or for frozen plasma specimens. Use of these specimen types for either of these test kits is considered a modification of the OraQuick testing procedure. 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]

**Confirmatory testing**

Some U.S. labs continue to use confirmatory testing algorithms that do not include Western blot (WB) or indirect immunofluorescence assay (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 WB or IFA test.[1,3]

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# Conclusions and Discussion, Continued

**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]

**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

5. Code of Federal Regulations: Laboratory Requirements, 42 C.F.R. Chapter IV, Part 493 (2003). http://www.phppo.cdc.gov/clia/regs/toc.aspx

# Topical Issues in HIV Rapid Testing

**Introduction**

The HIV Rapid Testing Model Performance Evaluation Program (HIV-RT MPEP) strives to be a resource for facilities using HIV rapid testing kits. This section of the HIV-RT MPEP Report of Results, "Topical Issues in HIV Rapid Testing," is intended to address that part of our mission. We are including:

- ***Frequently Asked Questions (FAQs)*** by HIV RT MPEP participants to share with all participants our responses to some recent queries,
- ***CDC websites*** to provide participants with access to timely relevant material published online by the CDC, and
- ***HIV Rapid Testing Resources*** as a link to long-term references.

**FAQs: January 2005 survey**

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

**Q: What types of samples can be used in performing HIV rapid testing?**
A: The type(s) of sample (e.g. whole blood, serum, plasma, oral fluid, etc.) that are appropriate to use for HIV rapid testing depends on the test kit that is used. Each manufacturer should have information regarding approved sample type(s) in the package insert for their HIV rapid testing kit.

**Q: What is a package insert, and why should I want one?**
A: These are detailed, printed instructions from the manufacturer that are included with the test kit. All testing sites should have a copy of the current package insert on hand, in the work area, as new aspects of testing protocols may be described. They contain valuable information, which generally includes:

- acceptable sample type(s),
- how to perform the test,
- proper storage for both samples and test kit, and
- information about quality assurance issues and/or quality control material.

If you do not have a copy of the package insert for your HIV rapid testing kit, you should be able to obtain a copy by contacting the company that makes your kit.

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# Topical Issues in HIV Rapid Testing, Continued

**Highlights of previous 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.

To view other FAQs in previous HIV RT MPEP reports, please visit our website at:
http://www.phppo.cdc.gov/mpep/HIV-1rt.aspx

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**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

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**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/

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