HIV-1 Rapid Testing MPEP June 2005 Report of Results


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<table>
<thead>
<tr>
<th>Panel Letter</th>
<th>Vial Label</th>
<th>CDC Donor Bulk Number</th>
<th>CDC Test Result$^{1,3}$</th>
<th>Donor HIV Status</th>
<th>Laboratory Interpretation$^2$ and/or Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A1</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A2</td>
<td>1</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A3</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A4</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A5</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A6</td>
<td>4</td>
<td>Negative</td>
<td>Uninfected</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>B1</td>
<td>1</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B2</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
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<tr>
<td></td>
<td>B3</td>
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<td>Positive (W)</td>
<td>Infected</td>
<td></td>
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<tr>
<td></td>
<td>B4</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
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<tr>
<td></td>
<td>B5</td>
<td>4</td>
<td>Negative</td>
<td>Uninfected</td>
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</tr>
<tr>
<td></td>
<td>B6</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
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<tr>
<td>C</td>
<td>C1</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C2</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
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<tr>
<td></td>
<td>C3</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
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<tr>
<td></td>
<td>C4</td>
<td>4</td>
<td>Negative</td>
<td>Uninfected</td>
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<tr>
<td></td>
<td>C5</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C6</td>
<td>1</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>D1</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D2</td>
<td>9</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D3</td>
<td>4</td>
<td>Negative</td>
<td>Uninfected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D4</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D5</td>
<td>1</td>
<td>Positive (W)</td>
<td>Infected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D6</td>
<td>11</td>
<td>Positive (S)</td>
<td>Infected</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Positive Donors</th>
<th>Negative Donors</th>
<th>Overall Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive/ Reactive Results</td>
<td>Indeterminate</td>
<td>False Negative (% False Neg.)</td>
</tr>
<tr>
<td>Total # of facilities</td>
<td>459</td>
<td>2897</td>
<td>2387</td>
</tr>
</tbody>
</table>

- 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).
  - Overall Accuracy for all testing sites was 98.9% (2387/2414)
  - 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).
  - 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).
  - Overall Accuracy was 98.8% (477/483).
  - Incorrect results appeared to be random.
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 56°C for 60 minutes to inactivate infectious agents, whereas HIV-antibody-negative samples were not heat-treated.

- The serostatus of both positive and negative samples was confirmed by all FDA-approved rapid HIV antibody tests, as well as selected FDA-approved EIA and Western blot kits.

- Negative samples were negative for HIV-1 antigen using an FDA-approved monoclonal antibody-based p24 antigen test.

- 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

Continued on next page
Demographics, Continued

The following table shows the breakdown of participants outside the United States.

Table 3

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

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.
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).

<table>
<thead>
<tr>
<th>Donor Number</th>
<th># of Participants</th>
<th># of Results</th>
<th># Pos.</th>
<th># Neg.</th>
<th># Indeter</th>
<th>% Pos.</th>
<th># of Participants</th>
<th># of Results</th>
<th># Pos.</th>
<th># Neg.</th>
<th># Indeter</th>
<th>% Neg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Weak Pos)</td>
<td>456</td>
<td>482</td>
<td>480</td>
<td>2</td>
<td>99.6%</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>4 (Negative)</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>457</td>
<td>483</td>
<td>4</td>
<td>477</td>
<td>2</td>
<td>98.8%</td>
<td></td>
</tr>
<tr>
<td>9/9-dup (Weak Pos)</td>
<td>459</td>
<td>966</td>
<td>949</td>
<td>12</td>
<td>5</td>
<td>98.2%</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>11/11-dup (Strong Pos)</td>
<td>458</td>
<td>966</td>
<td>958</td>
<td>5</td>
<td>3</td>
<td>99.2%</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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)

Continued on next page
Table 5 gives the accuracy by kit type.

<table>
<thead>
<tr>
<th>Kit Type (manufacturer)</th>
<th>Reactive/Positive</th>
<th>Non-Reactive/Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reveal G2 Rapid HIV-1/2 Ab Test (OraSure)</td>
<td>114</td>
<td>698</td>
</tr>
<tr>
<td>OraQuick Rapid HIV-1 Ab (OraSure)</td>
<td>696</td>
<td>1</td>
</tr>
<tr>
<td>Oraquick Advance Rapid HIV-1/2 Ab Test (OraSure)</td>
<td>578</td>
<td>10</td>
</tr>
<tr>
<td>Reveal G2 Rapid HIV-1 Antibody Test (MedMira)</td>
<td>547</td>
<td>10</td>
</tr>
<tr>
<td>Determine HIV-1/2 (Abbott)</td>
<td>213</td>
<td>1</td>
</tr>
<tr>
<td>Biotech Uni-Gold Recombigen HIV (Trinity)</td>
<td>145</td>
<td>29</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 (Bio-Rad)</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>Biotech Capillus (Trinity)</td>
<td>18</td>
<td>6</td>
</tr>
<tr>
<td>Serodia HIV 1/2 (Fujirebio)</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>Biotech Uni-Gold (Trinity)</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Totals</td>
<td>140</td>
<td>140</td>
</tr>
</tbody>
</table>

Table 5: Results for all samples by test kit
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

<table>
<thead>
<tr>
<th>Kit Type</th>
<th>U.S. (n=401)</th>
<th>Non-U.S. (n=84)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Rapid HIV-1 Ab</td>
<td>136</td>
<td></td>
</tr>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Ab</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>Reveal G2 Rapid HIV-1 (MedMira)</td>
<td>109</td>
<td></td>
</tr>
<tr>
<td>Reveal Rapid HIV-1 Antibody (MedMira)</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Abbott Determine HIV-1/2</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Trinity Biotech Uni-Gold HIV (recombinant)</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Trinity Biotech Uni-Gold</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Trinity Biotech Capillus</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Bio-Rad Multispot HIV-1/HIV-2</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Fujirebio Serodia HIV 1/2</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>HIV-TRIDOT (J. Mitra &amp; Co, Ltd)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Hema-Strip HIV 1/2 (Chembio)</td>
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</tr>
<tr>
<td>Efoora</td>
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<td></td>
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<tr>
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(n=485 responses)
(N=459 unique facilities)
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.

*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
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:

*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.
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**

- WB, sent out
- EIA, sent out
- EIA in our facility
- Second rapid test, same test kit, in our facility
- WB in our facility
- Second rapid test, different test kit, in our facility
- No confirmatory testing
- IFA sent out
- IFA in our facility
- Other in our facility
- Second rapid test, same test kit, sent out
- Other, sent out

(n=762 responses)
(N=459 unique facilities)

<table>
<thead>
<tr>
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<th>U.S. Participant Responses, n=620</th>
<th>Non-U.S. Participant Responses, n=142</th>
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<td>0</td>
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<tr>
<td>Other, sent out</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
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). 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
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


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](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.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](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5146a5.htm)

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.**

*Continued on next page*
### 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](http://www.phppo.cdc.gov/mpep/HIV-1rt.aspx)

### CDC websites

- **Quick Facts: Rapid Testing April 2003 - April 2004**

- **MMWR:**
  - Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests
    [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm)

- **Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test**

- **International Laboratory-related Resource and Activity Directory**

### HIV rapid testing resources

- **HIV Rapid Testing MPEP website**

- **Model Performance Evaluation Program (MPEP) Home page**

- **Food and Drug Administration (FDA) Licensed / Approved HIV, HTLV and Hepatitis Tests**
  [http://www.fda.gov/cber/products/testkits.htm](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](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](http://www.cdc.gov/nchstp/od/nchstp.html)

- **The World Health Organization**
  [http://www.who.int/en/](http://www.who.int/en/)