DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
Model Performance Evaluation Program
Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing

Report of Results for the Performance Evaluation Survey Conducted

During January 2007

CDC
CENTERS FOR DISEASE™ CONTROL AND PREVENTION

COORDINATING CENTER FOR HEALTH INFORMATION AND SERVICE
DIVISION OF LABORATORY SERVICES
ATLANTA, GEORGIA

Report of the January 2007 Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Performance Evaluation Sample Testing Results Provided by Participant Laboratories in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC)

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Analysis of Testing Results Reported by Laboratories Participating in the Model Performance Evaluation Program for HIV-1 Antibody During January 2007

Introduction

Purpose

The purpose of this report is to present the analysis of results provided to the CDC by laboratories participating in the Model Performance Evaluation Program (MPEP) after they tested the human plasma samples shipped to them in January 2007.

Response

Of the 724 laboratories that received performance evaluation panels,

- 650 (90.0%) laboratories submitted results (overall response rate)
  - – 644 of those responses are included in this report,
  - – 6 laboratories submitted results too late to be included.
- 405 (62.3%) of the 650 laboratories submitted results on-line.

Contents

This report contains the analysis of results for

- screening tests, including enzyme immunoassay (EIA) antibody tests and antibody/antigen combination tests
- Western blot (WB, a confirmatory test)
- indirect immunofluorescence assay (IFA, a confirmatory test), and
- "other" tests (test types other than EIA, WB or IFA, such as line or strip assays, etc.).

Executive Summary

Overall performance

Table 1 summarizes the results grouped by test type: EIA, WB, IFA, and Other.

Table 1: Results Summary

			Positive Donors			Negative Donor			
Method	**Total # of Laboratories**	**Total # of results**	**Positive**	**I***	**False-negative (% false negative)**	**Negative**	**I**	**False-positive (% false positive)**	**Overall Performance (TP+TN/total # results)†**
EIA	644	4203	2797	nv‡	23 (0.8%)	1362	nv	21 (1.5%)	99.0%
WB	223	964	848	42	0	69	3 (4.0%)	2 (2.7%)	99.5%§
IFA	28	152	100	12	0	38	2 (5.0%)	0	98.7%§
Other¶	29	152	115	0	0	37	0	0	100%

* I, Indeterminate results.
† TP, true positives; TN, true negatives.
‡ nv, not valid. Indeterminate is not a valid interpretation for reporting final EIA results.
§ When calculating overall performance, indeterminate interpretations are considered to be correct for HIV-1 antibody-positive donors, and incorrect for HIV-1 antibody-negative donors.
¶ "Other" test methods refer to test types other than EIA, WB or IFA, such as line or strip assays.

Laboratory demographics

Of the 644 laboratories reporting results for the January 2007 samples panel shipment:

- 480 (74.5%) were in the United States (U.S.) and U.S. territory laboratories and
- 164 (25.5%) were non-U.S. laboratories.

These laboratories identified themselves as:

- 235 (36.5%) hospitals,
- 173 (26.9%) health departments,
- 113 (17.5%) independent laboratories,
- 85 (13.2%) blood banks, and
- 38 (5.9%) other types, which include university-associated research centers, university clinics, Federal government facilities, STD clinics, counseling and testing sites, community-based organizations, etc.

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Test summary

Of the 644 laboratories reporting results;

- 378 (58.7 %) performed EIA only
- 230 (35.7%) performed EIA and a supplemental test
- 29 (4.5%) performed an "Other" test in addition to, or instead of EIA, WB, and IFA, and
- 7 (1.1%) performed only a supplemental test.

Laboratory practice questions

To obtain more information about laboratory practices, three questions were added to the EIA section of the result booklet and online data entry system.

Of the laboratories that responded

- 593 laboratories provided answers to the question concerning supplemental/confirmatory testing
- 7 laboratories reported using the Aptima HIV-1 RNA Qualitative Assay and
- 575 laboratories reported the algorithms that are normally used in their laboratories.

Their specific responses to those questions are shown on pages 17-18.

Survey Samples

The survey samples used in this survey were the same as the samples sent in the July 2006 survey. The table below shows the overall performance of laboratories for the July 2006 and the January 2007 surveys.

	Overall Performance by test type			
Shipment	EIA	WB	IFA	OTHER
July 2006	99.1%	99.6%	98.3%	99.4%
January 2007	99.0%	99.5%	98.7%	100%

Challenge Samples

Survey samples

The survey samples were undiluted, defibrinated plasma obtained from individual donors who were either

HIV-1 infected (HIV-1 antibody positive):

These samples were heat-treated at 56º C for 60 minutes to inactivate blood-borne viruses including HIV-1, human T-lymphotropic virus types I and II (HTLV-I/II), and hepatitis B and C viruses.

HIV-1 uninfected (HIV-1 antibody-negative):

These samples were not heat-treated.

Donor testing

Before shipment, each donor sample was tested with the following:

- two HIV-1 EIA kits,
- two HIV-1/HIV-2 EIA kits (including one HIV-1/HIV-2 Plus O)
- supplemental tests;
  - two HIV-1 Western blot (WB) kits, and
  - one HIV-1 indirect immunofluorescence assay (IFA).

Note: These donor samples were not tested using Bayer ADVIA Centaur.

Donor status

Donor 1: strong-positive HIV-1.

Donors 2 (duplicate samples) and **3** (single samples): HIV-1 antibody positive donors demonstrating factors consistent with seroconversion, including:

- a positive p24 antigen test,
- positive test for HIV-1 ribonucleic acid (RNA),
- rising HIV-1 antibody titers in EIA tests, and
- WB reactivity changing from one donation to the next from nonreactive (no bands) to indeterminate or reactive.

Donor 4: HIV-1 (duplicate samples) negative sample**.**

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Challenge Samples, Continued

Laboratory worksheet This worksheet is provided for use in comparing individual laboratory results with target results.

Table 2: Human Immunodeficiency Virus Type 1 (HIV-1) Antibody (Ab) Testing for the January 2007 Shipment

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results[1]	Donor HIV Status	Laboratory Interpretation[2]			
					EIA			
					Initial	Final	WB	IFA
A	**A1**	4	Negative	Uninfected				
	A2	1	Positive	Infected				
	A3	2	Positive	Infected				
	A4	2	Positive	Infected				
	A5	3	Positive	Infected				
	A6	4	Negative	Uninfected				
B	**B1**	2	Positive	Infected				
	B2	1	Positive	Infected				
	B3	4	Negative	Uninfected				
	B4	3	Positive	Infected				
	B5	2	Positive	Infected				
	B6	4	Negative	Uninfected				
C	**C1**	1	Positive	Infected				
	C2	2	Positive	Infected				
	C3	2	Positive	Infected				
	C4	3	Positive	Infected				
	C5	4	Negative	Uninfected				
	C6	4	Negative	Uninfected				
D	**D1**	2	Positive	Infected				
	D2	2	Positive	Infected				
	D3	1	Positive	Infected				
	D4	4	Negative	Uninfected				
	D5	3	Positive	Infected				
	D6	4	Negative	Uninfected				

1. The CDC results were obtained after composite testing with all commercially available HIV-1 and HIV-1/HIV-2 EIA, HIV-1 WB and IFA kits licensed by the Food and Drug Administration (FDA). All CDC results are consistent with the manufacturer's criteria for interpretation. WB interpretations are also consistent with Association of Public Health Laboratories/Centers for Disease Control and Prevention (AHPL/CDC) interpretative criteria.

2. Laboratory Interpretation space is to be completed by participant laboratories to facilitate comparison of their result with CDC result.

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Challenge Samples, Continued

CDC WB results

Table 3: CDC Western blot (WB) testing results for the January 2007 shipment

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Band Detected[1]	HIV-1 WB Test Kit Manufacturer	CDC Interpretation[2]
A	A1, A6	4	No Bands	Both Manufacturers	Negative
	A2	1	17, 24, 31, 41, 51, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech[3] Genetic Systems	Positive Positive
	A3, A4	2	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	A5	3	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
B	B1, B5	2	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B2	1	17, 24, 31, 41, 51, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B3, B6	4	No Bands	Both Manufacturers	Negative
	B4	3	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
C	C1	1	17, 24, 31, 41, 51, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C2, C3	2	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C4	3	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C5, C6	4	No Bands	Both Manufacturers	Negative
D	D1, D2	2	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D3	1	17, 24, 31, 41, 51, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D4, D6	4	No Bands	Both Manufacturers	Negative
	D5	3	24, 31, 41, 51, 55, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive

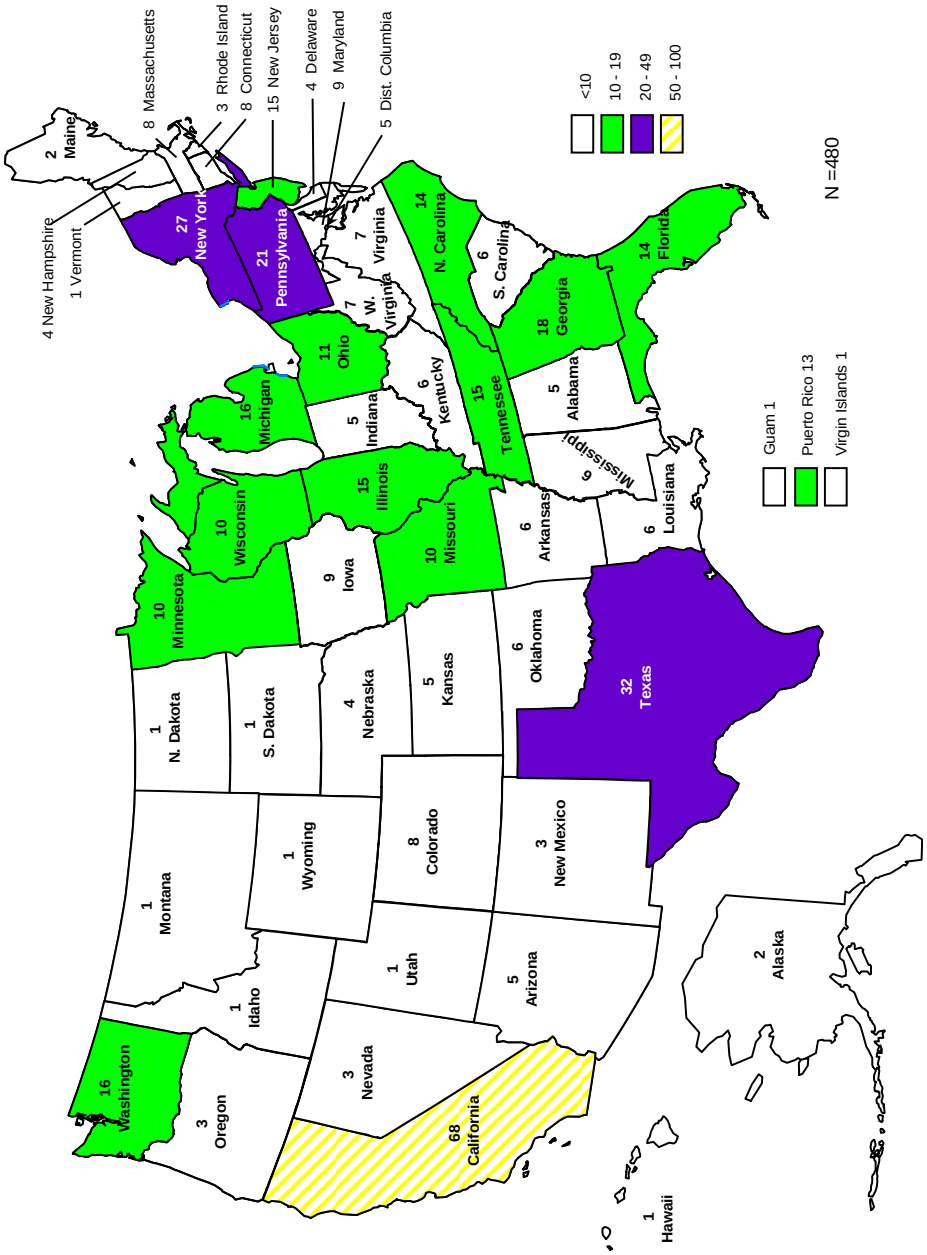
1. Western blot (WB) results are based on the band intensity of ≥1+ staining.
2. The CDC interpretation is consistent with APHL/CDC and the manufacturers' criteria for the interpretation of WB results.
3. Cambridge Biotech/Calypte Biomedical.

Demographics

U. S. laboratories

Figure 1 shows the number and location of MPEP laboratories in the U.S. and U.S. territories submitting results for the January 2007 shipment.

Figure 1: Geographic distribution of MPEP participant laboratories in the United States and U.S. territories



All MPEP laboratories

Including the United States and U. S. Territories, MPEP participants are located in 73 countries.

Table 4: Location of MPEP participants reporting HIV-1 Ab results

N=644

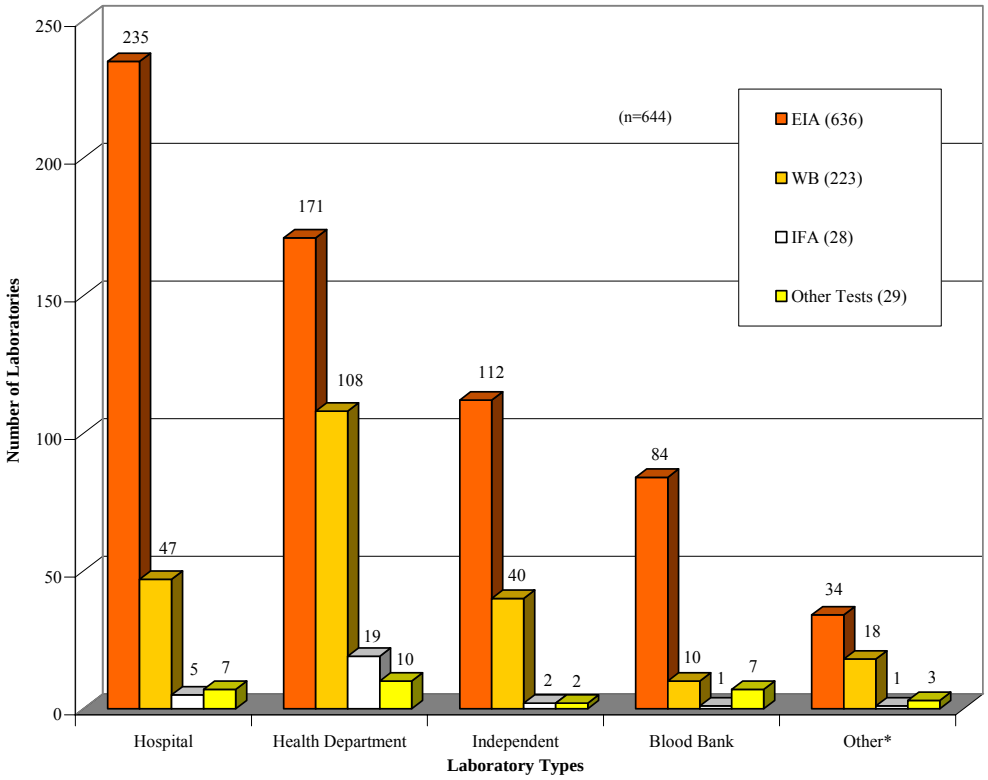
Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Algeria	1	Honduras	2	Romania	1
Argentina	2	Hong Kong	2	Saudi Arabia	2
Australia	5	Hungary	1	Scotland	1
Austria	3	India	5	Senegal	1
Bahamas	1	Ireland	1	Slovakia	2
Barbados	1	Israel	4	Slovenia	2
Belgium	2	Italy	1	South Africa	3
Bolivia	1	Jamaica	1	South Korea	2
Botswana	2	Japan	1	Spain	3
Brazil	3	Kazakhstan	6	Sri Lanka	4
Cameroon	2	Kenya	2	Suriname	1
Canada	16	Kyrgyzstan	3	Switzerland	1
Chile	1	Malaysia	2	Taiwan	2
Colombia	1	Mali	2	Tanzania	4
Cote d'Ivoire	1	Malta	1	Thailand	9
Croatia	1	Mexico	1	Trinidad	2
Denmark	3	Morocco	1	Uganda	2
Dominican Republic	2	Myanmar	1	United Arab Emirates	1
Ecuador	1	Nicaragua	1	United Kingdom	2
Egypt	1	Nigeria	2	United States	465
El Salvador	1	Panama	1	U.S. Territory	15
Eritrea	1	Paraguay	1	Uzbekistan	10
Ethiopia	1	Peru	2	Venezuela	3
Germany	1	Philippines	2	Vietnam	1
Ghana	2	Portugal	1		
Guyana	1	Republic of Singapore	1		

Test methods by laboratory type

Figure 2 shows laboratory types and the test methods used. Some laboratories reported using more than one method. Therefore, the sum is greater than the total number of laboratories.

The "n" value in all figures refers to the number of laboratories reporting results, not the methods or test kits used.

Figure 2: Number of HIV-1 participants reporting EIA, WB, IFA, and "Other" results, by laboratory type



* "Other" laboratories include university-associated research centers, university clinics, Federal government facilities, STD clinics, etc.

EIA Methods and Results

Introduction

Of the 644 laboratories reporting results, 636 (98.8%) performed enzyme immunoassay (EIA) testing using test kits that are designed to detect the presence of HIV-1 and/or HIV-2 antibodies (2nd and 3rd generation tests). In May 2006, Bayer ADVIA Centaur HIV 1/2/O enhanced immunoassay, a chemiluminescence method for detection of HIV-1/2 and subgroup O was approved by the FDA for qualitative determinations of HIV antibodies. Results from laboratories using this test are included in this report.

Participant laboratories located in the U.S. reported using seven different EIA test kits and one chemiluminescence method for detection of antibodies in plasma and serum. These test kits are listed in Figure 4 below, and include:

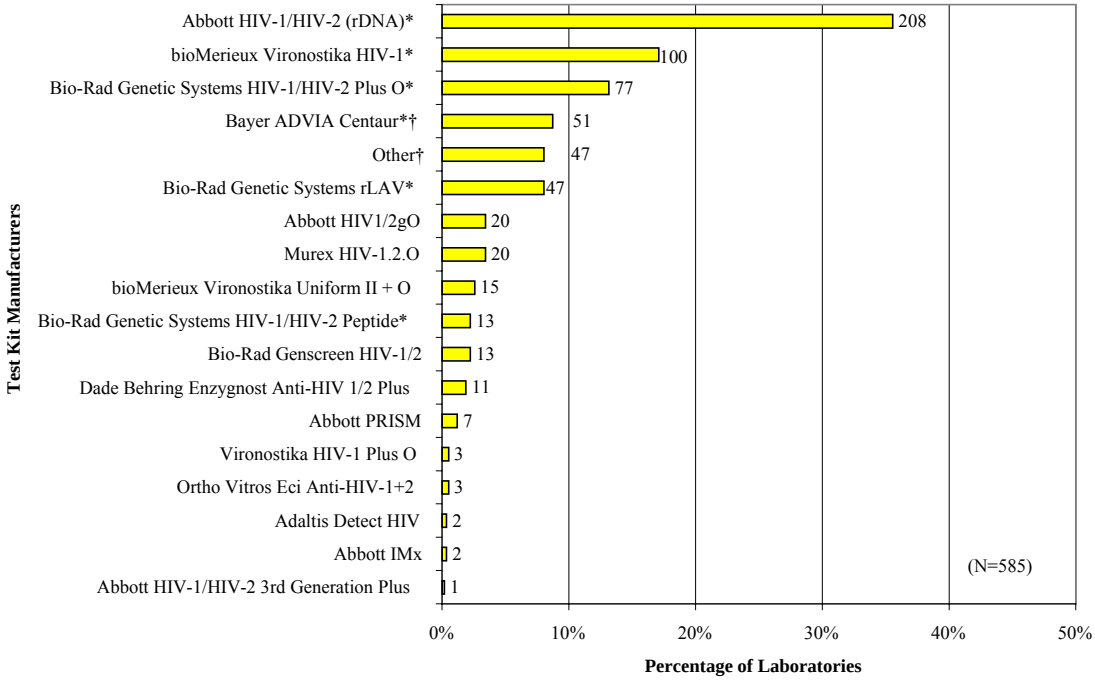
- 5 for HIV-1 and HIV-2, and
- 2 for HIV-1 only.

MPEP participant laboratories outside the U.S. reported using 14 different EIA test kits for detection of antibodies to the HIV-1 and/or HIV-2 virus and HIV p24 antigen.

EIA antibody test kit manufacturers

Figure 3 shows the percentage and number of laboratories using a particular EIA antibody-only test kit. The numbers at the end of the bars show the number of laboratories using each test kit.

Figure 3: Percentage and number of laboratories using EIA test kits, by manufacturer



* FDA approved EIA test kits.
† Other EIA test kits for which no manufacturers' code is provided in the result booklet.

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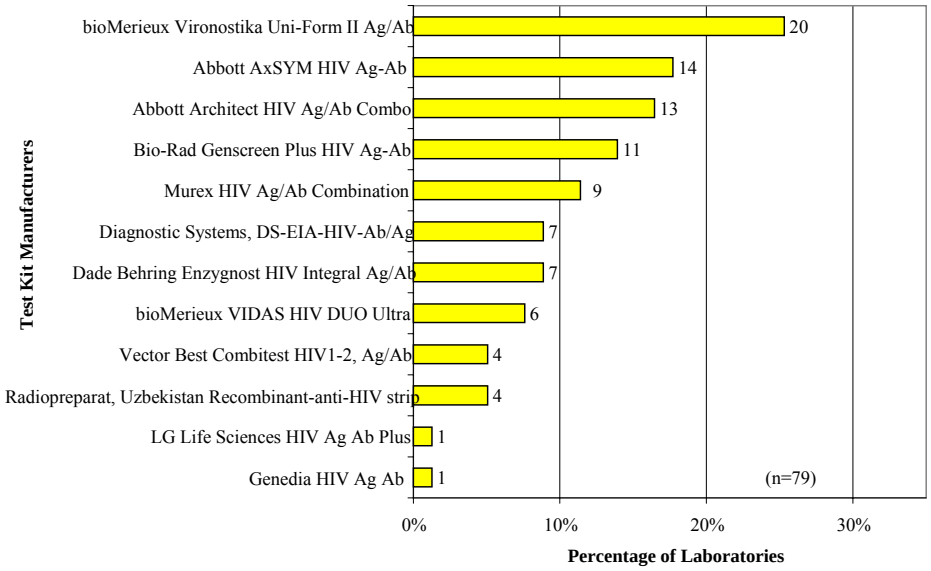
EIA Ag/Ab test kit manufacturers

Many laboratories outside the U.S. use test kits that detect the presence of antibodies to HIV and the presence of p24 antigen (HIV Ag/Ab test kits, 4th generation assays). These test kits are not yet FDA approved, therefore are not used by U.S. participants.

Figure 4 shows the percentage and number of laboratories that used antigen-antibody test kits for simultaneous detection of antigen and antibody.

Figure 4: Percentage and number of non-U.S. laboratories using Ag/Ab test kits, by manufacturer



Other EIA test kits

Laboratories reported using 14 other EIA kits for which no manufacturers' codes are listed in the results booklet or online. Some of these EIA test kit manufacturers are listed below. The number in parenthesis is the number of laboratories that reported using these kits.

- Genedia HIV Ag-Ab, (1)
- LG HIV Ag Ab, (1)
- Diagnostic Systems EIA Anti-HIV (7), and
- Roche ELECSYS HIV Combitest, (1).

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EIA false-positive and false-negative results

Table 5: False-positive and false-negative EIA results, reported by participant laboratories, by kit manufacturer[§]

Manufacturer	Total # of Results	Negative Donor		Positive Donors	
		Negative	False-positive (% false positive)	Positive	False-negative (% false negative)
Abbott Architect	84	28	0	53	3 (5.4%)
Abbott HIV1/2 gO	117	36	2 (5.3%)	77	2 (2.5%)
Abbott HIV-1/HIV-2 (rDNA)	1248	412	4 (1.0%)	830	2 (0.2%)
Abbott IMx	12	3	1 (25.0%)	8	0
Abbott PRISM	41	8	5 (38.5%)	28	0
Bayer ADVIA Centaur	306	100	2 (2.0%)	199	5 (2.5%)
bioMérieux Vironostika HIV-1	598	198	0	398	2 (0.5%)
bioMérieux Vironostika HIV-1 Plus O	16	4	0	11	1 (8.0%)
Bio-Rad Genetic Systems HIV-1 Ag EIA*	12	4	0	5	3 (37.5%)
Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide	78	26	0	51	1 (1.9%)
Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O	462	153	1 (0.6%)	306	2 (0.6%)
Bio-Rad Genetic Systems rLAV	282	94	0	186	2 (1.0%)
Diagnostic Systems EIA Anti-HIV (Russia)	42	10	4 (28.6%)	28	0
Nihol Peptoscreen strip-2 (Uzbekistan)	12	2	2 (0.5%)	8	0

* The challenge samples in this survey only contain HIV-1 antibodies.

[§]**Note:** Only false-positive and false-negative results are contained in this table. Those test kits for which false-positive and/or false-negative results were not reported are not included.

EIA results by donor

Incorrect results for donors for all reported EIA tests are as follows;

- Donor 1 (HIV-1 infected strong positive), 1 false negative,
- Donor 2 (HIV-1 infected seroconverter), 9 false negatives,
- Donor 3 (HIV-1 infected seroconverter), 13 false negatives, and
- Donor 4 (HIV-1 uninfected), 21 false positives.

Comments

In this survey, the overall performance of laboratories reporting EIA and enhanced EIA results is 99.0% correct results. The overall performance of laboratories performing EIA testing has remained stable over the last 3 shipments at between 99.0% and 99.3% correct results.

Laboratory Practice Questions

Introduction

Three questions were added to the January 2007 survey. The purpose of these questions was to

- determine if the MPEP participant laboratories are performing supplemental or confirmatory tests, and if so which confirmatory test,
- determine how Gen-Probe's Aptima HIV-1 RNA Qualitative Assay is being used, if at all, and
- determine what algorithm participants are presently using.

Note: The "N" value for each of the tables in the section represents the number of laboratories that responded to these questions.

Supplemental/ Confirmatory tests

1. What supplemental/confirmatory test(s) do you normally run for repeatedly reactive results obtained using the EIA test kit listed in the Repeat EIA section (or Initial EIA if no Repeat EIA is performed) on the opposite page? Check all that apply.

(N=593)

Number of Laboratories	Laboratory Responses
70	A. Supplemental/confirmatory test not run in our laboratory
279	B. Western blot (WB)
28	C. Immunofluorescence Assay (IFA)
7	D. Gen-Probe Aptima HIV-1 RNA Qualititive Assay
23	E. HIV-1 or HIV-1/2 Rapid Test
213	F. Send to reference laboratory
48	G. Other, (another EIA, line immunoassays, particle agglutination, HIV p24 antigen test, etc)

Interestingly, the 70 (11.8%) laboratories that reported performing no confirmatory testing in their laboratories did not indicate that they send these specimens to a reference laboratory. This includes 58 (82.9%) laboratories in the U.S. and U.S. territories, implying that no confirmatory testing is performed.

Use of Gen-Probe Aptima HIV-1 RNA test

2. If you indicated "Gen-Probe's Aptima HIV-1 RNA Qualitative Assay" in question 1, for what other purpose(s) do you use this assay? Check all that apply.

(N=7)

Number of Laboratories*	Laboratory Responses
4	A. Only use as Supplemental/Confirmatory test for EIA repeat reactive samples
1	B. Use as method for screening blood or plasma donors
1	C. Use to aid in diagnosis of acute or primary HIV infection
2	D. Other use (no other information reported)

*One laboratory reported using Aptima HIV-1 RNA Qualitative Assay for more than one purpose, as indicated in the table.

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Testing Sequences - Algorithms

3. Please indicate your normal testing sequence for samples to be tested for HIV antibody by placing a number in the box corresponding to the step (1st, 2nd, 3rd, etc.) of the testing algorithm. If two assays occur simultaneously in the testing sequence (e.g., WB and IFA), give both assays the same number.

The table below shows the responses to question 3.

N= 575

Step 1	Step 2	Step 3	Step 4	Total Number (418) of U.S. Laboratories (%)	Total Number (157) of Non-U.S. Laboratories (%)	Total Number of Laboratories (%)
EIA-S	EIA-E	WB		235 (56.2%)	44 (28.0%)	279 (48.5%)
EIA-S	EIA-E			90 (21.5%)	46 (29.3%)	136 (23.7%)
EIA-S	EIA-E	IFA		17 (4.1)	1 (0.6%)	18 (3.1%)
EIA-S	WB			6 (1.4%)	11 (7.0%)	17 (3.0%)
EIA-S	EIA-E	WB	RT	8 (1.9%)	5 (5.0%)	13 (2.3%)
EIA-S				7 (1.7%)	4 (2.6%)	11 (1.9%)
EIA-D	WB			9 (2.2%)	2 (1.3%)	11 (1.9%)
EIA-S	EIA-E	WB	IFA	10 (2.4%)	1 (0.6%)	11 (1.9%)
EIA-S	EIA-D	WB		7 (1.7%)	4 (2.6%)	11 (1.9%)
EIA-S	RT			0	9 (5.7%)	9 (1.6%)
EIA-S	EIA-E	RT		2 (0.5%)	4 (2.6%)	6 (1.0%)
EIA-D	EIA-E			2 (0.5%)	3 (1.9%)	5 (0.9%)
EIA-E	WB			1 (0.2%	4 (2.6%)	5 (0.9%)
EIA-D				2 (0.5%)	3 (1.9%)	5 (0.9%)
EIA-S	WB	RT		2 (0.5%)	3 (1.9%)	4 (0.7%)
Other Algorithms				21 (4.8%)	13 (13.0%)	34 (5.9%)

EIA-S = EIA in singlicate
EIA-D = EIA in duplicate
EIA-E = Repeat EIA, if initial is reactive
WB = Western Blot
RT= HIV-1 or HIV-2 rapid test

Comments

Most U.S. laboratories reported testing according to CDC guidelines (see reference below). However, 103 laboratories reported performing EIA testing only. It is unclear from these results how many of these sites refer confirmatory testing to other laboratories.

The HIV testing algorithm recommended by CDC consists of initial screening with an EIA followed by confirmatory testing of repeatedly reactive EIAs with a more specific supplemental test (e.g., Western blot or IFA test).

For more information on HIV-1 testing algorithms log onto www.http//Revised Guidelines for HIV Counseling, Testing, and Referral.

Western Blot Methods and Results

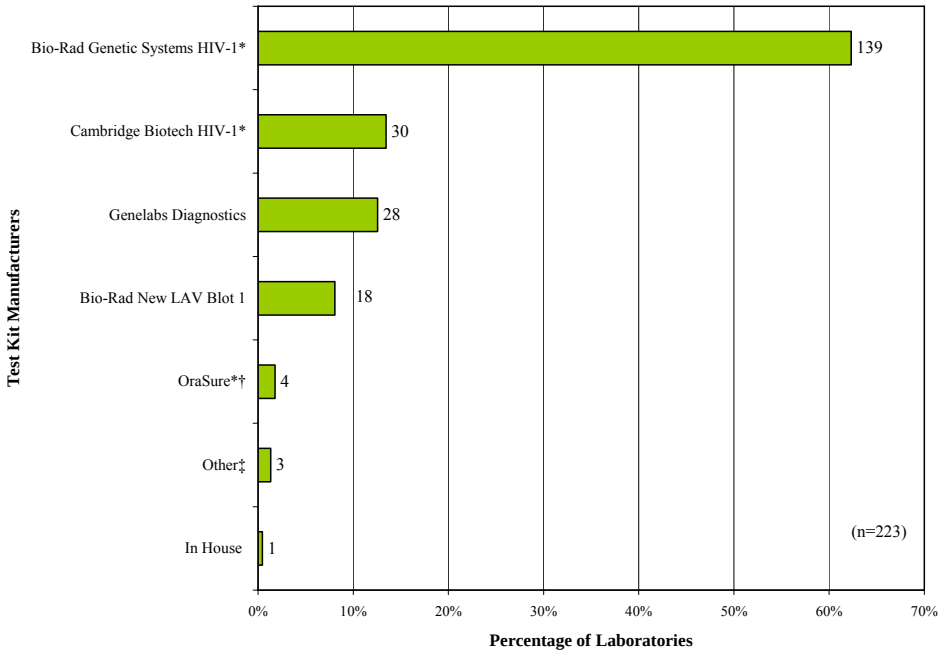
Introduction

Of the 644 laboratories reporting test results in this survey, 223 (34.6%) performed WB testing using four different commercially manufactured WB test kits and one in-house preparation. Four U.S. laboratories used the OraSure HIV-1 test kit to obtain results for these samples. However, OraSure HIV-1 Western blot is not FDA approved for testing serum or plasma.

WB test kits

The WB test kits used by MPEP participant laboratories are shown below. The numbers at the end of the bars show the number of laboratories using that test kit.

Figure 5: Percentage and number of laboratories using WB test kits, by manufacturer



* FDA approved WB test kits.
† Orasure HIV-1 Western Blot Kit is only FDA approved for oral fluid.
‡ Other, WB tests for which no manufacturers' codes are included in the result booklet.

Continued on next page

Western Blot Methods and Results, Continued

WB interpretive criteria

Of the 223 laboratories reporting WB test results, 220 (98.7%) indicated which WB criteria they used to interpret tests results. Most laboratories used the Association of Public Health Laboratories/Centers for Disease Control and Prevention (APHL/CDC) WB interpretive criteria.

The number of laboratories using specific criteria are as follows:

- 190 (86.4%) APHL/CDC,
- 24 (10.9%) World Health Organization (WHO), and
- 6 (2.7%) stated "other" (Manufacturers' insert, Australian National Reference Laboratory, etc.).

WB interpretive guidelines

The WB interpretive guidelines recommended by the two FDA-licensed WB kit manufacturers are *identical* to the APHL/CDC HIV-1 WB interpretive criteria. According to these guidelines:

- A *Positive* test result is defined by the presence of any two of the following bands: p24, gp41, and gp120/160. (Distinguishing the gp120 band from the gp160 band is often very difficult. These two glycoproteins can be considered as one reactant for purposes of interpreting WB test results.)
- An *Indeterminate* result is defined as bands present that do not meet the criteria for positive.
- A *Negative* result is defined as no bands present.

WB band patterns

The WB bands for the donor samples in this survey, as determined in pre-shipment testing with two FDA-licensed WB test kits, are shown in Table 2, page 10.

WB results by donor

The results by donor are

- Donor 1 (HIV-1 strong positive): no false-negatives or indeterminates,
- Donor 2 (HIV-1 seroconverter): no false-negatives and 3 indeterminates,
- Donor 3 (HIV-1 seroconverter): no false-negatives and 39 indeterminates, and
- Donor 4 (HIV-1 negative): 2 false-positives and 3 indeterminates.

Continued on next page

WB false-positive and false-negative results by test kits

Table 6: False-positive and indeterminate interpretations for Western blot test, by manufacturer[§]

Manufacturer	Total # of Results	Negative Donor			Positive Donors		
		Negative	False-positive	I*	Positive	False-negative	I
Bio-Rad Genetic Systems HIV-1	588	31	2	1	519	0	35
Bio-Rad New LAV Blot 1	84	10	0	2	72	0	0
Genelabs Diagnostics HIV-1 Blot	130	18	0	0	108	0	4
In-house	4	0	0	0	1	0	3

*I, Indeterminates

[§]**Note: Only false-positive and false-negative results are contained in this table. Those test kits for which false-positive and/or false-negative results were not reported are not included.**

WB comments

There were 40 interpretations reported for Donor 4, the negative donor, although most laboratories do not normally perform WB testing of EIA nonreactive specimens as part of their routine algorithm for HIV antibody testing.

This shipment included duplicate samples of Donor 4, the negative donor.

While most laboratories reported the correct results, four laboratories reported either reactive or indeterminate for one or both of the samples even though they reported nonreactive EIA results. Of these,

- 2 laboratories reported WB reactive,
- 1 laboratory reported indeterminate for both of the negative samples,
- 1 laboratory reported indeterminate for just one of the samples, and
- 1 lab reported indeterminate for one of the samples although no bands were reported.

The overall performance for laboratories reporting WB results was 99.5% correct results, the same overall performance as the July 2006 shipment.

IFA Methods and Results

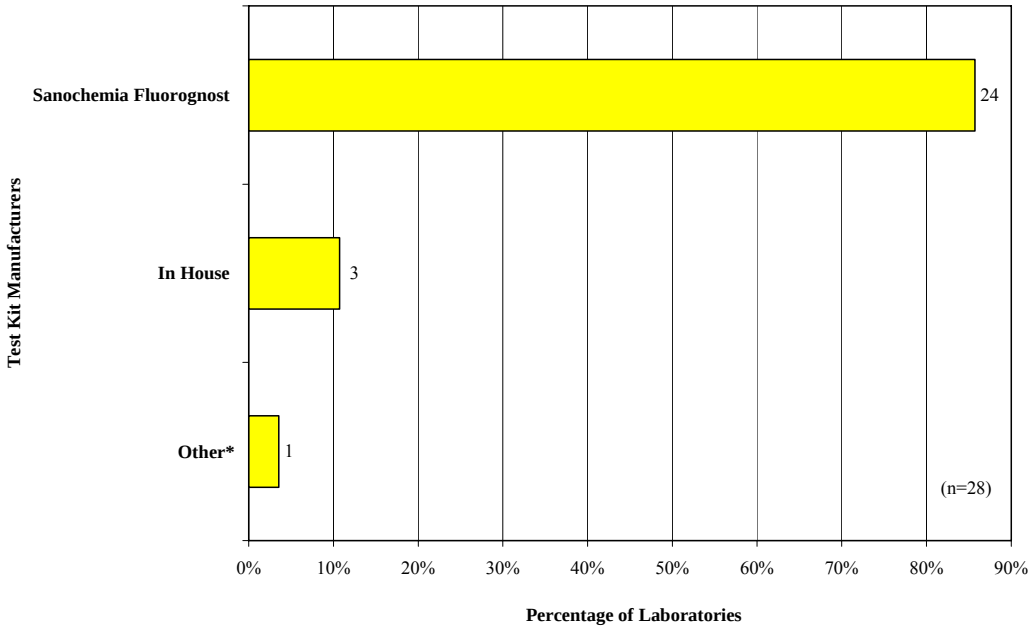
Introduction

Of the 644 laboratories reporting results, 28 (4.3%) performed IFA tests. Of these, 85.7% (24/28) used Sanochemia Fluorognost IFA, the only commercially available IFA test kit. Four laboratories used in-house methods (Figure 6).

IFA test kits by manufacturer

The IFA test kits reported are shown in Figure 6. The numbers at the end of the bars are the number of laboratories using that test kit.

Figure 6: Percentage and number of laboratories using IFA test kits, by manufacturer



* Other, the laboratory did not specify.

IFA indeterminate results

Table 7: Indeterminate IFA results reported by laboratories, by manufacturer

Methods/Manufacturer	Total # of Results	Negative Donors			Positive Donors		
		Negative	False-positive	I*	Positive	False-negative	I
Sanochemia Fluorognost	130	34	0	0	88	0	8
In-House	22	4	0	2	12	0	4

*I, indeterminates

Continued on next page

IFA Methods and Results, Continued

IFA results by donor

Incorrect results for each donor are as follows;

- Donor 1, 2 indeterminates, no false-negatives,
- Donor 2, 6 indeterminates, no false-negatives,
- Donor 3, 4 indeterminates, no false-negatives, and
- Donor 4, 2 indeterminates and no false-positives.

Comments

IFA was performed by 4.3% of MPEP participant laboratories. The overall performance of laboratories that performed IFA was 98.7% correct results; similar to the July 2006 overall performance of 98.3%.

“Other” Test Methods and Results

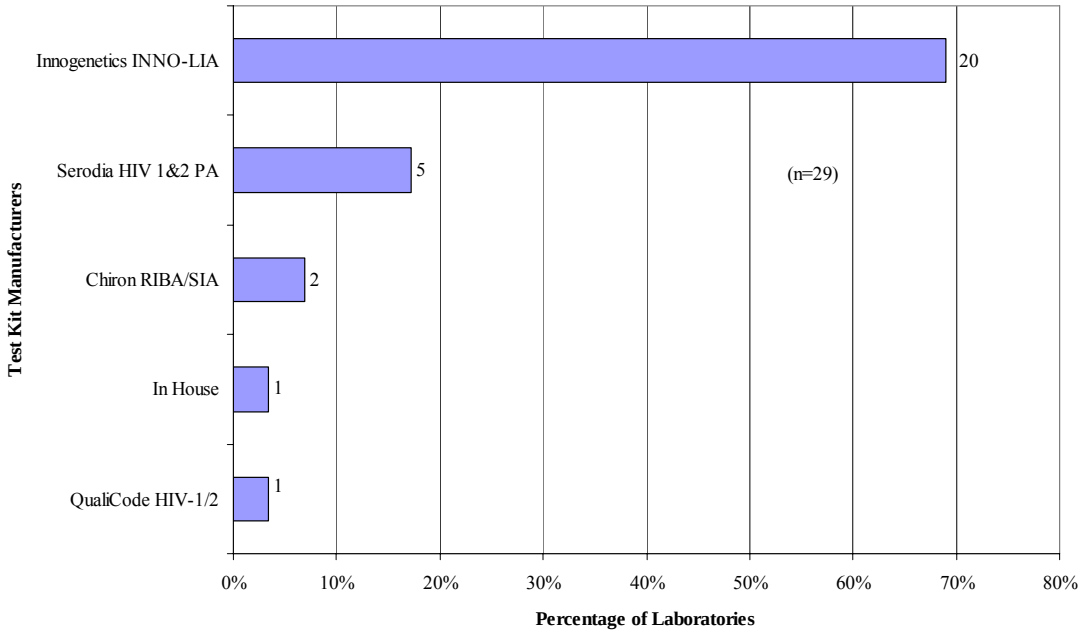
Introduction

Twenty-nine (4.5%) of the 644 laboratories reported using “Other” tests. Tests in this category are based on line immunoblot assay technology or particle agglutination. Laboratories reported their results in the “Other” test type section of the result form since the form is not designed to capture all reporting formats for these types of results.

“Other” test kits, by manufacturer

Figure 7 shows the “Other” test kits used by laboratories participating in this survey. The numbers at the end of the bars show the number of laboratories using that test kit.

Figure 7: Percentage and number of "Other" HIV-1 antibody test kits reported by participants, by manufacturer



Comments

Laboratories using these “other” test methods reported 100% correct results. In this shipment, there were no false positives, indeterminates or false negatives reported for any of the donor samples.

Appendix

Glossary of Terms

EIA: Enzyme immunoassay, sometimes referred to as ELISA (enzyme-linked immunosorbent assay), is a screening test to detect antibodies to HIV and other viruses and some bacteria.

False-negative: A negative test result for a sample that is actually positive.

False-positive: A positive test result for a sample that is actually negative.

HIV Antibody: Specific immunoglobulin produced the body's immune system in response to the HIV virus.

HIV Antigen: Specific immune-recognizable proteins, such as p24, which cause the production of antibodies.

HIV test: More correctly referred to as an HIV antibody test, this test detects antibodies to HIV, rather than detecting the virus itself.

IFA test: Indirect immunofluorescence assay, a confirmatory test for the detection of antibodies to Human Immunodeficiency Virus Type I (HIV-1) in human serum or plasma.

Indeterminate test result: A possible result for IFA, WB or "Other" test that might represent a recent HIV infection, but does not meet the criteria for positive.

Positive test: For HIV, a specimen that is reactive on a screening test such as an EIA test and confirmed positive on Western blot or other confirmatory test indicating that the donor is infected with HIV.

Seroconversion: Initial development of detectable antibodies specific to a particular antigen; the change of a serologic test result from negative to positive as a result of antibodies induced by the introduction of antigens or microorganisms into the host.

Western blot: For HIV, a laboratory test that detects antibodies specific for components of the HIV virus. It is chiefly used to confirm the presence of HIV antibodies in specimens found reactive using a screening test such as the EIA test.