



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 2005**



**COORDINATING CENTER FOR HEALTH INFORMATION AND SERVICE
DIVISION OF PUBLIC HEALTH PARTNERSHIPS
ATLANTA, GEORGIA**

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Department of Health and Human Services.

Report of the January 2005 Human Immunodeficiency Virus Type I (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 in January 2005

Executive Summary

Six hundred and ninety-one laboratories reported results for the January 2005 samples panel shipment. In this shipment

- 535 (77.4%) were U.S. and U.S. territories laboratories and
- 156 (22.6%) were non-U.S. laboratories.

The 691 laboratories identified themselves as

- 262 (37.9%) hospitals,
- 168 (24.3%) health departments,
- 132 (19.1%) independent laboratories,
- 91 (13.2%) blood banks, and
- 38 (5.5%) other types, which include university-associated research centers, university clinics, Federal government facilities, STD clinics, etc.

EIA

The overall performance of laboratories reporting EIA test results in the January 2005 shipment was similar to July 2004 shipment, with 98.9% and 98.1% correct results respectively.

Laboratories using the Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide test continue to report false-positive results similar to the previous survey. Fifteen (83.3%) of the 18 laboratories using this test kit reported a false positive result on the HIV-1 antibody negative sample. All 15 laboratories are U.S. laboratories. No false-negative results were reported by laboratories using the test kit.

WB

The overall performance of laboratories reporting WB results in January 2005 was similar to the July 2004 shipment with 98.5% and 99.2 % correct results respectively.

In the January shipment four U.S. laboratories reported using interpretive criteria other than APHL/CDC criteria:

- 3 used World Health Organization (WHO) and
- 1 used Consortium for Retrovirus Serology Standard (CRSS).

IFA

The number of laboratories reporting IFA results has remained between 33 and 38 over the last 8 shipments. In this shipment, as in the July 2004 shipment, the overall performance of laboratories reporting IFA test results was 100% correct.

Other Tests

Laboratories reporting results using test kits other than EIA methods, WB or IFA, reported overall 97.1% correct results as compared to 98.9% with EIA test kits. Test kits in the “other” category are not FDA approved, and are therefore not used in U.S. laboratories.

Introduction

Purpose The purpose of this report is to present the analysis of results provided to the CDC by laboratories participating in the MPEP after they tested the human plasma samples shipped to them in January 2005.

Response Of the 786 laboratories that were sent performance evaluation panels,

- 691 (87.9%) submitted results (overall response rate) and
- 377 (54.6%) of the 691 laboratories submitted results on-line.

Contents This report contains the analysis of results for

- enzyme immunoassay (EIA) screening,
- 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, microparticle capture, chemiluminescence, etc.).

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Challenge Samples

Survey Samples

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

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

These samples were heat-treated at 56° 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:

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

Donor status

Donors 1 (single sample) and **3** (duplicate samples) are HIV-1 antibody positive donors demonstrating factors consistent with seroconversion, such as

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

Donor 2: strong-positive HIV-1 (duplicate samples)

Donor 4: HIV-1 negative.

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Challenge Samples, Continued

Laboratory Worksheet

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

Table 1: Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing for the January 2005 Shipment

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

1. The CDC result was 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). The CDC WB interpretation is consistent with Association of Public Health Laboratories/Centers for Disease Control and Prevention (APHL/CDC) interpretations which are identical to the manufacturer's interpretive criteria for WB results.
2. Laboratory Interpretation space is to be completed by participant laboratories to facilitate comparison of their result with CDC result.

Continued on next page

Challenge Samples, Continued

CDC WB results **Table 2: CDC Western blot (WB) testing results for the January 2005 shipment**

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Band Detected ¹	WB Test Kit Manufacturer	CDC Interpretation ²
A	A1, A2	3	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	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
	A4	4	No Bands	Both Manufacturers	Negative
	A5, A6	2	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
B	B1, B4	2	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
	B2, B5	3	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	4	No Bands	Both Manufacturers	Negative
	B6	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
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	4	No Bands	Both Manufacturers	Negative
	C3, C6	2	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
	C4, C5	3	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
D	D1	4	No Bands	Both Manufacturers	Negative
	D2, D5	2	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
	D3, D6	3	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	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

1. Western blot (WB) results are based on the band intensity of $\geq 1+$ staining.

2. The CDC interpretation is consistent with APHL/CDC and the manufacturer's criteria for the interpretation of WB results.

3. Cambridge Biotech/Calypte Biomedical.

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Results Summary

Overall results

Table 3 summarizes the results grouped by test type: EIA, WB, IFA, and Other.

Table 3: Results Summary

Method	Total # of laboratories	Total # of results	Positive Donors			Negative Donor			Overall Performance (TP+TN/total # results)†
			Positive	I*	False-negative (% false negative)	Negative	I	False-positive (% false positive)	
EIA	640	4128	3418	nv‡	24 (0.7%)	664	nv	22 (3.2%)	98.9%
WB	231	1268	1144	6	3 (0.3%)	108	5	2 (6.1%)	99.2%§
IFA	33	188	164	0	0	24	0	0	100%§
Other¶	71	511	429	1	4 (0.9%)	66	2	9 (14.3%)	97.1%

* I, Indeterminate results

† TP, true positives; TN, true negatives.

‡ nv, not valid. Indeterminate is a not 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, microparticle capture, chemiluminescence, etc.

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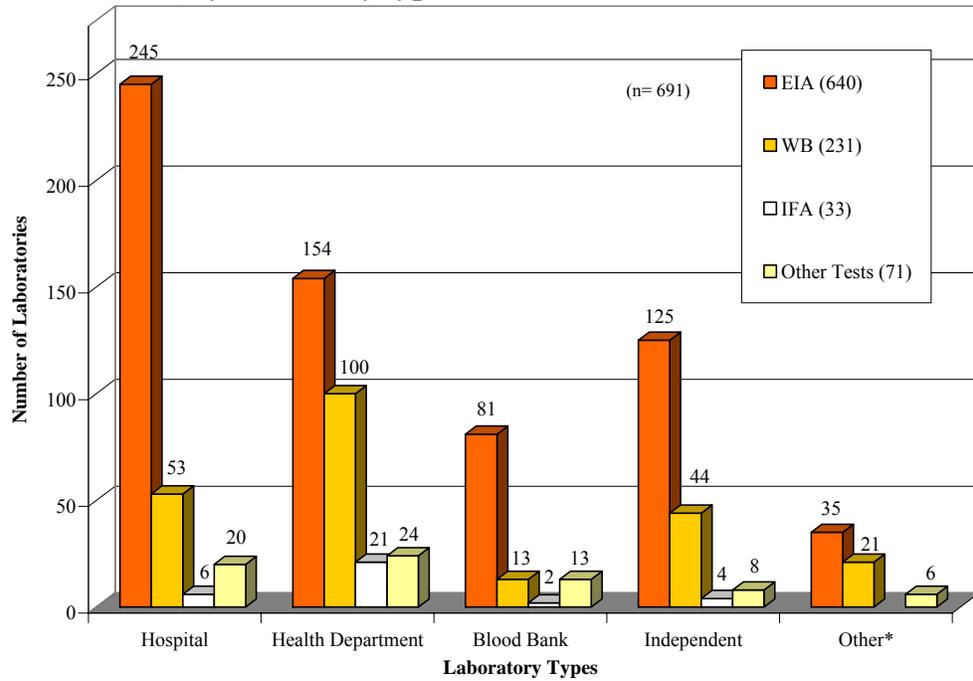
Laboratory Demographics and Methods

Test methods by laboratory type

Figure 1 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, not the number of methods or tests kits used.

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



*Other laboratory types include university-associated research centers, university clinics, Federal government facilities, STD clinic, etc.

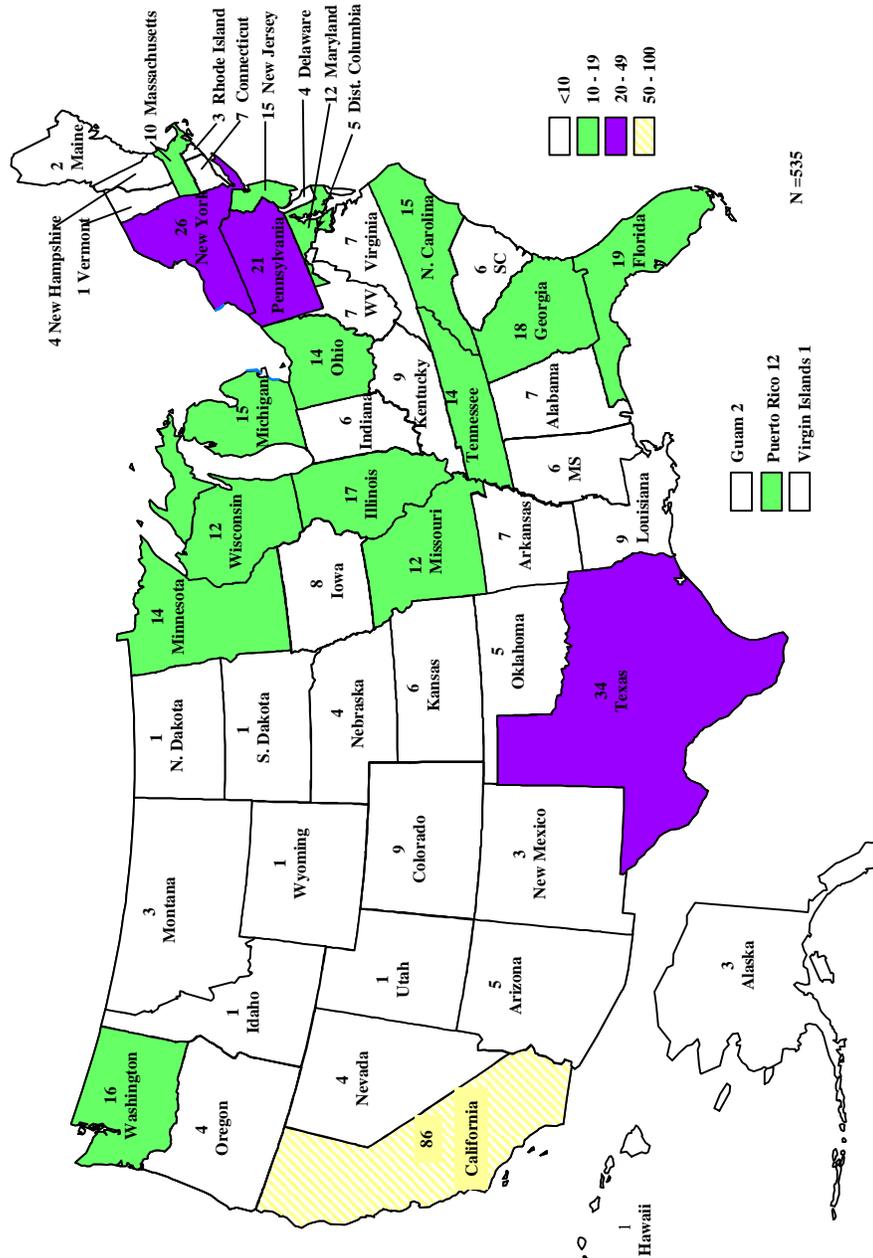
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Laboratory Demographics and Methods, Continued

U.S. laboratories

Figure 2 shows the number and location of MPEP laboratories in the U.S. and U.S. Territories.

Figure 2: Geographic distribution of laboratories in the United States and U.S. Territories



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Laboratory Demographics and Methods, Continued

All MPEP laboratories

Including the United States and U. S. territories, MPEP participants are located in 72 countries.

Table 4: Location of laboratories by country reporting HIV-1 Ab results

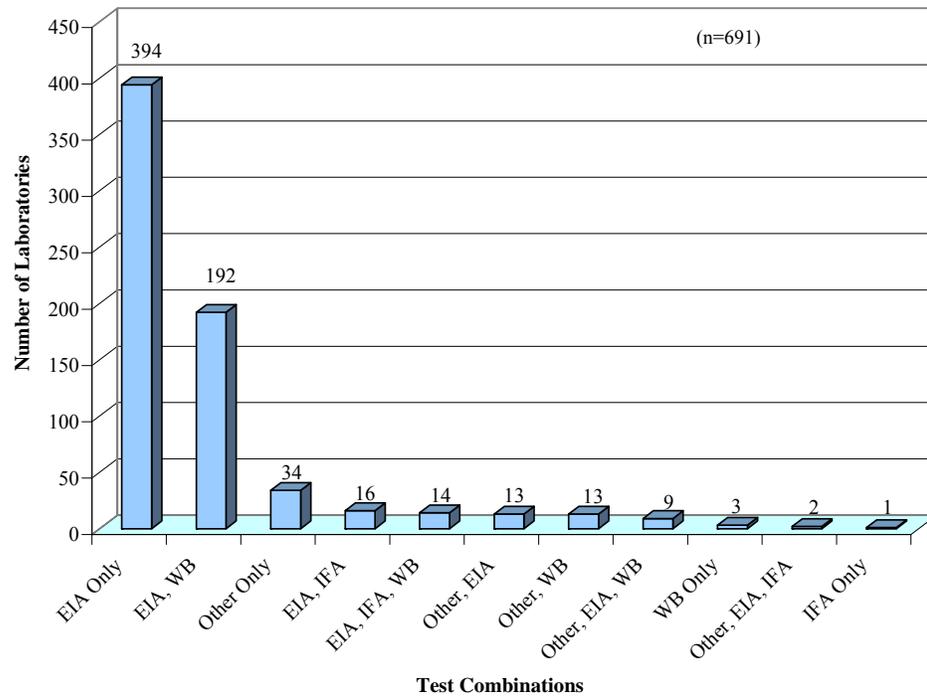
N=691

Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Algeria	1	Honduras	2	South Africa	3
Argentina	7	Hong Kong	2	Australia	1
Australia	5	Hungary	1	South Korea	1
Austria	3	India	3	Spain	3
Bahamas	1	Israel	3	Sri Lanka	4
Barbados	1	Italy	1	St. Kitts/Nevis	1
Belgium	2	Japan	1	Suriname	1
Botswana	1	Kazakhstan	6	Switzerland	1
Brazil	3	Kenya	1	Taiwan	2
Cameroon	2	Kyrgyzstan	2	Tanzania	3
Canada	16	Mali	1	Thailand	9
Chile	1	Malta	1	Trinidad	1
Columbia	1	Morocco	1	Turkey	1
Costa Rica	1	Nicaragua	1	Turkmenistan	1
Cote d'Ivoire	3	Panama	1	U.S. Territory	15
Croatia	1	Paraguay	1	Uganda, East Africa	1
Denmark	3	Peru	2	United Arab Emirates	2
Dominican Republic	2	Philippines	2	United Kingdom	1
Ecuador	1	Portugal	1	United States	520
El Salvador	1	Republic of Singapore	1	Uruguay	1
England	1	Romania	1	Uzbekistan	10
Eritrea	1	Saudi Arabia	2	Venezuela	3
Germany	2	Scotland	1	Vietnam	1
Ghana	2	Senegal	1	Zimbabwe	1

Laboratory Demographics and Methods, Continued

Test methods The test combinations used by the MPEP laboratories are shown in Figure 3.

Figure 3: The combination of HIV-1 antibody tests reported by participant laboratories



Of the 691 laboratories reporting results;

- 394 (57.0%) only performed EIA,
- 222 (32.1%) only performed EIA and a supplemental test,
- 71 (10.3%) laboratories performed an “Other” test in addition to, or instead of, EIA, WB and IFA, and
- 4 (0.6%) performed only a supplemental test.

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EIA Methods and Results

Introduction

Of the 691 laboratories reporting results 640 (92.6%) performed EIA testing. MPEP laboratories outside the U.S. reported using 22 different EIA test kits for detection of antibodies to the HIV-1 and/or HIV-2 virus.

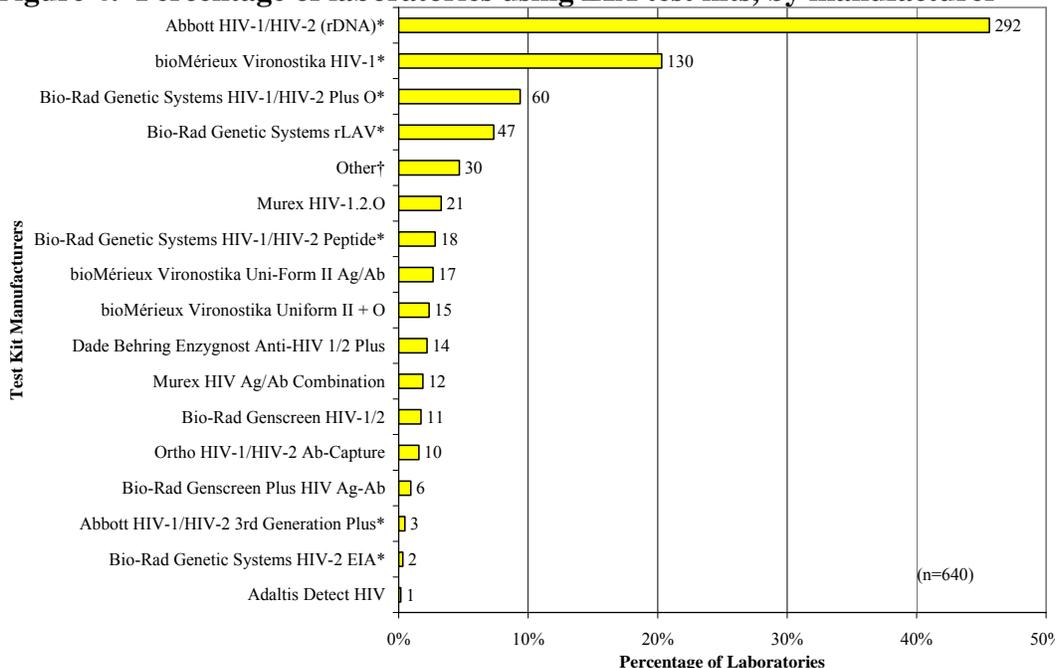
Laboratories located in the U.S. reported using seven EIA test kits for detection of antibodies in plasma and serum. These tests include:

- 4 HIV-1/2,
- 2 HIV-1 only, and
- 1 HIV-2.

EIA test kit manufacturer

Figure 4 shows the percentage of laboratories using a particular HIV-1 test kit. The numbers at the end of the bars show the number of laboratories using that test kit.

Figure 4: Percentage 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 Methods and Results, Continued

Other EIA test kits

There are 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.

- Biotest Anti HIV Tetra ELISA (4),
- Dade Behring Integral (3),
- J. Mitra & Co.(2),
- MBS Recombinant HIV-1, 2 (2),
- Radiopreparat (7), and
- Vector Best (5).

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 HIV-1/HIV-2 (rDNA)	1751	289	3 (1.0%)	1452	7 (0.48%)
BioMérieux Vironostika HIV-1	779	127	2 (1.6%)	646	4 (0.62%)
BioMérieux Vironostika Uniform II + O	90	14	1 (6.7%)	74	1 (1.3%)
Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide*	108	3	15 (83.3%)	90	0
Dade Behring Enzygnost Anti-HIV-1/2 Plus	83	13	0	68	2 (2.9%)
Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O	360	60	0	299	1 (0.33%)
Bio- Rad Genetic Systems HIV-2 EIA†	12	2	0	4	6 (60.0%)
Murex HIV-1.2.O	125	20	1 (4.8%)	102	2 (1.9%)
Nihol Peptoscreen-2	18	3	0	14	1 (6.7%)

* Of the 22 false-positive results reported, 15 (68.2%) were reported by laboratories using the Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide.

† Bio-Rad Genetic Systems HIV-2 EIA detects the presence of HIV-2 antibody. 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 are as follows;

- Donor 1 (HIV-1 infected seroconverter), 6 false negatives,
- Donor 2 (HIV-1 infected strong positive), 8 false negatives,
- Donor 3, (HIV-1 infected seroconverter), 10 false negatives, and
- Donor 4, (HIV-1 uninfected), 22 false positives.

Continued on next page

EIA Methods and Results, Continued

EIA comments

The laboratories using EIA test kits reported 98.9% correct results (Table 3 on page 9) compared to 98.1% in the July 2004 shipment. However, laboratories using the Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide test continue to report a high percentage of false positive results [15 of 18 (83.3%) laboratories]. (Table 5 on page 15)

Questions concerning changes in test kits

In the survey we asked two additional questions. The purpose of the questions were to determine

1. if the MPEP laboratories had changed and/added EIA tests in the past year, and
 2. whether they plan to add and/or change EIA test kits within the next year.
-

Changed or added EIA test kits

The responses to the question did you change/add EIA test kits within the last year were as follows:

Of the 314 laboratories responding,

- 254 (80.9%) had not changed or added EIA test kits and
 - 60 (19.1%) changed or added EIA tests. Of those,
 - 41 changed only,
 - 5 added only,
 - 13 laboratories added and changed EIA test kits, and
 - 1 laboratory answered “yes” they changed or added, but did not answer further.
-

Planning to change or add test kits

The responses to the question are you planning to change/add EIA test kits within the next year was as follows:

Of the 619 laboratories responding,

- 562 (90.8%) do not plan to add or change,
 - 56 (9.0%) plan to add or change. Of those,
 - 45 plan to only change,
 - 10 plan to only add, and
 - 1 plans to change and add.
-

Continued on next page

EIA Methods and Results, Continued

Comments on EIA questions Several EIA test kit manufacturers either have replaced or plan to replace their current assays containing only Group M antigen with assays that contain both the traditional Group M and additional Group O antigens.

In this shipment

- 19.1% (60/314) of the responding laboratories reported that in the last year they changed or added EIA test kits.
 - Of the 60 laboratories that indicated they added and /or changed, 50% changed or added EIA test kits that contain Group M and Group O antigens.
 - Of the 56 laboratories that plan to add or change test kits, 48.2% plan to add or change to EIA test kit that contain both Group M and Group O antigens.
-

Western Blot Methods and Results

Introduction

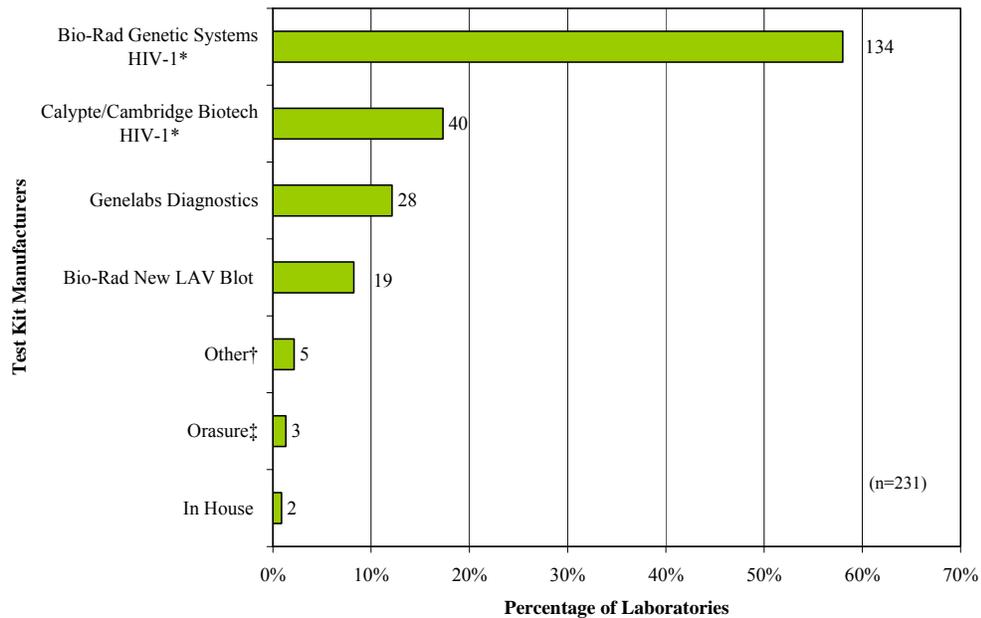
Of the 691 laboratories reporting test results in this survey, 231 (33.4%) performed WB testing using 6 different commercially manufactured WB test kits and one in-house preparation.

In the U.S., two FDA approved WB kits are available for testing serum or plasma.

WB test kits

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

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



* FDA approved WB test kits.

†Other, WB tests for which no manufacturers' codes are included in the result booklet.

‡ Oraure HIV-1 Western Blot Kit is only FDA approved for oral fluid.

WB interpretative criteria

Of the 231 laboratories reporting WB test results, 229 (99.1%) 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:

- 199 (86.9%) APHL/CDC,
- 15 (6.6%) WHO,
- 13 (5.7%) stated "other" (Manufacturers' insert, Australian National Reference Laboratory, etc.), and
- 2 (0.9%) CRSS.

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Western Blot Methods and Results, Continued

WB interpretive guidelines

The WB interpretive guidelines published 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 8.

WB results by donor

The results by donor are

- Donor 1 (HIV-1 seroconverter): no false negatives and 1 indeterminate,
- Donor 2 (HIV-1 infected, strong positive): 2 false negatives and 3 indeterminates,
- Donor 3 (HIV-1 seroconverter): 1 false negative and 2 indeterminates, and
- Donor 4 (negative): 2 false-positives and 5 indeterminates.

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

Table 6: False-positive, false-negative, 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	730	58	0	2	665	1	4
Bio-Rad New LAV Blot I	108	13	1	0	93	1	0
Genelabs Diagnostics Bioblot HIV-1	158	16	0	3	136	1	2
In-House	11	0	1	0	10	0	0

*I, Indeterminate

Continued on next page

Western Blot Methods and Results, Continued

WB comments There were 115 WB interpretations reported for Donor 4, the HIV-1 antibody-negative donor, although most laboratories do not normally include WB testing of EIA non-reactive specimens in their routine algorithm for HIV antibody testing.

Note: Some laboratories report indeterminate results when non-viral bands are observed on the nitrocellulose test strip, in accordance with current APHL/CDC guidelines.

IFA Methods and Results

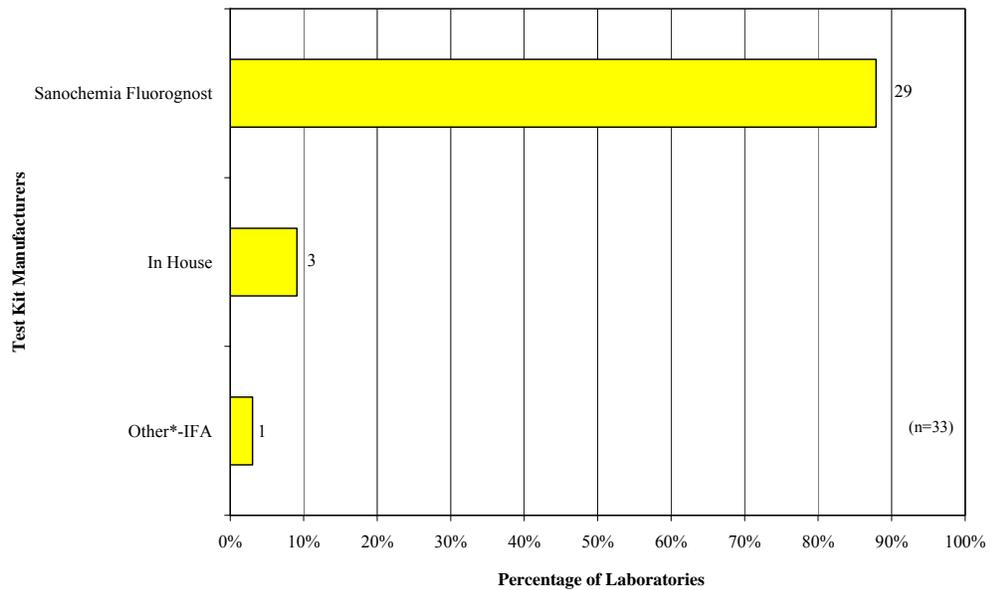
Introduction

Of the 691 laboratories reporting results, 33 (4.8%) performed IFA tests. Most used the only commercial IFA test kit, Sanochemia Fluorognost IFA. However, a few laboratories used in-house or other 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 of laboratories using IFA test kits, by Manufacturer



Other-IFA: Manufacturers for which no codes are included in the result booklet.

Continued on next page

IFA Methods and Results, Continued

IFA results There were no false-positive or false-negative results reported by laboratories performing IFA tests.

Comments The table below lists the overall performance of laboratories reporting IFA testing results in the last six shipments.

Shipment Date	# of Participants	Overall Performance (% correct results)*
July 2002	35	93.3%
January 2003	38	95.8%
July 2003	37	93.7%
January 2004	34	96.8%
July 2004	35	100%
January 2005	33	100%

*When calculating overall performance for IFA, indeterminate interpretations are considered to be correct for HIV-1 antibody-positive donors, and incorrect for HIV-1 antibody-negative donors.

“Other” Test Methods and Results

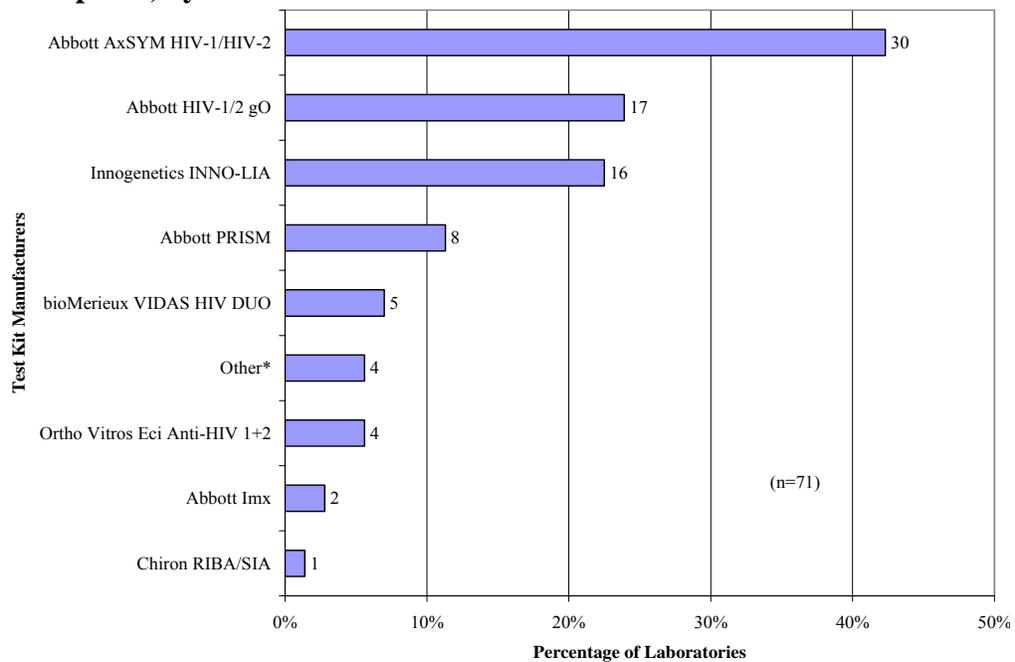
Introduction Seventy-one (10.3%) of the 691 laboratories reported using “Other” tests.

These laboratories reported using 9 different commercially manufactured tests kits which MPEP groups into the “other” category. These tests are based on microparticle capture and chemiluminescence measurement, and the results differ from the traditional microtiter-format EIA tests. Laboratories reported their results in the “Other” test type section of the result form since it is not designed for these types of results.

“Other” tests 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: Percentages of "Other" HIV-1 antibody test kits reported by participants, by manufacturer



*Other includes tests for which no manufacturers’ codes are included in the result booklet.

Other “other” test kits

Test kits for which no manufacturers’ code is included in the result booklet or the test kits were too new to be included are listed below. The number in parenthesis is the number of laboratories using that test kit.

- Abbott Architect (1),
- Bio-Rad SFD HIV-1/2 Particle Agglutination, (1)
- Serodia Particle Agglutination (1), and
- Organics Immunocomb II HIV 1/2 (1).

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“Other” Test Methods and Results, Continued

Results by donor

The results by donor are as follows;

- Donor 1 (HIV-1 seroconverter): 0 indeterminates and 0 false-negative,
- Donor 2 (HIV-1 strong positive): 1 indeterminate and 2 false-negatives,
- Donor 3 (HIV-1 seroconverter): 0 indeterminate, 2 false-negatives, and
- Donor 4 (negative): 2 indeterminates and 9 false-positives.

“Other” results

Table 7: False-positive, false-negative and indeterminate determinations for "Other" test kits

Methods/Manufacturer	Total # of Results	Negative Donor			Positive Donors		
		Negative	False-positive	I*	Positive	False-negative	I
Abbott AxSYM HIV-1/HIV-2	179	28	2	0	147	2	0
Abbott HIV-1/2 gO	101	14	1	1	85	0	0
Abbott PRISM	48	6	1	1	40	0	0
BioMérieux VIDAS HIV DUO	30	4	2	0	23	1	0
Bio-Rad SFD HIV-1/2 Particle Agglutination	6	0	1	0	4	1	0
Innogenetics INNO-LIA	95	8	2	0	84	0	1

*I, Indeterminate

Comment

In this shipment the overall performance of the tests in the “other” category was 97.1% compared to 98.3% in the July 2004 shipment.

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.

Evaluation: A process for determining how well health systems, either public or private, deliver or improve services and for demonstrating the results of resource investments.

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 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.
