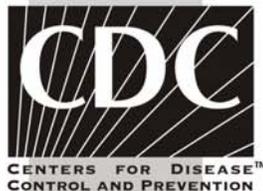




DEPARTMENT OF HEALTH AND HUMAN SERVICES

**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 2006**



**Coordinating Center for Infectious Diseases
Division of Laboratory Systems
Atlanta, Georgia**

Report of the January 2006 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 2006

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 2006.

Response Of the 757 laboratories that were sent performance evaluation panels,

- 671 (88.6%) laboratories submitted results (overall response rate)
- 663 of those responses are included, 8 laboratories submitted results too late to be included in this report.
- 376 (56.7%) of the 663 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, etc.).

Executive Summary

Laboratory demographics Six hundred and sixty-three laboratories reported results for the January 2006 samples panel shipment. In this shipment

- 505 (76.2%) were U.S. and U.S. territories laboratories and
- 158 (23.8%) were non-U.S. laboratories.

The 663 laboratories identified themselves as

- 243 (36.7%) hospitals,
 - 168 (25.3%) health departments,
 - 127 (19.2%) independent laboratories,
 - 87 (13.1%) blood banks, and
 - 38 (5.7%) other types, which include university-associated research centers, university clinics, Federal government facilities, STD clinics, counseling and testing sites, Community based organizations, etc.
-

EIA The percentage of false-negatives increased to 1.0% (35/3659) in this shipment, from 0.7% (20/2811) in the July 2005 shipment. The percentage of false-positives remained the same, 0.8%, in this shipment (6/727) as in the 2005 July shipment (11/1394). However, the overall performance is nearly the same, with 99.1% correct responses for this shipment and 99.3% in the July 2005 shipment.

WB The overall performance for laboratories reporting WB results was 99.6% correct results compared to 99.3% in the July 2005 shipment.

There were 53 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. Four laboratories that reported reactive WB reported EIA nonreactive results.

IFA The overall performance for IFA in this shipment was 97.8% (due primarily to false-negative results) compared with 96.0% in the July 2005 shipment.

Other Tests The overall performance of the laboratories using tests in the “other” category decreased slightly compared to the previous survey: In this shipment, laboratories reported 97.2% correct results, compared to 99.2% in the July 2005 shipment.

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 (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).
-

Donor status

Donors 1 (single samples) and **2** (duplicate samples) are 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 3: strong-positive HIV-1 (duplicate samples)

Donor 4: HIV-1 negative sample.

Continued on next page

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 (Ab) Testing for the January 2006 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	2	Positive	Infected	_____	_____	_____	_____
	A2	3	Positive	Infected	_____	_____	_____	_____
	A3	4	Negative	Uninfected	_____	_____	_____	_____
	A4	1	Positive	Infected	_____	_____	_____	_____
	A5	2	Positive	Infected	_____	_____	_____	_____
	A6	3	Positive	Infected	_____	_____	_____	_____
B	B1	3	Positive	Infected	_____	_____	_____	_____
	B2	4	Negative	Uninfected	_____	_____	_____	_____
	B3	1	Positive	Infected	_____	_____	_____	_____
	B4	2	Positive	Infected	_____	_____	_____	_____
	B5	3	Positive	Infected	_____	_____	_____	_____
	B6	2	Positive	Infected	_____	_____	_____	_____
C	C1	4	Negative	Uninfected	_____	_____	_____	_____
	C2	1	Positive	Infected	_____	_____	_____	_____
	C3	2	Positive	Infected	_____	_____	_____	_____
	C4	3	Positive	Infected	_____	_____	_____	_____
	C5	2	Positive	Infected	_____	_____	_____	_____
	C6	3	Positive	Infected	_____	_____	_____	_____
D	D1	1	Positive	Infected	_____	_____	_____	_____
	D2	2	Positive	Infected	_____	_____	_____	_____
	D3	3	Positive	Infected	_____	_____	_____	_____
	D4	4	Negative	Uninfected	_____	_____	_____	_____
	D5	2	Positive	Infected	_____	_____	_____	_____
	D6	3	Positive	Infected	_____	_____	_____	_____

1. The CDC results were obtained after composite testing with all commercially available HIV-1 and HIV-1/HIV-2, HIV-1 WB, and IFA 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 manufacturers' interpretive criteria for WB results.
2. Laboratory Interpretation space is to be completed by participant laboratories to facilitate comparison of their results with CDC results.

Continued on next page

Challenge Samples, Continued

CDC WB results **Table 2: CDC Western blot (WB) testing results for the January 2006 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, A5	2	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
	A2, A6	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
	A3	4	No Bands	Both Manufacturers	Negative
	A4	1	24, 31, 41, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
B	B1, 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
	B2	4	No Bands	Both Manufacturers	Negative
	B3	1	24, 31, 41, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B4, B6	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
C	C1	4	No Bands	Both Manufacturers	Negative
	C2	1	24, 31, 41, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C3, C5	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, C6	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	1	24, 31, 41, 55, 66, 120, 160 18, 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	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	4	No Bands	Both Manufacturers	Negative

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 manufacturers' criteria for the interpretation of WB results.
3. Cambridge Biotech/Calypte Biomedical.

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	656	4386	3624	nv [‡]	35 (1.0%)	721	nv	6 (0.8%)	99.1%
WB	216	1132	1027	51	1 (0.09%)	49	2	2 (3.8%)	99.6% [§]
IFA	32	179	142	11	4 (2.5%)	22	0	0	97.8% [§]
Other [¶]	31	182	150	2	5 (3.2%)	25	0	0	97.3%

* 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.

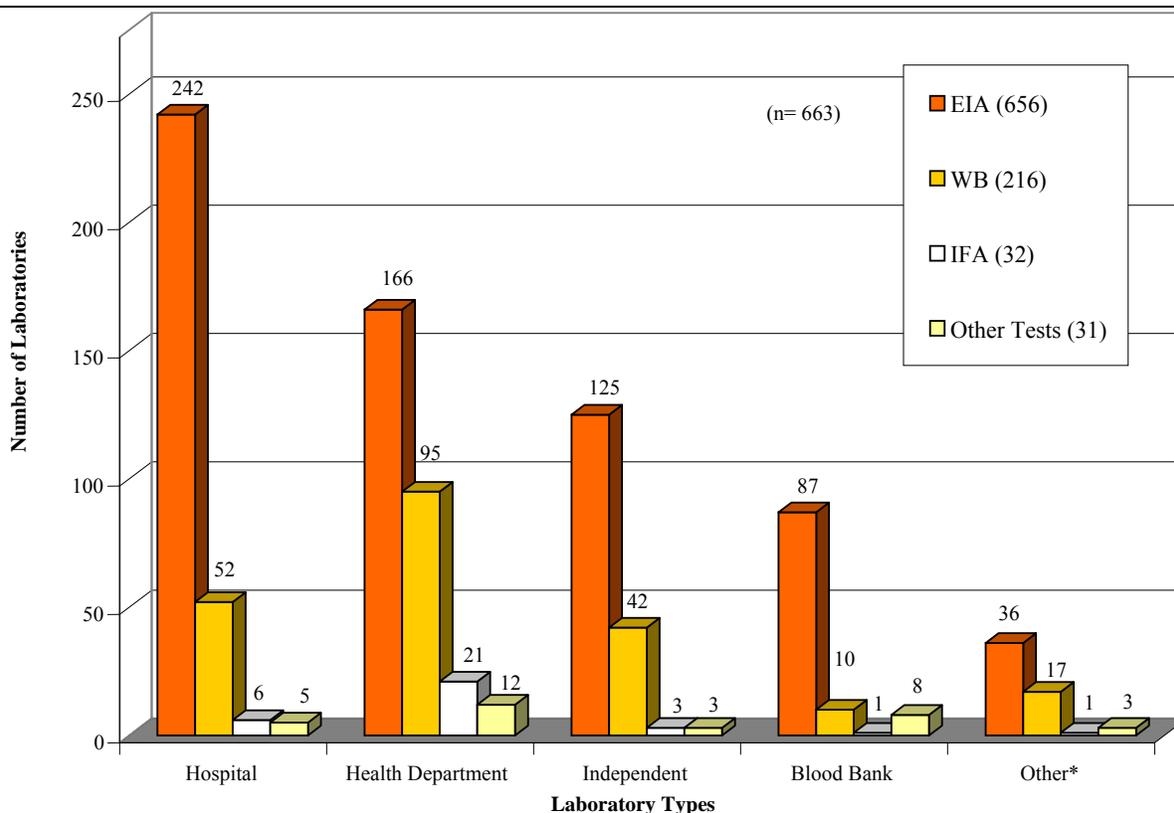
Laboratory Demographics and Methods

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 reporting results, 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” laboratories include university-associated research centers, university clinics, Federal government facilities, STD clinics, etc.

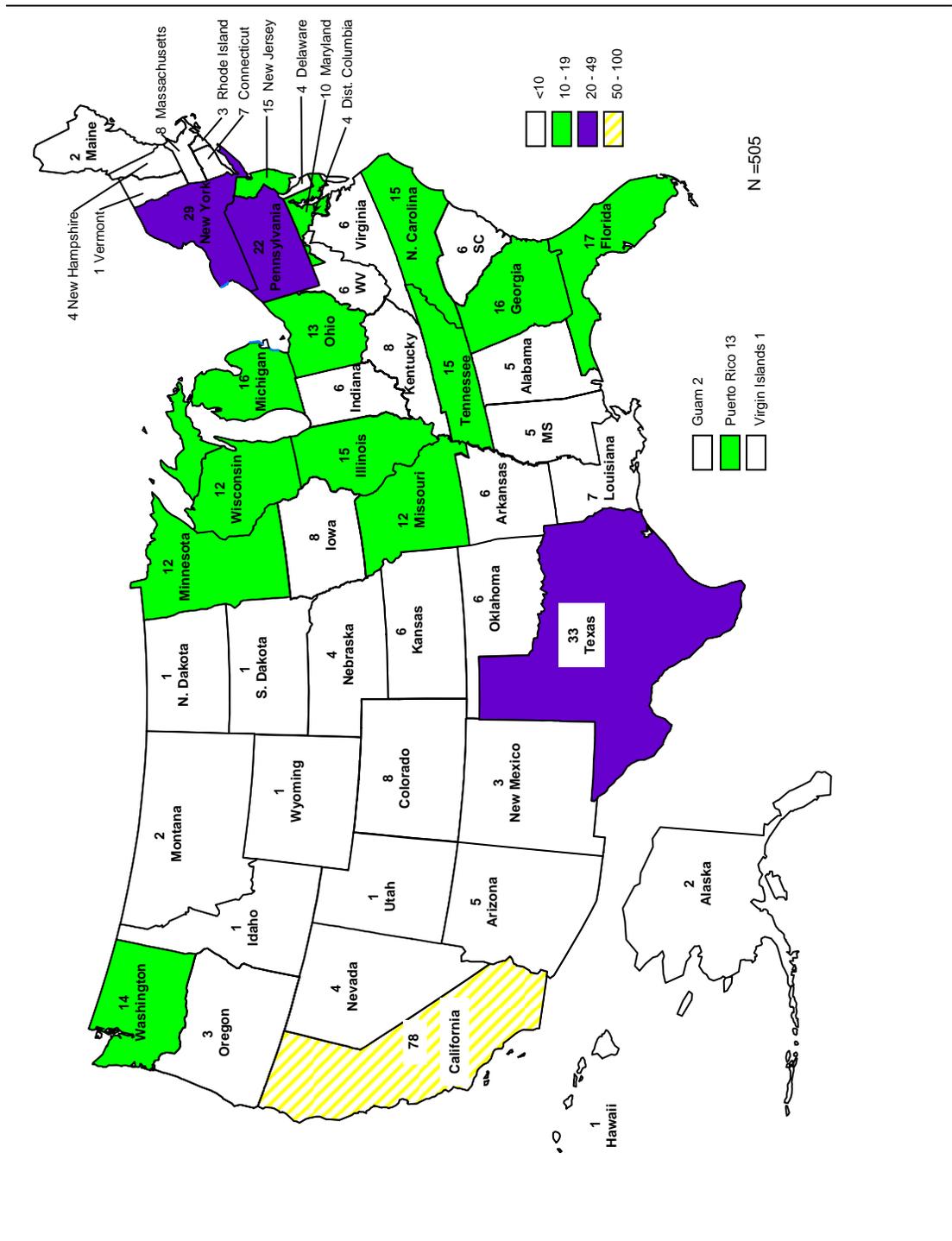
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Laboratory Demographics and Methods, Continued

U. S. laboratories

Figure 2 shows the number and location of MPEP laboratories in the U.S. and U.S. Territories submitting results for the January 2006 shipment.

Figure 2: Geographic distribution of MPEP participant 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 73 countries.

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

N=663

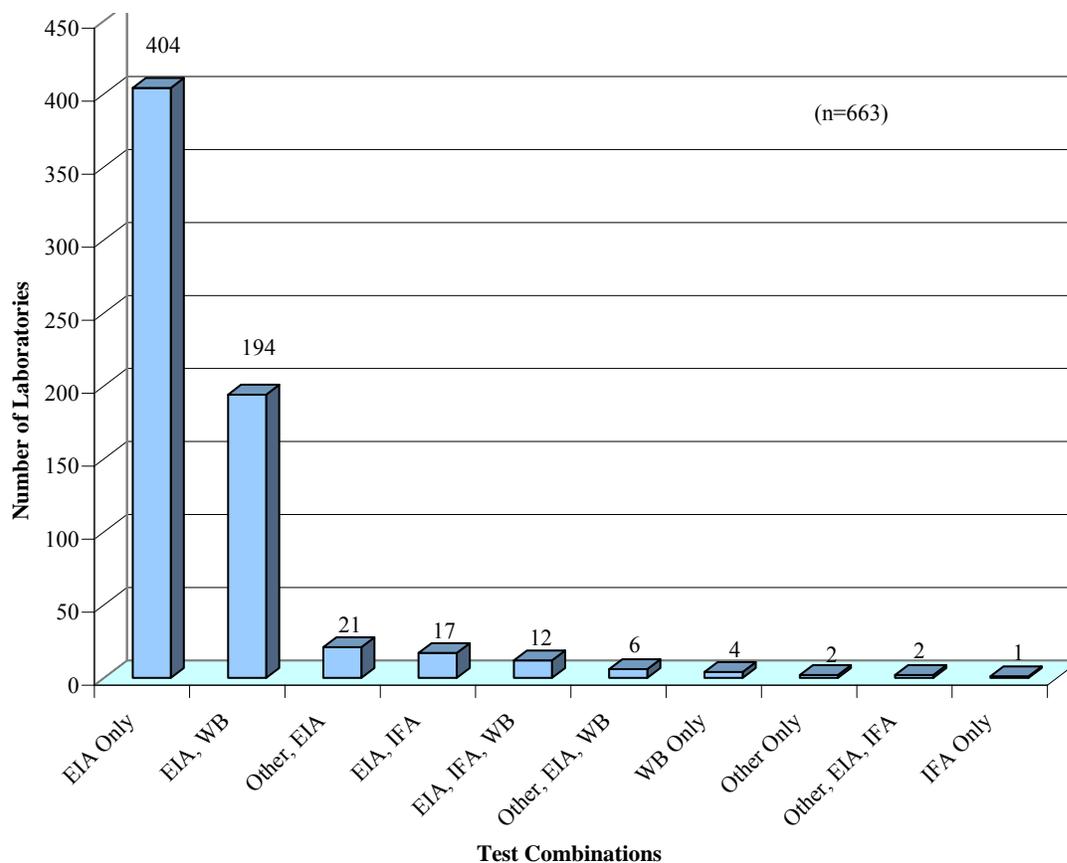
Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Algeria	1	Guyana	1	Slovenia	2
Argentina	1	Honduras	2	South Africa	3
Australia	6	Hong Kong	2	South Korea	2
Austria	3	Hungary	1	Spain	3
Bahamas	1	India	6	Sri Lanka	5
Barbados	1	Ireland	1	St. Kitts/Nevis	1
Belgium	2	Israel	3	Suriname	3
Bolivia	1	Italy	1	Switzerland	1
Botswana	3	Jamaica	1	Taiwan	2
Brazil	3	Japan	1	Tanzania	3
Cameroon	1	Kazakhstan	6	Thailand	5
Canada	15	Kenya	2	Trinidad	2
Chile	1	Kyrgyzstan	3	Turkey	1
Columbia	2	Malaysia	2	US Territory	16
Costa Rica	1	Mali	1	Uganda, East Africa	3
Cote d'Ivoire	2	Malta	1	United Arab Emirates	1
Croatia	1	Mexico	1	United Kingdom	1
Denmark	3	Myanmar	1	United States	489
Dominican Republic	2	Peru	2	Uruguay	1
Ecuador	1	Philippines	2	Uzbekistan	10
England	1	Portugal	1	Venezuela	3
Eritrea	1	Republic of Singapore	1	Vietnam	1
Ethiopia	1	Romania	1	Zimbabwe	1
Germany	2	Saudi Arabia	1		
Ghana	3	Scotland	1		

Continued on next page

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



Test Summary

Of the 663 laboratories reporting results;

- 404 (60.9%) only performed EIA,
- 231 (34.8%) performed EIA and a supplemental test,
- 31 (4.7%) laboratories performed an “Other” test in addition to, or instead of EIA, WB, and IFA, and
- 5 (0.8%) performed only a supplemental test.

EIA Methods and Results

Introduction

Of the 663 laboratories reporting results, 656 (98.9%) performed 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). Many laboratories outside the U.S. use test kits that detect the presence of these 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.

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

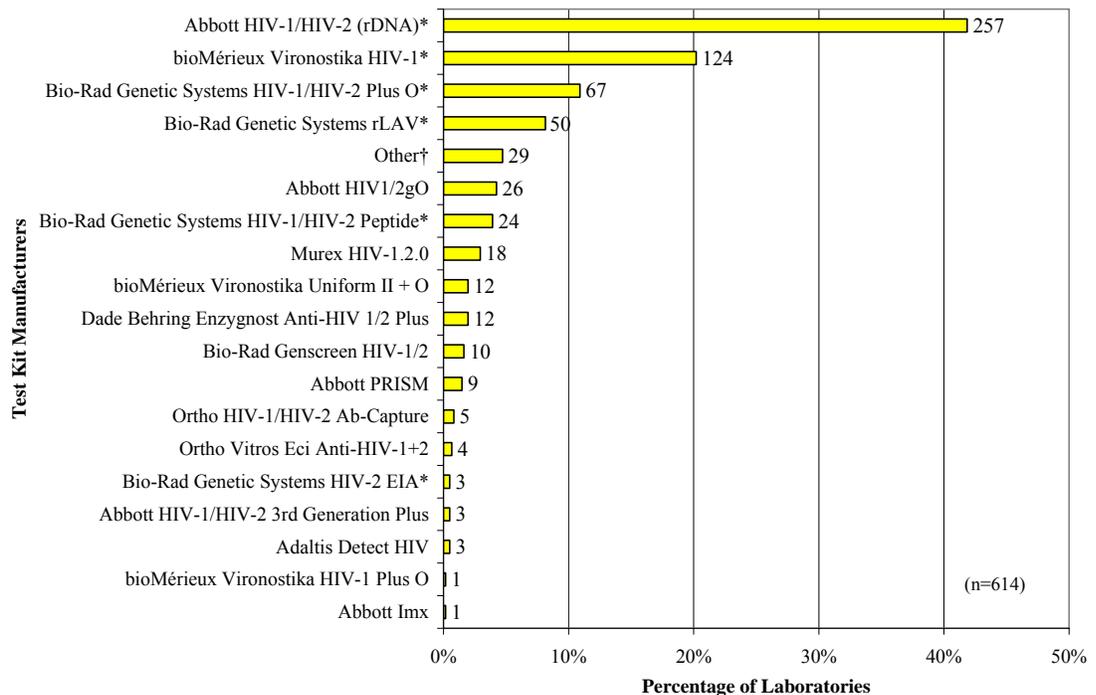
- 4 for HIV-1 and HIV-2,
- 2 for HIV-1 only, and
- 1 for HIV-2 only.

MPEP participant laboratories outside the U.S. reported using 30 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 4 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 4: 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.

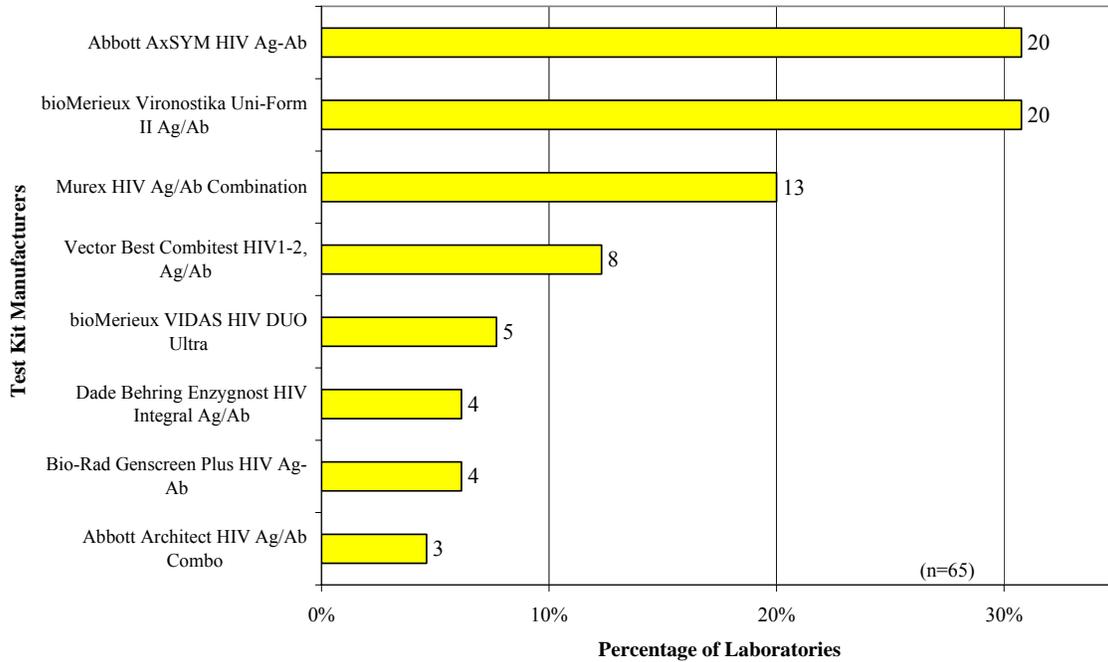
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EIA Methods and Results, Continued

EIA Ag/Ab test kit manufacturers

Figure 5 shows the percentage and number of laboratories that used antigen-antibody test kits. These test kits are not FDA approved, and therefore are not used by U. S. participants.

Figure 5: Percentage and number of laboratories using Ag/Ab test kits, by manufacturer



Other EIA test kits

Laboratories reported using 15 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.

- Human HIV-1+2 ELISA (1)
- BIOTEST Anti-HIV TETRA ELISA (3)
- RANDOX HIV-1+O and HIV-2 (1)
- DIA PROF MED, Ukraine DIA-HIV1/2, (2) and
- Diagnostic Systems EIA Anti-HIV (3).

Continued on next page

EIA Methods and Results, Continued

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 AxSYM HIV Ag-Ab	120	19	1 (5.0%)	99	1 (1.0%)
Abbott HIV-1/HIV-2 (rDNA)	1548	254	4 (1.6%)	1283	7 (0.5%)
BioMérieux Vironostika Uni-form II Ag/Ab	71	12	0	58	1 (1.7%)
Bio-Rad Genetic Systems HIV-1 Antigen*	4	0	0	0	4 (100%)
Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O	402	66	1 (1.5%)	333	2 (0.6%)
Bio-Rad Genetic Systems HIV-2 EIA†	17	2	0	0	15 (100%)
Murex HIV Ag/Ab Combination	78	13	0	64	1 (1.5%)
Vironostika HIV-1 Antigen*	4	0	0	0	4 (100%)

* Bio-Rad Genetic Systems HIV-1 Antigen and Vironostika HIV-1 Antigen* tests detect the presence of HIV antigen. The survey samples do not contain HIV antigens.

† 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 for all reported EIA tests are as follows;

- Donor 1 (HIV-1 infected seroconverter), 5 false negatives,
- Donor 2 (HIV-1 infected seroconverter), 13 false negatives,
- Donor 3, (HIV-1 infected strong positive), 17 false negatives, and
- Donor 4, (HIV-1 uninfected), 6 false positives.

EIA comments

The percentage of false-negatives increased to 1.0% (35/3659) in this shipment, from 0.7% (20/2811) in the July 2005 shipment. The percentage of false-positives remained the same, 0.8%, in this shipment (6/727) as in the 2005 July shipment (11/1394). However, the overall performance is nearly the same, with 99.1% correct responses for this shipment and 99.3% in the July 2005 shipment.

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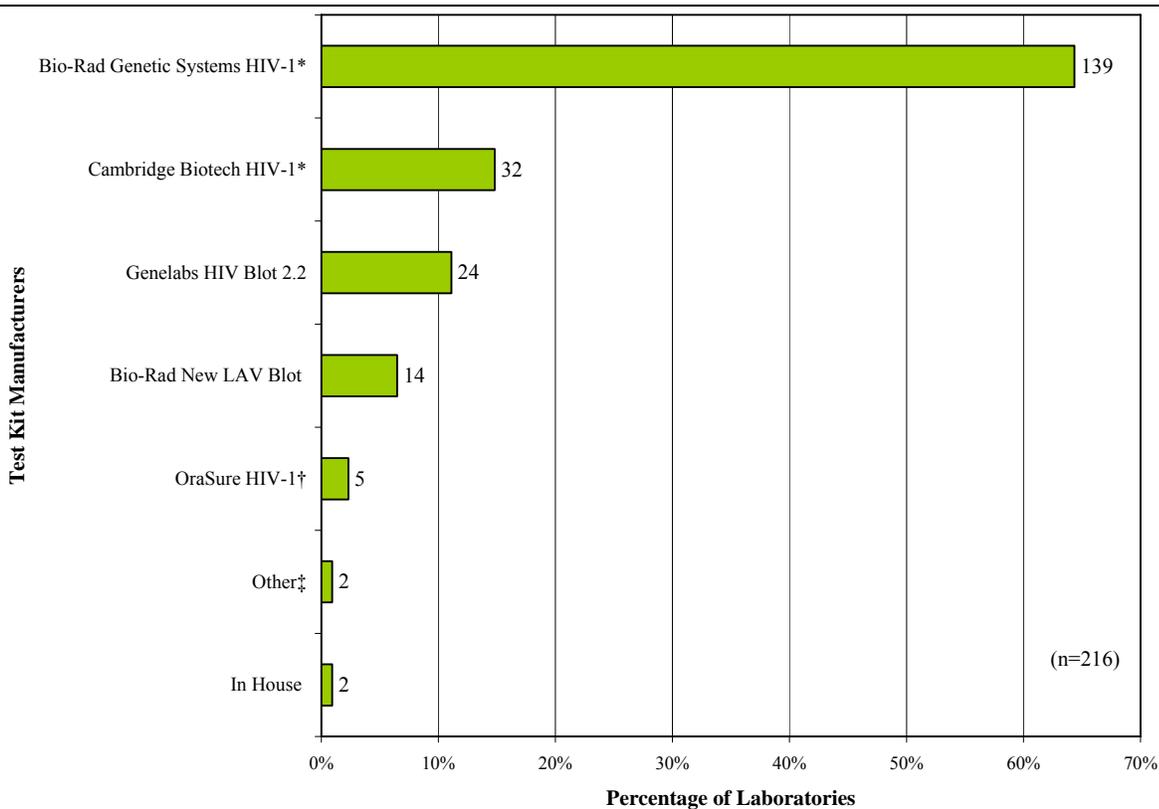
Western Blot Methods and Results

Introduction Of the 663 laboratories reporting test results in this survey, 216 (32.6%) performed WB testing using 7 different commercially manufactured WB test kits and one in-house preparation. Five laboratories use OraSure HIV-1 to test these survey samples, however OraSure HIV-1 Western Blot is not FDA approved for testing serum or plasma.

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 participant laboratories are shown below. The numbers at the end of the bars show the number of laboratories using that test kit.

Figure 6: 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.

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Western Blot Methods and Results, Continued

WB interpretative criteria

Of the 216 laboratories reporting WB test results, 214 (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:

- 187 (87.4%) APHL/CDC,
 - 19 (8.9%) World Health Organization (WHO),
 - 6 (2.8%) stated “other” (Manufacturers’ insert, Australian National Reference Laboratory, etc.), and
 - 2 (0.9%) Consortium for Retrovirus Serology Standardization (CRSS).
-

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 seroconverter): no false-negatives and 13 indeterminates,
 - Donor 2 (HIV-1 seroconverter): no false-negatives and 37 indeterminates,
 - Donor 3 (HIV-1 strong positive): 1 false-negative and 1 indeterminate, and
 - Donor 4 (negative): 2 false-positives and 2 indeterminates.
-

Continued on next page

Western Blot Methods and Results, Continued

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	716	27	1	0	649	1	38
Bio-Rad New LAV Blot I	75	5	0	1	67	0	2
Genelabs HIV Blot 2.2	126	5	1	1	114	0	5

*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 53 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. Four laboratories reported reactive WB for the HIV-negative donor although the EIA results were reported as nonreactive. Laboratories are reminded to handle and report the MPEP challenge samples in the same manner as patient specimens.

Several laboratories reported indeterminate results for the HIV-1 positive donors although the correct bands were present and of sufficient intensity to have been reported reactive.

The overall performance for laboratories reporting WB results was 99.6% correct answers compared to 99.3% in the July 2005 shipment.

IFA Methods and Results

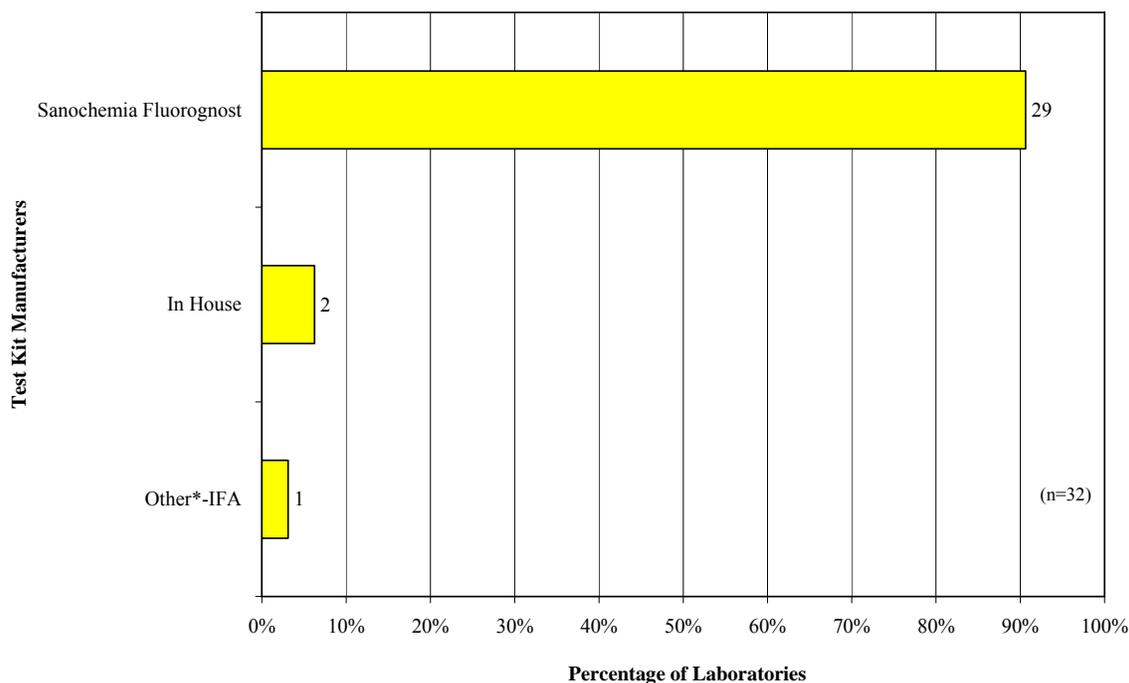
IFA Introduction

Of the 663 laboratories reporting results, 32 (4.8%) performed IFA tests. Most (90.6%) used the only commercially available IFA test kit, Sanochemia Fluorognost IFA. However, a few laboratories used in-house or other methods. (Figure 7).

IFA test kits, by manufacturer

The IFA test kits reported are shown in Figure 7. The numbers at the end of the bars are the number of laboratories using that test kit.

Figure 7: Percentage and number of laboratories using IFA test kits, by manufacturer



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

IFA false-negative and indeterminate results

Table 7: False-negative and indeterminate IFA results reported by participant laboratories, by kit manufacturer

Methods/Manufacturer	Total # of Results	Negative Donors			Positive Donors		
		Negative	False-positive	I*	Positive	False-negative	I
In House	17	2	0	0	12	0	3
Other†	6	1	0	0	4	0	1
Sanochemia Fluorognost	156	19	0	0	126	4	7

*I, indeterminates

†Other, Manufacturer for which no code is included in the result booklet.

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IFA Methods and Results, Continued

- IFA results by donor** Incorrect results for each donor are as follows;
- Donor 1, 3 false negatives and 5 indeterminates and
 - Donor 2, 1 false negative and 6 indeterminates.

Comments The overall performance for IFA in this is 97.8%, due primarily to false-negative results.

“Other” Test Methods and Results

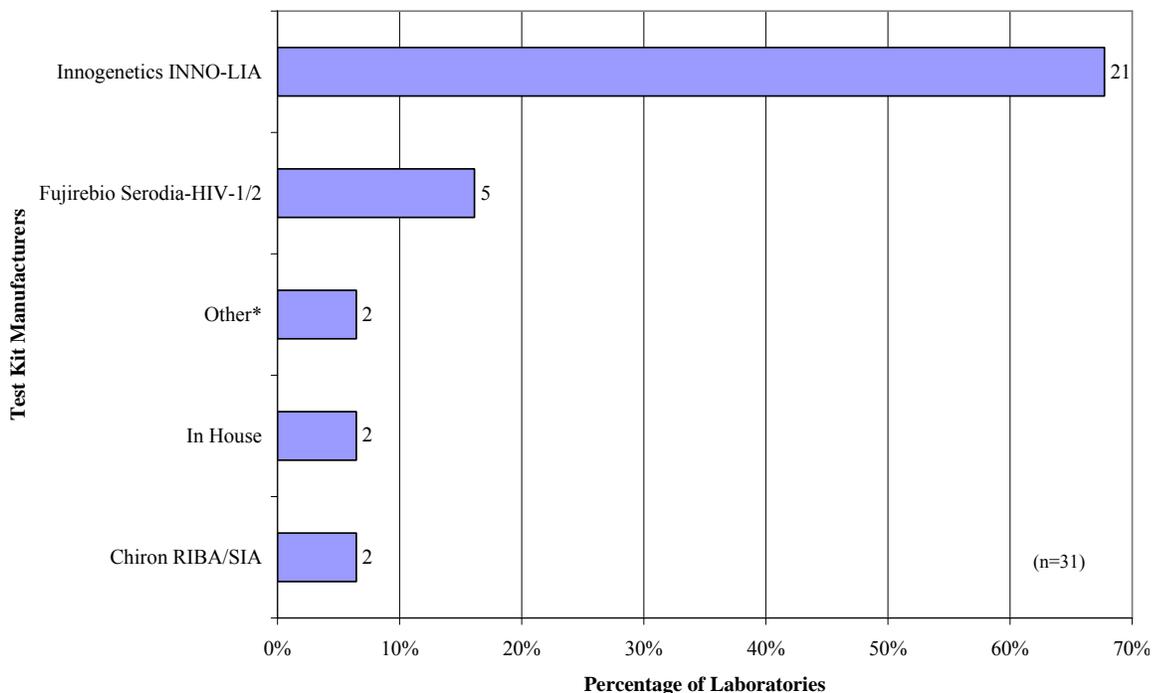
Introduction

Thirty-one (4.7%) of the 663 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 these types of results.

“Other” test kits, by manufacturer

Figure 8 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 8: Percentage and number 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 parentheses is the number of laboratories using that test kit.

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

Continued on next page

“Other” Test Methods and Results, Continued

Results by donor

The results by donor are as follows;

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

“Other” results

Table 8: False-positive and indeterminate determinations for "Other" test kits*

Methods/Manufacturer	Total # of Results	Negative Donor			Positive Donors		
		Negative	False-positive	I*	Positive	False-negative	I
In-House	12	2	0	0	5	5	0
Innogenetics INNO-LIA	119	14	0	0	103	0	2

*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.**

Comments

The overall performance of the laboratories using tests in the “other” category decreased slightly compared to the previous survey: In this shipment, laboratories reported 97.2% correct results, compared to 99.2% in the July 2005 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 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.