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 July 2003

CENTERS FOR DISEASE™
CONTROL AND PREVENTION

PUBLIC HEALTH PRACTICE PROGRAM OFFICE
DIVISION OF LABORATORY SYSTEMS
ATLANTA, GEORGIA

Report of the July 2003 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)

The production of this report was coordinated in CDC by:

Public Health Practice Program Office.....Suzanne Smith, M.D., M.P.H., M.P.A., Acting Director
Division of Laboratory Systems ..... Robert Martin, M.P.H., Dr. P.H., Director
Laboratory Practice Evaluation and Genomics Branch....Devery Howerton, Ph.D., Chief

The content of this report was developed by:
Model Performance Evaluation Program (MPEP).....G. David Cross, M.S., Laurina O. Williams, Ph.D., M.P.H., Co-Managers

MPEP HIV-1 Performance Evaluation.....Sandra W. Neal, B.S., MT(ASCP), M.S., HIV-1 Project Coordinator

Inquiries about this report should be directed to the Model Performance Evaluation Program by calling (770) 488-8125 or (770) 488-8091.

Table of Contents

List of Tables

List of Figures

Analysis of Testing Results Reported by Laboratories Participating in the Model Performance Evaluation Program for HIV-1 Antibody in July 2003

Introduction

This report analyzes results provided to the Centers for Disease Control and Prevention (CDC) by laboratories participating in the Model Performance Evaluation Program (MPEP) after they tested the human immunodeficiency virus type 1 (HIV-1) performance evaluation samples shipped to them in July 2003. Test results were reported by 689 (87.8%) of the 785 laboratories that received sample panels.

This report contains the analysis of results for EIA screening and confirmatory tests and does not include analysis of the test results from HIV rapid tests. Rapid test results and analysis are contained in a separate report.

Survey Samples

Samples used in the MPEP surveys are undiluted, defibrinated plasma obtained from individual donors who are HIV-1 infected (positive) or HIV-1-uninfected (negative). The HIV-1 antibody-positive 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. The HIV-1 antibody-negative samples were not heat treated. Before shipment, each donor sample was tested with the following:

- two HIV-1 enzyme immunoassay (EIA) kits,
- two HIV-1/HIV-2 EIA kits,
- two rapid test (RT) kits, and
- supplemental tests;
    - o two HIV-1 Western blot (WB) kits and
    - o one HIV-1 indirect immunofluorescence assay (IFA).

In pre-shipment testing, the strong-positive HIV-1 donor sample (Donor 2) was repeatedly EIA reactive with all of the HIV-1 EIA and the HIV-1/HIV-2 EIA kits. It was also WB reactive with the two HIV-1 FDA-licensed WB kits. The negative donor sample (Donor 5) was repeatedly EIA non-reactive and demonstrated no bands with the FDA-licensed HIV-1 WB kits. Donor samples 1 and 3, obtained from individual donors recently infected with HIV-1, were positive for HIV-1 antibody and demonstrated EIA and WB reactivity with the FDA-licensed EIA, WB, and RT kits used for pre-shipment testing. Testing information for sequential serum samples from Donors 1 and 3 demonstrated 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.

Table 1 is provided for the participant laboratories to record and compare their results with the CDC MPEP results for survey samples.

Table 1: Laboratory Worksheet for HIV-1 Antibody Testing Results for the July 2003 Shipment

Panel Letter	Vial Label	CDC Donor Number[1]	CDC Test Results[2]	Donor HIV Status	Laboratory Interpretation[3]			
					EIA			
					Initial	Final	WB	IFA
A	A1	2	Positive	Infected				
	A2	3	Positive	Infected				
	A3	5	Negative	Uninfected				
	A4	1	Positive	Infected				
	A5	5	Negative	Uninfected				
	A6	1	Positive	Infected				
B	B1	2	Positive	Infected				
	B2	5	Negative	Uninfected				
	B3	1	Positive	Infected				
	B4	5	Negative	Uninfected				
	B5	1	Positive	Infected				
	B6	3	Positive	Infected				
C	C1	5	Negative	Uninfected				
	C2	1	Positive	Infected				
	C3	3	Positive	Infected				
	C4	1	Positive	Infected				
	C5	2	Positive	Infected				
	C6	5	Negative	Uninfected				
D	D1	1	Positive	Infected				
	D2	5	Negative	Uninfected				
	D3	1	Positive	Infected				
	D4	2	Positive	Infected				
	D5	5	Negative	Uninfected				
	D6	3	Positive	Infected				

1. Donor 4 was intentionally omitted.

2. The CDC result was obtained after composite testing with the 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 the manufacturer's criteria for interpretation of WB results.

3. Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

Table 2 shows the CDC results for Western blot testing and is provided for the participant laboratories to compare their results with CDC MPEP results for the survey samples.

Table 2: CDC Western Blot (WB) Testing Results for the July 2003 Shipment

Panel Letter	Vial Label	CDC Donor Number[1]	CDC Western Blot Test Results Specific WB Band Detected[2]	WB Test Kit Manufacturer	CDC Interpretation[3]
A	A1	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech[4] Genetic Systems	Positive Positive
	A2	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	A3, A5	5	No bands	Both Manufacturers	Negative
	A4, A6	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
B	B1	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B2, B4	5	No bands	Both Manufacturers	Negative
	B3, B5	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B6	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
C	C1, C6	5	No bands	Both Manufacturers	Negative
	C2, C4	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C3	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C5	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
D	D1, D3	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D2, D5	5	No bands	Both Manufacturers	Negative
	D4	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D6	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive

1. Donor 4 was intentionally omitted.
2. Western blot (WB) result based on band intensity of $\geq$ 1+ staining.
3. The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.
4. Cambridge Biotech/Calypte Biomedical

Overall Summary of Results and Key Findings

Results Summary

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

Table 3: Results Summary

			Positive Donors	Negative Donor	
Method	**Total # of laboratories**	**Total # of results**	**False-negative or indeterminate results**	**False-positive or indeterminate results**	**Overall Performance (TP+TN/total # results)[1]**
EIA	648	4143	13/2772 (0.5%)	13/1371 (0.9%)	99.4%
WB	238	1098	49/945 (5.2%)[3]	16/153 (10.4%)[4]	98.5%[7]
IFA	37	191	35/143 (24.4%)[5]	2/48 (4.2%)[6]	93.7%[7]
OTHER[2]	64	450	None	None	100%

1. TP, true positives; TN, true negatives.
2. "Other" test methods refer to test types other than EIA, WB or IFA, such as line or strip assays, microparticle capture, chemiluminescence, etc.
3. One false negative and 48 indeterminates.
4. One false positive and 15 indeterminates.
5. Ten false negatives and 25 indeterminates.
6. Two indeterminates.
7. 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.

Key Findings

- For Western blot testing:
  - Several laboratories performed WB testing on negative challenges. This may be a result of a departure from the accepted algorithm or part of the quality assurance program for that laboratory.
  - Over the last three shipments there has been an increase in the number of indeterminate WB results reported, from 20 in the July 2002 shipment to 40 in January 2003 shipment, and 63 indeterminates in this shipment.
    - Of the 63 indeterminate WB results, 41 (65.1%) were from laboratories using Bio-Rad Genetic Systems HIV-1, and 13 (20.6%) from laboratories using Cambridge Biotech HIV-1.
  - Seven U.S. laboratories used interpretive criteria different from that recommended by the kit manufacturer as licensed by the FDA.
- When considering overall analytic performance, the IFA test did not perform as well as EIA or WB. In this shipment the IFA tests showed relatively poor performance, 93.7% when compared with EIA (99.4%) and WB (98.5%).
- Tests reported in the "Other" section of the result booklet (microparticle, chemiluminescence, and other formats that differ from the traditional microtiter-format EIA tests) showed good performance. This group reported all correct results.

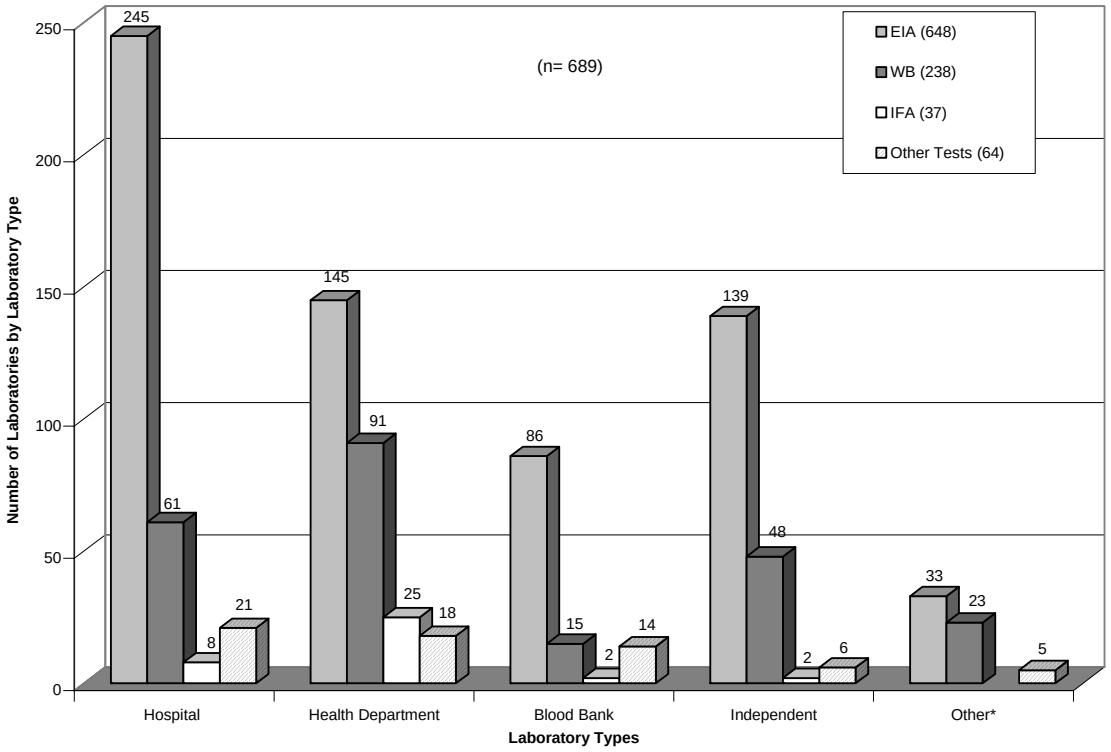
Adequate training is essential in the performance of all laboratory testing. This is especially important for WB and IFA testing because of the subjectivity involved in interpreting the test results. Also, for IFA testing, proper maintenance of the fluorescent microscope is imperative. The results of this survey for Western blot and IFA may also point to the need for greater understanding of test methods and procedures.

Laboratory Demographics

The types of laboratories reporting results are shown in Figure 1 below. Each laboratory type is listed with 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 reflected in all figures refers to the number of laboratories, not the number of methods or tests kits used.

The locations of laboratories participating in the MPEP for HIV-1 antibody are pictured in Figure 2 on page 10 (U.S. laboratories) and Table 4 on page 11 (participants by country). Including the United States, MPEP participants are located in a total of 67 countries.

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



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

Figure 2: Laboratories in the United States and US Territories reporting MPEP HIV-1 Results

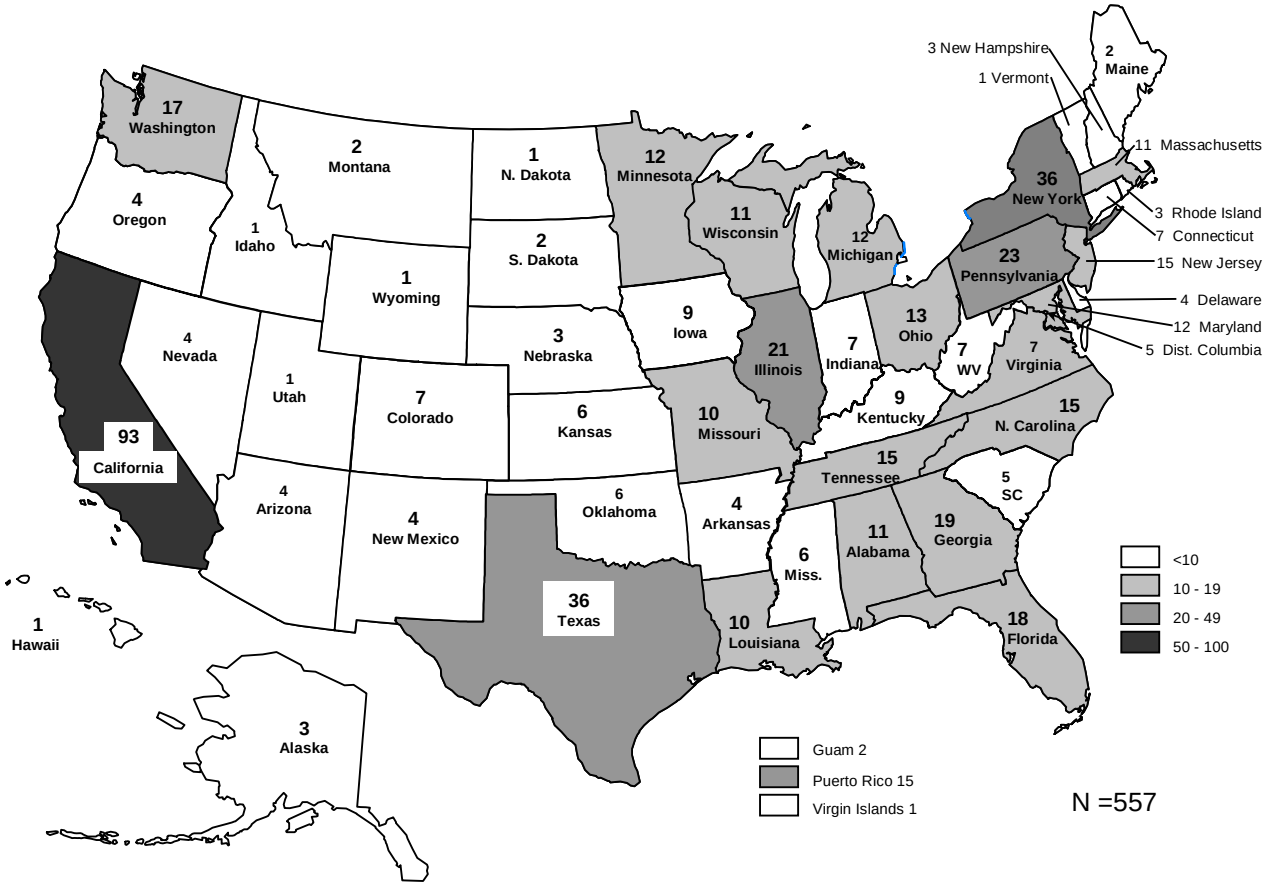


Table 4: Location of Laboratories by Country Reporting HIV-1 Ab Results

N = 689

Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Algeria	1	Guyana	1	South Africa	4
Argentina	3	Honduras	1	South Korea	2
Australia	3	Hong Kong	2	Spain	2
Austria	2	Hungary	1	Sri Lanka	5
Bahamas	1	India	2	St. Kitts/Nevis	1
Barbados	1	Israel	3	Suriname	2
Belgium	2	Italy	2	Switzerland	1
Bolivia	1	Japan	1	Taiwan	2
Brazil	1	Malaysia	2	Tanzania	2
Cameroon	1	Malta	1	Thailand	8
Canada	18	Mexico	1	Trinidad	2
Chile	1	Morocco	1	Turkmenistan	1
Costa Rica	2	Nicaragua	1	US Territory	18
Cote d'Ivoire	1	Nigeria	1	Uganda, East Africa	3
Croatia	2	Paraguay	1	United Arab Emirates	3
Denmark	3	Peru	2	United Kingdom	1
Dominican Republic	2	Philippines	2	United States	539
Ecuador	1	Republic of Singapore	1	Uruguay	1
El Salvador	1	Romania	1	Venezuela	3
England	1	Saudi Arabia	2	Vietnam	1
Eritrea	1	Scotland	1	Zimbabwe	2
Germany	2	Slovakia	1		
Ghana	2	Slovenia (Yugoslavia)	2		

Test Methods and Results

The combinations of test methods employed by participant laboratories and the frequency of use are shown in Figure 3 below. Of the 689 laboratories reporting results, 387 (56.2%) performed only EIA, 233 (33.8%) performed EIA and a supplemental test, and 5 (0.7%) performed only a supplemental test. These numbers do not include the 64 (9.3%) laboratories that performed an "Other" test in addition to, or instead of EIA, WB and IFA. The data for these "Other" tests are presented in Figure 7, page 18.

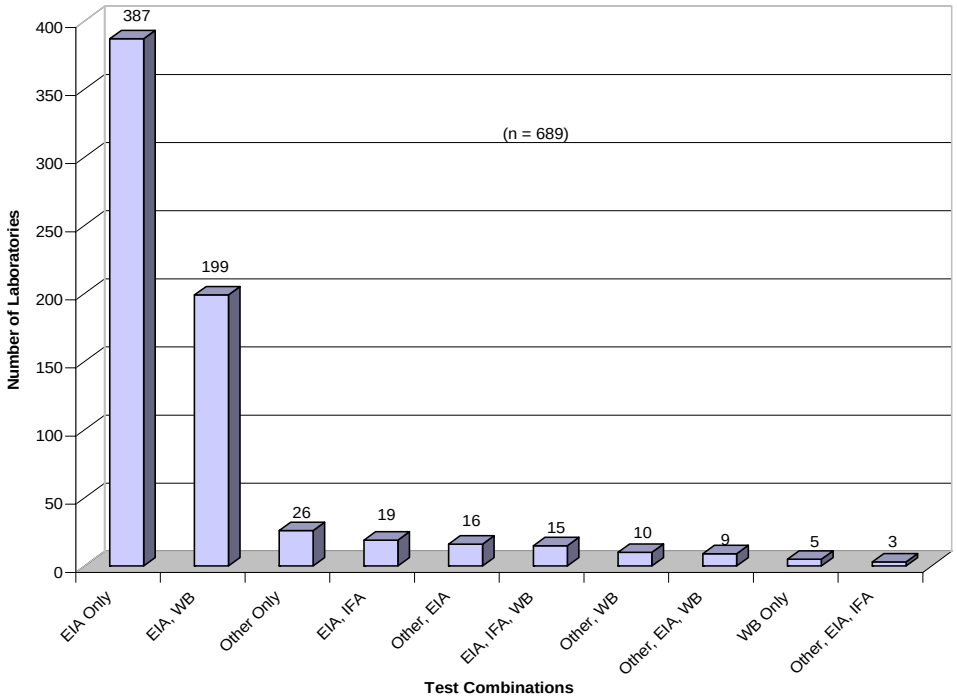
The percentages of test kits used, listed by kit manufacturer, for the EIA, WB, and IFA, are shown in Figures 4, 5, and 6, respectively. Some laboratories indicated using test kits for which no unique manufacturer codes were provided in the report booklet. These responses have been grouped as "Other" manufacturer kits.

Some "Other" EIA kits and the number of laboratories reporting include;

- BioTest Anti-HIV Tetra Elisa, 5
- Bio-Chem Immunosystems (Adaltis) Detect HIV, 2
- Murex HIV Ag/Ab Combination, 3
- Genedia, Greencross Life Sciences Corporation, 1
- Equip-Diagnostics Italy, 1
- Enzynost HIV Integral, Dade Behring, 2

There were laboratories located outside the United States that used the Abbott AxSYM system or the Abbott PRISM analyzer that reported results as S/CO (sample/cutoff ratio). Since the S/CO data can not be entered correctly on the MPEP EIA result form, the data from laboratories using either AxSYM or PRISM systems are also reported with "Other" tests in Figure 7, page 18.

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

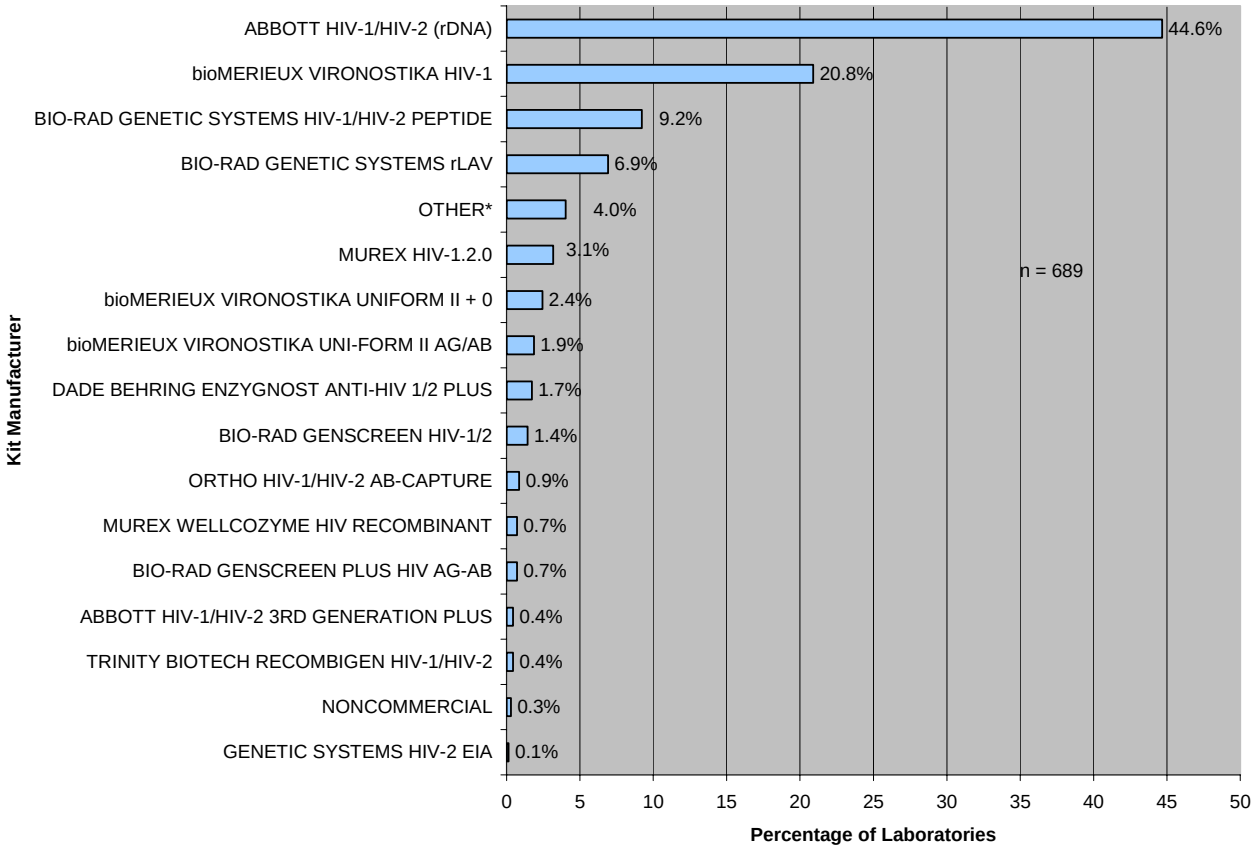


The reports of false-negative and false-positive results for the HIV-1-positive and HIV-1-negative samples for the EIA, WB, and IFA methods, listed by kit manufacturer, are shown in Tables 5, 6, and 7, respectively.

EIA Methods and Results

Figure 4 shows the percentage of laboratories using various EIA test kit manufacturers.

Figure 4: Percentages of laboratories using EIA test kits, by manufacturer



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

Table 5, shows the test kit manufacturers used by seven different laboratories reporting twelve false-positive EIA interpretations for Donor 5, the negative donor. There were 13 false-negative interpretations reported by seven different laboratories for HIV-1 positive samples; Donor 1, ten false-negatives; Donor 2, one false-negative; and Donor 3, two false-negatives.

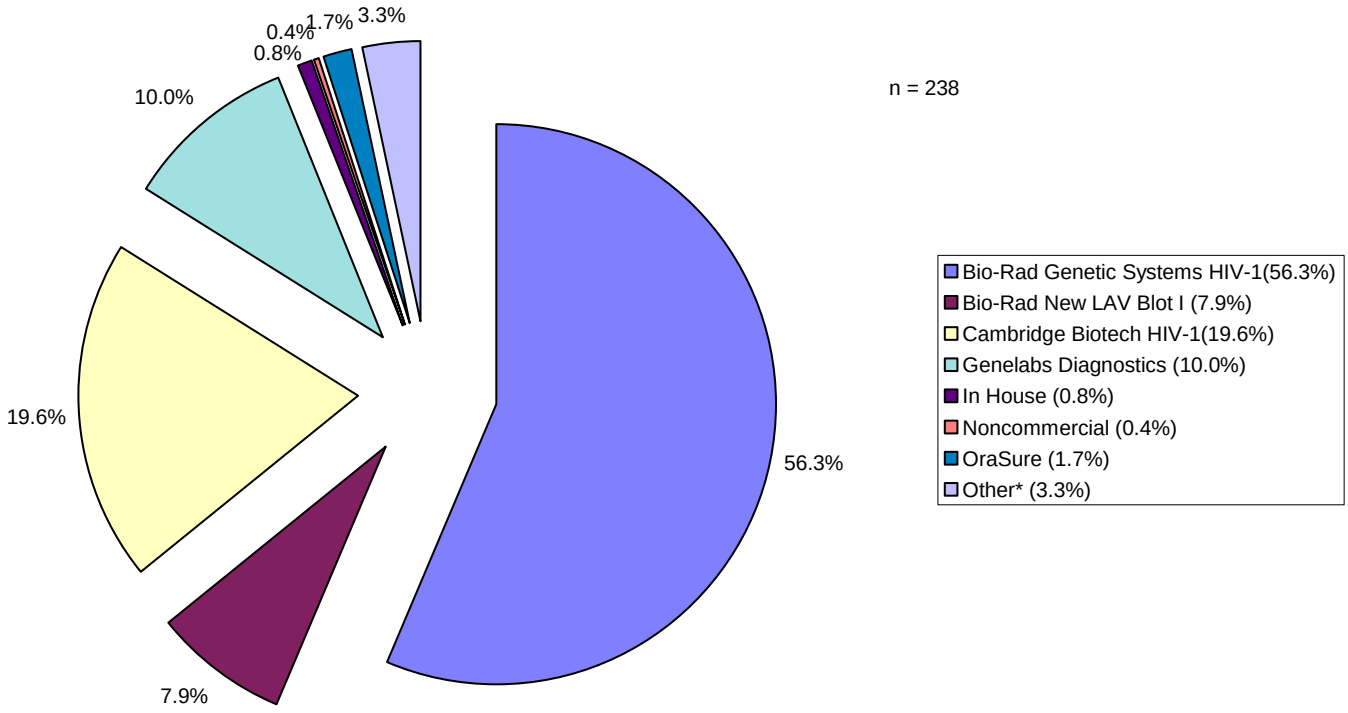
Table 5: False-positive and false-negative EIA results, reported by participant laboratories, by kit manufacturer

Manufacturer	Total # of Results	False-positive	False-negative
Abbott HIV-1/HIV-2 (rDNA))	1856	6	3
Bio-Rad Genetic Systems rLAV	288	1	1
Bio-Rad Genetic Systems HIV-1/2 Peptide	384	2	1
Bio-Rad Genscreen HIV-1/2	60	2	2
bioMerieux Vironostika HIV-1	864	1	1
Labsystems HIV-1/2	12	1	1
Genetic Systems HIV-2 EIA	4	0	4
Total	3468	13	13

WB Methods and Results

Of the 689 laboratories reporting test results in this survey, 238 (34.5%) performed WB testing. The OraSure test is included in Figure 5 separate from the "other" for which no manfacturers' code is included in the MPEP result booklet.

Figure 5: Percentages of WB test reagents, reported by participant laboratories, by kit manufacturer



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

WB Results Interpretations

For Western blot there was one false-positive and one false-negative and 63 indeterminate interpretations reported for this shipment. However, there were 15 indeterminate results for the HIV-1 uninfected donor sample (Donor 5) reported by 10 laboratories using 4 different test kits. There were 48 indeterminate results for the positive donors; the indeterminates were reported by 32 laboratories using four different test kits, as shown in Table 6 on page 15.

Donor 1 (HIV-1 infected seroconverter)

- 40 indeterminates
- 1 false-negative

Donor 2 (HIV-1 strong positive)

- 4 indeterminates

Donor 3 (HIV-1 infected seroconverter)

- 4 indeterminates

Donor 5 (HIV-1 negative)

- 15 indeterminates
- 1 false-positive

Table 6: False-positive, false-negative, and indeterminate interpretations for Western blot test, by manufacturer

Manufacturer	Total # of Results	Negative Donors		Positive Donors	
		False-positive	Indeterminate	False-negative	Indeterminate
Bio-Rad Genetic Systems HIV-1	619	0	4	1	37
Bio-Rad New LAV Blot I	98	0	8	0	0
Cambridge Biotech HIV-1	209	1	2	0	11
Genelabs Diagnostics	118	0	1	0	0
Total	1044	1	15	1	48

WB Interpretative Criteria

Of the 238 laboratories reporting WB test results, 231 indicated which WB criteria they used to interpret their WB tests. Most used the Association of Public Health Laboratories/Centers for Disease Control and Prevention (APHL/CDC) WB interpretive criteria;

- 198 (85.7%) APHL/CDC,
- 20 (8.2%) World Health Organization,
- 11 (4.8%) stated "other" (Red Cross, Manufacturers' insert, Australian National Reference Laboratory, etc.), and
- 2 (0.9%) Consortium for Retrovirus Serology Standardization.

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 interpretive criteria, 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.) Seven U.S. laboratories indicated they were using interpretive criteria different from those recommended by the kit manufacturer as licensed by the FDA:

- 2 used Consortium for Retrovirus Serology Standardization criteria, and
- 5 used World Health Organization criteria.

WB Band Patterns

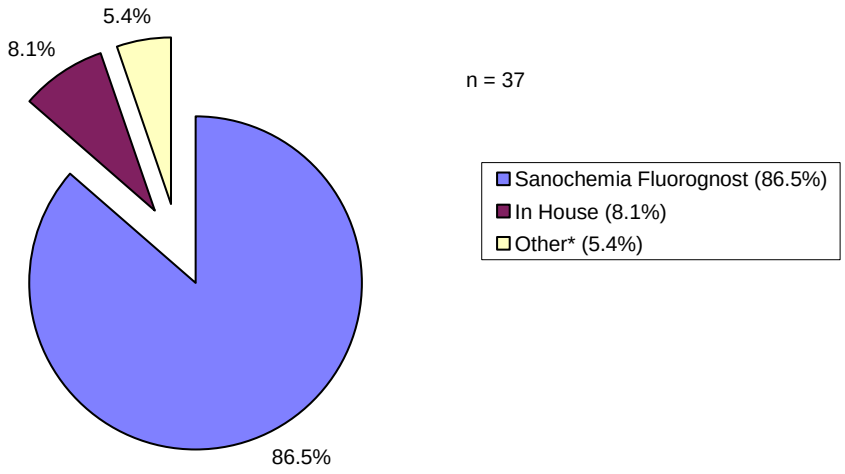
The WB bands for the donor samples in this survey, as determined in pre-shipment testing with two FDA-licensed WB test kits, are shown in Table 2, page 7. Only bands scoring greater than or equal to 1+ intensity are listed in the table.

Note that 153 WB interpretations were reported for Donor 5, the HIV-1 antibody-negative donor, although most laboratories do not normally include WB testing of EIA non-reactive donor samples in their routine algorithm for HIV antibody testing. Ten laboratories reported indeterminate WB interpretations for Donor 5. All ten of these laboratories reported non-reactive EIA results. For the HIV-1 antibody strong-positive sample (Donor 2) and the seroconversion samples (Donor 1 and Donor 3), most laboratories had no difficulty in detecting antibodies to gag (p24), pol (p31), and env (gp41, gp120, gp160) antigens. However, according to some participants, the bands though present, were of insufficient intensity, especially for the seroconverter samples (Donors 1 and 3), to report the sample as positive. One laboratory reported a negative interpretation even though the band patterns and band intensity appeared to fit the reported criteria for positive results.

IFA Methods and Results

Figure 6 shows the percentages of laboratories using the various IFA test reagents.

Figure 6: Percentage IFA test kits reported by participant laboratories, by manufacturer



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

As shown in Table 7, the 27 indeterminates interpretations were reported by 15 different laboratories, while the 10 false-negative interpretations were reported by 7 laboratories. One laboratory reported an indeterminate interpretation for Donor 2, the strongly reactive donor.

Table 7: Indeterminate and false-negative results reported by participants, by test kit manufacturer, for IFA tests

		Negative Donors		Positive Donors	
Methods/Manufacturer	Total # of Results	False-positive	Indeterminate	False-negative	Indeterminate
In House	16	0	0	1	2
Other*	12	0	0	0	1
Sanochemia Fluorognost	163	0	2	9	22
Total	191	0	2	10	25

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

For the 191 IFA interpretations reported, the interpretations by donor are as follows:

Donor 1 (HIV-1 infected seroconverter)
- 9 indeterminates
- 7 false negatives

Donor 2 (HIV-1 strong positive)
- 1 indeterminate

Donor 3 (HIV-1 infected seroconverter)
- 15 indeterminates
- 3 false negatives

Donor 5 (HIV-1 negative)
- 2 indeterminates

IFA Intensity Patterns

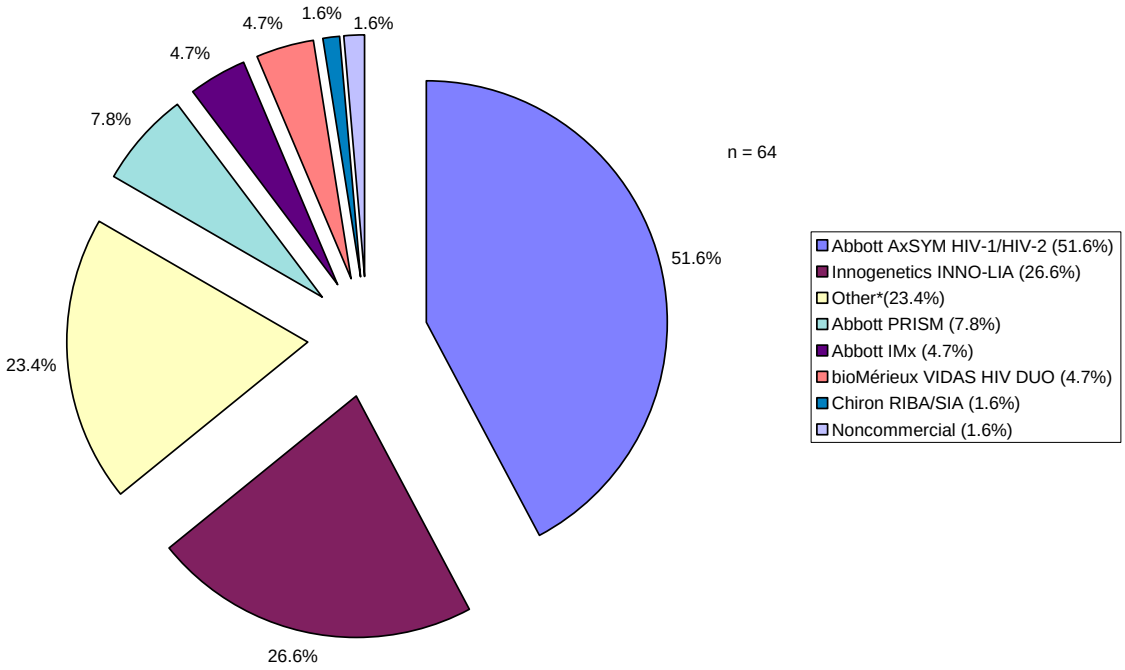
The IFA intensity patterns for HIV-1 infected cells were reported by participating laboratories. However, scoring of fluorescence intensity is not required for interpreting seroreactivity with the FDA-licensed Sanochemia (formerly know as Waldheim) Fluorognost HIV-1 IFA kit; therefore, some laboratories provided interpretations, but did not score fluorescent intensity. Several laboratories did report high background fluorescence that interfered with reading the test results for Donor 1.

"Other" Tests Performed

Figure 7, page 18, shows manufacturers of "Other" types of tests and percentages of use by the reporting laboratories.

Sixty-four laboratories reported using "Other" tests. Some of the participating laboratories used more than one test kit. The results of "Line" or "Strip Immunoassay" tests such as Qualitative Immunoblot (1), Anti-HIV 1+2 Immunodot Test (1), Orgenics LTD HIV 1 & 2 BiSpot (1) and Vitrose ECI HIV-1/2 (1) are not included in Figure 7. Note that laboratories using the Abbott AxSYM (35 laboratories) or PRISM (5 laboratories) systems reported their results on the "Other" test type result form, since these tests are based on microparticle capture and chemiluminescence measurement and differ from the traditional microtiter-format EIA tests.

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



*Other: tests for which no codes are included in the result booklet.

"Other" Results Interpretations

Among the 450 final interpretations reported for both the HIV-1 negative and HIV-1 positive samples, there were no false-positive or false-negative results reported.

Quality Control Testing

Table 8 describes the external quality control (QC) practices of most of the participating laboratories. Positive and negative samples included in manufactured kits are internal kit control material used to validate the test run, calculate test run cut-off values, and may not validate the analytic testing process, which may include testing problems such as faulty pipettors, inadequate incubation conditions, or sensitivity of the test kits.

Table 8: Summary of External Quality Control Material Sources

Test Type (Total # of Laboratories)[1]	Number of Laboratories (%) Reporting External QC	Source of External Quality Control Materials[2]		
		In-House	Commercial	Both
EIA (648)	488 (75.3%)	146 (29.9%)	316 (65.0%)	25 (5.1%)
WB (238)	94 (39.5%)	52 (55.3%)	38 (40.4%)	3 (3.2%)
IFA (37)	12 (32.4%)	8 (66.7%)	4 (33.3%)	0
Other (64)	30 (46.9%)	13 (43.3%)	15 (50.0%)	1 (3.3%)

1. Not all laboratories completed the QC section of the result booklet.
2. For EIA, WB and Other, one laboratory for each method did not report the source of their external QC material.

Glossary of Terms

EIA: Enzyme immunoassay, sometimes referred to as ELISA, is a commonly used 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: Immunofluorescent antibody test for HIV is the use of antibodies chemically linked to a fluorescent dye to identify the presences of antigens in a test samples.

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.

Oral fluid test: A test using oral mucosal transudate, a serous fluid. To differentiate this fluid from saliva, an absorbent material is left in the mouth for several minutes. In an HIV-infected person, oral mucosal transudate is likely to contain HIV antibodies.

Positive test: For HIV, a specimen that is reactive on an initial EIA test, repeatedly reactive on a second EIA run on the same specimen, and confirmed positive on Western blot or other supplemental test indicating that the specimen donor is infected with HIV.

Rapid HIV test: An HIV test that is simple (requiring only the reagents and equipment found in the test kit) and provides results within a short period of time.

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 repeatedly reactive using the EIA test.