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 2004

CENTERS FOR DISEASE™
CONTROL AND PREVENTION

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

Report of the January 2004 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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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 January 2004. Test results were reported by 733 (88.7%) of the 826 laboratories that received sample panels. Of the 733 laboratories reporting, 295 (40.2%) submitted results on-line.

This report contains the analysis of results for enzyme immunoassay (EIA) screening and confirmatory tests but does not include analysis of any results from HIV rapid tests. Samples for HIV rapid testing will be shipped in late May 2004.

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 EIA kits,
- two HIV-1/HIV-2 EIA 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 sample (from Donor 2) was repeatedly EIA reactive with all of the HIV-1 EIA and the HIV-1/HIV-2 EIA kits. The Donor 2 sample 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, and WB 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: Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing for the January 2004 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**	3	Positive	Infected	_____	_____	_____	_____
	A2	3	Positive	Infected	_____	_____	_____	_____
	A3	1	Positive	Infected	_____	_____	_____	_____
	A4	5	Negative	Uninfected	_____	_____	_____	_____
	A5	2	Positive	Infected	_____	_____	_____	_____
	A6	2	Positive	Infected	_____	_____	_____	_____
B	**B1**	2	Positive	Infected	_____	_____	_____	_____
	B2	3	Positive	Infected	_____	_____	_____	_____
	B3	5	Negative	Uninfected	_____	_____	_____	_____
	B4	2	Positive	Infected	_____	_____	_____	_____
	B5	3	Positive	Infected	_____	_____	_____	_____
	B6	1	Positive	Infected	_____	_____	_____	_____
C	**C1**	1	Positive	Infected	_____	_____	_____	_____
	C2	5	Negative	Uninfected	_____	_____	_____	_____
	C3	2	Positive	Infected	_____	_____	_____	_____
	C4	3	Positive	Infected	_____	_____	_____	_____
	C5	3	Positive	Infected	_____	_____	_____	_____
	C6	2	Positive	Infected	_____	_____	_____	_____
D	**D1**	5	Negative	Uninfected	_____	_____	_____	_____
	D2	2	Positive	Infected	_____	_____	_____	_____
	D3	3	Positive	Infected	_____	_____	_____	_____
	D4	1	Positive	Infected	_____	_____	_____	_____
	D5	2	Positive	Infected	_____	_____	_____	_____
	D6	3	Positive	Infected	_____	_____	_____	_____

1. Donor 4 was intentionally omitted.

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

3. Laboratory Interpretation space is to be completed by participants to facilitate comparison of their results with CDC results.

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

Table 2: CDC Western blot (WB) testing results for the January 2004 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, A2	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech[4] Genetic Systems	Positive Positive
	A3	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	A4	5	No Bands	Both Manufacturers	Negative
	A5, A6	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
B	B1, B4	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B2, B5	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	B3	5	No Bands	Both Manufacturers	Negative
	B6	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
C	C1	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C2	5	No Bands	Both Manufacturers	Negative
	C3, C6	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	C4, C5	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
D	D1	5	No Bands	Both Manufacturers	Negative
	D2, D5	2	24, 31, 41, 51, 66, 120, 160 18, 24, 31, 41, 51, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D3, D6	3	17, 24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 55, 65, 120, 160	Cambridge Biotech Genetic Systems	Positive Positive
	D4	1	24, 31, 41, 51, 66, 120, 160 24, 31, 40, 41, 51, 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

Method	Total # of laboratories	Total # of results	Positive Donors: False-negative or indeterminate results	Negative Donor: False-positive or indeterminate results	Overall Performance (TP+TN/total # results)[1]
EIA	678	4340	14/3624 (0.4%)	5/716 (0.7%)	99.6%
WB	234	1227	16/1160 (1.4%)[3]	9/67 (13.4%)[4]	99.2%[8]
IFA	34	186	31/162 (19.1%)[5]	0/24	96.8%[8]
Other[2]	76	560	1/470 (0.2%)[6]	2/90 (2.2%)[7]	99.5%[8]

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 15 indeterminates.
4. Two false positives and 7 indeterminates.
5. Six false negatives and 25 indeterminates.
6. One false negative.
7. One false positive and one indeterminate.
8. 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

- In general, the percentage of laboratories reporting results has remained steady at about 87-91% over the last three shipments.
- More laboratories are using on-line data entry to report test results.
  - 40.2% of all MPEP participants reported results on-line.
  - Laboratories from 43 countries, including the United States, currently use on-line data entry.
- The overall testing performance has improved:
  - EIA: There were 0.7% false-positive and 0.4% false-negative interpretations in this shipment. In the July 2003 shipment, there were 0.9% false-positive and 0.5% false-negative interpretations reported.
  - WB: Western blot results have shown the greatest improvement:
    - In the July 2003 shipment there were 5.2% indeterminate and false-negative interpretations for the positive donors. However, in this shipment, January 2004, there were 1.4% indeterminate and false-negative interpretations the positive donors.
    - All U.S. laboratories reported using APHL/CDC interpretive criteria, which is the same as that recommended by the kit manufacturers licensed by the FDA.
  - IFA: These results showed slight improvement, with 19.1% false-negative and indeterminate interpretations for the positive donors in this shipment, compared to 24.4% in the July 2003 shipment.
  - "Other": Laboratories using tests other than EIA, WB or IFA showed an overall decrease in the quality of performance, with one false-positive, one indeterminate, and one false-negative. In the July 2003 shipment, all laboratories reported correctly.

Note: Adequate training is essential in performing 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, and the use of external control materials is

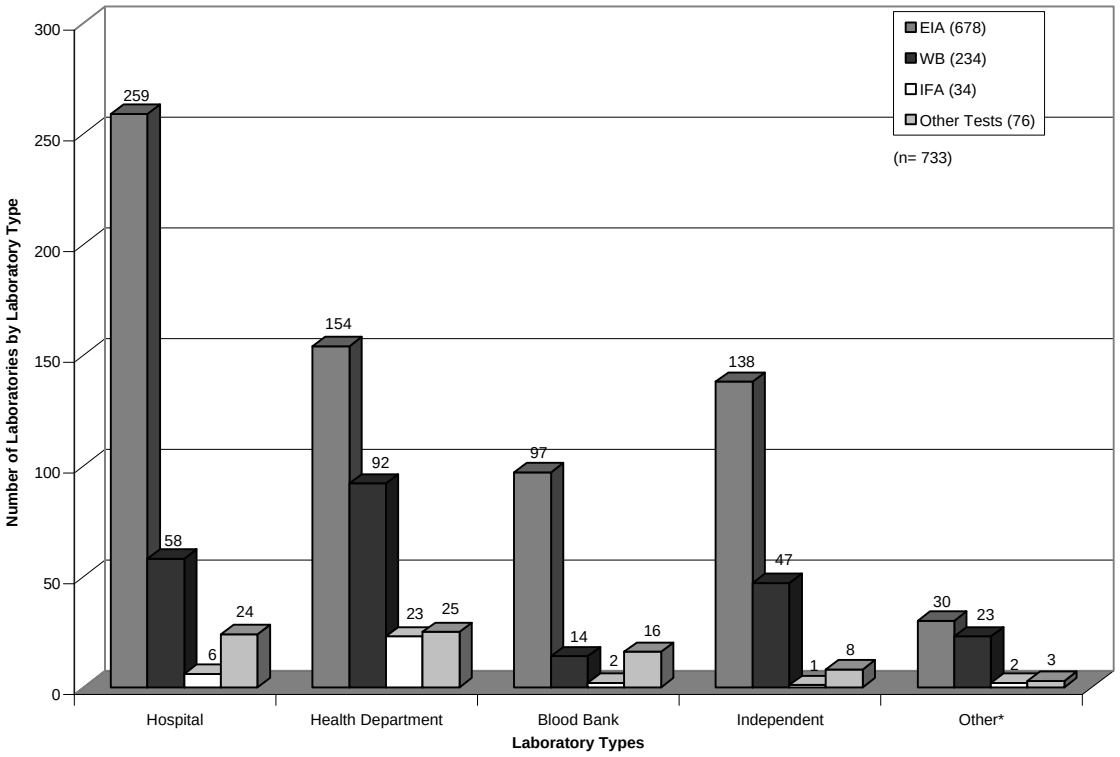
recommended. The results of this survey for WB and IFA may point to an improved understanding of test methods and procedures.

Laboratory Demographics

The types of laboratories reporting results are shown in Figure 1 below. Each type is listed by 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 9 (U.S. laboratories) and Table 4 on page 10 (participants by country). Including the United States, MPEP participants are located in 72 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 U.S. Territories reporting MPEP HIV-1 Results

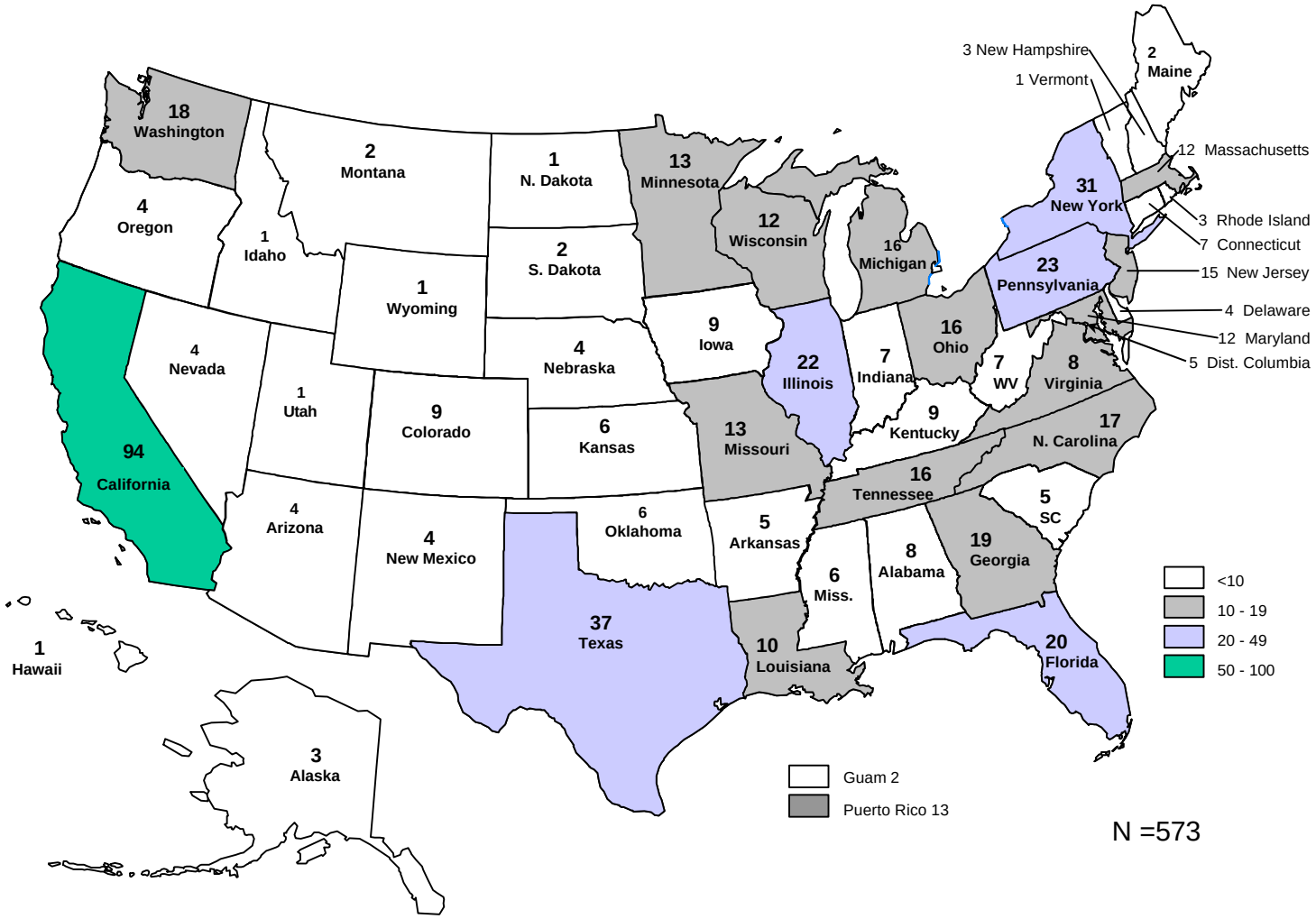


Table 4: Location of Laboratories by Country Reporting HIV-1 Ab Results

N = 733

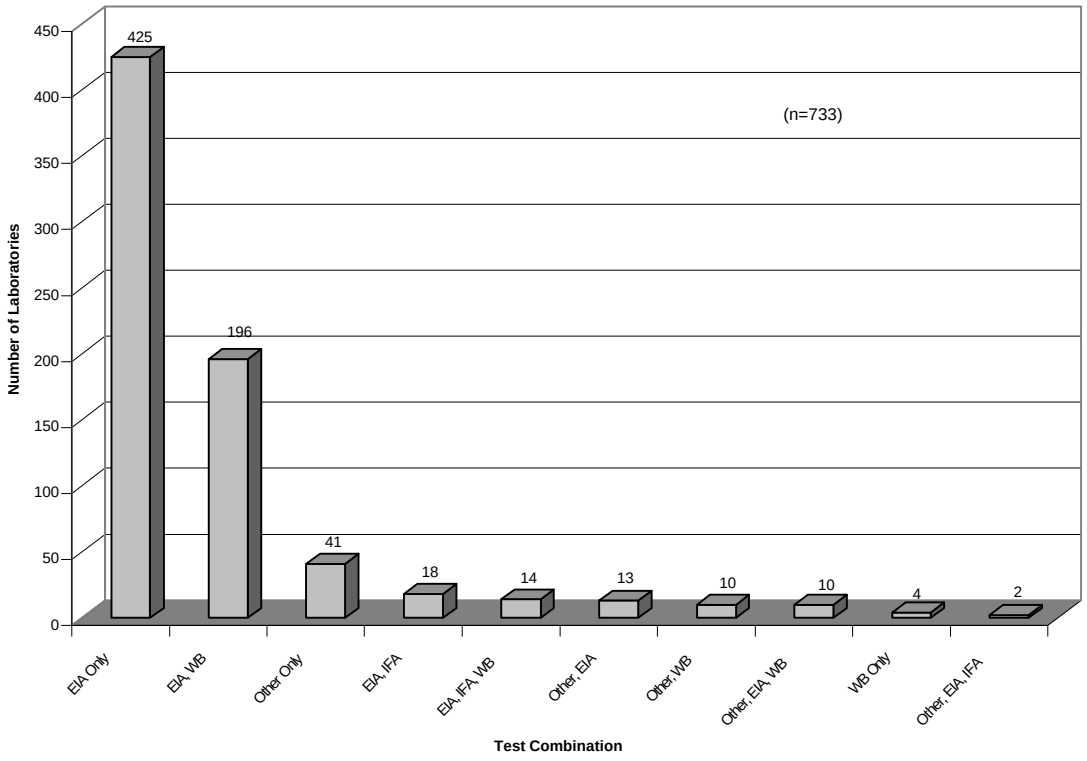
Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Argentina	3	Honduras	2	Scotland	1
Australia	6	Hong Kong	2	Slovakia	1
Austria	2	Hungary	1	Slovenia (Yugoslavia)	2
Bahamas	1	India	5	South Africa	3
Barbados	1	Ireland	1	South Korea	2
Belgium	2	Israel	5	Spain	4
Bolivia	1	Italy	2	Sri Lanka	4
Brazil	2	Jamaica	1	Suriname	1
Cameroon	1	Japan	1	Switzerland	1
Canada	18	Kazakhstan	5	Taiwan	2
Chile	1	Kenya	2	Tanzania	1
Columbia	1	Kyrgyzstan	2	Thailand	8
Costa Rica	2	Malaysia	2	Trinidad	2
Cote d'Ivoire	3	Mali, West Africa	1	Turkmenistan	1
Croatia	2	Malta	1	U.S. Territory	15
Denmark	3	Mexico	1	Uganda, East Africa	2
Dominican Republic	1	Morocco	1	United Arab Emirates	3
Ecuador	1	Myanmar (Burma)	1	United Kingdom	1
El Salvador	1	Nicaragua	1	United States	558
England	2	Nigeria	1	Uruguay	1
Eritrea	1	Panama	1	Uzbekistan	10
Ethiopia	1	Peru	2	Venezuela	2
Germany	3	Philippines	2	Zimbabwe	2
Ghana	1	Republic of Singapore	1		
Guyana	1	Saudi Arabia	1		

Test Methods and Results

The combinations of test methods used by MPEP laboratories and the frequency of use are shown in Figure 3 below. Of the 733 laboratories reporting results;

- 425 (58.0%) performed only EIA,
- 228 (31.1%) performed EIA and a supplemental test,
- 4 (0.5%) performed only a supplemental test, and
- 76 (10.4%) laboratories performed an "Other" test in addition to, or instead of, EIA, WB and IFA.

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



The percentages of laboratories using the various test kits, 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.

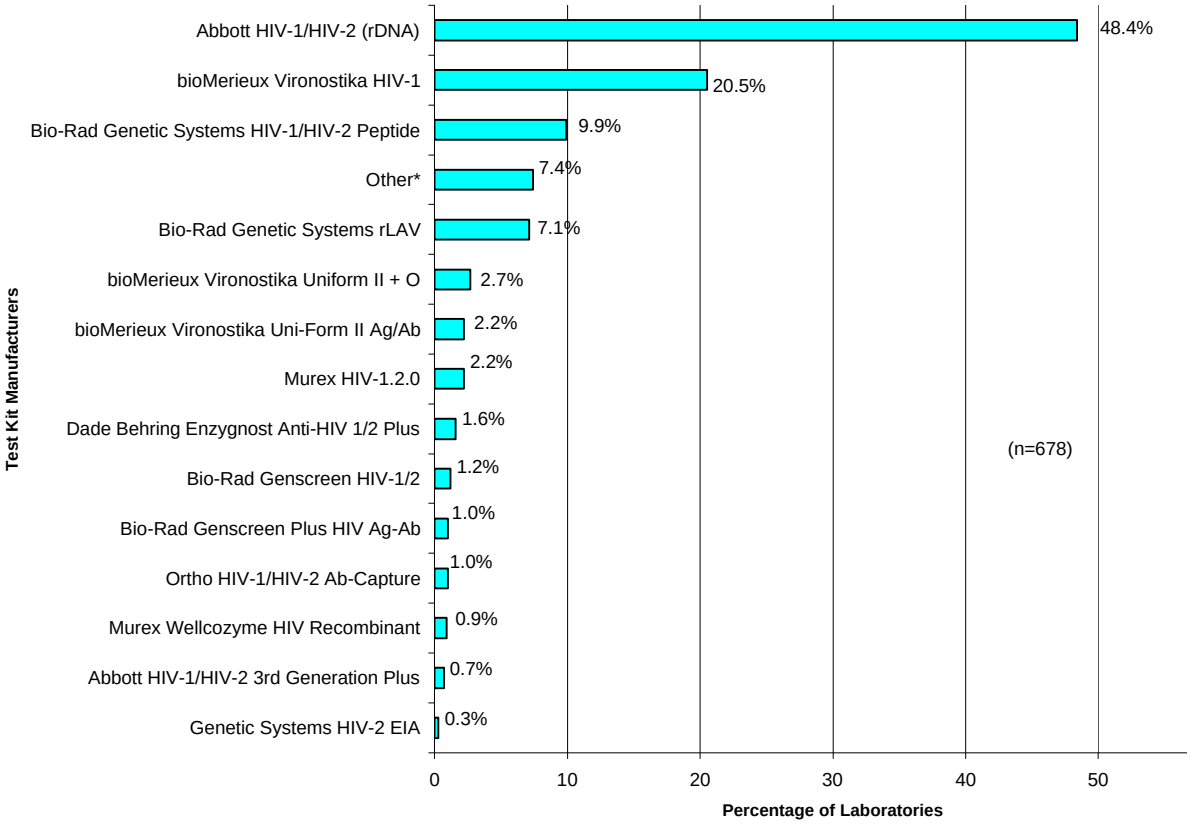
Some laboratories outside the United States used the Abbott AxSYM system or the Abbott PRISM analyzer and reported results as S/CO (sample/cutoff ratio). Since the S/CO data can not be entered correctly on the MPEP EIA result form, the data from laboratories using either AxSYM or PRISM systems are also reported with "Other" tests in Figure 7, page 16.

The reports of false-negative and false-positive results for the HIV-1-positive and HIV-1-negative samples for the EIA, WB, IFA, and “Other” methods, listed by kit manufacturer, are shown in Tables 5, 6, 7, and 8, respectively.

EIA Methods and Results

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

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



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

"Other" EIA kits and the number of laboratories reporting include:

- Bio-Chem Immunosystems (Adaltis) Detect HIV, 6,
- Biokit BioElisa HIV1+2 (BIOKIT), 2,
- EIA Anti-HIV-UNIF (Diagnostic Systems), 1,
- Genedia, Greencross Life Sciences Corporation, 1,
- Murex HIV Ag/Ab Combination, 7,
- Pareekshak (BHAT Bio-Tech), 1, and
- Vector Best Kombibest Anti HIV1+2, 4.

Table 5, page 13, shows the number of false-positive and false-negative results by test kit manufacturer. Five different laboratories reported five false-positive interpretations, and 10 different laboratories reported 14 false-negative interpretations. The results by Donor were as follows:

Donor 1, (HIV-1 infected, seroconverter)	4 false-negatives
Donor 2, (HIV-1 infected, strong positive)	6 false-negatives
Donor 3, (HIV-1 infected, seroconverter)	4 false-negatives
Donor 5, (HIV-1 negative)	5 false-positives

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

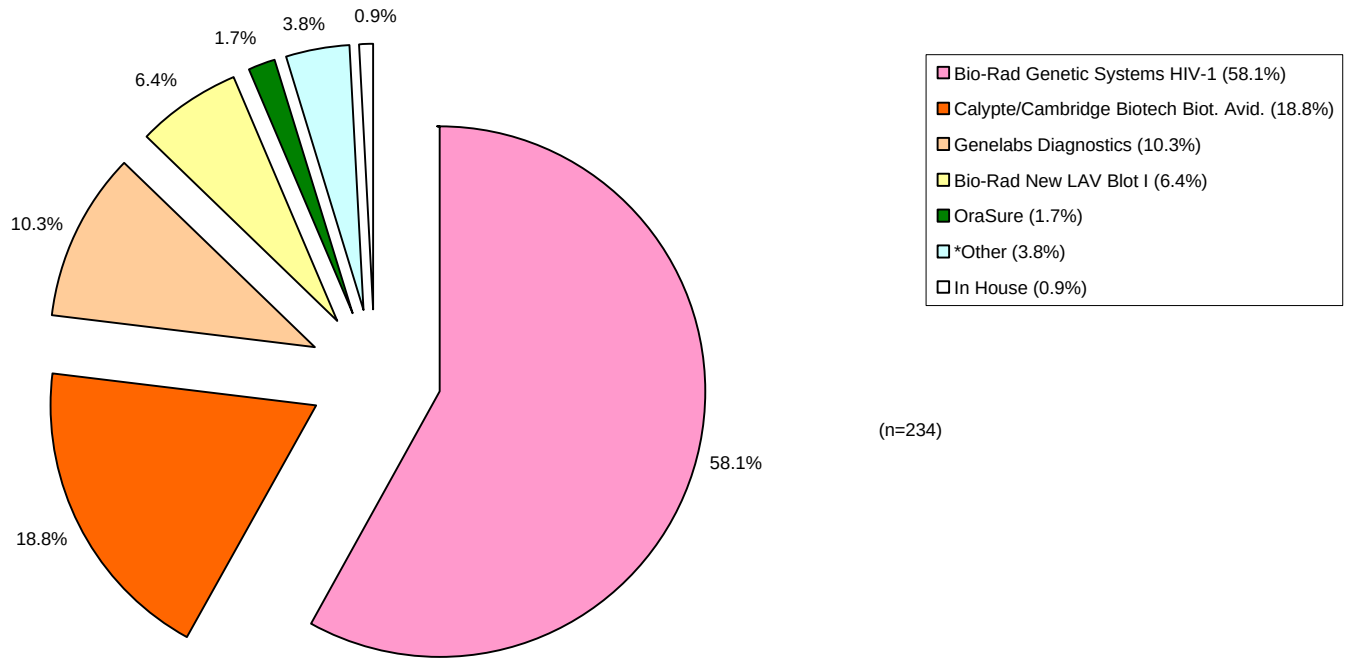
Manufacturer	Total # of Results	False-positive	False-negative
Abbott HIV-1/HIV-2 (rDNA))	1967	2 (0.10%)	3 (0. 15%)
bioMerieux Vironostika HIV-1	831	0	1 (0. 12%)
bioMerieux Vironostika HIV-1 *Antigen**	1	0	1 (100%)
bioMerieux Vironostika Uniform II plus O	106	1(0.94%)	0
Bio-Rad Genetic Systems HIV-1/2 Peptide	401	0	2 (0.50%)
Bio-Rad Genetic Systems rLAV	288	0	1 (0.35%)
Genetic Systems HIV-2 EIA	12	0	5 (41.7%)
Murex HIV 1.2.O	90	1 (1.11%)	1 (1.11%)
Nihol Peptoscreen-2	48	1 (2.08%)	0
Total	3744	5 (0.13%)	14 (0.37%)

*Comment: One laboratory used an HIV-1 antigen on one sample, rather than HIV-1 antibody test kit (bioMerieux Vironostika HIV-1 Antigen). This laboratory reported a negative result for this HIV-1 antibody positive sample.

WB Methods and Results

Of the 733 laboratories reporting test results in this survey, 234 (31.9%) 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

Two false-positives, one false-negative and 22 indeterminate interpretations were reported for this shipment. Seven indeterminate results were reported for the HIV-1 uninfected donor sample (Donor 5) by 7 laboratories using two different commercial test kits. The other 15 indeterminate results were reported for the positive donors. These indeterminates were reported by 13 laboratories using two different test kits, as shown in Table 6. The results by donor were as follows:

Donor 1 (HIV-1 infected),
- 12 indeterminates,

Donor 2 (HIV-1infected),
- 2 indeterminates

Donor 3 (HIV-1 infected),
- 1 indeterminate
- 1 false negative

Donor 5 (HIV-1 negative),
- 7 indeterminates,
- 2 false positives

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

Manufacturer	Total # of Results	Negative Donor		Positive Donors	
		False-positive	Indeterminate	False-negative	Indeterminate
Bio-Rad Genetic Systems HIV-1	711	0	0	0	12
Bio-Rad New LAV Blot I	86	0	4	1	0
Cambridge Biotech HIV-1 (biotin)	223	1	3	0	0
J. Mitra and Co.	5	0	0	0	3
In-House	10	1	0	0	0
Total	1035	2	7	1	15

WB Interpretative Criteria

Of the 234 laboratories reporting WB test results, 229 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 these and other criteria were as follows:

- 197 (86.0%) APHL/CDC,
- 17 (7.4%) World Health Organization,
- 14 (6.1%) stated “other” (Red Cross, Manufacturers’ insert, Australian National Reference Laboratory, etc.), and
- 1 (0.4%) 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.) A negative result is defined as no bands present. All participating U.S. laboratories indicated they were using the APHL/CDC HIV-1 WB interpretive criteria.

WB Band Patterns

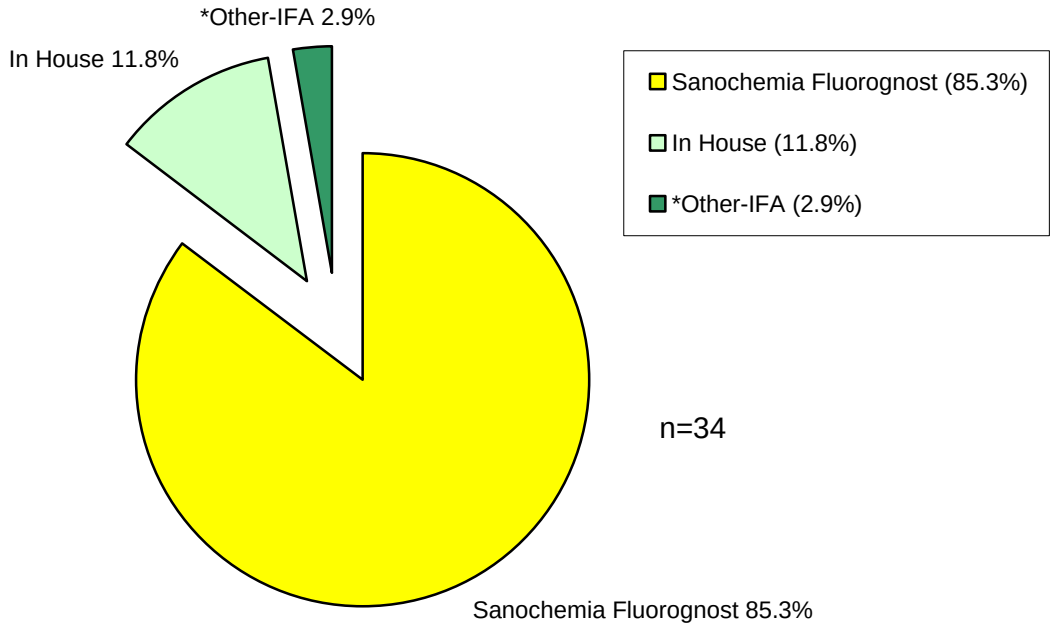
The WB bands for the donor samples in this survey, as determined in pre-shipment testing with two FDA-licensed WB test kits, are shown in Table 2, page 6. Only bands scoring greater than or equal to 1+ intensity are listed in the table.

Note that 67 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. Seven laboratories reported indeterminate and two laboratories reported positive WB interpretations for Donor 5. Four of these laboratories reported non-reactive EIA results. For the HIV-1 antibody strong-positive sample (Donor 2), all participants reported the correct results. Also, for 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. According to some participants, the bands, though present, were of insufficient intensity, especially for the seroconverter samples (Donors 1 and 3), to report the results as positive.

IFA Methods and Results

Figure 6 shows the percentages IFA test reagents used by MPEP laboratories.

Figure 6: Percentage of 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, on page 16, the 25 indeterminate interpretations were reported by 12 different laboratories, while the 6 false-negative interpretations were reported by two laboratories. One laboratory reported false-negative interpretations for all three positive Donors (Donors 1 and 3, weak-positives and Donor 2, the strong-positive). That laboratory also reported that when performing IFA they did **not** use external quality control materials in addition to controls that are included in the manufactured IFA kit.

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

Methods/Manufacturer	Total # of Results	Negative Donor		Positive Donors	
		False-positive	Indeterminate	False-negative	Indeterminate
In House	23	0	0	0	4
Sanochemia Fluorognost	158	0	0	6	21
Total	181	0	0	6	25

For the 186 IFA total interpretations reported, the interpretations by donor are as follows:

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

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

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

Donor 5 (HIV-1 uninfected)
- 0 indeterminate
- 0 false positive

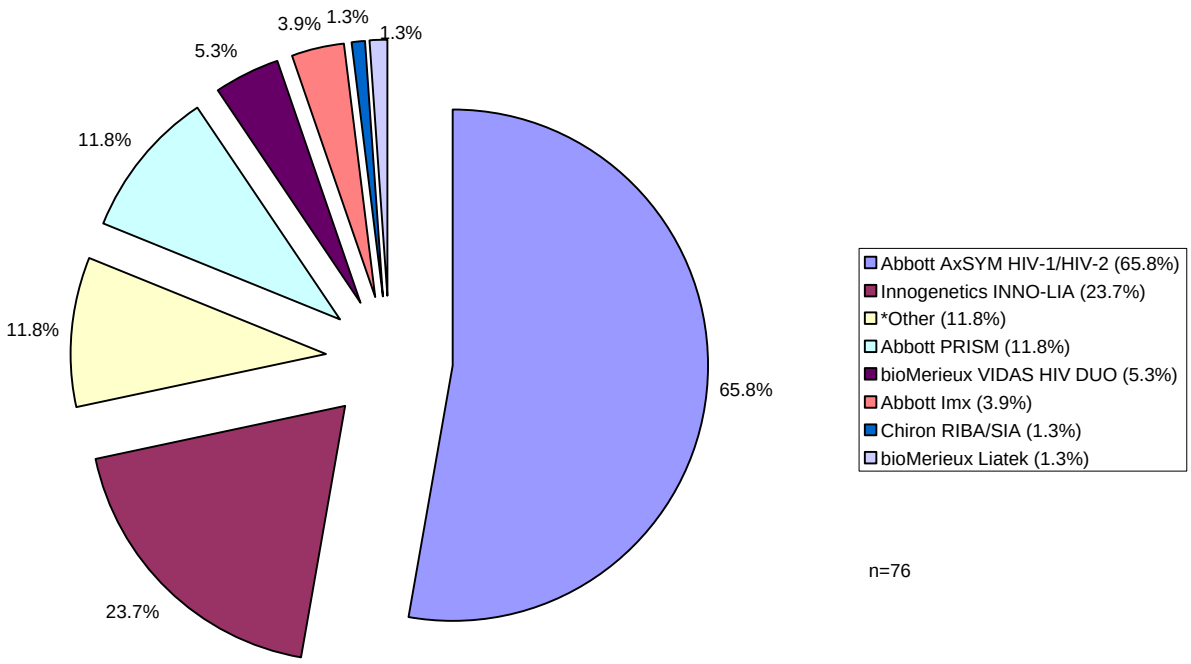
"Other" Tests Performed

Figure 7, page 16, shows manufacturers of "Other" types of tests and percentage of use by the reporting laboratories.

Laboratories located outside of the United States using the Abbott AxSYM system (50) or the Abbott PRISM analyzer (9) reported results as S/CO (sample/cutoff ratio). These laboratories report their results in the "Other" test type section of the result form. This is because the S/CO data can not be entered correctly on the MPEP EIA result form since these tests are based on microparticle capture and chemiluminescence measurement, and because the results differ from the traditional microtiter-format EIA tests.

Seventy-six 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 ImmunoComb II (1), Vitros ECi HIV-1/2 (4), HIV EIA Comb (J. Mitra and Co) and Abbott AxSYM HIV1/2 Go (3) are included in Figure 7 as "other" 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 560 final interpretations reported, one laboratory reported one indeterminate and one laboratory reported one false-positive for the HIV-1 negative donor. Both laboratories used Abbott AxSYM HIV-1/HIV-2. One laboratory reported a false-negative for Donor 2, the strong positive donor.

Table 8: False-positive, false-negative and indeterminate determinations for "Other" test kits

Methods/Manufacturer	Total # of Results	Negative Donor		Positive Donors	
		False-positive	Indeterminate	False-negative	Indeterminate
Abbott AxSYM HIV-1/HIV-2	295	1	1	0	0
Ortho Vitros Anti-HIV-1/2	30	0	0	1	0
Total	325	1	1	1	0

Quality Control Testing

Table 9 describes the external quality control (QC) practices reported by most of the MPEP 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 9: Summary of External Quality Control Material Sources

Test Type (Total # of Laboratories)*	Number of Laboratories (%) Reporting External QC	Source of External Quality Control Materials		
		In-House	Commercial	Both
EIA (678)	499 (73.6%)	143 (28.7%)	330 (66.1%)	26 (5.2%)
WB (234)	89 (38.0%)	53 (59.6%)	33 (37.1%)	3 (3.4%)
IFA (34)	13 (38.2%)	8 (61.5%)	4 (30.8%)	1 (7.7%)
Other (76)	41 (53.9%)	19 (46.3%)	20 (48.8%)	2 (4.9%)

* Not all laboratories completed the QC section of the result booklet.

Glossary of Terms

EIA: Enzyme immunoassay, sometimes referred to as ELISA (enzyme-linked immunoassay), 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: Immunofluorescent antibody test for HIV is the use of antibodies chemically linked to a fluorescent dye to identify the presence of antigens in a test sample.

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 supplemental test indicating that the specimen donor is infected with HIV.

Quality control: Operational techniques or tasks that are performed to find and correct problems that might occur.

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.