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 2002

CENTERS FOR DISEASE™
CONTROL AND PREVENTION

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

Report of the July 2002 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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Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program

Table1. Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing for July 2002 Participant Laboratory Shipment

Panel Letter	Vial Label	CDC Donor Number*	CDC Test Result[1]	Donor HIV Status	Laboratory Interpretation[2] EIA INIT.[3]	EIA FINAL[4]	WB	IFA
A	A1	3	Positive	Infected	___	___	___	___
	A2, A3	1	Negative	Uninfected	___	___	___	___
	A4, A5	4	Positive	Infected	___	___	___	___
	A6	5	Positive	Infected	___	___	___	___
B	B1, B6	1	Negative	Uninfected	___	___	___	___
	B2	3	Positive	Infected	___	___	___	___
	B3, B4	4	Positive	Infected	___	___	___	___
	B5	5	Positive	Infected	___	___	___	___
C	C1, C6	4	Positive	Infected	___	___	___	___
	C2	5	Positive	Infected	___	___	___	___
	C3, C5	1	Negative	Uninfected	___	___	___	___
	C4	3	Positive	Infected	___	___	___	___
D	D1	5	Positive	Infected	___	___	___	___
	D2, D5	4	Positive	Infected	___	___	___	___
	D3	3	Positive	Infected	___	___	___	___
	D4, D6	1	Negative	Uninfected	___	___	___	___

[1] The CDC result was obtained after composite testing with all commercially available HIV-1 and HIV-1/HIV-2 EIA and HIV-1 WB 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.

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

[3] Initial EIA interpretation

[4] Final EIA interpretation

* Donor 2 was intentionally omitted

Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program for
Human Immunodeficiency Virus Type I (HIV-1) Antibody Testing
Table 2. CDC Western Blot (WB) Testing Results for July 2002 Shipment

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

[1] Western blot (WB) result based on band intensity of $\geq$ 1+ staining.
[2] The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

Analysis of the July 2002 Performance Evaluation
HIV-1 Antibody Testing Results
Reported by Laboratories Participating in the Model Performance Evaluation Program

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 2002. Test results were reported by 757 (91.4%) of 828 laboratories that received sample panels.

Methods and Materials

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 56ºC 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 two HIV-1 enzyme immunoassay (EIA) kits, two HIV-1/HIV-2 EIA kits and one rapid test (RT) kit (SUDS HIV-1) licensed by the Food and Drug Administration (FDA). Supplemental testing was performed with two FDA-licensed HIV-1 Western blot (WB) kits. Donor samples were also tested with an HIV-1 indirect immunofluorescence assay (IFA) prior to shipment.

In pre-shipment testing, the strong-positive HIV-1 donor sample (Donor 5) 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 1) was repeatedly EIA non-reactive and demonstrated no bands with the FDA-licensed HIV-1 WB kits. Donor samples 3 and 4, 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 3 and 4 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.

Overall Summary of Results

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

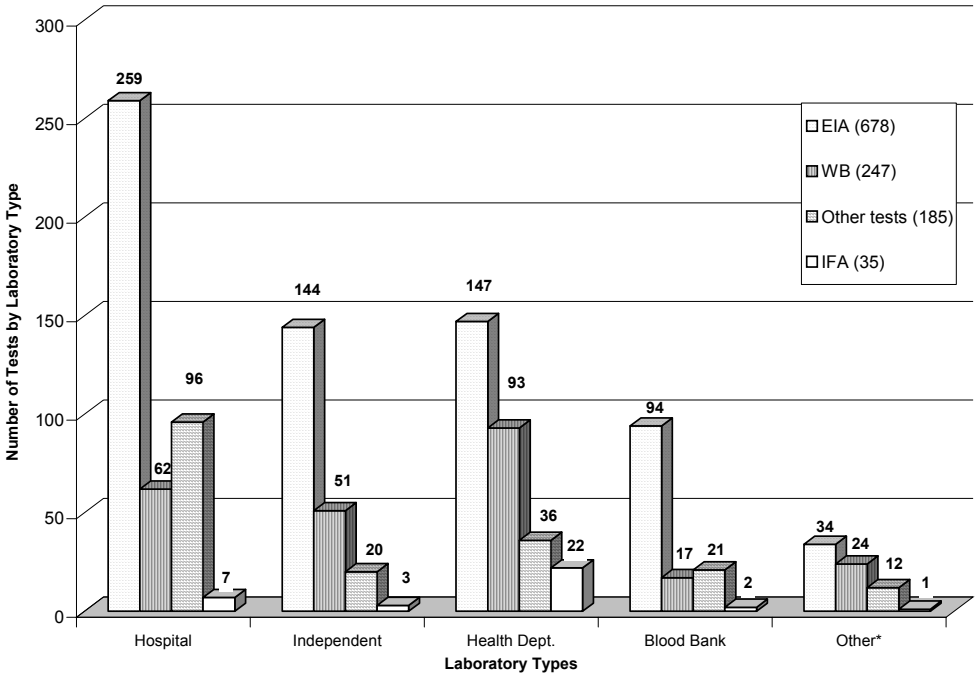
Table 3. Results Summary

			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 # result)[4]**
EIA	678	4284	10/2864 (0.3%)	4/1420 (0.3%)	99.7%
WB	247	1201	15/968 (1.6%)[1]	6/233 (2.6%)[2]	98.3%[5]
IFA	35	185	13/138 (9.4%)	none	93.0%[5]
OTHER[3]	185	1208	8/831 (1.0%)	3/377 (0.8%)	Not applicable

1. All indeterminate.
2. One positive, 5 indeterminate.
3. "Other" test methods refers to test types other than EIA, WB or IFA, such as line or strip assays, microparticle capture, chemiluminescence, etc.
4. TP, true positives; TN, true negatives
5. 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.

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.

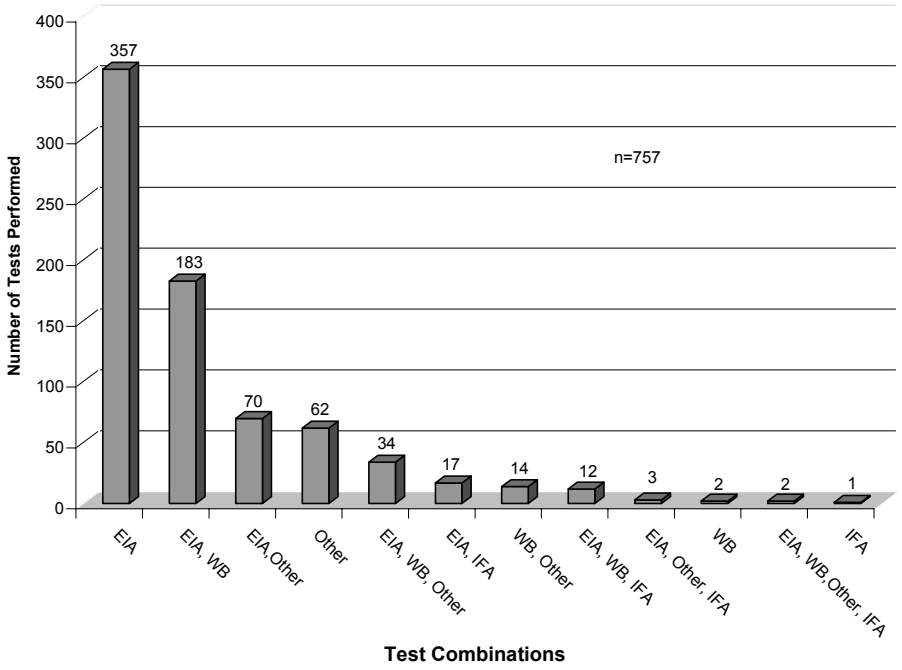
Figure 1. Number of HIV-1 participants (757 total) , by laboratory type, that reported EIA, WB, IFA and "Other" results



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

The combinations of test methods used by the laboratories and the frequency of use are shown in Figure 2, page 8. Of the 757 laboratories reporting results, 357 (47.1%) performed only EIA, 212 (28.0%) performed only EIA and a supplemental test, and three (0.4%) performed only a supplemental test. These numbers do not include the 185 (24.1%) 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 8, page 15.

Figure 2. The combination of HIV-1 antibody tests reported by participant laboratories



The types of test kits used, by kit manufacturer, for the EIA, WB, and IFA methods are shown in Figures 3, 4, and 6, respectively. Some laboratories indicated using test kits for which there were no unique manufacturer codes provided in the report booklet. These responses have been grouped as "Other" manufacturer kits. Some “Other” EIA kits reported as being used for EIA include Bio-Chem Immunosystems Detect HIV (four laboratories), Abbott HIV-1/2 gO EIA (one laboratory), and Genetic Systems HIV-2 EIA (one laboratory). 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 reported with “Other” tests in Figure 8, page 15.

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 4, 5 and 6, respectively.

EIA Results

Table 4, page 9, shows the four false-positive EIA interpretations reported for Donor 1. There were ten false-negative interpretations reported by seven different laboratories for HIV-1 positive samples, five were reported for Donor 3 by laboratories using three different test kits. The remaining five false-negative interpretations were reported for Donor 4 by laboratories using four different test kits.

Figure 3. Percentage of Laboratories (678 total) Using Various EIA Test Reagents

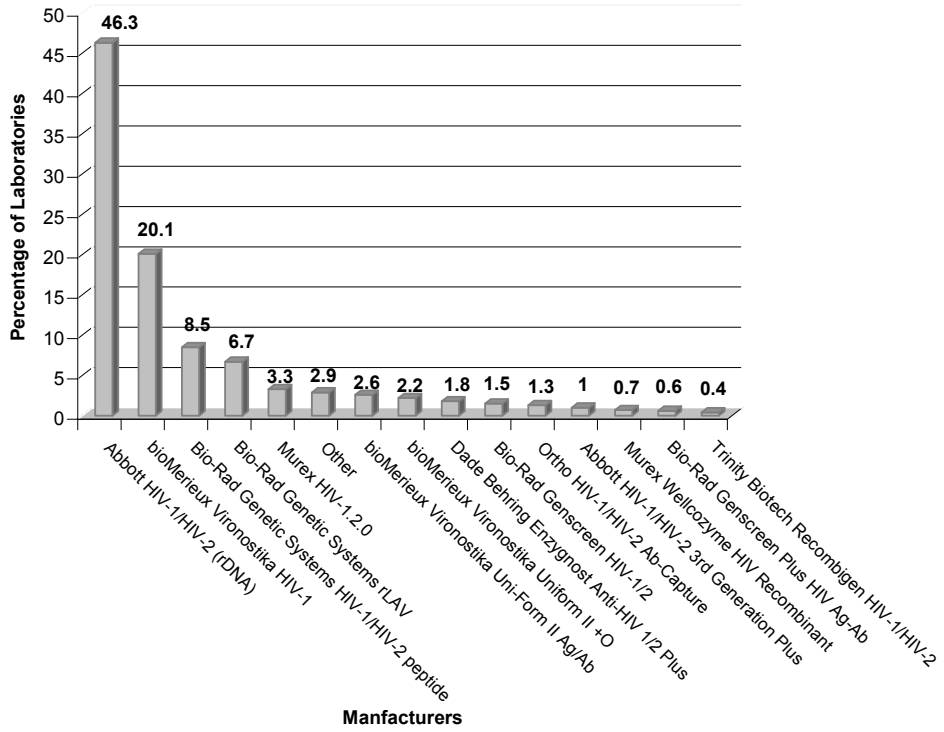


Table 4. False-positive and False-negative EIA Results, by Kit Manufacturer, Reported by Participant Laboratories

Enzyme Immunoassay (EIA)

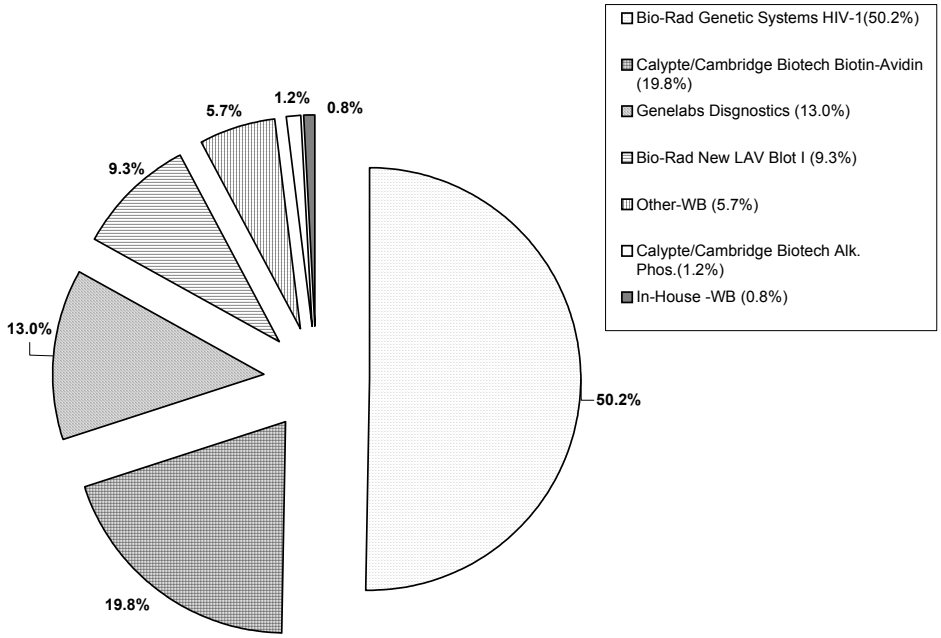
Manufacturer	Total # of Results	False-positive	False-negative
Abbott HIV-1/HIV-2 (rDNA)	1991	1	0
Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide	366	0	1
Bio-Rad Genetic Systems rLAV	288	0	4
bioMerieux Vironostika Uniform II+0	90	2	2
Other* (See the manufacturers listed below)	122	1	3
Total	2857	4	10

*Other: One false-positive Anti-HIV 1+2+0 EIA (Roche): Three false-negative results: one HIV-2 Genetic Systems EIA (Genetic Systems) and two Enzaids (Span Diagnosticss LTD). There are no manufacturers' codes for these manufacturers in the report booklet.

WB Results

Of the 757 laboratories reporting test results in this survey, 247 (32.6%) performed WB testing. Nine laboratories reported WB testing results on the plasma performance evaluation samples using the OraSure HIV WB test which is FDA licensed only for oral fluids. Of these nine laboratories, seven were Health Department laboratories and two were Independent laboratories.

Figure 4. Percentage of laboratories using various WB test reagents (247 laboratories total)



WB Results Interpretations

One positive and five indeterminate WB interpretations were reported by seven different laboratories for the HIV-1 uninfected donor sample (Donor 1), using four different WB kits, including one laboratory that used the Orasure WB kit which is FDA approved only for use with oral fluids. Normally, Western blot tests are not performed on specimens that are non-reactive by other test methods.

Table 5. False-positive, False-negative and Indeterminate Results for both positive and negative donor samples for Western Blot Tests, by Manufacturer

Western Blot (WB)

		Negative Donor		Positive Donors	
Manufacturer	Total # of Results	False positive	Indeterminate	False Negative	Indeterminate
Bio-Rad Genetic Systems HIV-1	615	0	2	0	7
Bio-Rad New LAV Blot 1	115	0	2	0	2
Calypte/Cambridge Biotech (Biot. Avid.)	220	0	0	0	3
Genelabs Diagnostics	165	0	1	0	1
OraSure HIV-1*	38	1	0	0	0
Immunetics*	10	0	0	0	1
Transasia Biomedical*	6	0	0	0	1
Total	1169	1	5	0	15

*There are no manufacturers' codes in the report booklet.
Note: No false-negative results were reported for WB.

Of the fifteen indeterminate WB results reported for samples from the HIV-1-infected donors, nine were reported for Donor 3 and five for Donor 4, both HIV-1-infected seroconverting donors. Indeterminate WB interpretations were reported by laboratories using six different WB kits (Table 5, page 10). There was one indeterminate interpretation reported for the HIV-1 antibody strong positive Donor 5.

WB Interpretative Criteria

Of the 247 laboratories reporting WB test results, 219 indicated which WB criteria they used to interpret their WB tests. Most used the Association of Public Health Laboratories (APHL)/Centers for Disease Control and Prevention (CDC) WB interpretive criteria;

- 186 (84.9%) APHL/CDC,
- 18 (8.2%) stated "other" (Red Cross, Manufacturers' insert, National Centre for Retroviruses, etc.),
- 14 (6.4%) World Health Organization, and
- 1 (0.5%) 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.) Ten U.S. laboratories indicated they were using interpretive criteria different from that recommended by the kit manufacturer as licensed by the FDA:

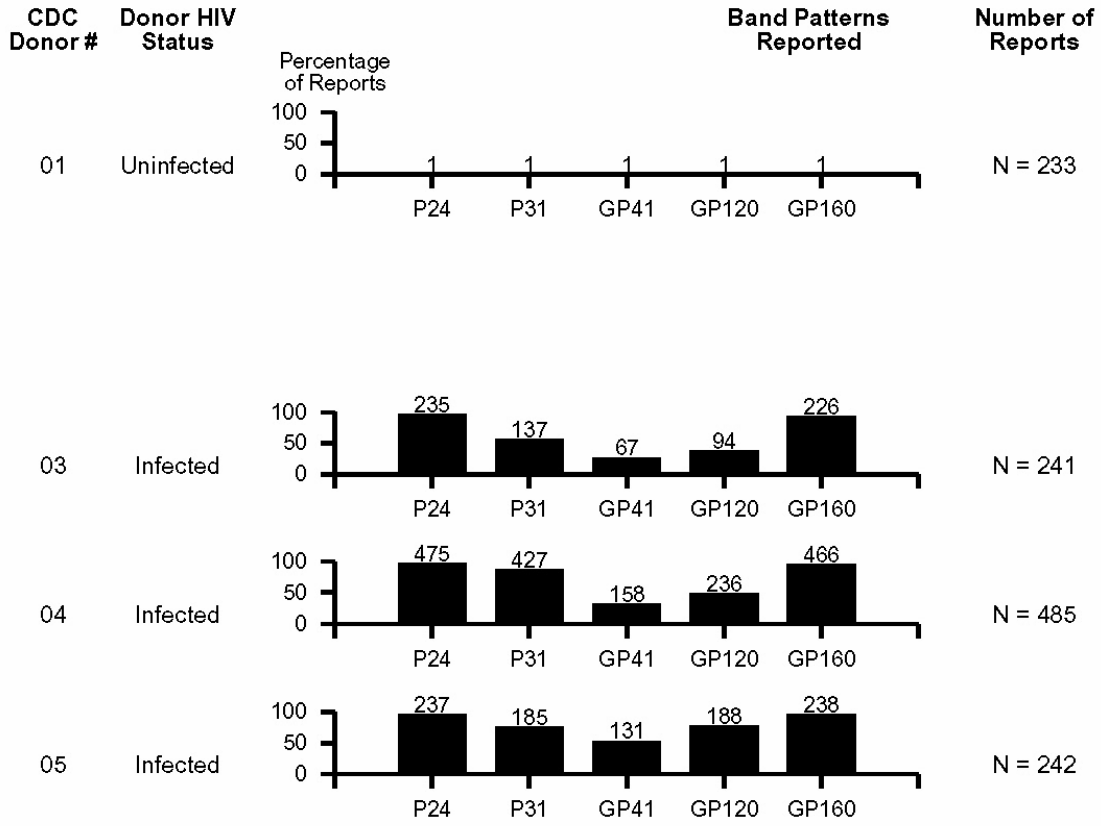
- 5 used World Health Organization criteria,
- 4 used "other" Criteria, and
- 1 used Consortium for Retrovirus Serology Standardization criteria.

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 5. Only bands scoring greater than or equal to 1+ intensity are listed in Table 2.

The protein band patterns for the major viral proteins, as reported by participant laboratories for each donor sample, are shown in Figure 5, page 12. The frequency of a reported band is listed above the column. The number of WB reports received for the donor sample is indicated in the far right column. This figure does not include WB bands reported as "W" or "weak," indicating intensity less than that of the designated band of the weak positive control provided in the WB kit, nor does it include bands of greater than1+ intensity reported for p15, p17, p51, p55, or p66. Note that 233 WB results were reported for the sample from an HIV-1 antibody negative donor (Donor 1), although most laboratories do not normally include WB testing of EIA-nonreactive donor samples in their routine algorithm for HIV antibody testing. Six of seven laboratories that reported indeterminate or reactive WB results for the HIV-1 antibody-negative donor reported non-reactive results with EIA testing for this donor (the remaining laboratory did not report EIA testing results). One laboratory reported an indeterminate result and no bands for the HIV-1 antibody negative sample (Donor 1).

Figure 5. Western blot HIV-1 antibody band patterns reported by participant laboratories



For the HIV-1 antibody strong-positive sample (Donor 5) and the seroconversion samples (Donor 3 and Donor 4), most laboratories had no difficulty in detecting antibodies to gag (p24), pol (p31), and env (gp41, gp120, gp160) antigens. There were 11 indeterminate interpretations reported, even though the band patterns appeared to fit the reported criteria for reactive results.

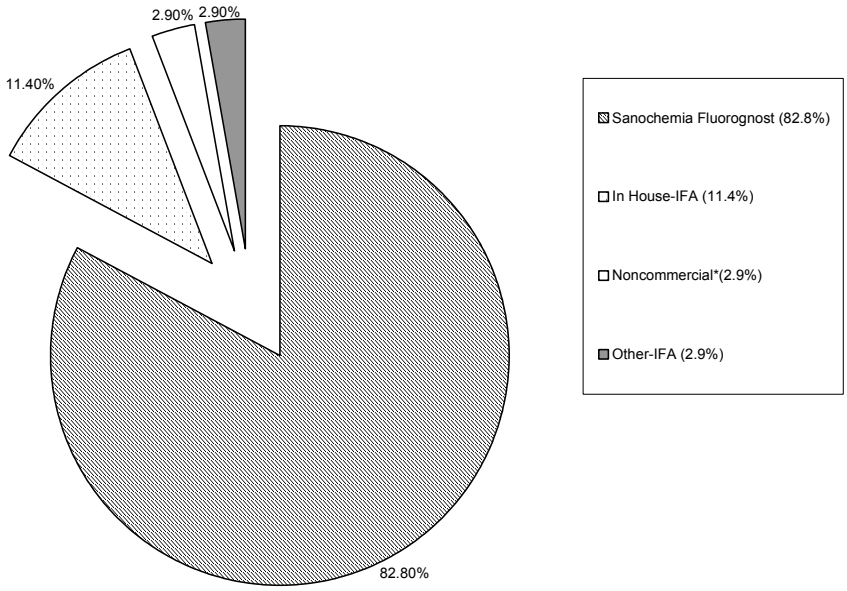
IFA Results

Figure 6, below, shows the percentages of laboratories using the various IFA test reagents.
Among the 138 IFA interpretations reported for the HIV-1-positive samples, five (3.6%) false-negative and eight (5.8%) indeterminate interpretations were reported (Table 6, below). Three (60.0%) of the false-negatives and three (37.5%) of the indeterminate results were reported for the samples from Donor 3. Two false-negative and four indeterminate results were reported for Donor 4. One laboratory reported indeterminate for Donor 5, the strongly reactive donor.

IFA Intensity Patterns

The IFA intensity patterns for HIV-1 infected cells, as reported by participating laboratories are shown in Figure 7, page 14. The frequency of reports of fluorescence intensity for each donor is listed in the far right column. A scoring of fluorescence intensity is not required for interpretation of seroreactivity with the FDA-licensed Sanochemia (formerly know as Waldheim) Fluorognost HIV-1 IFA kit; therefore, some laboratories provided interpretation, but did not score fluorescent intensity. Data from these laboratories were not included in Figure 7. No fluorescence was reported for five (14.3%) of the 35 IFA Donor 3 samples, four (5.9%) of the 68 IFA Donor 4 samples, and one of the 35 IFA Donor 5 (strong positive) samples.

Figure 6. Percentage of Laboratories (n=35) Using Various IFA Test Reagents



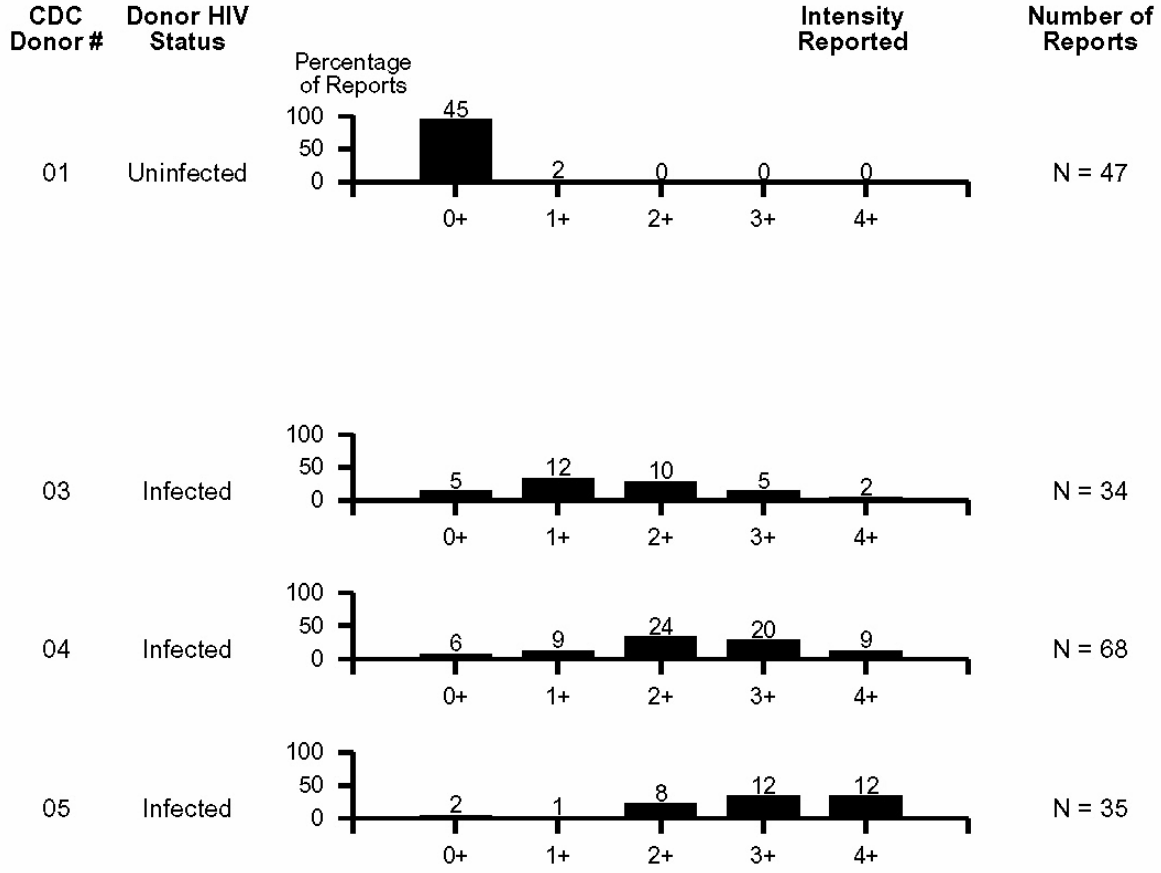
*Noncommericial, e.g., supplied by the State Health Department Laboratory

Table 6. Indeterminate and False-negative Results Reported, by Participants, by Manufacturer for Immunofluorescent Antibody

	Immunofluorescent Antibody		
Manufacturer	**Total # of results**	**Indeterminate**	**False-negative**
Sanochemia Fluorognost	152	8	2
In House	22	0	3
Total	174	8	5

Note: No false-positive results were reported

Figure 7. Fluorescence intensity patterns of HIV-1 infected cells, for IFA results reported by participant laboratories for the July 2002 shipment

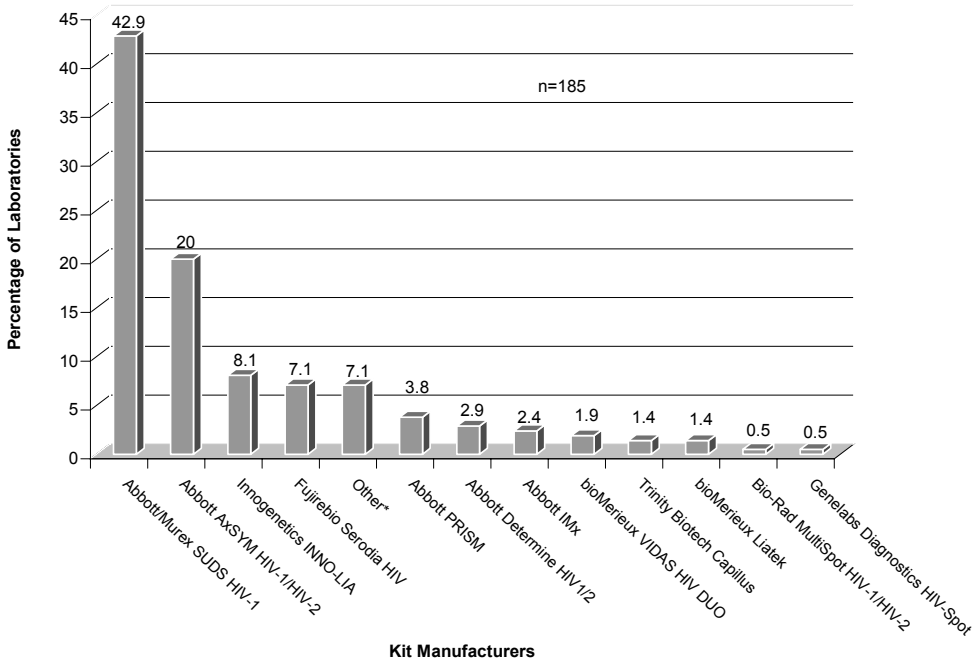


Other Tests Performed

Figure 8, page 15, shows manufacturers of "Other" types of tests and percentages of use by the reporting laboratories.

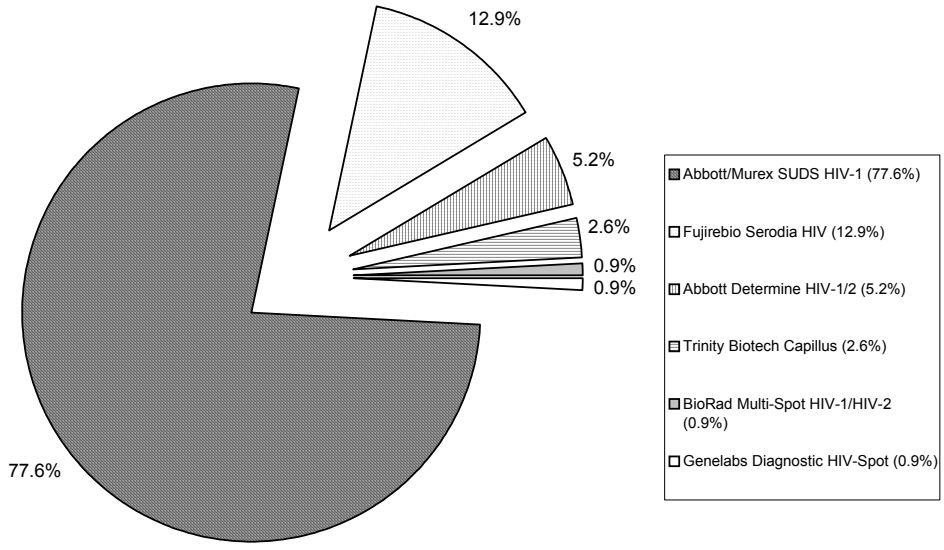
The procedures used by 116 (62.7%) of 185 laboratories that reported using “Other” tests can be described as “rapid tests” (see Figure 9, page 15). The results of “Line” or “Strip Immunoassay” tests such as Innogenetics INNO-LIA (17) and bioMerieux Liatek (3) were reported by a total of 20 laboratories. Also, note that all laboratories using the Abbott AxSYM (42 laboratories) or PRISM (8 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 8. Types of "Other" HIV antibody test kits used by participant laboratories (185 total)



*Other: tests for which there are no manufacturers' codes listed in the result booklet.

Figure 9. Percentage of Laboratories (116 total) Using Various HIV Rapid Test Reagents



"Other" Results Interpretations

Among the 377 final interpretations reported for the HIV-1-negative sample (Donor 1) tested by laboratories using these "Other" procedures, one false-positive and two indeterminate interpretations were reported by laboratories using three different test systems. The one false-positive interpretation was from a laboratory using the Abbott/Murex SUDS-HIV-1 test. Two indeterminate results were reported: one by a laboratory using Fujirebio Serodia HIV and one by a laboratory using Innogenetics INNO-LIA (See Table 7, below).

Table 7. "Other" Test Kits: False-positive, False-negative and Indeterminate Results

Manufacturer	HIV-1 Negative Donor			HIV-1 Positive Donors	
	Total # Results	False-positive	Indeterminate	False-negative	Indeterminate
Abbott/Murex SUDS HIV-1	538	1	0	0	0
Innogenetics INNO-LIA	86	0	1	0	2
Fujirebio Serodia HIV	85	0	1	0	0
Abbott Determine HIV-1	31	0	0	0	1
Trinity Biotech Capillus	16	0	0	0	2
Genelabs Diagnostic HIV-Spot	4	0	0	3	0
Total	760	1	2	3	5

Among the 831 interpretations reported for the HIV-1-positive samples tested by procedures other than EIA, WB, or IFA, there were three (0.4%) false-negative and five (0.6%) indeterminate interpretations, as shown in Table 7. These results were obtained with both of the seroconversion Donors, 3 and 4, but not with the strong positive Donor 5. These results are as follows:

Donor 3
- 1 false negative
- 2 indeterminates

Donor 4
- 2 false negatives
- 2 indeterminates

Quality Control Testing

Information was sought on the use of external quality control (QC) samples other than the controls provided in various test kits. 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. Most laboratories completing the QC section of the form followed instructions pertaining to this section and described only external QC samples used in their HIV testing procedures (see Table 8, below).

Table 8. 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* (640)	503 (78.6%)	149 (29.6%)	322 (64.0%)	30 (6.0%)
WB (224)	92 (41.1%)	54 (58.7%)	36 (39.1%)	2 (2.2%)
IFA (33)	15 (45.5%)	10 (66.7%)	5 (33.3%)	0
Other* (185)	55 (29.7%)	31 (56.4%)	21 (38.2%)	1 (1.8%)

*Two laboratories did not report the source of their external QC material.

Frequency of External QC Testing

Laboratories reported using external QC material for EIA, WB IFA and "Other" tests at the following frequencies:

- Most laboratories performing EIA tests ran QC material with each set/run of plates or each EIA plate and indicated the use of weakly-positive and/or negative serum/plasma controls.
- Most laboratories performing WB used weakly-positive serum/plasma and indicated running QC with set/run of WB strips.
- Less than half of the laboratories performing IFA reported using external controls.
- Of the 55 laboratories performing "Other" tests, 24 (43.6%) indicated using weakly-positive QC materials and 12 (21.8%) indicated using strong positive QC material with each set/run.

Discussion

This program provides challenging samples for participant laboratories to perform HIV-1 antibody testing. Most participants performed well in testing the HIV-1 donor samples in this shipment (see Table 3, page 6):

For the negative Donor, false-positive rates were:

- EIA 0.3%
- WB 2.6% (indeterminate results are considered to be positive),
- IFA, none

For the positive Donors, false-negative rates were:

- EIA 0.3%
- WB none
- IFA 3.6%

All laboratories participating in the MPEP should be aware of several points:

- Nine laboratories reported WB testing results using the OraSure HIV test. This test is FDA licensed only for oral fluid. All of the MPEP samples are defibrinated plasma.
- Several laboratories performed WB testing on the negative sample Donor 1, even though the sample tested negative by EIA. This appears to be a deviation from the accepted algorithm for HIV testing.
- Ten U.S. laboratories used interpretive criteria different from that recommended by the kit manufacturer as licensed by the FDA.
- In general, most laboratories performed well, with slight variations depending on the test type (see Table 3, page 6).

Results reported by the participant laboratories reflect their testing performance, including pre- and post-analytic steps using manufactured kits to evaluate MPEP samples, and do not necessarily reflect the performance of these commercially or in-house manufactured kits.

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 sample, that is actually positive

False-positive: A positive test result 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.

Indeterminate test result: A possible result IFA WB or "Other" test that might represent a recent HIV infection or a false-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: A test to detect antibodies to HIV that can be collected and processed providing results within a short interval of time (e.g., approximately 10-60 minutes).

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: 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.