

**Centers for Disease Control and Prevention
Model Performance Evaluation Program**

Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing

**Figures Used for the Analysis
of the August 18, 1997 Performance Evaluation
Testing Results Reported by Participant Laboratories**



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
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Report of the August 18, 1997 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
 Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing
 August 17, 1998 Participant Laboratory Shipment**

Table 1

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result ²	Donor HIV Status	Laboratory Interpretation ¹			
					EIA		WB	IIF
					INIT. ³	FINAL ⁴		
A	A1, A2	01	Positive	Infected	—	—	—	—
	A3	15	Negative	Uninfected	—	—	—	—
	A4, A6	17	Positive	Infected	—	—	—	—
	A5	08	Positive	Infected	—	—	—	—
B	B1, B5	18	Positive	Infected	—	—	—	—
	B2, B3	02	Positive	Infected	—	—	—	—
	B4	16	Negative	Uninfected	—	—	—	—
	B6	09	Positive	Infected	—	—	—	—
C	C1	10	Positive	Infected	—	—	—	—
	C2, C6	17	Positive	Infected	—	—	—	—
	C3, C4	03	Positive	Infected	—	—	—	—
	C5	15	Negative	Uninfected	—	—	—	—
D	D1, D3	18	Positive	Infected	—	—	—	—
	D2	11	Positive	Infected	—	—	—	—
	D4, D5	04	Positive	Infected	—	—	—	—
	D6	16	Negative	Uninfected	—	—	—	—

Table 1, Continued ►►

Table 1, Continued

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result ²	Donor HIV Status	Laboratory Interpretation ¹			
					EIA		WB	IIF
					INIT. ³	FINAL ⁴		
E	E1	15	Negative	Uninfected	—	—	—	—
	E2, E4	17	Positive	Infected	—	—	—	—
	E3	12	Positive	Infected	—	—	—	—
	E5, E6	05	Positive	Infected	—	—	—	—
F	F1, F6	06	Positive	Infected	—	—	—	—
	F2	16	Negative	Uninfected	—	—	—	—
	F3, F5	18	Positive	Infected	—	—	—	—
	F4	13	Positive	Infected	—	—	—	—
G	G1, G3	07	Positive	Infected	—	—	—	—
	G2, G6	17	Positive	Infected	—	—	—	—
	G4	14	Positive	Infected	—	—	—	—
	G5	15	Negative	Uninfected	—	—	—	—

¹ Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

² The CDC result was obtained after composite testing with all HIV-1 and HIV-1/HIV-2 EIA and HIV-1 WB kits licensed by the Food and Drug Administration (FDA), and employing the WB interpretive criteria of the Association of State and Territorial Public Health Laboratory Directors/CDC (ASTPHLD/CDC).

³ Initial EIA interpretation

⁴ Final EIA interpretation

**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 the
August 18, 1997 Participant Laboratory Panel Samples**

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, A2	01	18,24,55,160 24,51,66,120,160 24,51,65,160	BioRad Cambridge Biotech* Epitope/Organon	Positive Positive Positive
	A3	15	No Bands	All Manufacturers	Negative
	A4, A6	17	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 18,24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	A5	08	24,55,160 24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
B	B1, B5	18	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 24,31,41,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	B2, B3	02	18,24,32,41,55,65,120,160 24,31,41,51,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	B4	16	No Bands	All Manufacturers	Negative
	B6	09	18,24,55,160 17,24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
C	C1	10	24,32,41,51,55,65,120,160 24,31,41,51,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	C2, C6	17	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 18,24,31,41,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	C3, C4	03	18,24,32,55,65,160 17,24,31,41,51,55,66,120,160 24,51,55,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	C5	15	No Bands	All Manufacturers	Negative
D	D1, D3	18	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 24,31,41,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	D2	11	18,24,55,160 17,24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	D4, D5	04	24,41,55,160 24,160 24,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	D6	16	No Bands	All 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.

* bioMerieux Vitek/Cambridge Biotech

Table 2, Continued

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected ¹	WB Test Kit Manufacturer	CDC Interpretation ²
E	E1	15	No Bands	All Manufacturers	Negative
	E2, E4	17	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160 18,24,31,41,51,65,120,160	Cambridge Biotech* Epitope/Organon	Positive Positive
	E3	12	18,24,32,41,55,65,160 24,41,51,55,66,120,160 24,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
E5, E6	05	24,55,160 24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive	
F	F1, F6	06	18,24,55,160 17,24,55,66,120,160 18,24,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
			F2	16	No Bands
	F3, F5	18	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	F4	13	24,55,160 24,120,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
G	G1, G3	07	24,41,55,65,160 24,51,66,120,160 24,,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	G2, G6	17	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 18,24,31,41,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	G4	14	18,24,55,65,160 24,41,51,55,66,120,160 24,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	G5	15	No Bands	All Manufacturers	Negative

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

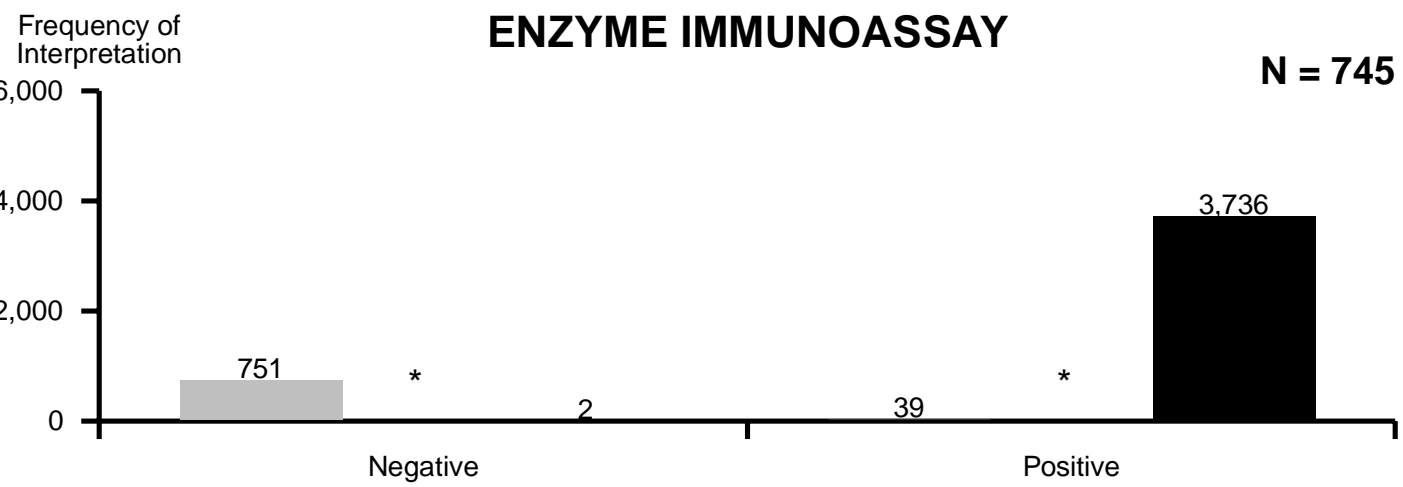
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

* bioMerieux Vitek/Cambridge Biotech

**SUPPLEMENTAL INFORMATION FOR COMPREHENDING
THE NUMBERS USED TO LABEL FIGURES
IN THIS REPORT**

The "N=" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test; therefore, the number of results may exceed the actual number of laboratories providing reports. In figures 1-7 and 10, the vertical axis is labeled either as frequency or percentage of results; in figures 8 and 9, this axis is labeled as percentage of reports. However, in all figures, the number appearing directly above or within each bar represents a frequency of results only.

Figure 1. Frequency of HIV-1 antibody test result interpretations, by sample type (reactivity), for enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the August 18, 1997 shipment



* = Indeterminate is not an EIA interpretation option; these areas have been left blank

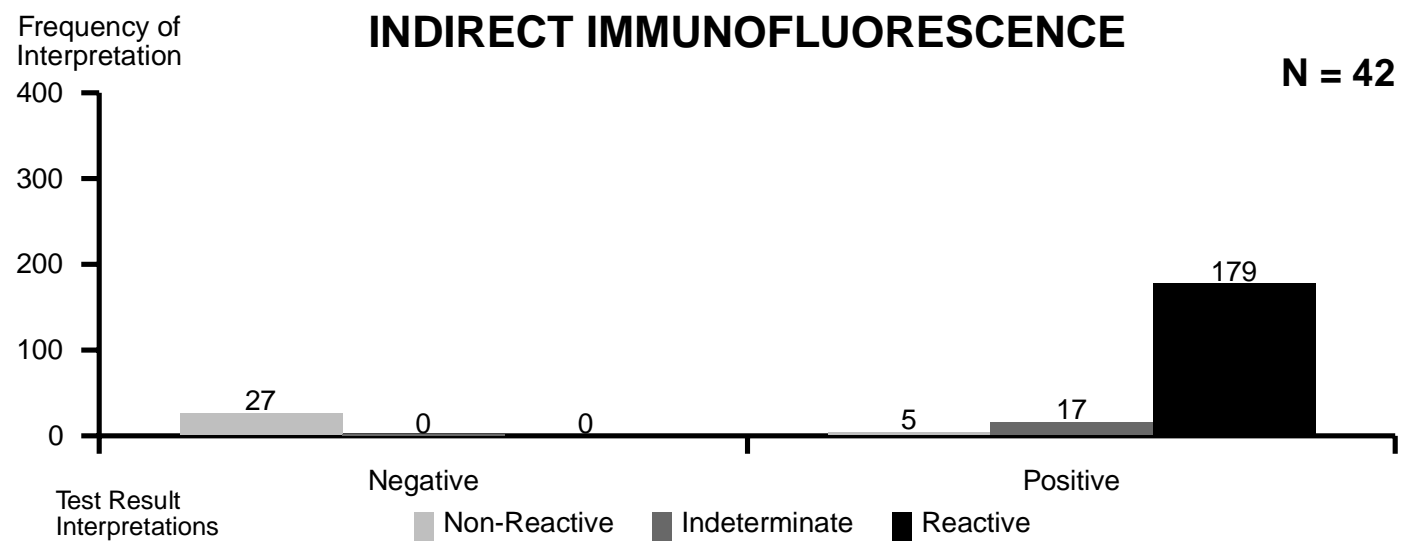
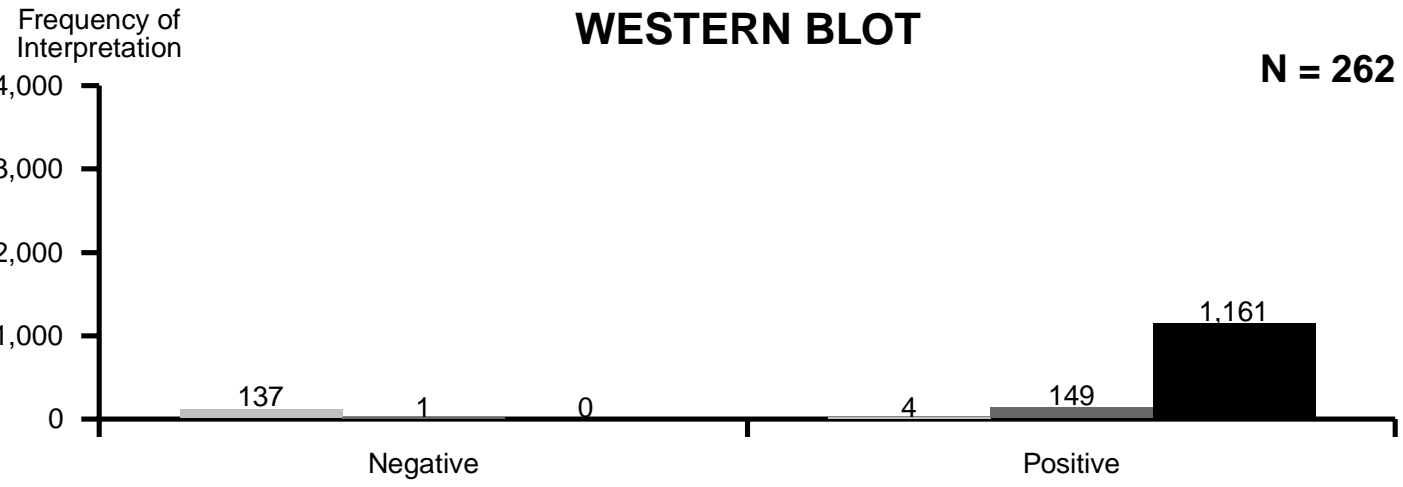


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the August 18, 1997 shipment

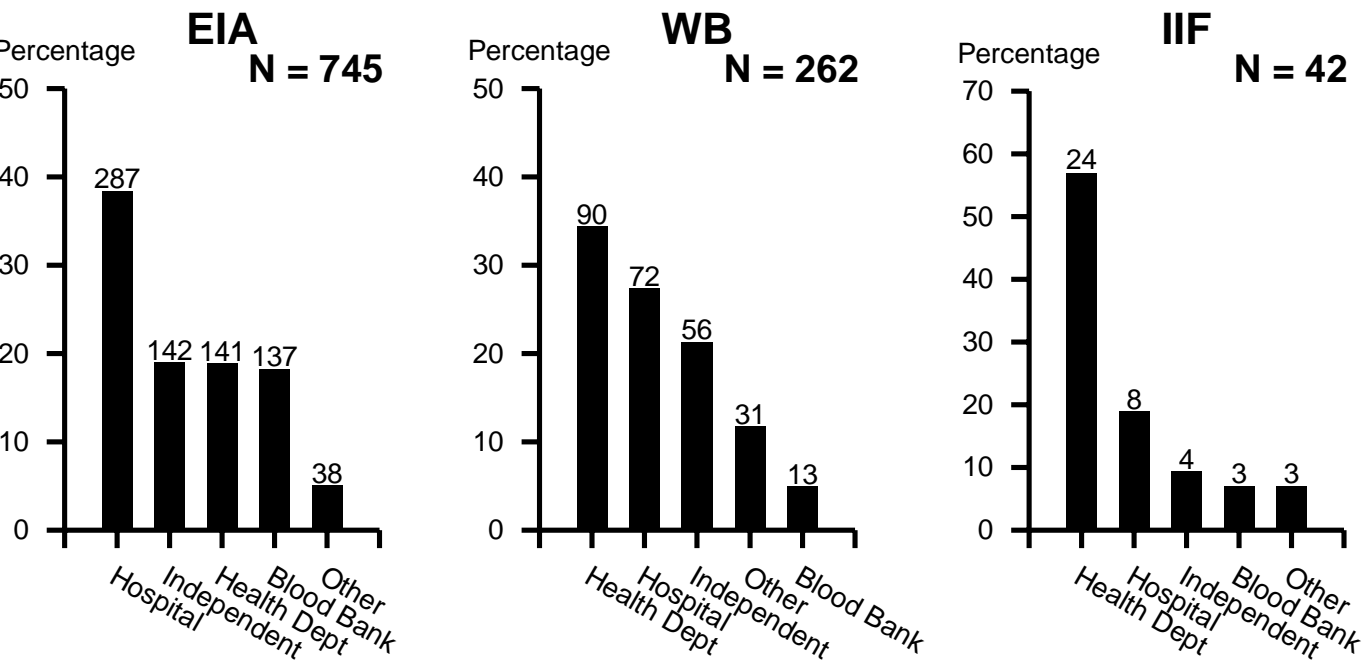


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the August 18, 1997 shipment

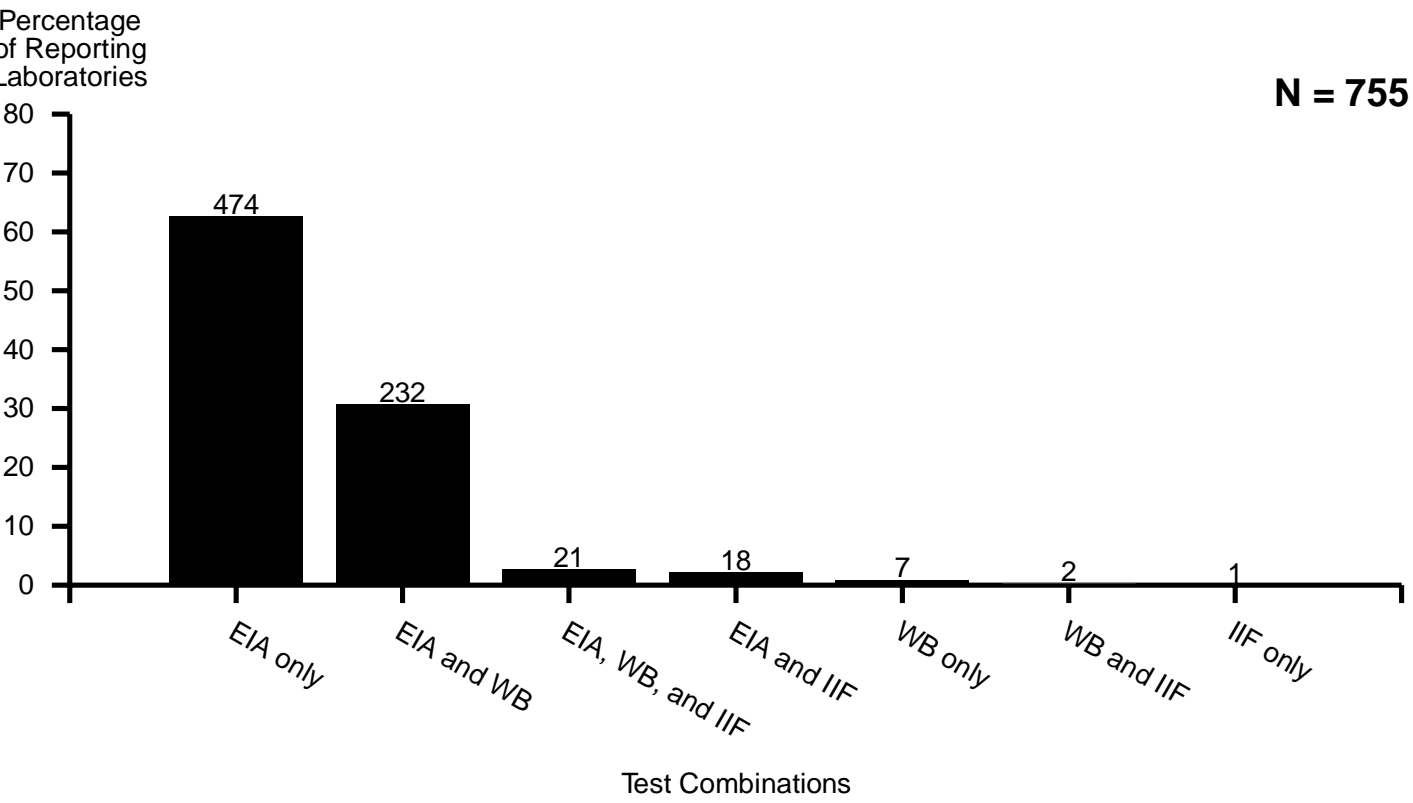


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the August 18, 1997 shipment

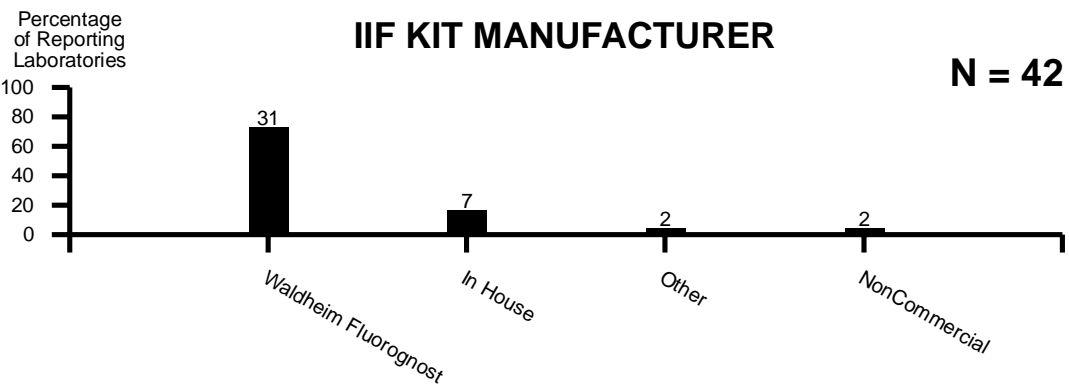
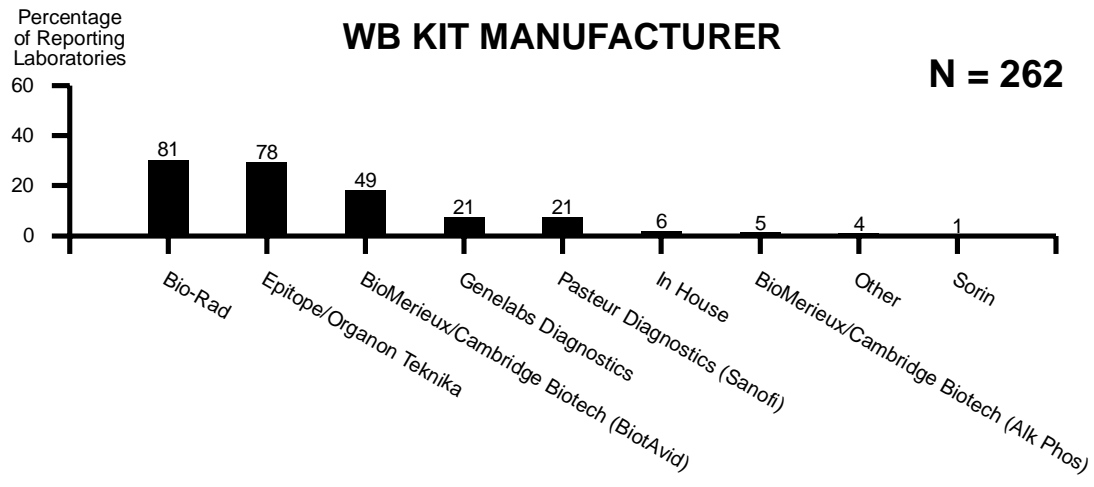
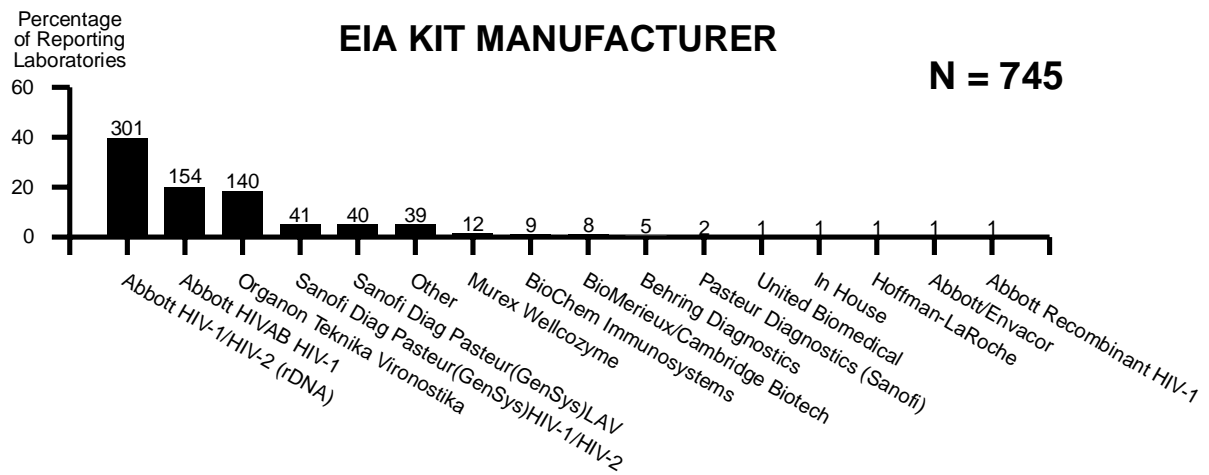
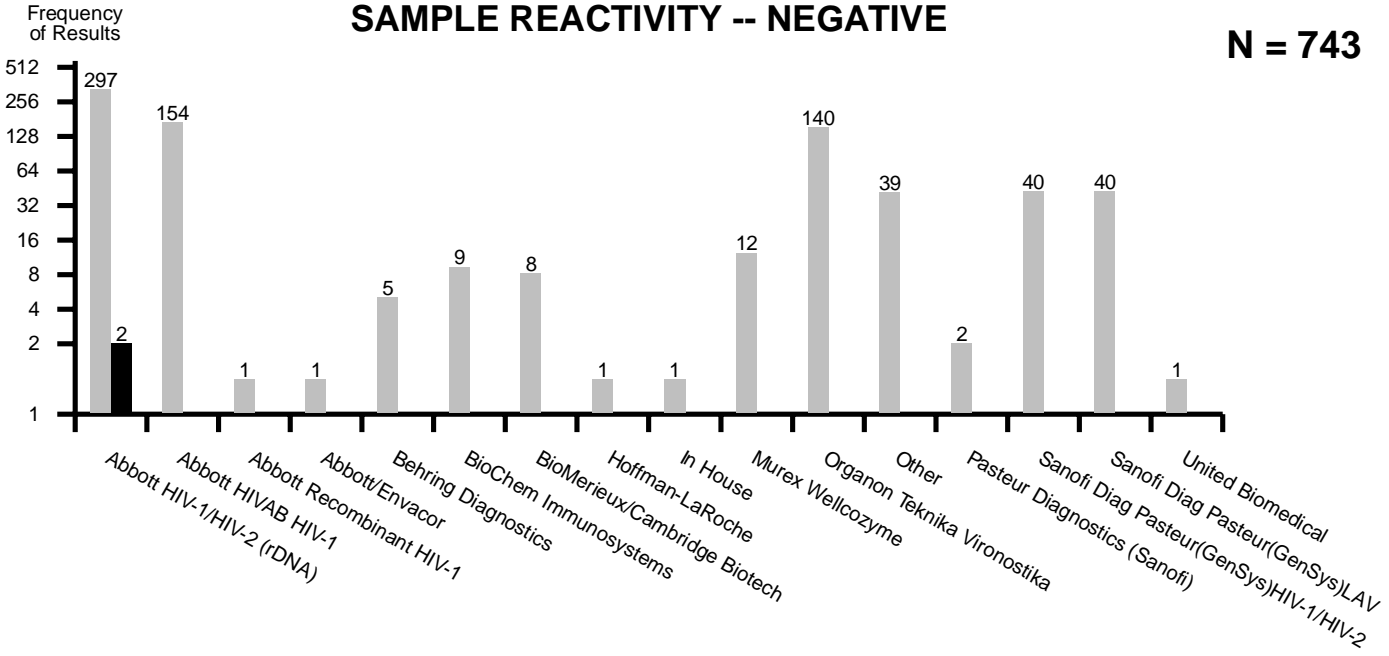


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 18, 1997 shipment

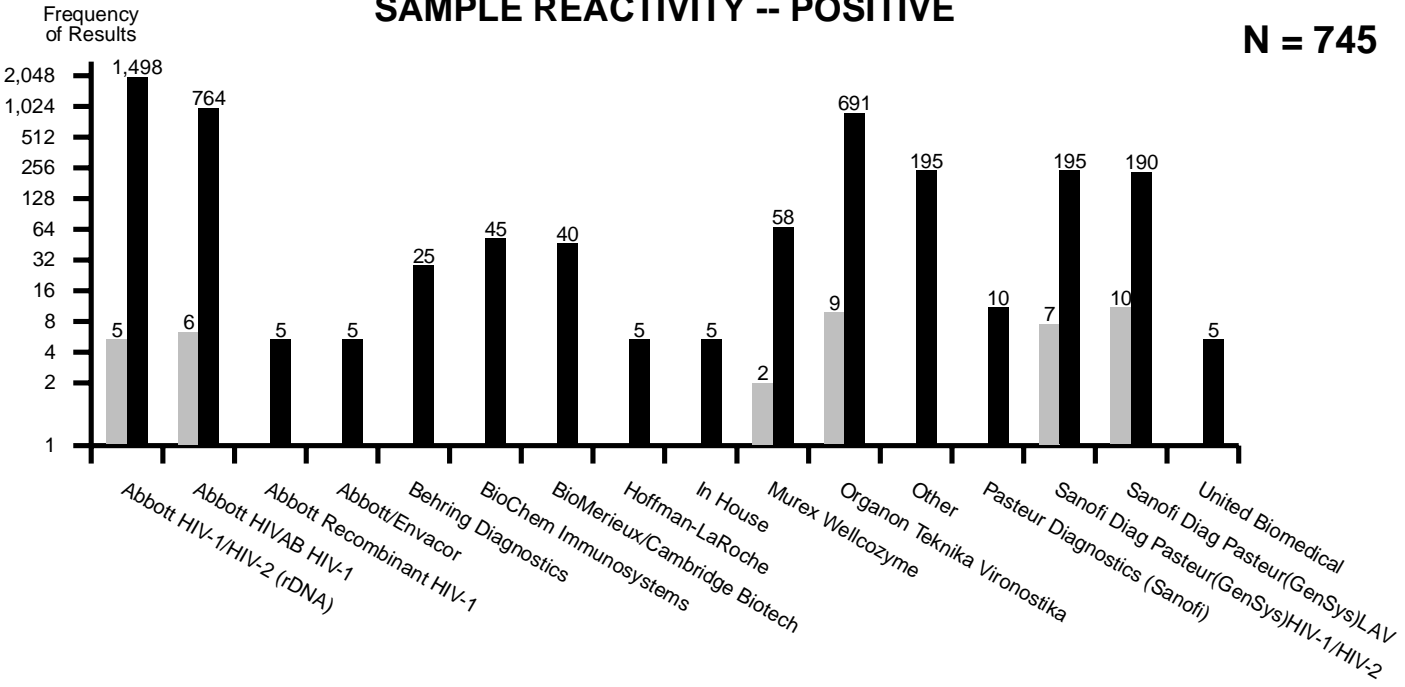
SAMPLE REACTIVITY -- NEGATIVE

N = 743



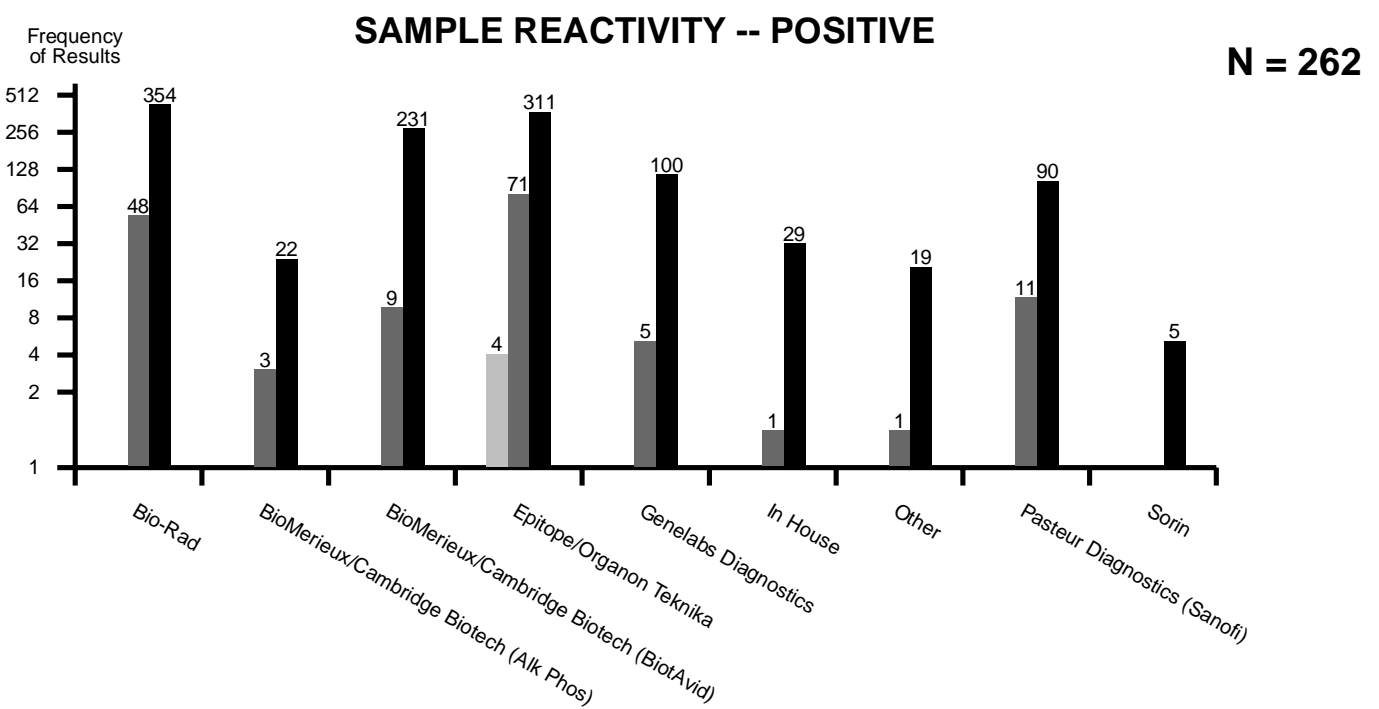
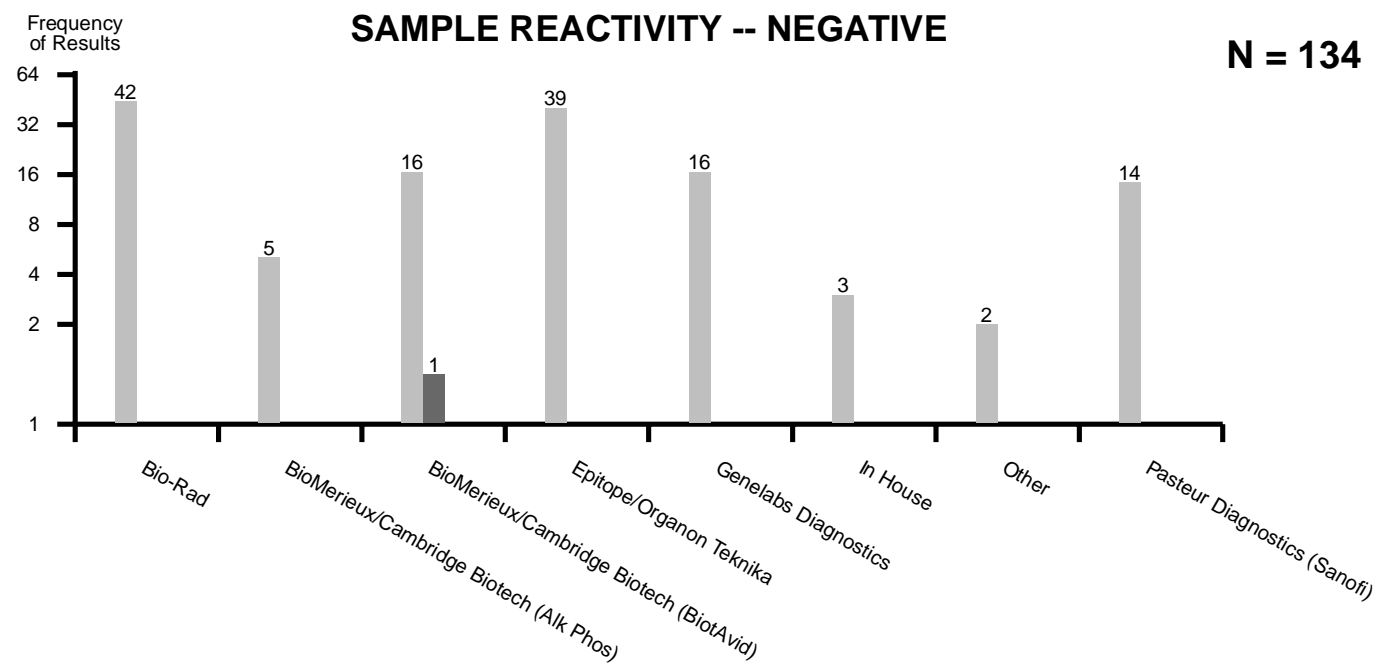
SAMPLE REACTIVITY -- POSITIVE

N = 745



Test Result Interpretations
 ■ Non-Reactive ■ Reactive

Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 18, 1997 shipment



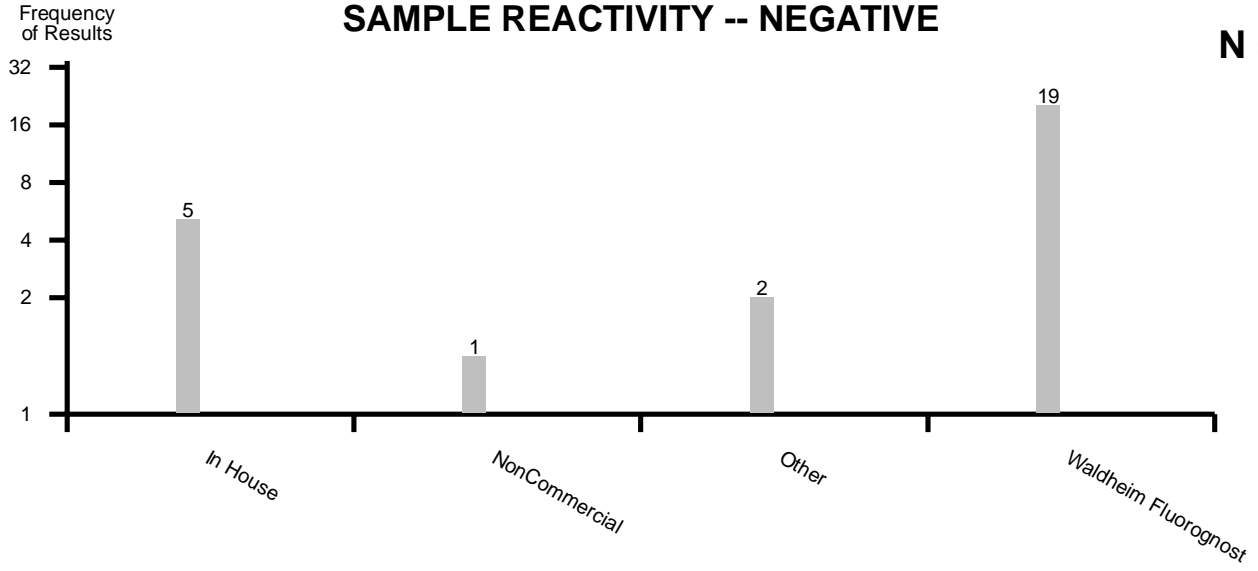
Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 18, 1997 shipment

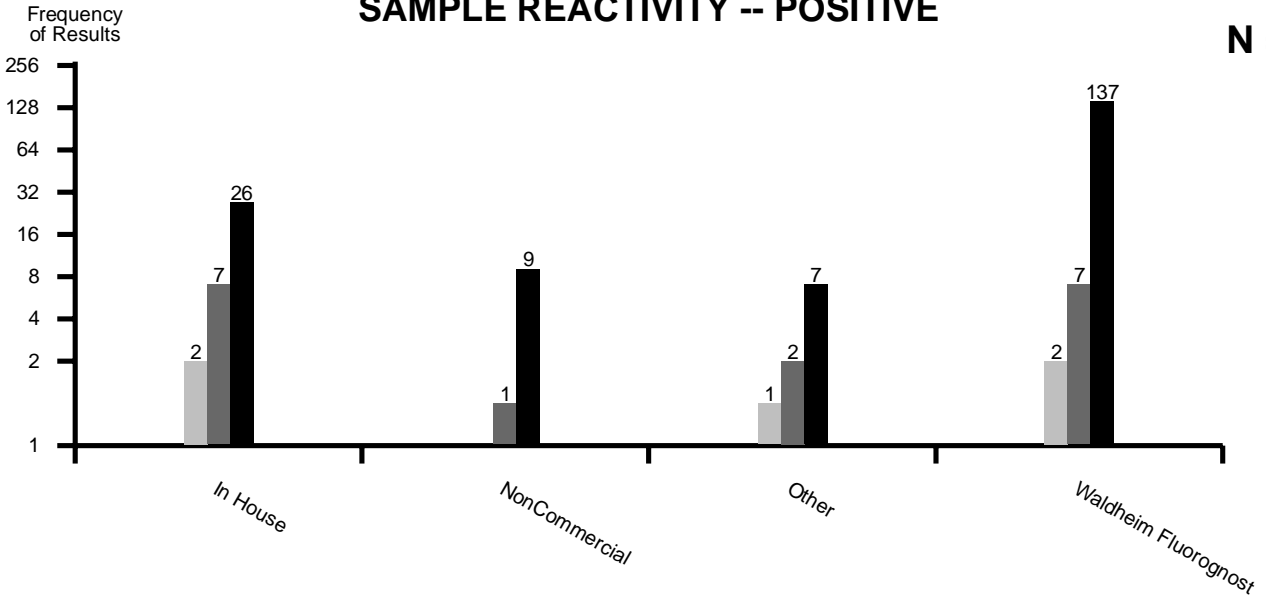
SAMPLE REACTIVITY -- NEGATIVE

N = 27



SAMPLE REACTIVITY -- POSITIVE

N = 42



Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 18, 1997 shipment

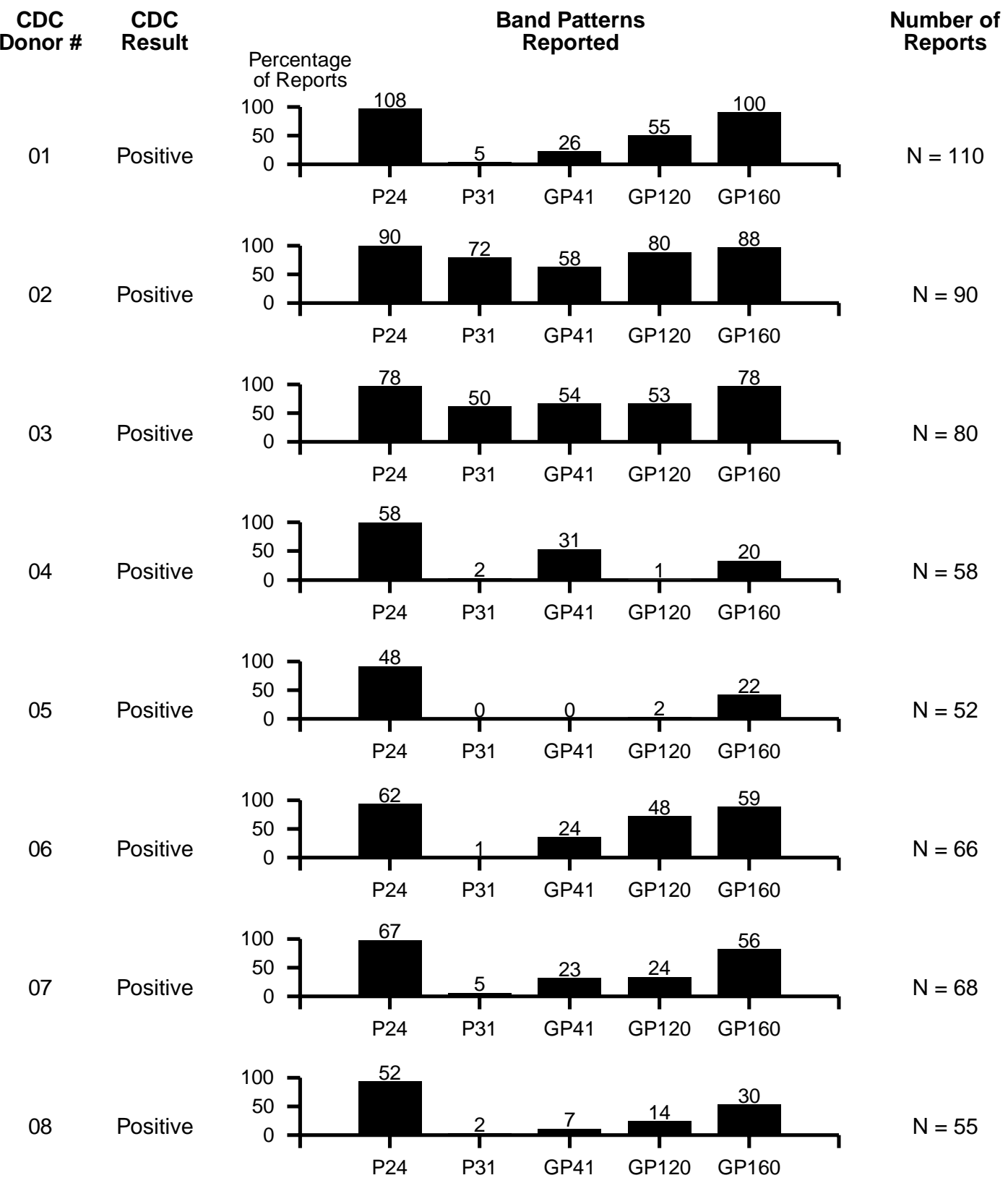


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 18, 1997 shipment

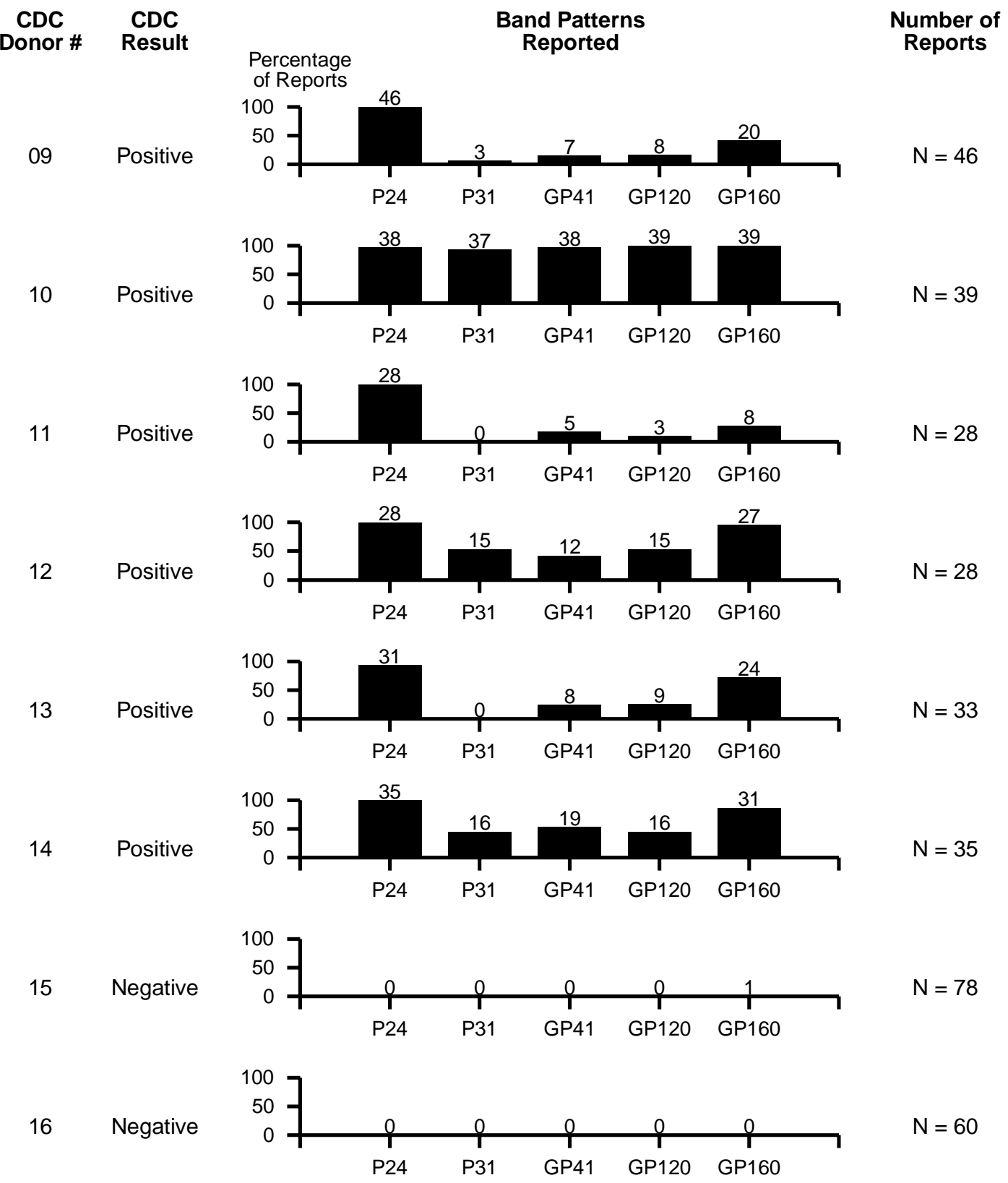


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 18, 1997 shipment

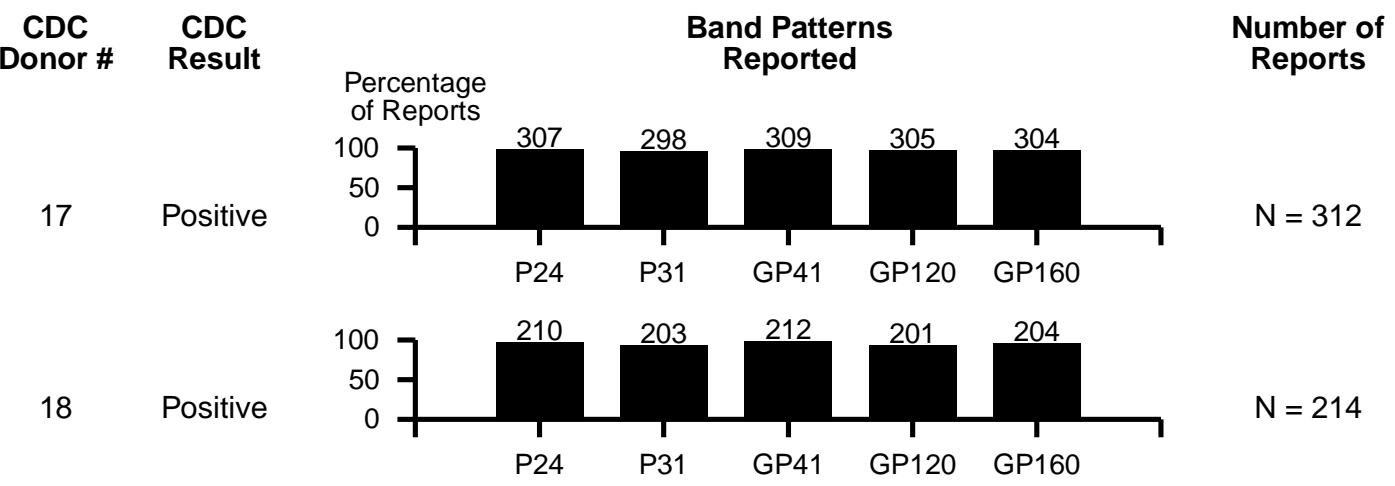


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 18, 1997 shipment

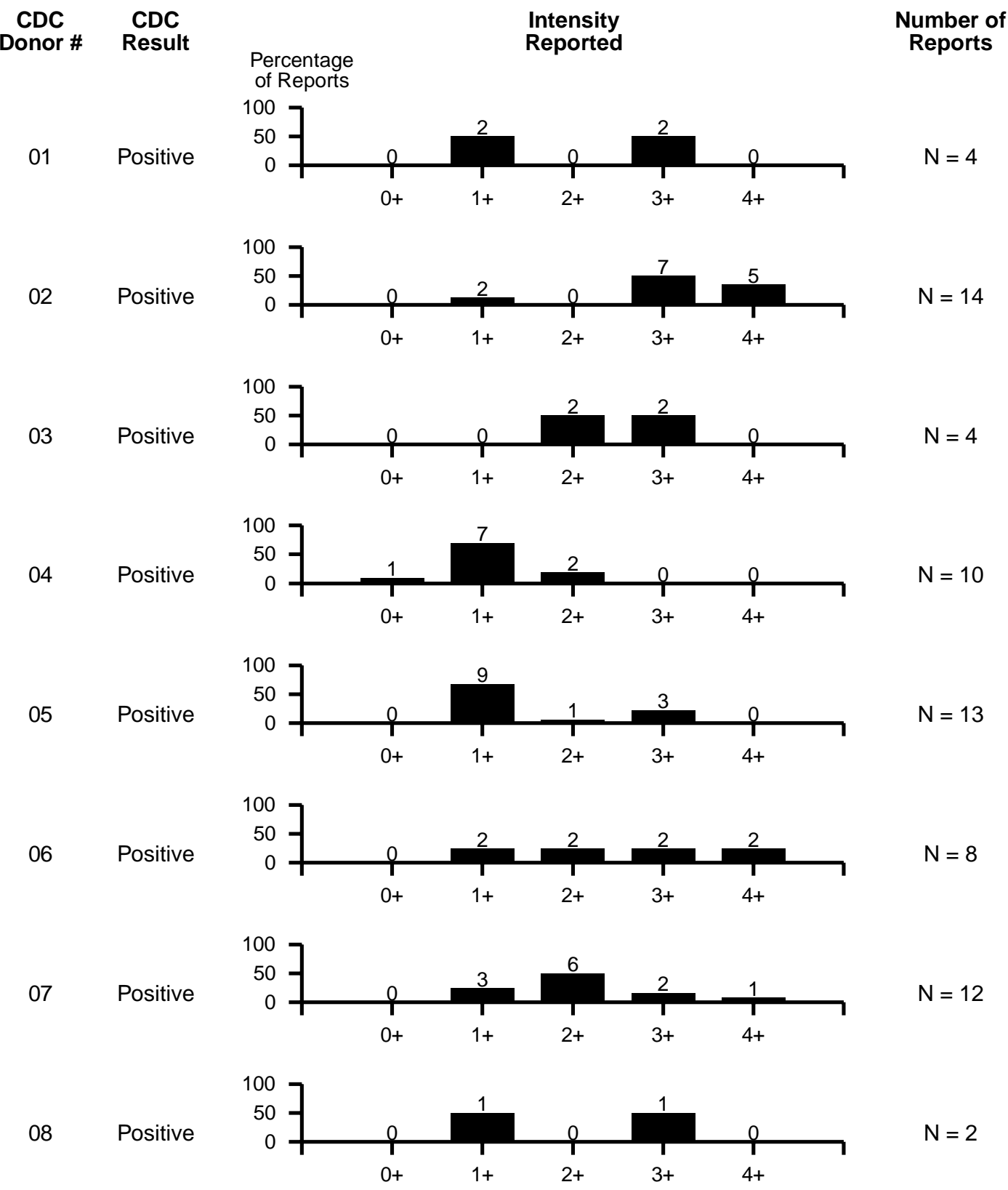


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 18, 1997 shipment

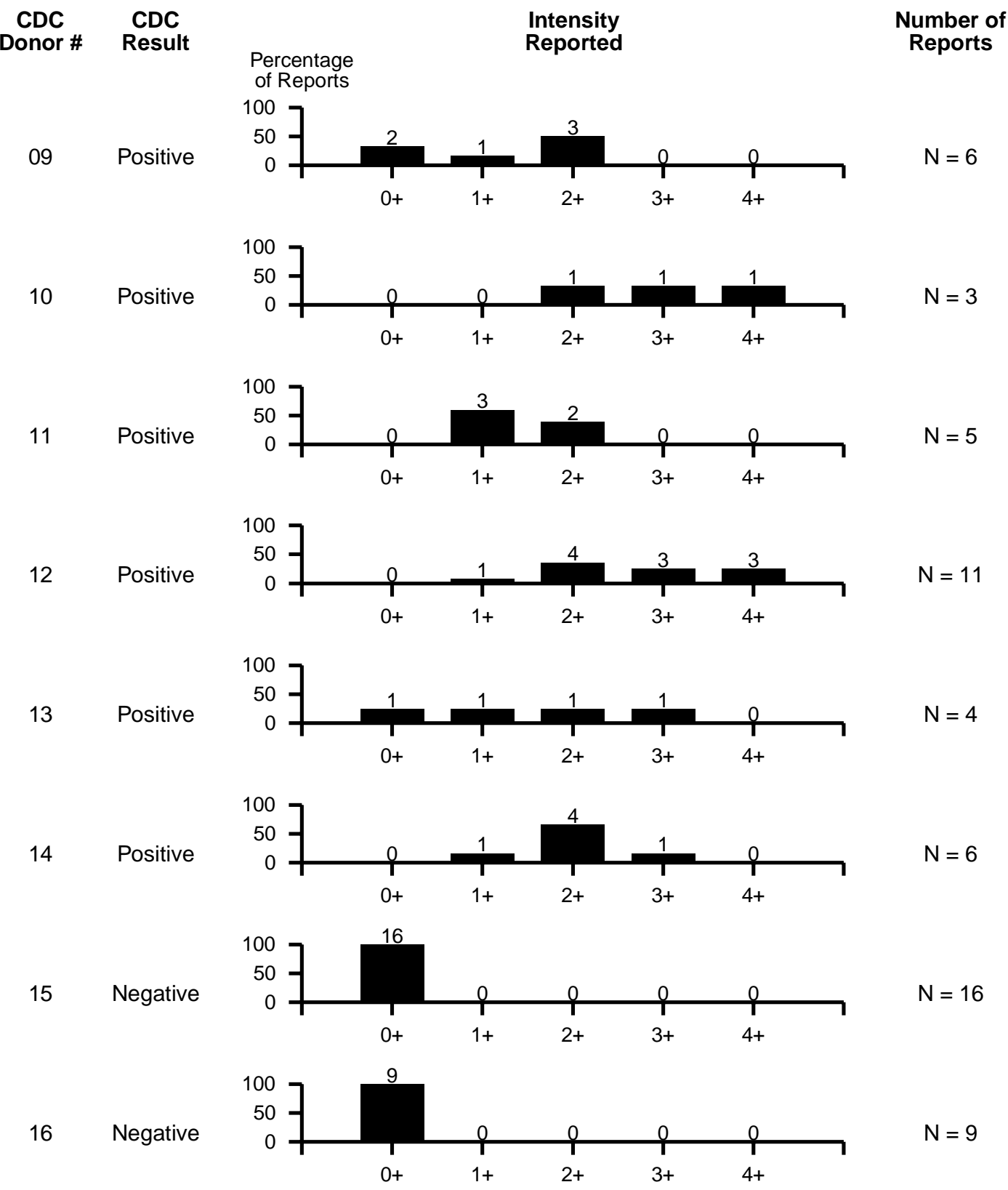


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 18, 1997 shipment

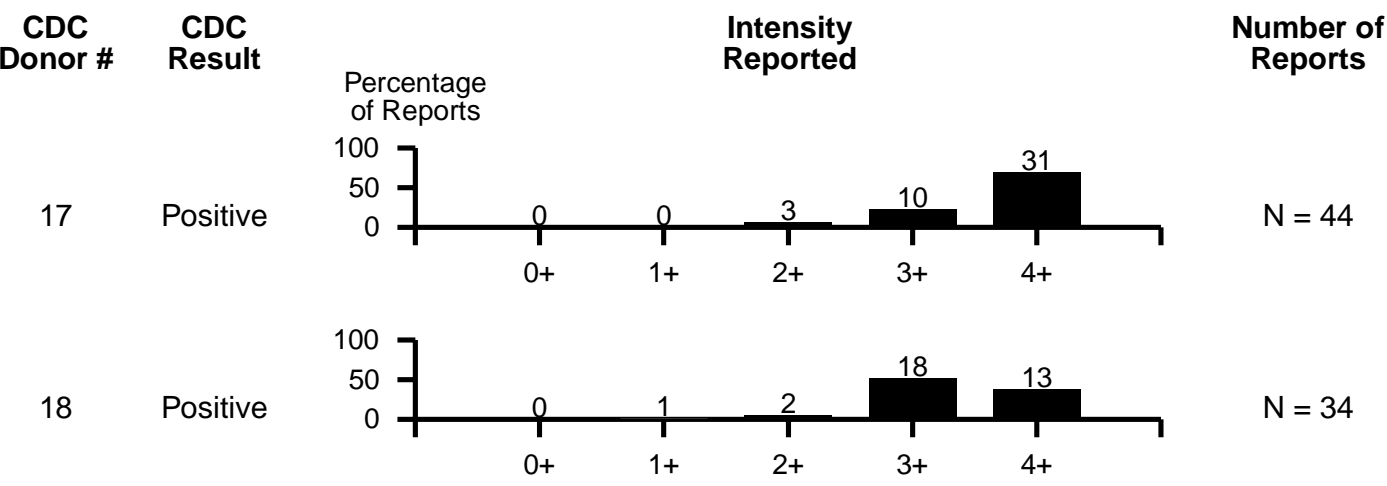


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the August 18, 1997 shipment

