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 17, 1998 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

Atlanta, Georgia 30333

Report of the August 17, 1998 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 INIT.[3]	EIA FINAL[4]	WB	IIF
A	A1, A2	01	Indeterminate	Infected	___	___	___	___
	A3	15	Negative		Uninfected		___	___
	A4, A6	17	Positive	Infected	___	___	___	___
	A5	08	See Table 2	Infected	___	___	___	___
B	B1, B5	18	Positive	Infected	___	___	___	___
	B2, B3	02	See Table 2	Infected	___	___	___	___
	B4	16	Negative	Uninfected	___	___	___	___
	B6	09	See Table 2	Infected	___	___	___	___
C	C1	10	Positive	Infected	___	___	___	___
	C2, C6	17	Positive	Infected	___	___	___	___
	C3, C4	03	Indeterminate	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 INIT.[3]	EIA FINAL[4]	WB	IIF
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 17, 1998 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	24,51	BioRad	Indeterminate
			24	Cambridge Biotech*	Indeterminate
			24	Epitope/Organon	Indeterminate
	A3	15	No Bands	All Manufacturers	Negative
	A4, A6	17	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,120,160	Epitope/Organon	Positive
	A5	08	24,55	BioRad	Indeterminate
			24,66,160	Cambridge Biotech	Positive
			24	Epitope/Organon	Indeterminate
B	B1, B5	18	24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	Positive
	B2, B3	02	24	BioRad	Indeterminate
			24,120,160	Cambridge Biotech	Positive
			24,160	Epitope/Organon	Positive
	B4	16	No Bands	All Manufacturers	Negative
	B6	09	24,55,160	BioRad	Positive
			24,66,160	Cambridge Biotech	Positive
			24	Epitope/Organon	Indeterminate
C	C1	10	24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	Positive
	C2, C6	17	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
	C3, C4	03	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,55,65,120,160	Epitope/Organon	Positive
	C5	15	No Bands	All Manufacturers	Negative
D	D1, D3	18	24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	Positive
	D2	11	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,160	Epitope/Organon	Positive
	D4, D5	04	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	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	Cambridge Biotech*	Positive
			18,24,31,41,51,65,120,160	Epitope/Organon	Positive
	E3	12	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,55,65,160	Epitope/Organon	Positive
	E5, E6	05	24,32,41,51,65,120,160	BioRad	Positive
			24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	Positive
F	F1, F6	06	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,55,65,120,160	Epitope/Organon	Positive
	F2	16	No Bands	All Manufacturers	Negative
	F3, F5	18	24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,160	Epitope/Organon	Positive
	F4	13	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,55,65,120,160	Epitope/Organon	Positive
G	G1, G3	07	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,120,160	Epitope/Organon	Positive
	G2, G6	17	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
	G4	14	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,55,65,120,160	Epitope/Organon	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 17, 1998 shipment

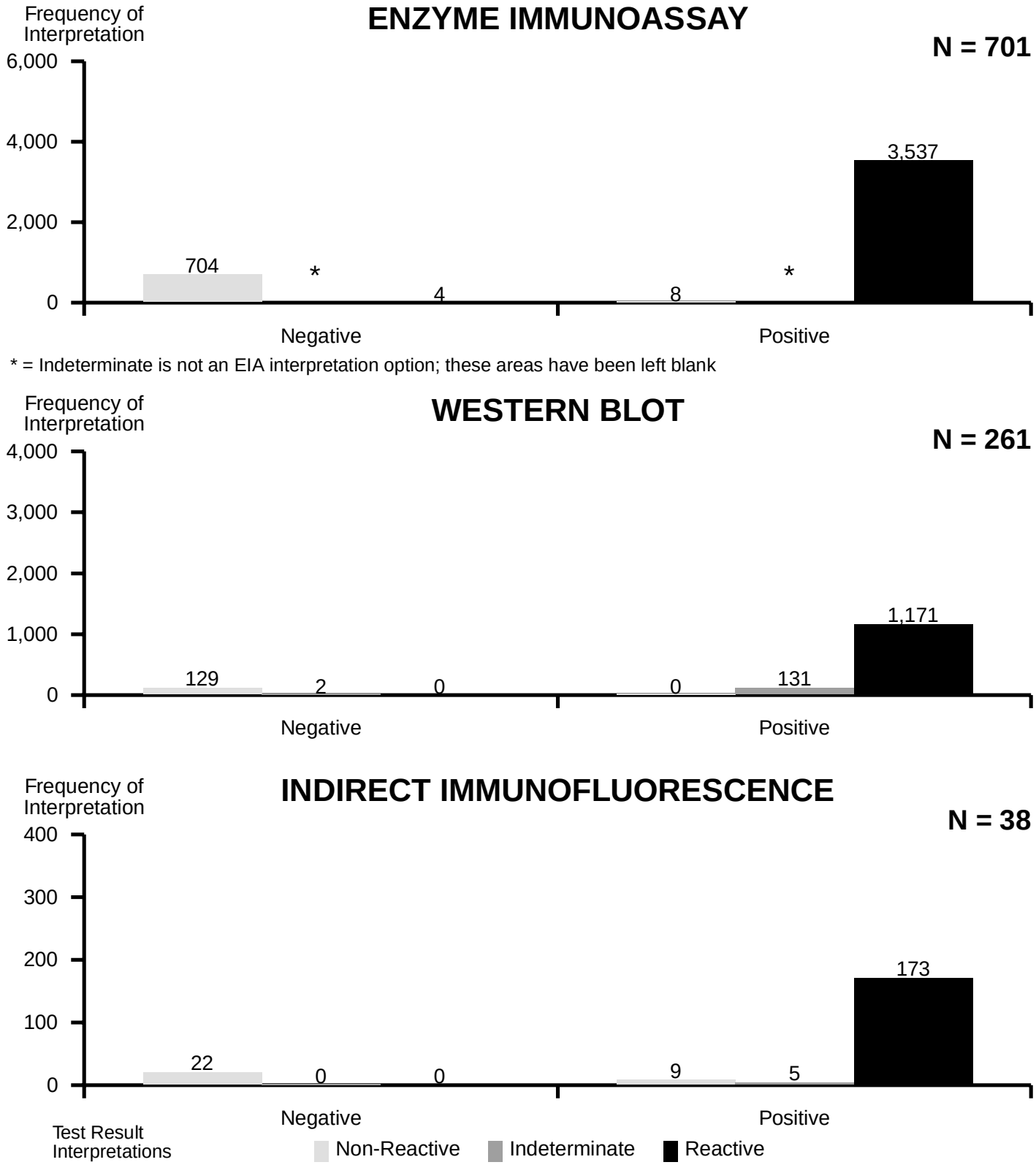


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the August 17, 1998 shipment

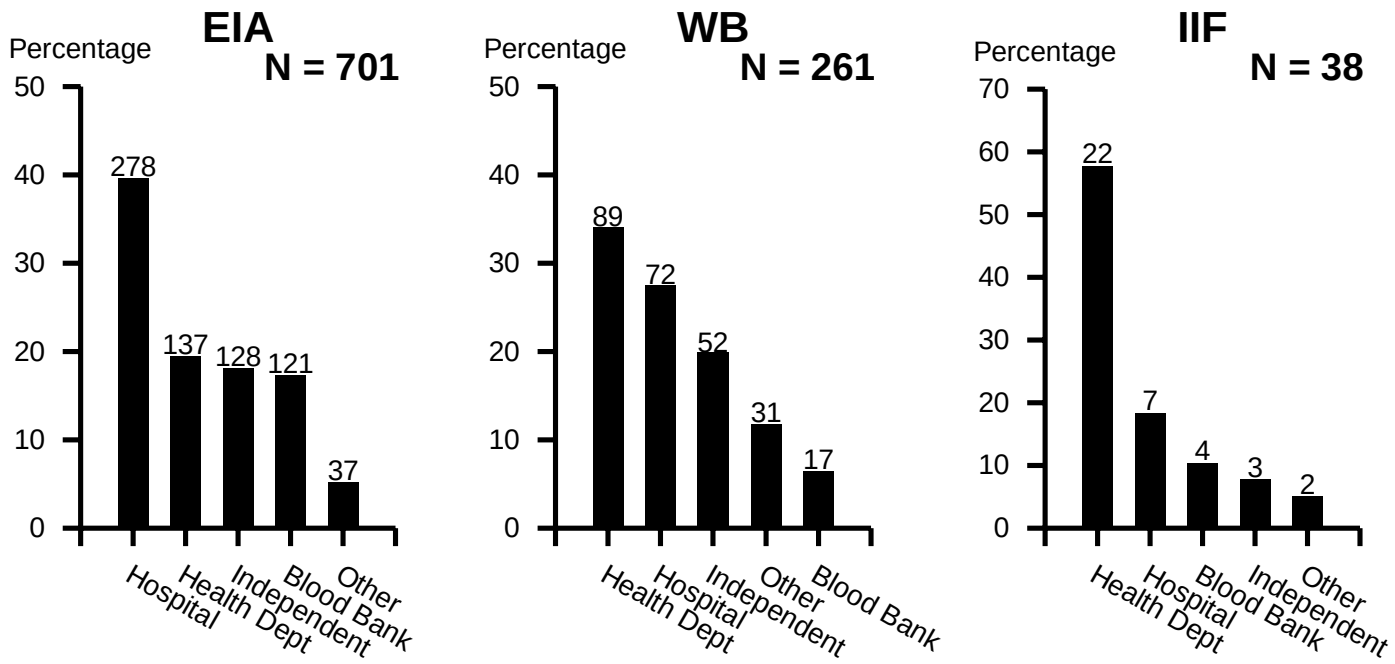


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the August 17, 1998 shipment

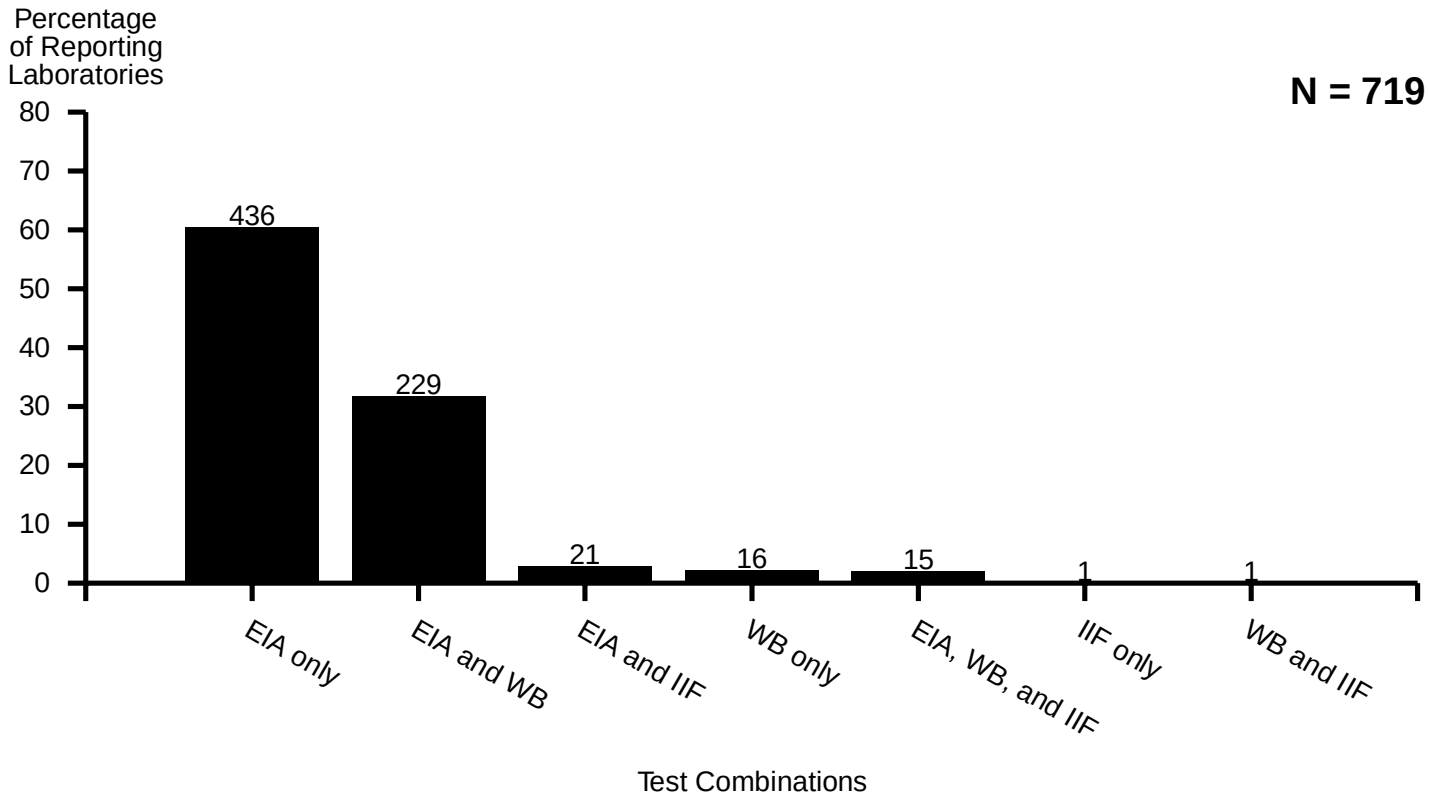
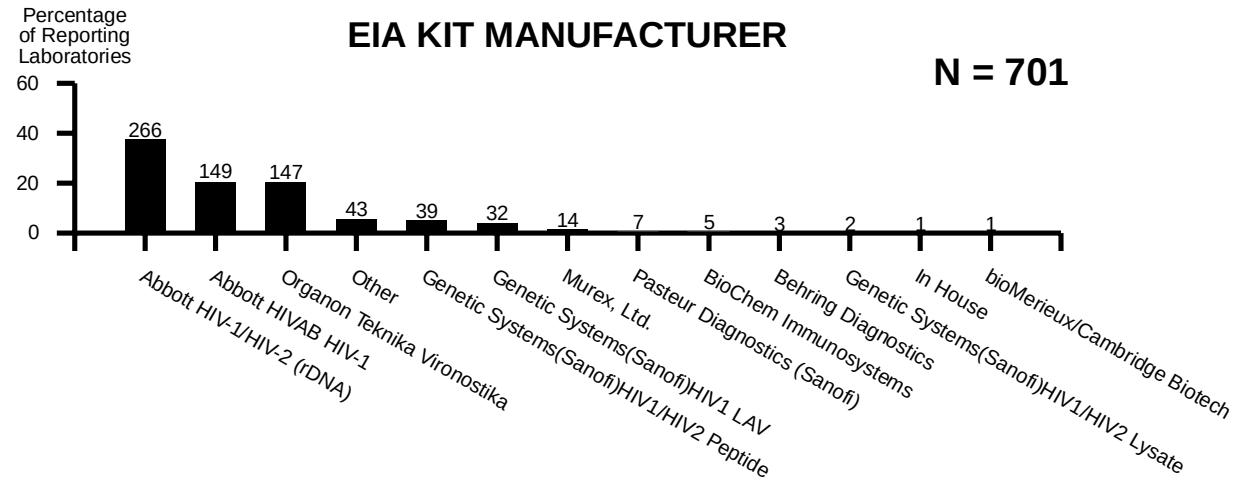
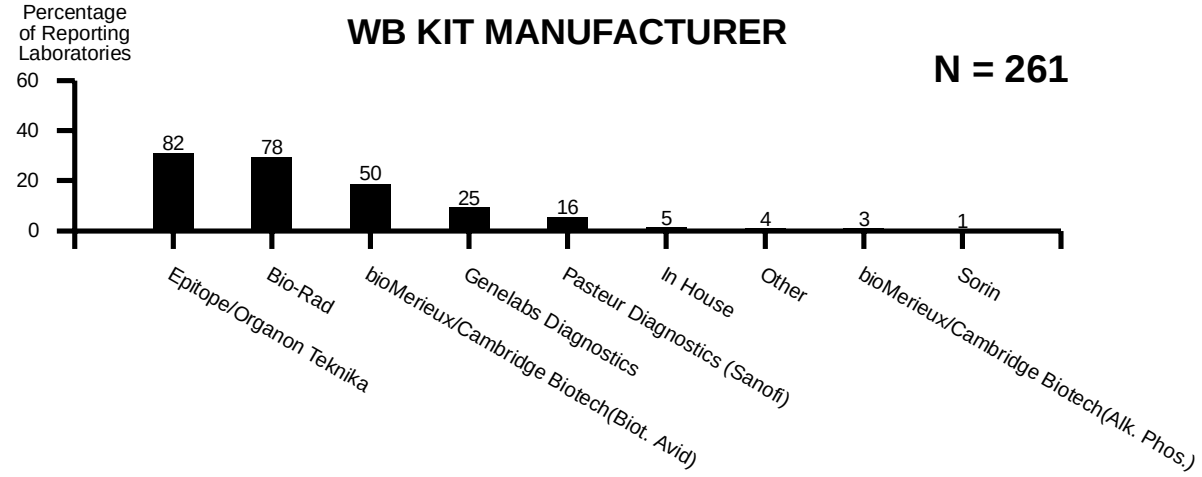


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the August 17, 1998 shipment





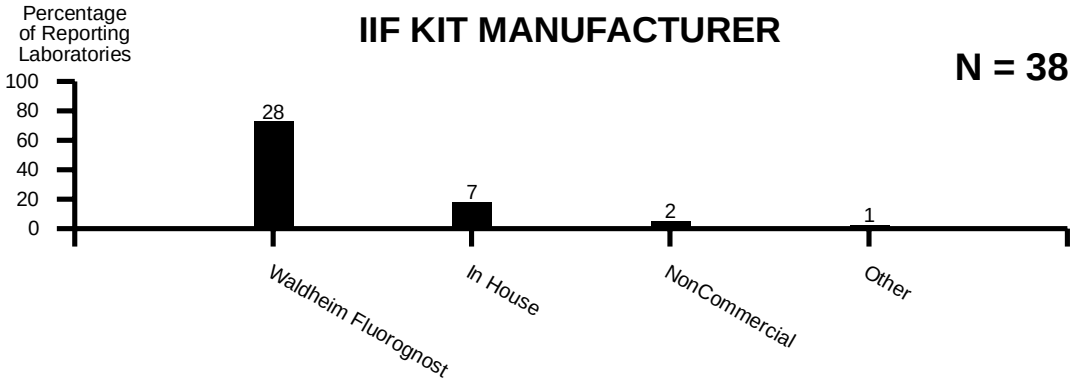


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 17, 1998 shipment

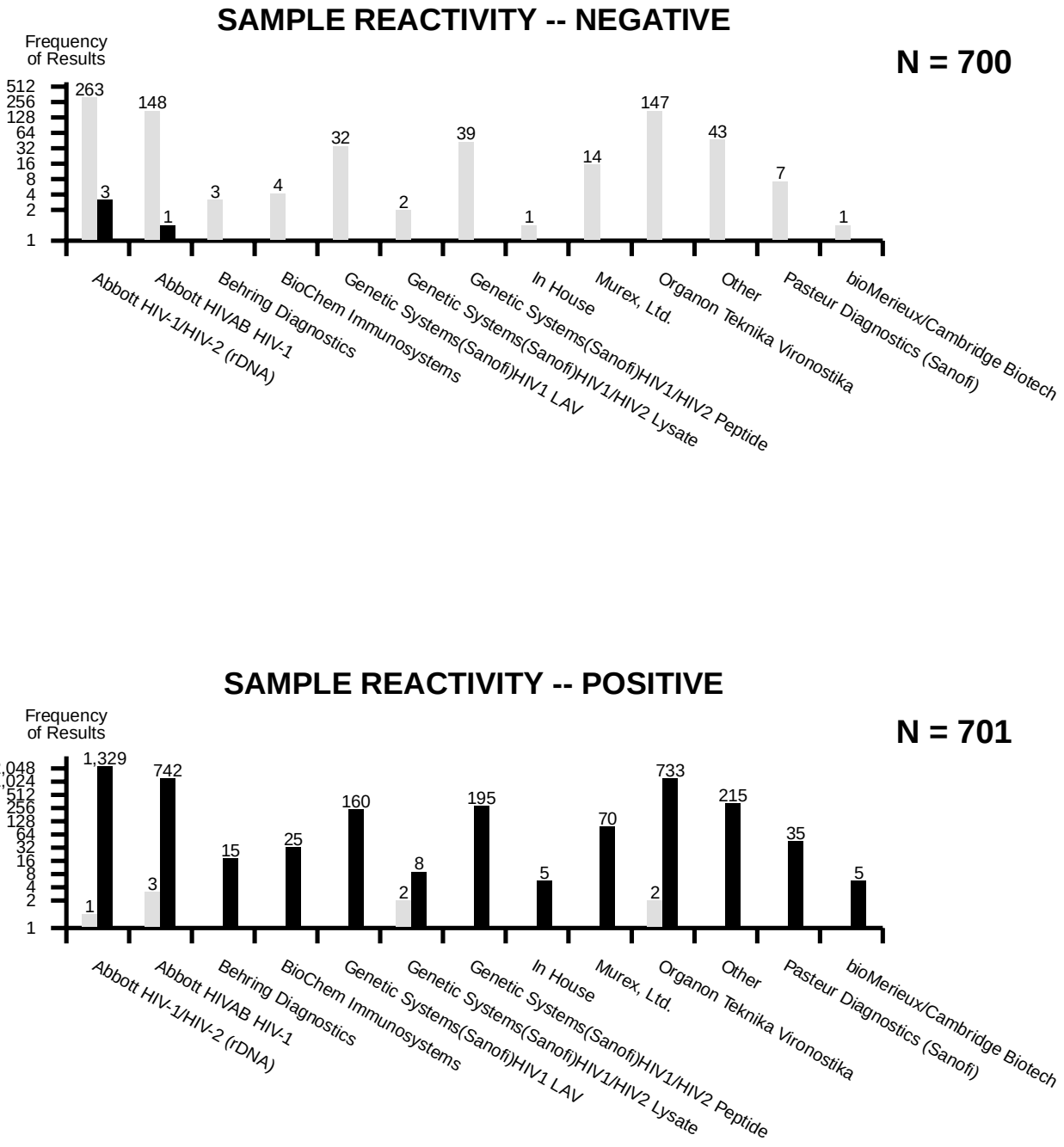
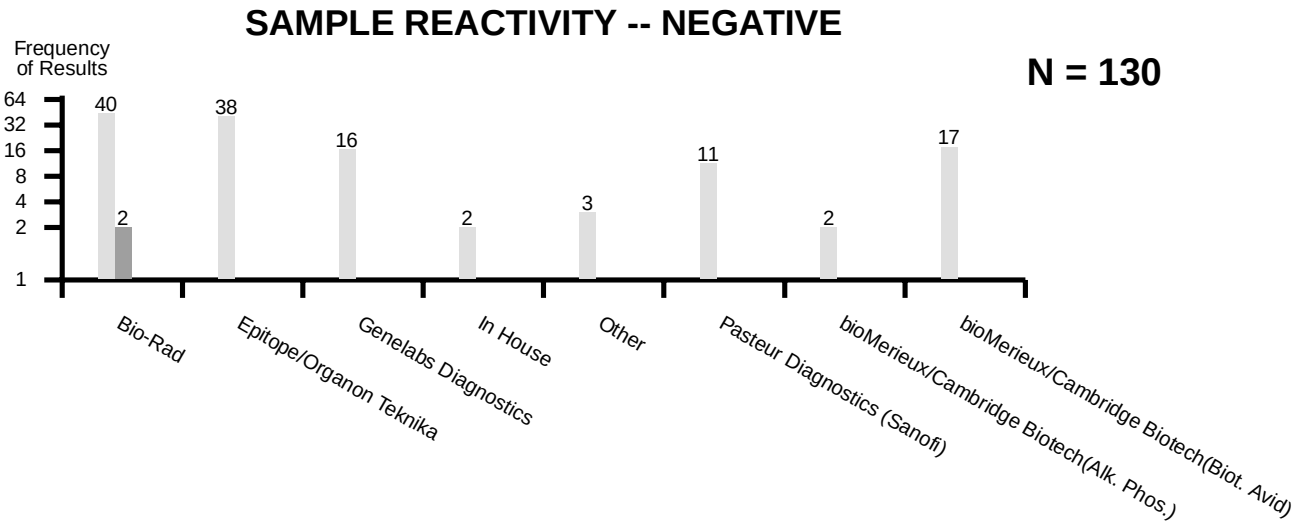
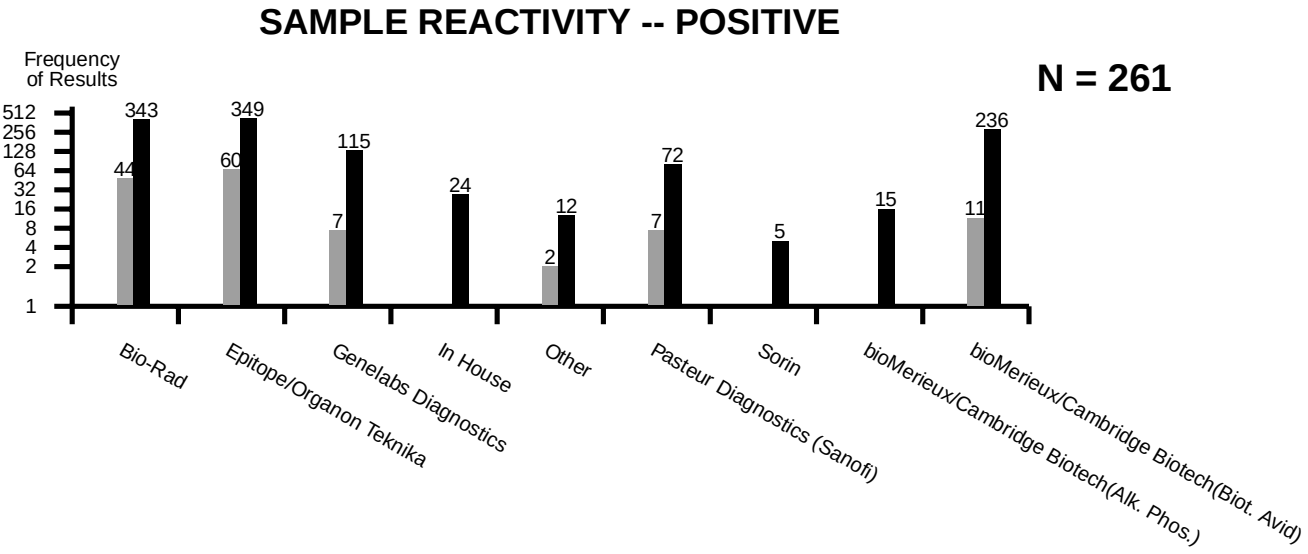


Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 17, 1998 shipment





Test Result Interpretations

Non-Reactive Indeterminate Reactive

CDC Model Performance Evaluation Program
HIV-1 Antibody Testing

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the August 17, 1998 shipment

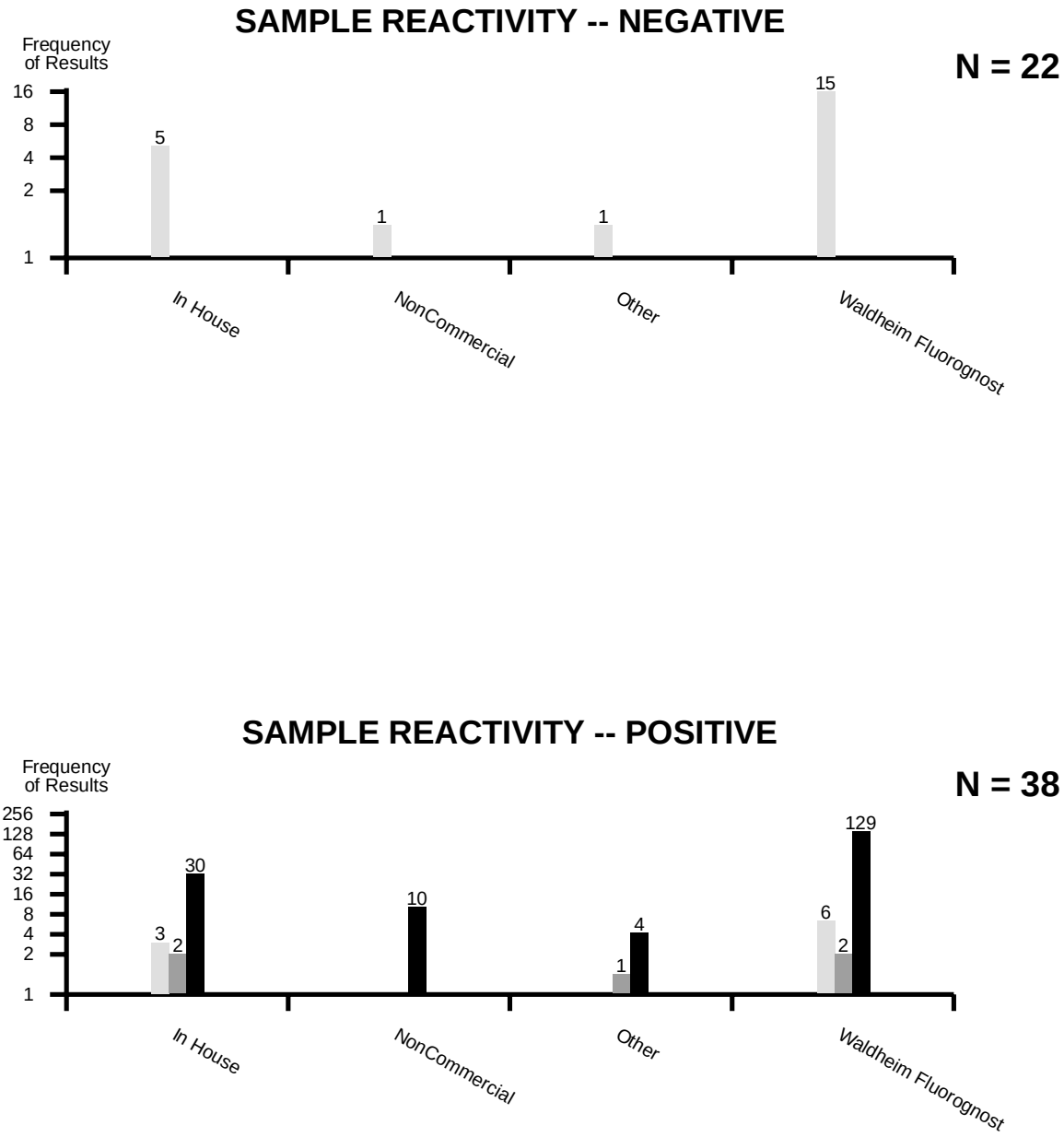


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 17, 1998 shipment

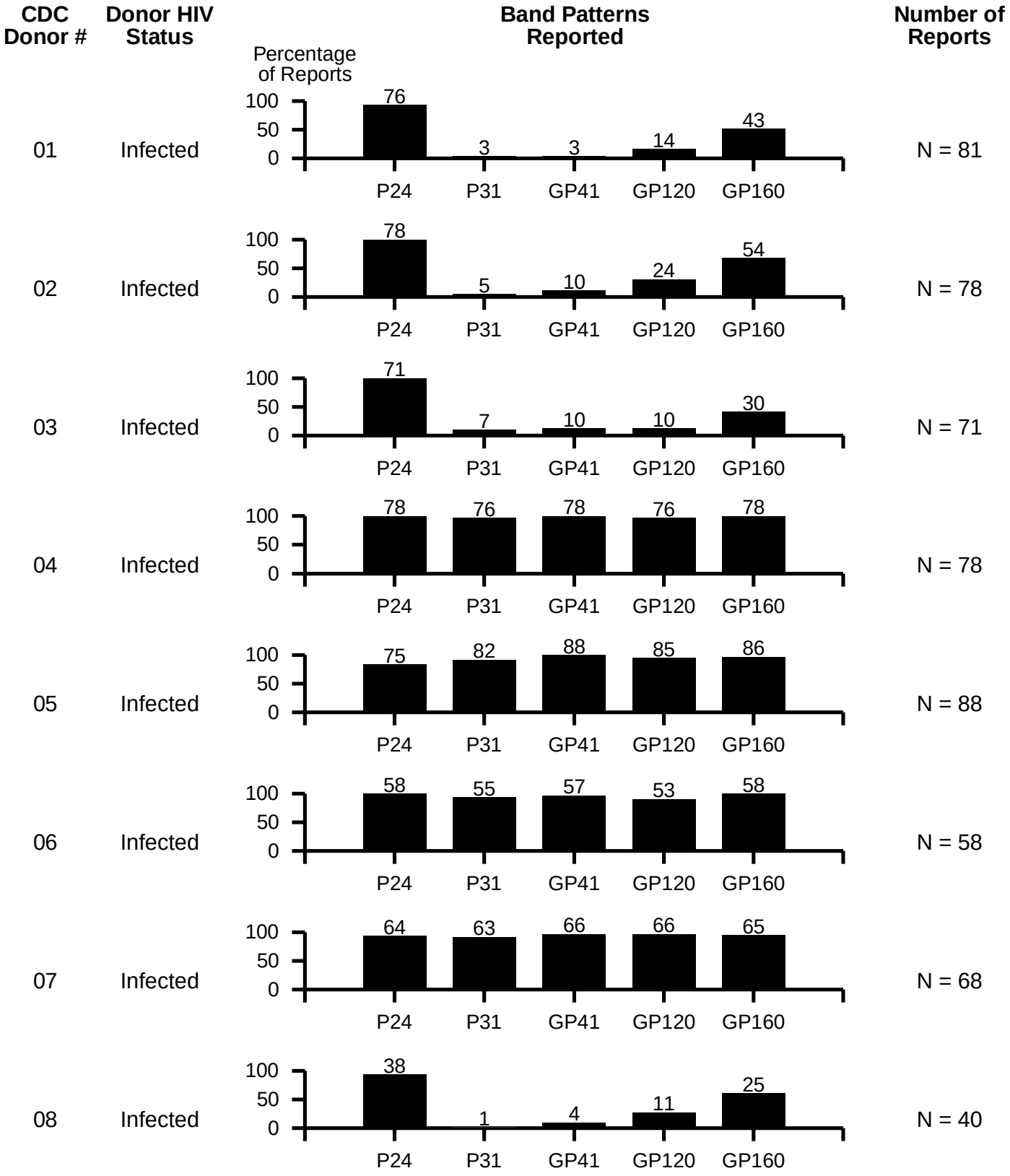


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 17, 1998 shipment

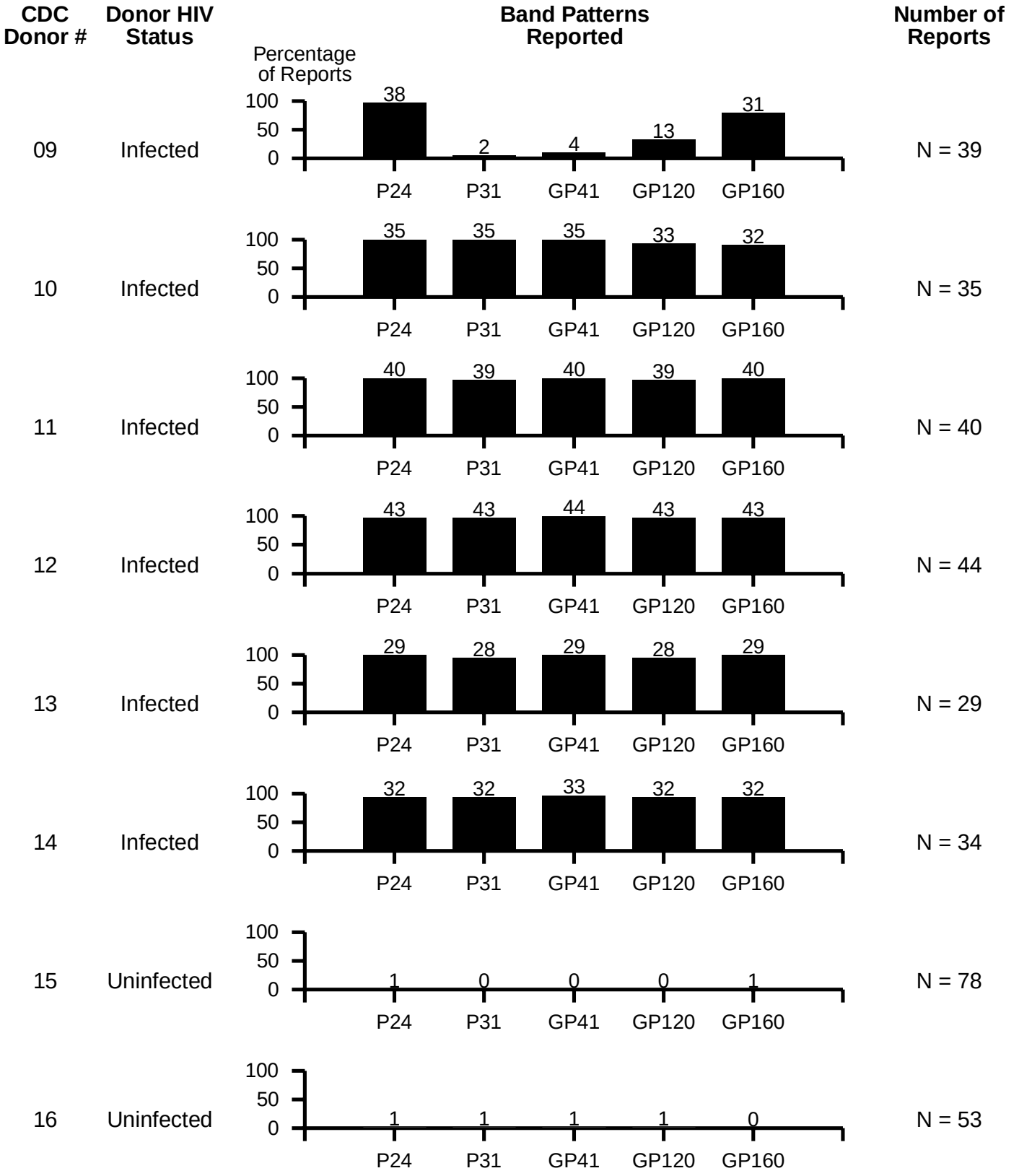


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the August 17, 1998 shipment

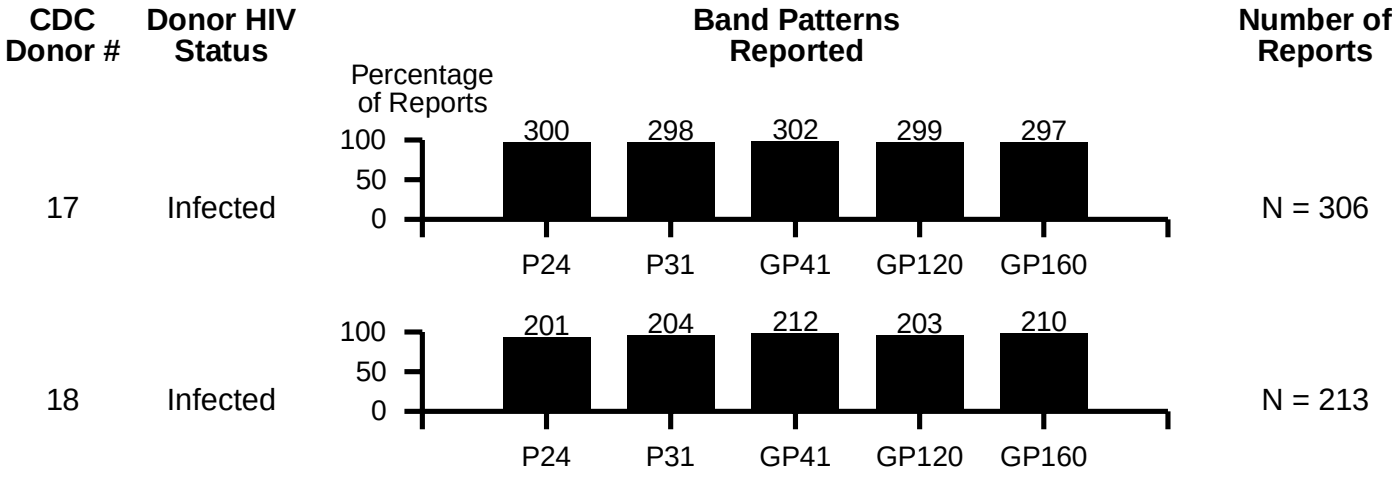


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 17, 1998 shipment

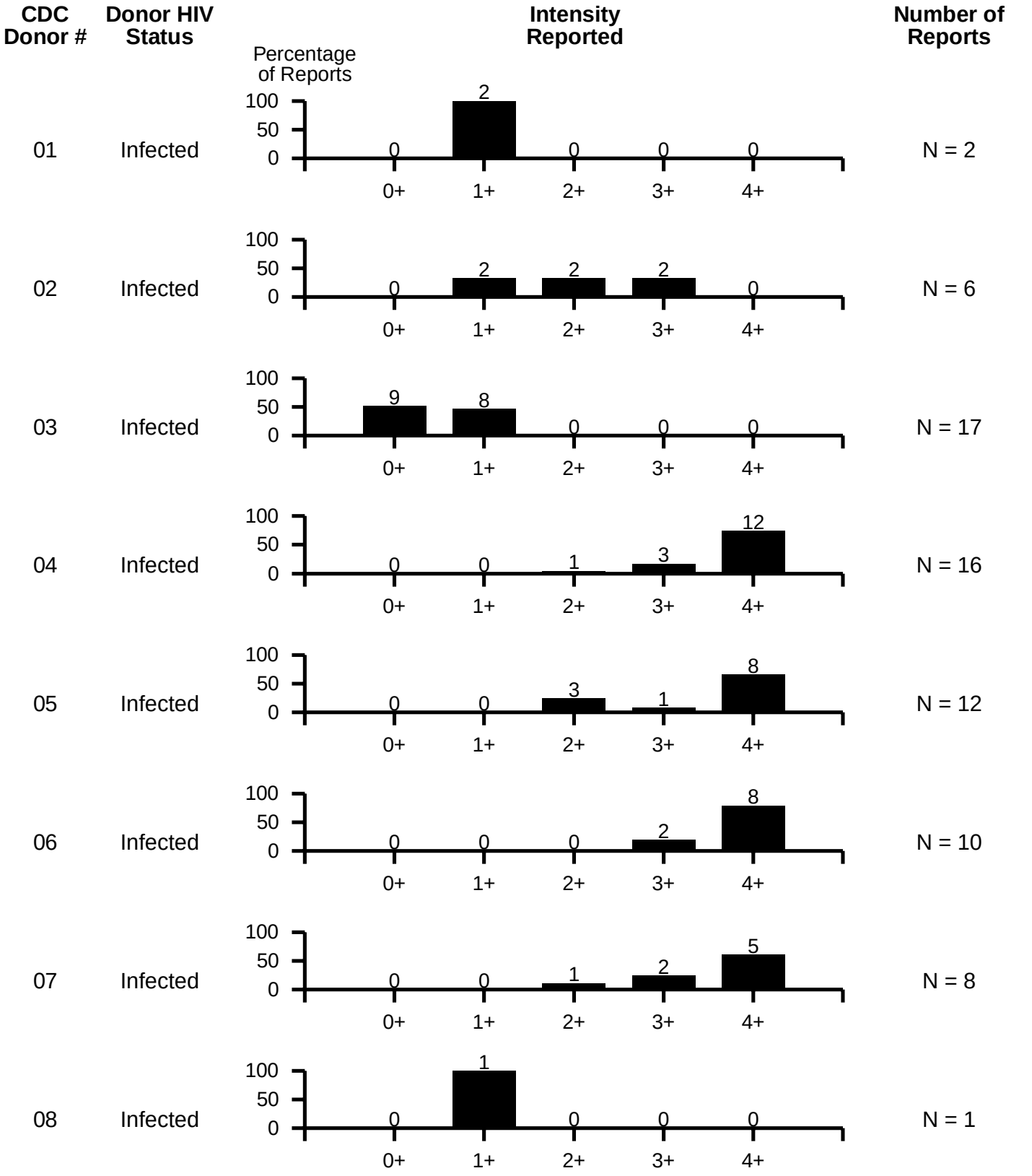


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 17, 1998 shipment

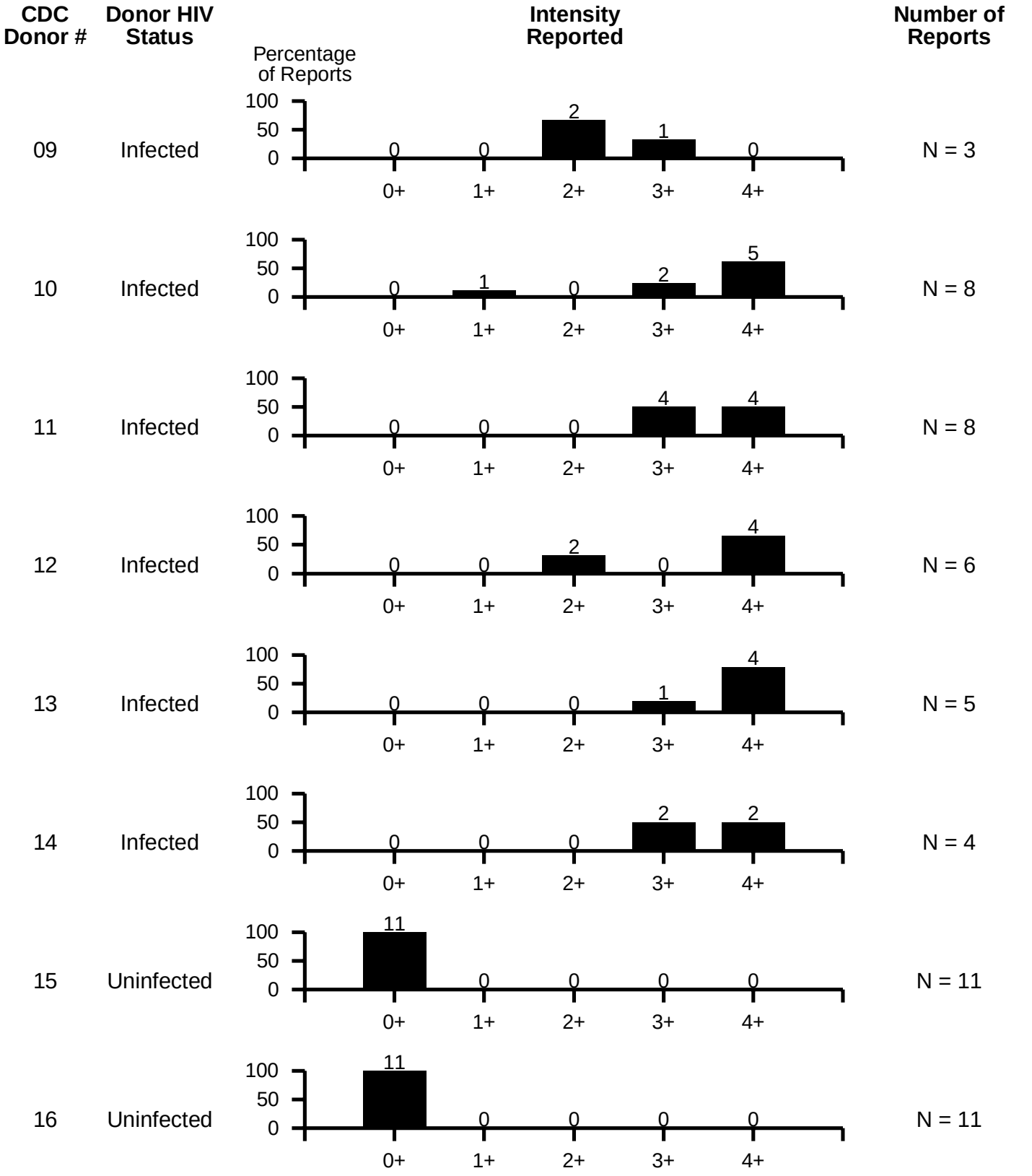


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 17, 1998 shipment

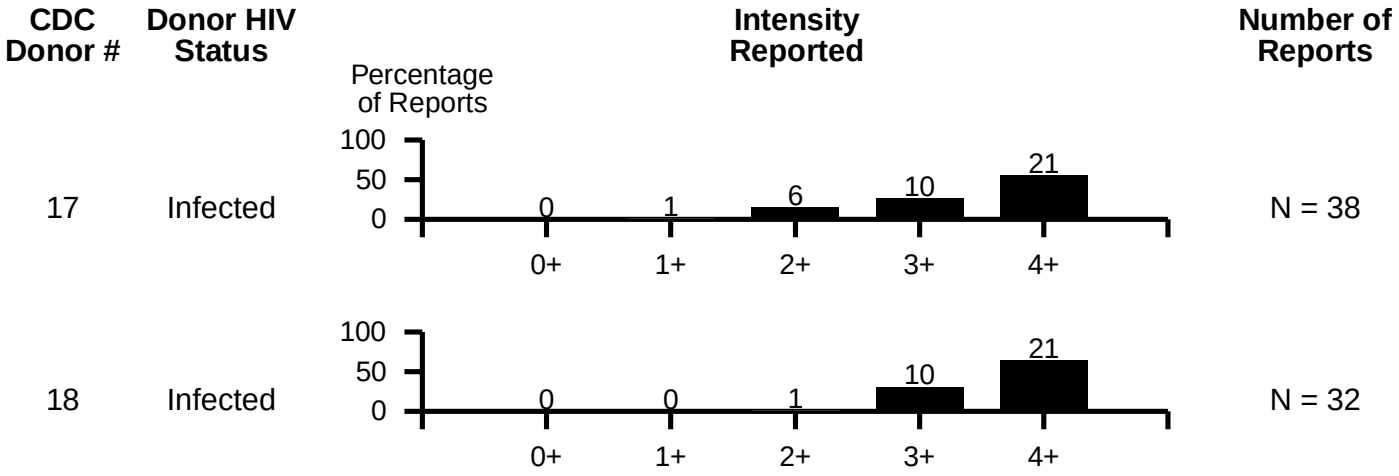


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the August 17, 1998 shipment