

**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 January 2001 Performance Evaluation
Testing Results Reported by Participant Laboratories**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



**Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Atlanta, Georgia 30341-3724**



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U.S. Department of Health and Human Services.**

Report of the January 2001 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
January 2001 Participant Laboratory Shipment

Table 1

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

¹ 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). 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

**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
January 2001 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	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech*	Positive
			24,51,55,65,120,160	Epitope/Organon	Positive
			24,40,55,120,160	Genetic Systems/Sanofi	Positive
	A2	5	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
			18,24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	A3, A5	2	24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,55,65,120,160	Epitope/Organon	Positive
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	A4, A6	3	No Bands	All Manufacturers	Negative
B	B1, B3	3	No Bands	All Manufacturers	Negative
	B2	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech	Positive
			24,51,55,65,120,160	Epitope/Organon	Positive
			24,40,55,120,160	Genetic Systems/Sanofi	Positive
	B4, B6	2	24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,55,65,120,160	Epitope/Organon	Positive
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	B5	5	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
			18,24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive

Table 2, continued ♂ ♂ ♂ ♂ ♂ ♂ ♂ ♂

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.

* Cambridge Biotech/Calypte Biomedical

**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
(Cont'd) January 2001 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
C	C1, C3	3	No Bands	All Manufacturers	Negative
	C2	5	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
			18,24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	C4	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech	Positive
			24,51,55,65,120,160	Epitope/Organon	Positive
			24,40,55,120,160	Genetic Systems/Sanofi	Positive
	C5, C6	2	24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,55,65,120,160	Epitope/Organon	Positive
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
D	D1	5	18,24,32,41,51,55,65,120,160 17,24,31,41,51,55,66,120,160 18,24,31,41,51,55,65,120,160 18,24,31,40,41,51,55,65,120,160	BioRad Cambridge Biotech Epitope/Organon Genetic Systems/Sanofi	Positive Positive Positive Positive
	D2, D3	2	24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,55,65,120,160	Epitope/Organon	Positive
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	D4, D6	3	No Bands	All Manufacturers	Negative
	D5	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech	Positive
			24,51,55,65,120,160	Epitope/Organon	Positive
			24,40,55,120,160	Genetic Systems/Sanofi	Positive

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.

* Cambridge Biotech/Calypte Biomedical

**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 January 23, 2001 shipment

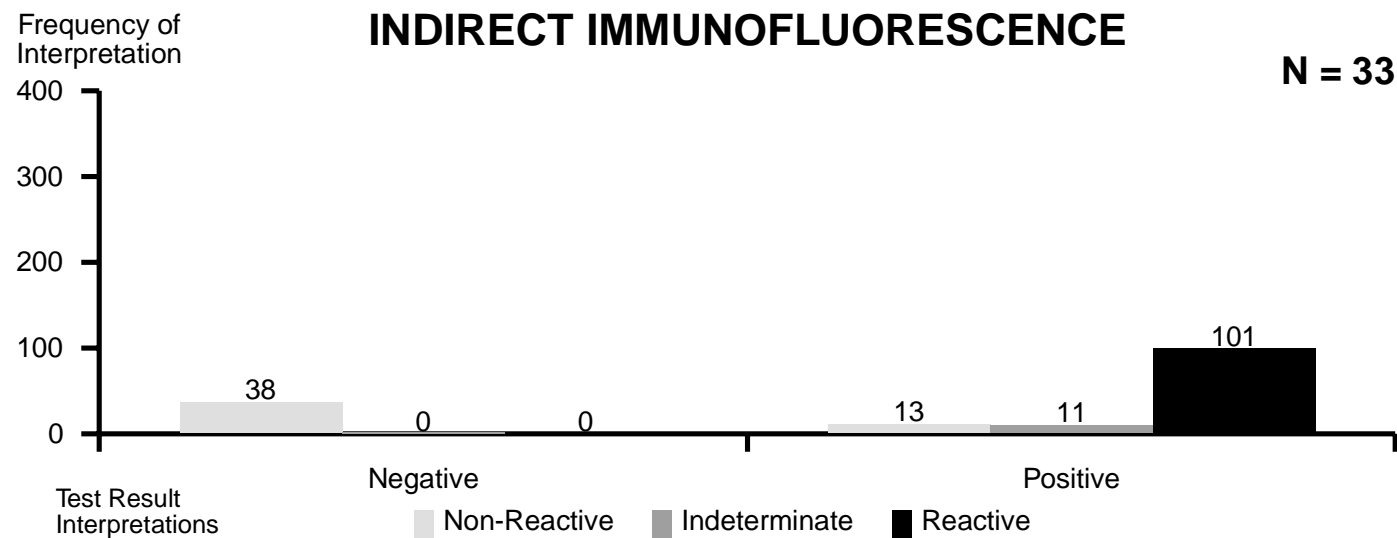
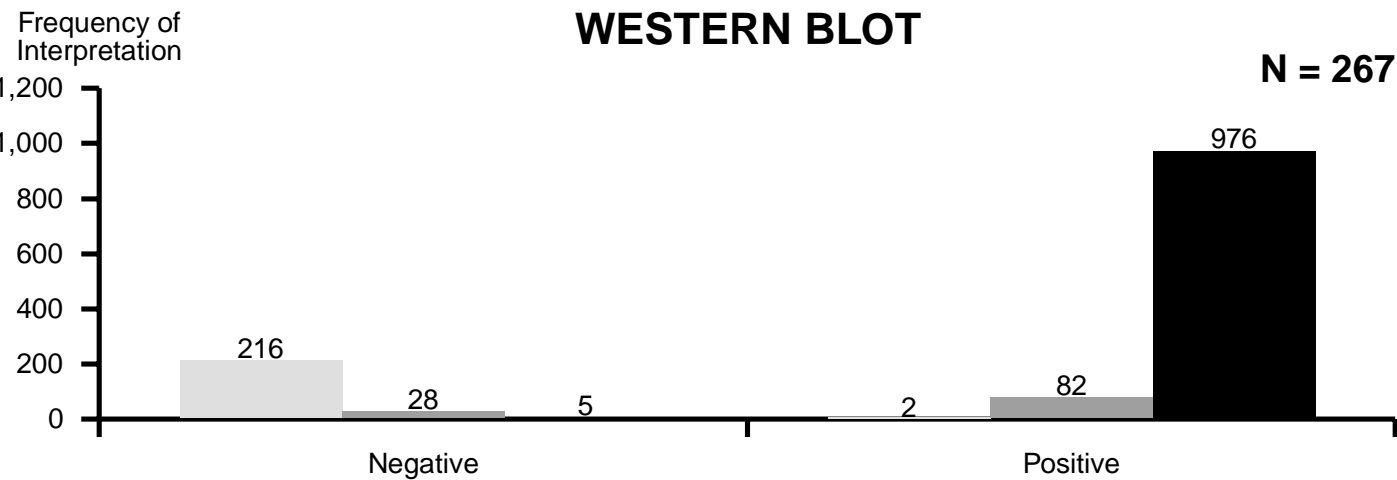
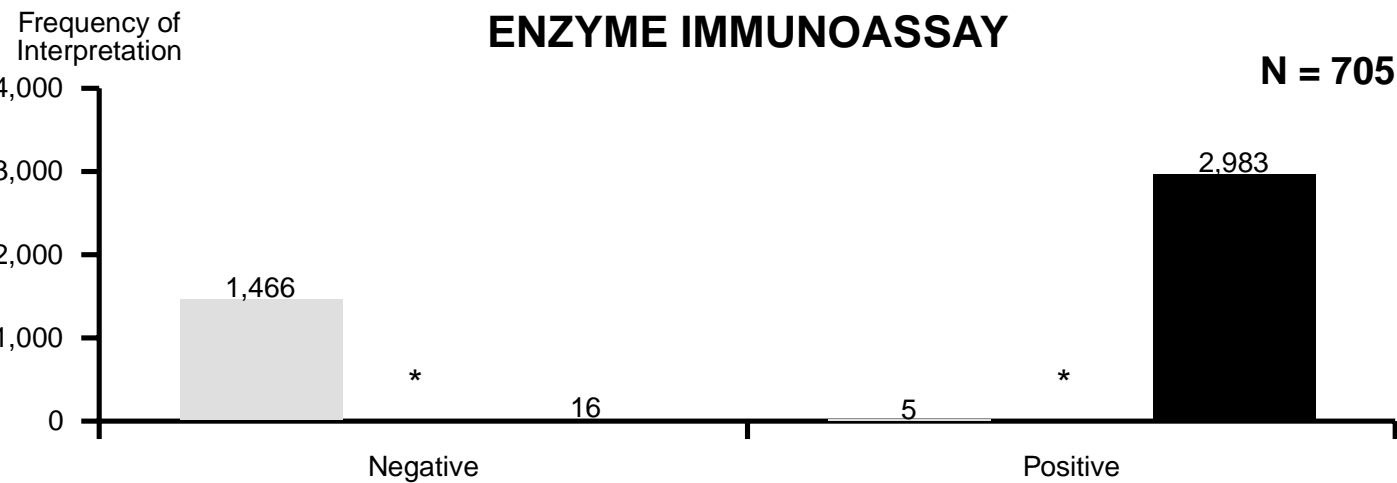


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the January 23, 2001 shipment

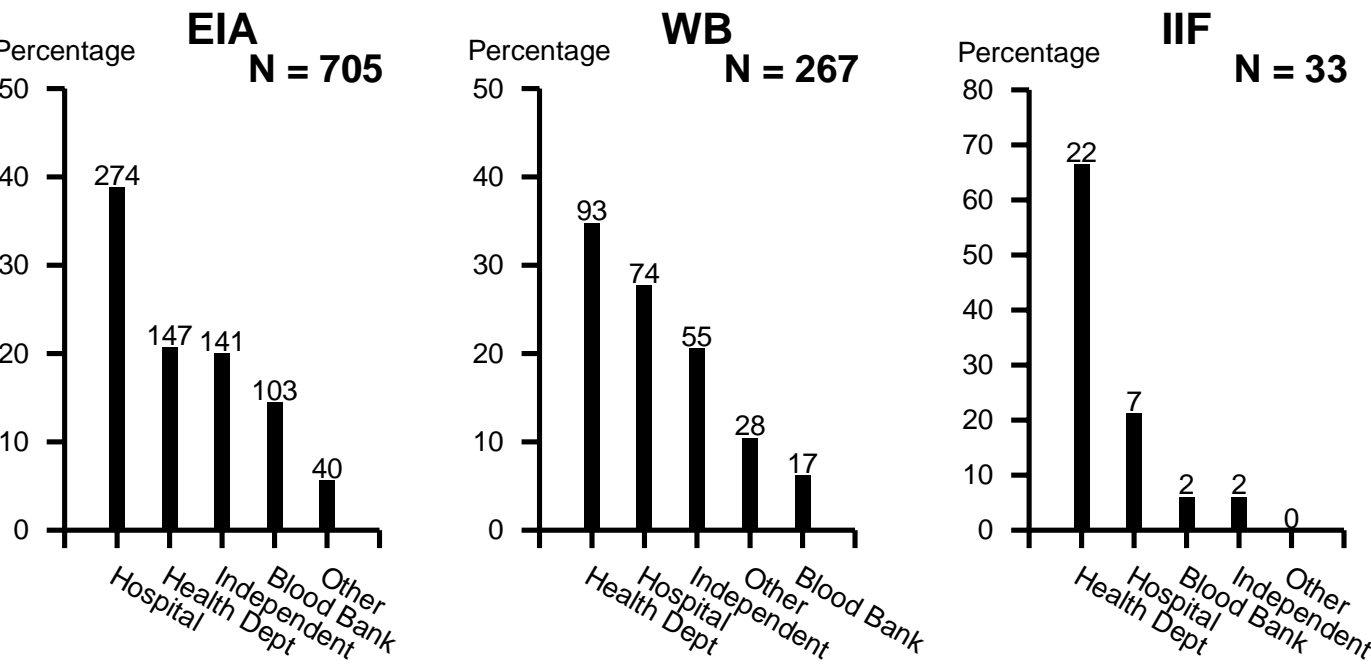


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the January 23, 2001 shipment

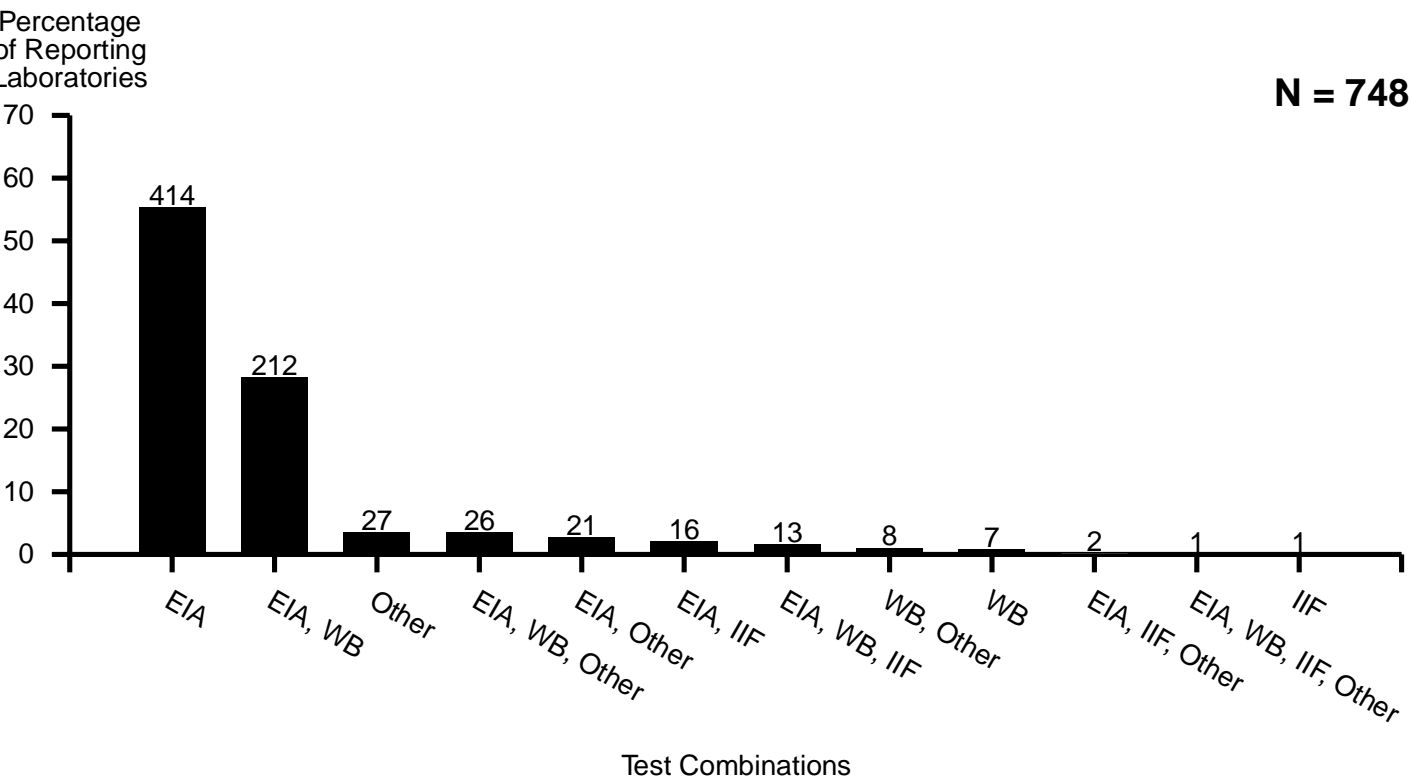


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the January 23, 2001 shipment

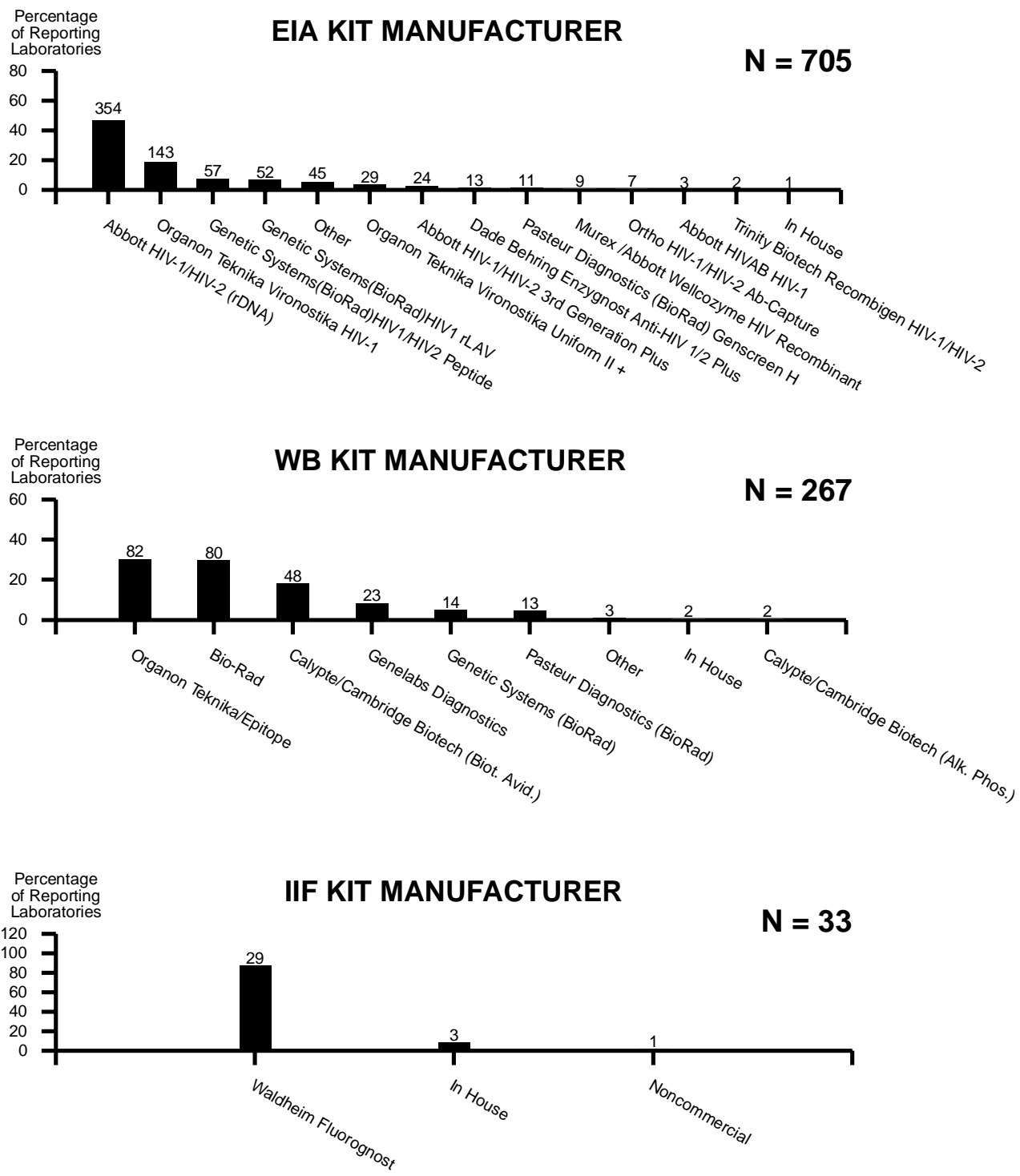


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 23, 2001 shipment

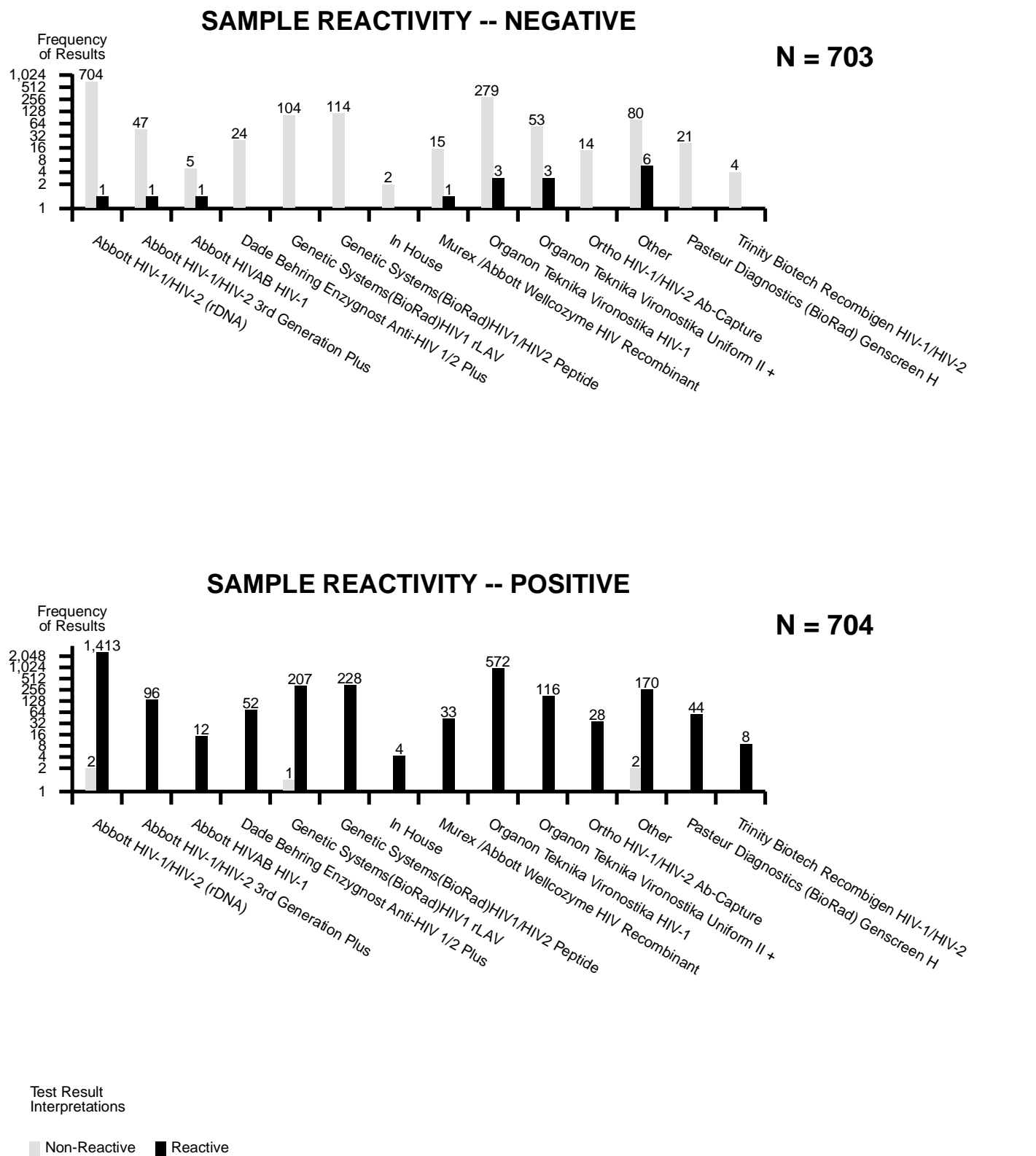
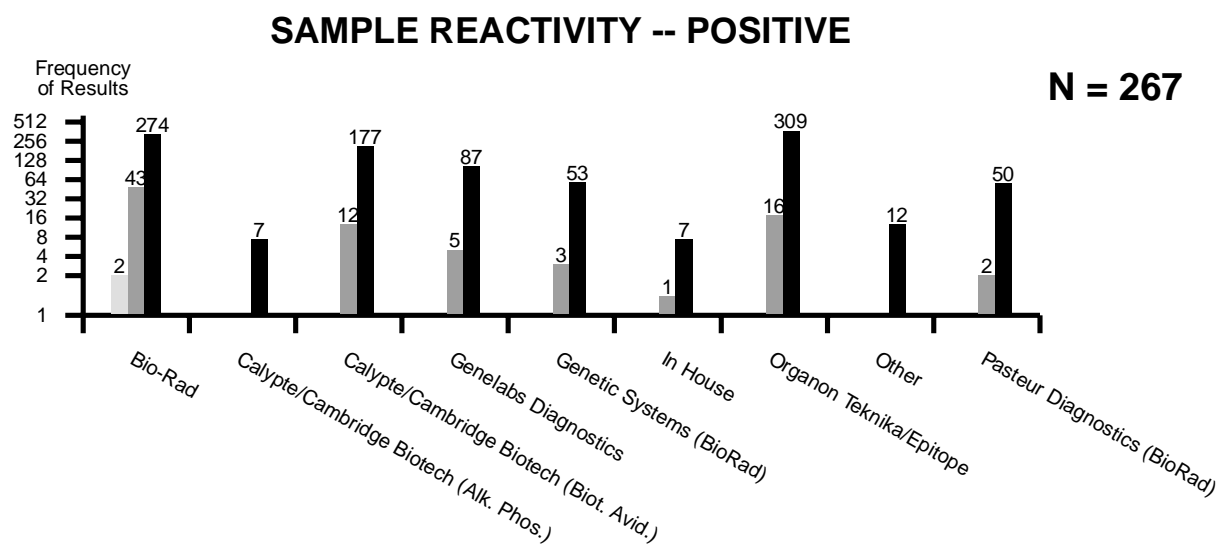
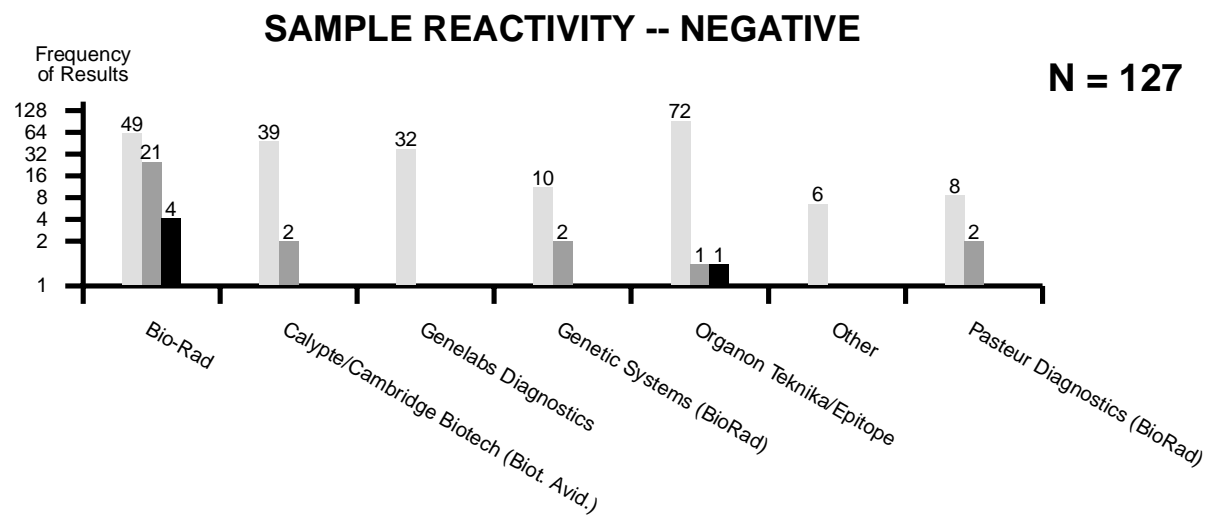


Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 23, 2001 shipment

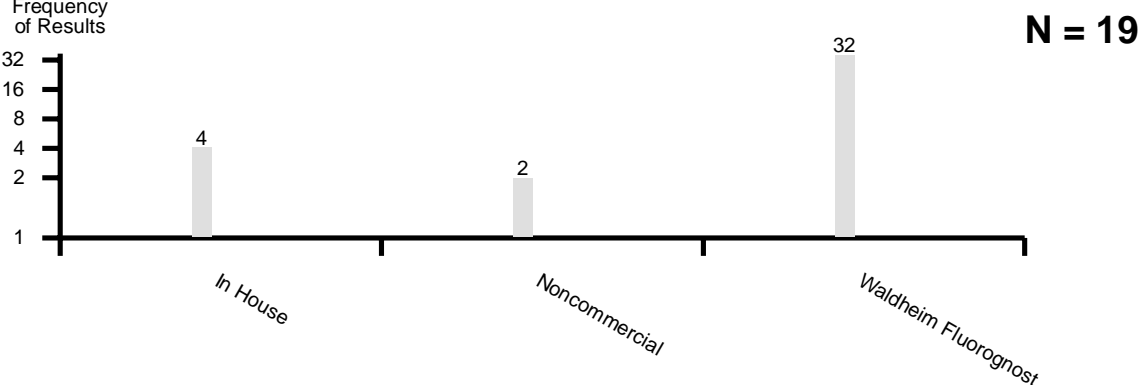


Test Result Interpretations

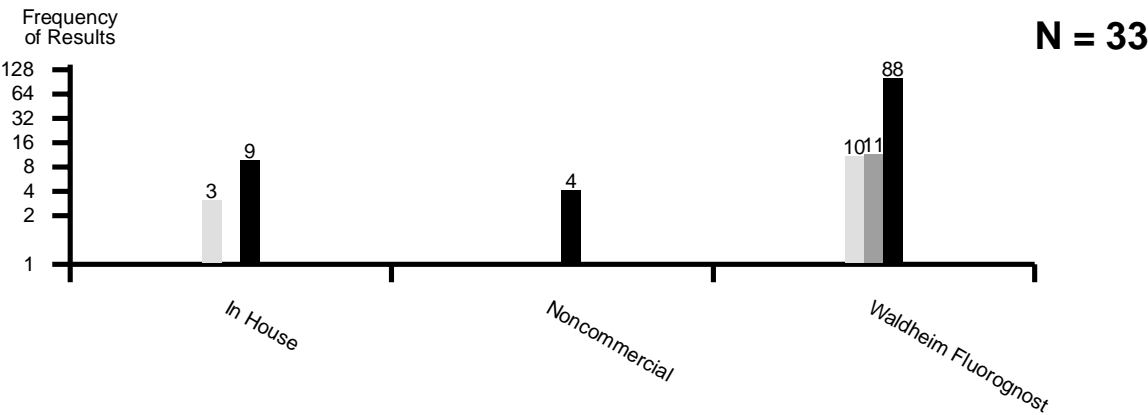
■ Non-Reactive ■ Indeterminate ■ Reactive

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 23, 2001 shipment

SAMPLE REACTIVITY -- NEGATIVE



SAMPLE REACTIVITY -- POSITIVE



Test Result Interpretations

■ Non-Reactive ■ Indeterminate ■ Reactive

Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 23, 2001 shipment

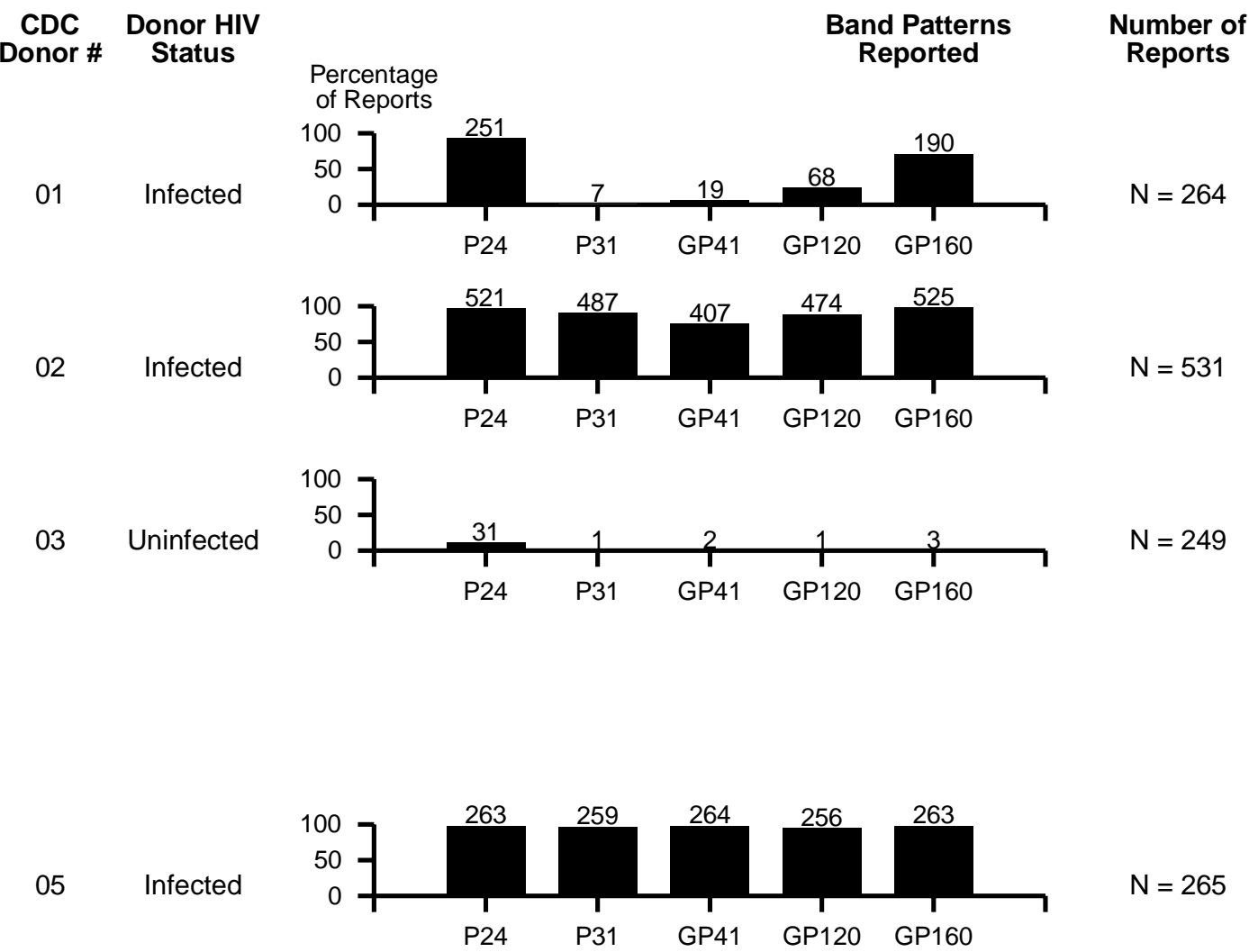


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 23, 2001 shipment

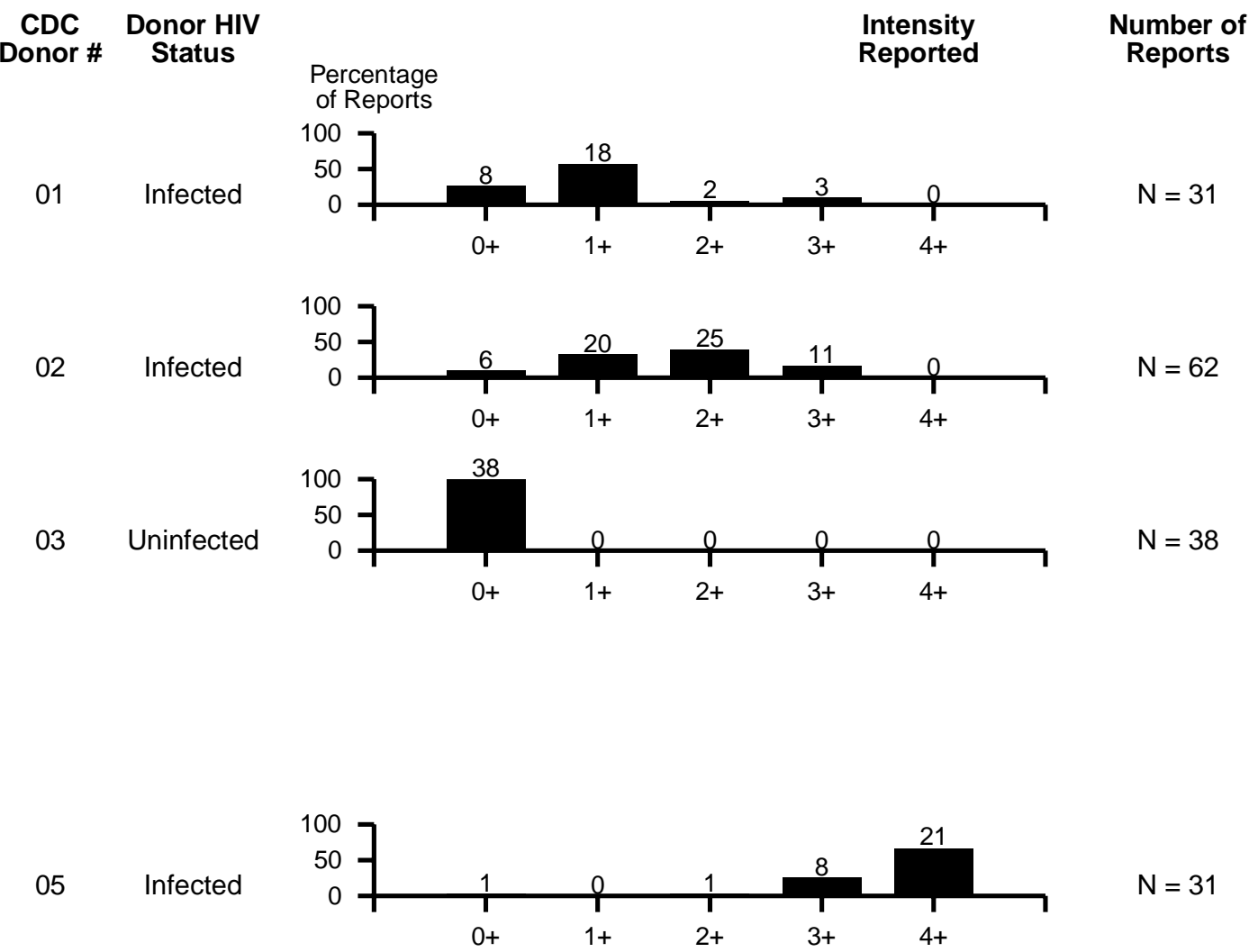
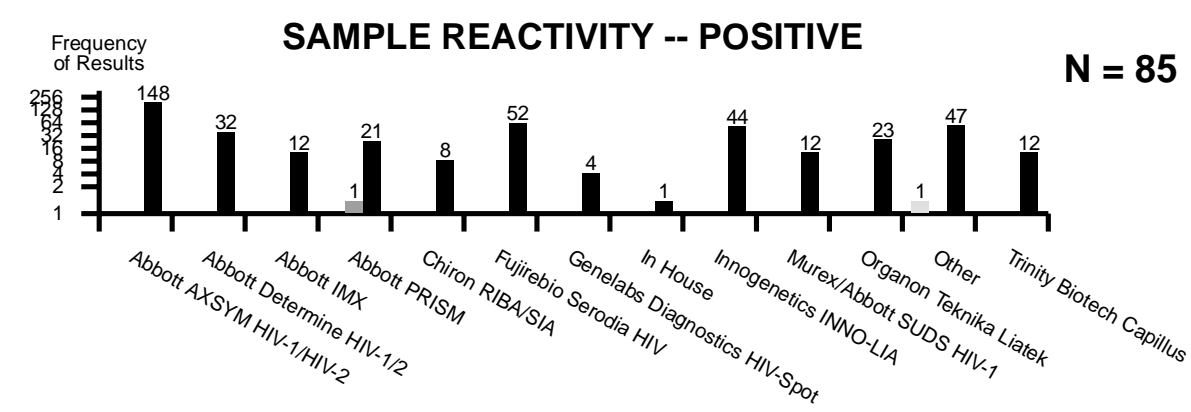
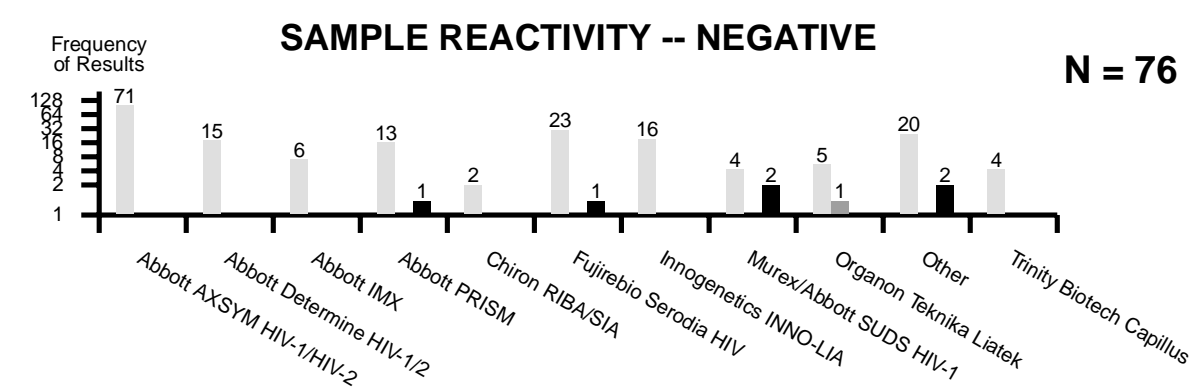
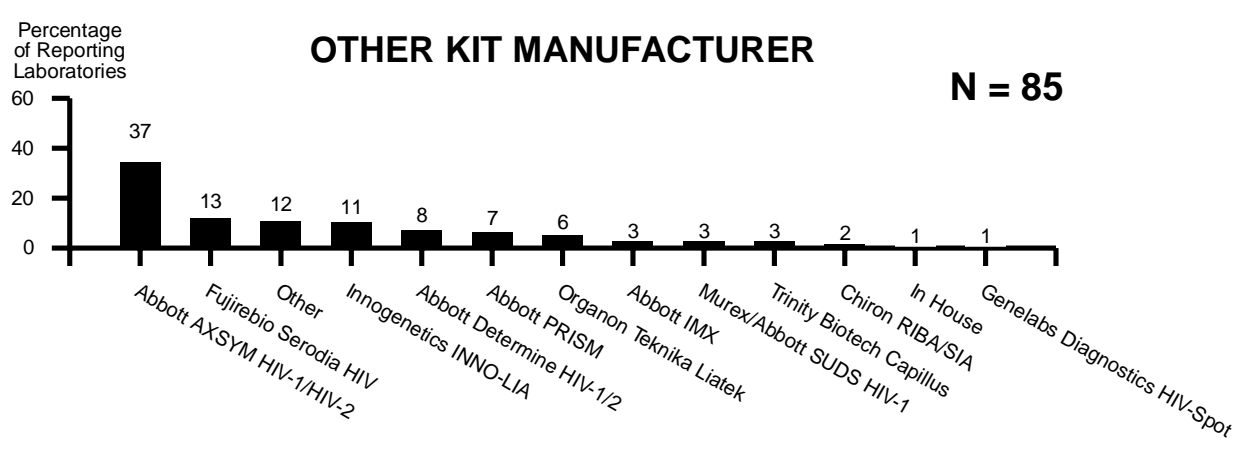


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the January 23, 2001 shipment



Test Result Interpretations

■ Non-Reactive ■ Indeterminate ■ Reactive