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 July 1999 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

Report of the July 1999 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
July 1999 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]	FINAL[4]	WB	IIF
A	A1 ,A3	1	Positive	Infected	___	___	___	___
	A2, A6	3	Positive	Infected	___	___	___	___
	A4	2	Negative	Uninfected	___	___	___	___
	A5	4	Positive	Infected	___	___	___	___
B	B1	4	Positive	Infected	___	___	___	___
	B2, B5	1	Positive	Infected	___	___	___	___
	B3, B6	3	Positive	Infected	___	___	___	___
	B4	2	Negative	Uninfected	___	___	___	___
C	C1	2	Negative	Uninfected	___	___	___	___
	C2, C4	1	Positive	Infected	___	___	___	___
	C3, C5	3	Positive	Infected	___	___	___	___
	C6	4	Positive	Infected	___	___	___	___
D	D1	4	Positive	Infected	___	___	___	___
	D2, D6	3	Positive	Infected	___	___	___	___
	D3,D5	1	Positive	Infected	___	___	___	___
	D4	2	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). The CDC WB interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

[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 July 1999 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, A3	1	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
	A2, A6	3	24,32,51,65,160 [3]	BioRad	Positive
			24,31,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
	A4	2	No Bands	All Manufacturers	Negative
	A5	4	24	BioRad	Indeterminate
			24,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
B	B1	4	24	BioRad	Indeterminate
			24,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
	B2, B5	1	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
	B3. B6	3	24,32,51,65,160	BioRad	Positive
			24,31,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
	B4	2	No Bands	All Manufacturers	Negative
C	C1	2	No Bands	All Manufacturers	Negative
	C2, C4	1	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
	C3, C5	3	24,32,51,65,160	BioRad	Positive
			24,31,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
	C6	4	24	BioRad	Indeterminate
			24,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
D	D1	4	24	BioRad	Indeterminate
			24,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
	D2, D6	3	24,32,51,65,160	BioRad	Positive
			24,31,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
	D3, D5	1	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
	D4	2	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.

[3] Note corrected BioRad WB band pattern for Donor 3

* 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 July 1999 shipment

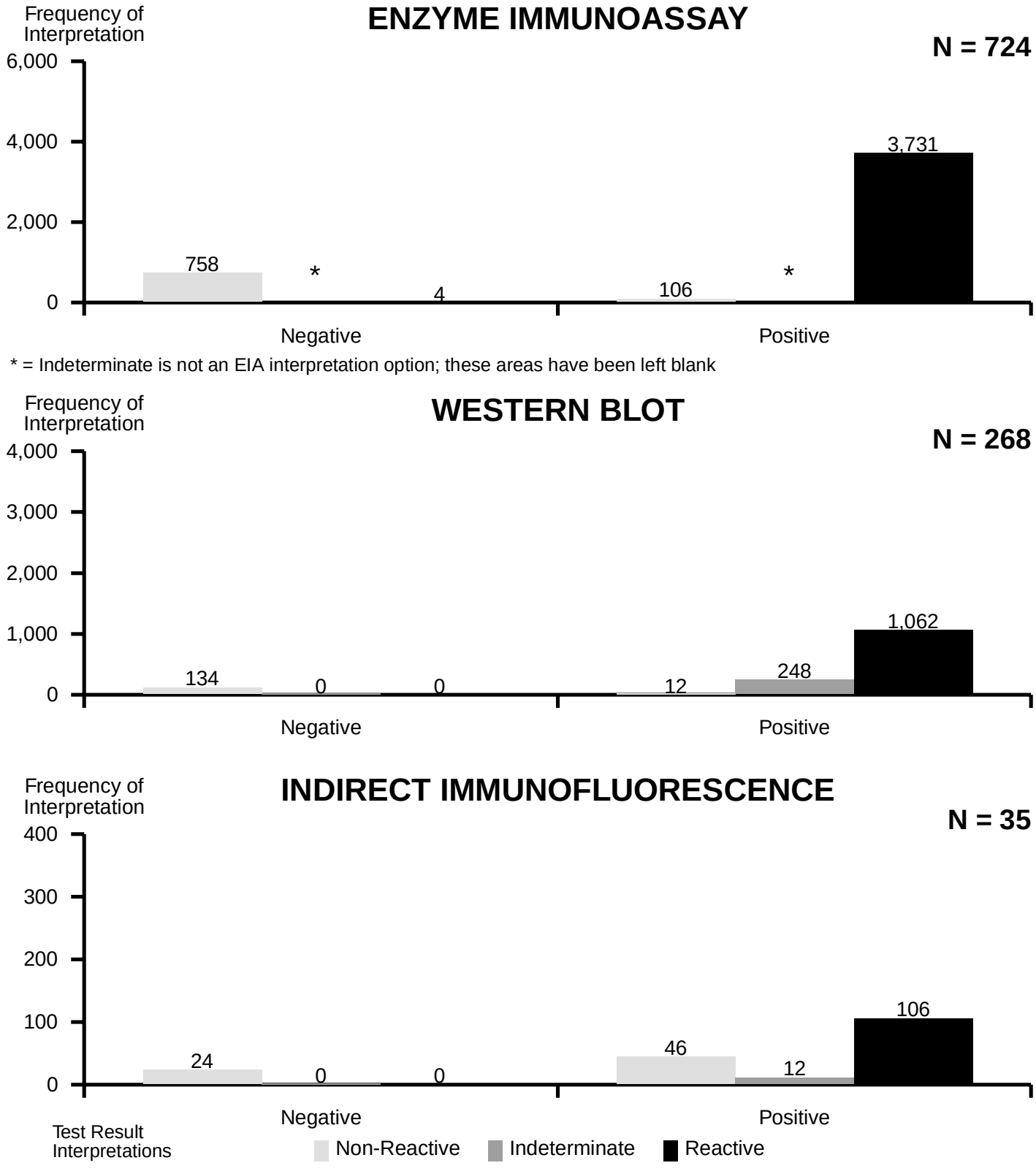


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the July 1999 shipment

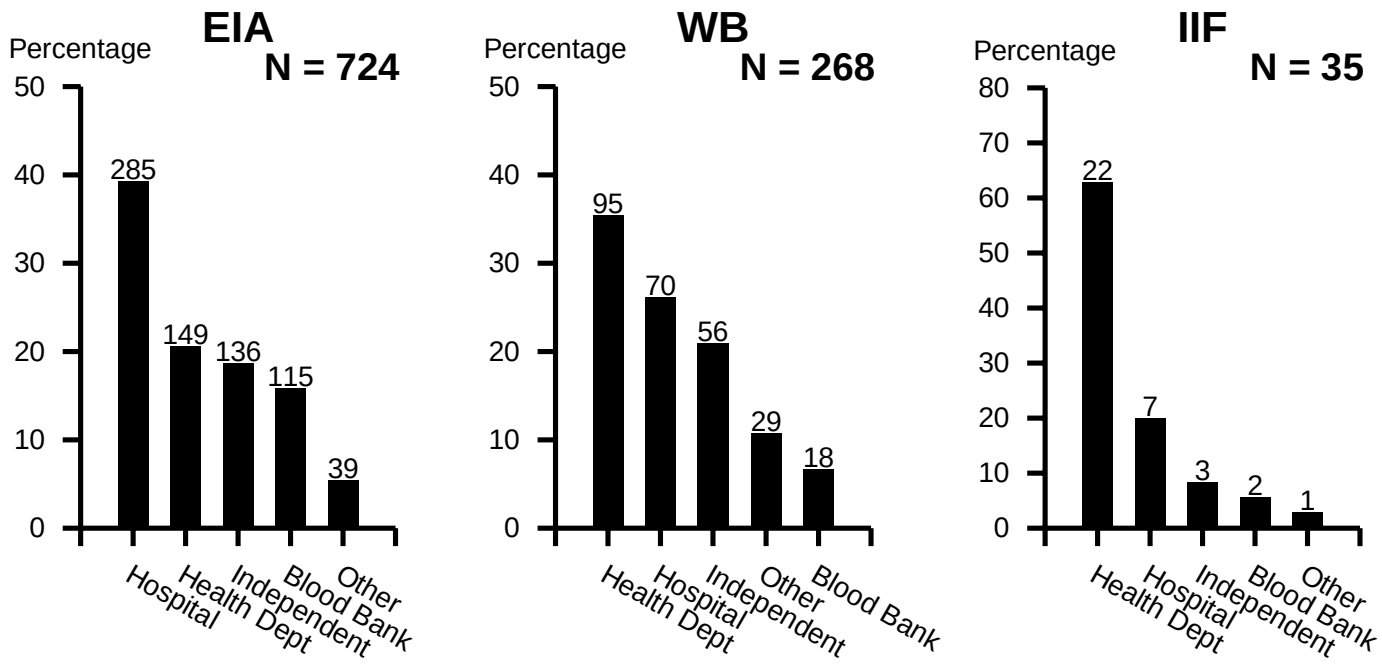


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the July 1999 shipment

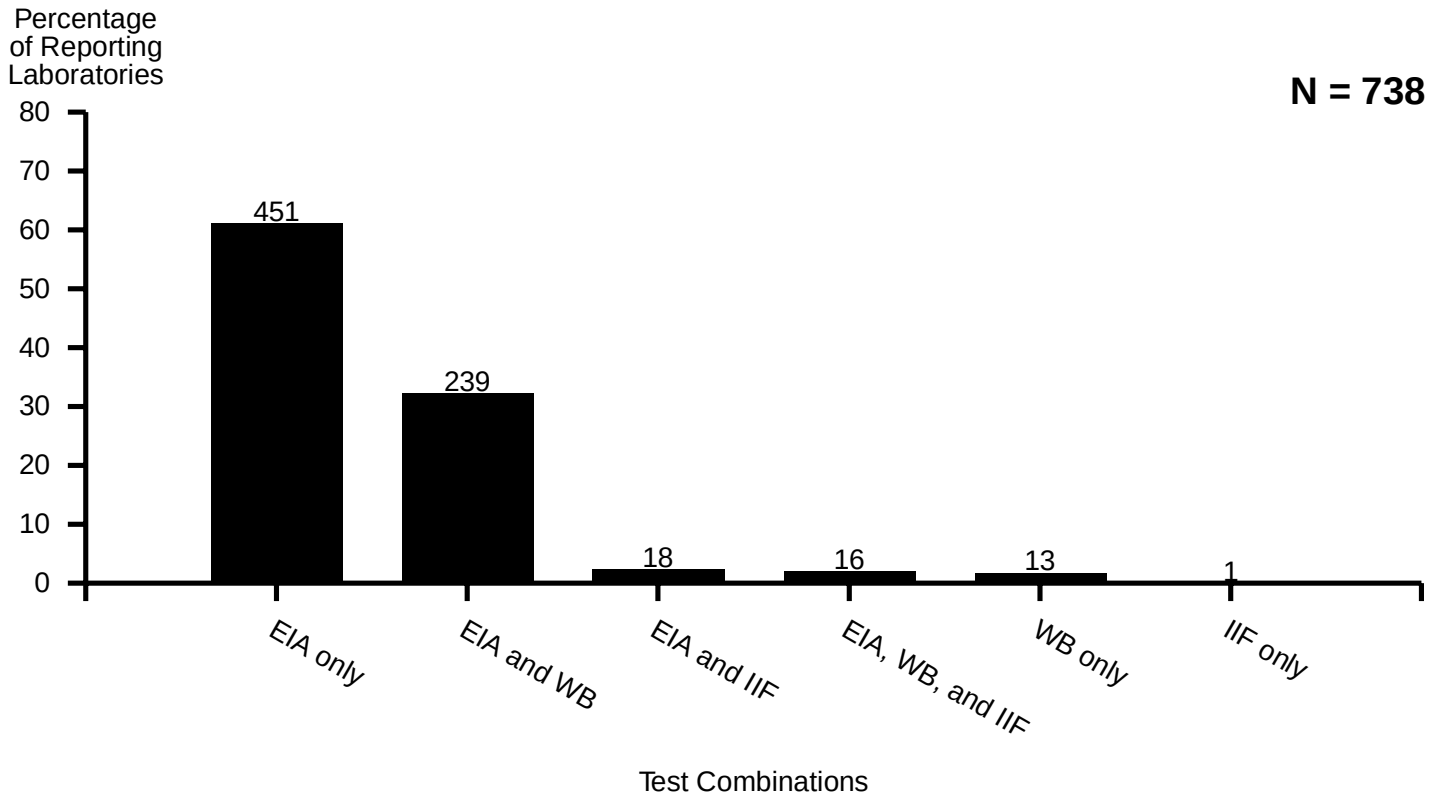
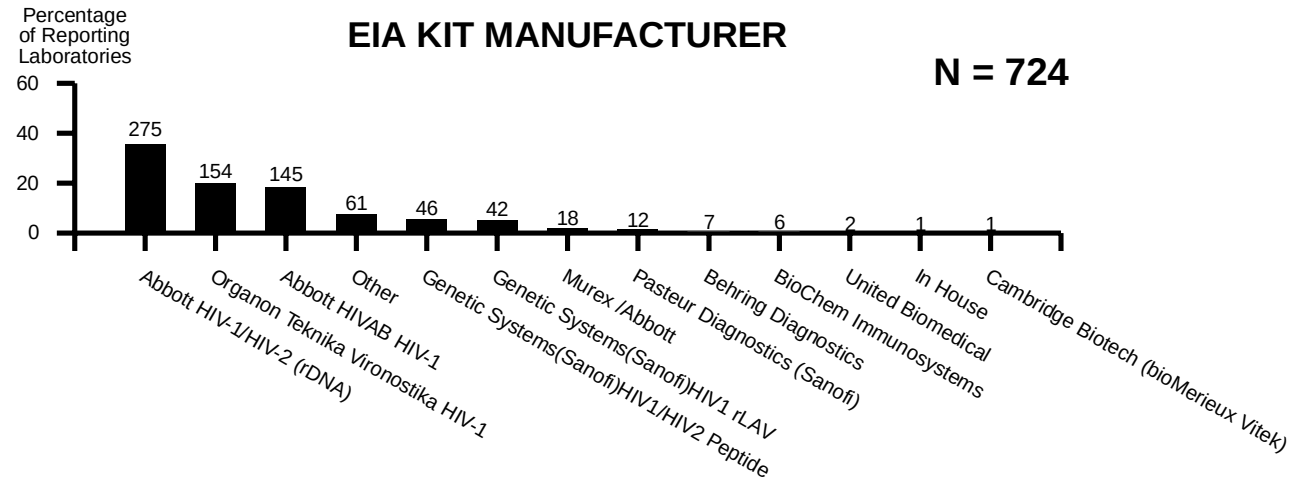
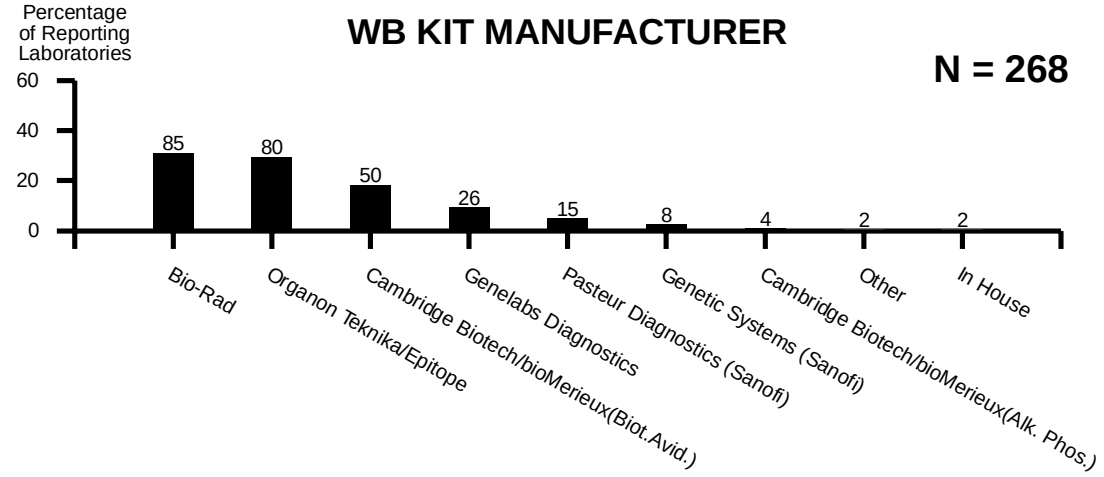


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the July 1999 shipment





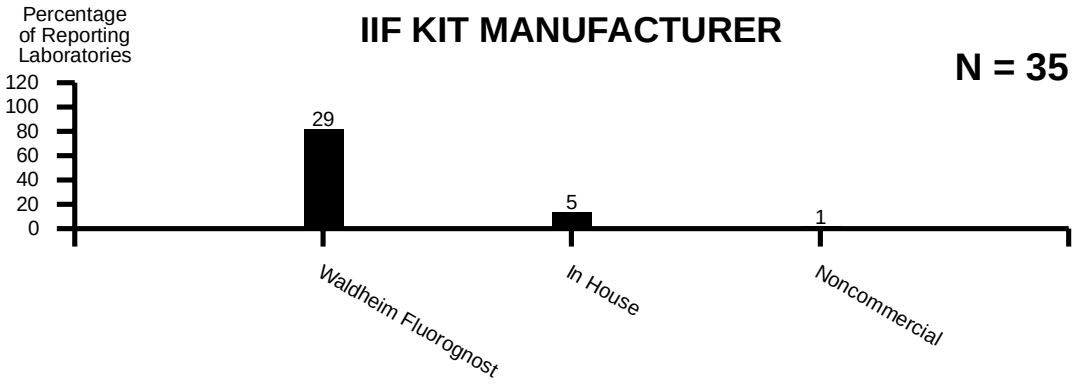
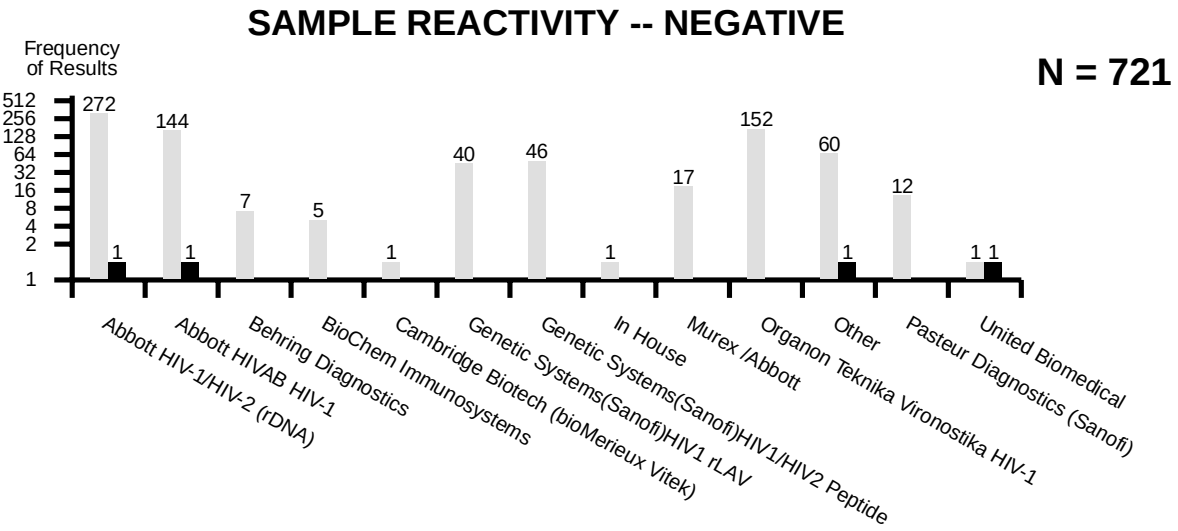


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 1999 shipment



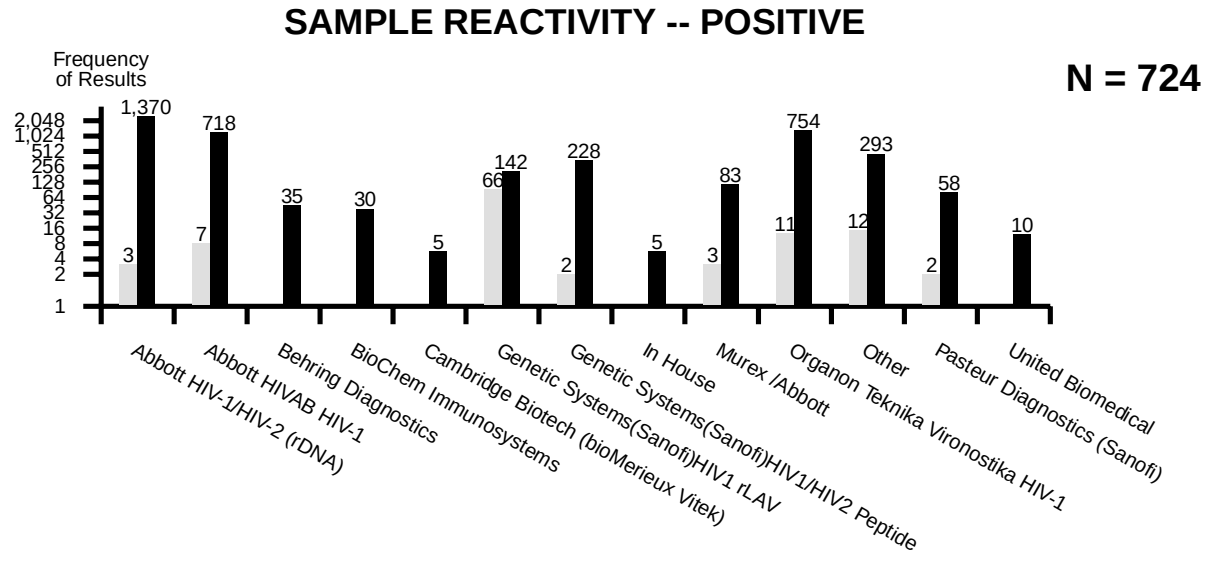
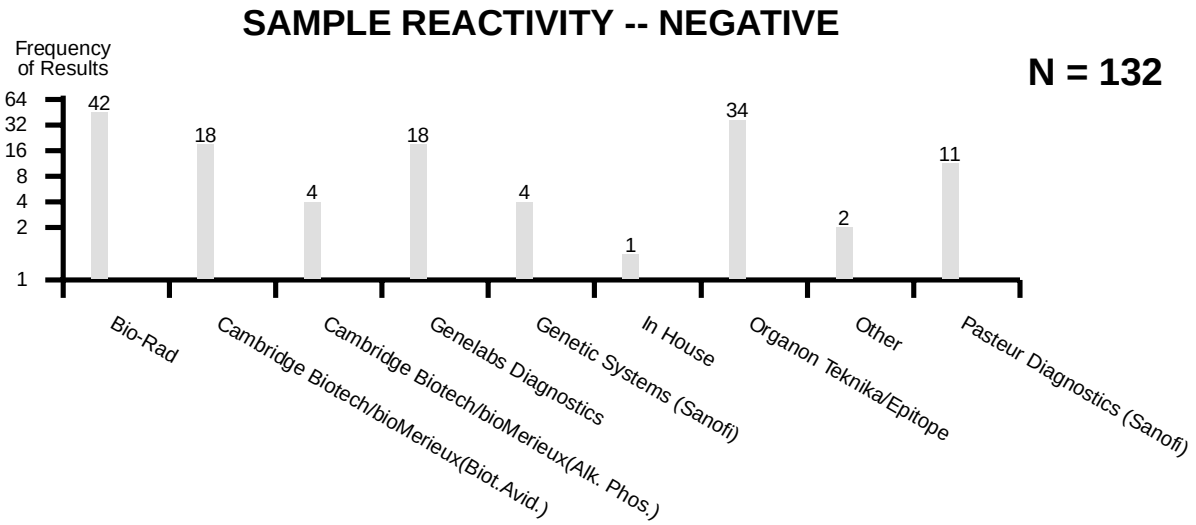
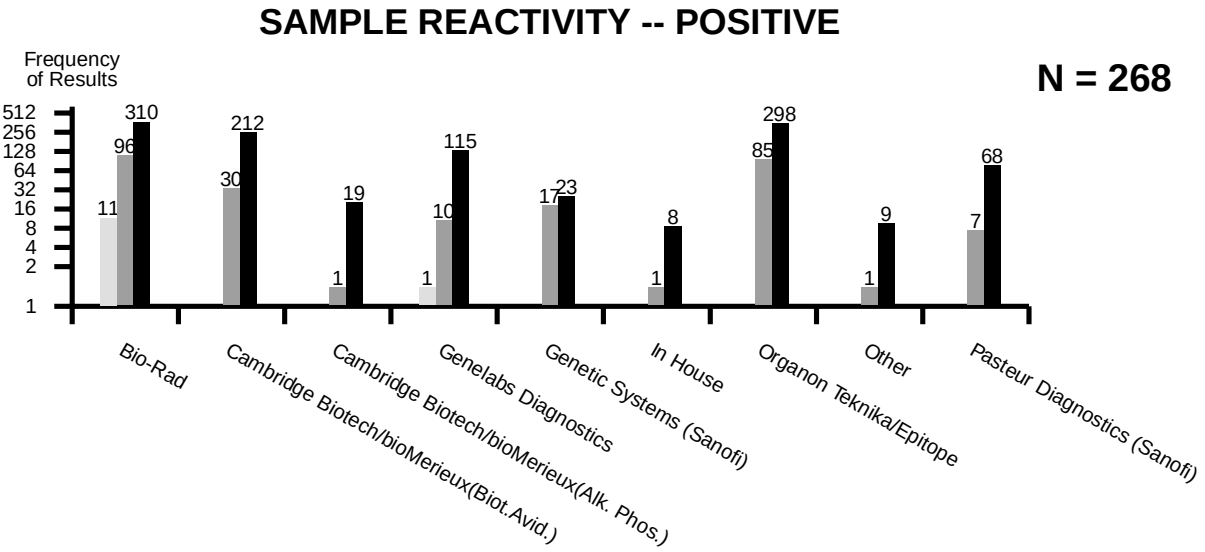


Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 1999 shipment





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 July 1999 shipment

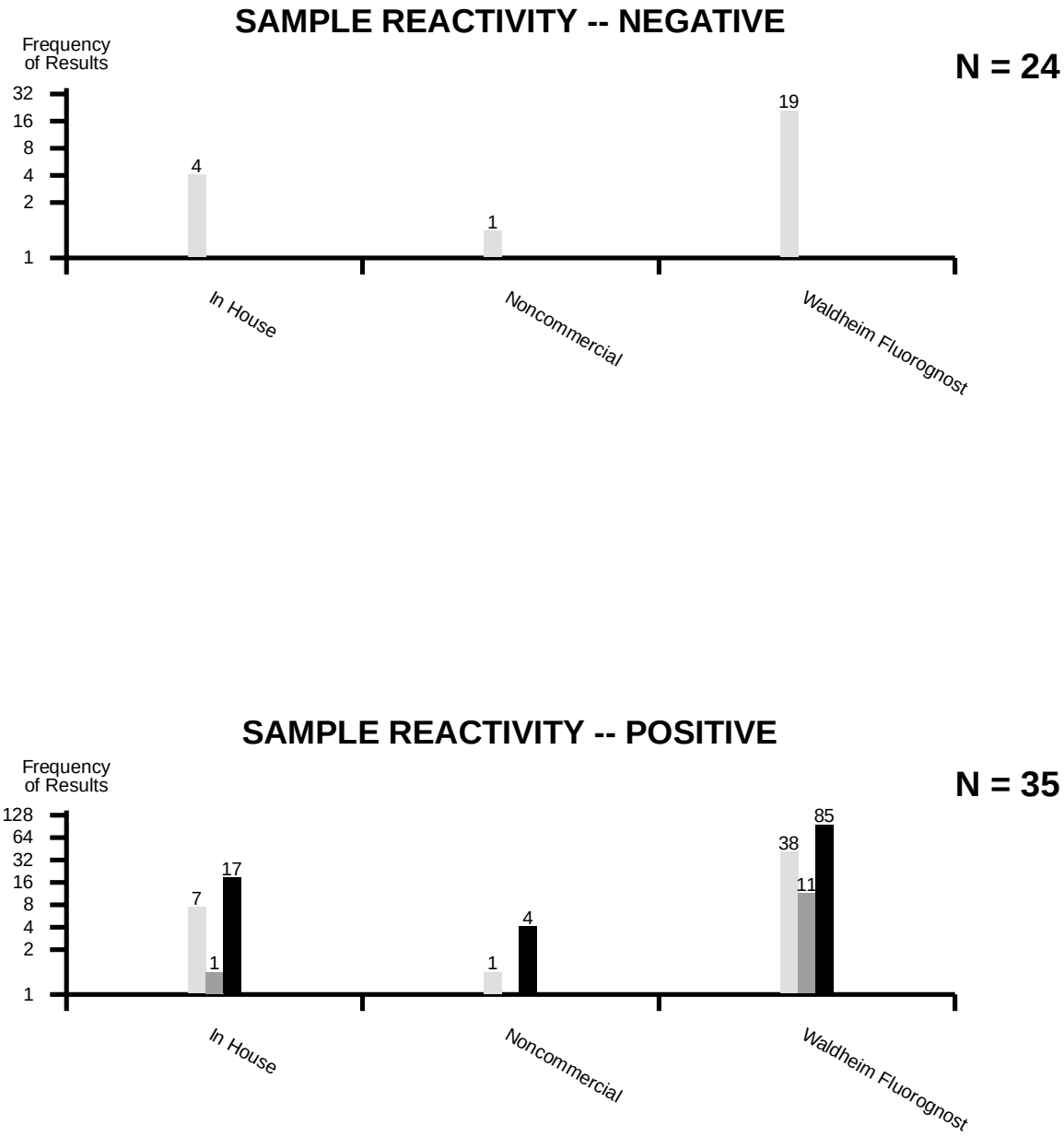


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the July 1999 shipment

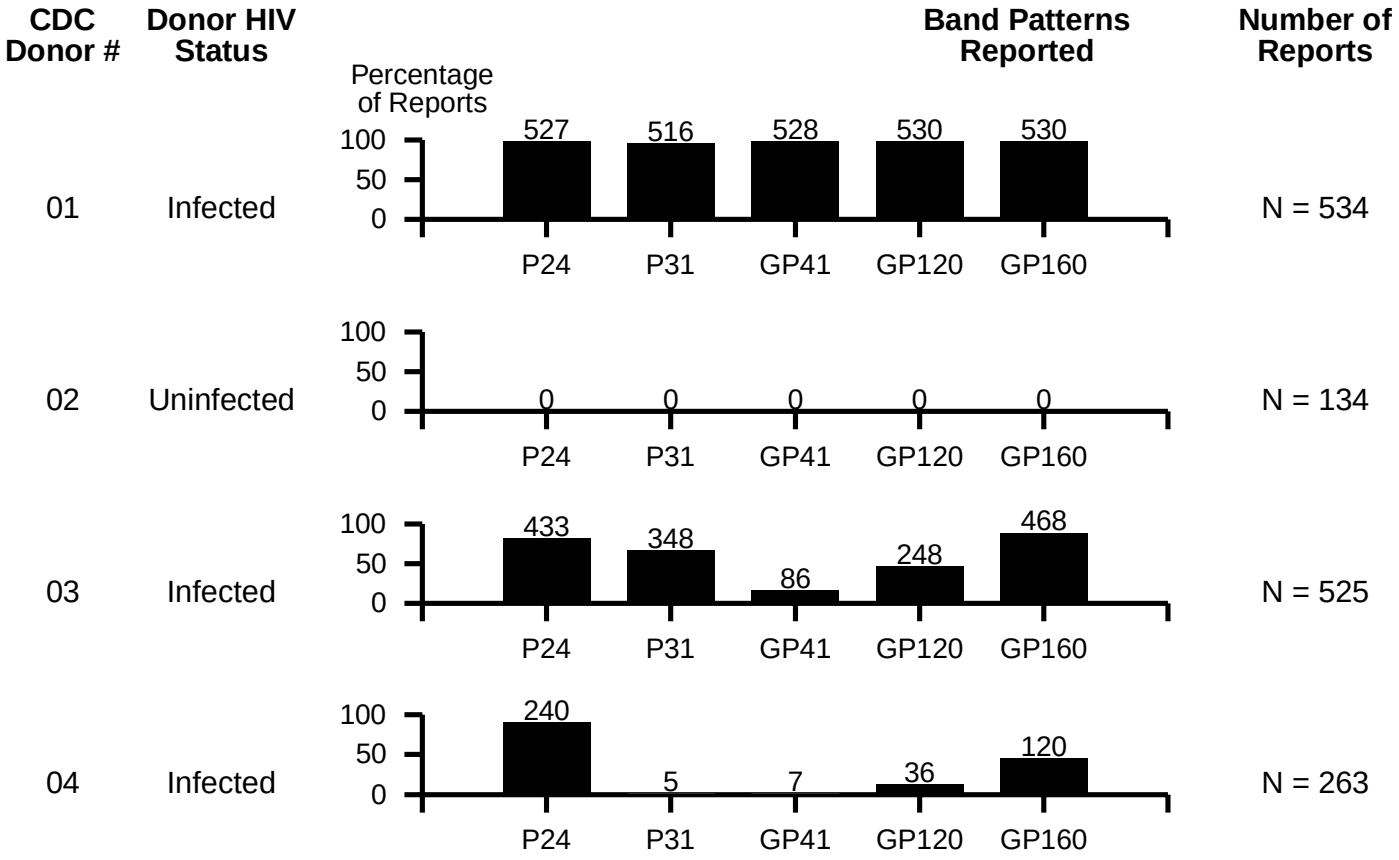


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the July 1999 shipment

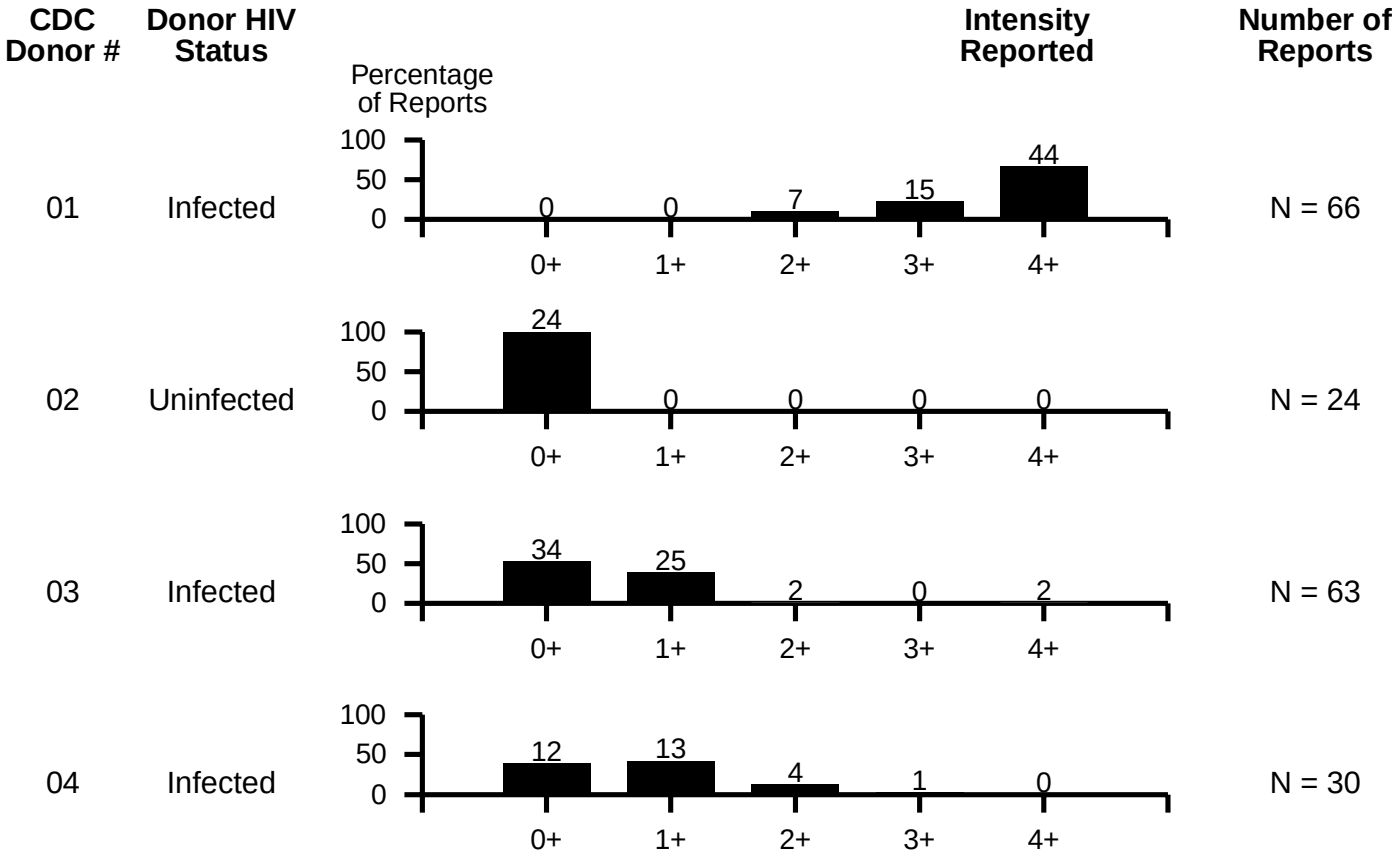


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the July 1999 shipment