

**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 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
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Atlanta, Georgia 30341-3724**



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U.S. Department of Health and Human Services.

Report of the July 2001 Human Immunodeficiency Virus Type I (HIV-1) Antibody Performance Evaluation Sample Testing Results Provided by Participant Laboratories in 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 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	5	Positive	Infected	—	—	—	—
	A2	4	Positive	Infected	—	—	—	—
	A3,A5	1	Negative	Uninfected	—	—	—	—
	A4,A6	3	Positive	Infected	—	—	—	—
B	B1	4	Positive	Infected	—	—	—	—
	B2,B4	1	Negative	Uninfected	—	—	—	—
	B3,B5	3	Positive	Infected	—	—	—	—
	B6	5	Positive	Infected	—	—	—	—
C	C1,C6	1	Negative	Uninfected	—	—	—	—
	C2,C4	3	Positive	Infected	—	—	—	—
	C3	4	Positive	Infected	—	—	—	—
	C5	5	Positive	Infected	—	—	—	—
D	D1,D3	3	Positive	Infected	—	—	—	—
	D2,D5	1	Negative	Uninfected	—	—	—	—
	D4	5	Positive	Infected	—	—	—	—
	D6	4	Positive	Infected	—	—	—	—

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

**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 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	5	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech* Genetic Systems/Sanofi	Positive Positive
	A2	4	24,160 24,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	A3, A5	1	No Bands	All Manufacturers	Negative
	A4, A6	3	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
B	B1	4	24,160 24,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	B2, B4	1	No Bands	All Manufacturers	Negative
	B3, B5	3	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	B6	5	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
C	C1, C6	1	No Bands	All Manufacturers	Negative
	C2, C4	3	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	C3	4	24,160 24,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	C5	5	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
D	D1, D3	3	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	D2, D5	1	No Bands	All Manufacturers	Negative
	D4	5	17,24,31,41,51,55,66,120,160 18,24,31,40,41,51,55,65,120,160	Cambridge Biotech Genetic Systems/Sanofi	Positive Positive
	D6	4	24,160 24,160	Cambridge Biotech Genetic Systems/Sanofi	Positive 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 July 2001 shipment

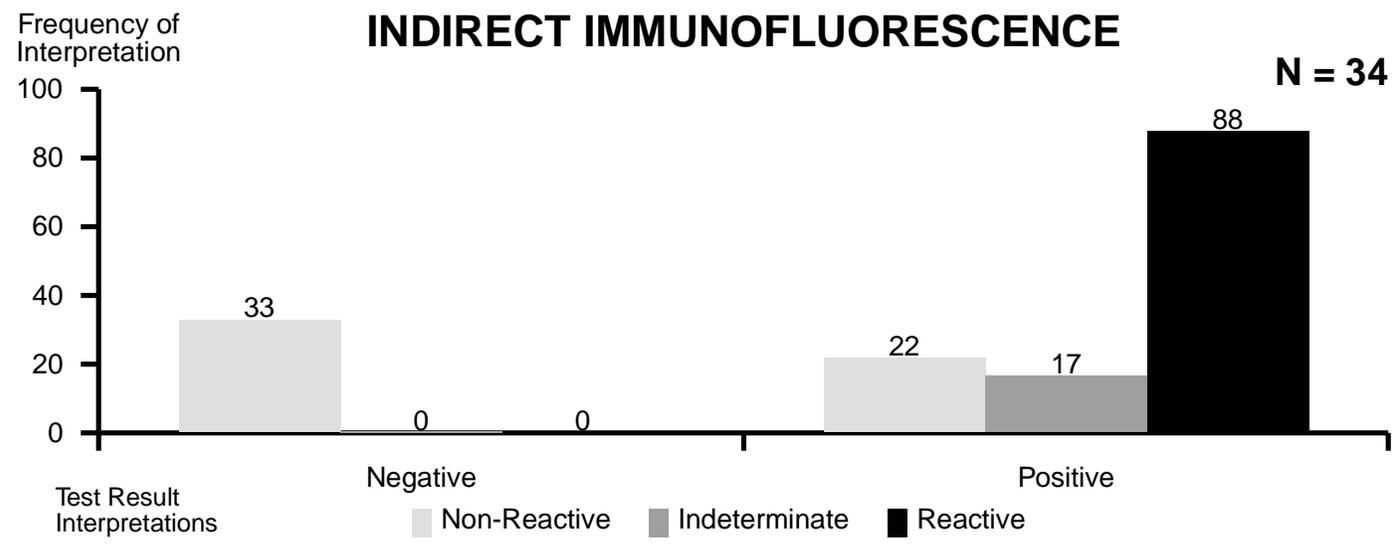
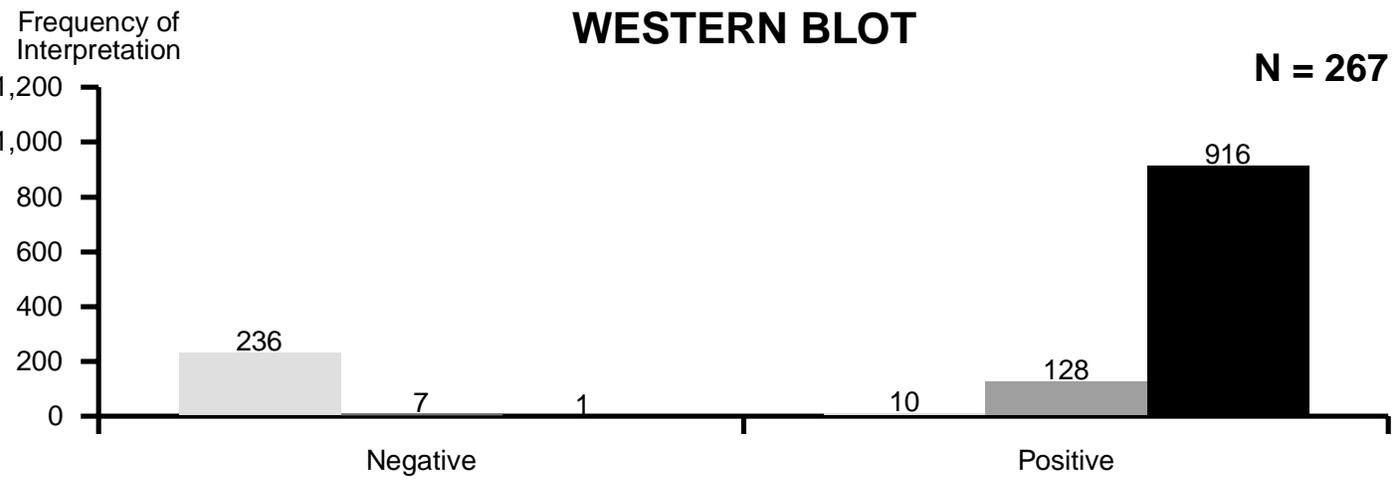
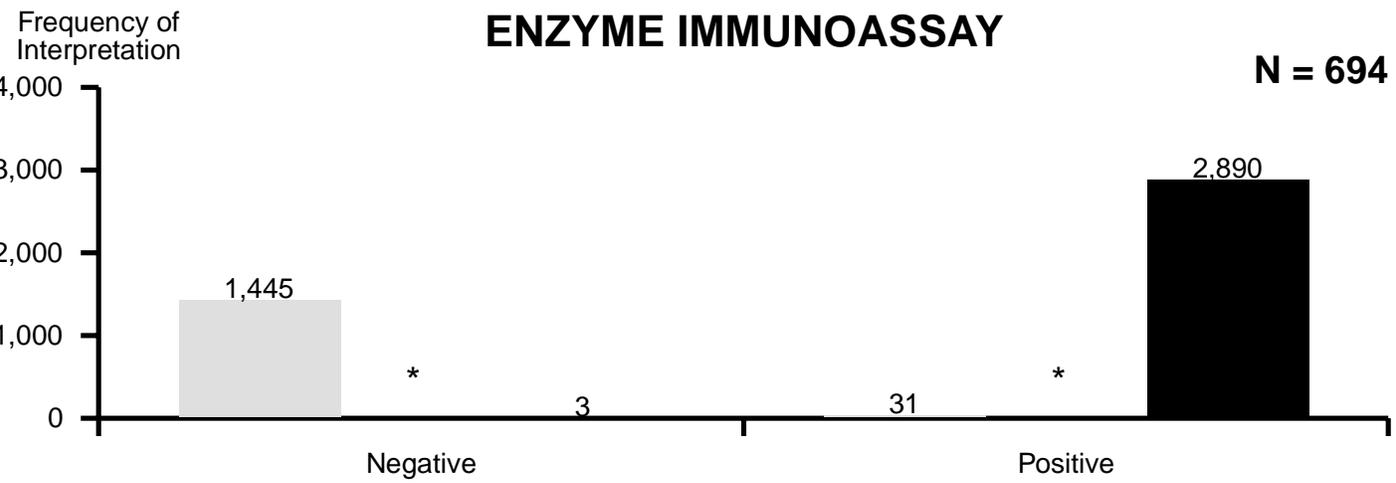


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the July 2001 shipment

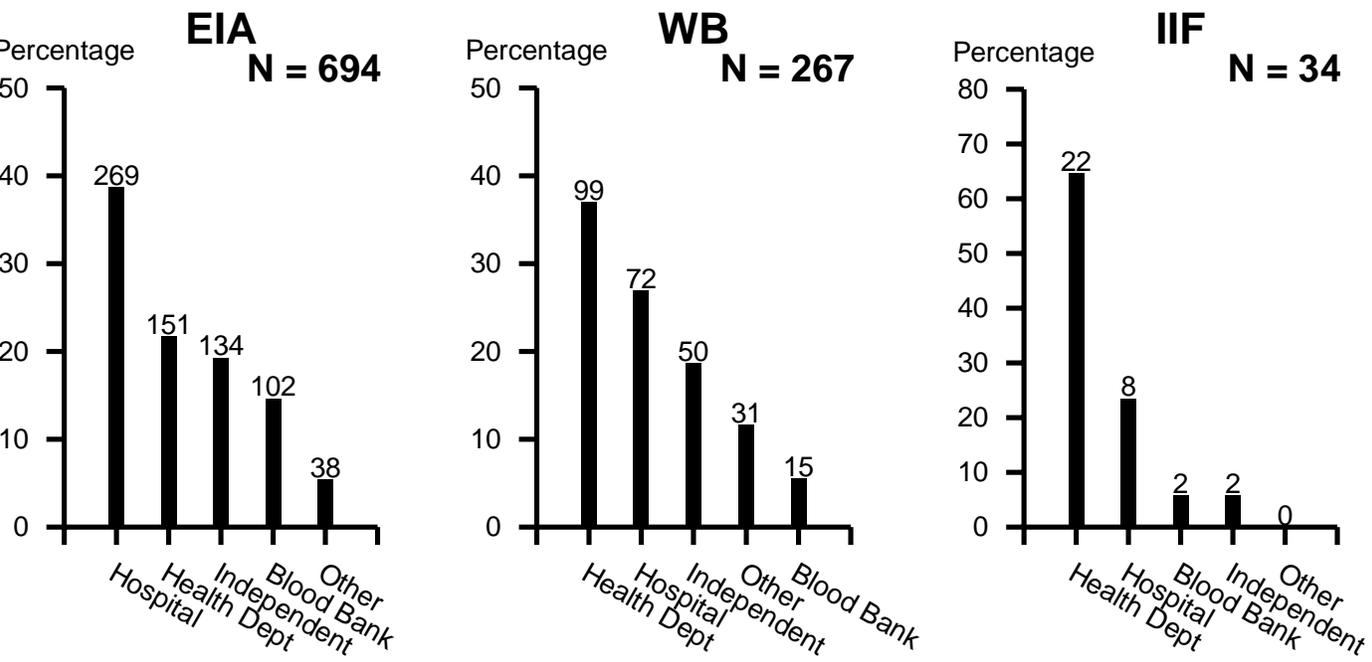


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the July 2001 shipment

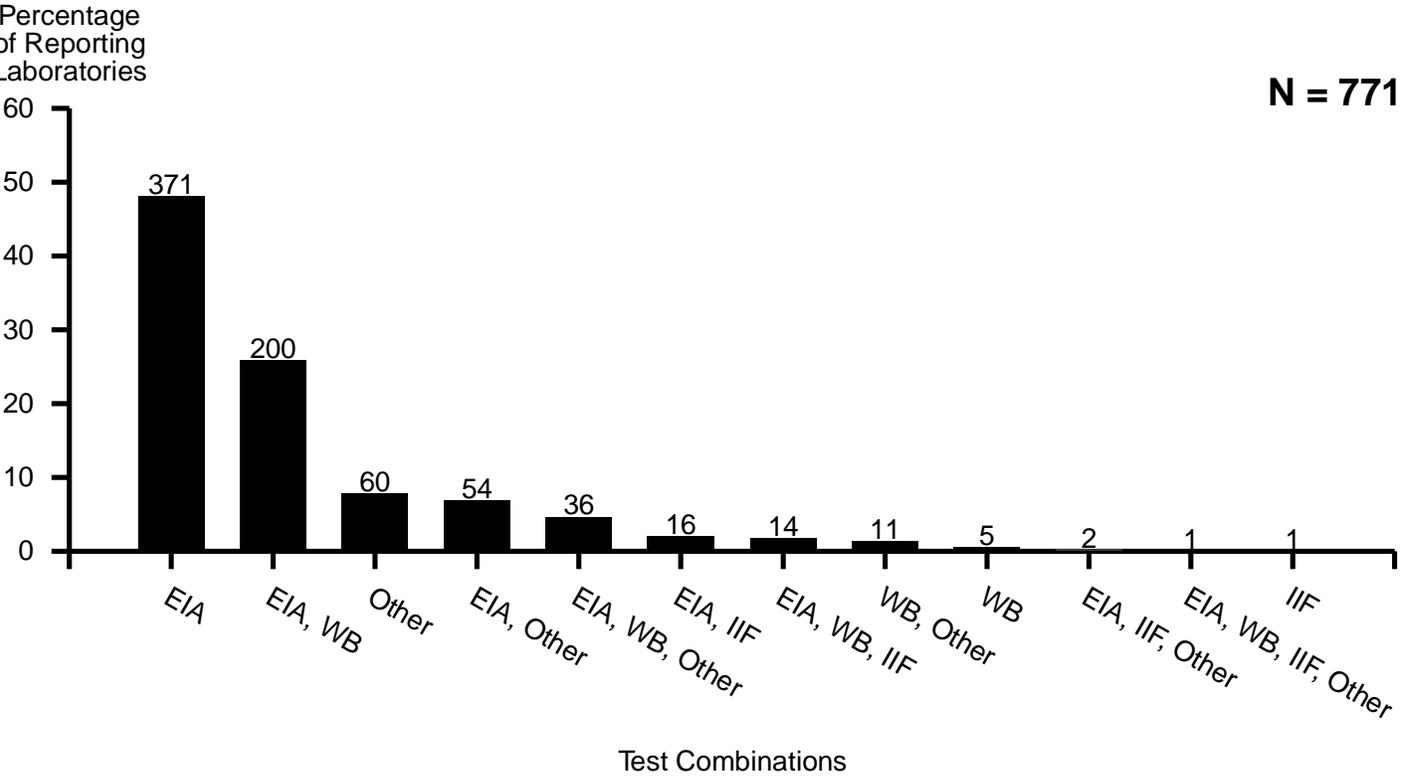


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the July 2001 shipment

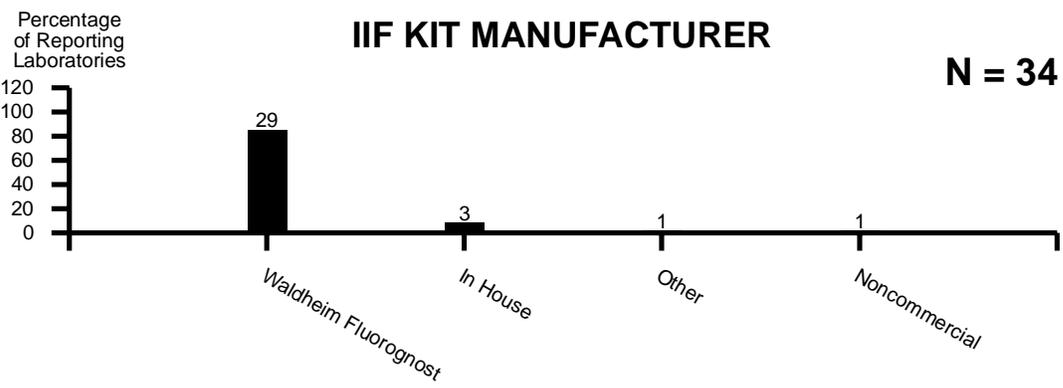
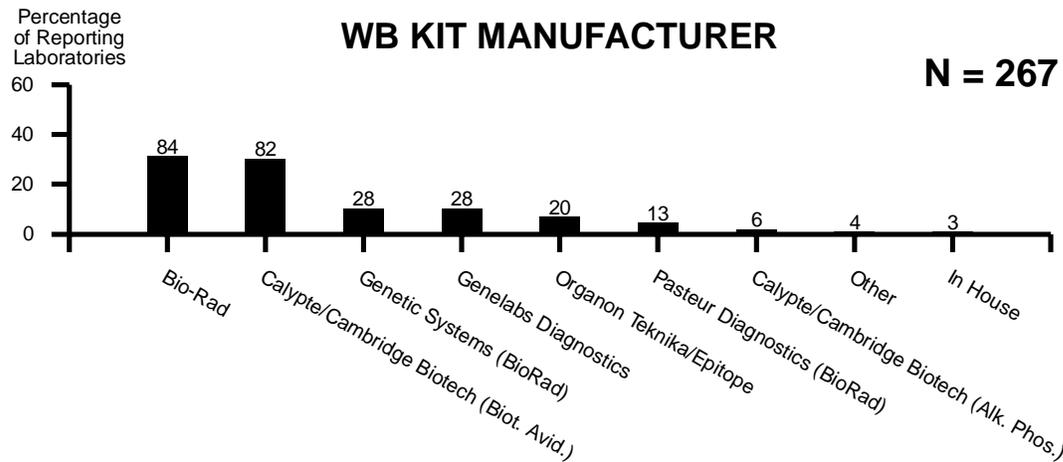
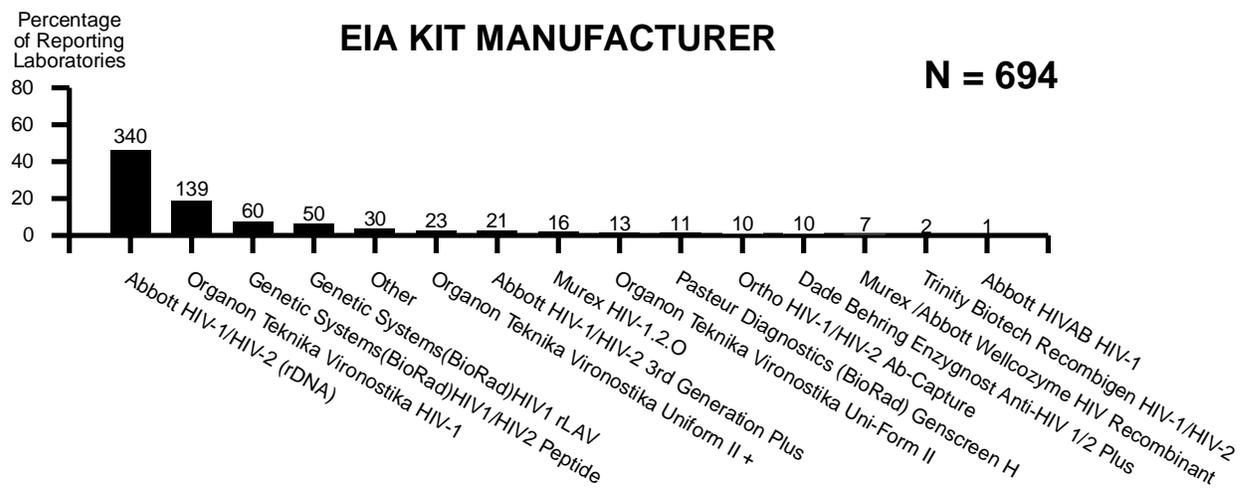
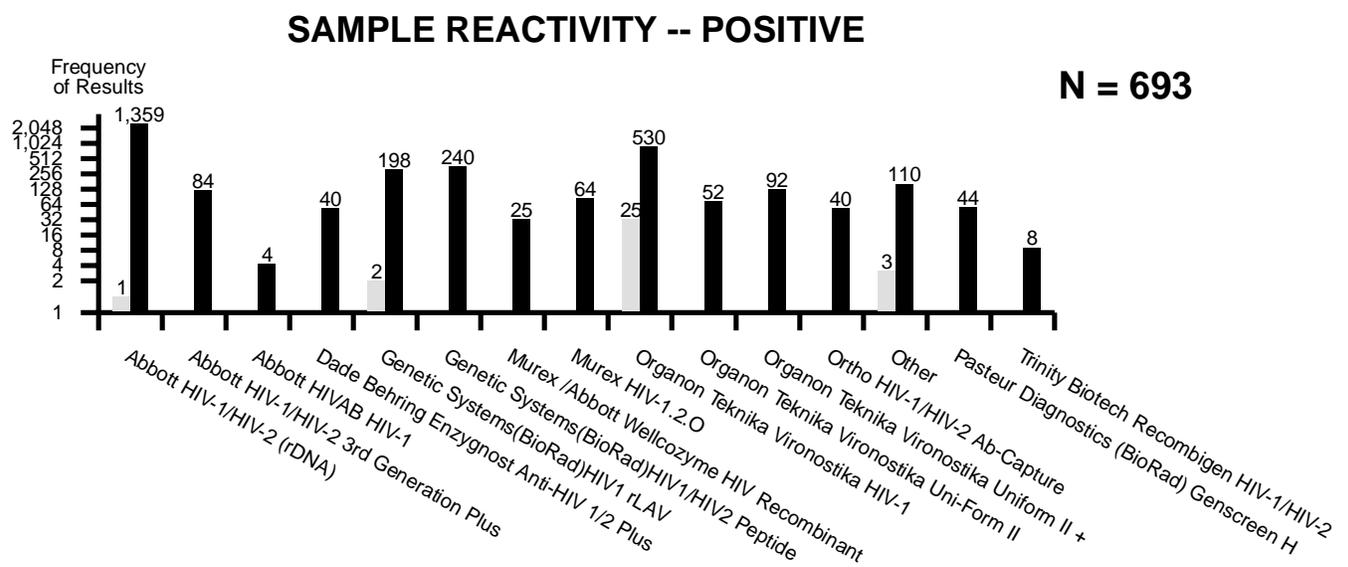
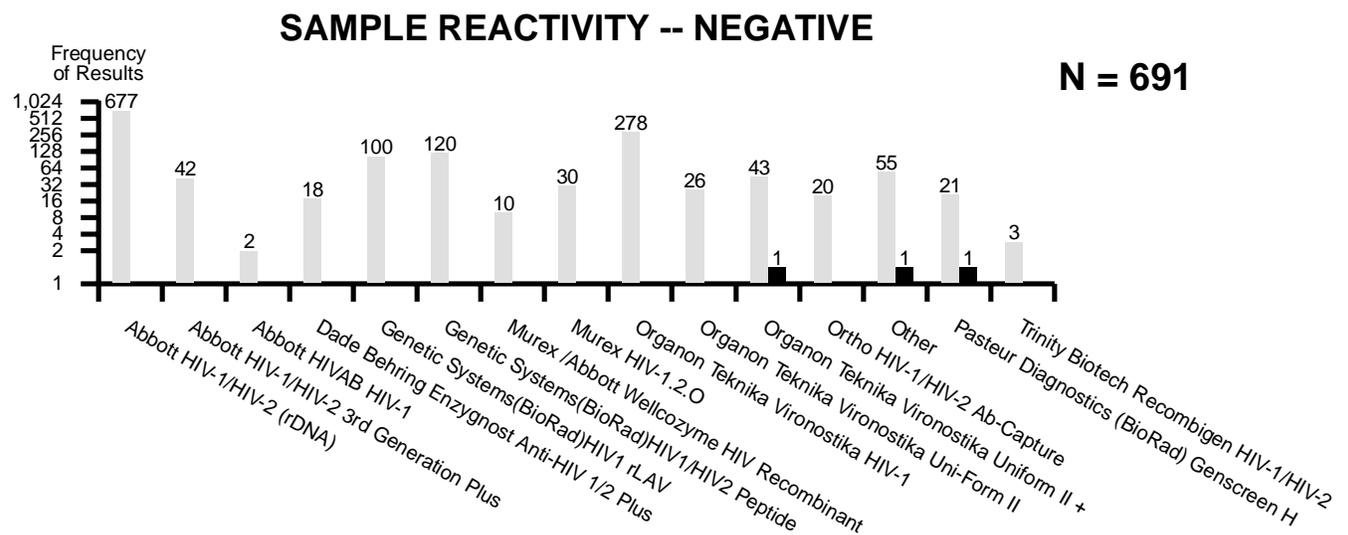


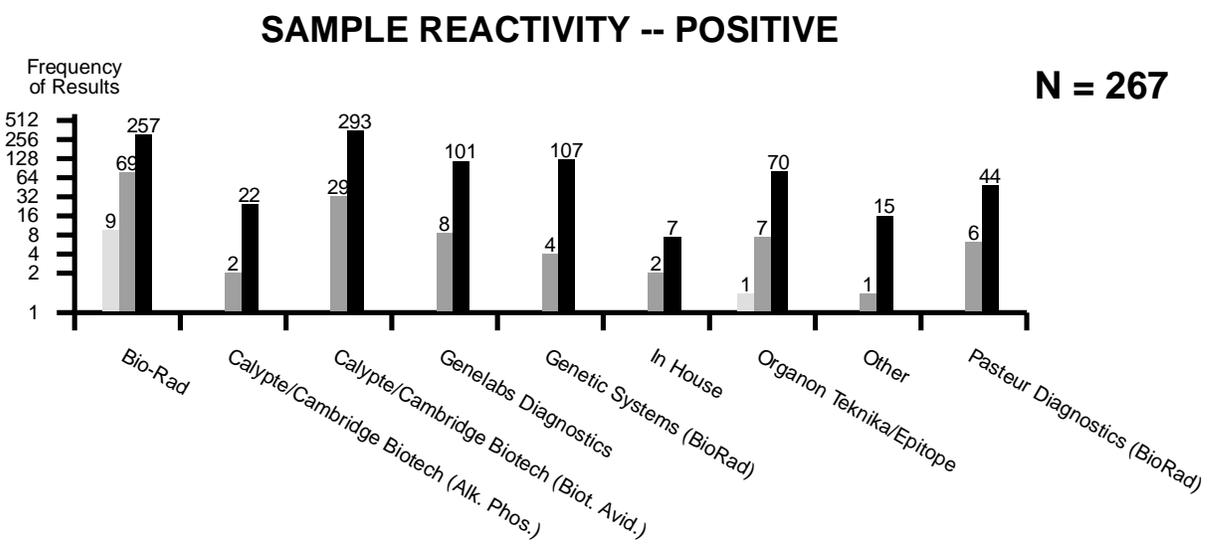
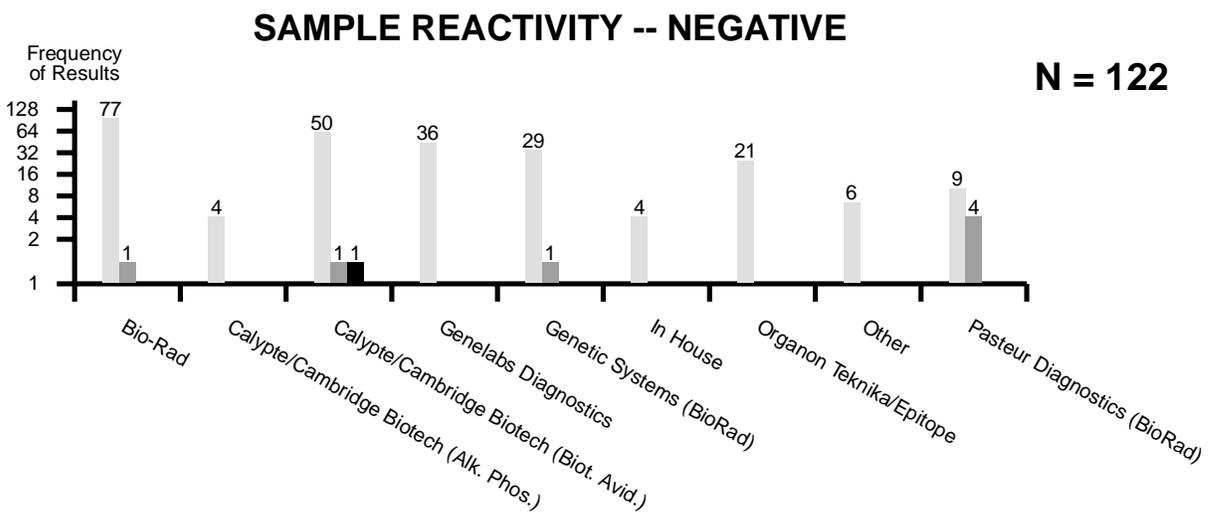
Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 2001 shipment



Test Result Interpretations

■ Non-Reactive ■ Reactive

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

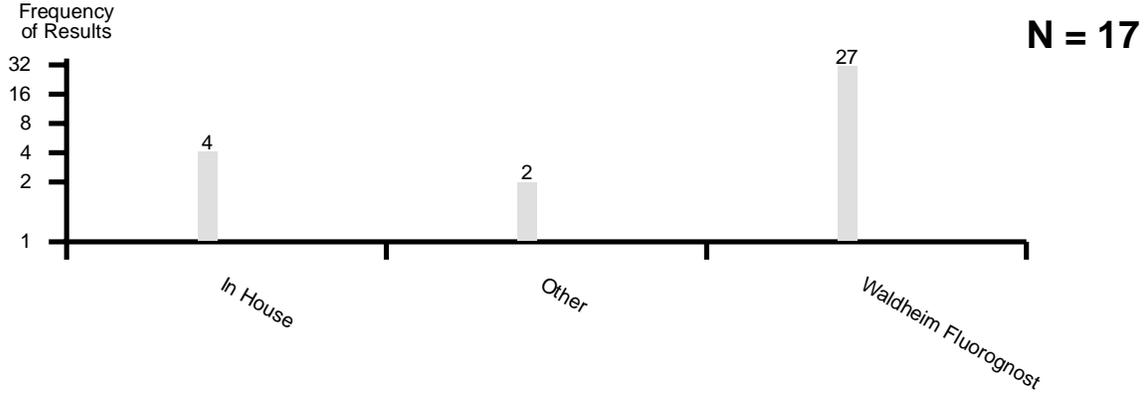


Test Result Interpretations

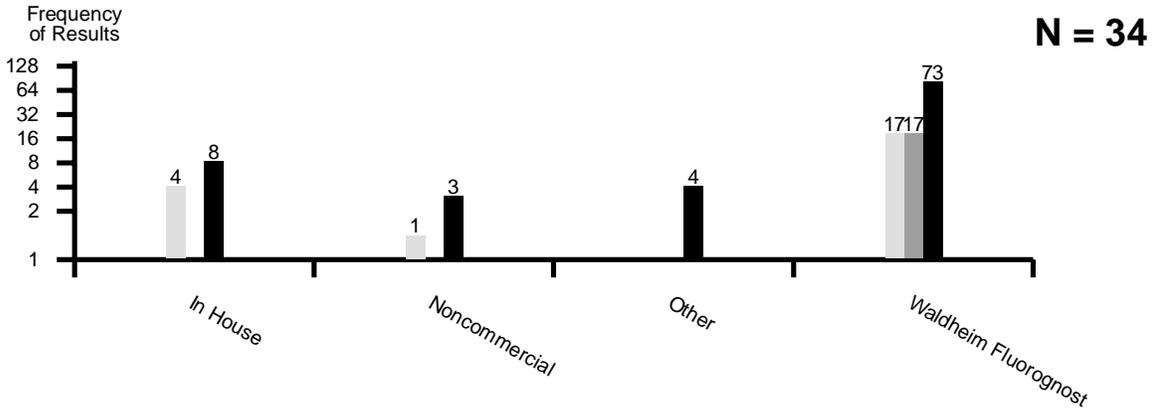
- Non-Reactive
- Indeterminate
- Reactive

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

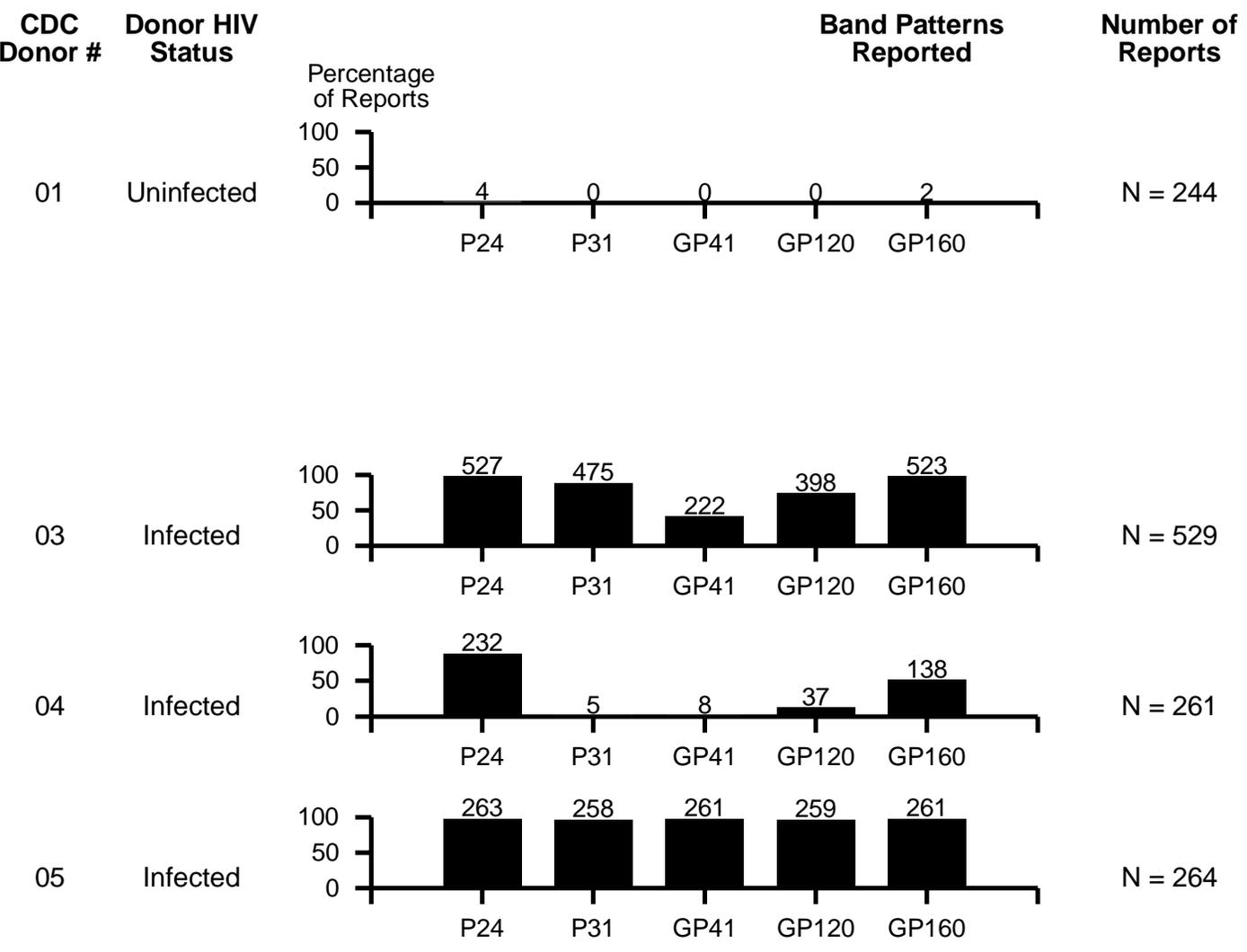


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the July 2001 shipment

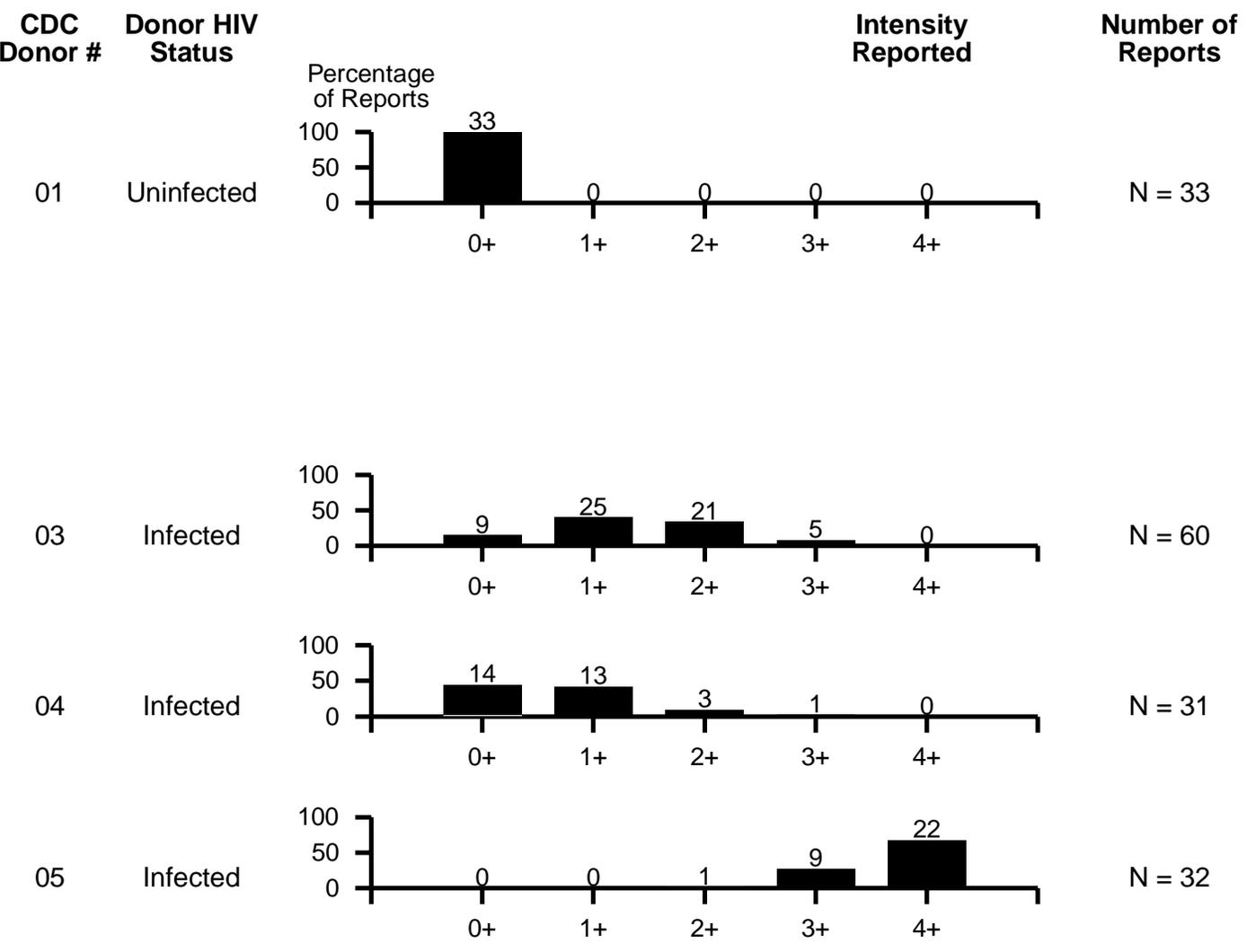


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the July 2001 shipment

