

**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 2000 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 July 2000 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 2000 Participant Laboratory Shipment**

Table 1

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result ¹	Donor HIV Status	Laboratory Interpretation ²			
					EIA INIT. ³	FINAL ⁴	WB	IIF
A	A1	3	Negative	Uninfected	—	—	—	—
	A2,A4	1	Positive	Infected	—	—	—	—
	A3,A5	5	Positive	Infected	—	—	—	—
	A6	2	Positive	Infected	—	—	—	—
B	B1,B5	1	Positive	Infected	—	—	—	—
	B2	3	Negative	Uninfected	—	—	—	—
	B3	2	Positive	Infected	—	—	—	—
	B4,B6	5	Positive	Infected	—	—	—	—
C	C1,C6	5	Positive	Infected	—	—	—	—
	C2, C3	1	Positive	Infected	—	—	—	—
	C4	2	Positive	Infected	—	—	—	—
	C5	3	Negative	Uninfected	—	—	—	—
D	D1	2	Positive	Infected	—	—	—	—
	D2	3	Negative	Uninfected	—	—	—	—
	D3,D6	1	Positive	Infected	—	—	—	—
	D4,D5	5	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
July 2000 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	3	No Bands	All Manufacturers	Negative
	A2, A4	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech*	Positive
			24,55,65,160	Epitope/Organon	Positive
			24,40,51,160	Genetic Systems/Sanofi	Positive
	A3, A5	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
	A6	2	18,24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,160	Epitope/Organon	Positive
24,31,40,41,51,55,65,120,160			Genetic Systems/Sanofi	Positive	
B	B1, B5	1	24,55,160	BioRad	Positive
			24,160	Cambridge Biotech	Positive
			24,55,65,160	Epitope/Organon	Positive
			24,40,51,160	Genetic Systems/Sanofi	Positive
	B2	3	No Bands	All Manufacturers	Negative
	B3	2	18,24,32,41,51,55,65,120,160	BioRad	Positive
			24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,31,41,51,65,160	Epitope/Organon	Positive
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	B4, B6	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 p p p p p p p p

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) July 2000 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, C6	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	
	C2, C3	1	24,55,160	BioRad	Positive	
			24,160	Cambridge Biotech	Positive	
			24,55,65,160	Epitope/Organon	Positive	
			24,40,51,160	Genetic Systems/Sanofi	Positive	
	C4	2	18,24,32,41,51,55,65,120,160	BioRad	Positive	
			24,31,41,51,66,120,160	Cambridge Biotech	Positive	
			24,31,41,51,65,160	Epitope/Organon	Positive	
			24,31,40,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive	
	C5	3	No Bands	All Manufacturers	Negative	
	D	D1	2	18,24,32,41,51,55,65,120,160	BioRad	Positive
				24,31,41,51,66,120,160	Cambridge Biotech	Positive
				24,31,41,51,65,160	Epitope/Organon	Positive
24,31,40,41,51,55,65,120,160				Genetic Systems/Sanofi	Positive	
D2		3	No Bands	All Manufacturers	Negative	
D3, D6		1	24,55,160	BioRad	Positive	
			24,160	Cambridge Biotech	Positive	
			24,55,65,160	Epitope/Organon	Positive	
			24,40,51,160	Genetic Systems/Sanofi	Positive	
D4, D5		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	

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

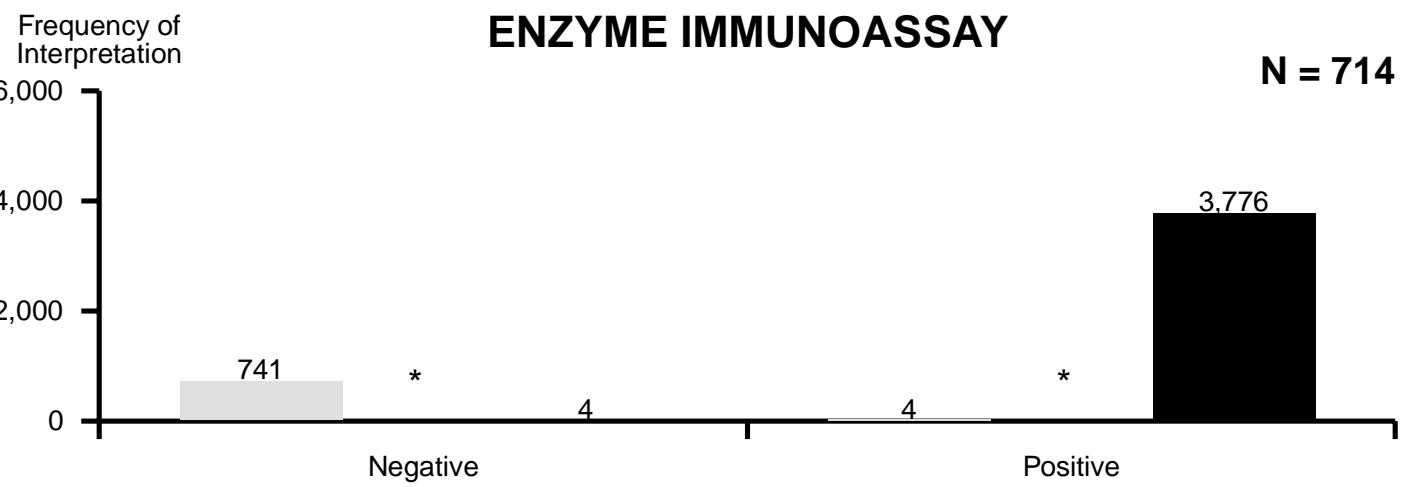
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

* 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 24,2000 shipment



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

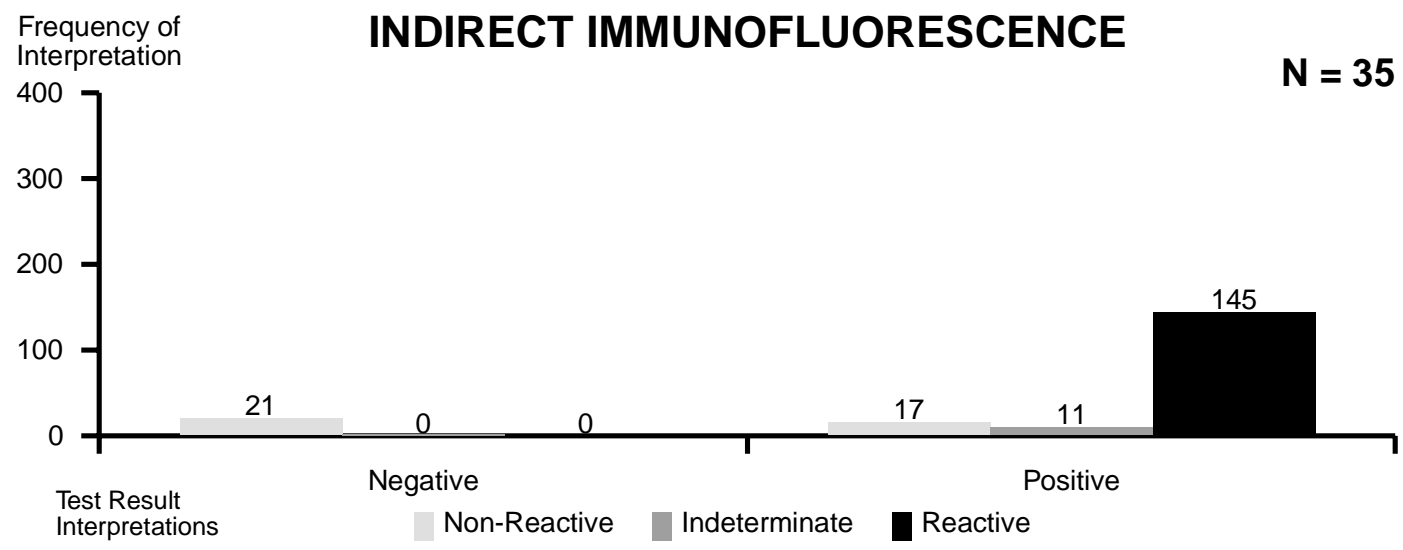
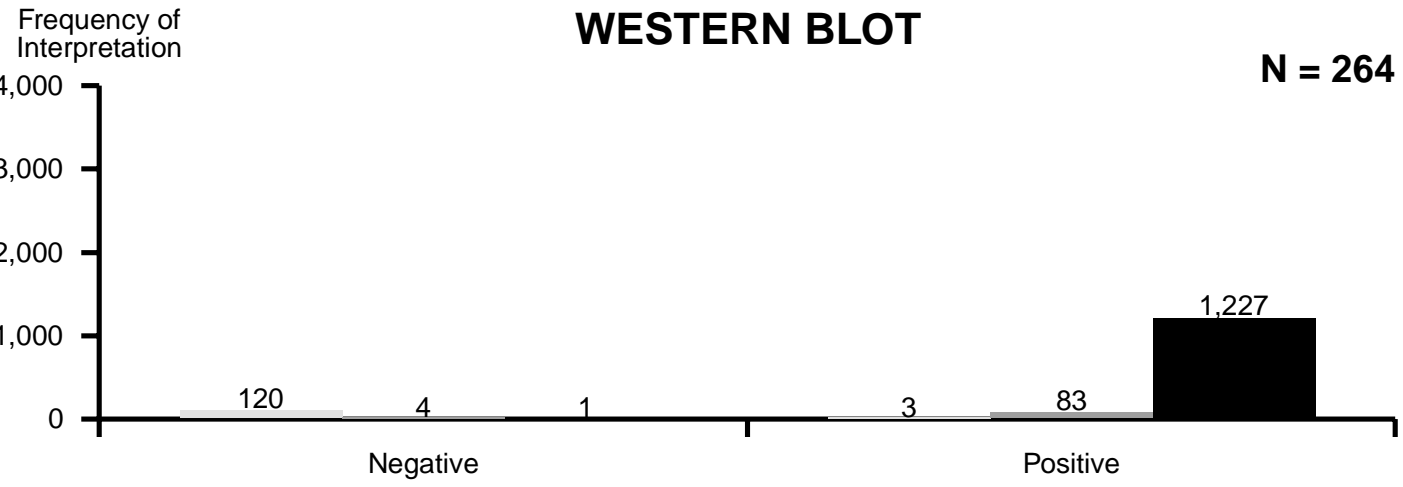


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the July 24,2000 shipment

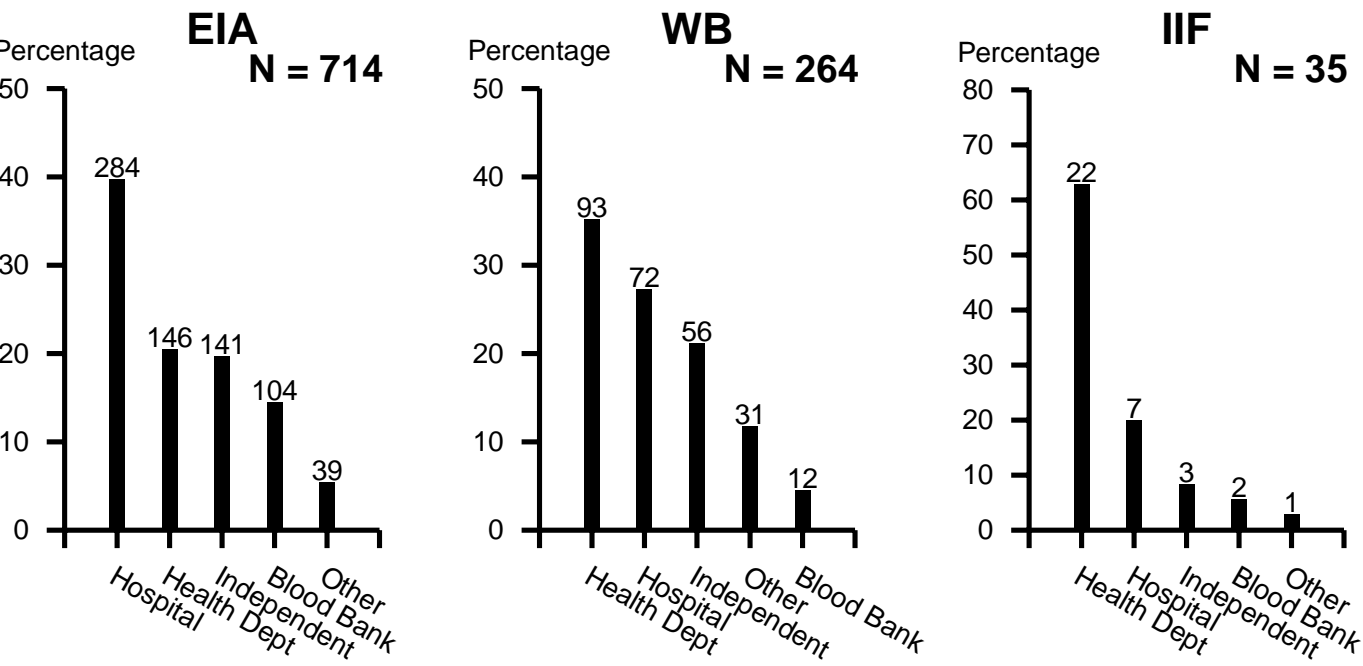


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the July 24,2000 shipment

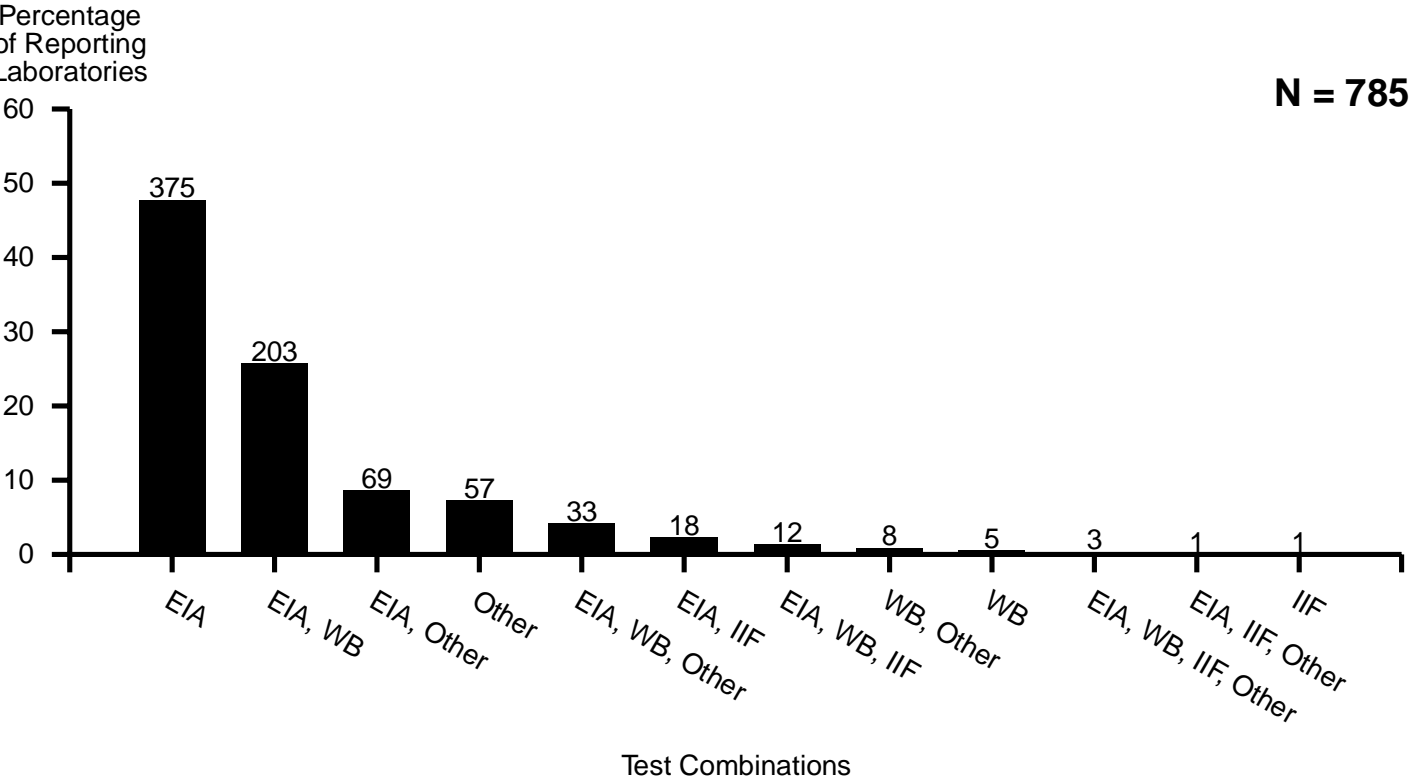


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the July 24,2000 shipment

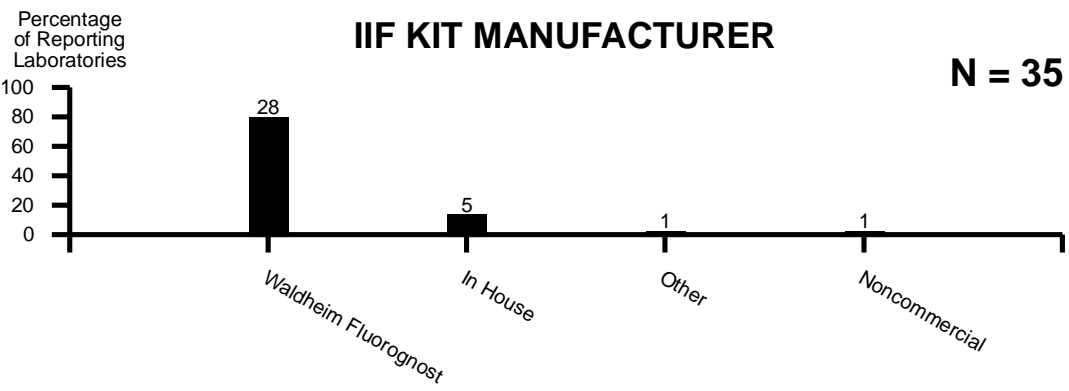
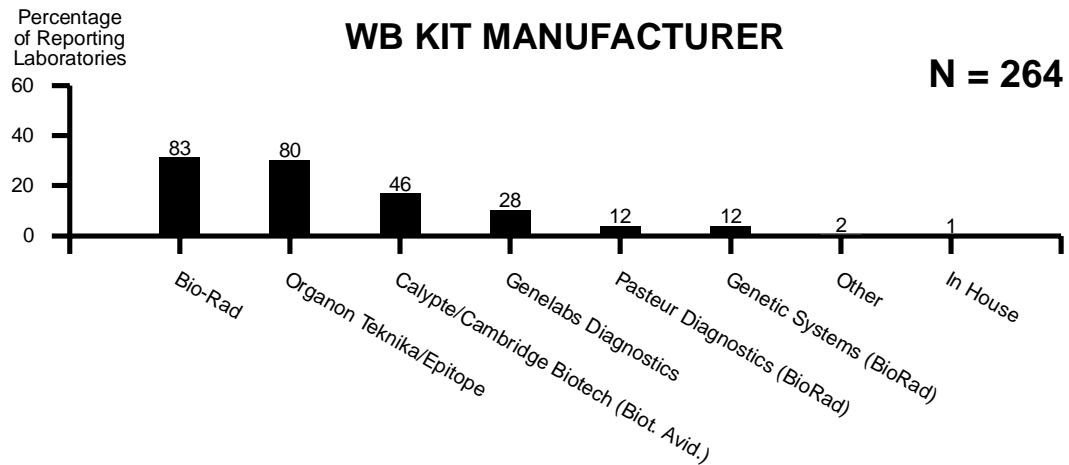
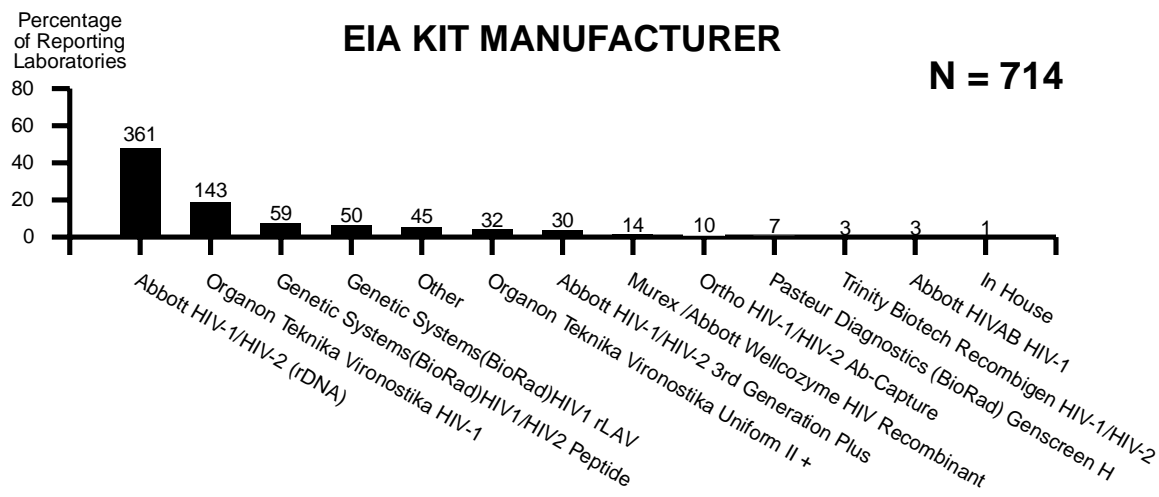
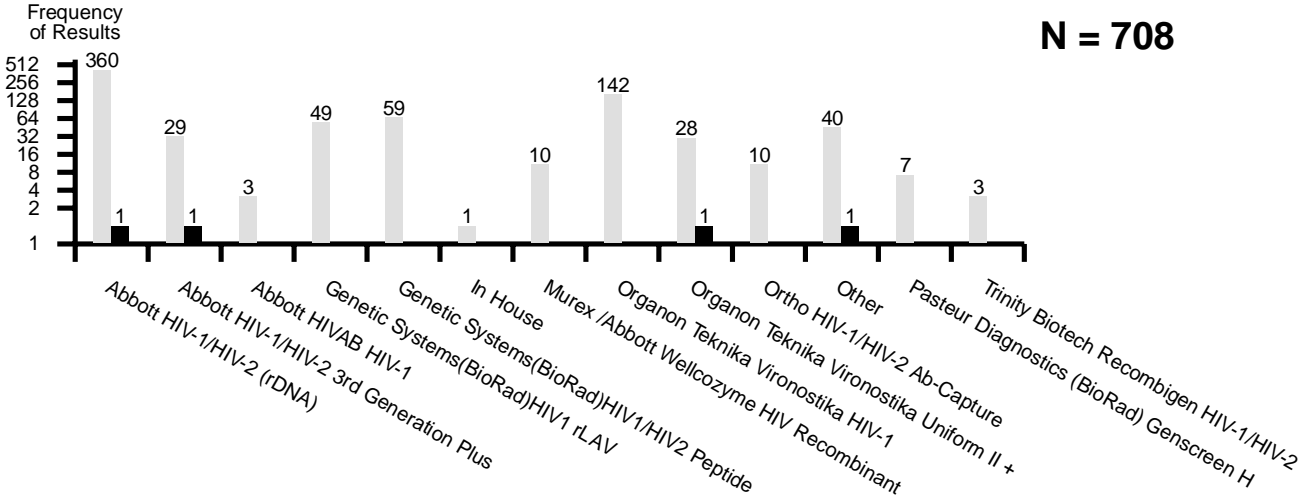


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 24,2000 shipment

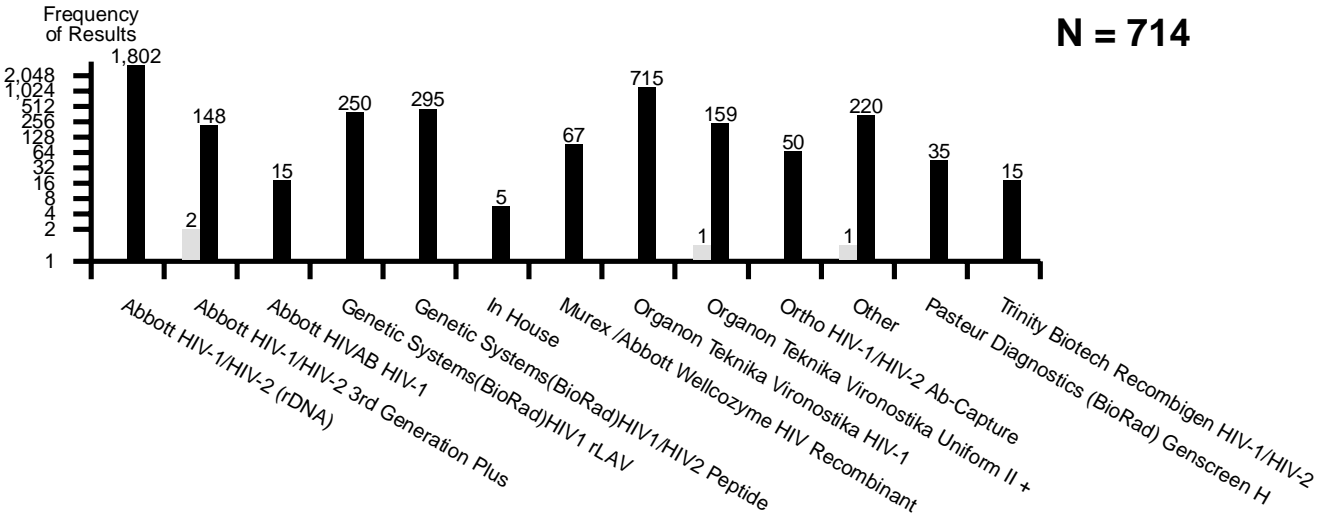
SAMPLE REACTIVITY -- NEGATIVE

N = 708



SAMPLE REACTIVITY -- POSITIVE

N = 714

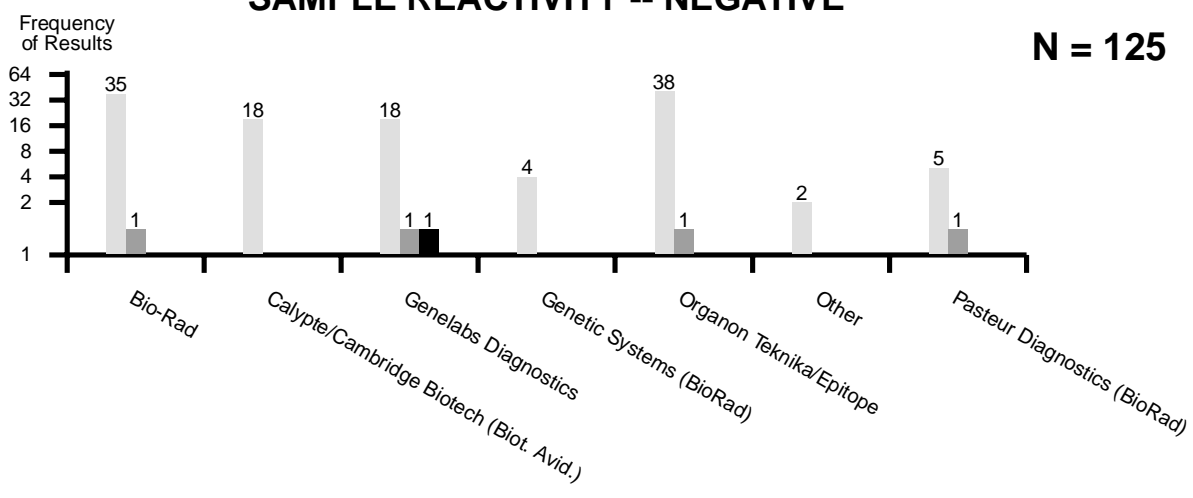


Test Result Interpretations
 Non-Reactive
 Reactive

Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 24,2000 shipment

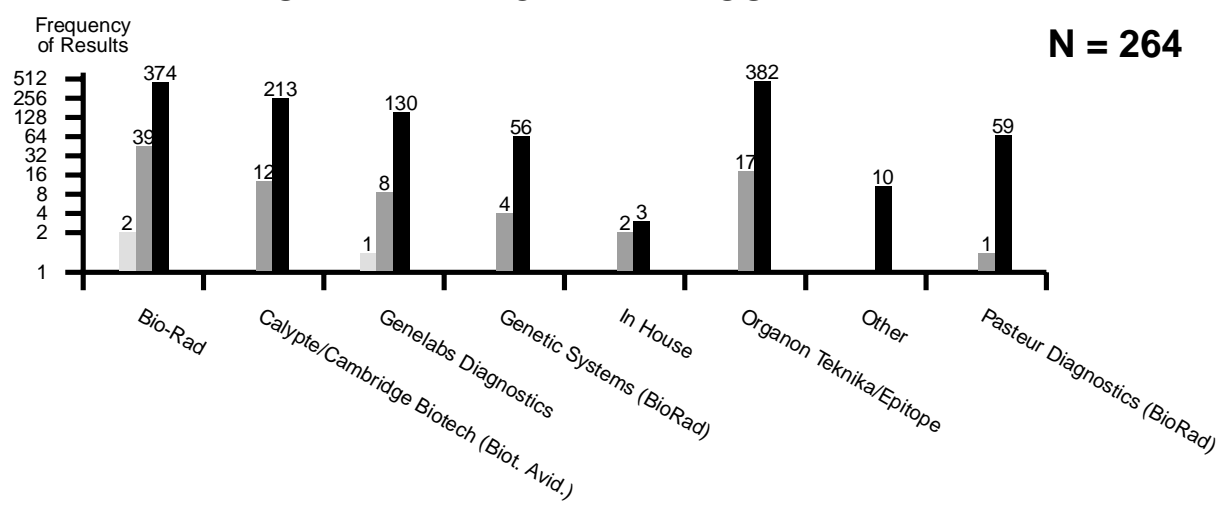
SAMPLE REACTIVITY -- NEGATIVE

N = 125



SAMPLE REACTIVITY -- POSITIVE

N = 264

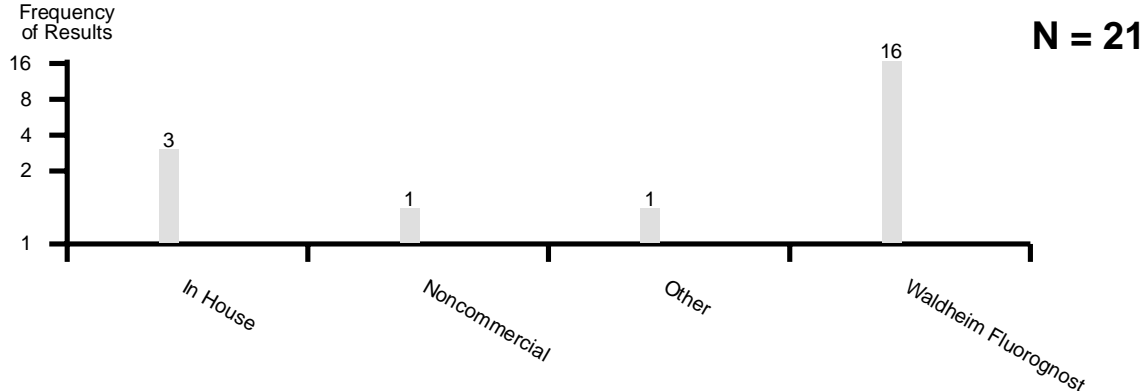


Test Result Interpretations

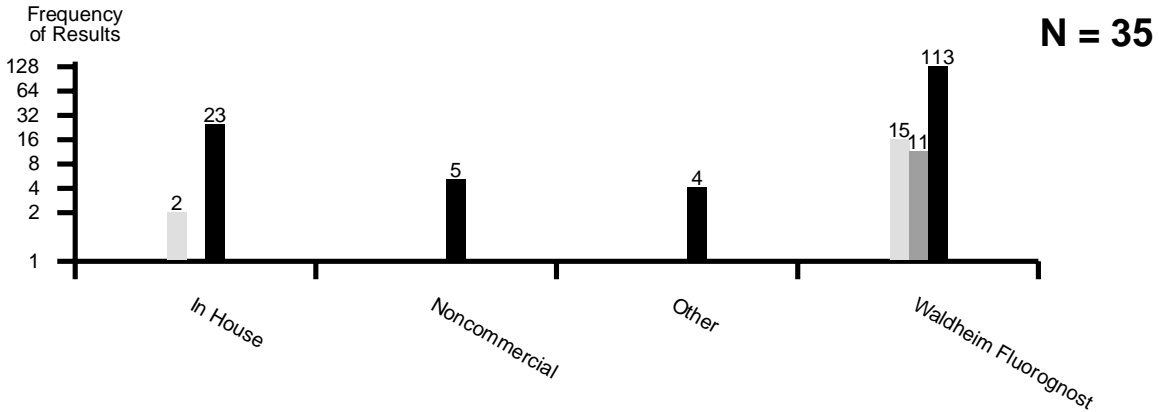
- Non-Reactive
- Indeterminate
- Reactive

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the July 24,2000 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 24,2000 shipment

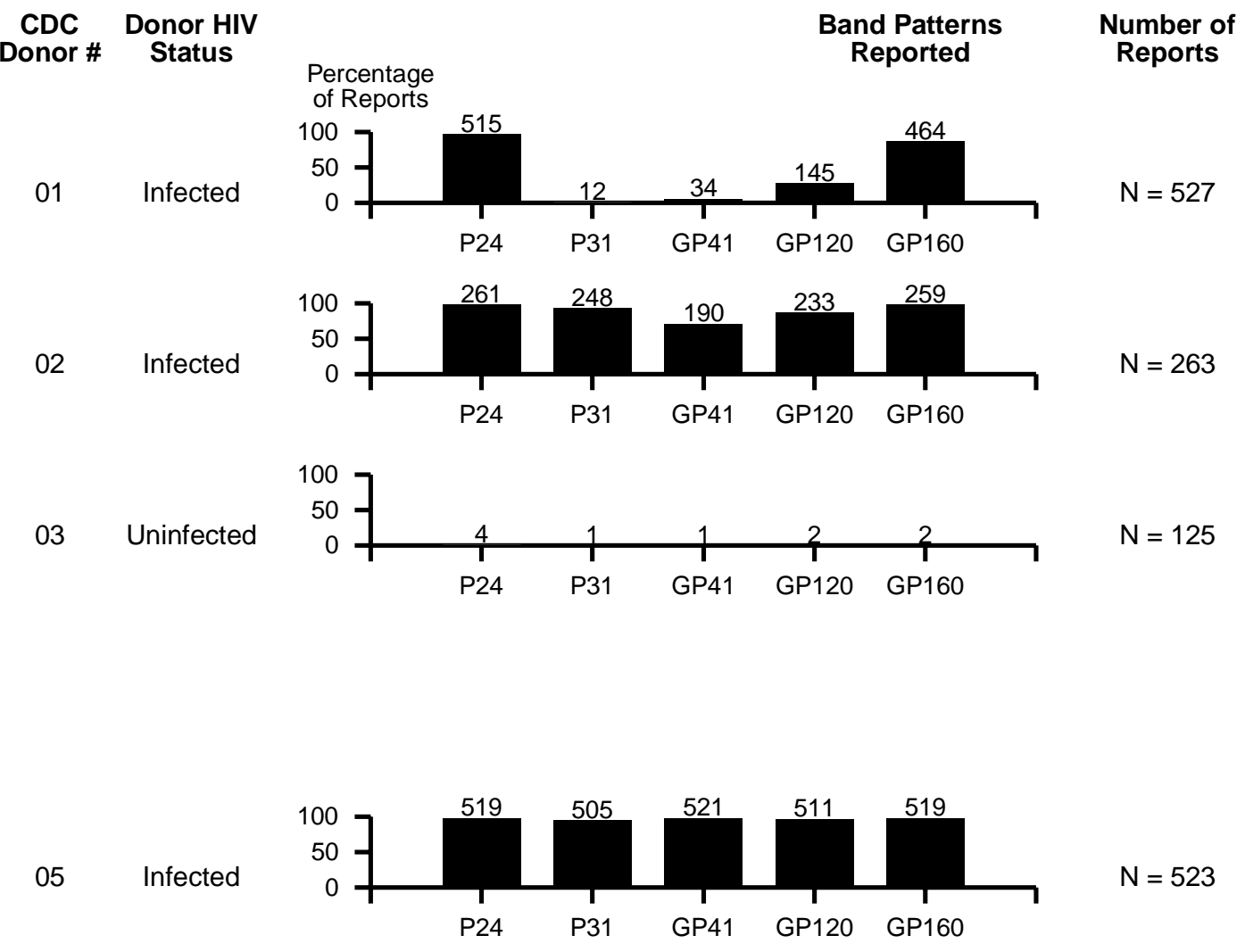


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the July 24,2000 shipment

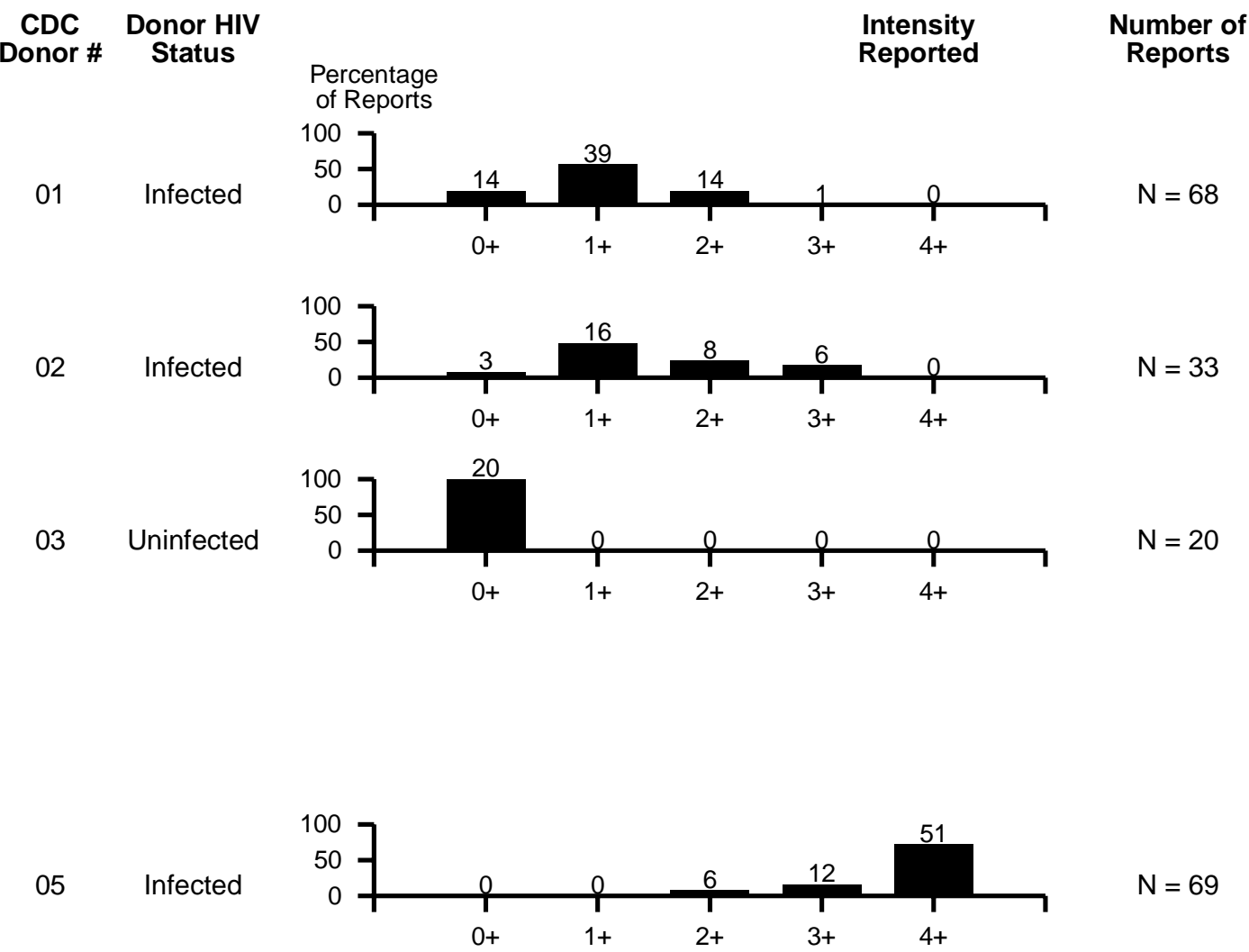
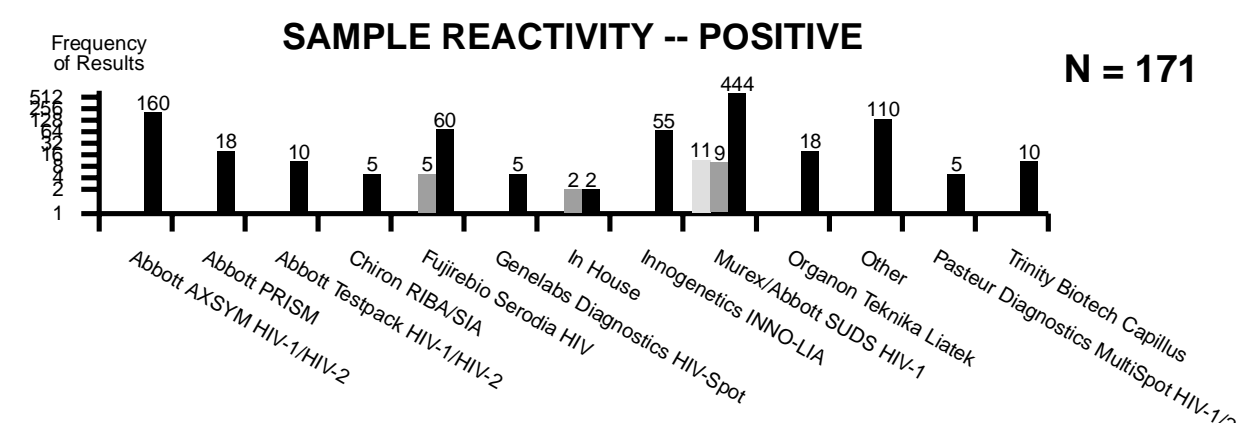
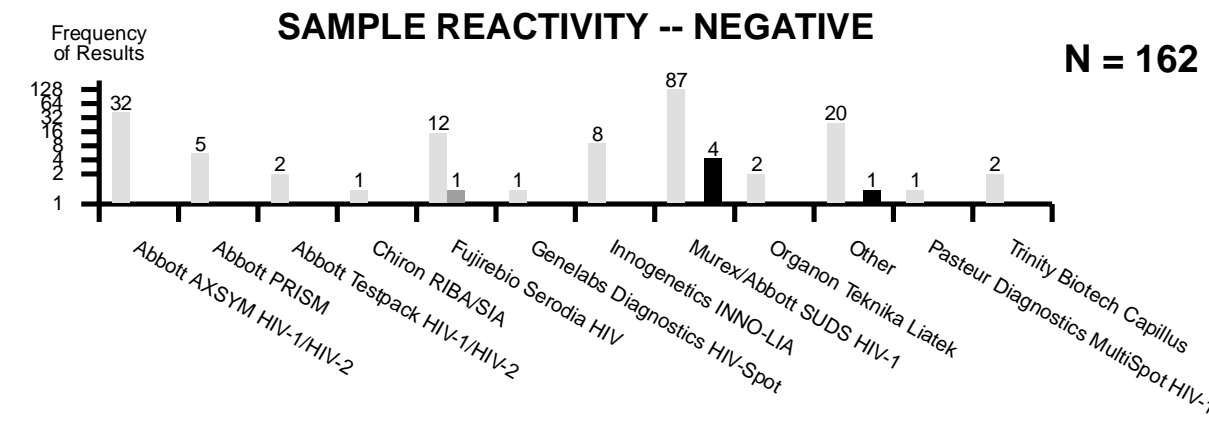
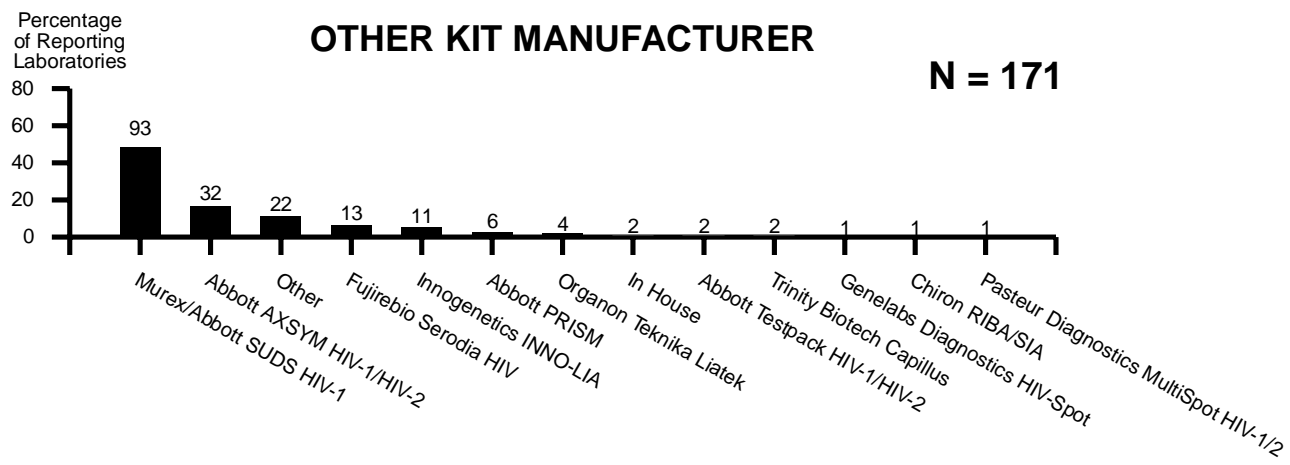


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the July 24,2000 shipment



Test Result Interpretations

Non-Reactive
 Indeterminate
 Reactive