

**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 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 January 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  
January 2000 Participant Laboratory Shipment**

**Table 1**

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

<sup>1</sup> Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

<sup>2</sup> 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.

<sup>3</sup> Initial EIA interpretation

<sup>4</sup> 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 2000 Participant Laboratory Panel Samples**

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected <sup>1</sup>	WB Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
A	A1, A5	2	No Bands	All Manufacturers	Negative
	A2	1	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech*	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
			18,24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	A3, A6	4	24,160	BioRad	Positive
			24,51,55,66,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
			24,31,55,65,160	Genetic Systems/Sanofi	Positive
	A4	3	18,24,32,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
			24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
B	B1	1	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
			18,24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	B2, B6	4	24,160	BioRad	Positive
			24,51,55,66,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
			24,31,55,65,160	Genetic Systems/Sanofi	Positive
	B3, B5	2	No Bands	All Manufacturers	Negative
	B4	3	18,24,32,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,160	Epitope/Organon	Positive
			24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive

Table 2, continued p p p p p p p p

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

<sup>2</sup> 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 2000 Participant Laboratory Panel Samples**

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected <sup>1</sup>	WB Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
C	C1	3	18,24,32,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech*	Positive
			24,51,65,160	Epitope/Organon	Positive
			24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	C2, C6	4	24,160	BioRad	Positive
			24,51,55,66,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
			24,31,55,65,160	Genetic Systems/Sanofi	Positive
	C3, C4	2	No Bands	All Manufacturers	Negative
	C5	1	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
			18,24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
D	D1	3	18,24,32,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,66,120,160	Cambridge Biotech	Positive
			24,51,65,16	Epitope/Organon	Positive
			24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive
	D2, D5	4	24,160	BioRad	Positive
			24,51,55,66,120,160	Cambridge Biotech	Positive
			24,65,160	Epitope/Organon	Positive
			24,31,55,65,160	Genetic Systems/Sanofi	Positive
	D3, D4	2	No Bands	All Manufacturers	Negative
	D6	1	18,24,32,41,51,55,65,120,160	BioRad	Positive
			17,24,31,41,51,55,66,120,160	Cambridge Biotech	Positive
			18,24,31,41,51,65,160	Epitope/Organon	Positive
			18,24,31,41,51,55,65,120,160	Genetic Systems/Sanofi	Positive

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

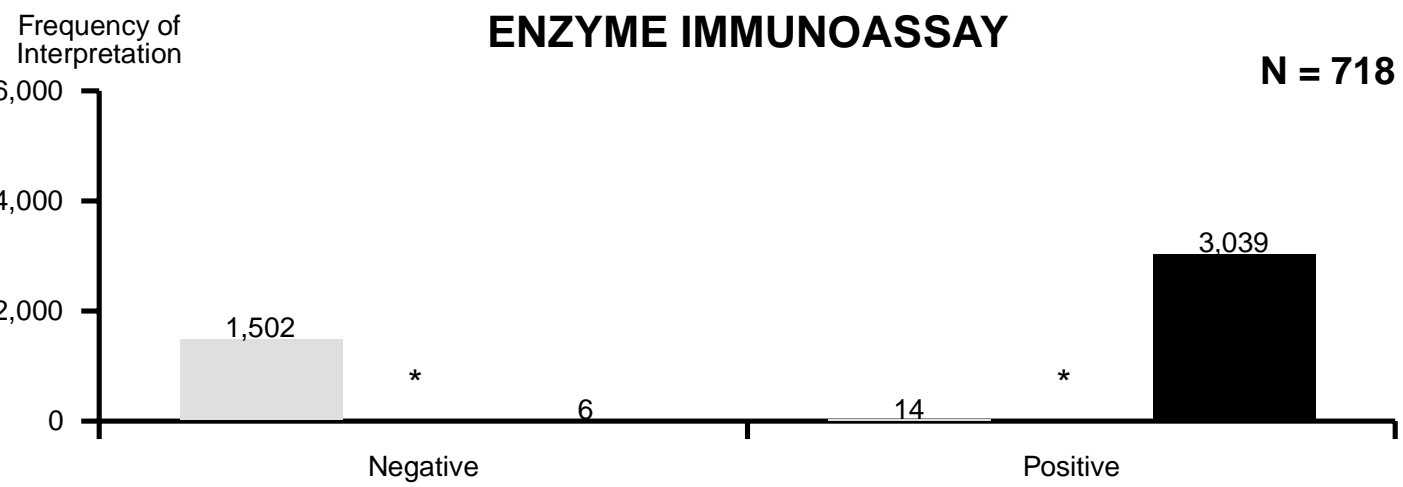
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

\* Cambridge Biotech/Calypte Biomedical

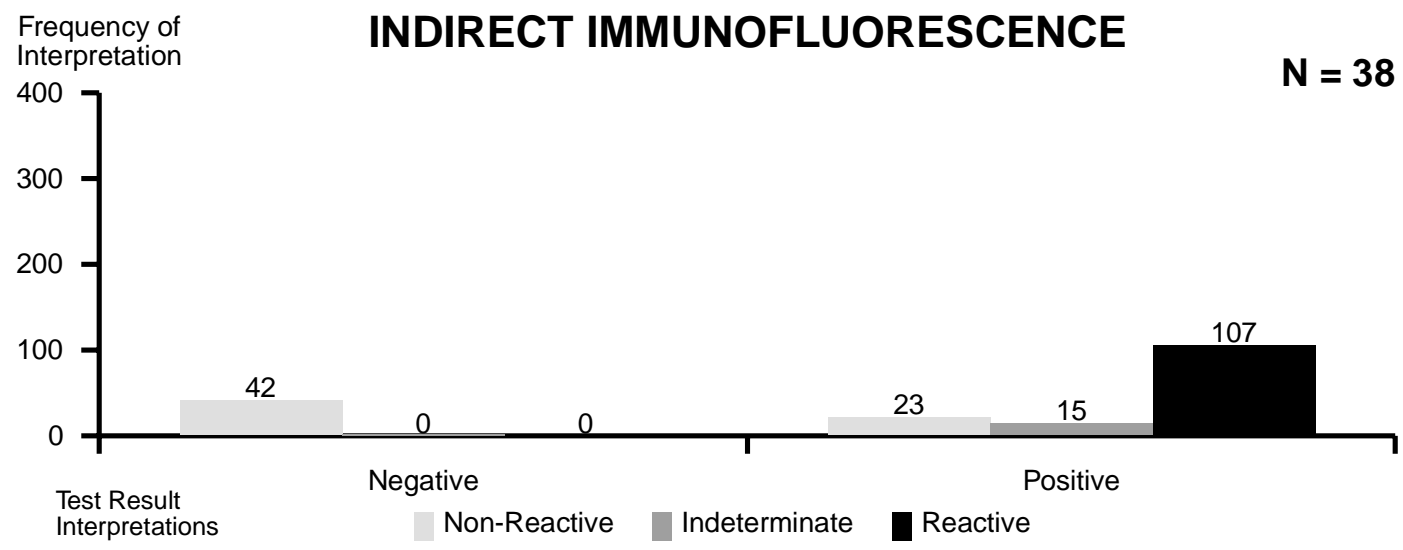
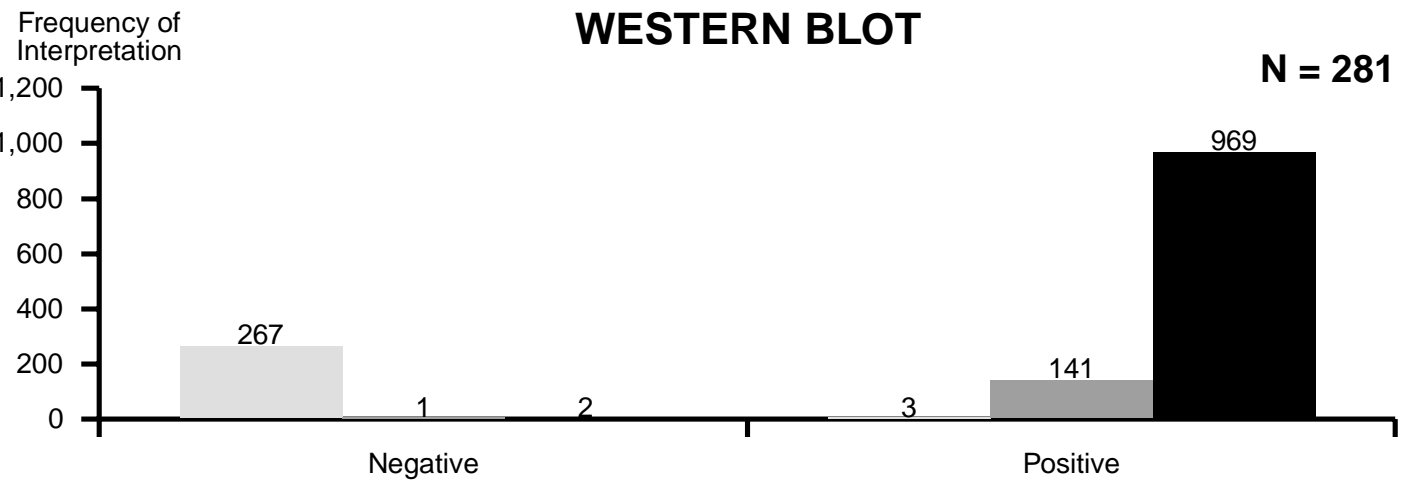
**SUPPLEMENTAL INFORMATION FOR COMPREHENDING  
THE NUMBERS USED TO LABEL FIGURES  
IN THIS REPORT**

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.

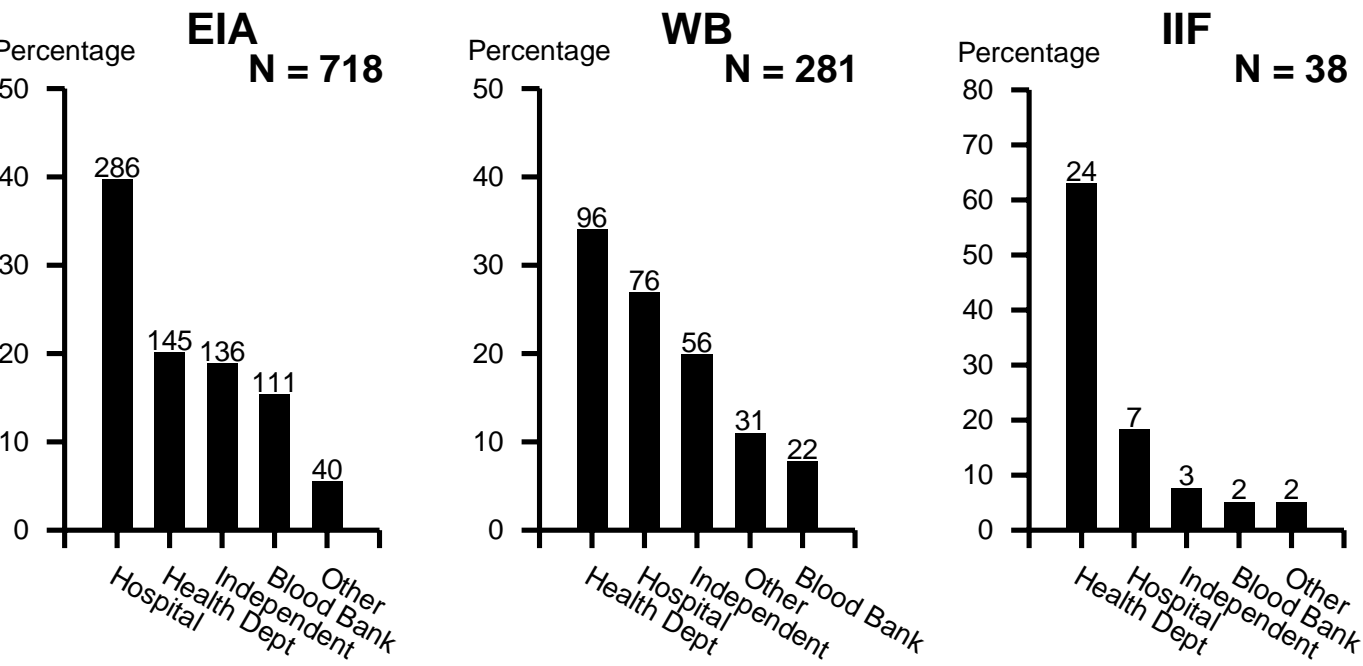
**Figure 1. Frequency of HIV-1 antibody test result interpretations, by sample type (reactivity), for enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the January 2000 shipment**



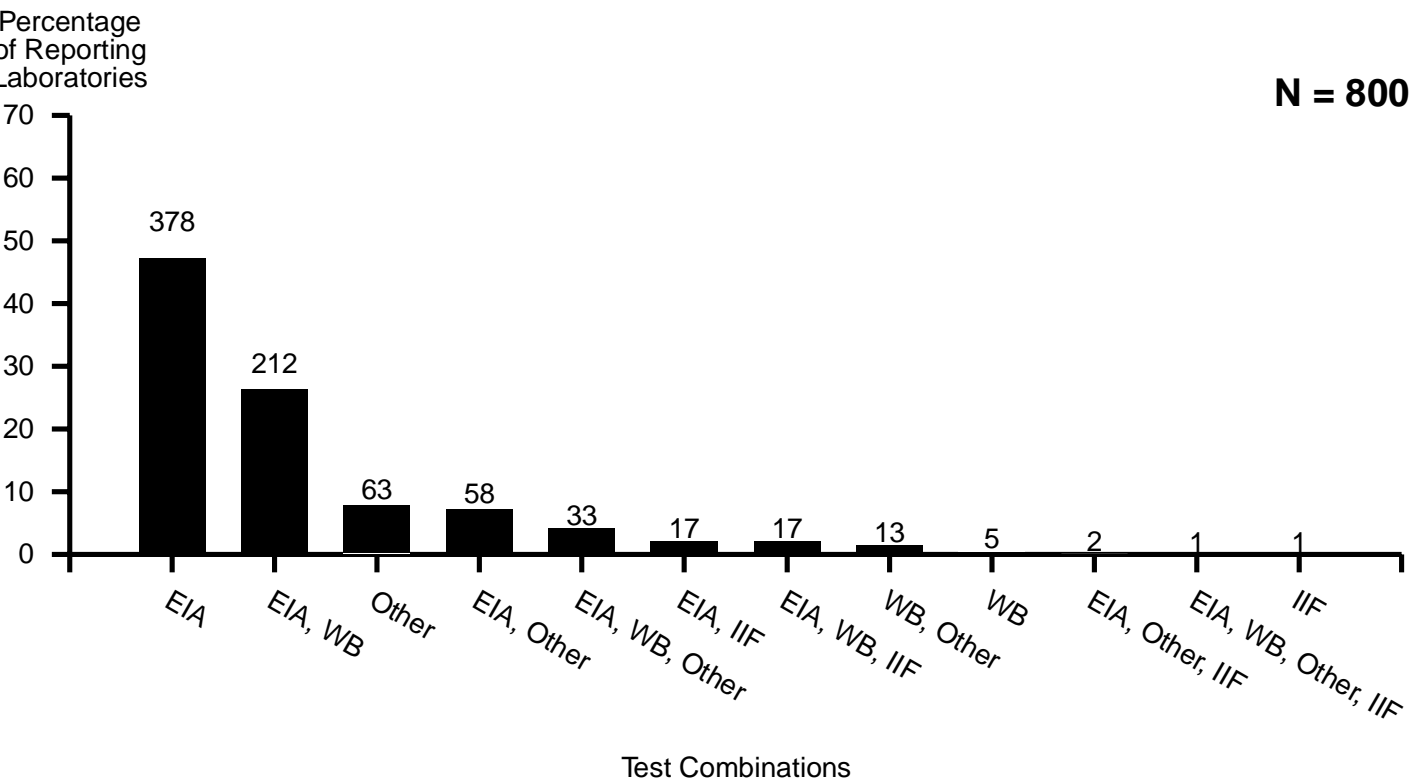
\* = Indeterminate is not an EIA interpretation option; these areas have been left blank



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

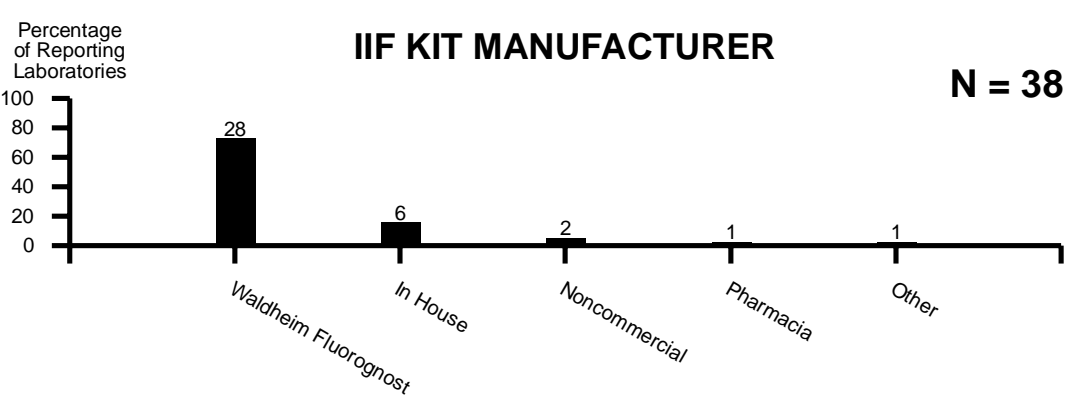
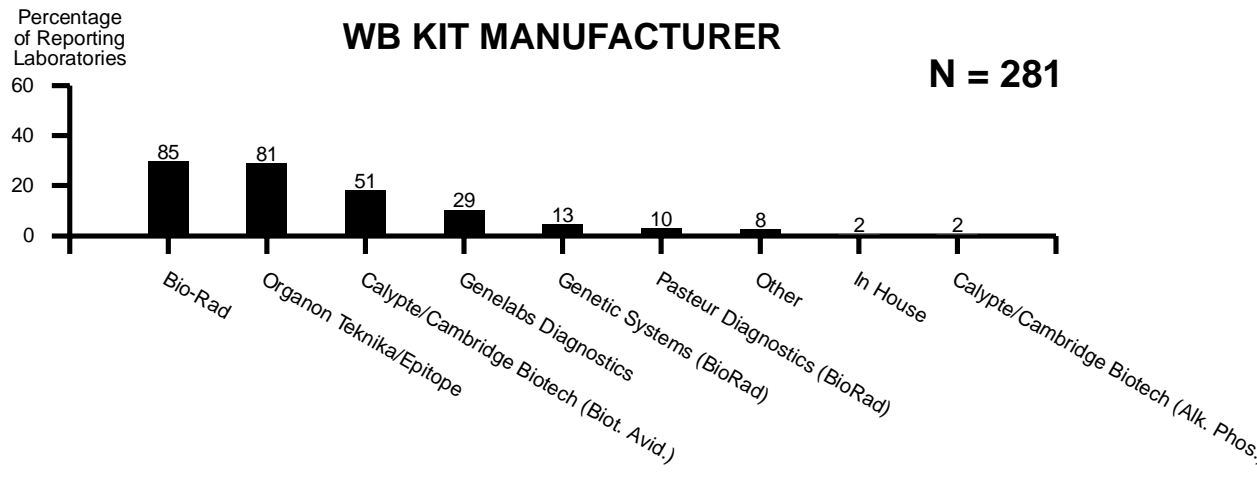
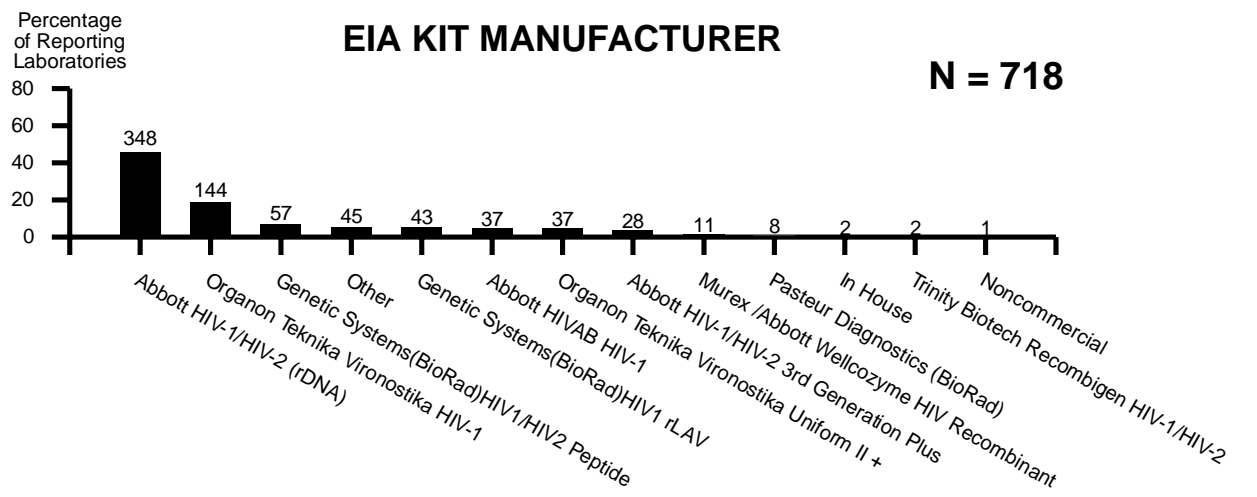


**Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the January 2000 shipment**





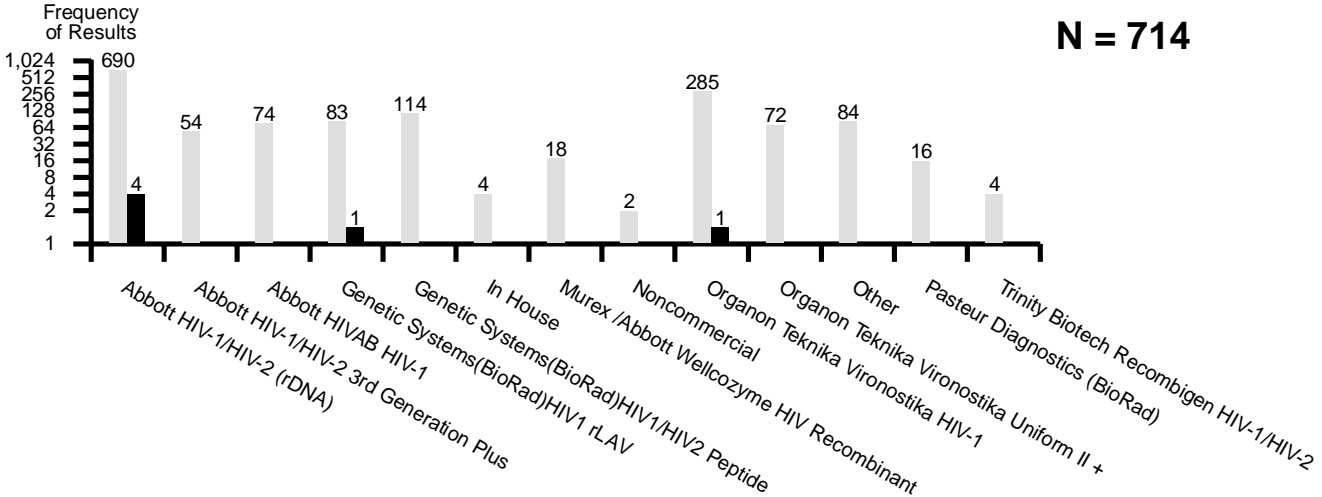
**Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the January 2000 shipment**



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

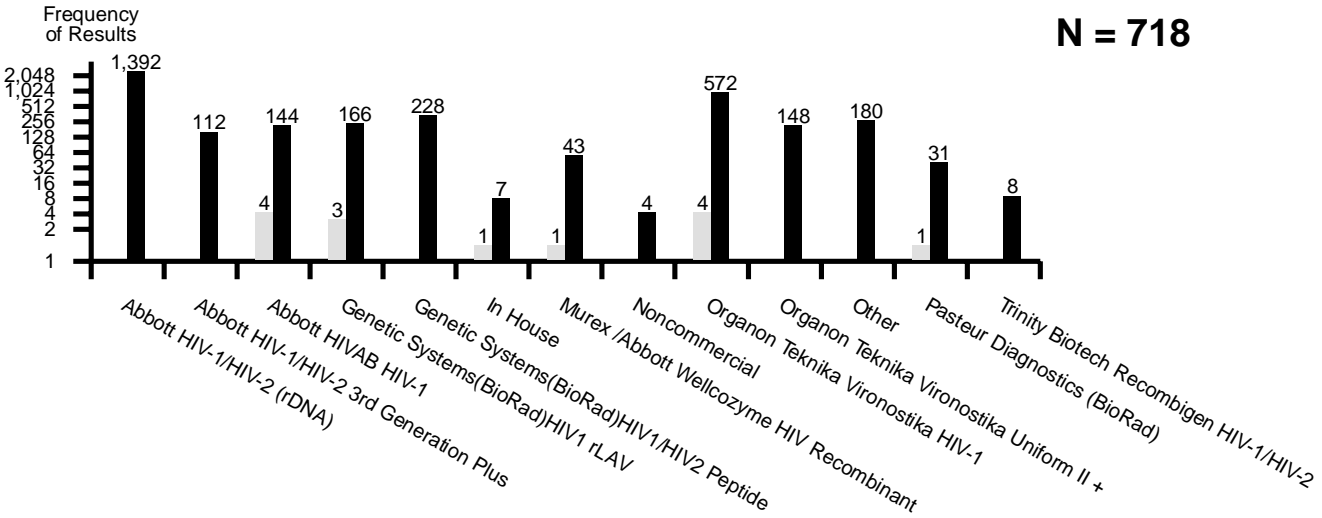
**SAMPLE REACTIVITY -- NEGATIVE**

**N = 714**



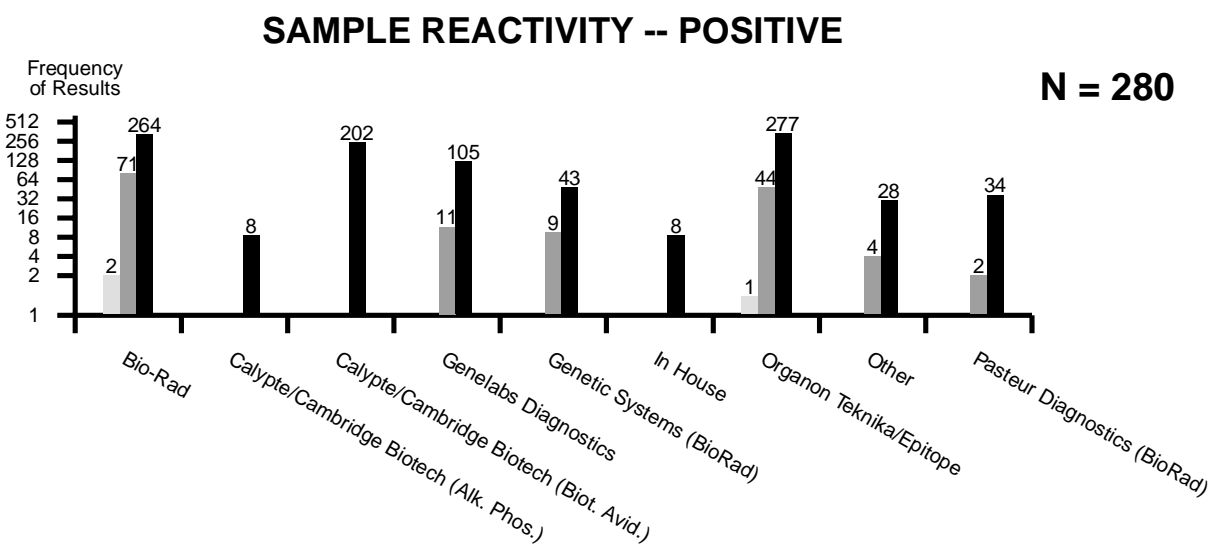
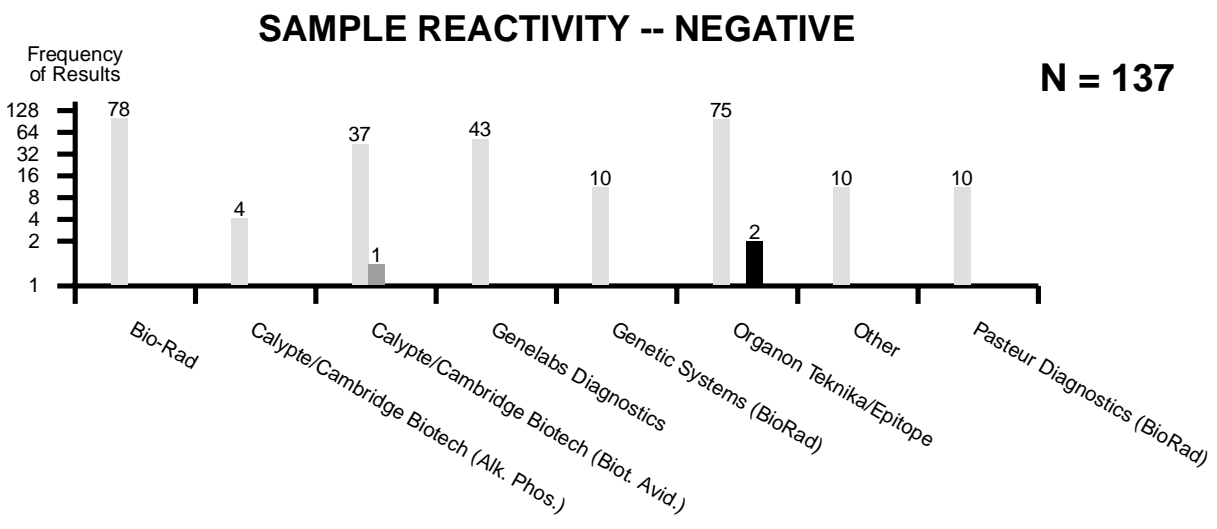
**SAMPLE REACTIVITY -- POSITIVE**

**N = 718**



Test Result Interpretations  
 ■ Non-Reactive ■ Reactive

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

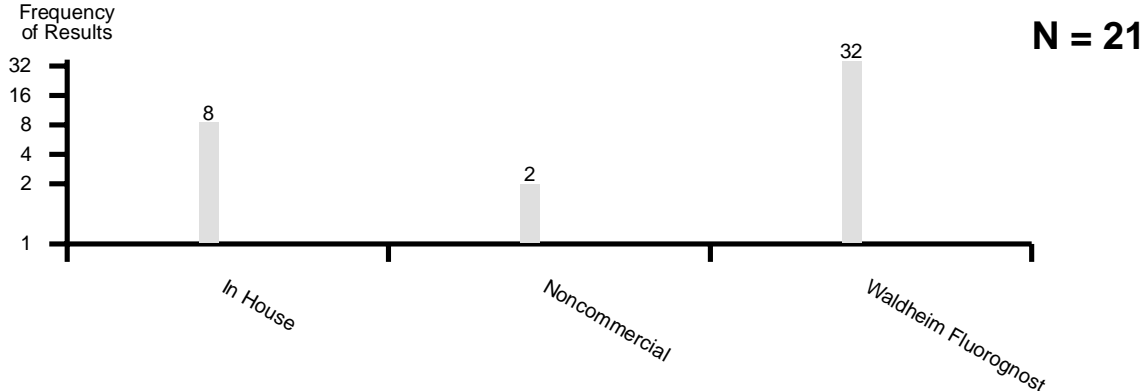


Test Result Interpretations

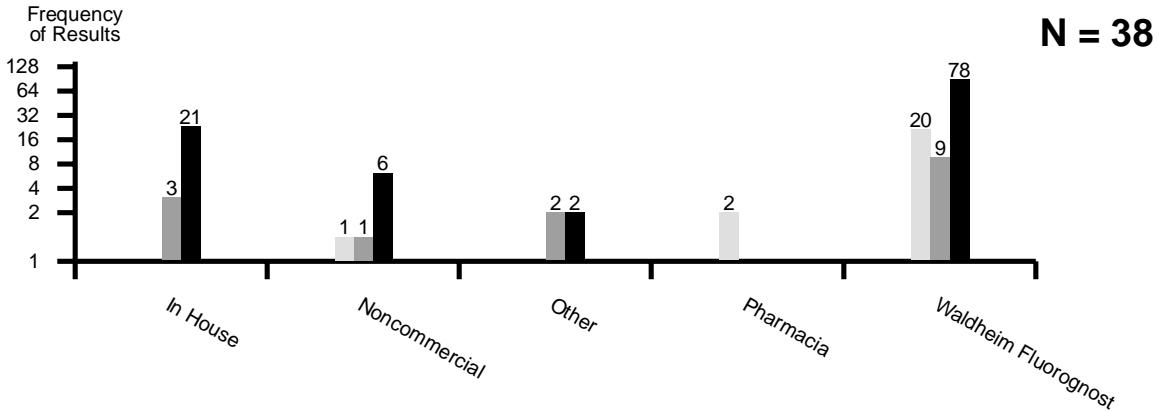
Non-Reactive
  Indeterminate
  Reactive

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

**SAMPLE REACTIVITY -- NEGATIVE**



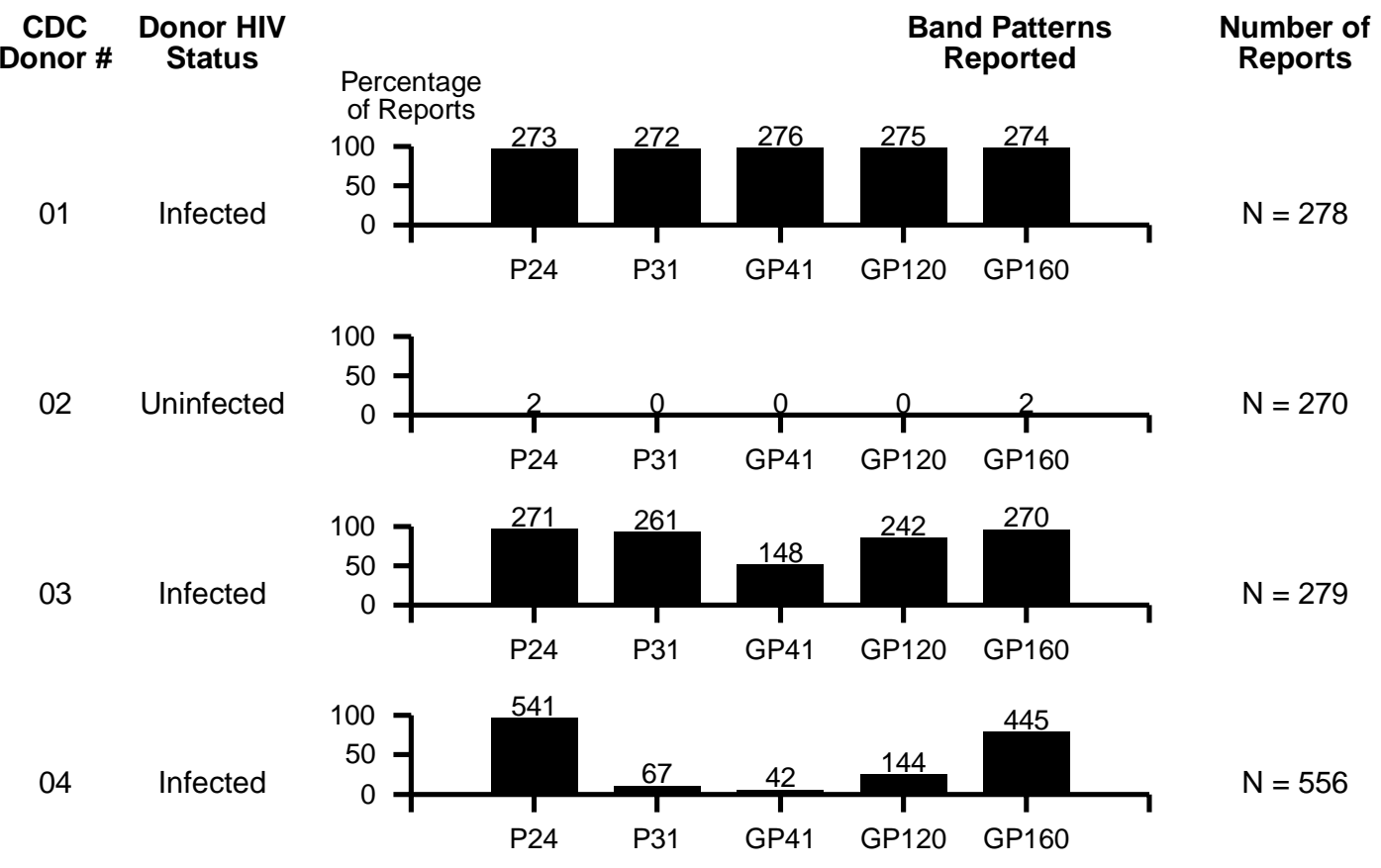
**SAMPLE REACTIVITY -- POSITIVE**



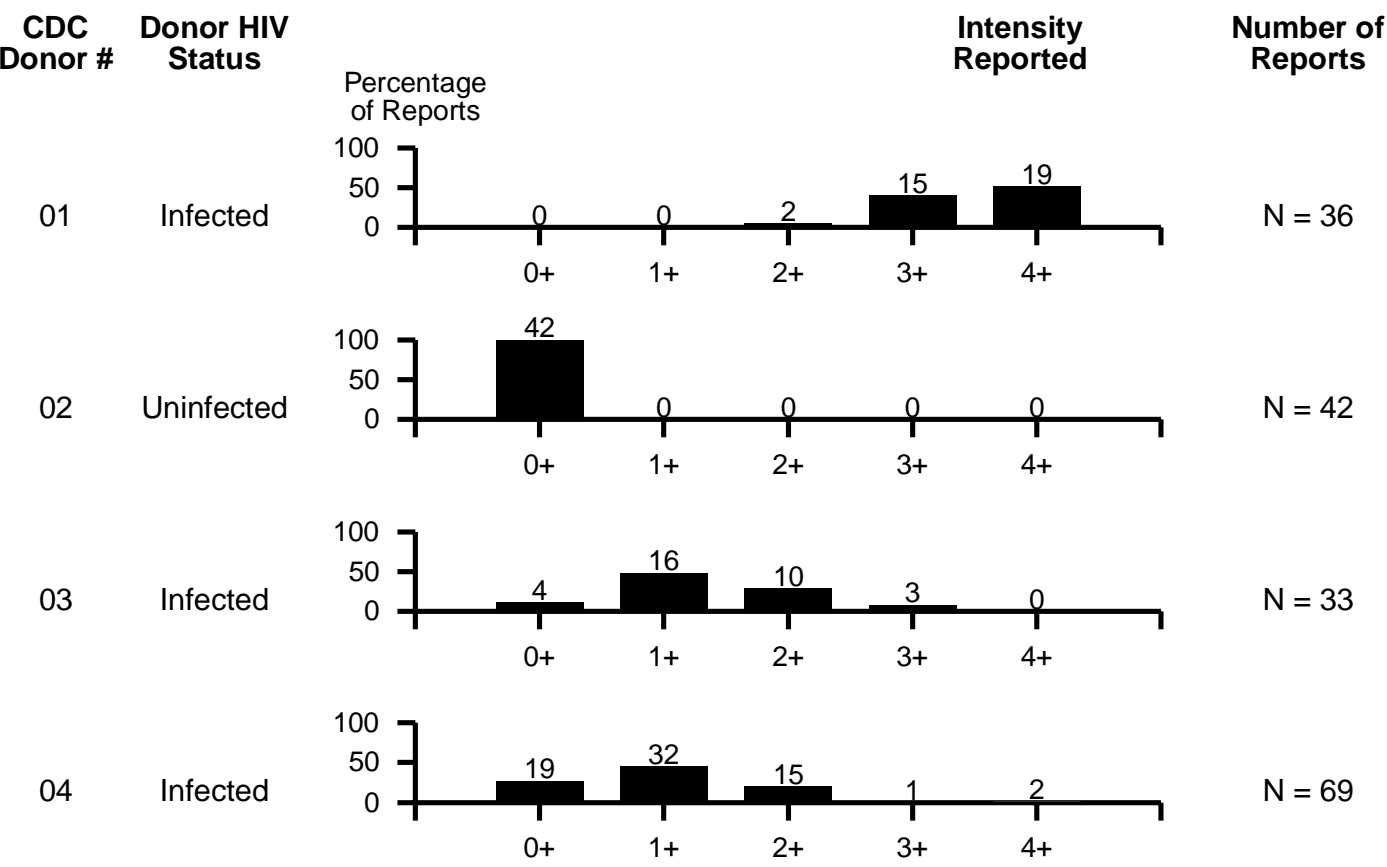
Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

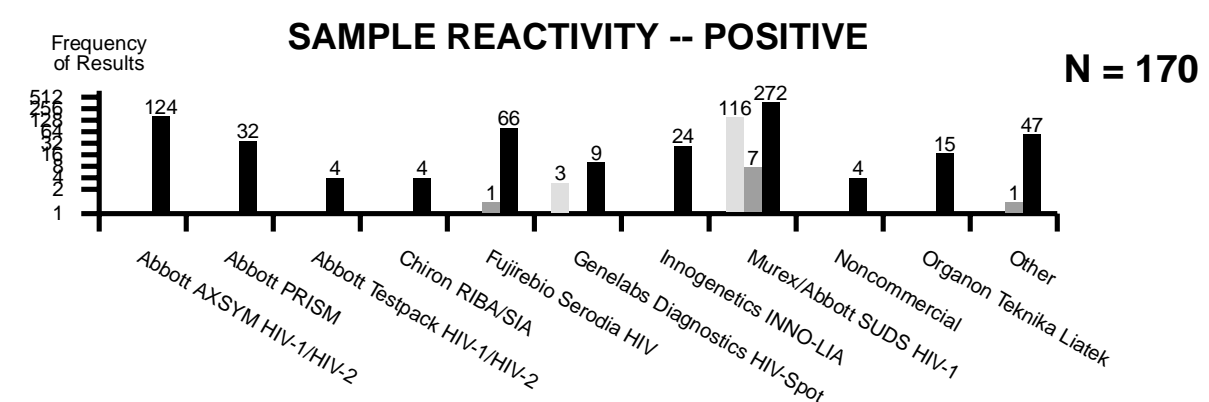
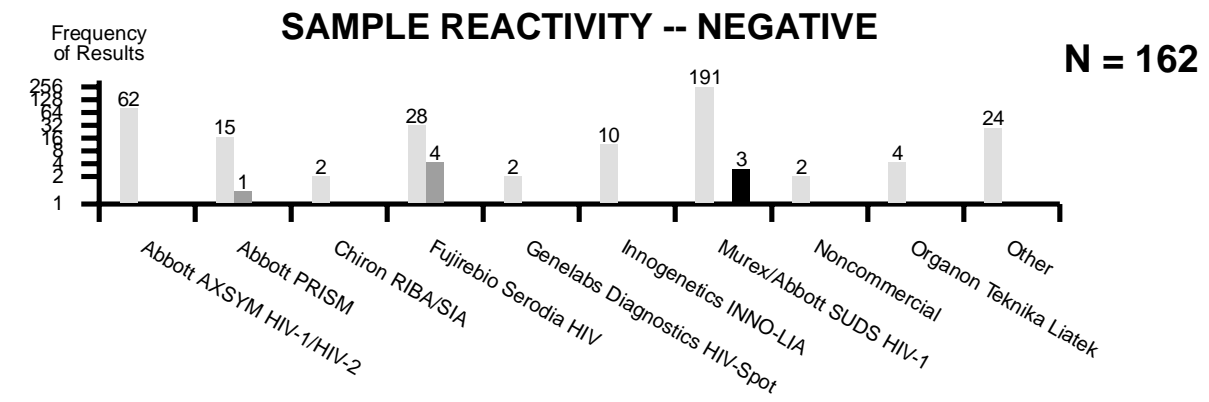
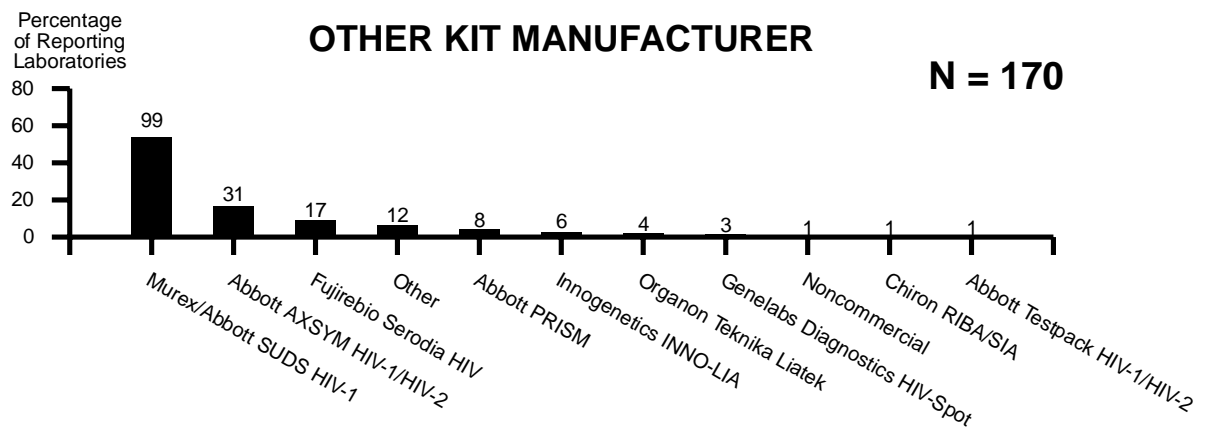
**Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 2000 shipment**



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



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



Test Result Interpretations

Non-Reactive
  Indeterminate
  Reactive