

**Centers for Disease Control and Prevention
Model Performance Evaluation Program
Human Immunodeficiency Virus Type 1 (HIV-1) Testing**

**Figures Used to Summarize the
Candidate Reference Laboratory Results
for the January 6, 1997 Shipment**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

Public Health Practice Program Office

Division of Laboratory Systems

Atlanta, Georgia 30333



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Report of the January 6, 1997 Human Immunodeficiency virus type I (HIV-1)
Performance Evaluation Sample Testing Results Provided by Candidate
Reference 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 6, 1997 Candidate Reference Laboratory Shipment**

Table 1

Label Number	CDC Donor Number	CDC ² Result	Laboratory Interpretation ¹			
			EIA		WB	IIF
			INIT. ³	FINAL ⁴		
01	05	Negative	—	—	—	—
02	11	Positive	—	—	—	—
03	07	Negative	—	—	—	—
04	02	Positive	—	—	—	—
05	17	Positive	—	—	—	—
06	09	Negative	—	—	—	—
07	01	Positive	—	—	—	—
08	04	Positive	—	—	—	—
09	06	Negative	—	—	—	—
10	18	Positive	—	—	—	—
11	15	Positive	—	—	—	—
12	14	Positive	—	—	—	—
13	03	Positive	—	—	—	—
14	10	Negative	—	—	—	—
15	08	Negative	—	—	—	—
16	13	Positive	—	—	—	—
17	16	Positive	—	—	—	—
18	12	Positive	—	—	—	—

¹ Laboratory Interpretation space (to be completed by candidate reference laboratory) provided to facilitate comparison of candidate reference 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), and employing the WB interpretive criteria of the Association of State and Territorial Public Health Laboratory Directors/CDC (ASTPHLD/CDC).

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 6, 1997 Candidate Reference Laboratory Panel Samples**

Label Number	CDC Donor Number	CDC Western Blot Specific WB Bands Detected ¹	WB Test Kit Manufacturer	CDC Laboratory Interpretation ²
01	05	No Bands	All Manufacturers	Negative
02	11	18,24,32,51,55,65,120,160 17,24,31,41,51,66,120,160 24,51,65,160	BioRad Cambridge Biotech* Epitope/Organon	Negative Positive Positive
03	07	No Bands	All Manufacturers	Negative
04	02	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	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
05	17	18,24,55,65,160 24,66,120,160 24,65,160	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
06	09	No Bands	All Manufacturers	Negative
07	01	18,24,32,41,51,55,65,120,160 17,24,31,41,51,66,120,160 24,31,41,51,55,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
08	04	18,24,32,41,51,55,65,120,160 17,24,31,41,51,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
09	06	No Bands	All Manufacturers	Negative
10	18	18,24,55,160 17,24,51,120,160 24,160	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
11	15	18,24,55,160 17,24,160 24	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Indeterminate
12	14	24,32,41,51,55,65,120,160 24,31,41,51,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
13	03	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	BioRad Cambridge Biotech Epitope/Organon	Negative Positive Positive
14	10	No Bands	All Manufacturers	Negative
15	08	No Bands	All Manufacturers	Negative
16	13	24,55 24,120,160 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Indeterminate
17	16	18,24,41,55,120,160 17,24,120,160 24,55	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Indeterminate
18	12	24,41,55,120,160 24,41,66,120,160 24,41,120,160	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Positive

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

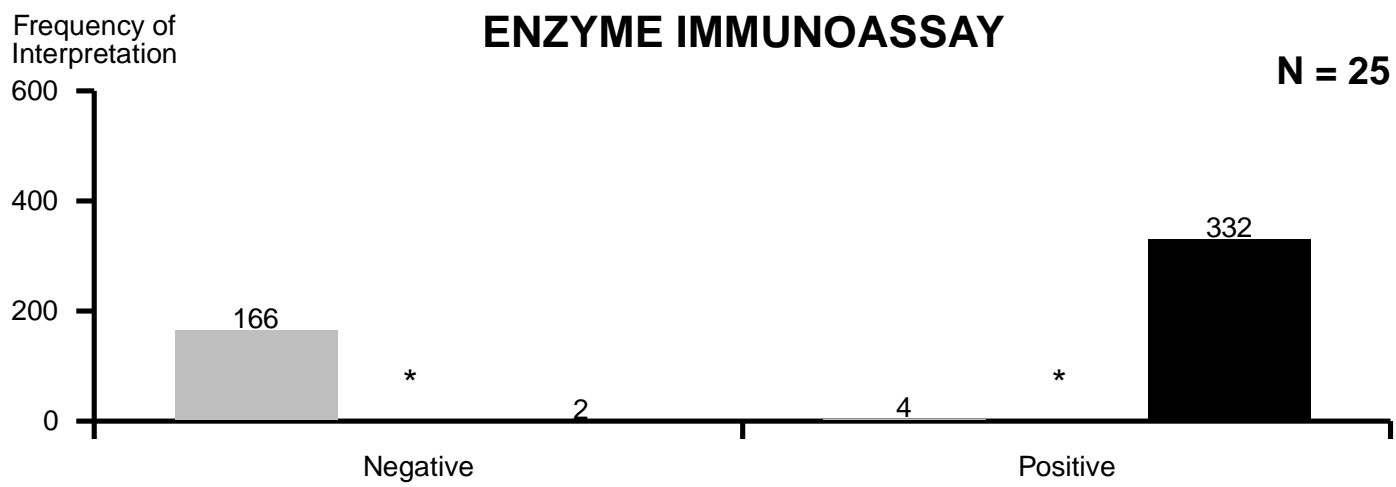
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

*BioMerieux Vitek/Cambridge Biotech

**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, 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 reference laboratories for the January 6, 1997 shipment



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

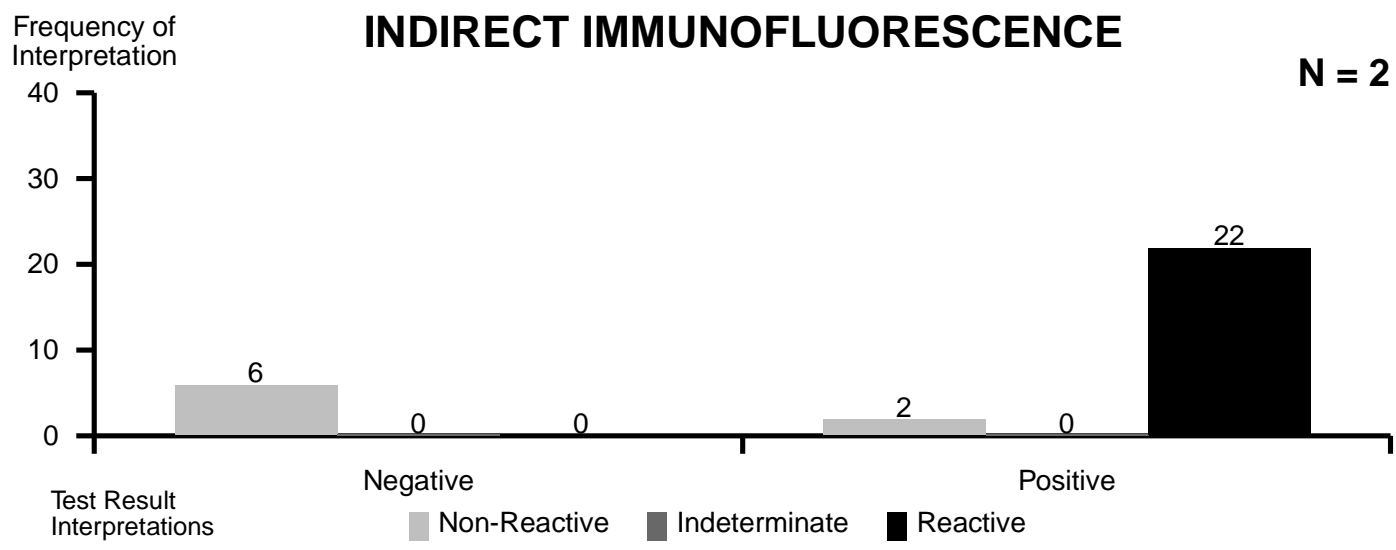
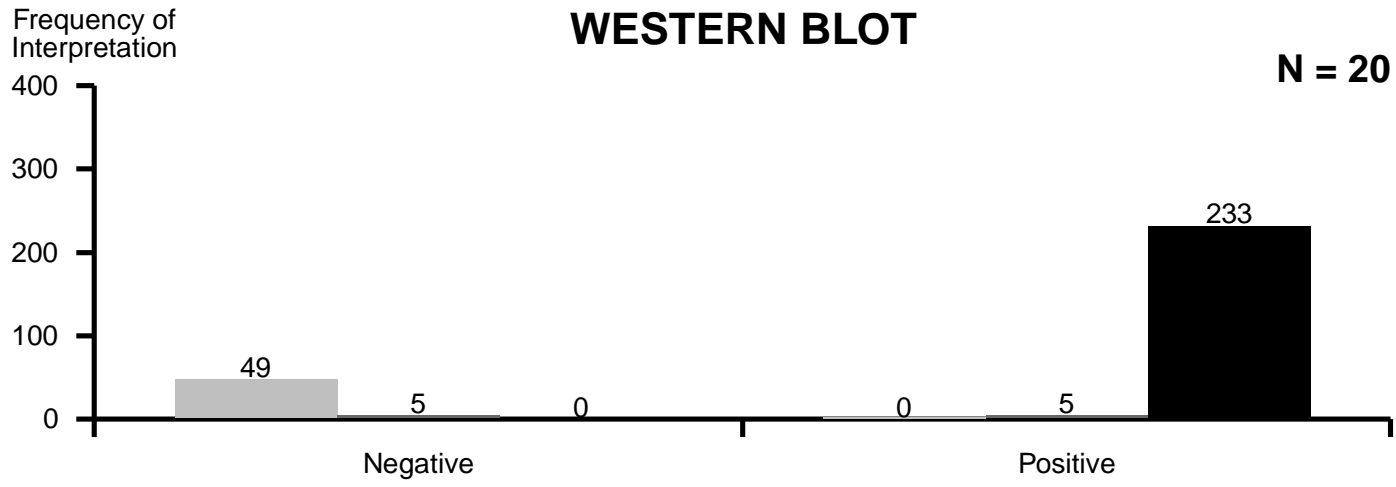


Figure 2. Percentage of HIV-1 reference laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the January 6, 1997 shipment

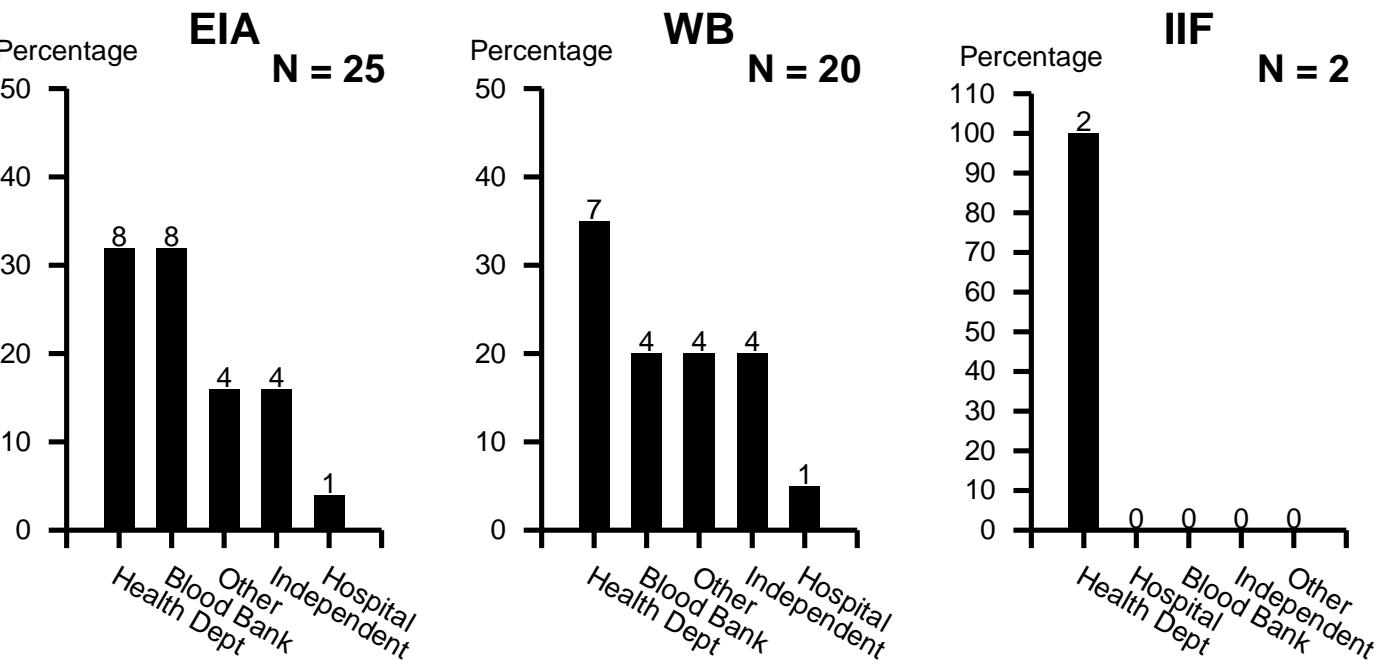


Figure 3. Combination of HIV-1 antibody tests reported by reference laboratories for the January 6, 1997 shipment

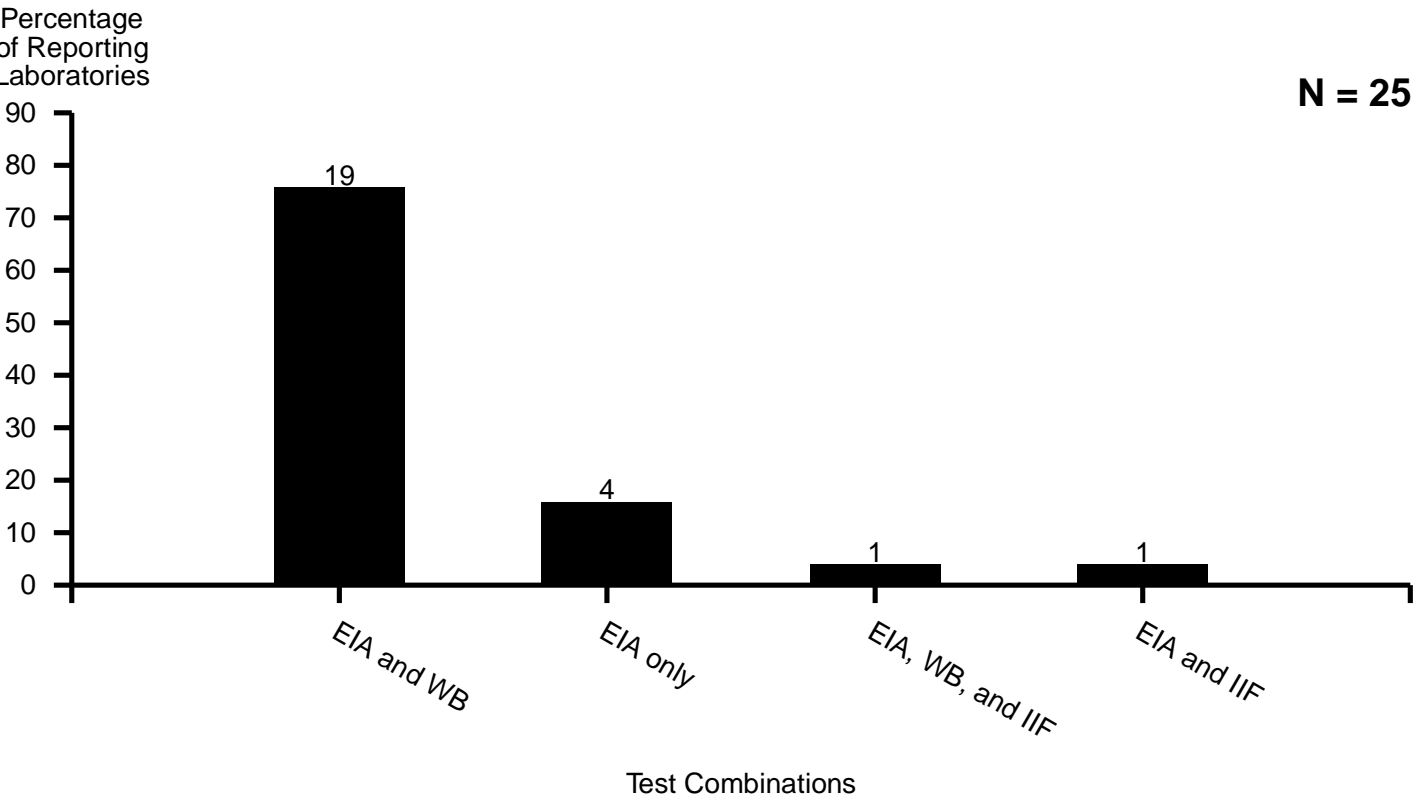


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the January 6, 1997 shipment

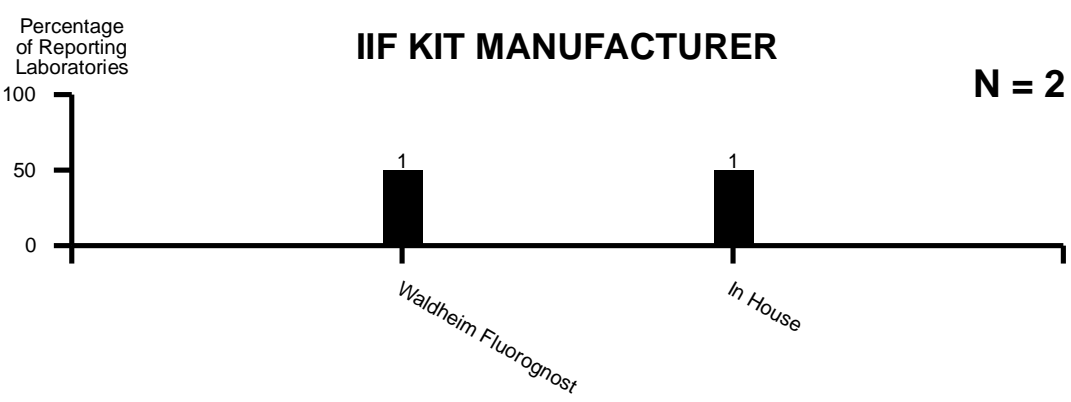
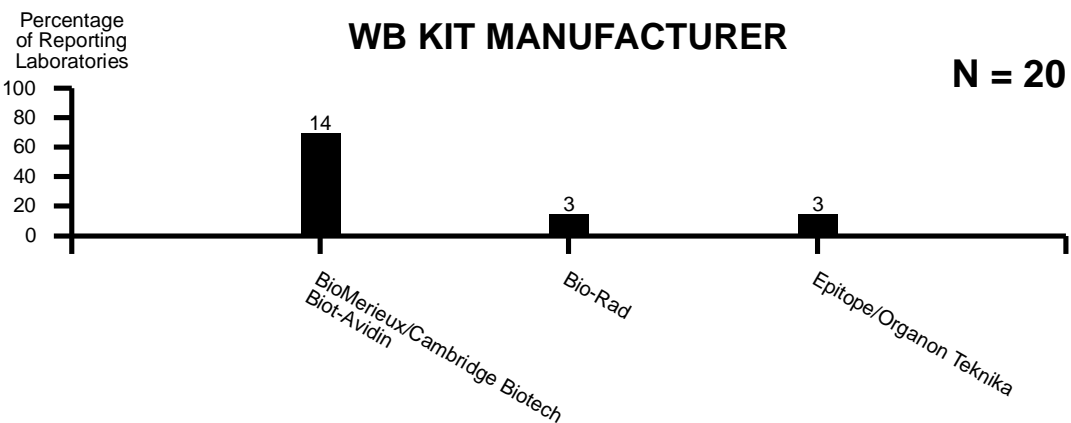
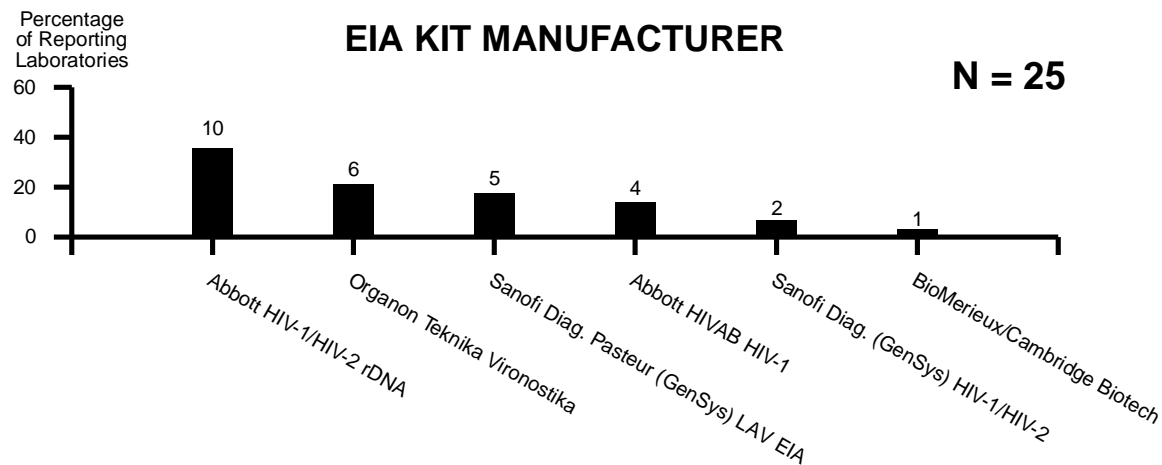
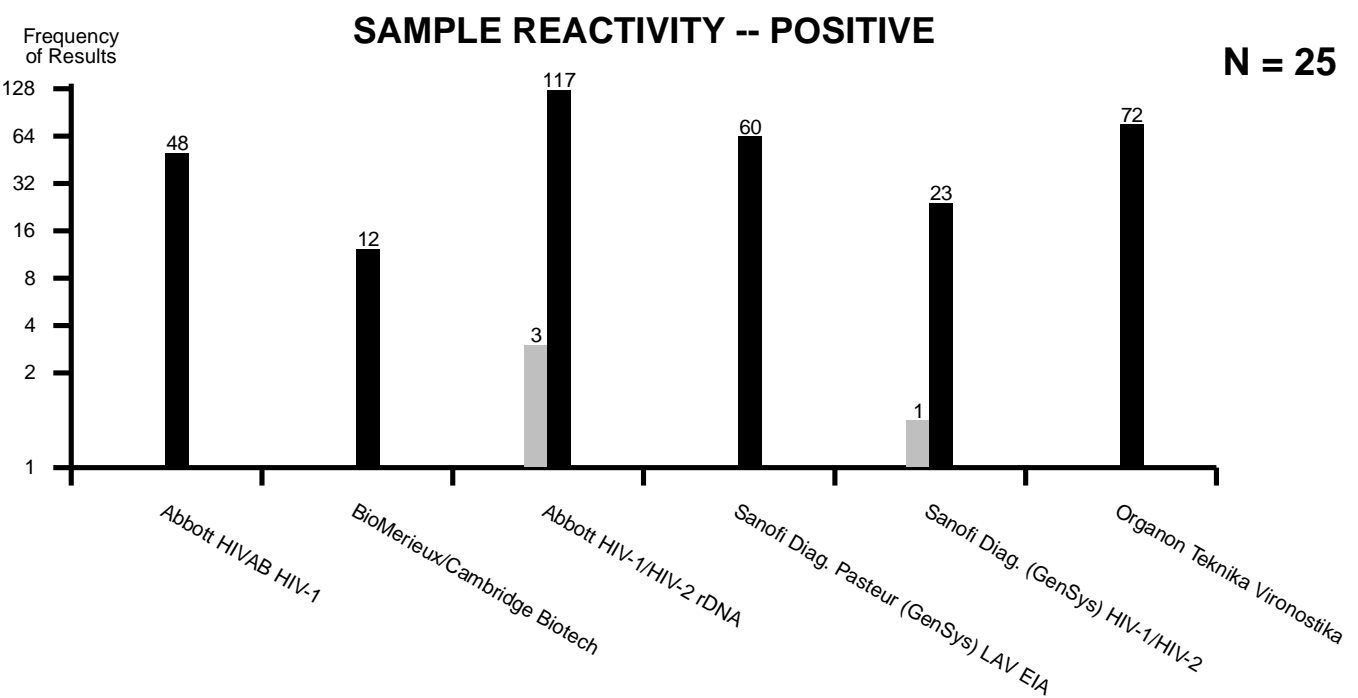
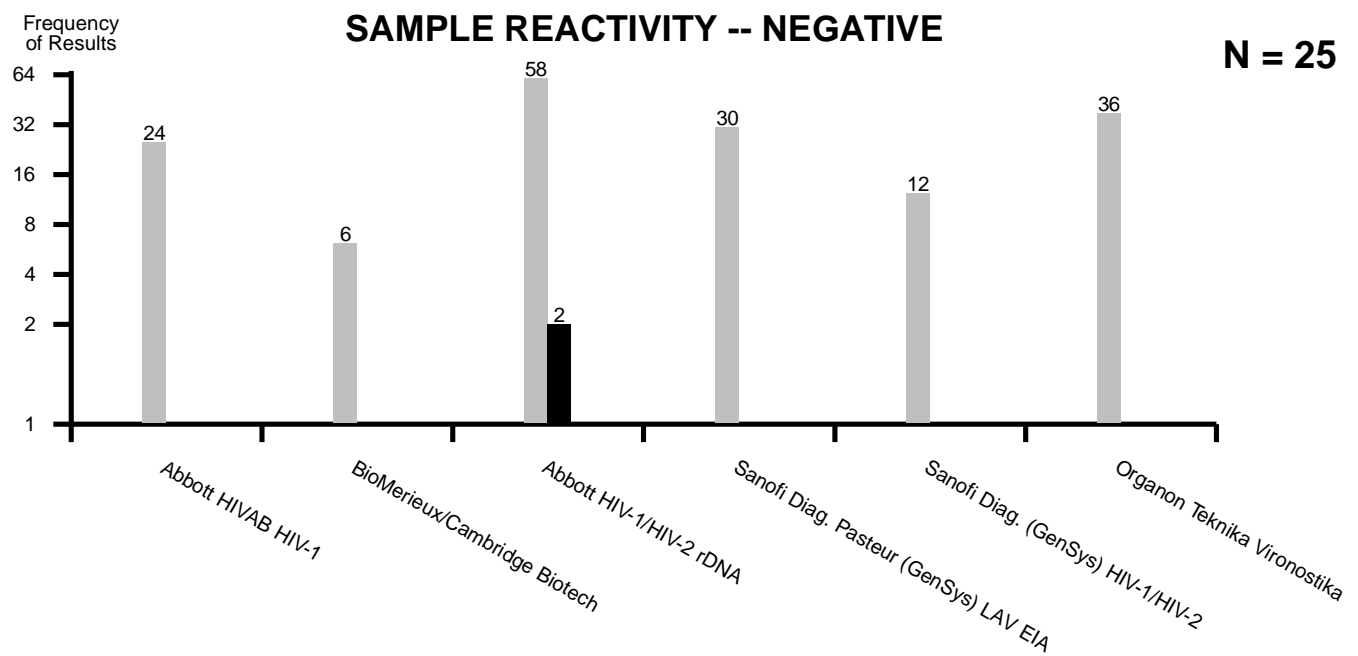


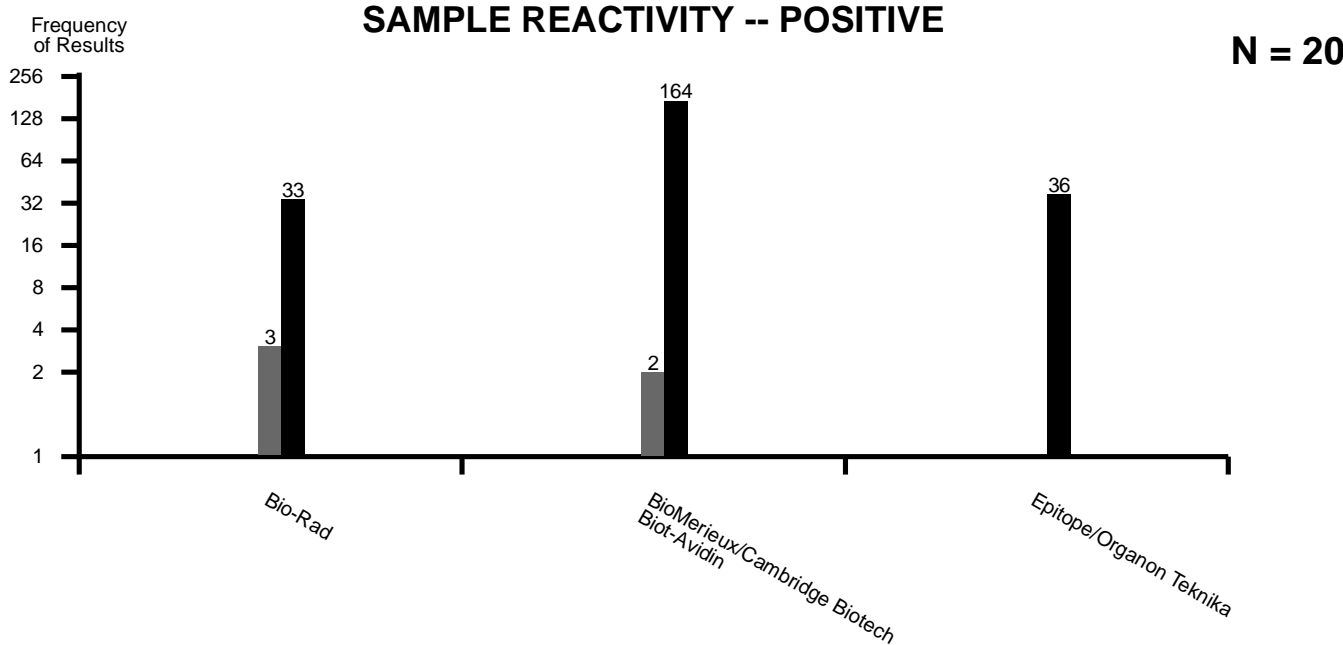
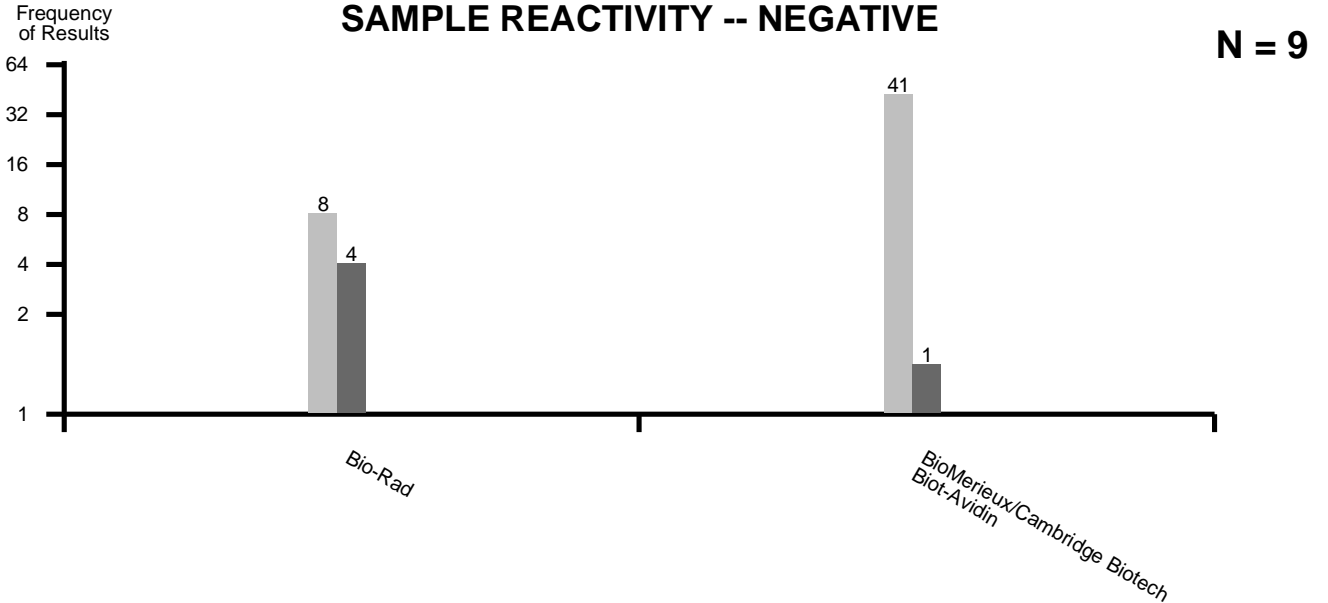
Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 6, 1997 shipment



Test Result Interpretations

■ Non-Reactive ■ Reactive

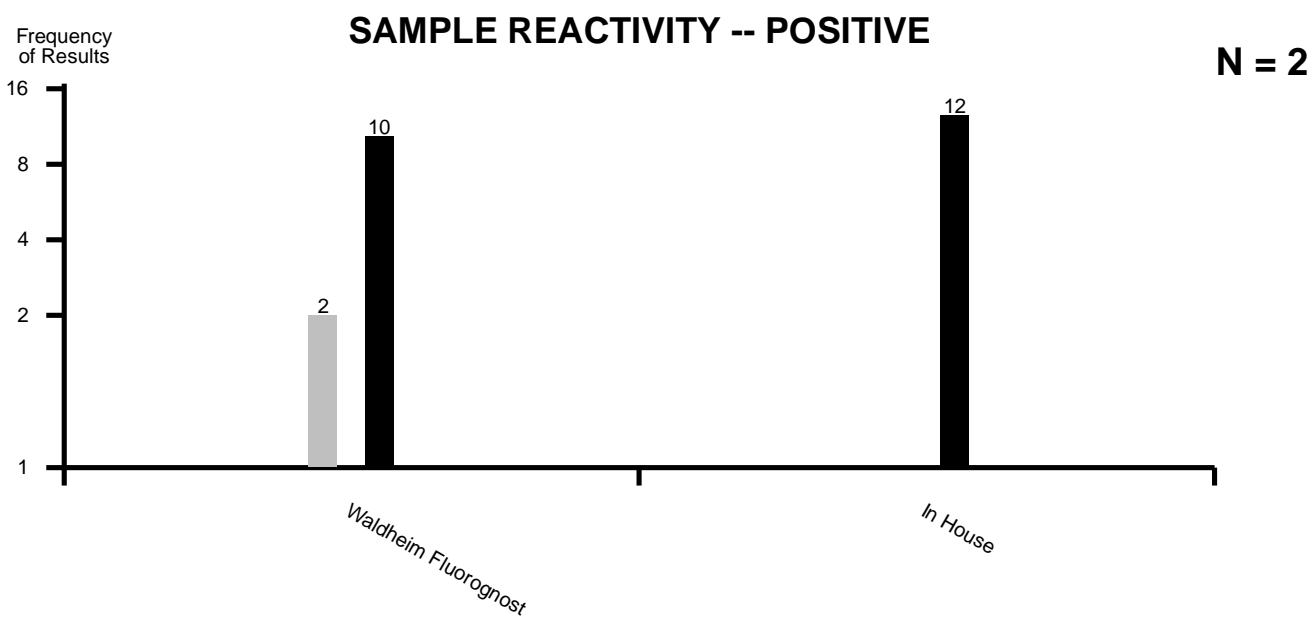
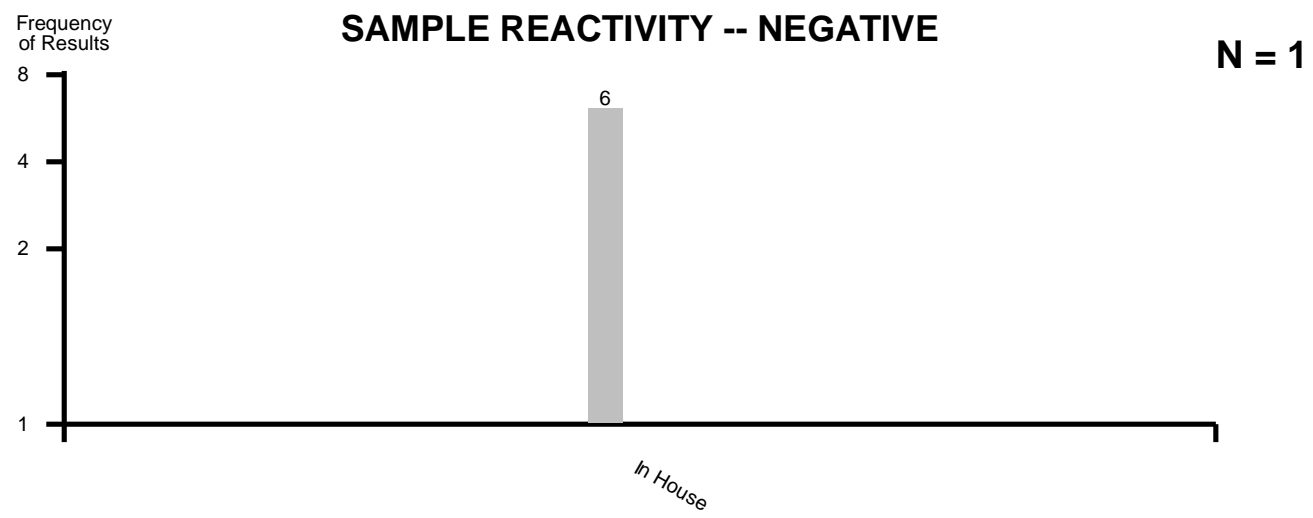
Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 6, 1997 shipment



Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 6, 1997 shipment



Test Result Interpretations

Non-Reactive
 Indeterminate
 Reactive

Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 6, 1997 shipment

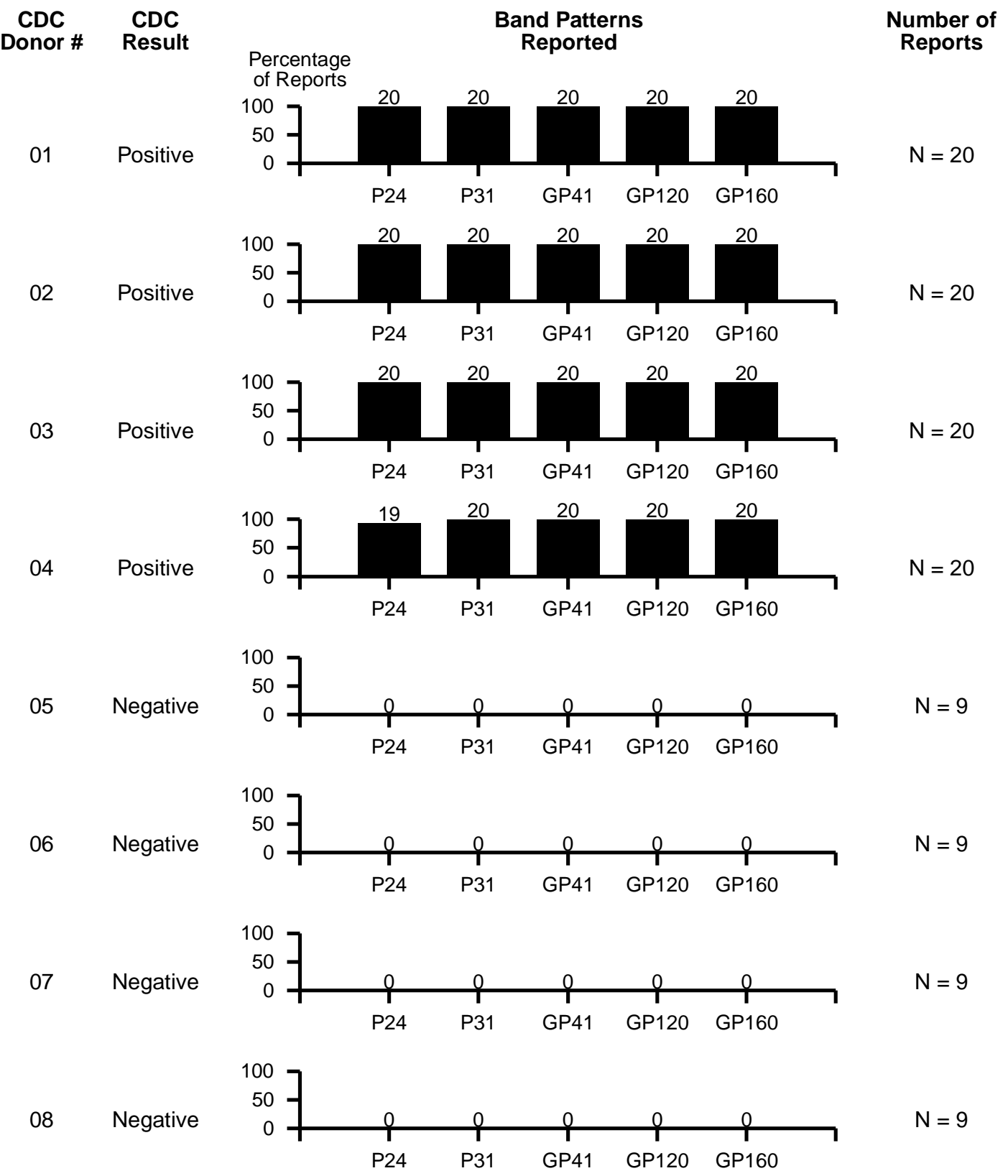


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 6, 1997 shipment

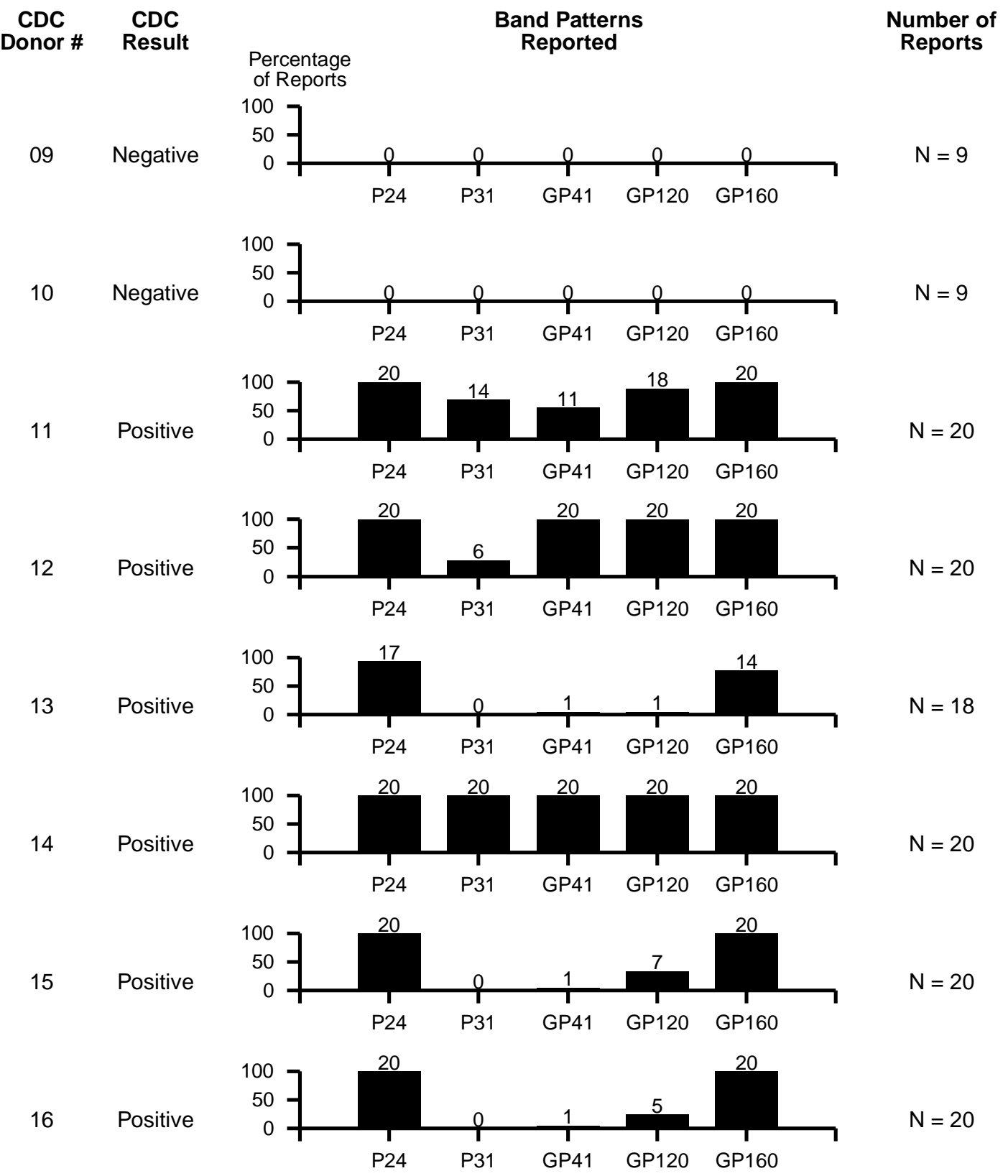


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 6, 1997 shipment

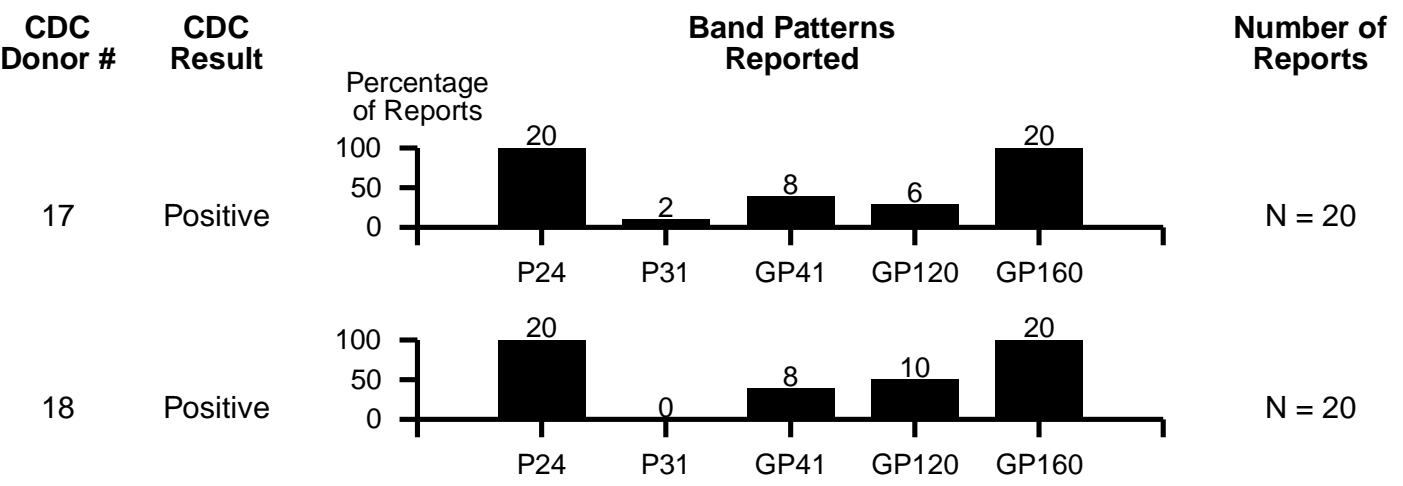


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 6, 1997 shipment

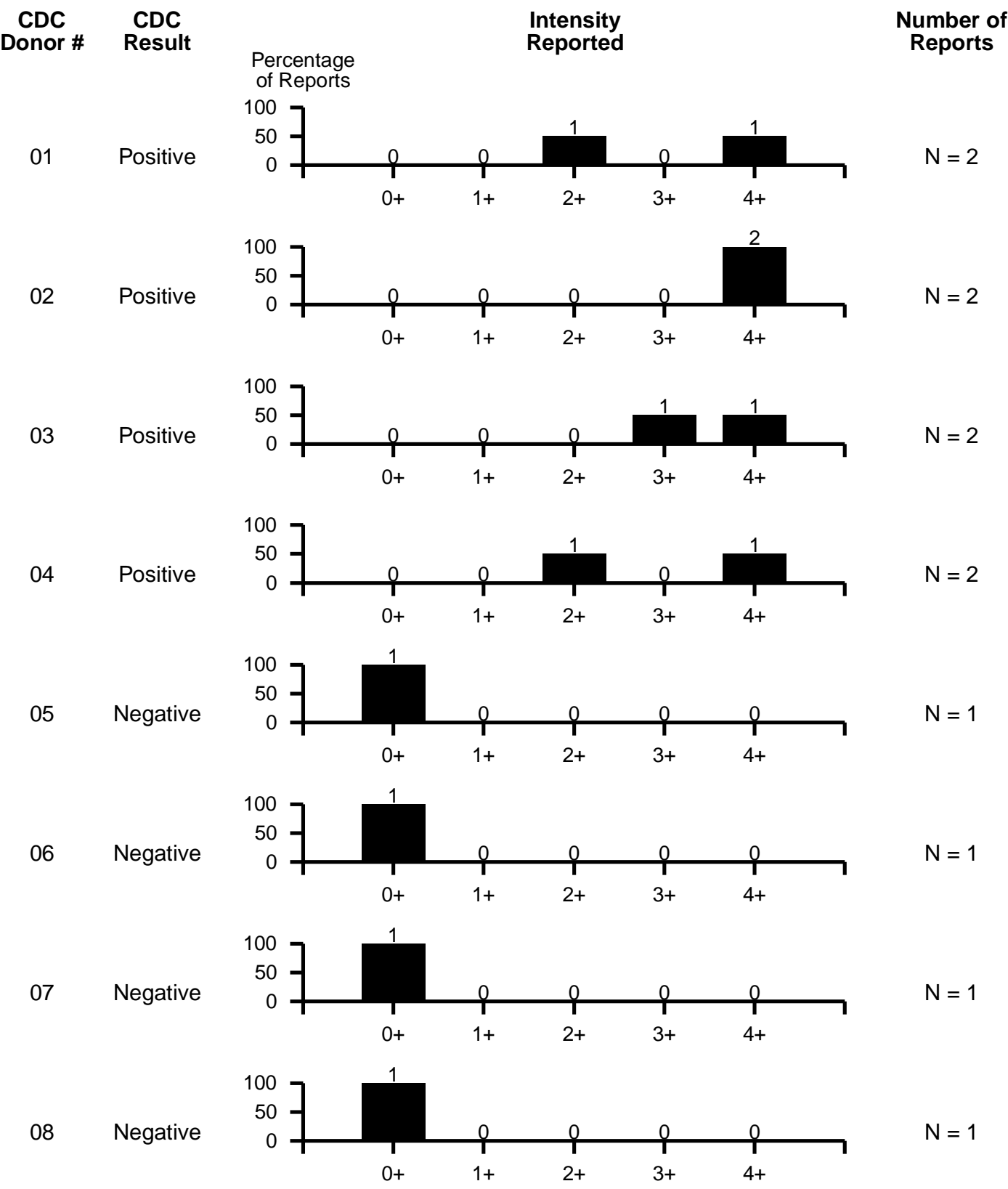


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 6, 1997 shipment

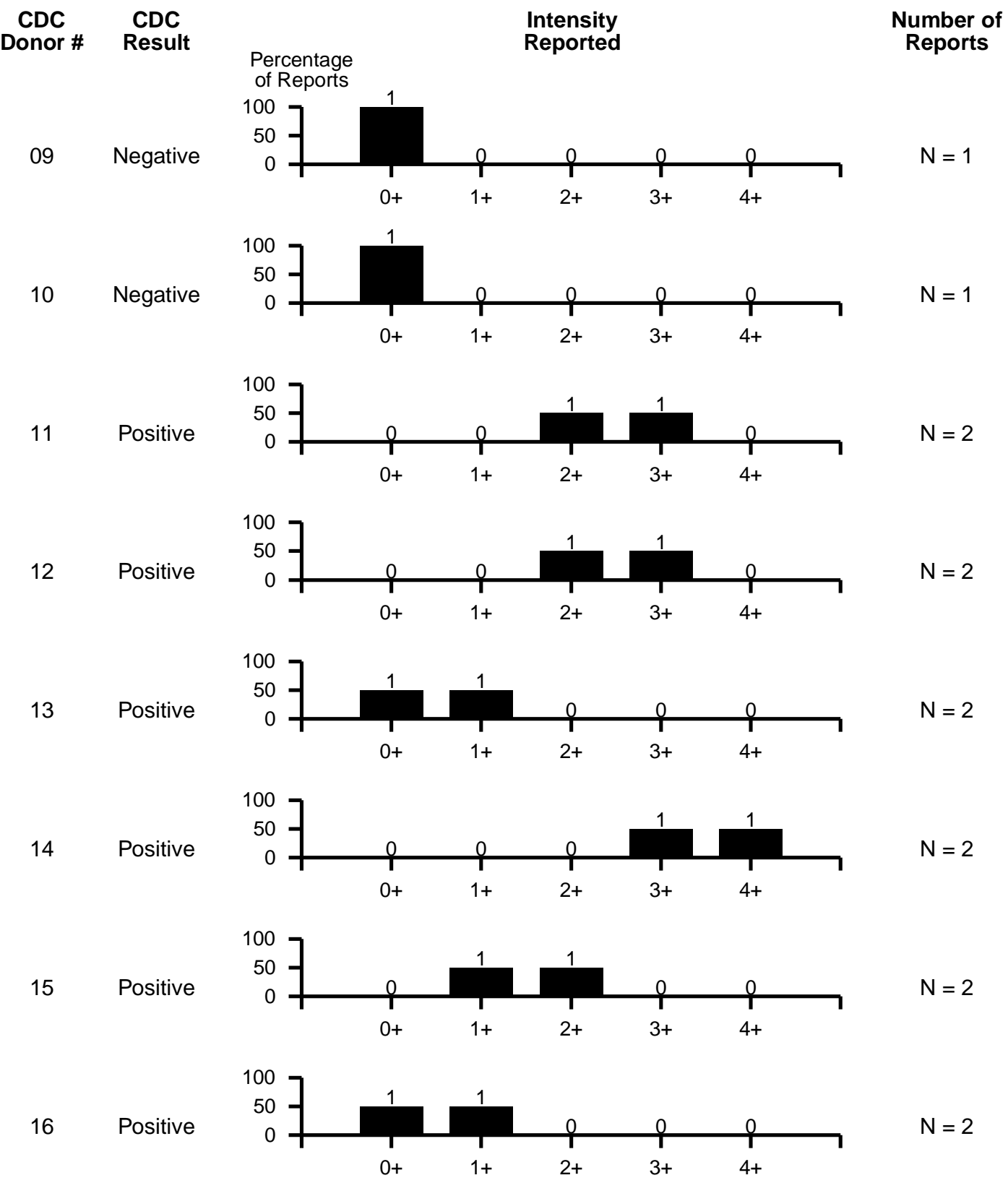


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 6, 1997 shipment

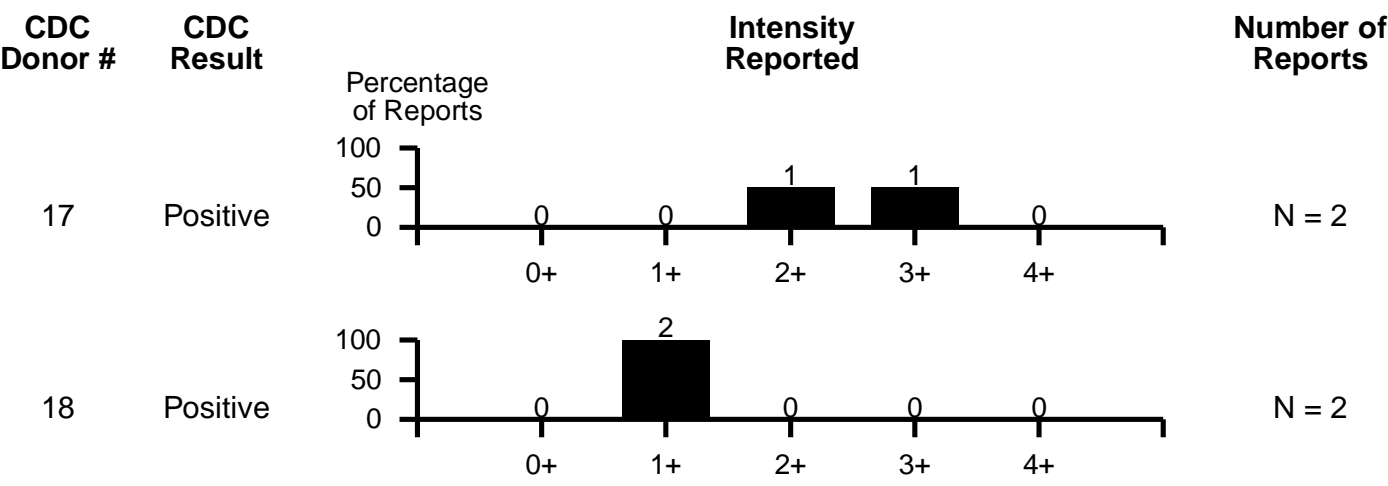


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by reference laboratories to the CDC for the January 6, 1997 shipment

