

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

**Figures Used to Summarize the  
Candidate Reference Laboratory Results  
for the January 4, 1999 Shipment**

**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**



**Use of trade names is for identification only and does not constitute endorsement  
by the U.S. Department of Health and Human Services.**

Report of the January 4, 1999 Human Immunodeficiency Virus Type I (HIV-1)  
Antibody Performance Evaluation Sample Testing Results Provided by  
Candidate Reference Laboratories in the Model Performance Evaluation  
Program, Centers for Disease Control and Prevention (CDC).

---

---

The production of this report was coordinated in CDC by:

Public Health Practice Program Office.....Edward L. Baker, M.D., M.P.H., Director  
Division of Laboratory Systems.....Robert Martin, Dr.P. H., Director  
Laboratory Practice Assessment Branch.....Thomas L. Hearn, Ph.D., Chief

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP).....William O. Schalla, M.S., Chief  
MPEP HIV -1 Performance Evaluation.....Sharon O. Blumer, M.S.  
HIV-1 Project Coordinator

---

---

Information about this report should be addressed to the Model Performance Evaluation  
Program by calling (770) 488-8090 or (770) 488-8098.

**Centers for Disease Control and Prevention (CDC)  
Model Performance Evaluation Program  
Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing  
January 4, 1999 Candidate Reference Laboratory Shipment**

**Table 1**

Label Number	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>		
01	03	Indeterminate	Infected	---	---	---	---
02	06	Positive	Infected	---	---	---	---
03	13	Positive	Infected	---	---	---	---
04	18	Positive	Infected	---	---	---	---
05	15	Negative	Uninfected	---	---	---	---
06	10	Positive	Infected	---	---	---	---
07	02	See Table 2	Infected	---	---	---	---
08	08	See Table 2	Infected	---	---	---	---
09	01	Indeterminate	Infected	---	---	---	---
10	09	See Table 2	Infected	---	---	---	---
11	14	Positive	Infected	---	---	---	---
12	11	Positive	Infected	---	---	---	---
13	05	Positive	Infected	---	---	---	---
14	17	Positive	Infected	---	---	---	---
15	04	Positive	Infected	---	---	---	---
16	07	Positive	Infected	---	---	---	---
17	16	Negative	Uninfected	---	---	---	---
18	12	Positive	Infected	---	---	---	---

<sup>1</sup> Laboratory Interpretation space (to be completed by candidate reference laboratory) provided to facilitate comparison of candidate reference 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 4, 1999 Candidate Reference Laboratory Panel Samples**

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

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

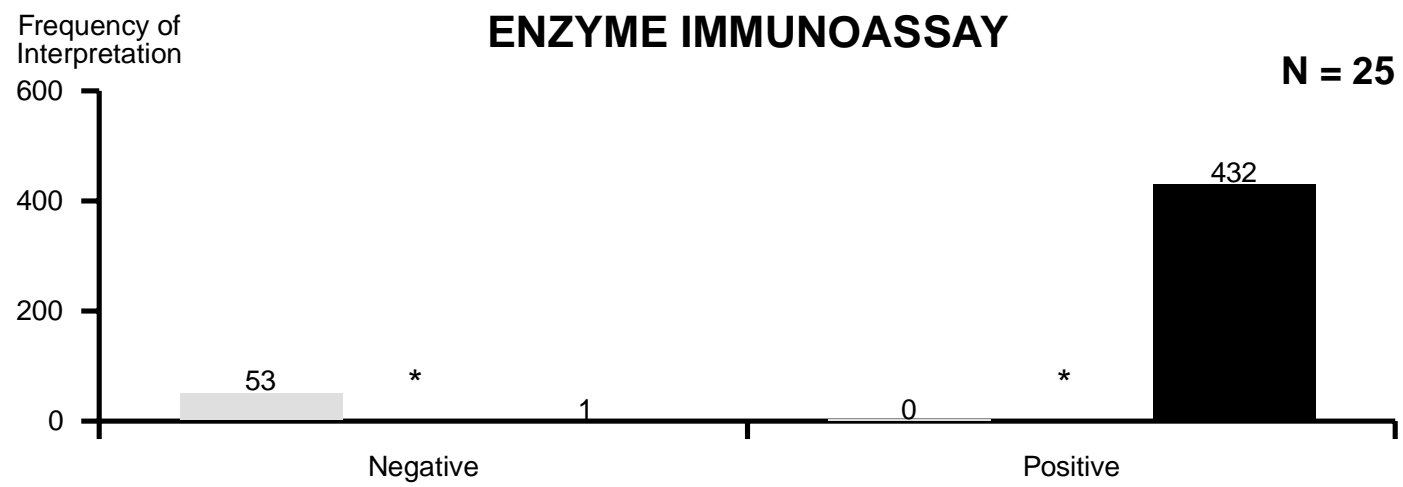
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

\* bioMerieux Vitek/Cambridge Biotech

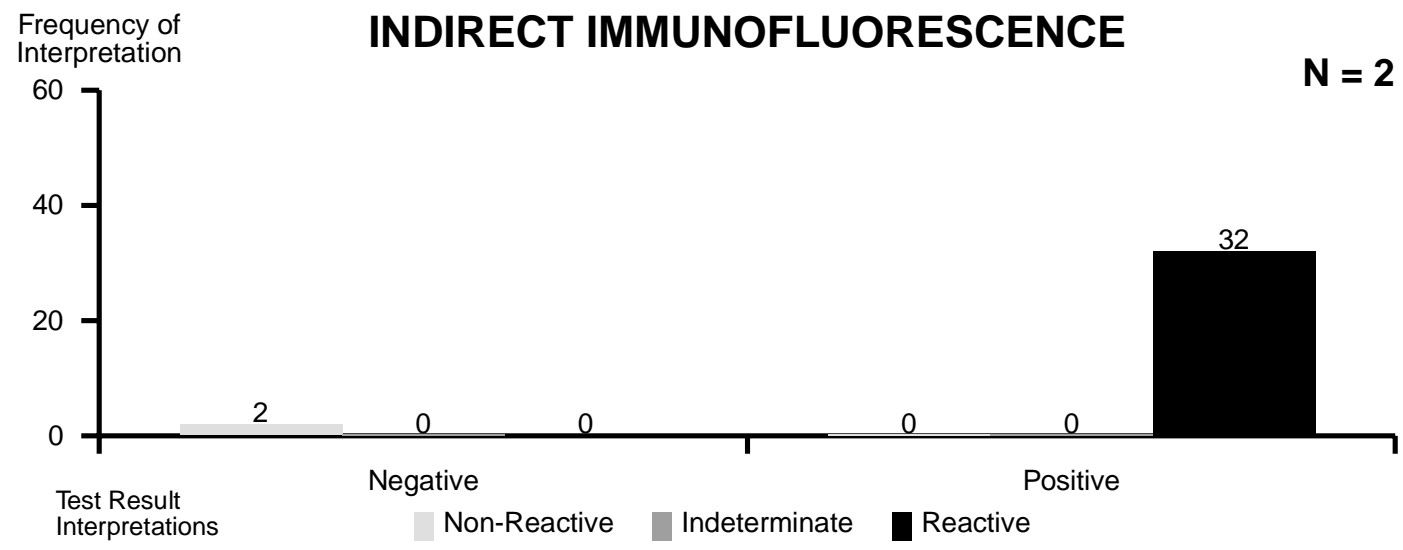
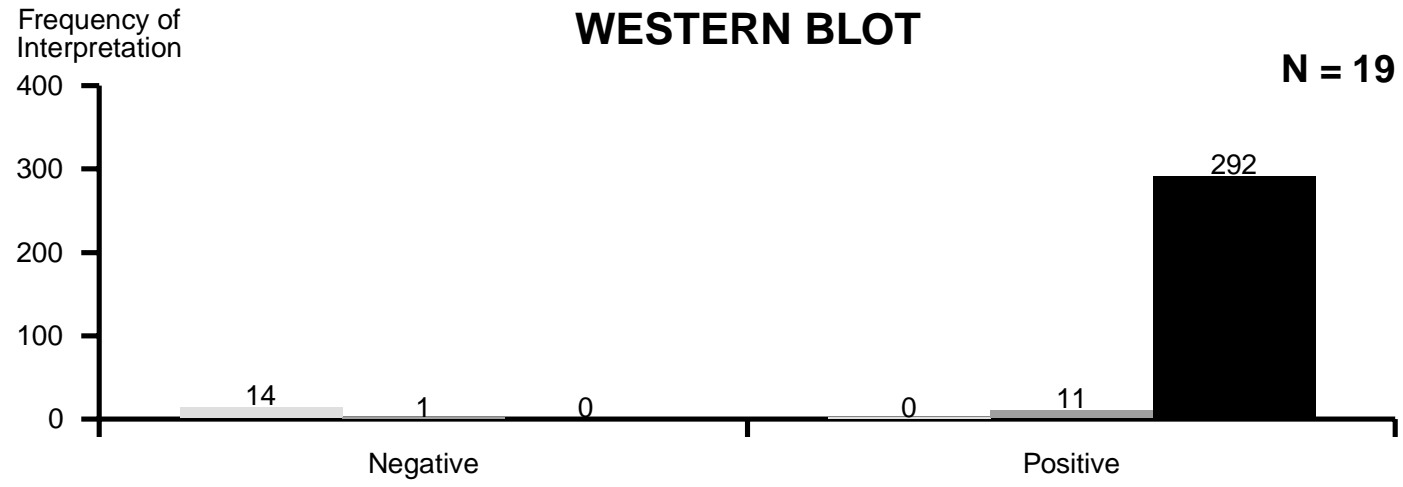
## **SUPPLEMENTAL INFORMATION FOR COMPREHENDING THE NUMBERS USED TO LABEL FIGURES IN THIS REPORT**

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.

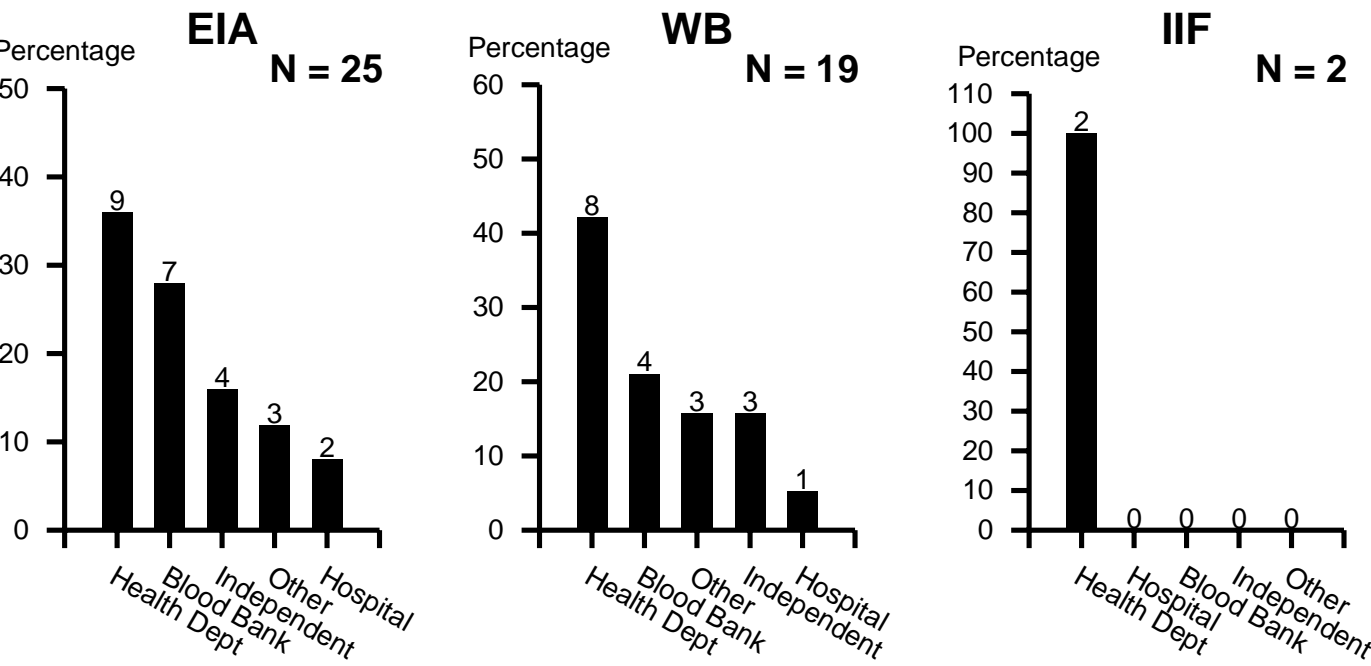
**Figure 1. Frequency of HIV-1 antibody test result interpretations, by sample type (reactivity), for enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by reference laboratories for the January 4, 1999 shipment**



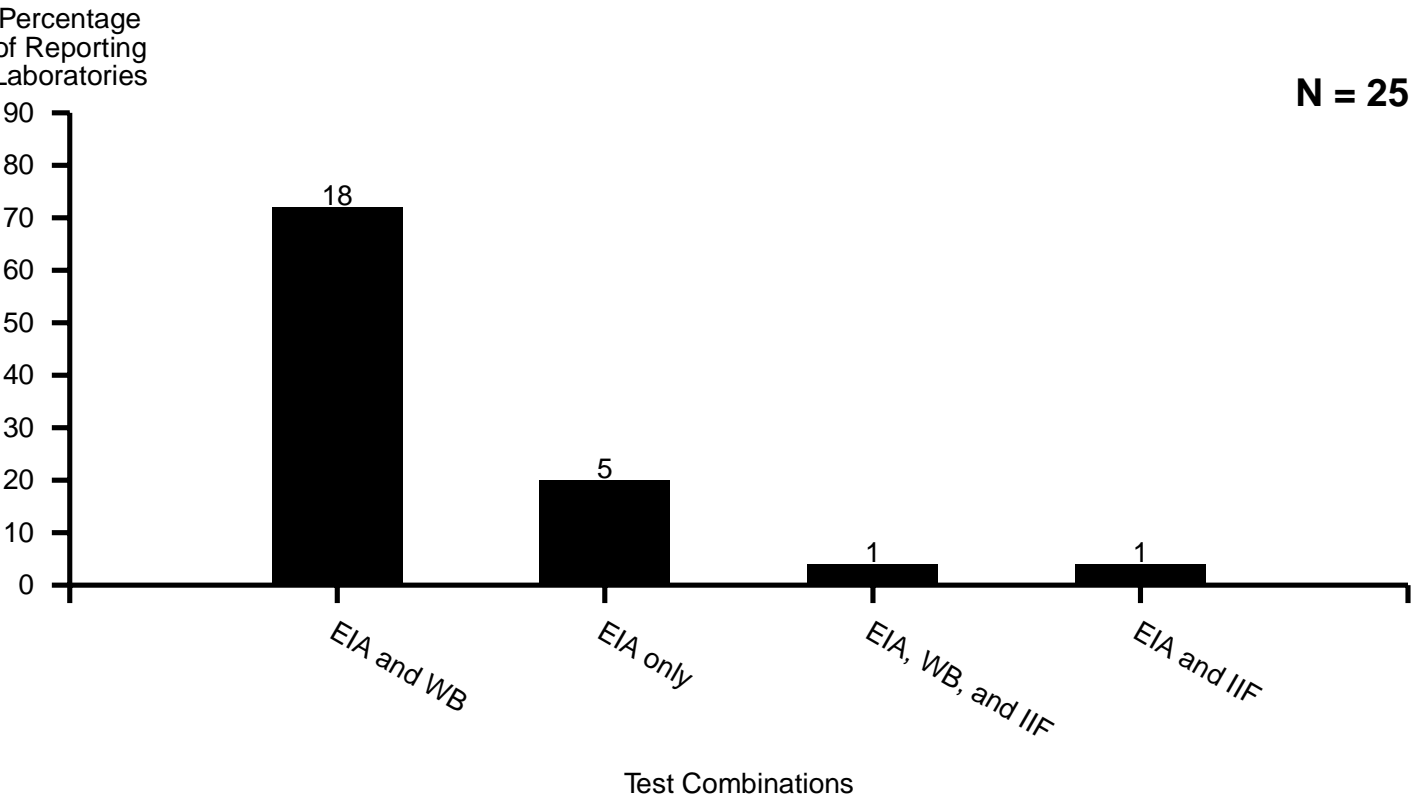
\* = Indeterminate is not an EIA interpretation option; these areas have been left blank



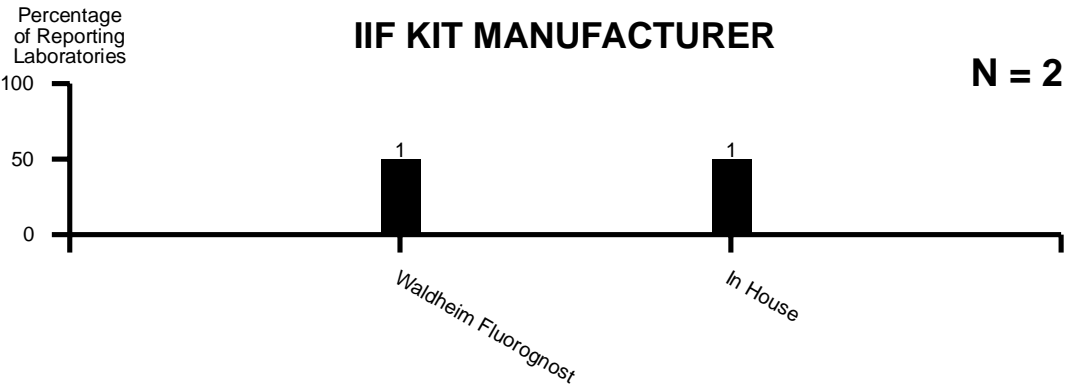
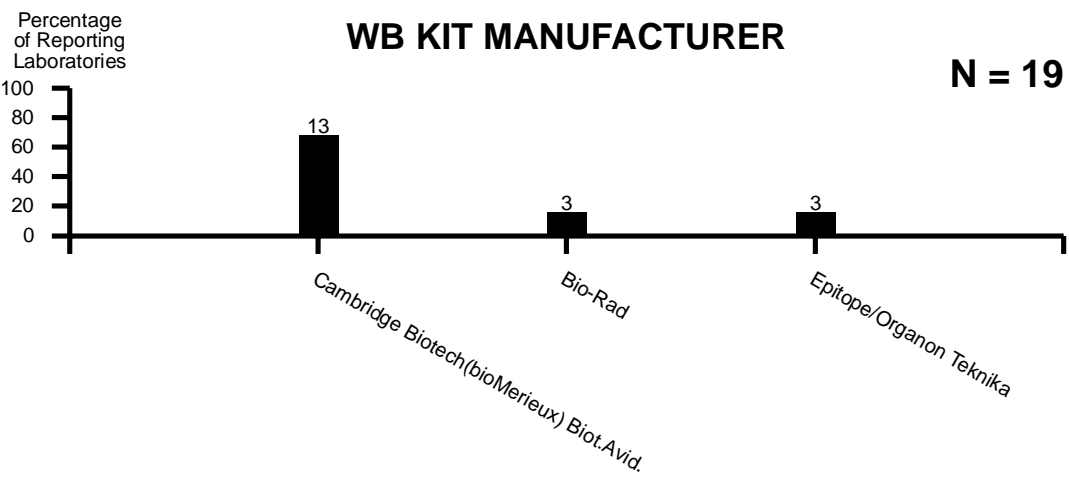
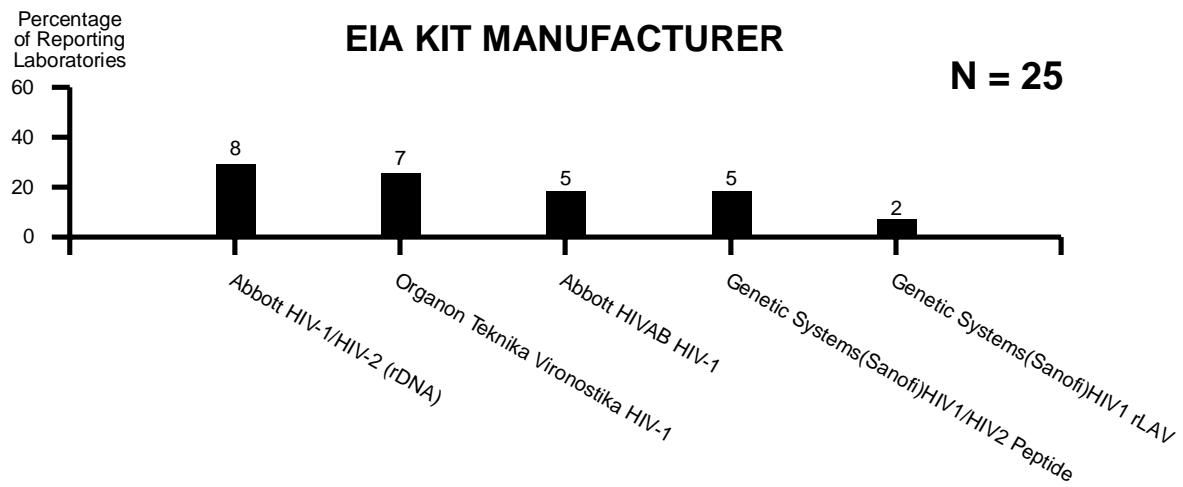
**Figure 2. Percentage of HIV-1 reference laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the January 4, 1999 shipment**



**Figure 3. Combination of HIV-1 antibody tests reported by reference laboratories for the January 4, 1999 shipment**

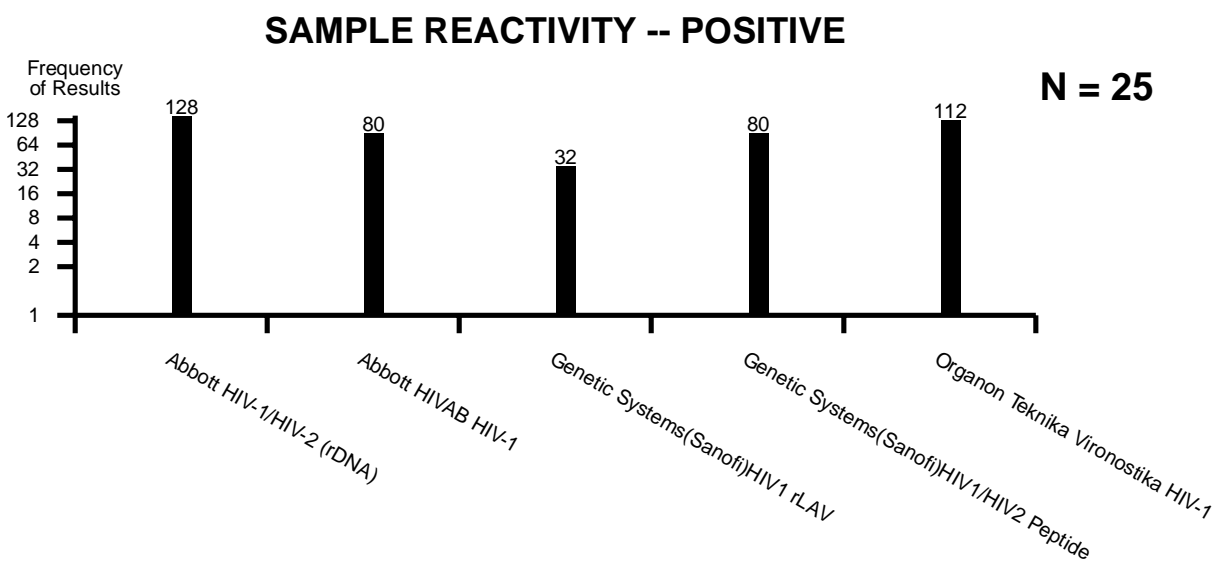
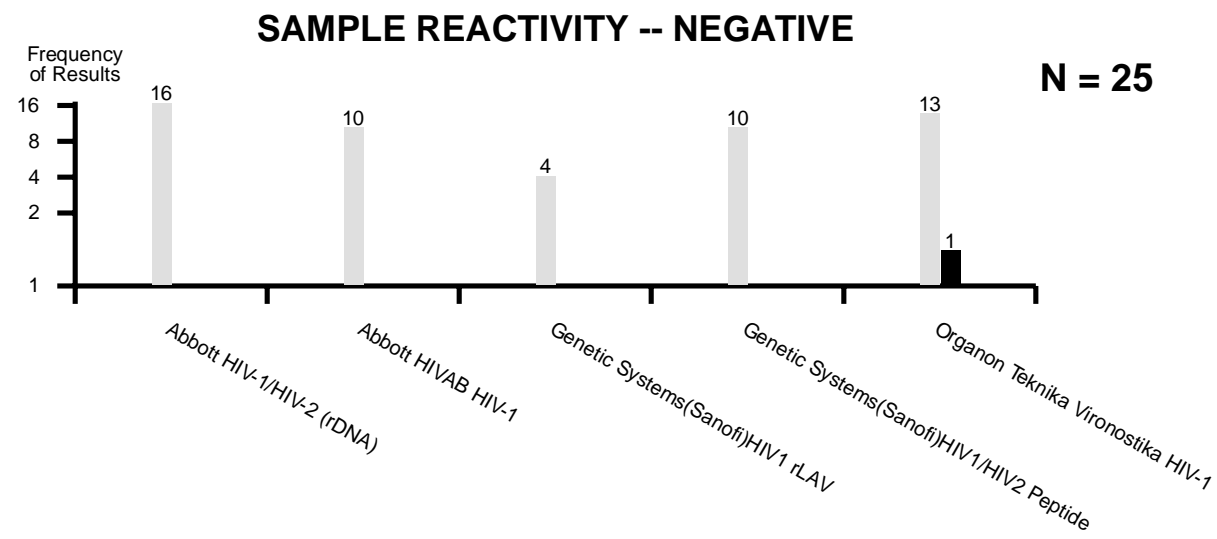


**Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the January 4, 1999 shipment**





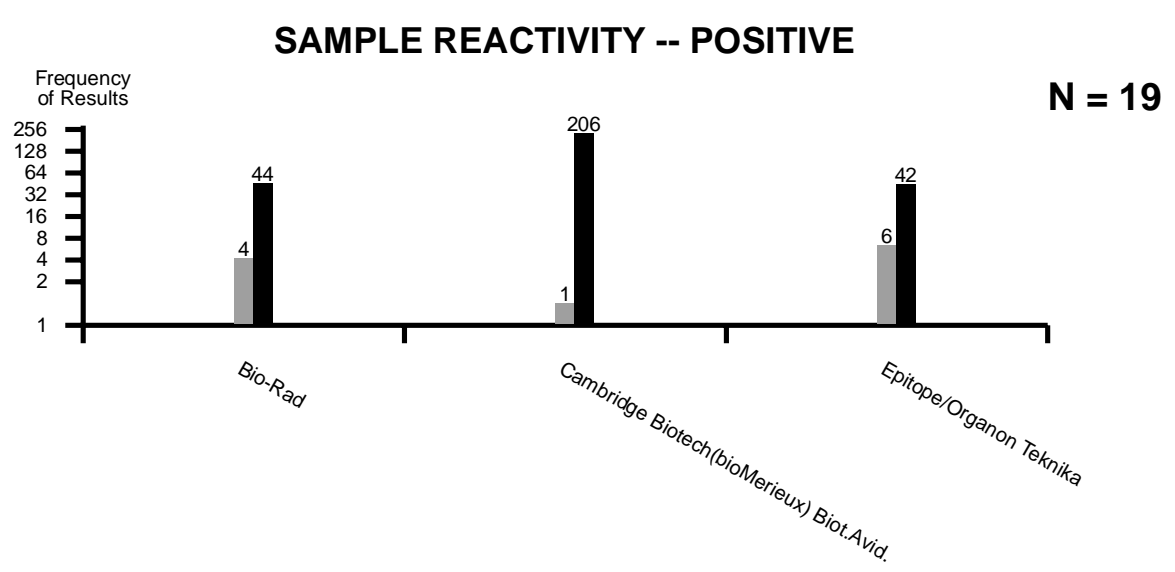
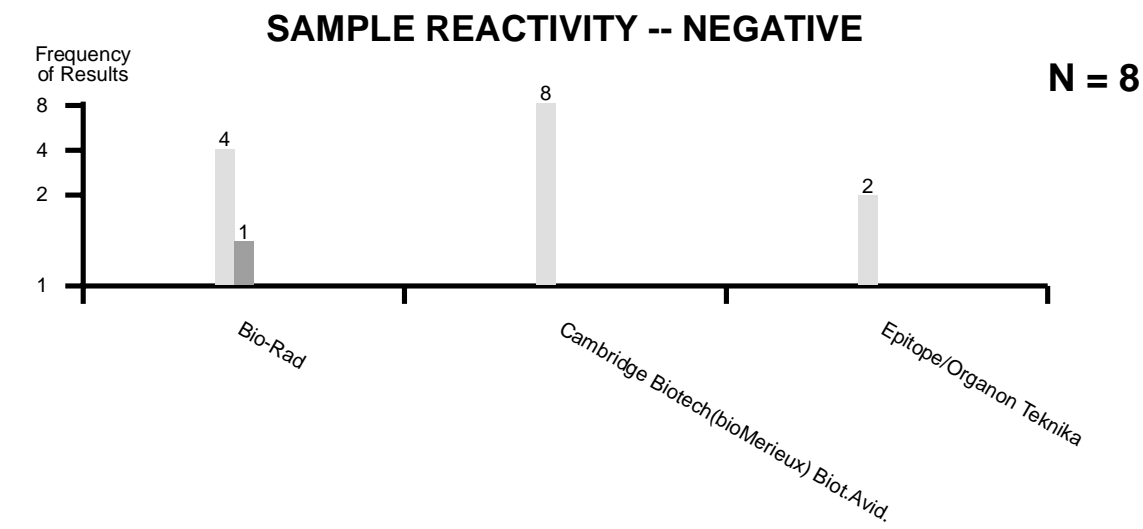
**Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 4, 1999 shipment**



Test Result Interpretations

■ Non-Reactive   ■ Reactive

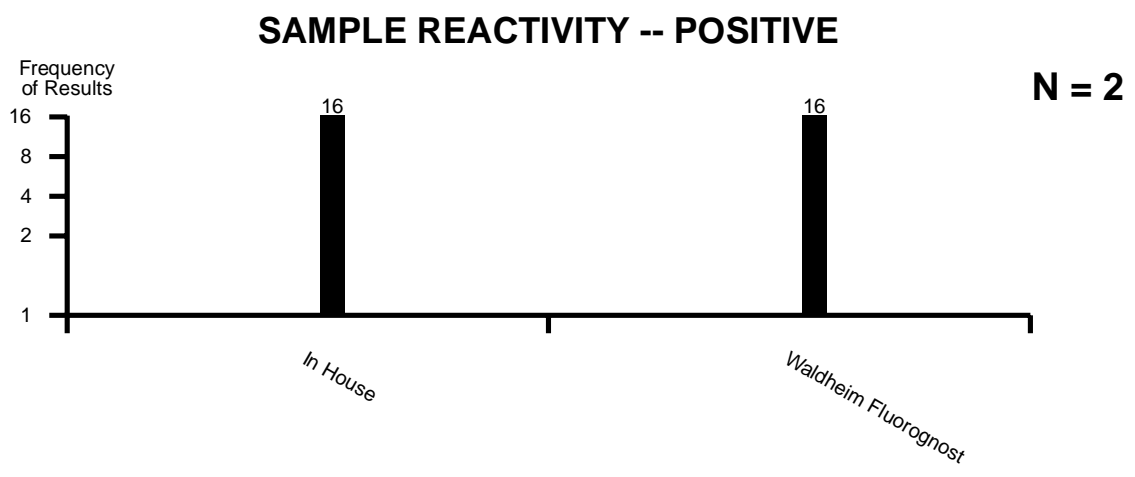
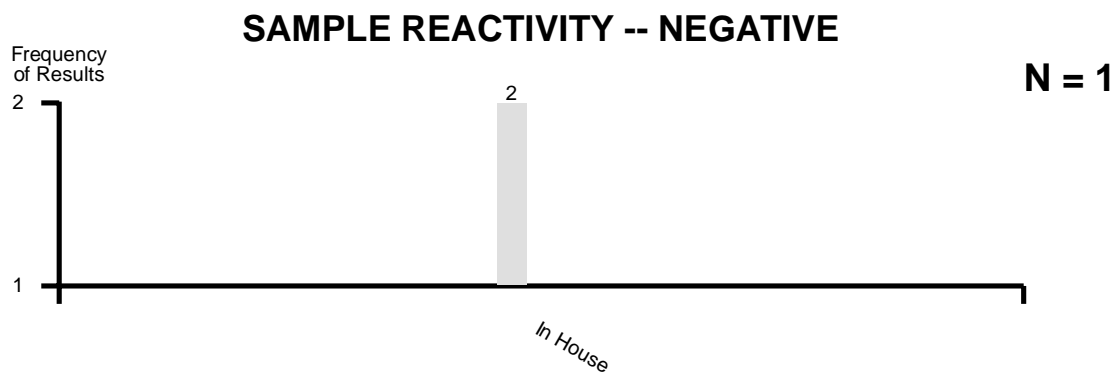
**Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 4, 1999 shipment**



Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

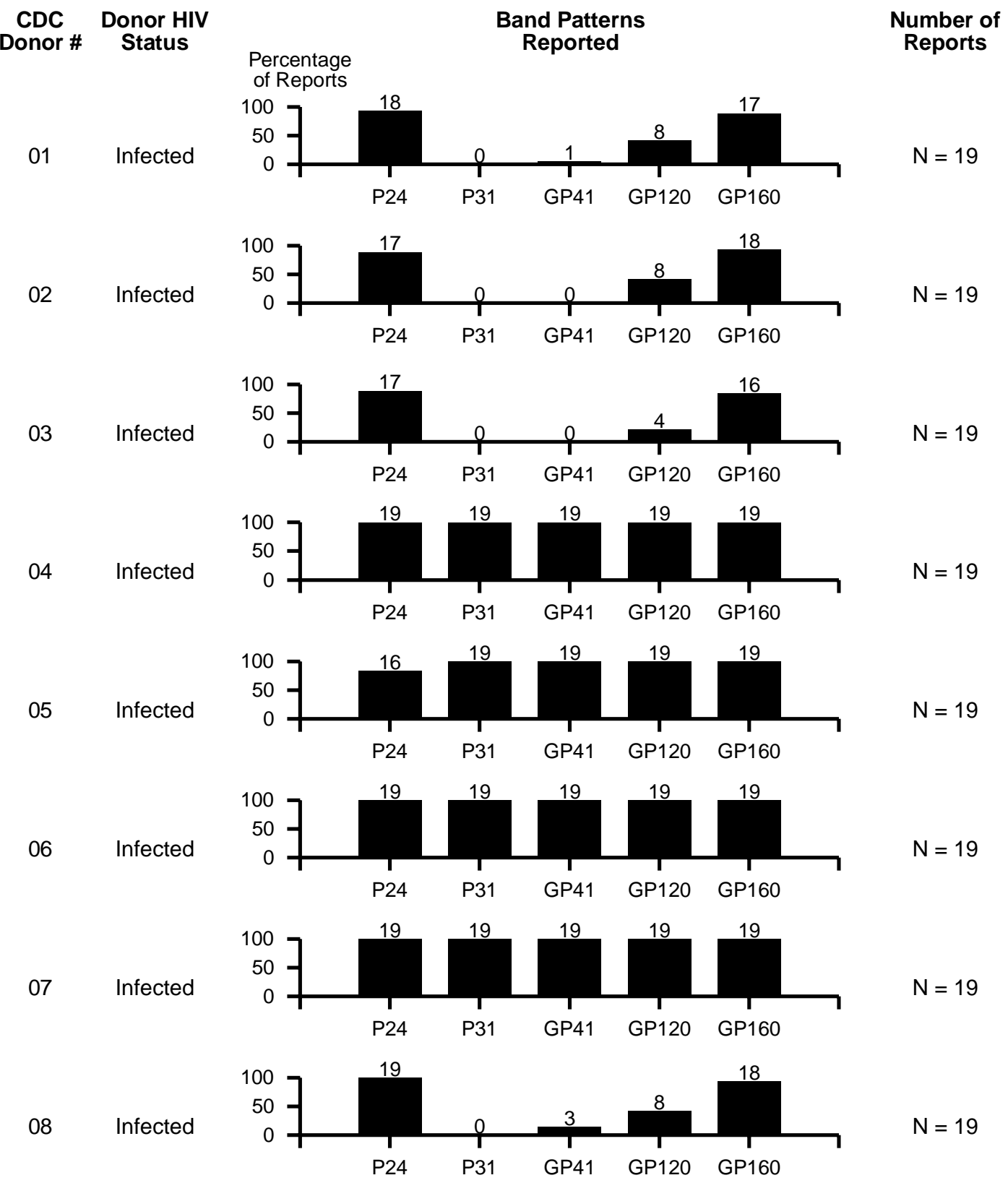
**Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the January 4, 1999 shipment**



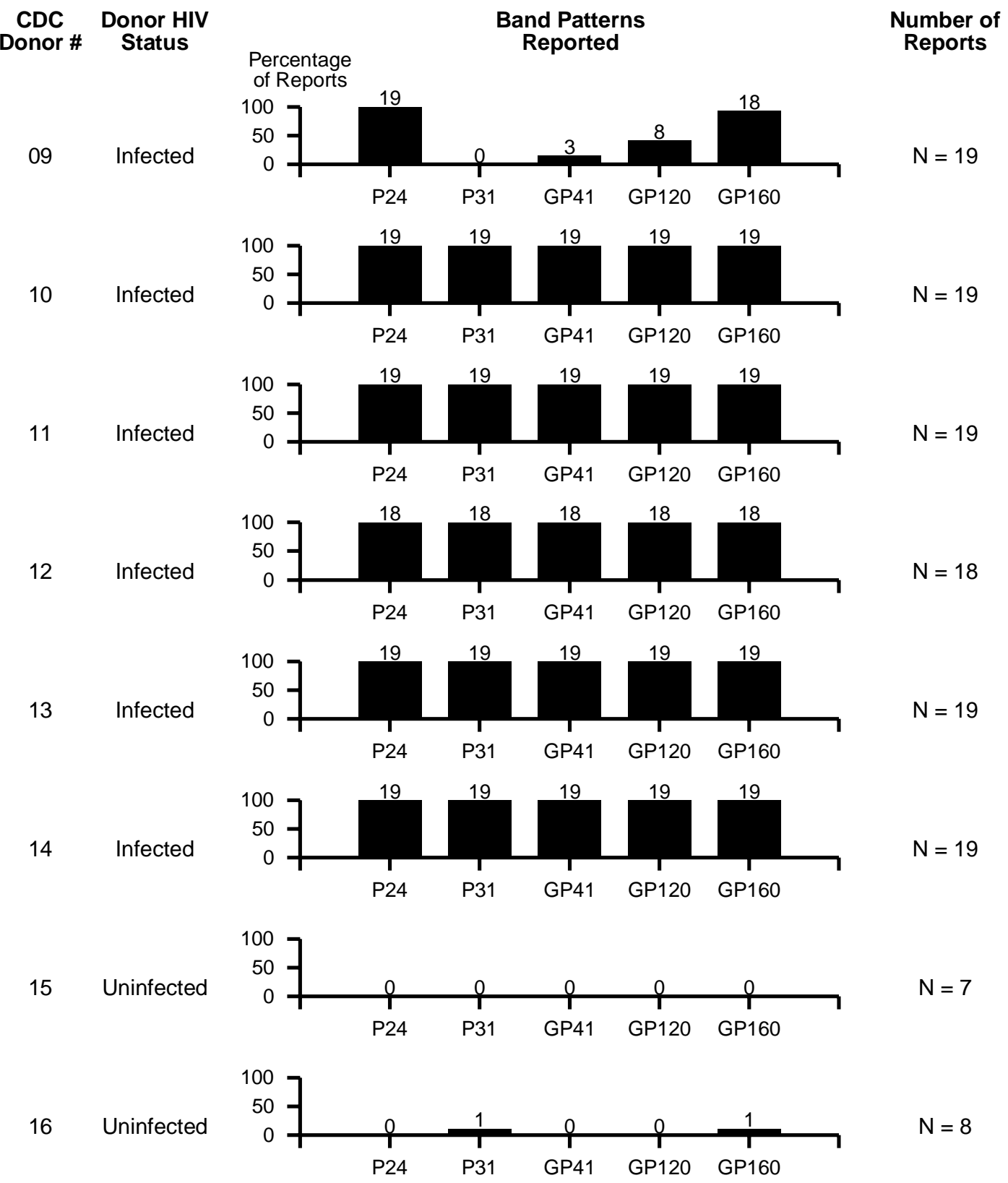
Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

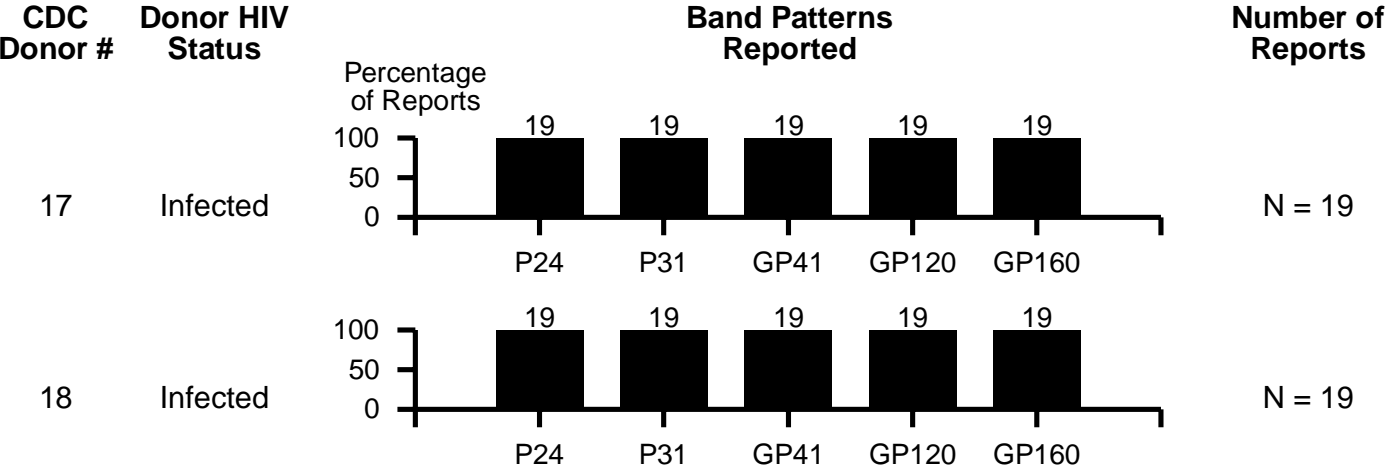
**Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 4, 1999 shipment**



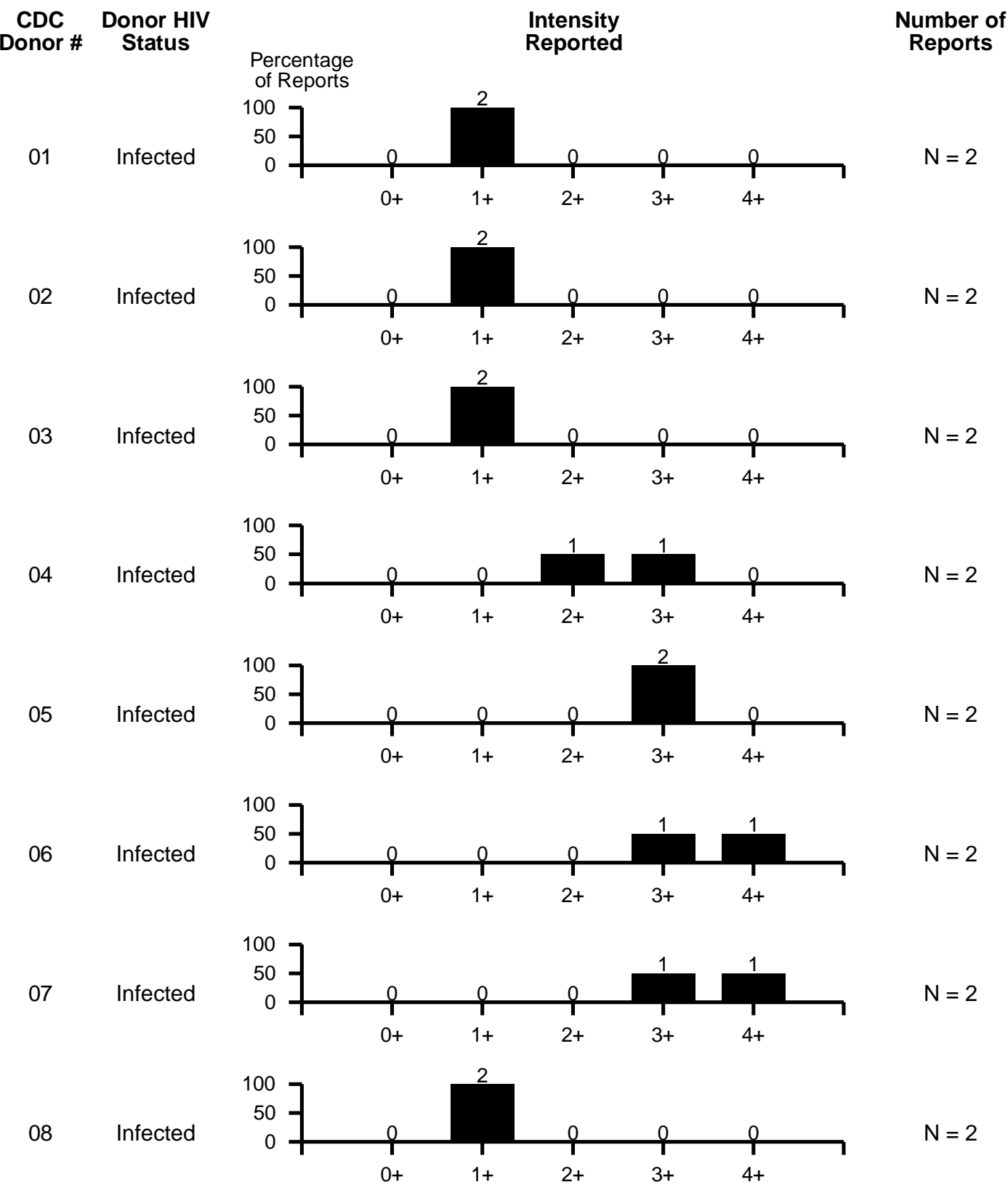
**Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 4, 1999 shipment**



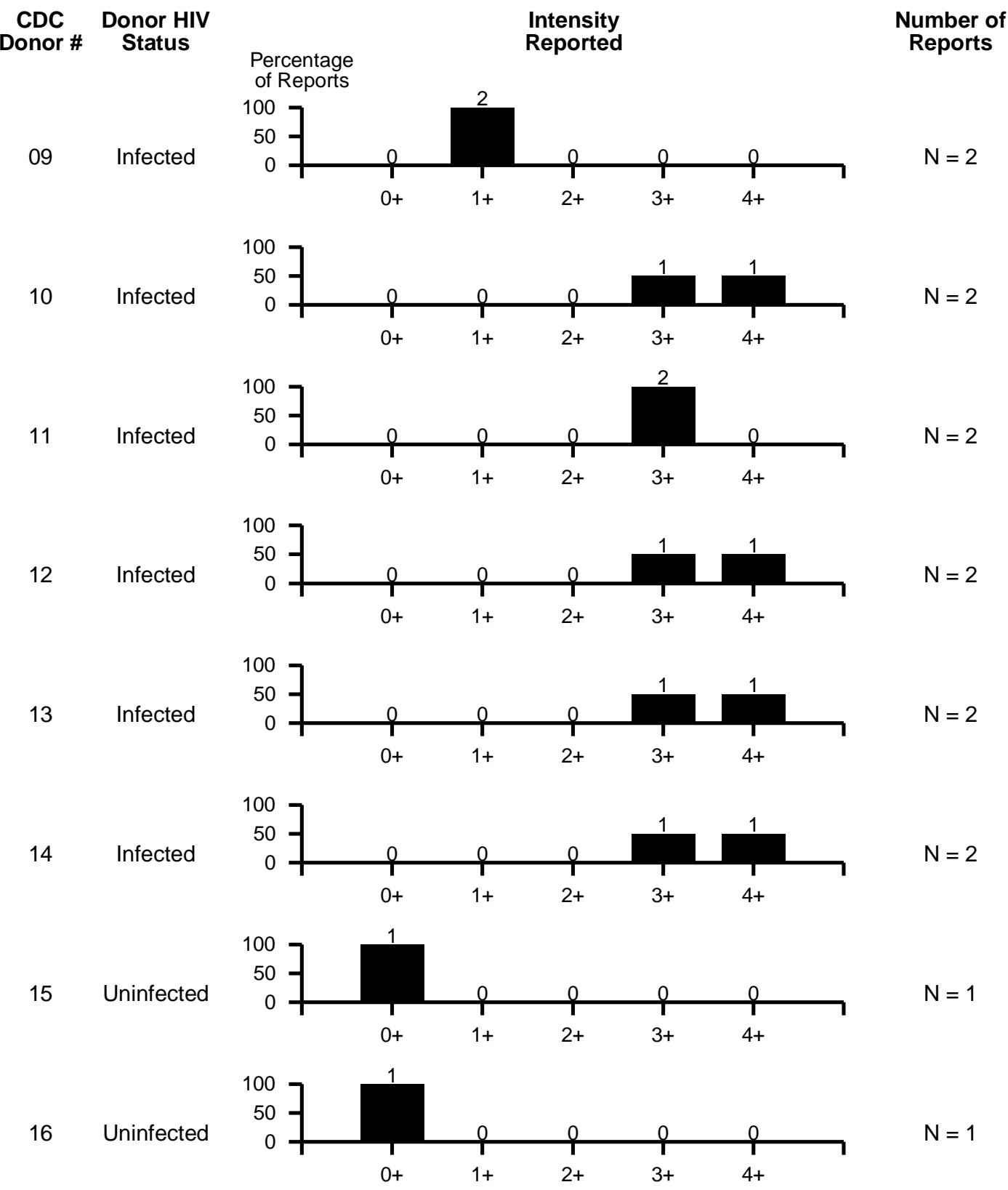
**Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the January 4, 1999 shipment**



**Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 4, 1999 shipment**

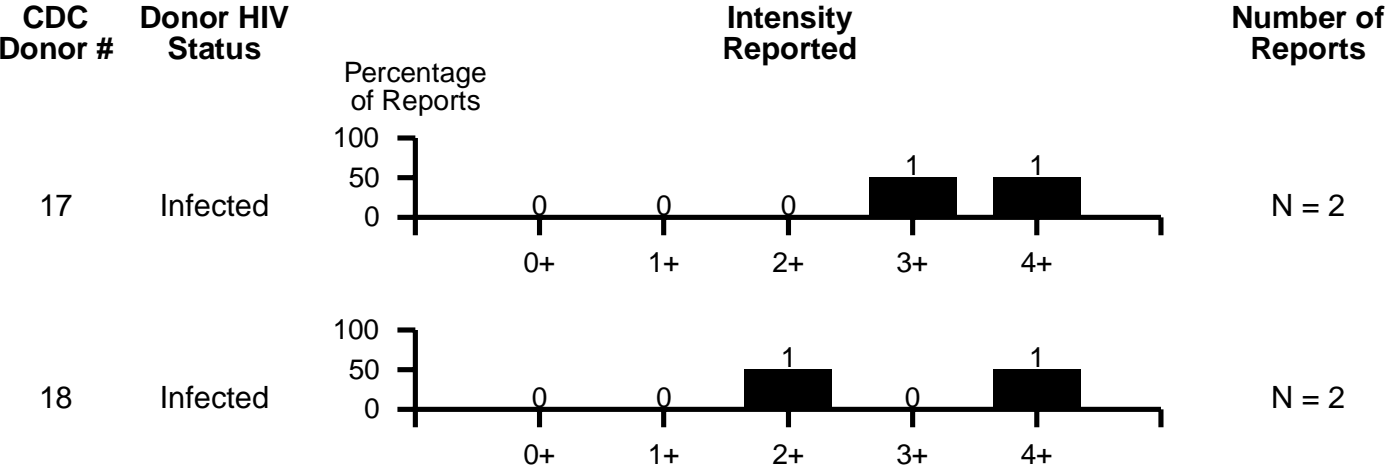


**Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 4, 1999 shipment**





**Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the January 4, 1999 shipment**



**Figure 10. Types of 'Other' HIV antibody test kits used and results reported by reference laboratories to the CDC for the January 4, 1999 shipment**

