

**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 July 14, 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 July 14, 1997 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).

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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 14, 1997 Candidate Reference Laboratory Shipment**

Table 1

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

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
July 14, 1997 Candidate Reference Laboratory Panel Samples**

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

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

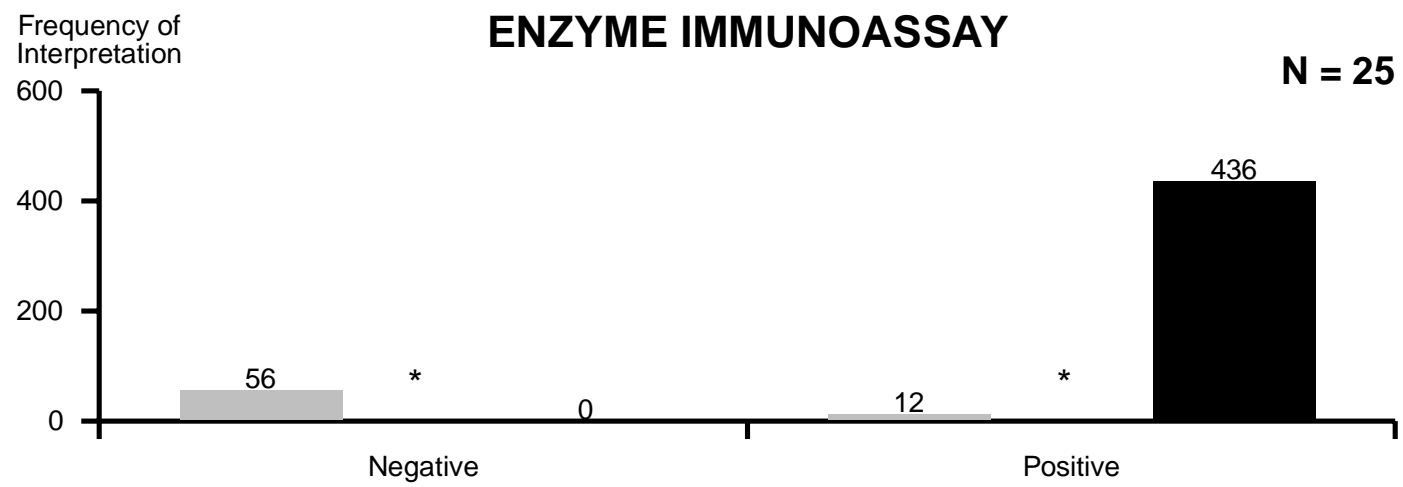
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

* 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 July 14, 1997 shipment



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

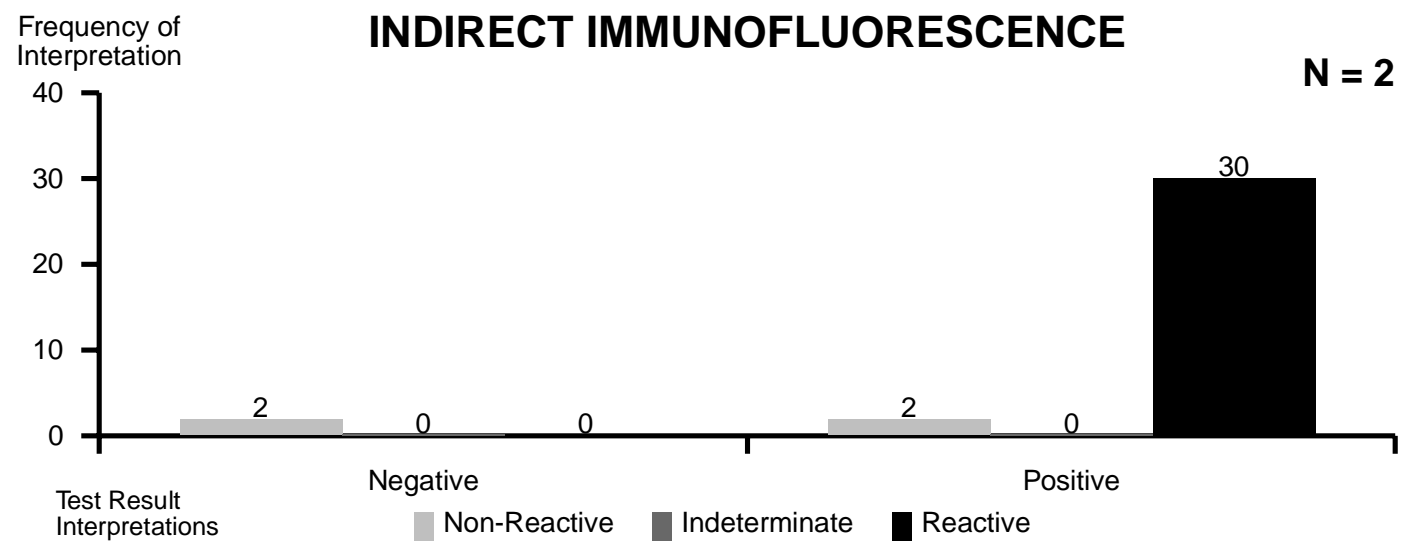
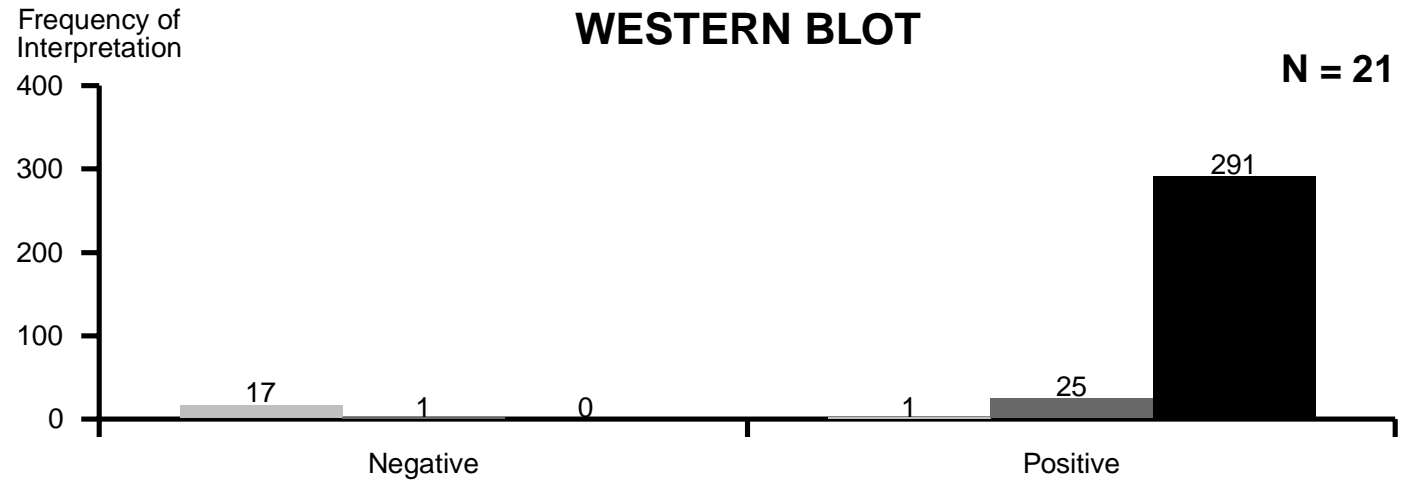


Figure 2. Percentage of HIV-1 reference laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the July 14, 1997 shipment

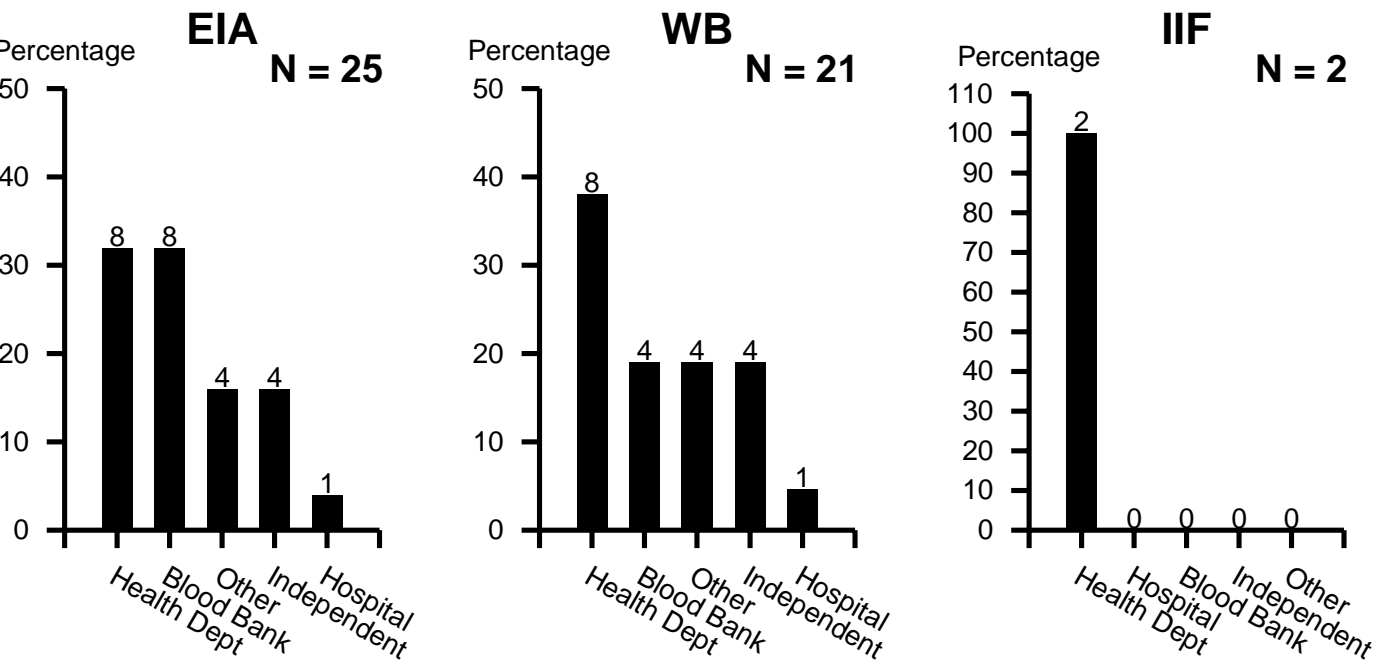


Figure 3. Combination of HIV-1 antibody tests reported by reference laboratories for the July 14, 1997 shipment

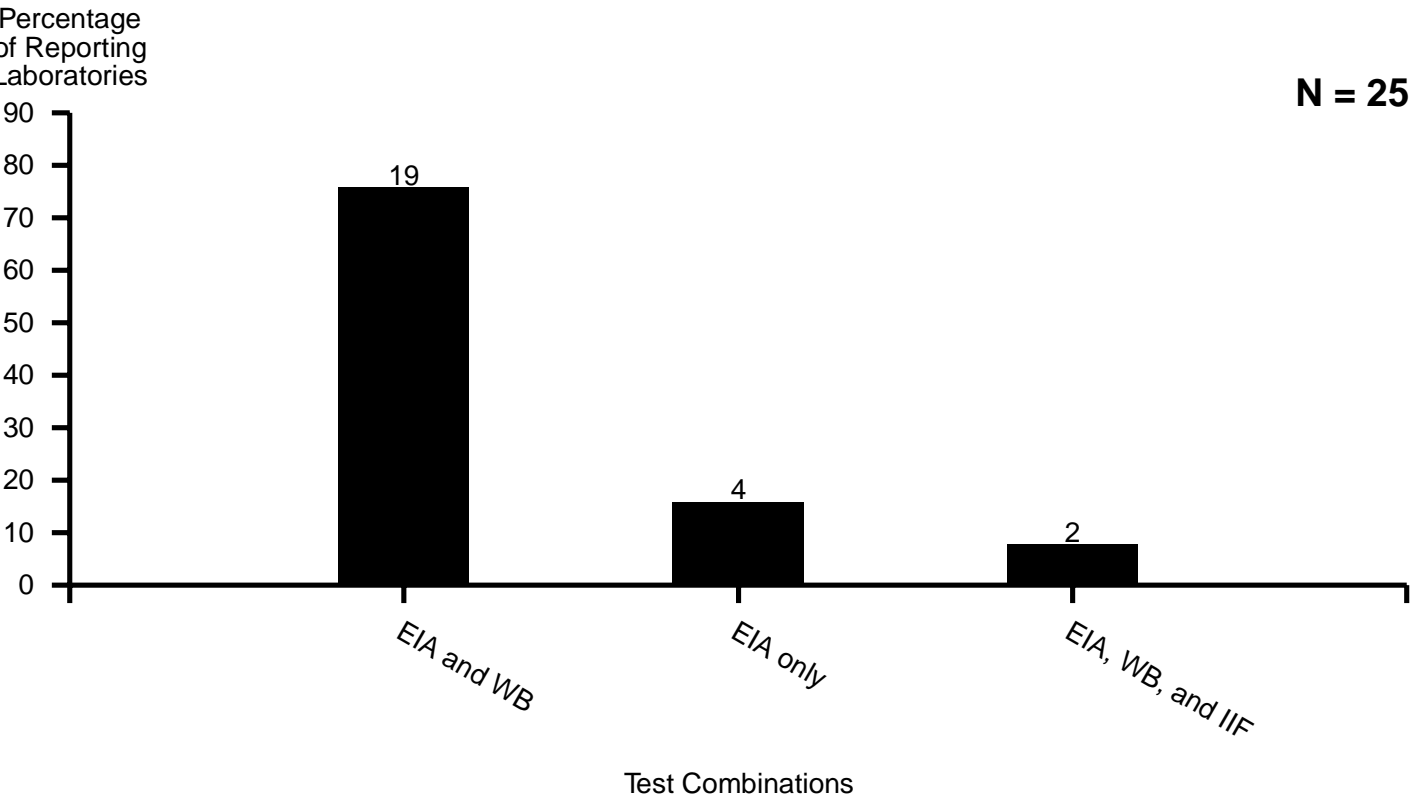


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the July 14, 1997 shipment

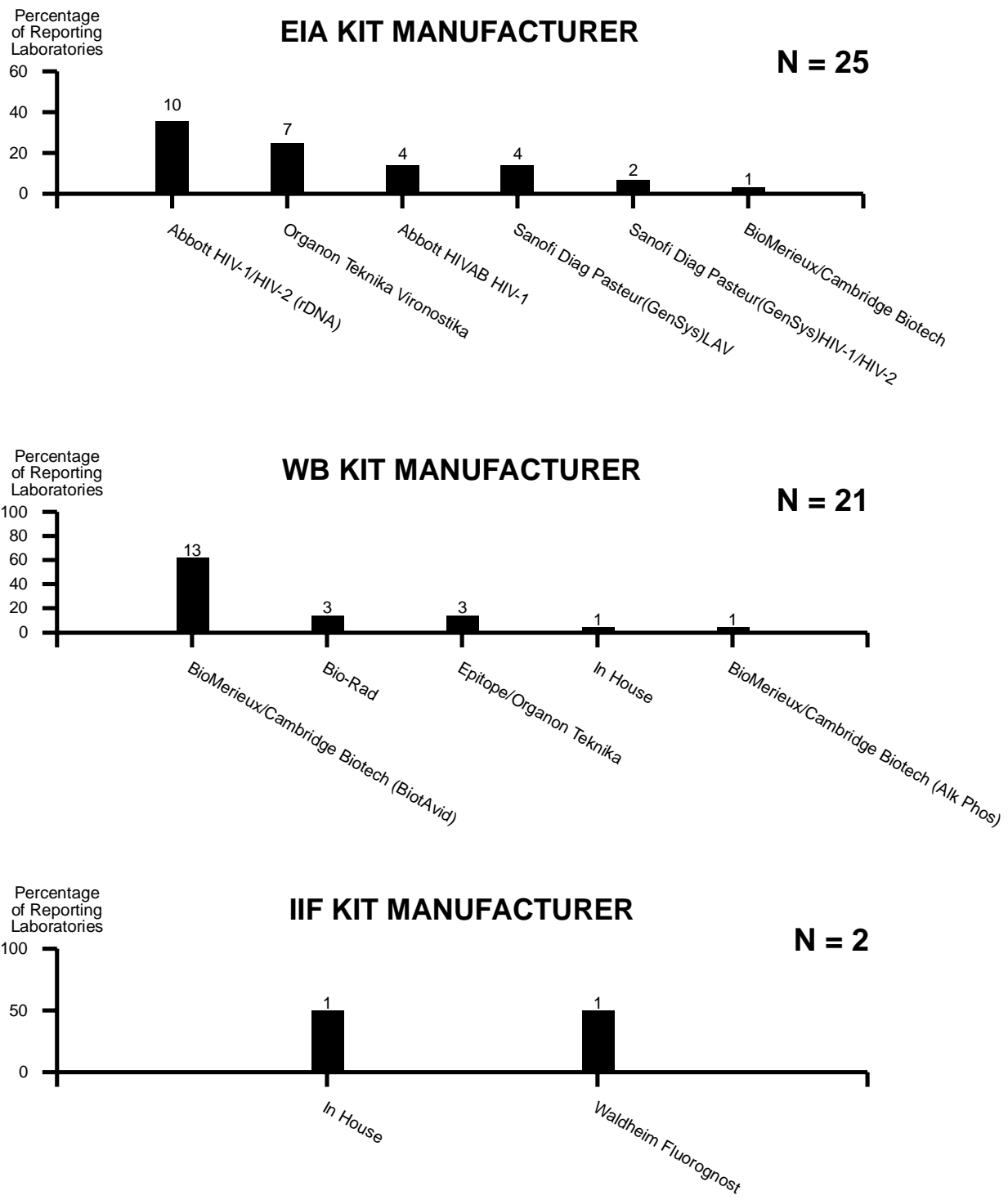
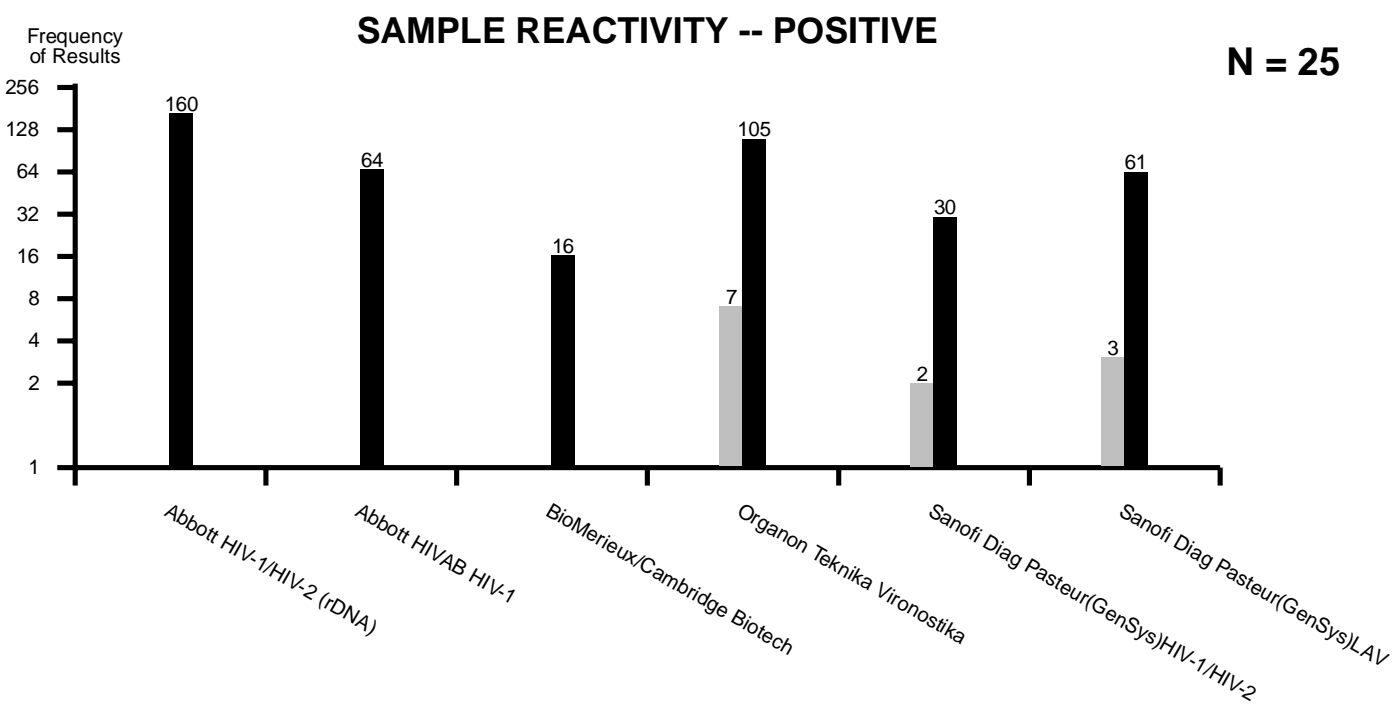
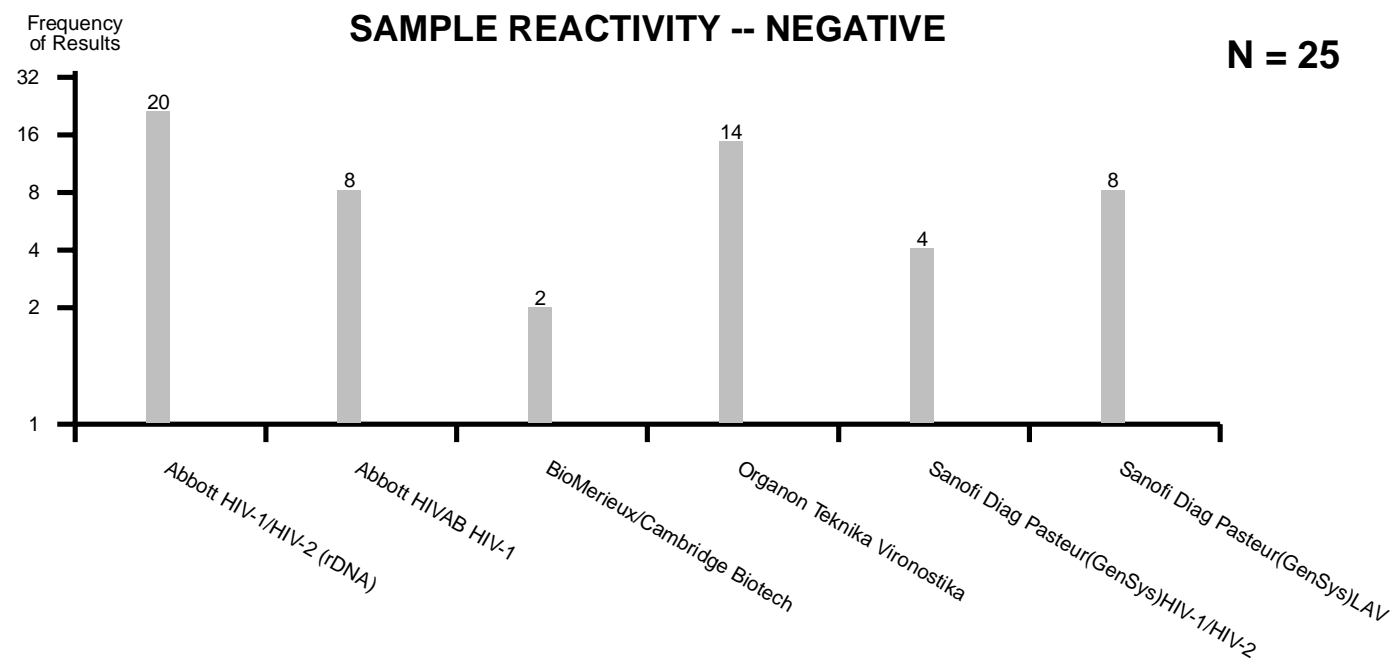


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the July 14, 1997 shipment

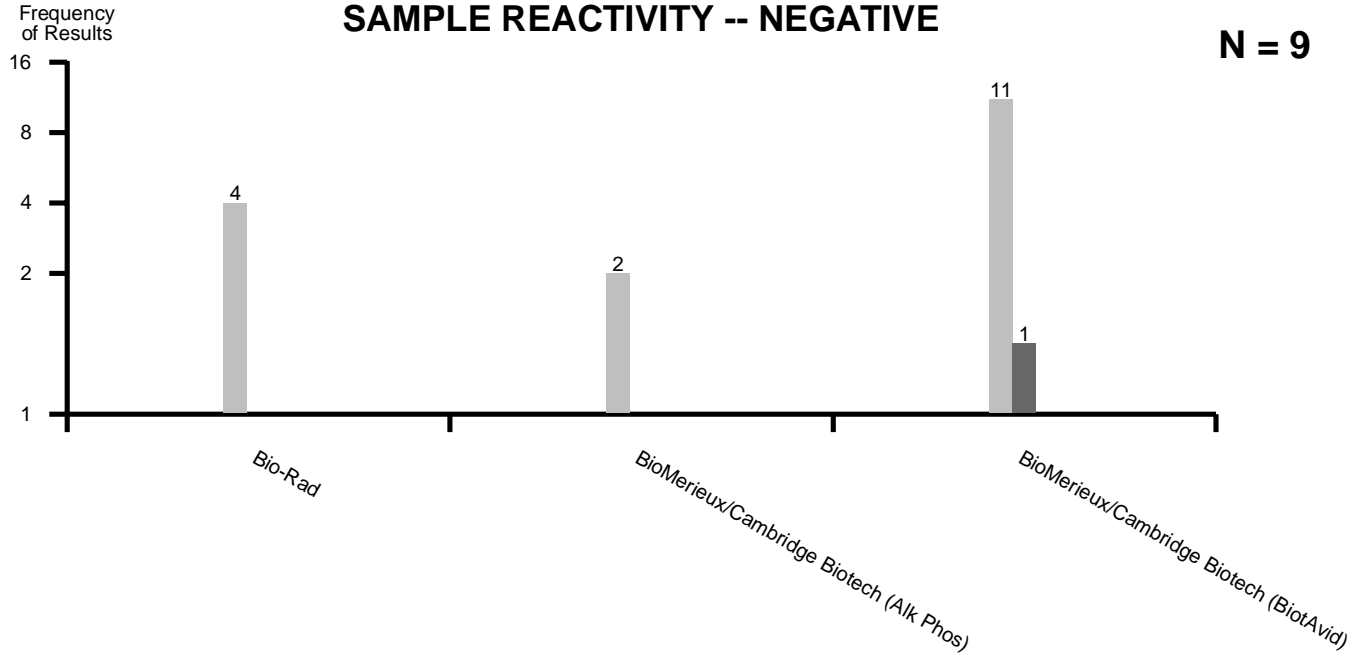


Test Result Interpretations
 ■ Non-Reactive ■ Reactive

Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the July 14, 1997 shipment

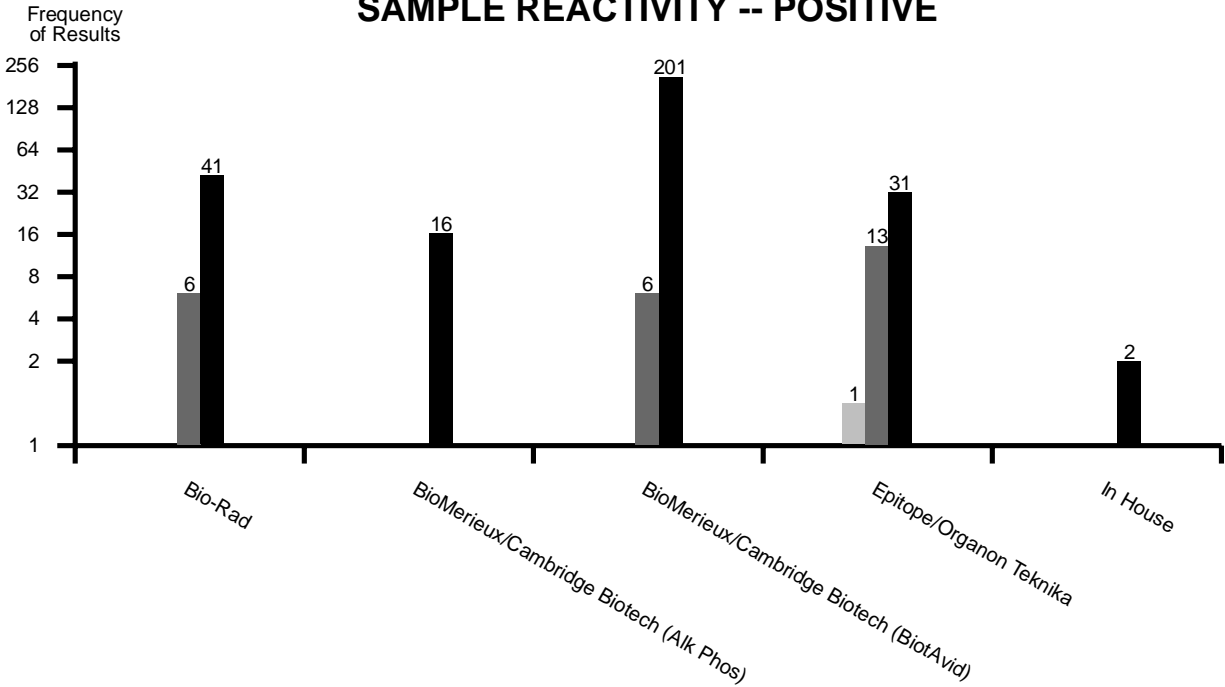
SAMPLE REACTIVITY -- NEGATIVE

N = 9



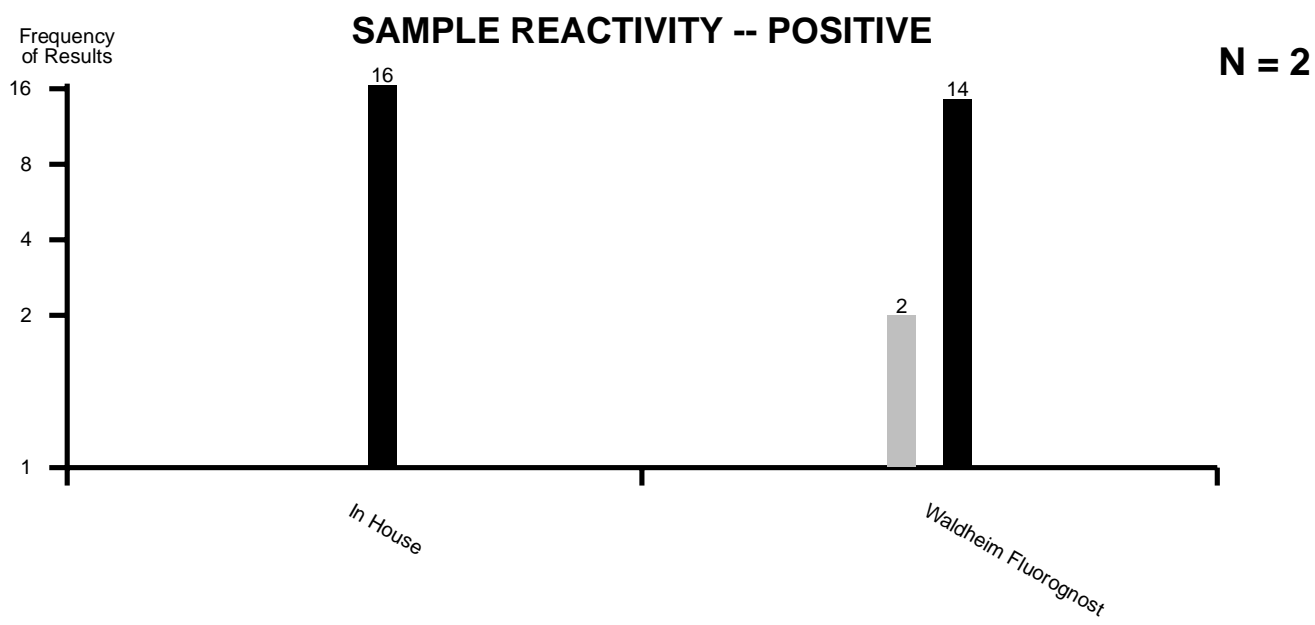
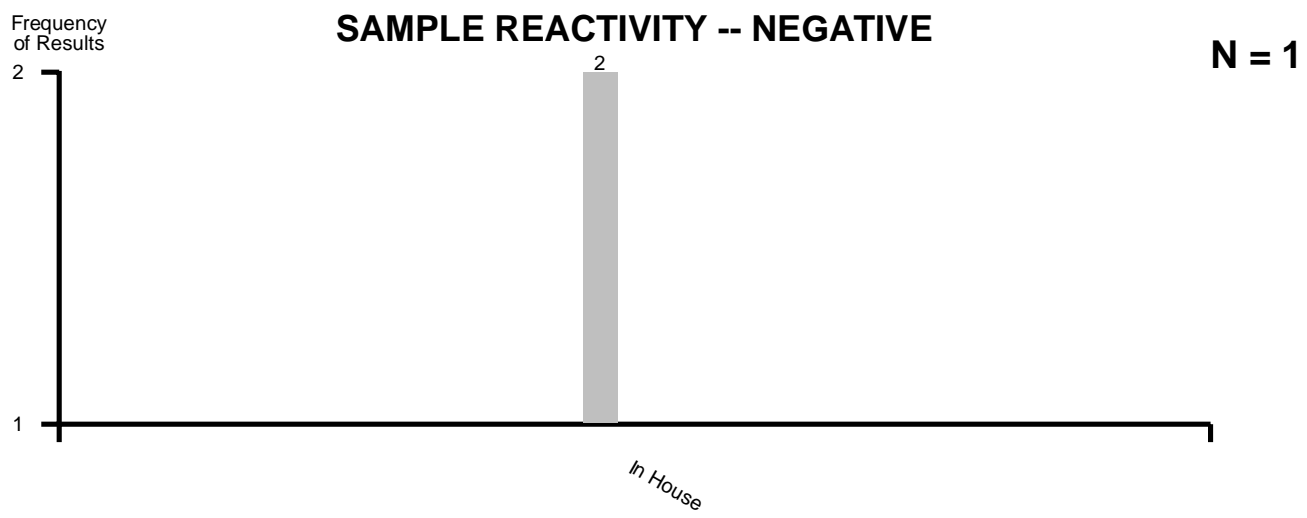
SAMPLE REACTIVITY -- POSITIVE

N = 21



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 July 14, 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 July 14, 1997 shipment

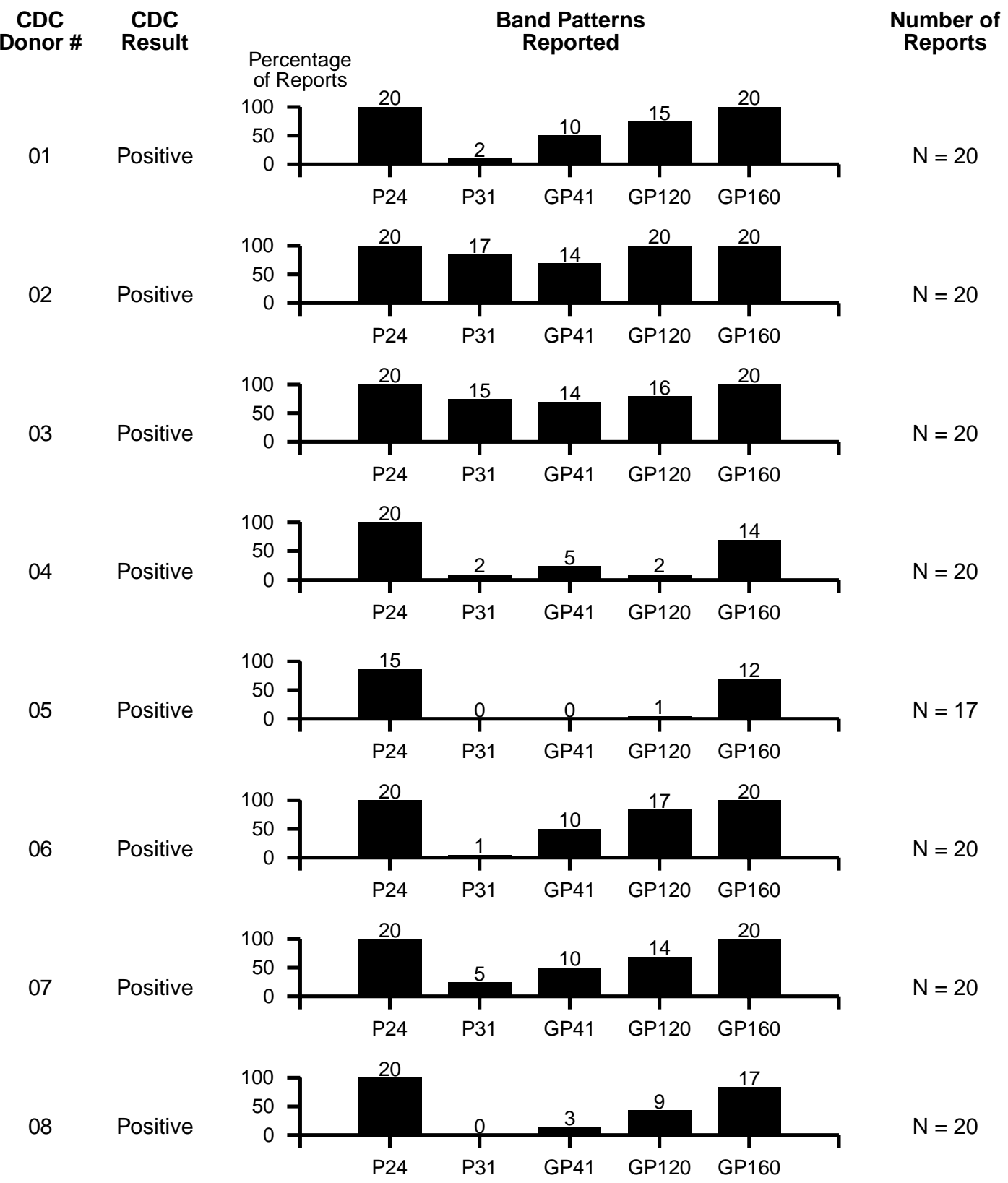


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the July 14, 1997 shipment

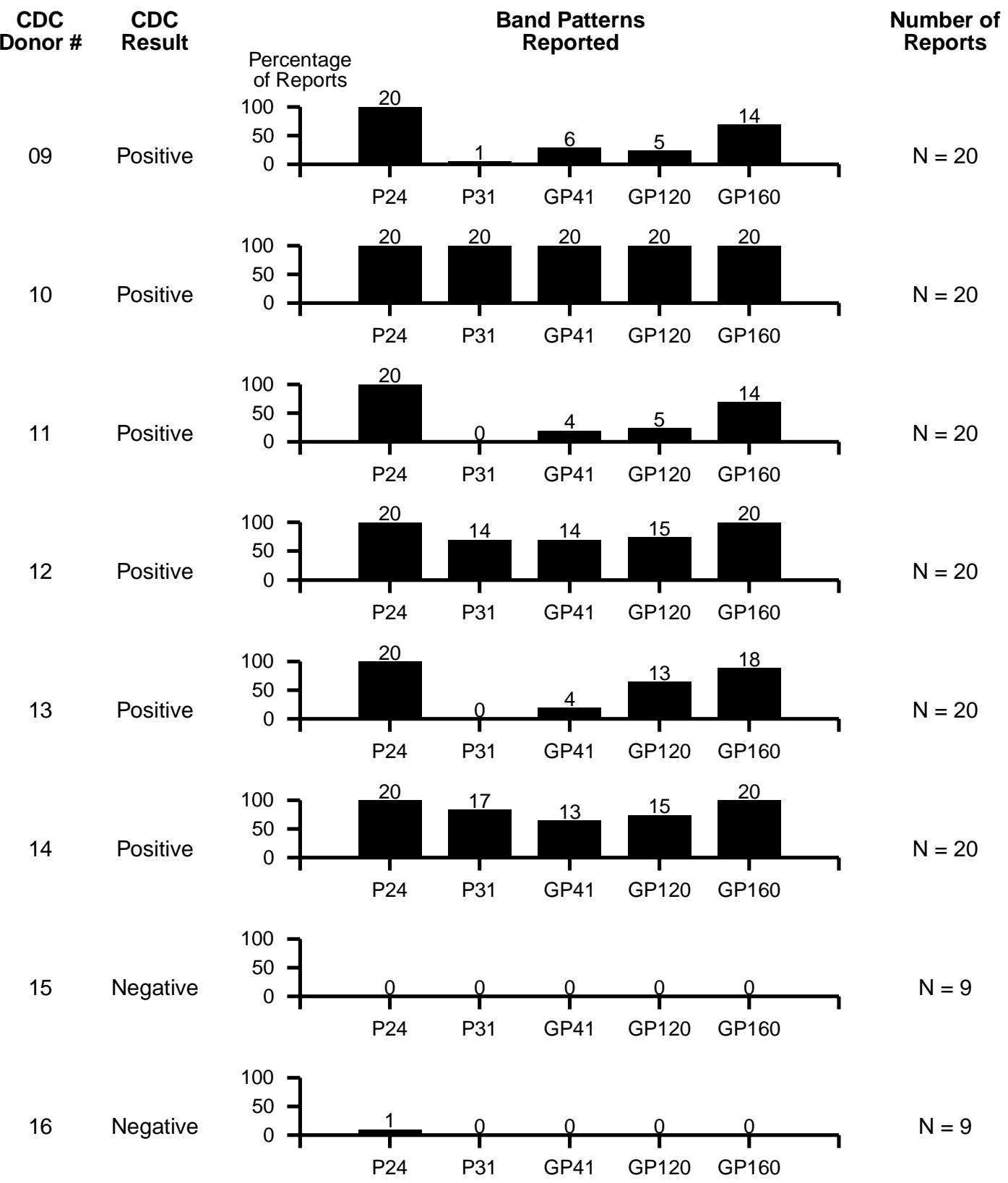


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the July 14, 1997 shipment

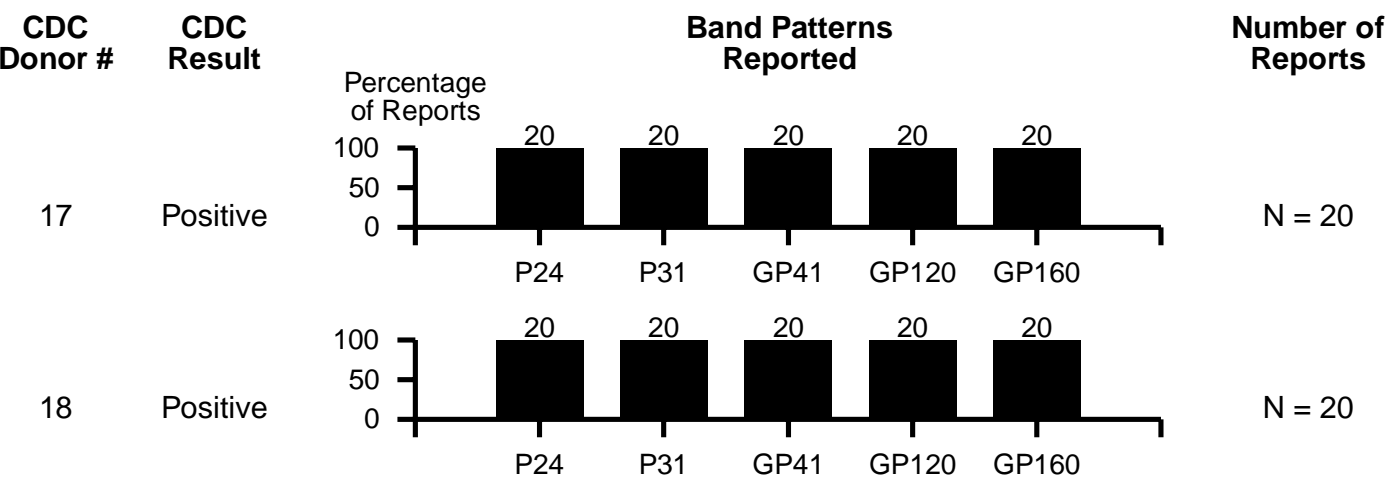


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 14, 1997 shipment

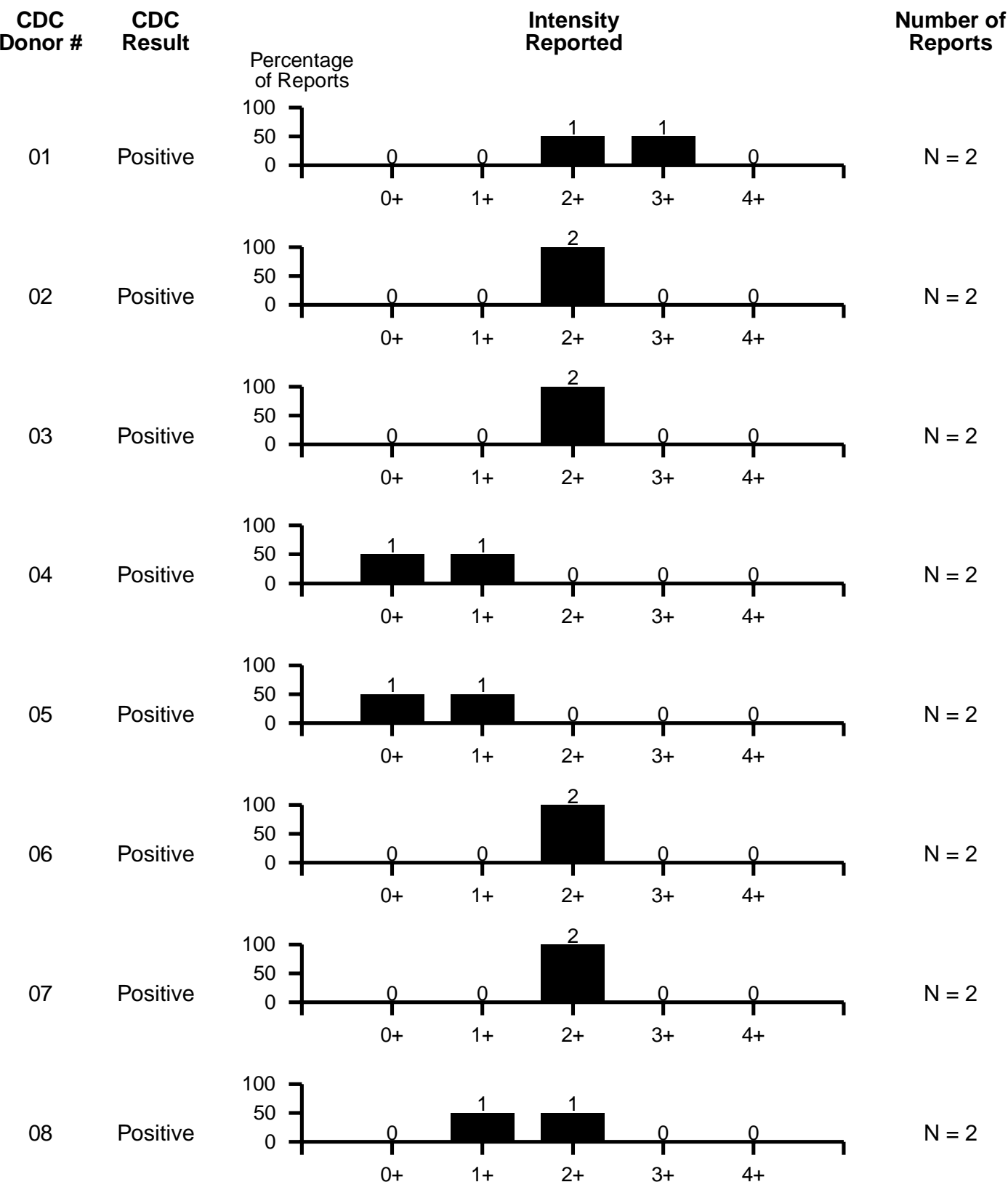


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 14, 1997 shipment

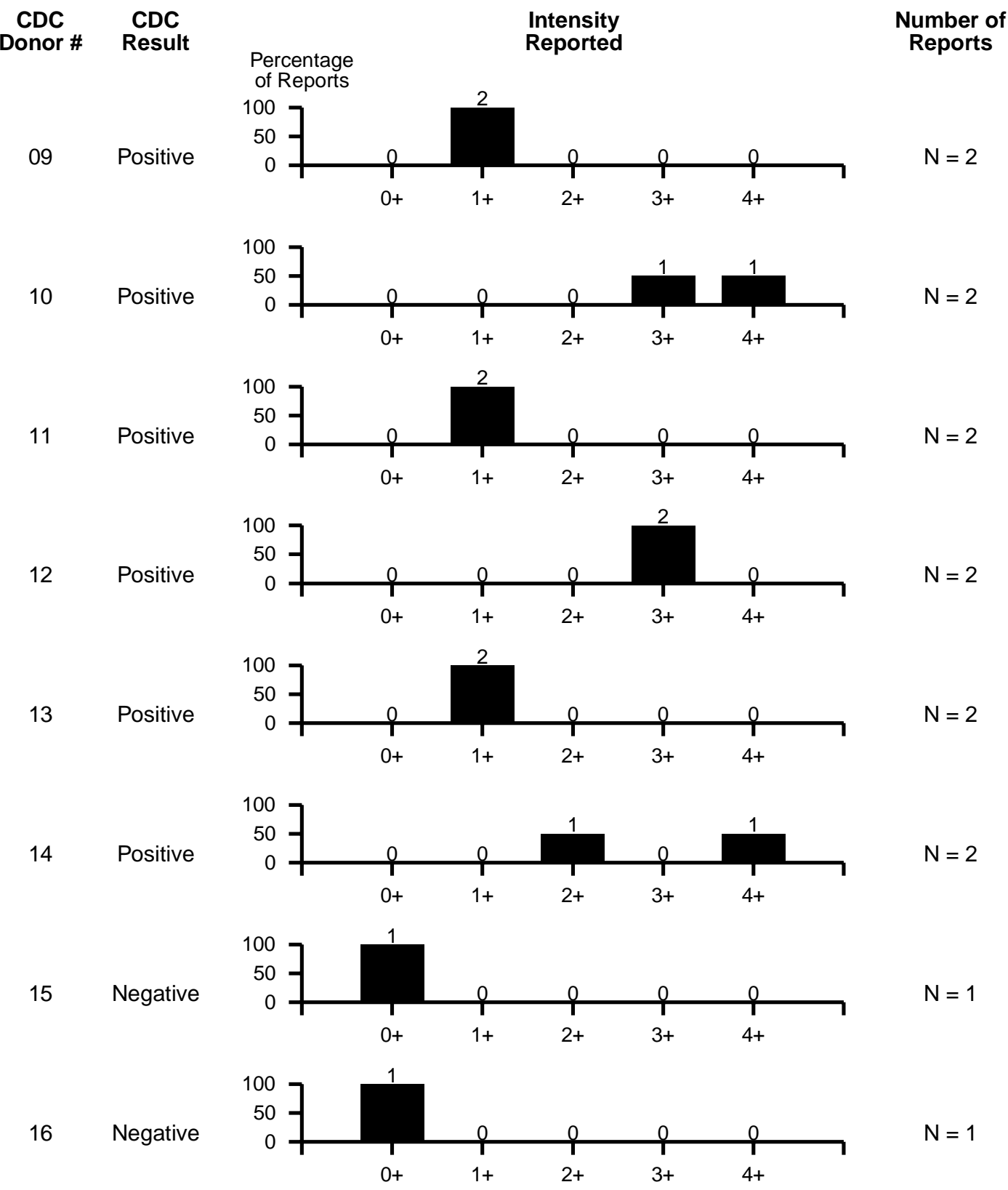


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 14, 1997 shipment

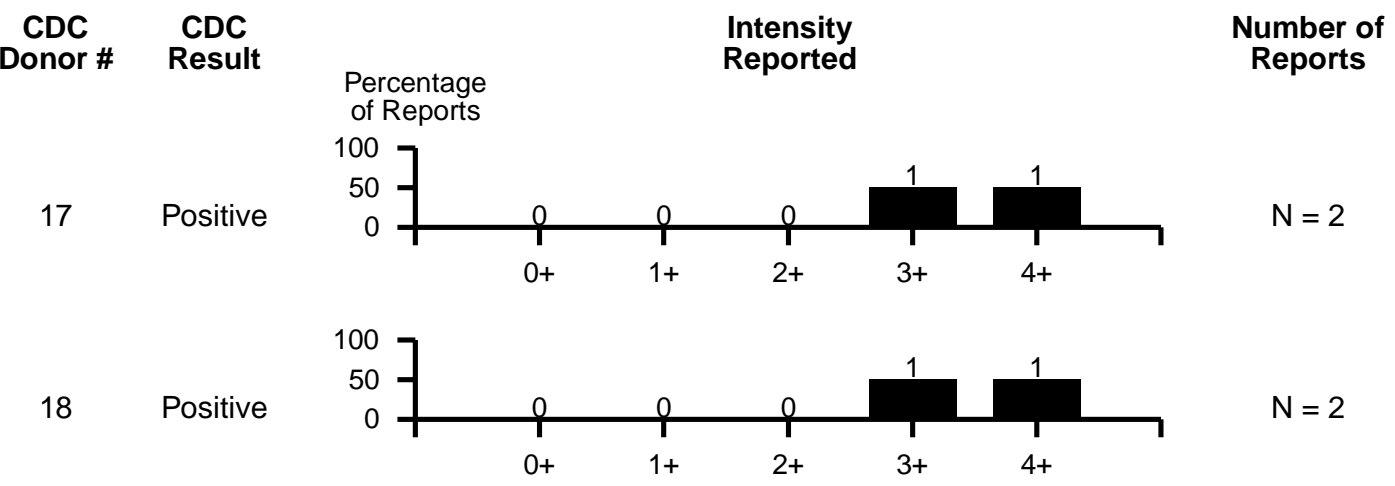


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by reference laboratories to the CDC for the July 14, 1997 shipment

