

**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 13, 1998 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 13, 1998 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 13, 1998 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	12	Positive	Infected	—	—	—	—
02	15	Negative	Uninfected	—	—	—	—
03	17	Positive	Infected	—	—	—	—
04	03	Indeterminate	Infected	—	—	—	—
05	06	Positive	Infected	—	—	—	—
06	08	See Table 2	Infected	—	—	—	—
07	10	Positive	Infected	—	—	—	—
08	01	Indeterminate	Infected	—	—	—	—
09	04	Positive	Infected	—	—	—	—
10	13	Positive	Infected	—	—	—	—
11	02	See Table 2	Infected	—	—	—	—
12	16	Negative	Uninfected	—	—	—	—
13	11	Positive	Infected	—	—	—	—
14	05	Positive	Infected	—	—	—	—
15	09	See Table 2	Infected	—	—	—	—
16	14	Positive	Infected	—	—	—	—
17	18	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 13, 1998 Candidate Reference Laboratory Panel Samples**

Label Number	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected¹	WB Test Kit Manufacturer	CDC Laboratory Interpretation²
01	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
02	15	No Bands	All Manufacturers	Negative
03	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
04	03	24,51 24, 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Indeterminate Indeterminate
05	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
06	08	24,55 24,66,160 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Indeterminate
07	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
08	01	24,51 24 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Indeterminate Indeterminate
09	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
10	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
11	02	24 24,120,160 24,160	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Positive
12	16	No Bands	All Manufacturers	Negative
13	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
14	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
15	09	24,55,160 24,66,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
16	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
17	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
18	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

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

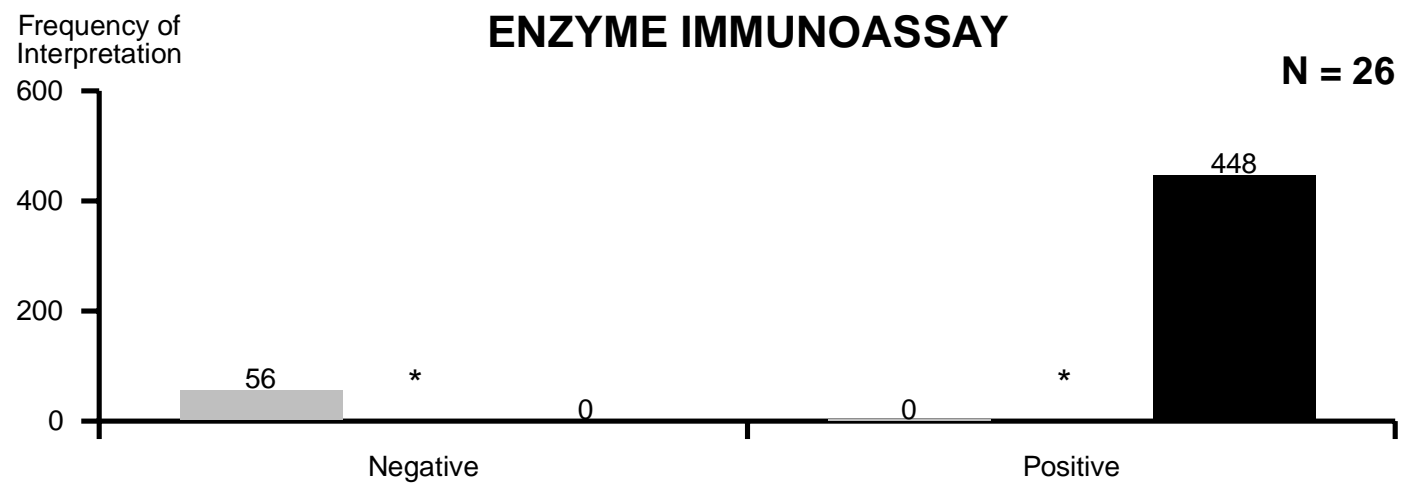
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

* 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 13, 1998 shipment



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

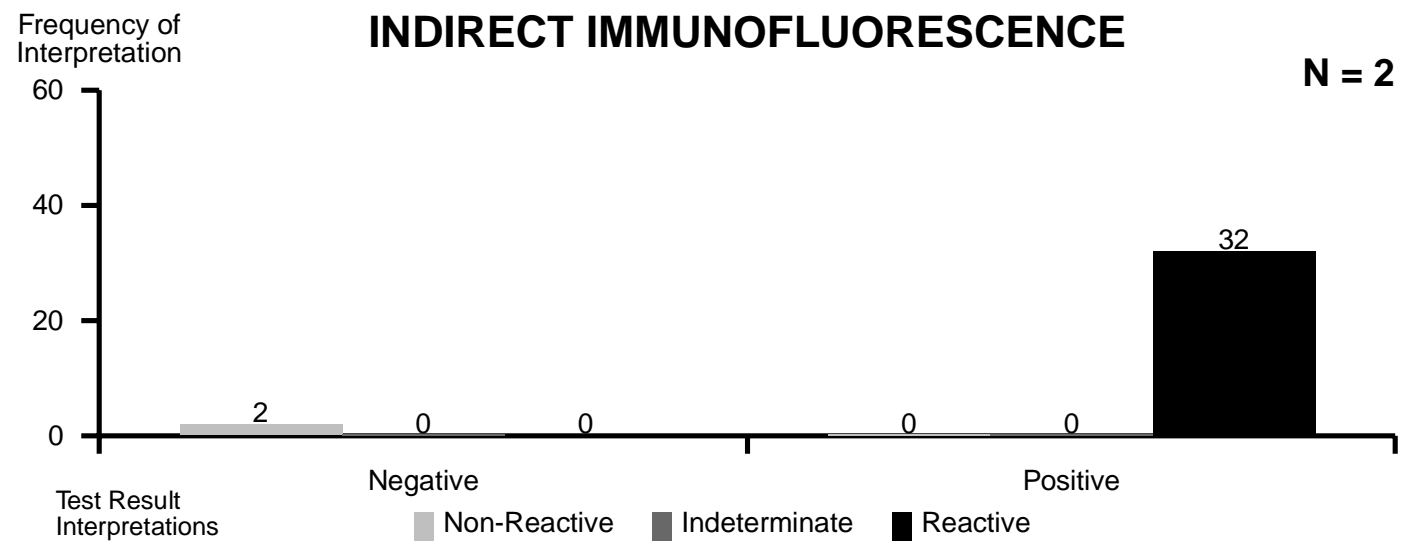
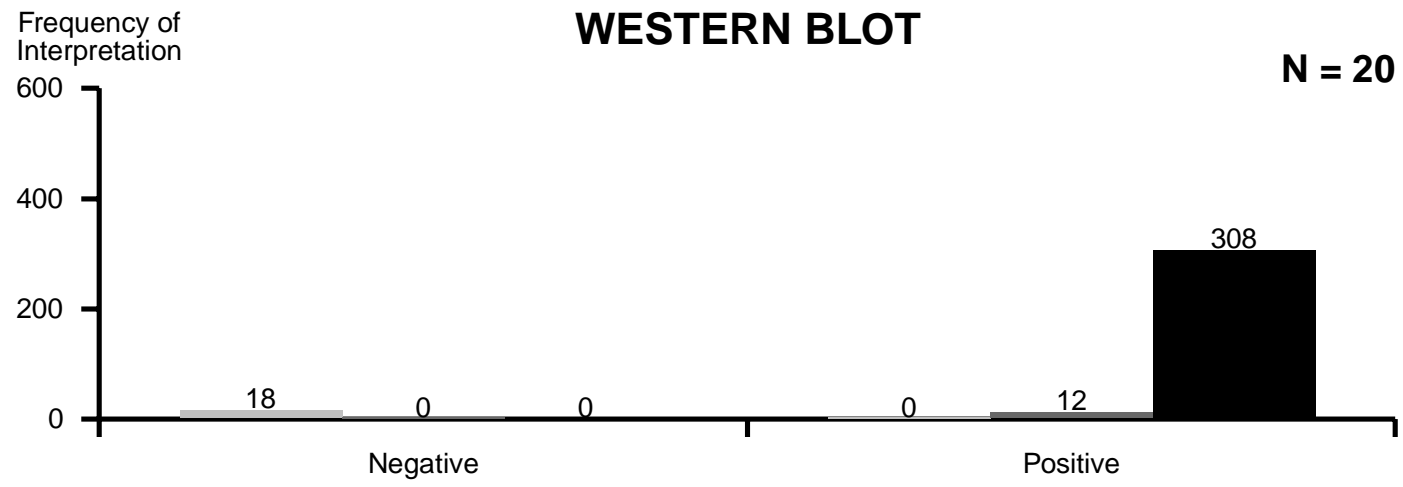


Figure 2. Percentage of HIV-1 reference laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the July 13, 1998 shipment

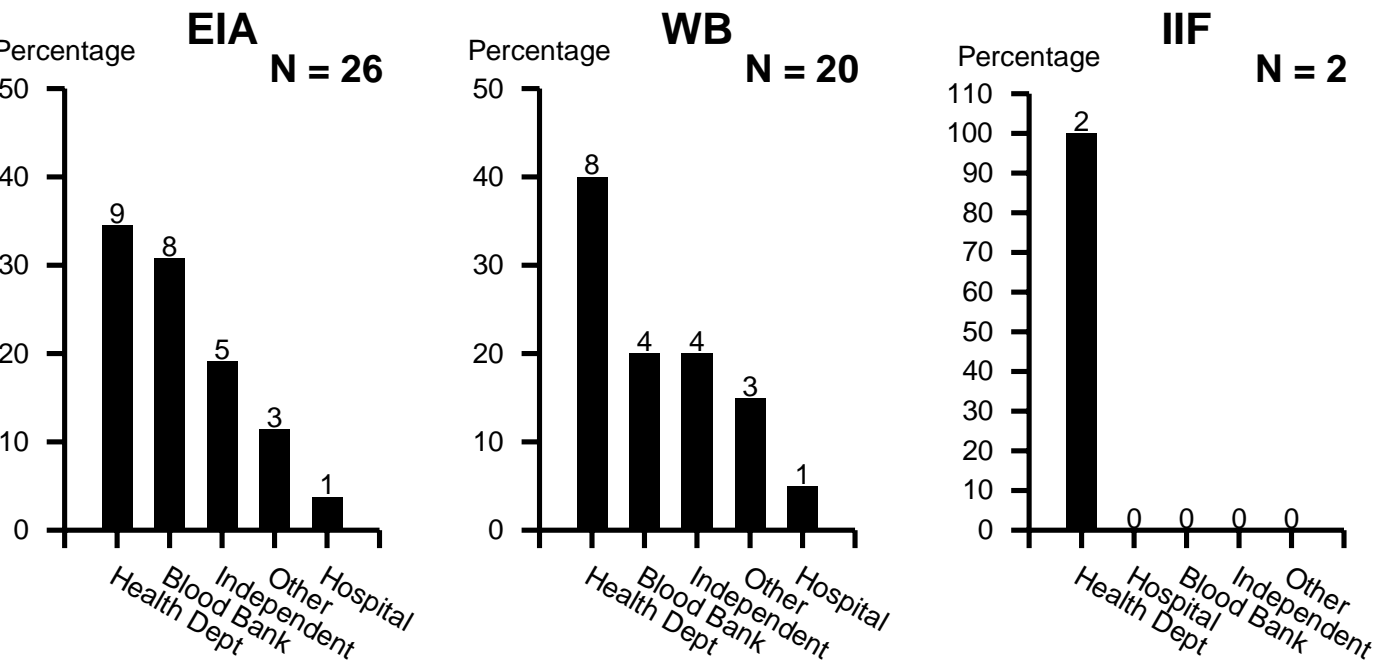


Figure 3. Combination of HIV-1 antibody tests reported by reference laboratories for the July 13, 1998 shipment

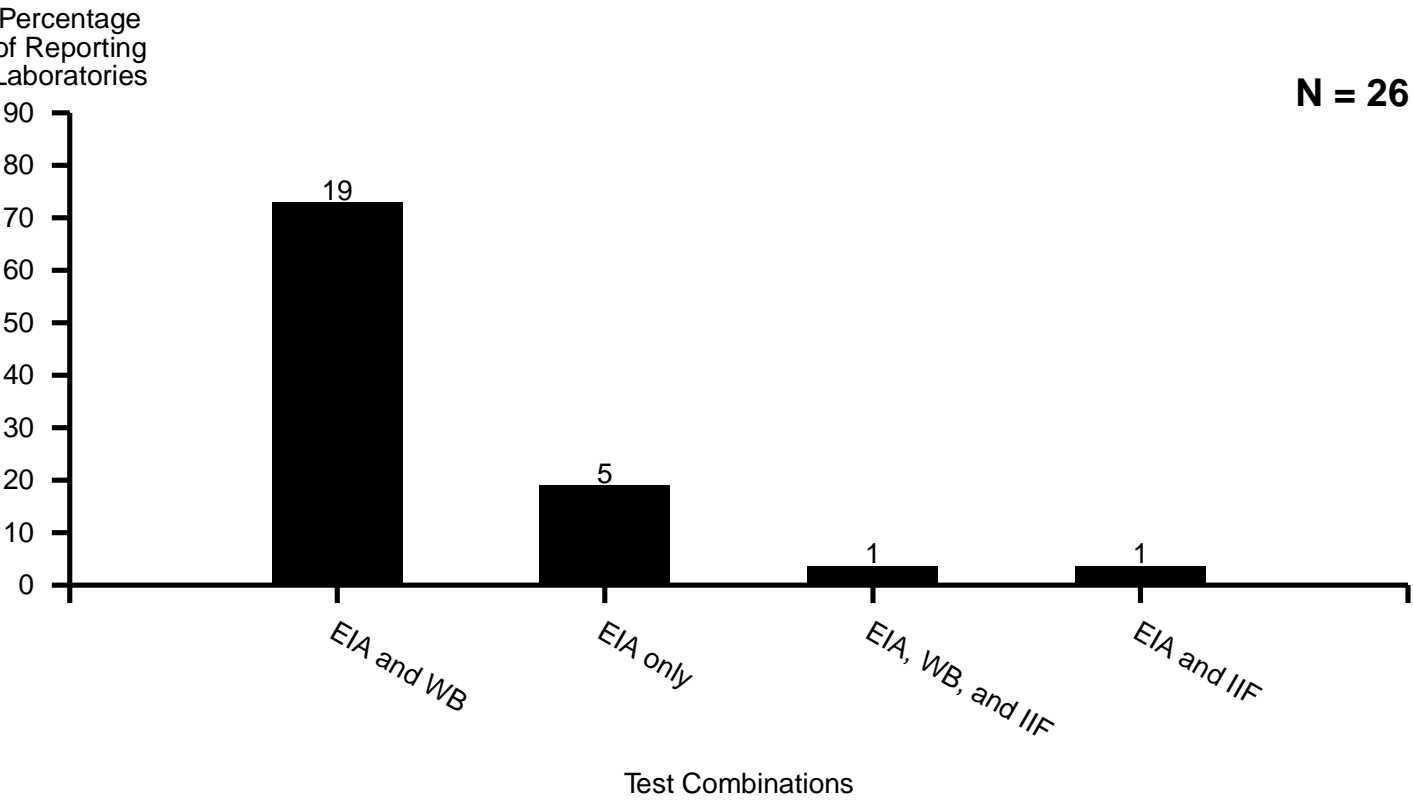


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the July 13, 1998 shipment

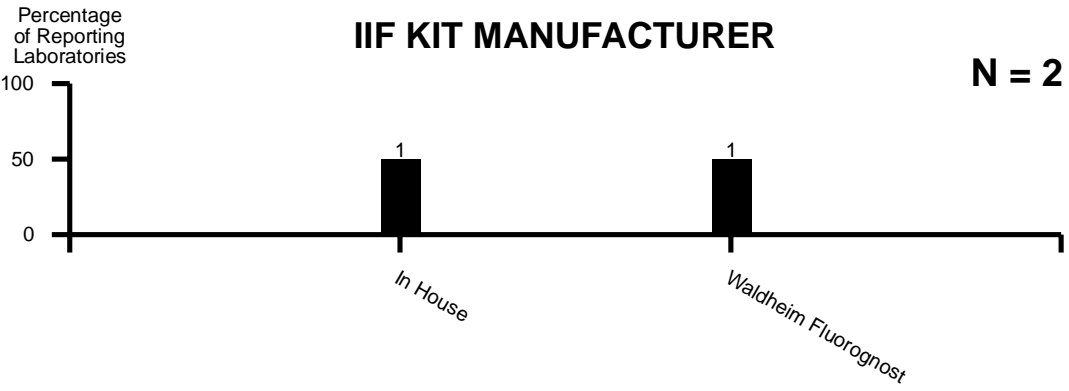
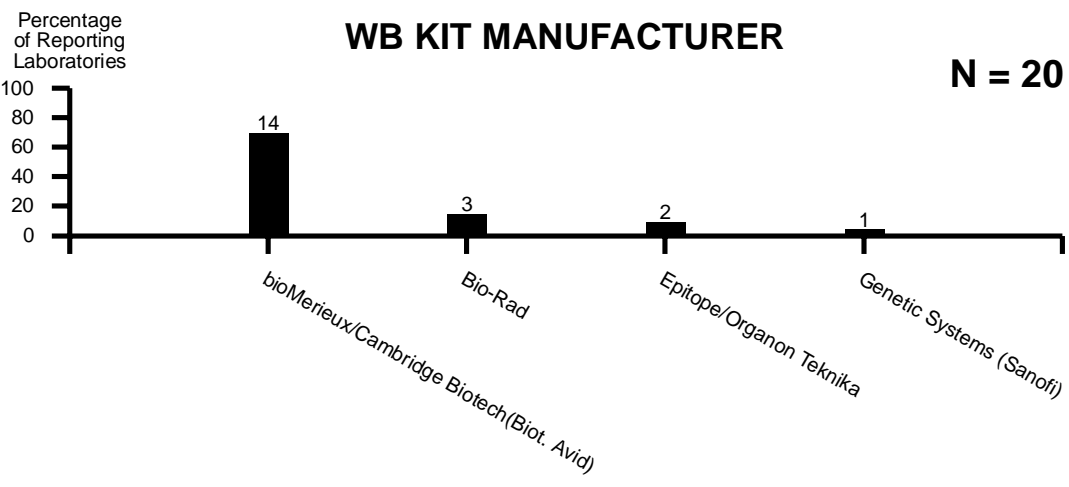
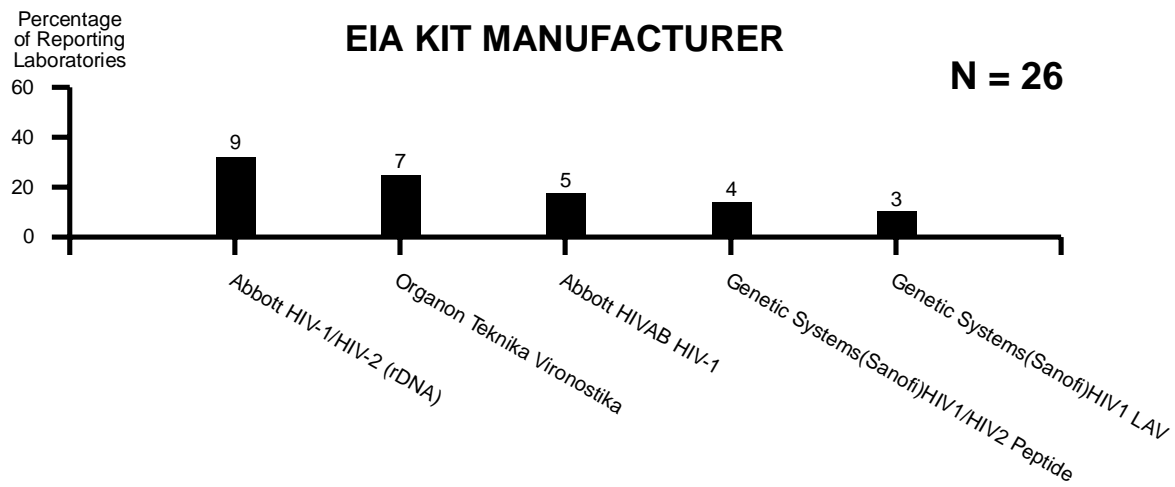
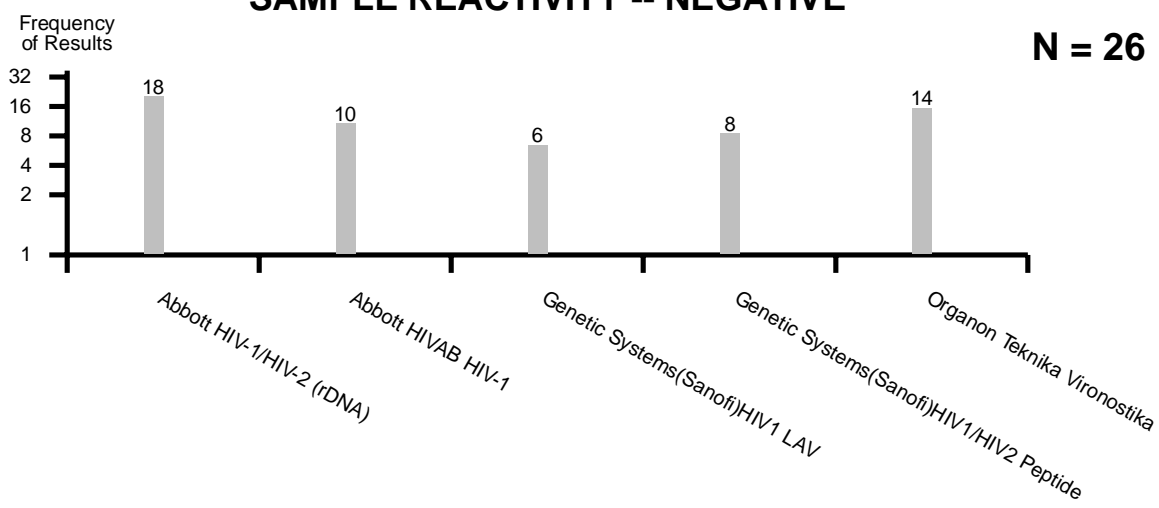
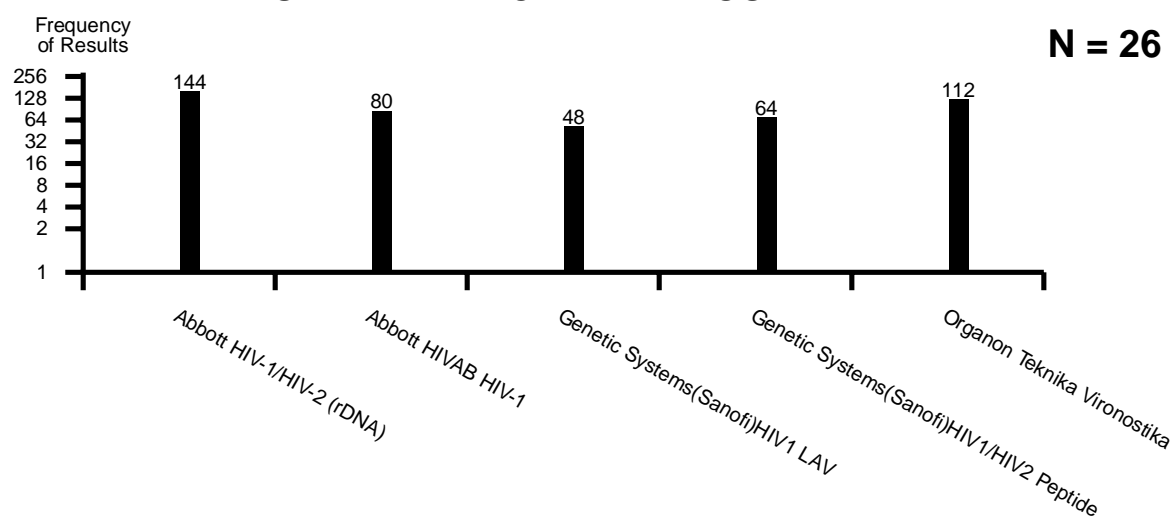


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the July 13, 1998 shipment

SAMPLE REACTIVITY -- NEGATIVE



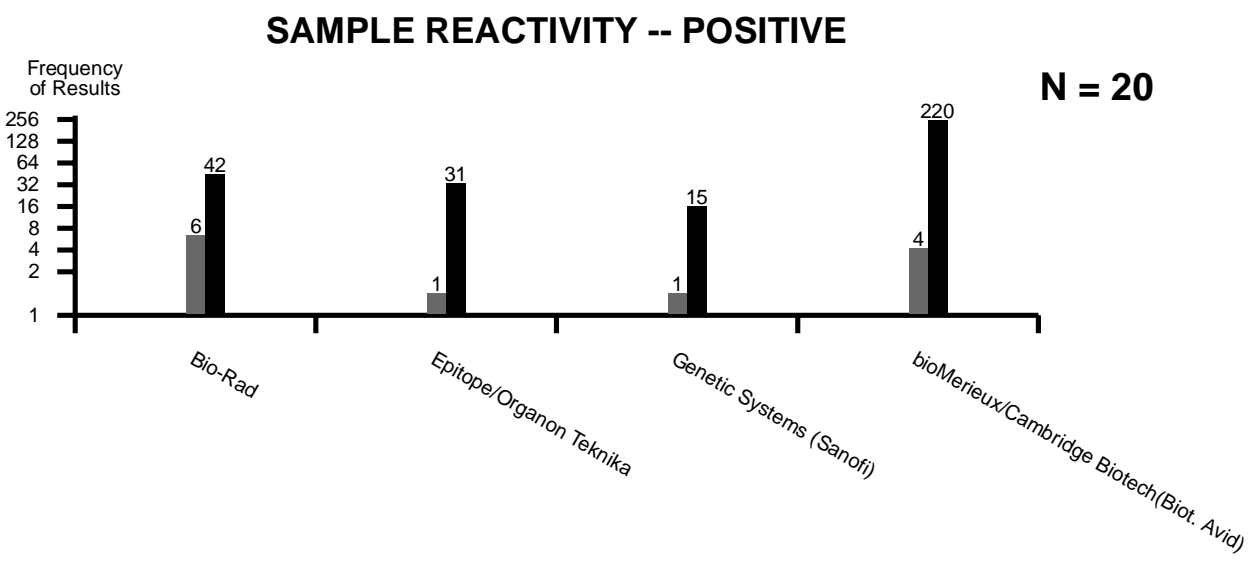
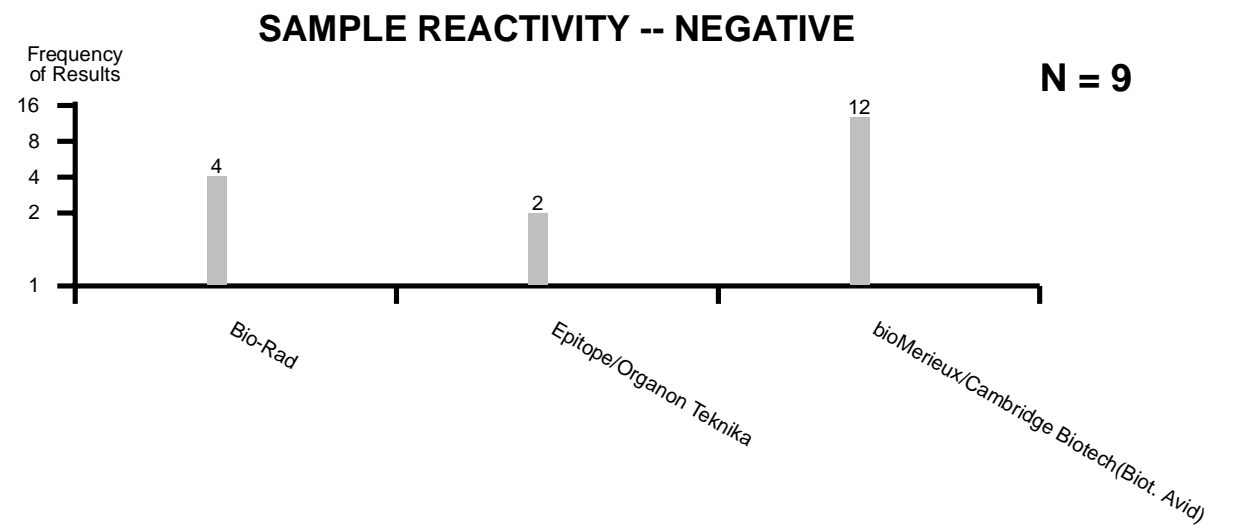
SAMPLE REACTIVITY -- POSITIVE



Test Result Interpretations

■ Non-Reactive ■ Reactive

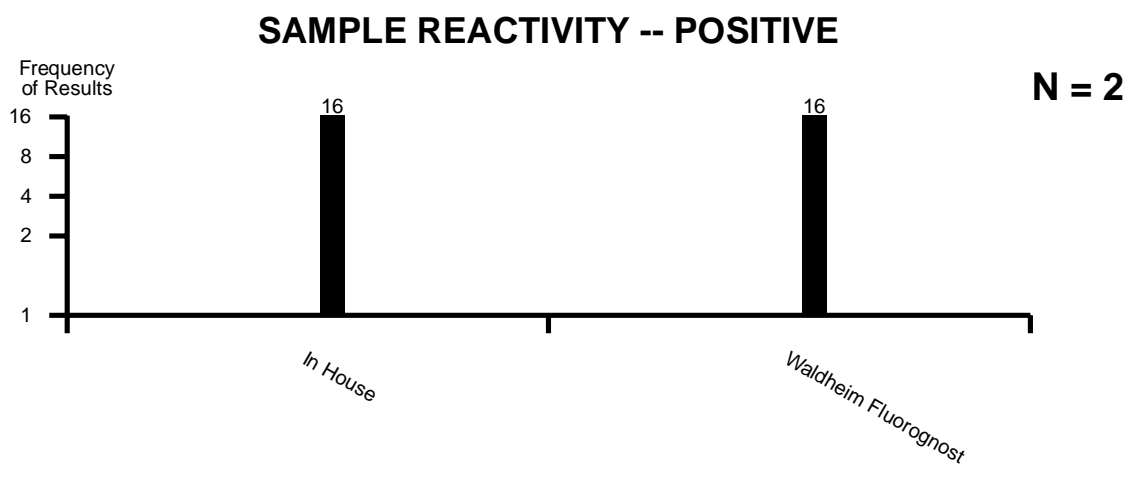
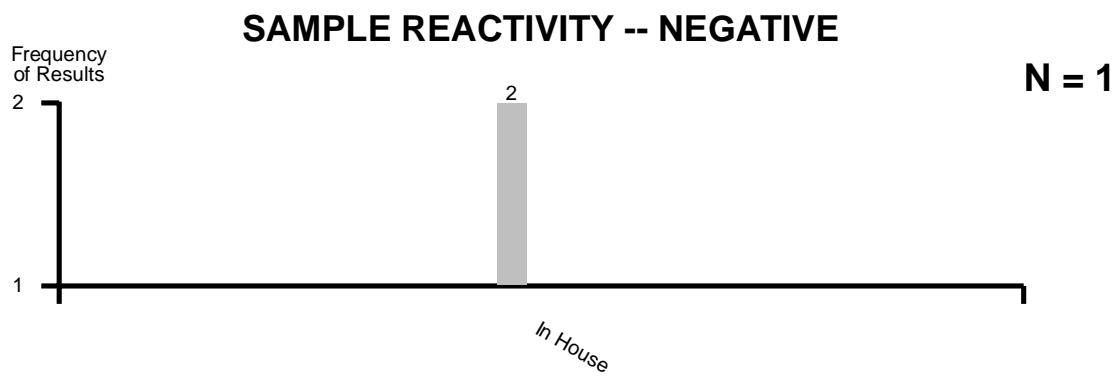
Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by reference laboratories for the July 13, 1998 shipment



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 July 13, 1998 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 13, 1998 shipment

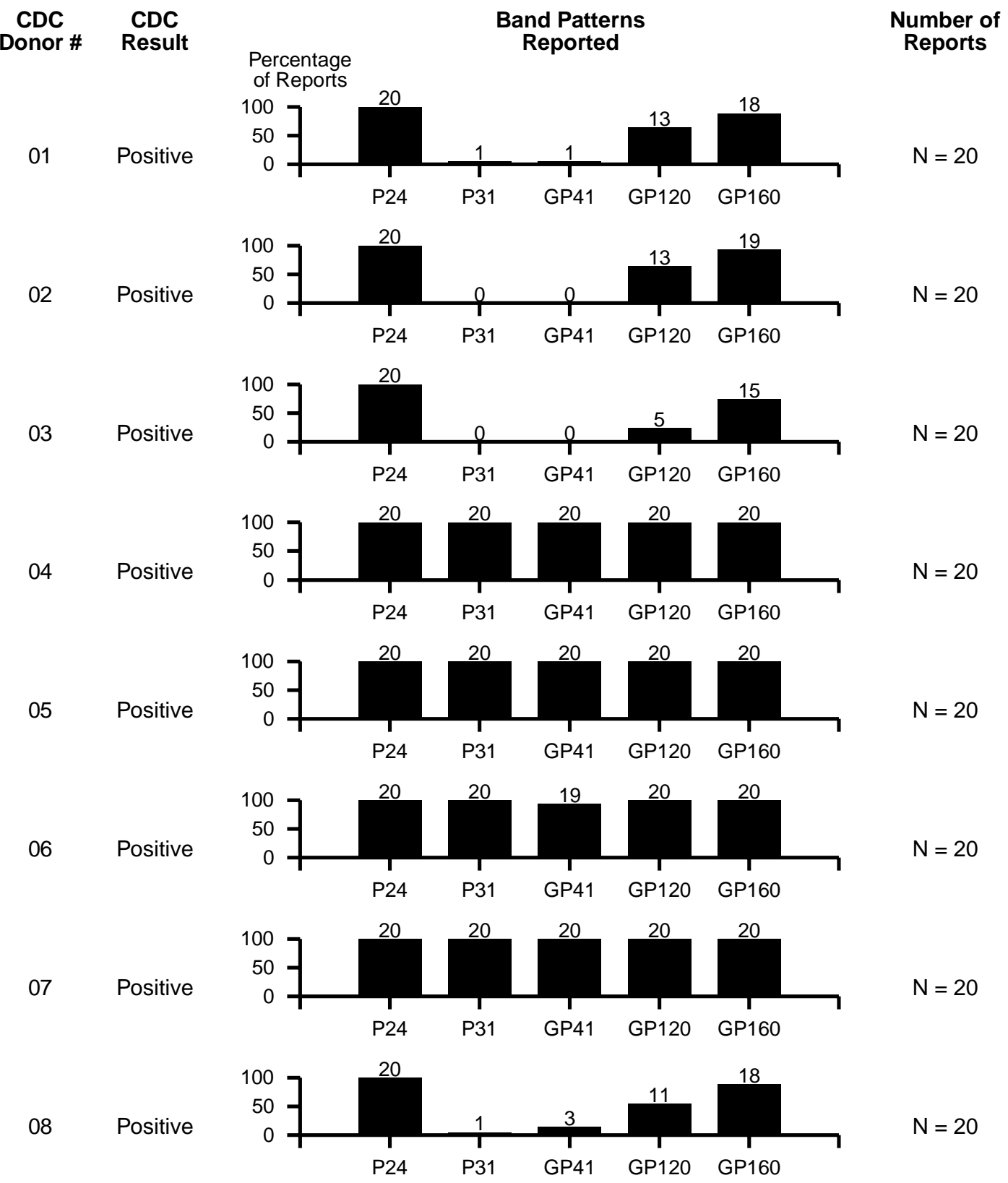


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the July 13, 1998 shipment

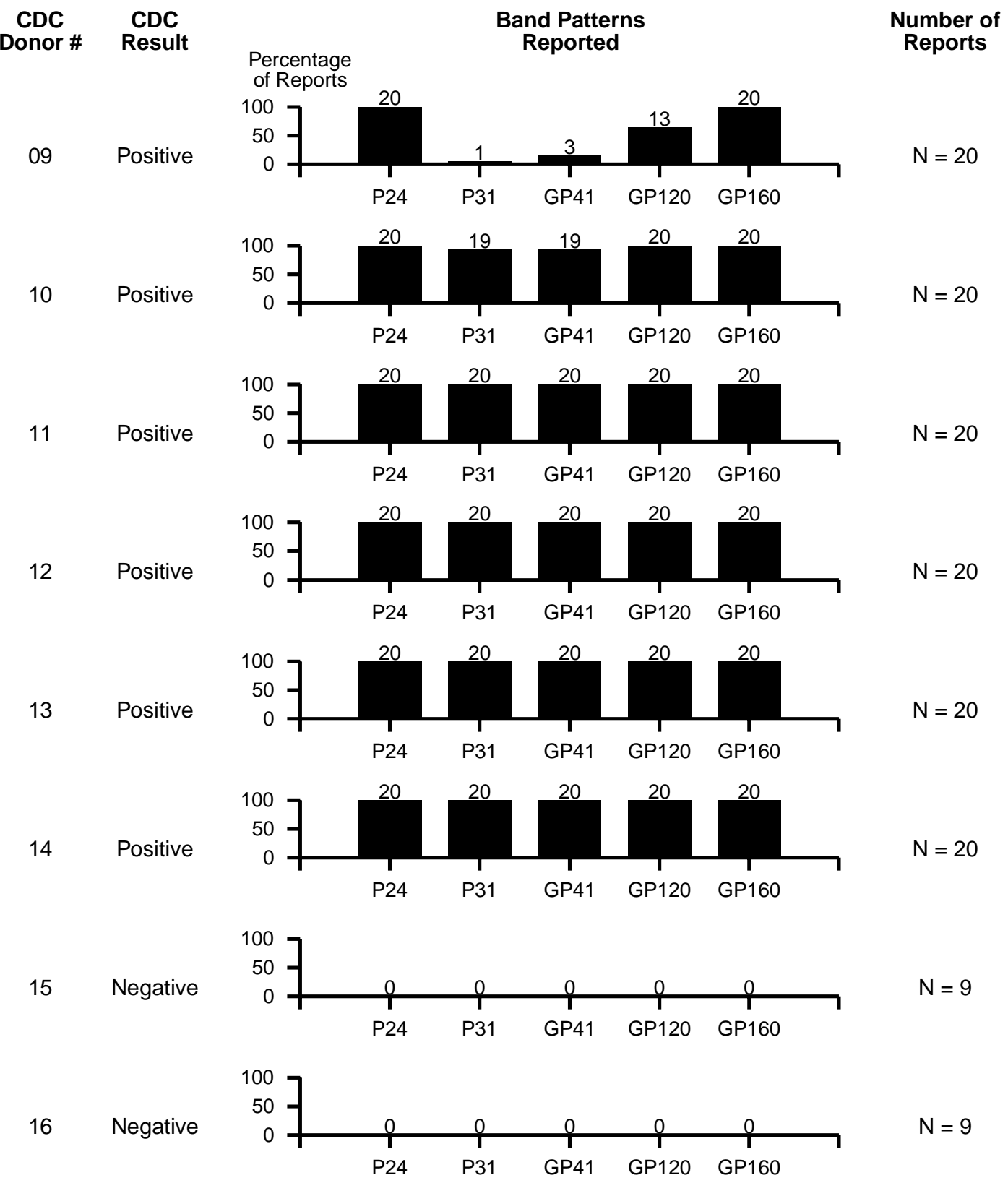


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by reference laboratories for the July 13, 1998 shipment

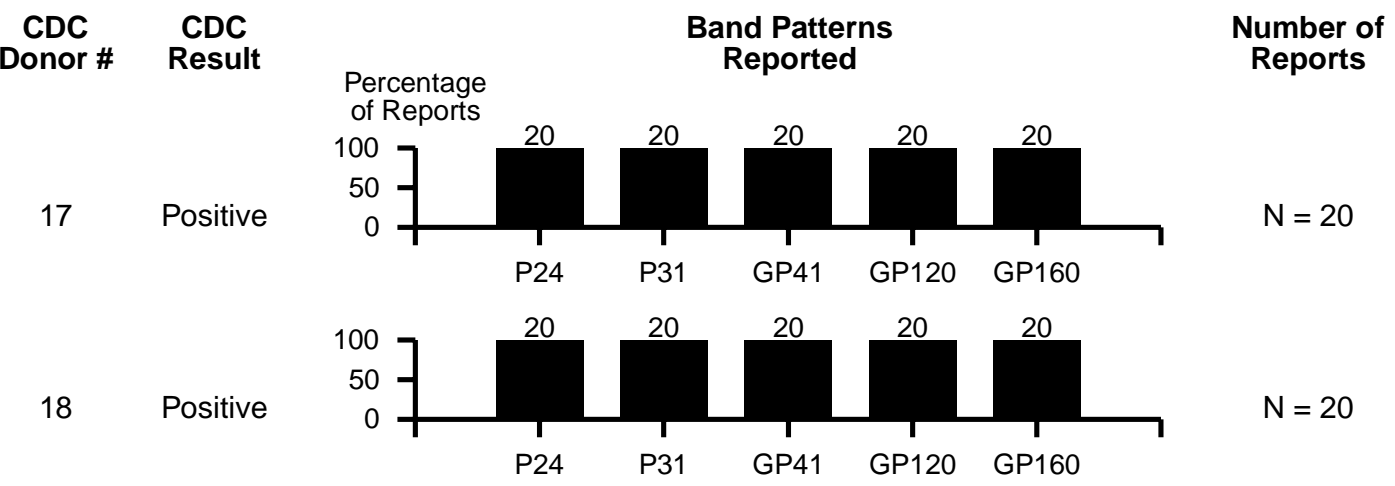


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 13, 1998 shipment

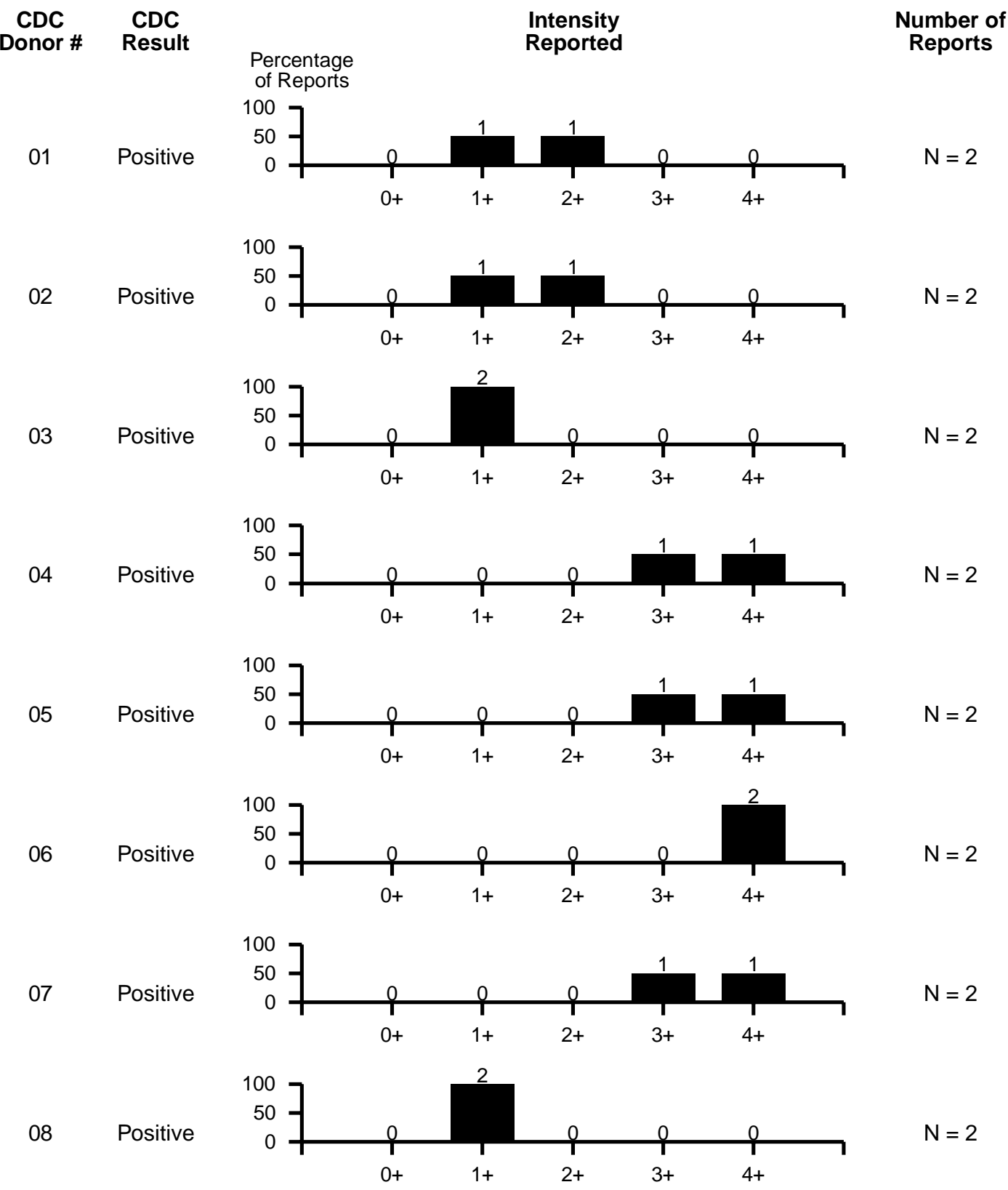


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 13, 1998 shipment

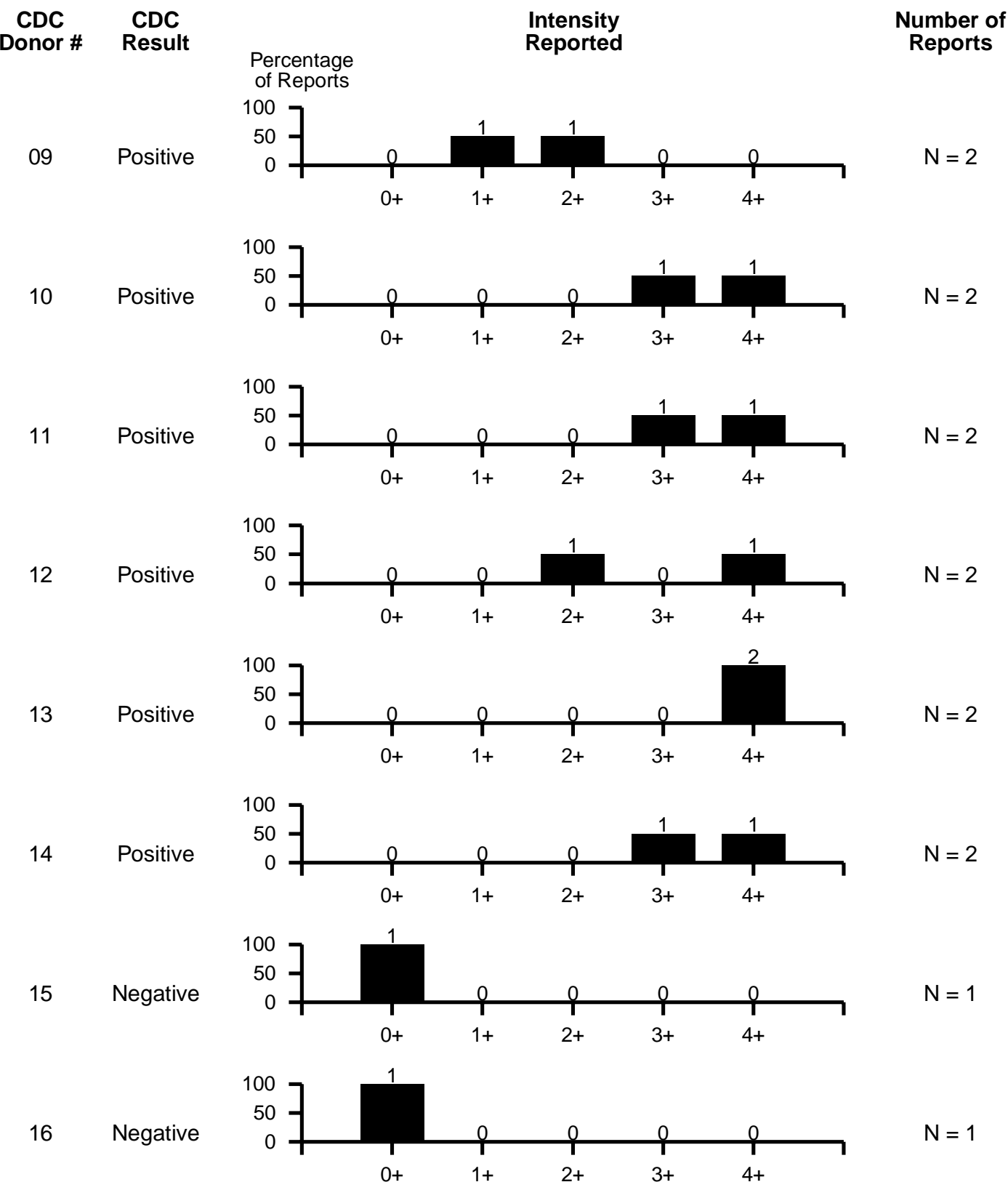


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by reference laboratories for the July 13, 1998 shipment

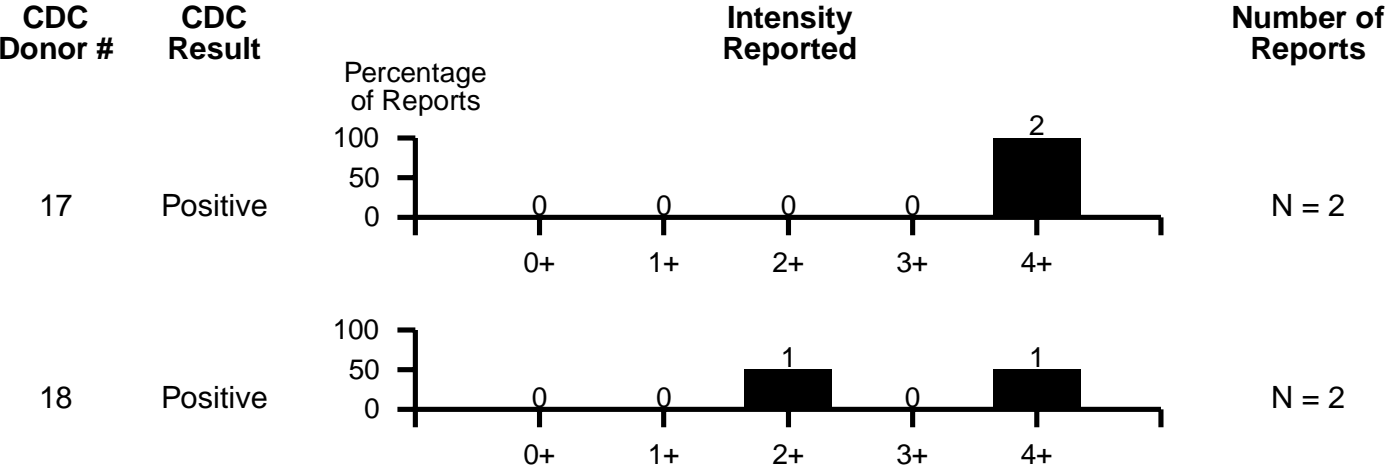


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by reference laboratories to the CDC for the July 13, 1998 shipment

