

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

**Figures Used for the
Analysis of the August 19, 1996
Performance Evaluation Testing Results
Reported by Participant Laboratories**

**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**

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

Report of the August 19, 1996 Human Immunodeficiency virus type I (HIV-1)
Performance Evaluation Sample Testing Results Provided by Participant
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.....Carlyn L. Collins, M.D., M.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 Retroviral Performance Evaluation.....Sharon O. Blumer, M.S.
Retroviral Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation
Program by calling (770) 488-4147 or (770) 488-4366.

**Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program
Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing
August 19, 1996 Participant Laboratory Shipment**

| Panel Letter | Vial Label | CDC Donor Number | CDC Result ² | Laboratory Interpretation ¹ | | | |
|--------------|------------|------------------|-------------------------|--|--------------------|----|-----|
| | | | | EIA | | WB | IIF |
| | | | | INIT. ³ | FINAL ⁴ | | |
| A | A01 | 05 | Negative | — | — | — | — |
| | A02 | 15 | Positive | — | — | — | — |
| | A03 | 07 | Negative | — | — | — | — |
| | A04 | 11 | Positive | — | — | — | — |
| | A05, A06 | 01 | Positive | — | — | — | — |
| B | B01, B04 | 02 | Positive | — | — | — | — |
| | B02 | 06 | Negative | — | — | — | — |
| | B03 | 12 | Positive | — | — | — | — |
| | B05 | 16 | Positive | — | — | — | — |
| | B06 | 08 | Negative | — | — | — | — |
| C | C01 | 17 | Positive | — | — | — | — |
| | C02 | 13 | Positive | — | — | — | — |
| | C03 | 09 | Negative | — | — | — | — |
| | C04, C05 | 03 | Positive | — | — | — | — |
| | C06 | 05 | Negative | — | — | — | — |
| D | D01 | 10 | Negative | — | — | — | — |
| | D02 | 14 | Positive | — | — | — | — |
| | D03, D06 | 04 | Positive | — | — | — | — |
| | D04 | 06 | Negative | — | — | — | — |
| | D05 | 18 | Positive | — | — | — | — |

¹ Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant 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**

**CDC Western Blot (WB) Testing Results for the
August 19, 1996 Participant Laboratory Panel Samples**

| Panel Letter | Vial Label | CDC Donor Number | CDC Western Blot Test Results Specific WB Bands Detected¹ | WB Test Kit Manufacturer | CDC Interpretation² |
|---------------------|-------------------|-------------------------|--|--|--|
| A | A01 | 05 | No Bands | All Manufacturers | Negative |
| | A02 | 15 | 18,24,55,160 17,24,160 24 | BioRad Cambridge Biotech Epitope/Organon | Positive Positive Indeterminate |
| | A03 | 07 | No Bands | All Manufacturers | Negative |
| | A04 | 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 | Positive Positive Positive |
| | A05, A06 | 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 | Positive Positive Positive |
| B | B01, B04 | 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 | Positive Positive Positive |
| | B02 | 06 | No Bands | All Manufacturers | Negative |
| | B03 | 12 | 24,41,55,120,160 24,41,66,120,160 24,41,120,160 | BioRad Cambridge Biotech Epitope/Organon | Positive Positive Positive |
| | B05 | 16 | 18,24,41,55,120,160 17,24,120,160 24,55 | BioRad Cambridge Biotech Epitope/Organon | Positive Positive Indeterminate |
| | B06 | 08 | No Bands | All Manufacturers | Negative |
| C | C01 | 17 | 18,24,55,65,160 24,66,120,160 24,65,160 | BioRad Cambridge Biotech Epitope/Organon | Positive Positive Positive |
| | C02 | 13 | 24,55 24,120,160 24 | BioRad Cambridge Biotech Epitope/Organon | Indeterminate Positive Indeterminate |
| | C03 | 09 | No Bands | All Manufacturers | Negative |
| | C04, C05 | 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 | Positive Positive Positive |
| | C06 | 05 | No Bands | All Manufacturers | Negative |
| D | D01 | 10 | No Bands | All Manufacturers | Negative |
| | D02 | 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 | Positive Positive Positive |
| | D03, D06 | 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 | Positive Positive Positive |
| | D04 | 06 | No Bands | All Manufacturers | Negative |
| | D05 | 18 | 18,24,55,160 17,24,51,120,160 24,160 | BioRad Cambridge Biotech Epitope/Organon | Positive Positive Positive |

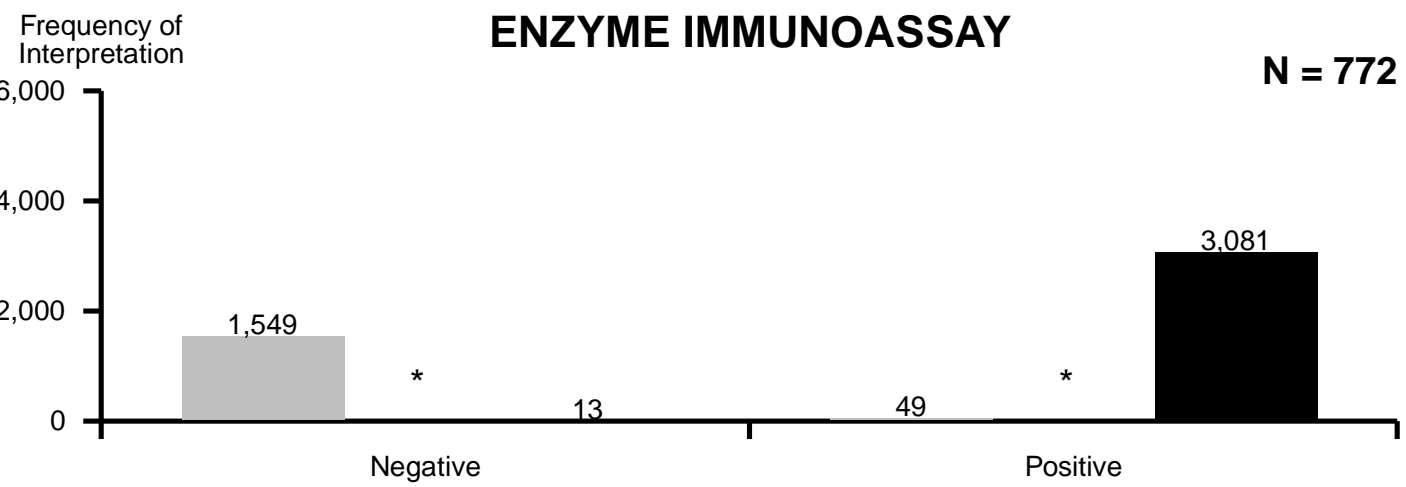
¹ Western blot (WB) result based on band intensity of $\geq 1+$ staining.

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

**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 the enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the August 19, 1996 shipment



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

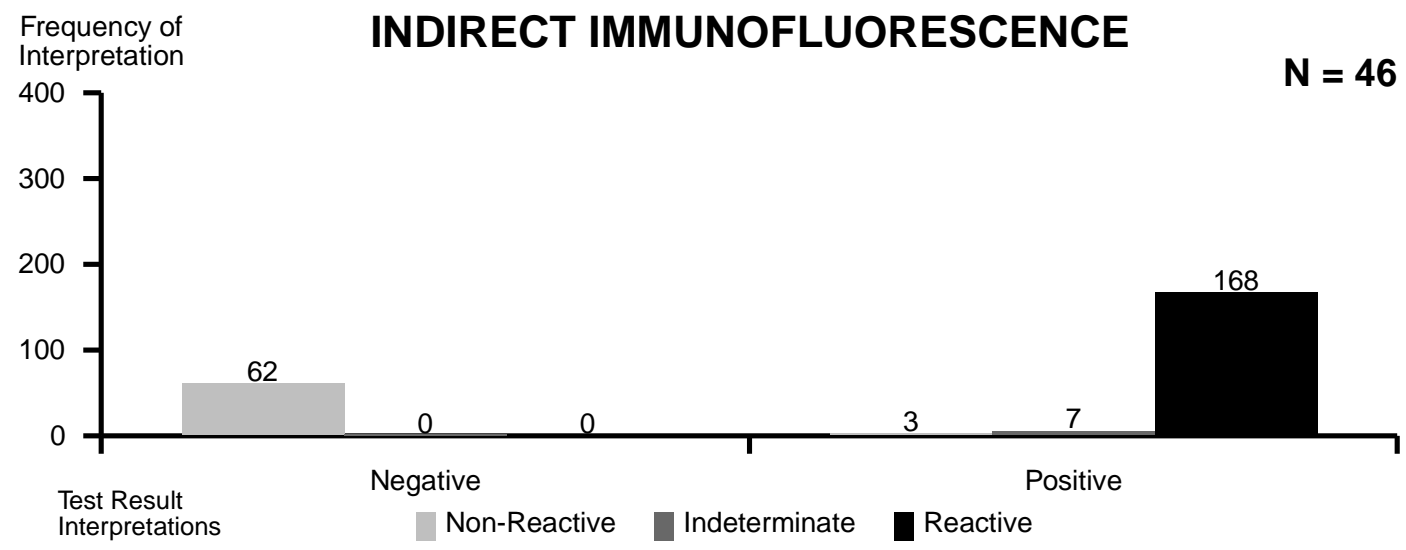
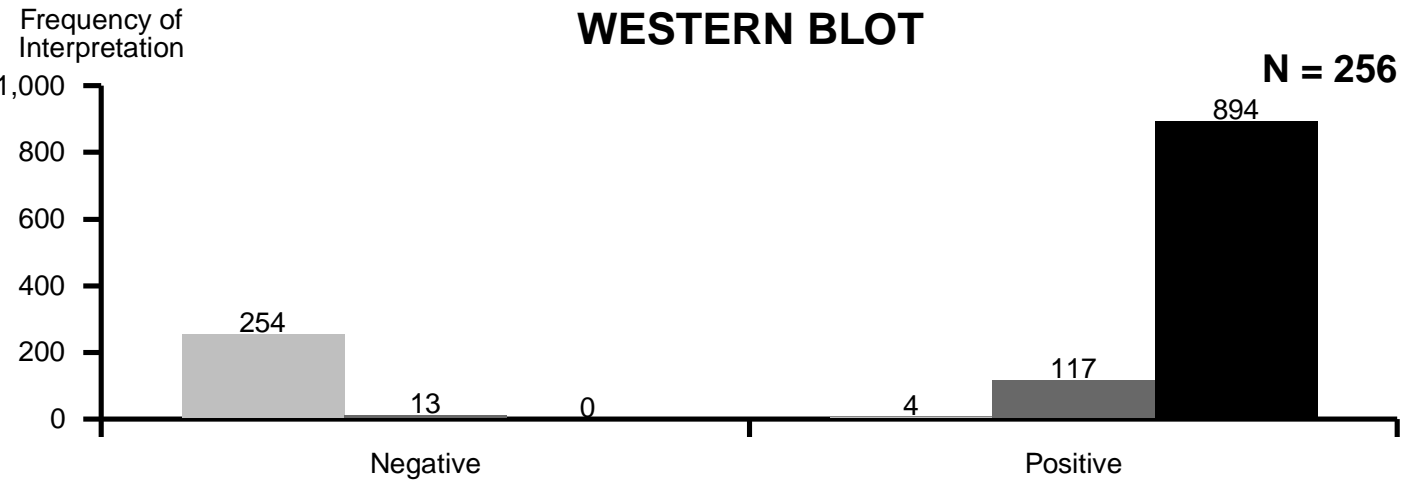


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported results to the CDC for the August 19, 1996 shipment

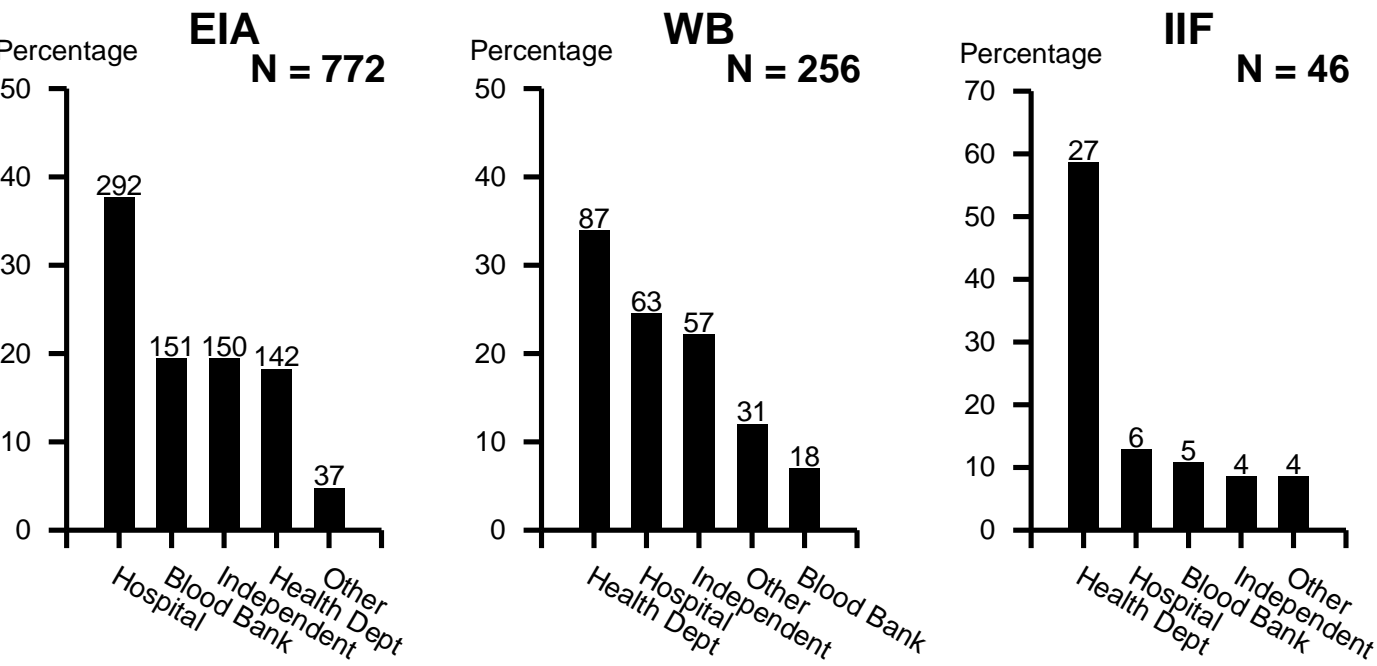


Figure 3. Combination of HIV-1 tests reported by participant laboratories for the August 19, 1996 shipment

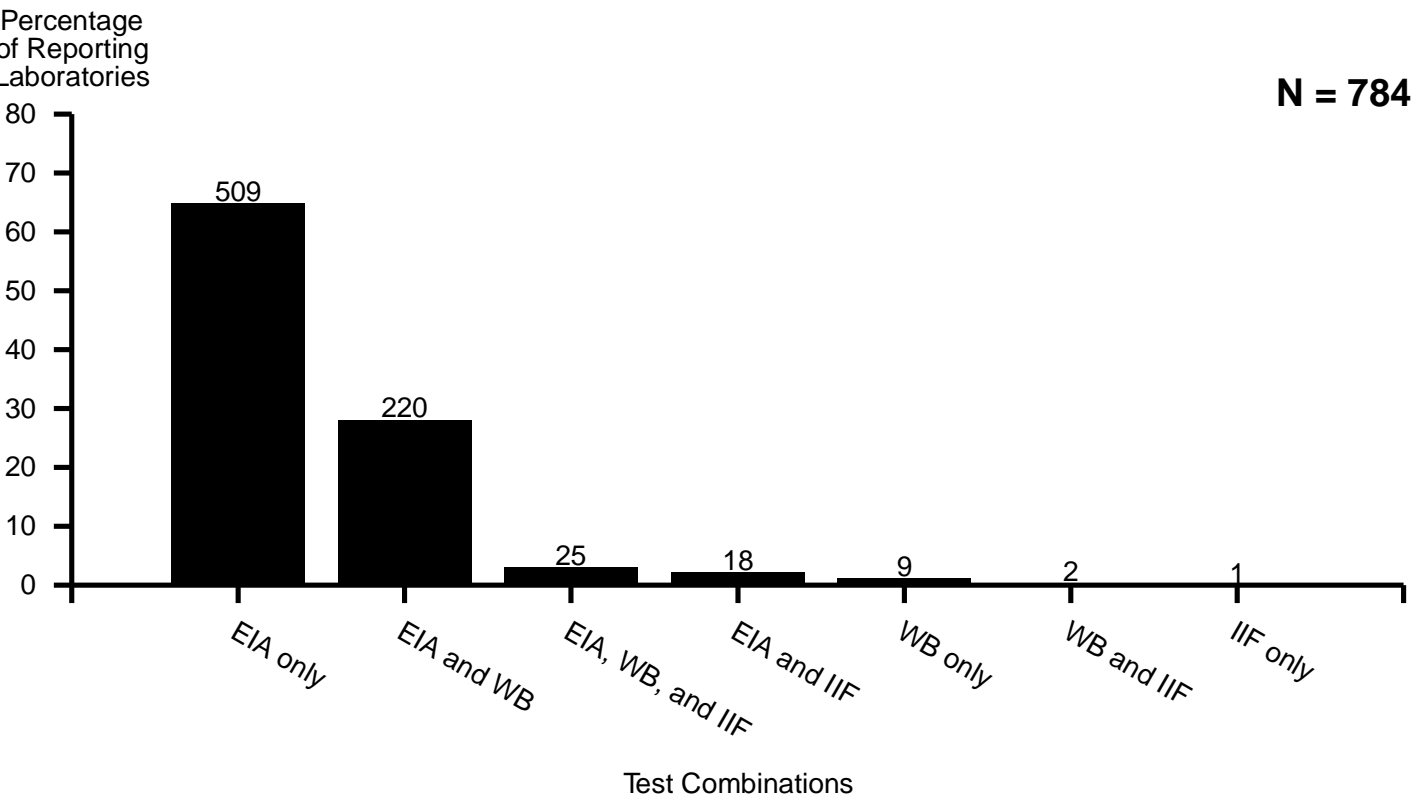


Figure 4. Types of HIV-1 kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the August 19, 1996 shipment

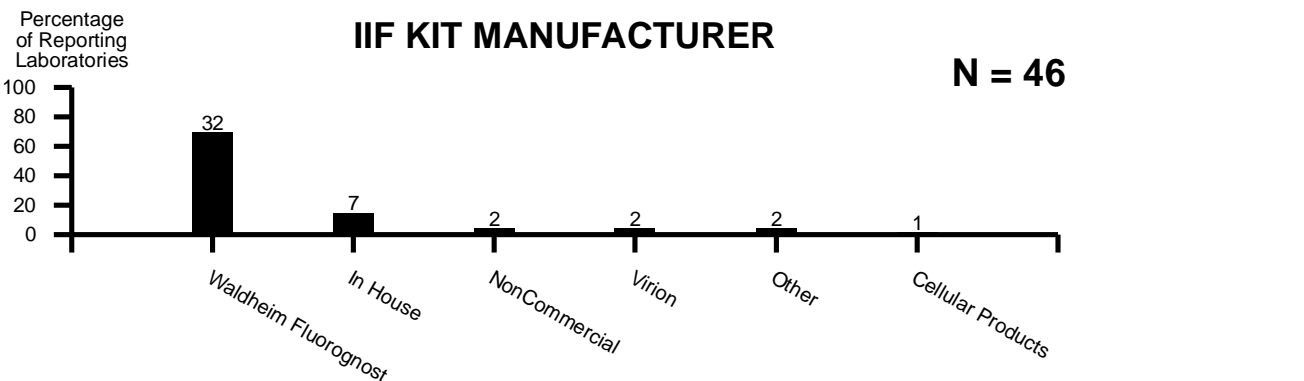
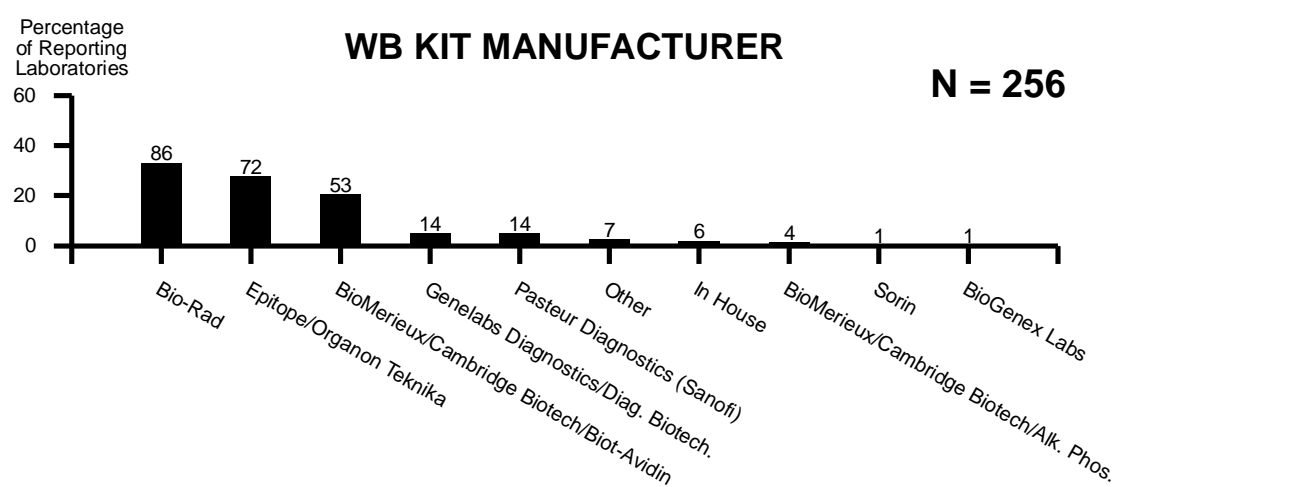
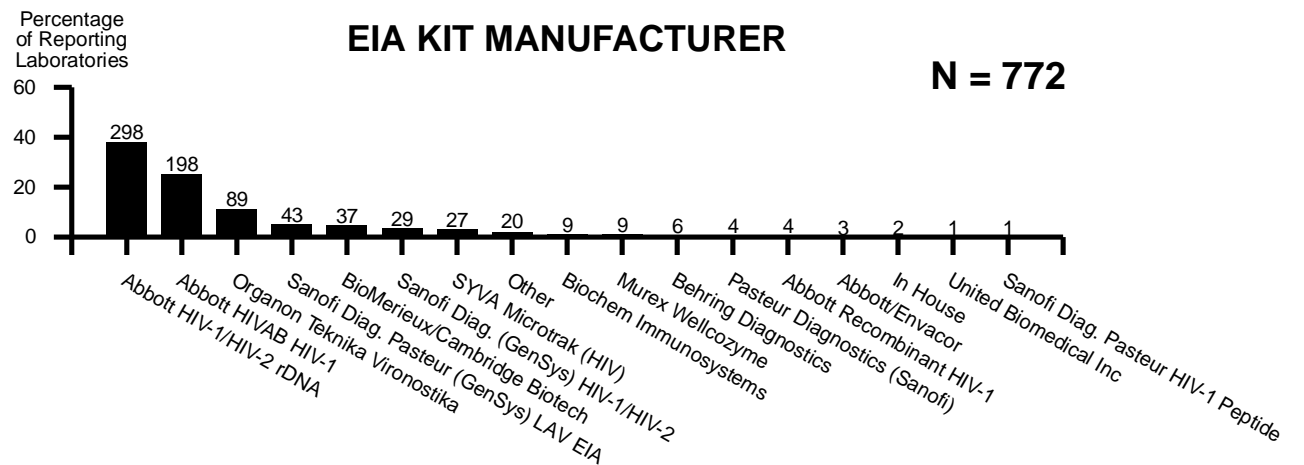


Figure 5. Enzyme immunoassay HIV-1 results, by kit manufacturer, reported by participant laboratories for the August 19, 1996 shipment

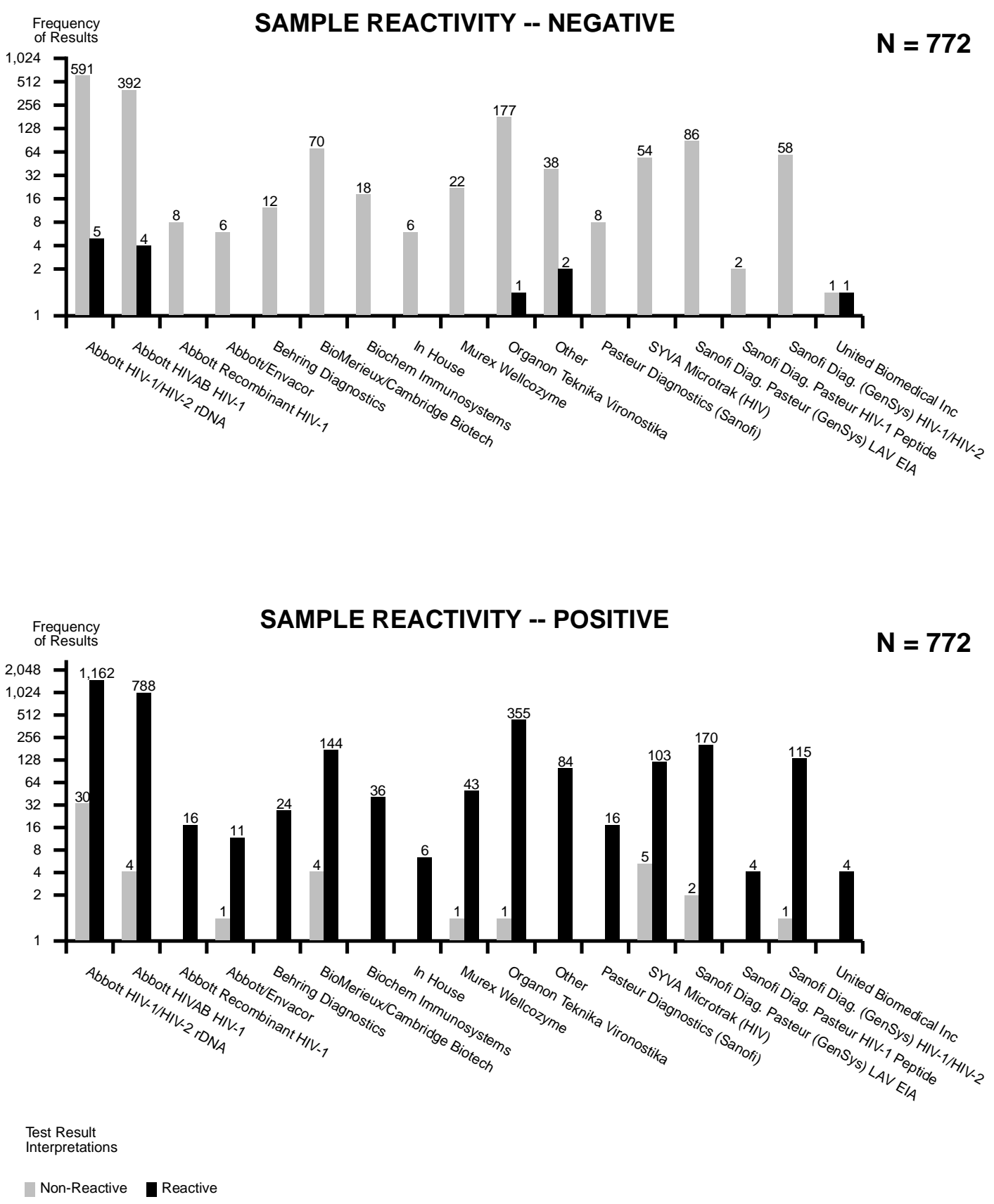
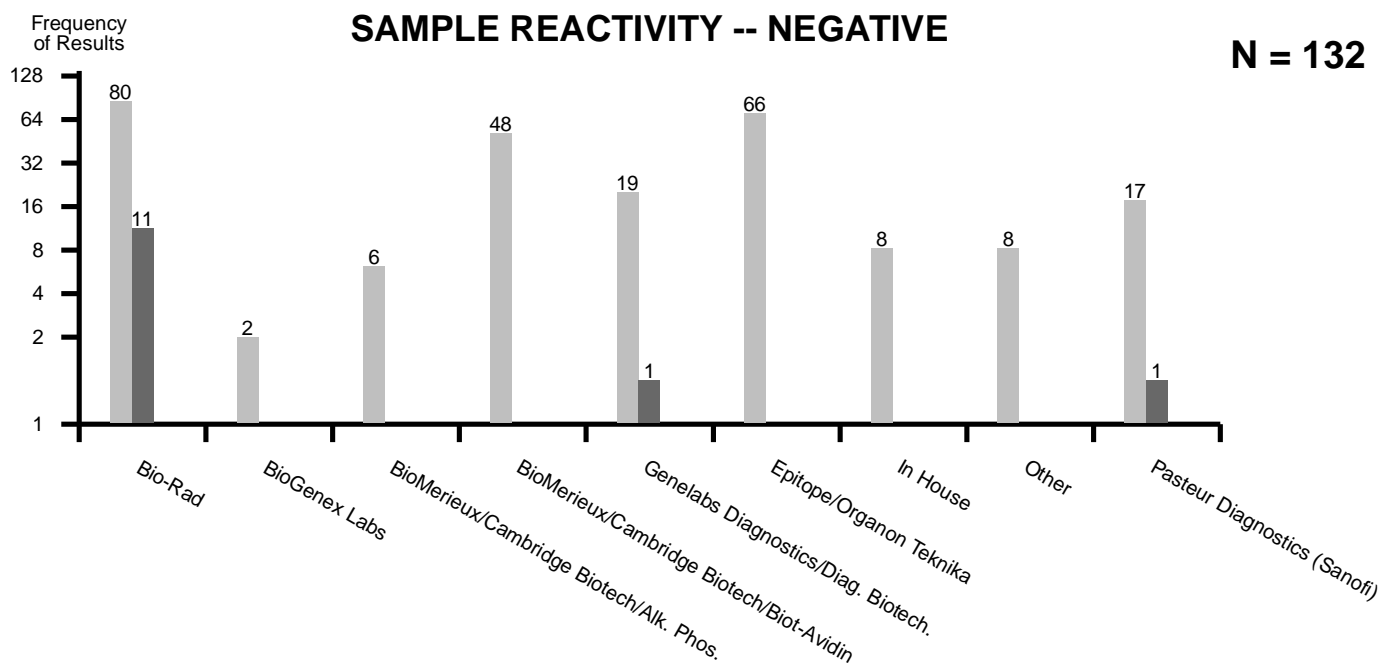


Figure 6. Western blot HIV-1 results, by kit manufacturer, reported by participant laboratories for the August 19, 1996 shipment

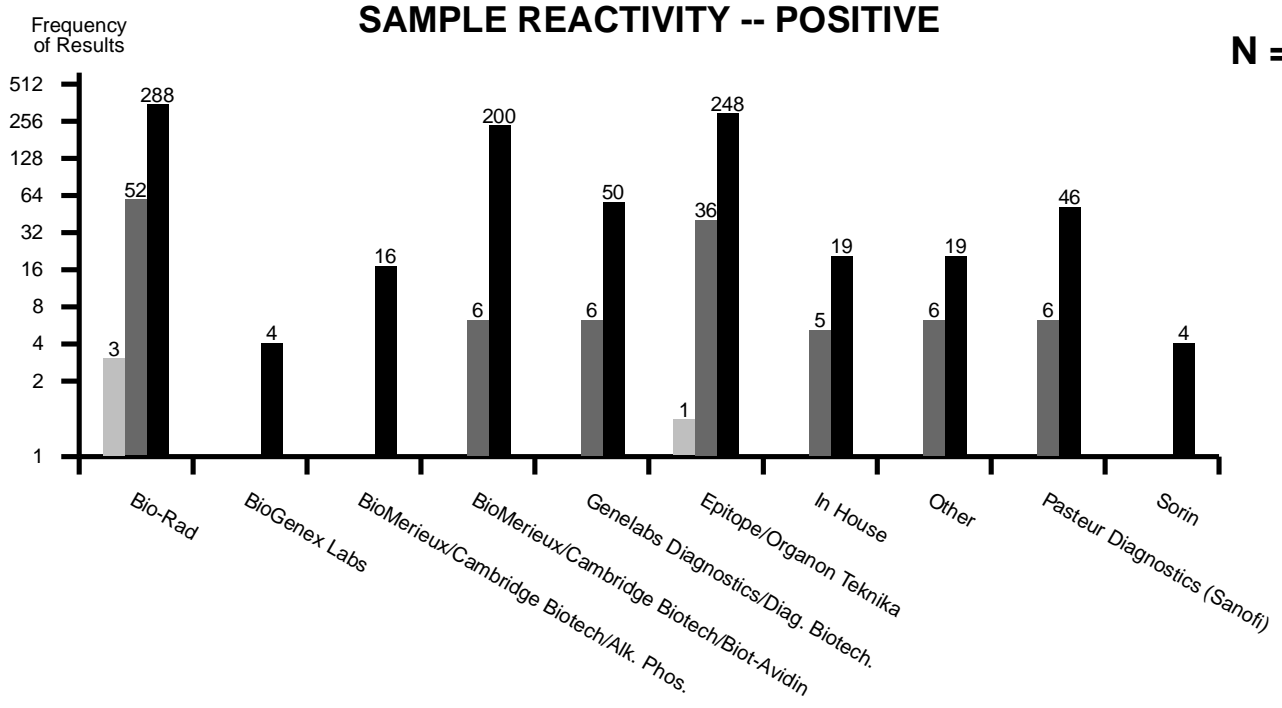
SAMPLE REACTIVITY -- NEGATIVE

N = 132



SAMPLE REACTIVITY -- POSITIVE

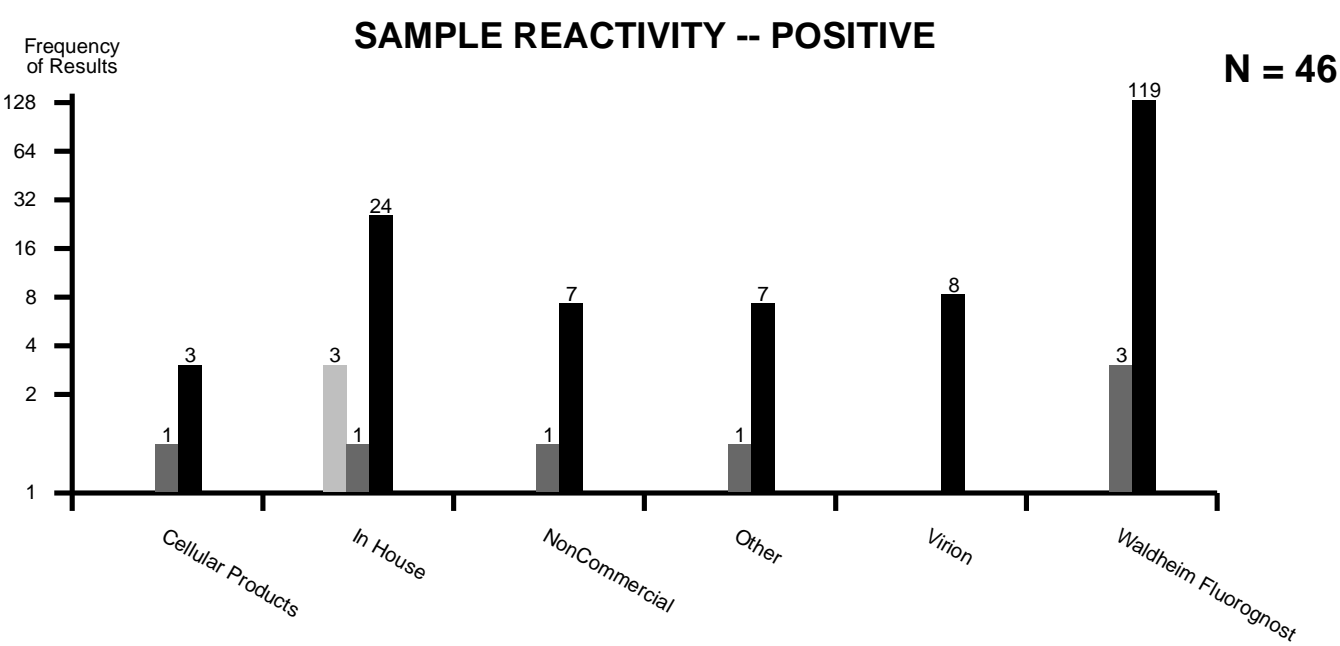
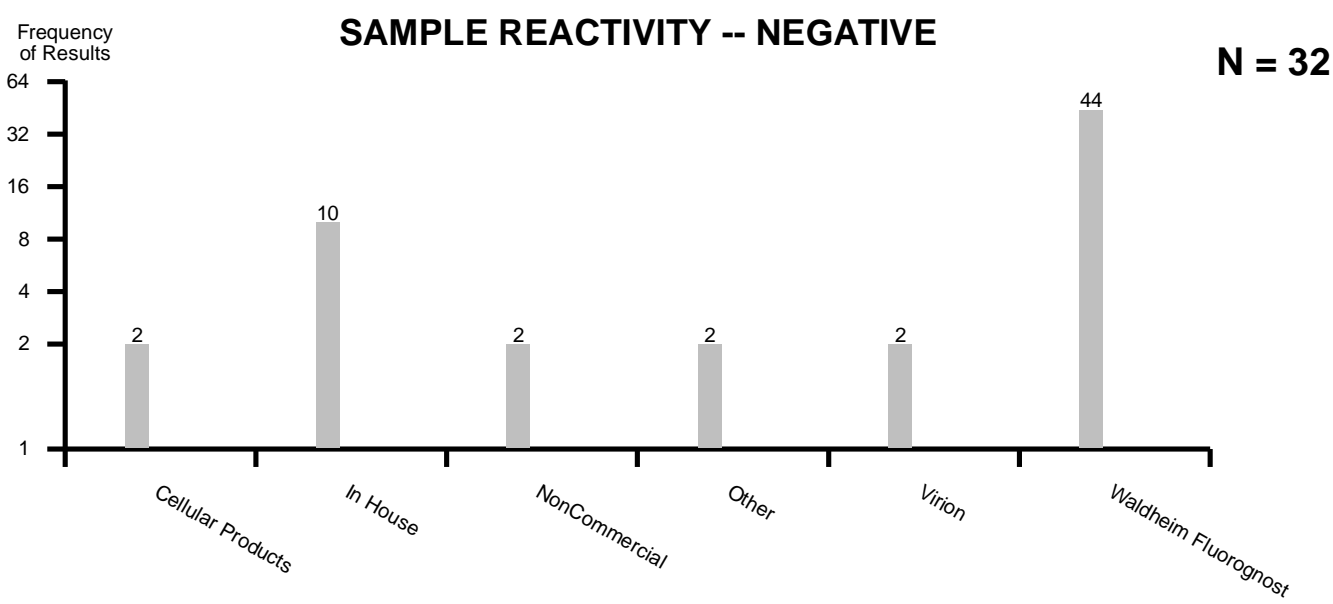
N = 256



Test Result Interpretations

■ Non-Reactive ■ Indeterminate ■ Reactive

Figure 7. Indirect immunofluorescence HIV-1 results, by kit manufacturer, reported by participant laboratories for the August 19, 1996 shipment



Test Result Interpretations

Non-Reactive
 Indeterminate
 Reactive

Figure 8. Western blot HIV-1 band patterns reported to CDC by participant laboratories for the August 19, 1996 shipment

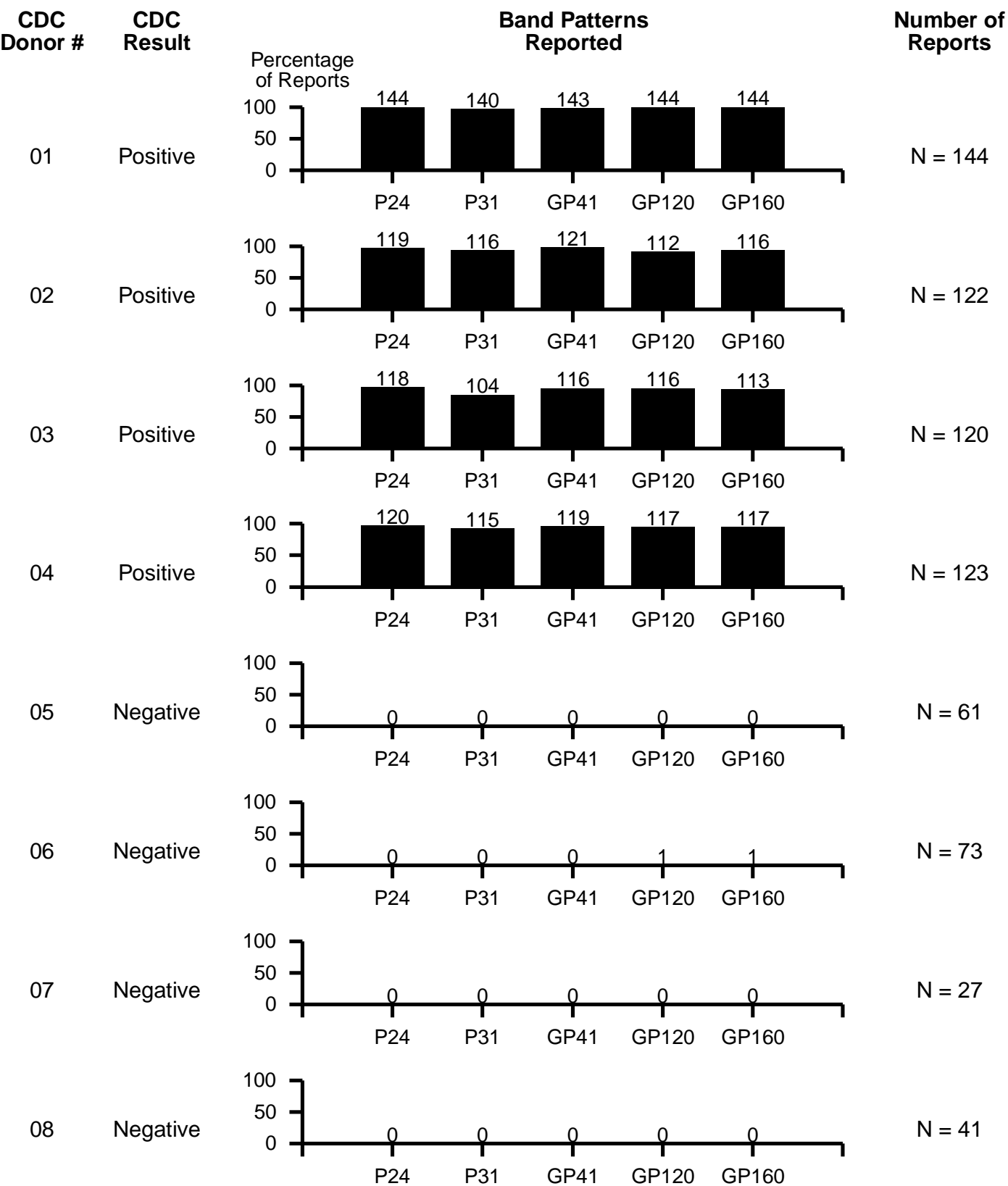


Figure 8. Western blot HIV-1 band patterns reported to CDC by participant laboratories for the August 19, 1996 shipment

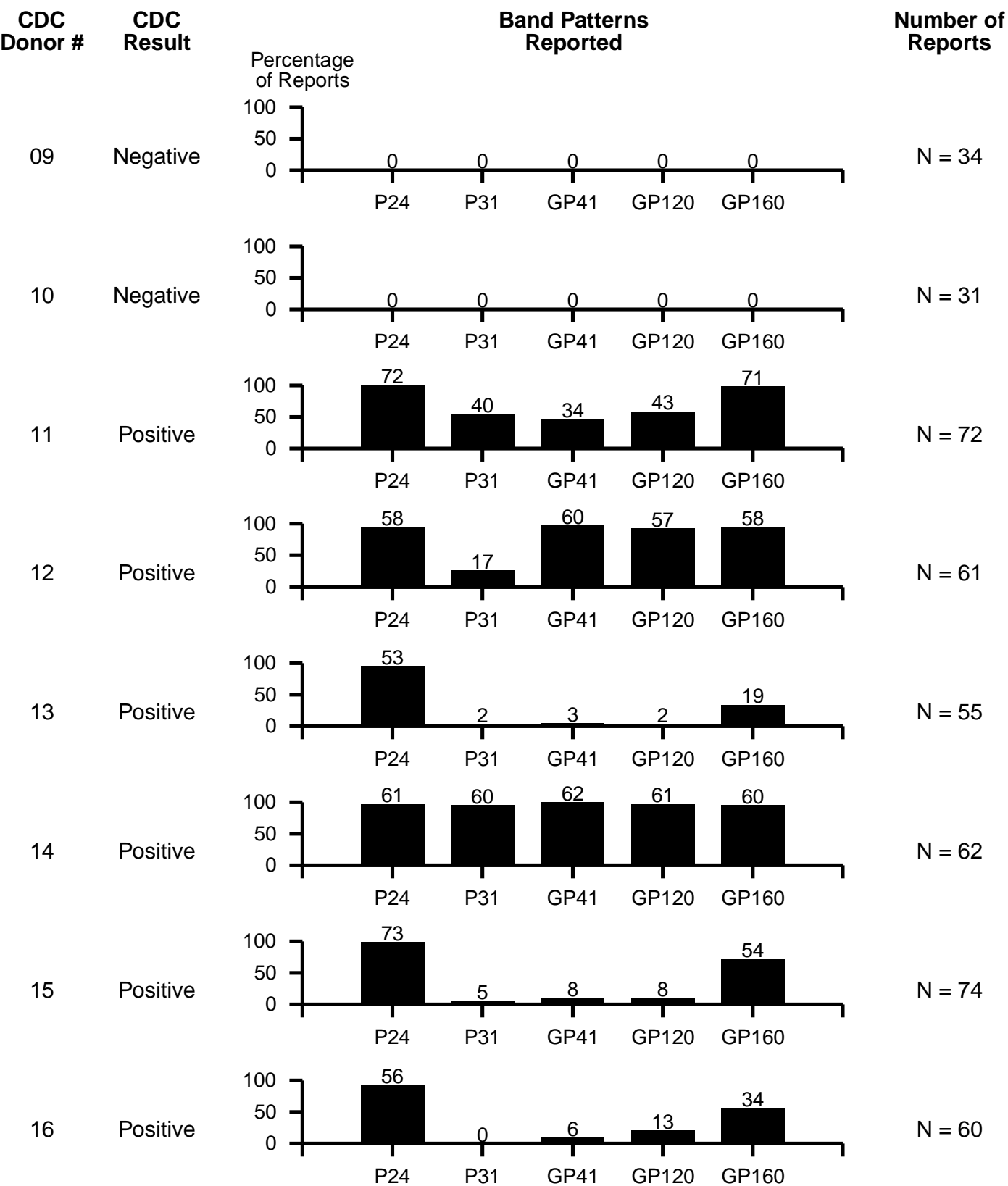


Figure 8. Western blot HIV-1 band patterns reported to CDC by participant laboratories for the August 19, 1996 shipment

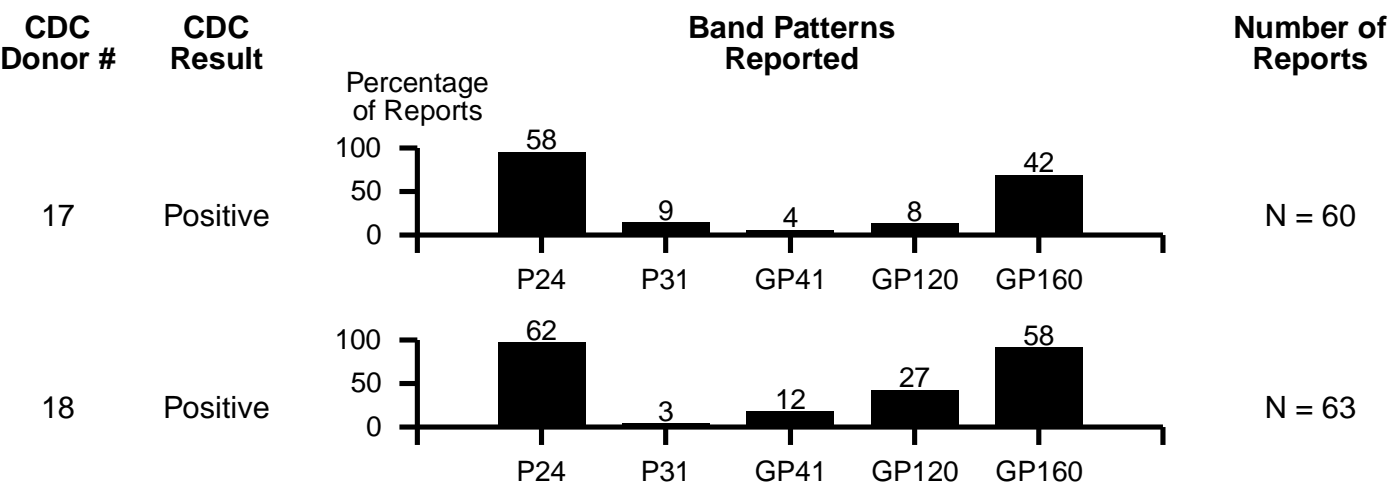


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 19, 1996 shipment

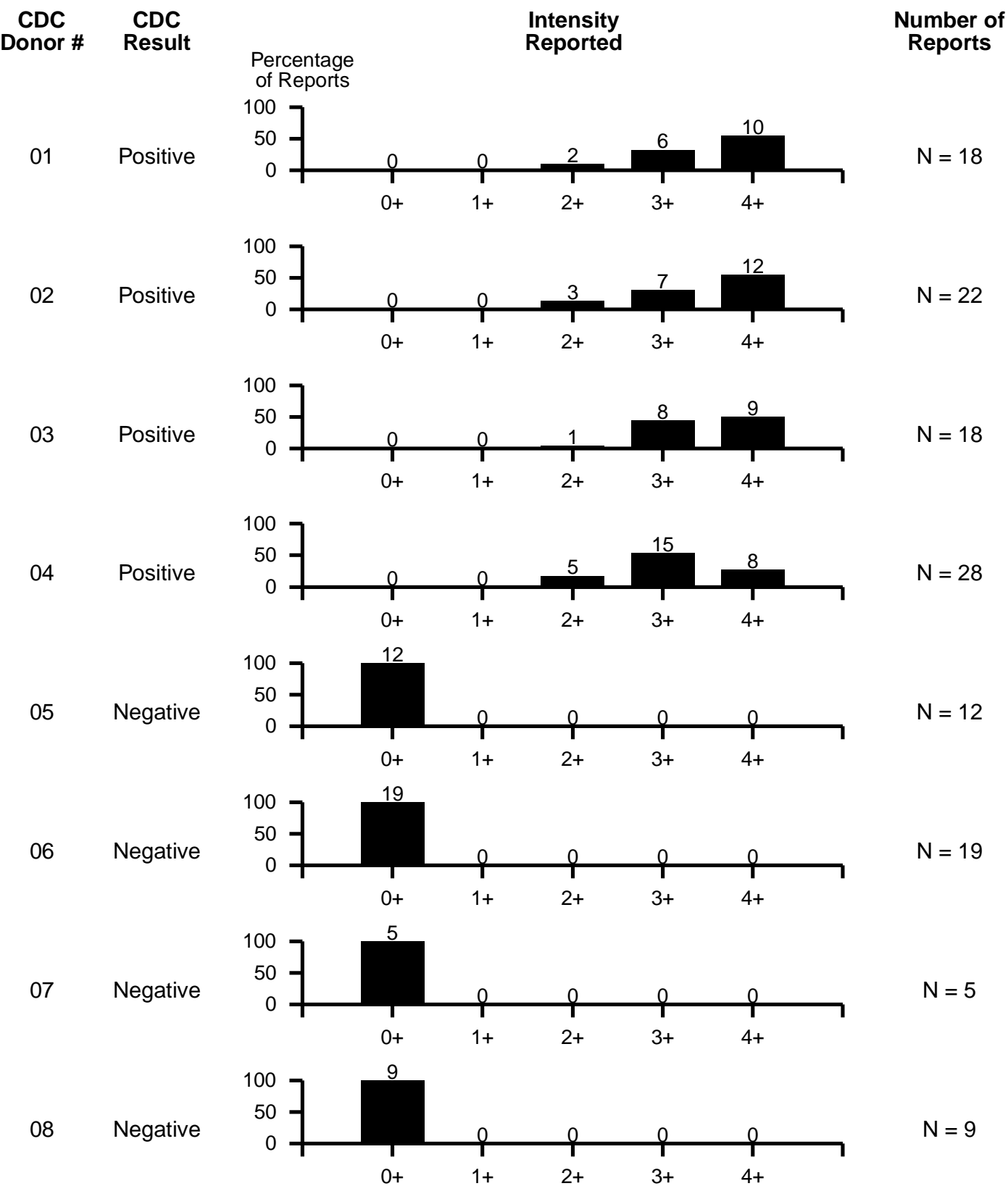


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 19, 1996 shipment

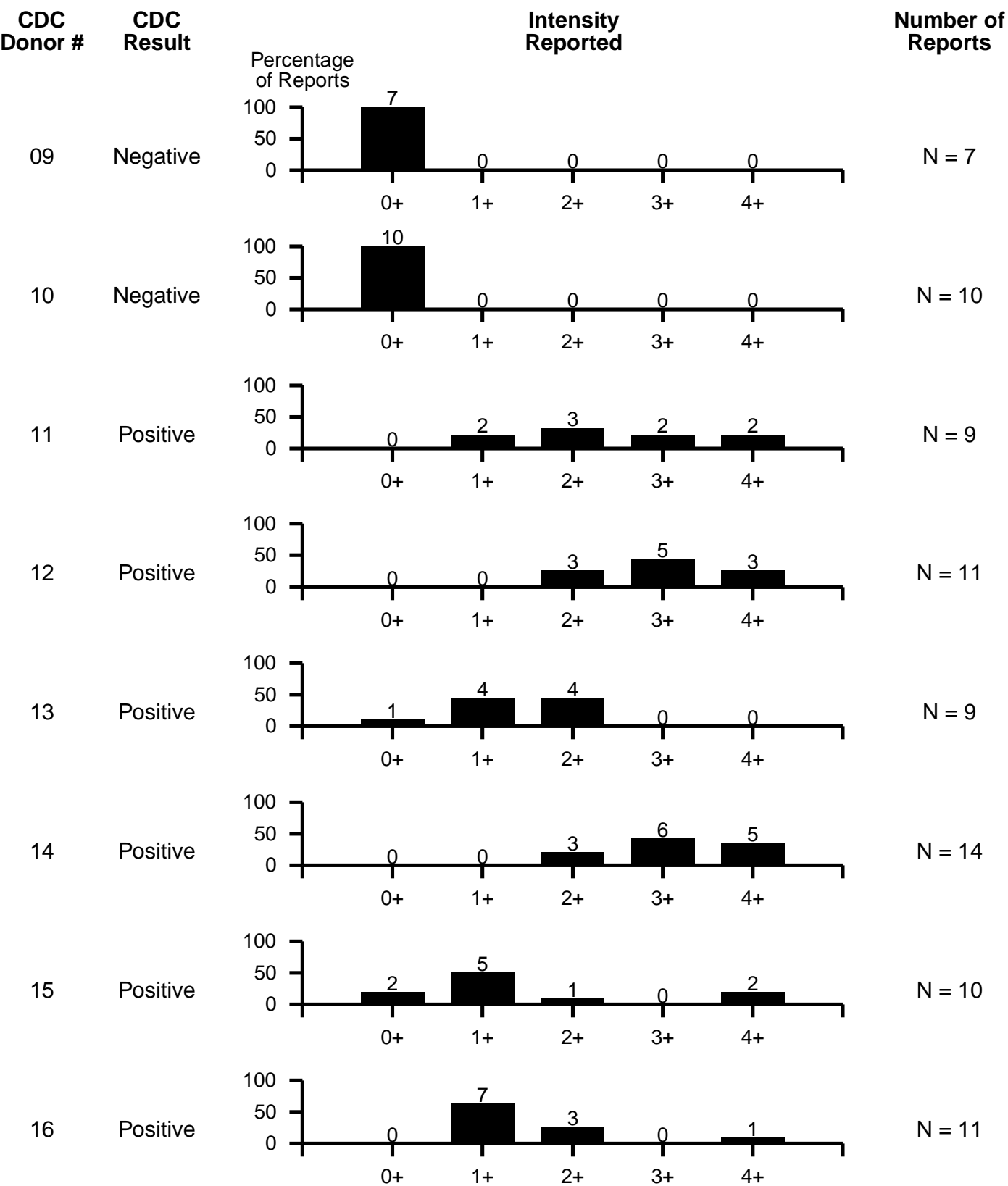


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the August 19, 1996 shipment

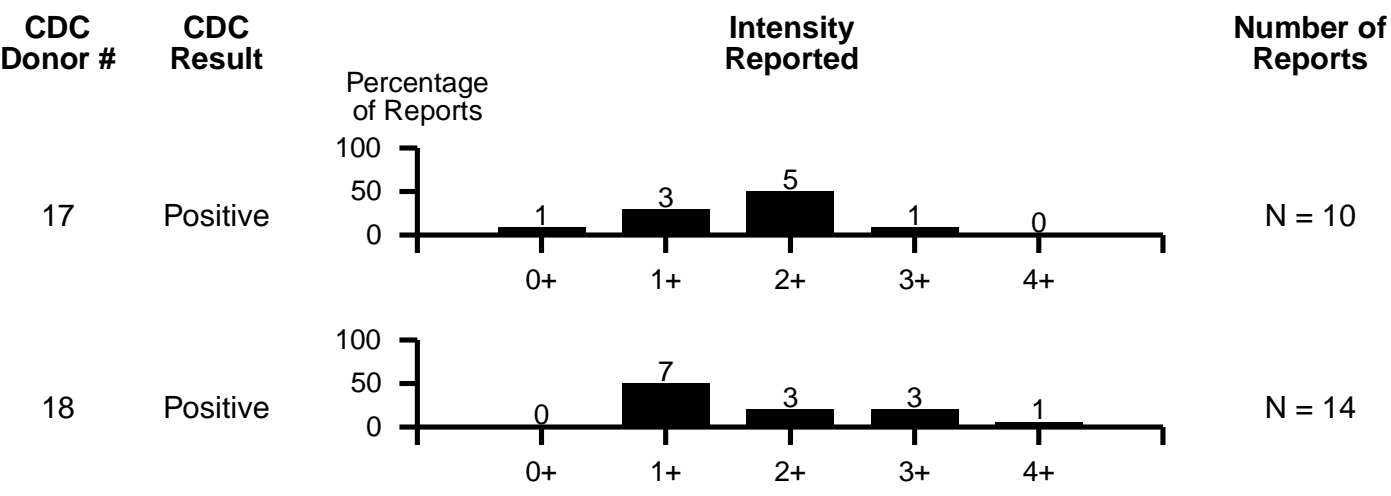


Figure 10. Types of 'Other' HIV test kits used and results reported by participant laboratories to the CDC for the August 19, 1996 shipment

