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

Figures Used for the Analysis of the January 26, 1998 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



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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 26, 1998 Participant Laboratory Shipment

Panel Letter	Vial Label	CDC Donor Number	CDC Result <sup>2</sup>	Laboratory Interpretat EIA	
				INIT. <sup>3</sup> FINAL <sup>4</sup>	WB IIF
Н	H1 H2 H3, H4 H5, H6	17 01 08 15	Positive Positive Positive Negative		
Ι	I1 I2 I3, I4 I5, I6	02 18 09 16	Positive Positive Positive Negative		
J	J1, J4 J2, J5 J3 J6	15 10 17 03	Negative Positive Positive Positive		
К	K1 K2, K5 K3, K6 K4	04 11 16 18	Positive Positive Negative Positive		

#### Table 1

#### Table 1, Continued

Panel Vial Letter Label		CDC Donor Number	CDC Result <sup>2</sup>	Laboratory Inter EIA	Laboratory Interpretation <sup>1</sup> EIA		
				INIT. <sup>3</sup> FINAL <sup>4</sup>	WB IIF		
L	L1, L4 L2	15 05	Negative Positive				
	L3, L6 L5	12 17	Positive Positive				
Μ	M1, M4 M2, M5 M3 M6	13 16 06 18	Positive Negative Positive Positive				
Ν	N1 N2, N5 N3, N6 N4	17 14 15 07	Positive Positive Negative Positive				

- <sup>1</sup> Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant 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), and employing the WB interpretive criteria of the Association of State and Territorial Public Health Laboratory Directors/CDC (ASTPHLD/CDC).
- <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 26, 1998 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected	WB Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
н	H1	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
	H2	01	18,24,55,160 24,51,66,120,160 24,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	H3, H4	08	24,55,160 24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	H5, H6	15	No Bands	All Manufacturers	Negative
I	I1	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
	I2	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
	I3, I4	09	18,24,55,160 17,24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	I5, I6	16	No Bands	All Manufacturers	Negative
J	J1, J4	15	No Bands	All Manufacturers	Negative
	J2, J5	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
	J3	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
	J6	03	18,24,32,55,65,160 17,24,31,41,51,55,66,120,160 24,51,55,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
К	K1	04	24,41,55,160 24,160 24,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	K2, K5	11	18,24,55,160 17,24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	K3, K6	16	No Bands	All Manufacturers	Negative
	K4	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

<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

#### Table 2, Continued

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Specific WB Bands Detected	WB Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
L	L1, L4	15	No Bands	All Manufacturers	Negative
	L2	05	24,55,160 24,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	L3, L6	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
	L5	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
М	M1, M4	13	24,55,160 24,120,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	M2, M5	16	No Bands	All Manufacturers	Negative
	М3	06	18,24,55,160 17,24,55,66,120,160 18,24,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	M6	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
N	N1	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
	N2, N5	14	18,24,55,65,160 24,41,51,55,66,120,160 24,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive
	N3, N6	15	No Bands	All Manufacturers	Negative
	N4	07	24,41,55,65,160 24,51,66,120,160 24,51,65,160	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Positive

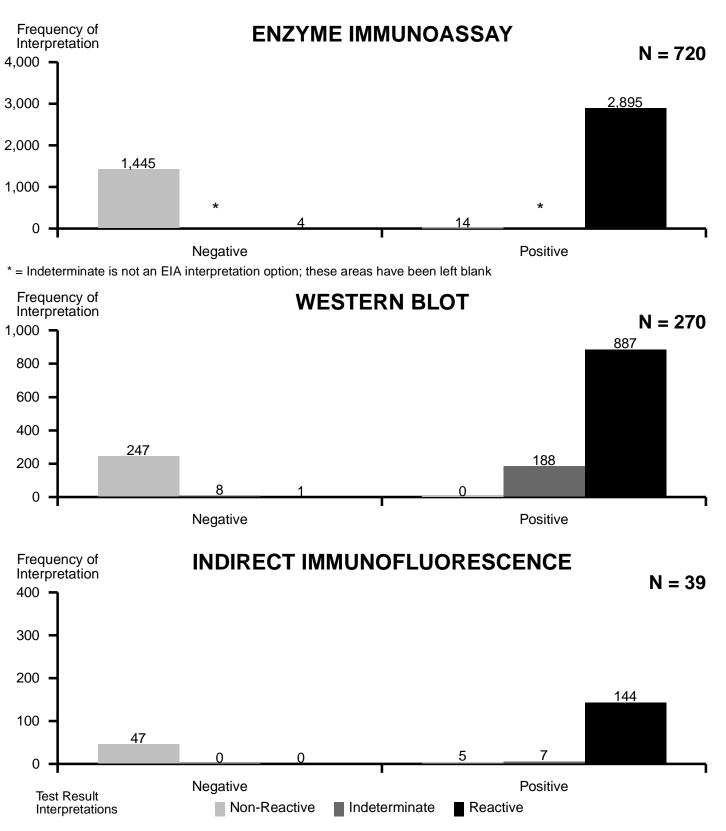
<sup>1</sup> Western blot (WB) result based on band intensity of  $\geq$  1+ staining. <sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results .

\* 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 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 enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the January 26, 1998 shipment



CDC Model Performance Evaluation Program HIV-1 Antibody Testing

Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the January 26, 1998 shipment

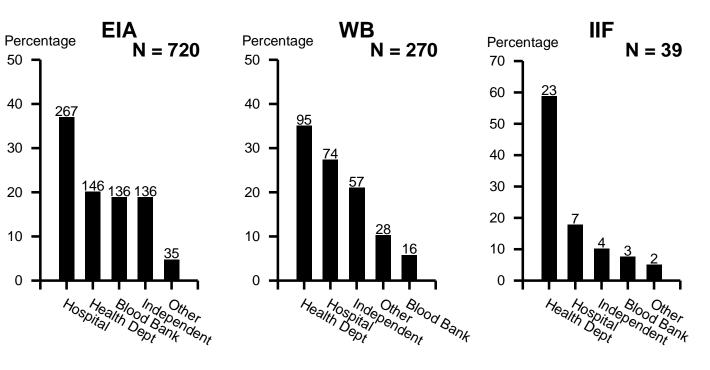
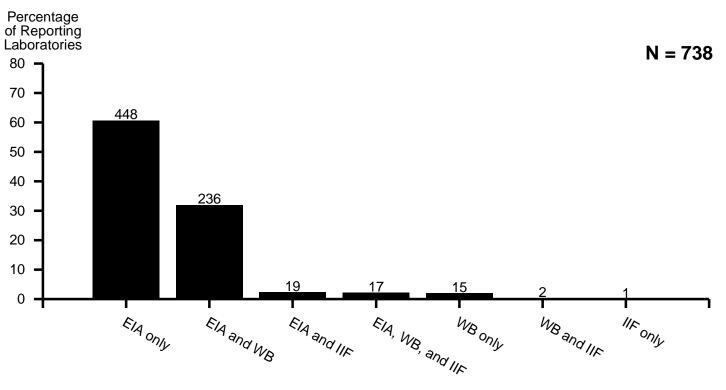


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the January 26, 1998 shipment



**Test Combinations** 

Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the January 26, 1998 shipment

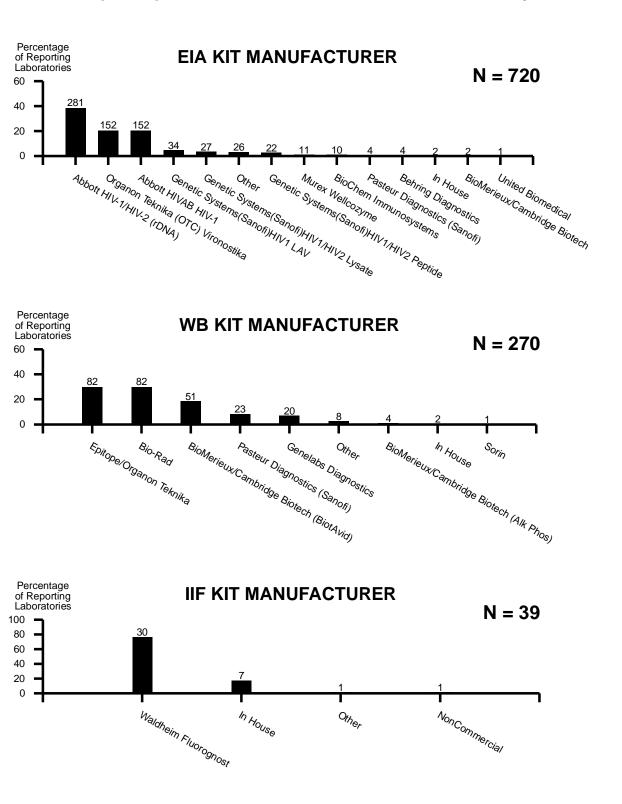
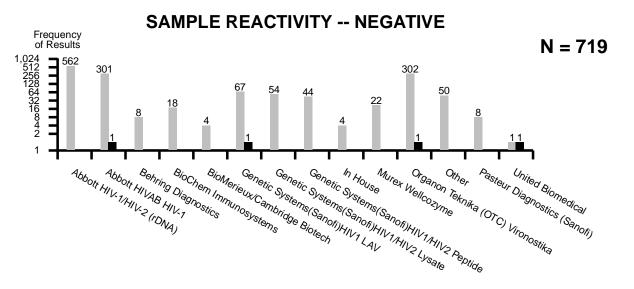


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 26, 1998 shipment



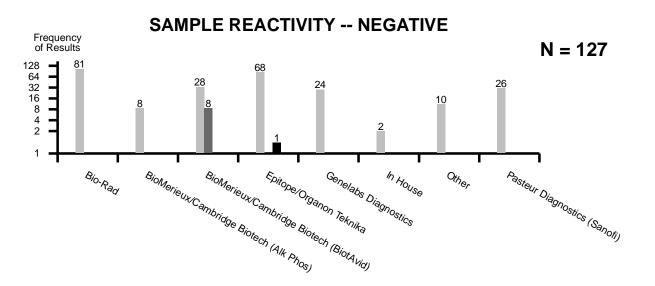
**SAMPLE REACTIVITY -- POSITIVE** Frequency N = 720of Results 1.124 2,0242 2,0242 2558 1258 1258 1258 1682 1684 2 1684 2 604 606 105 104 44 1 Genetic Systems (Sanoti) HIV 1/HIV2 Peptide Genetic Systems (Sanof)HIV1 LAV Organon Teknika (OTC) Vironostika Abbott HIV. IHIV. 2 (rDNA) BioChem Immunosystems BioMerieux Cambridge Biotech Pasteur Diagnostics (Sanofi) Abbott HIVAB HIV.1 Behring Diagnostics

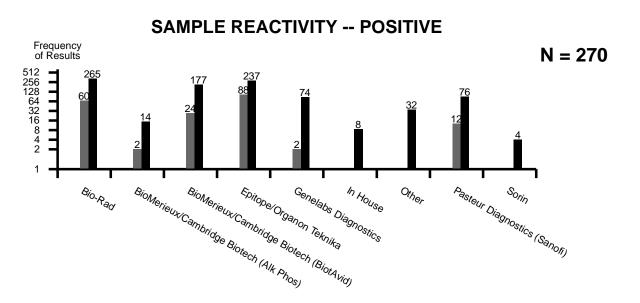
Test Result Interpretations

Non-Reactive Reactive

CDC Model Performance Evaluation Program HIV-1 Antibody Testing

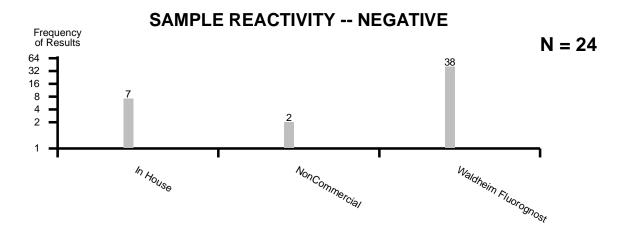
Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 26, 1998 shipment

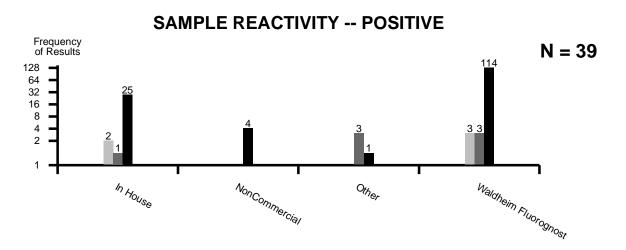




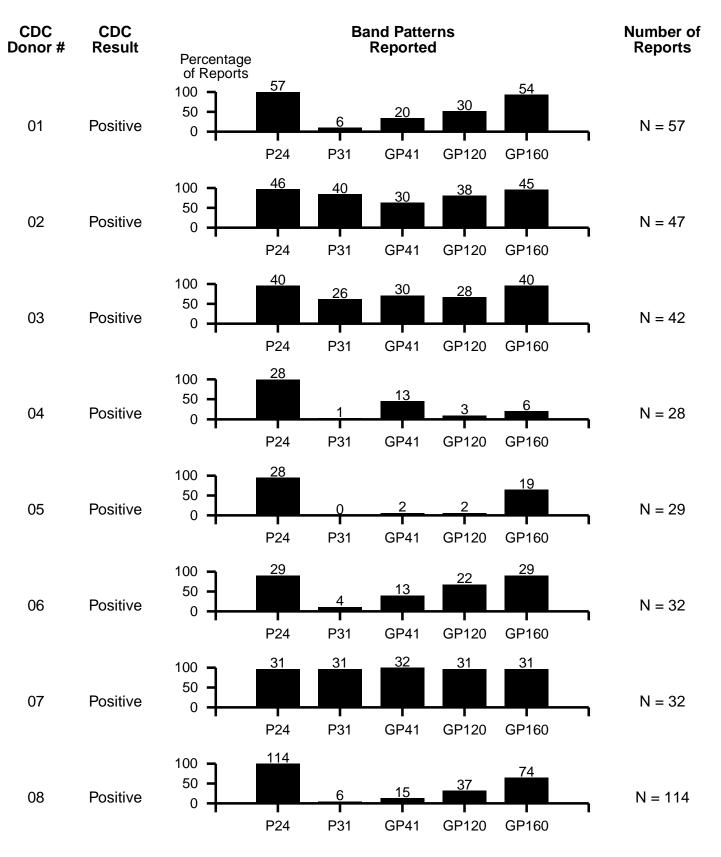
Test Result Interpretations

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 26, 1998 shipment

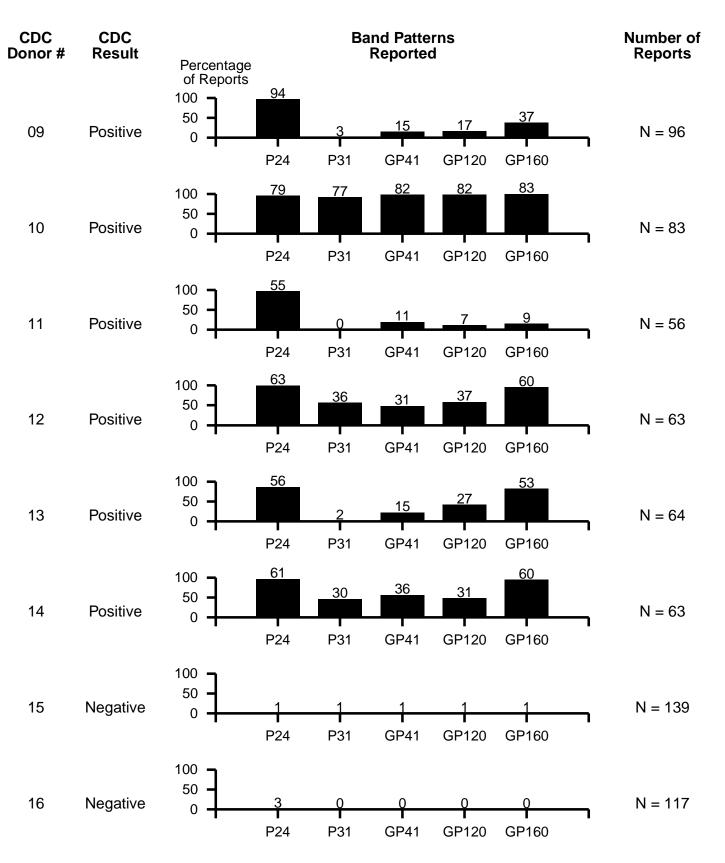




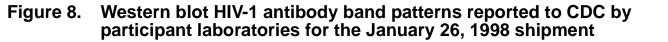
Test Result Interpretations



# Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 26, 1998 shipment



# Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 26, 1998 shipment



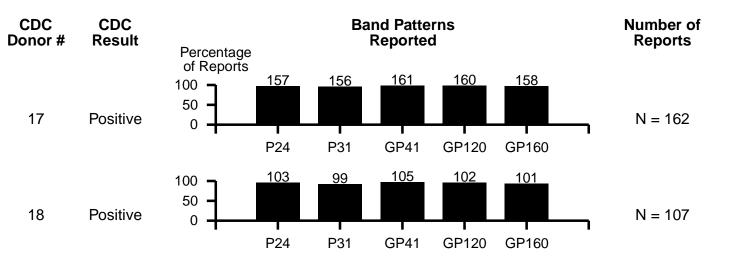


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 26, 1998 shipment

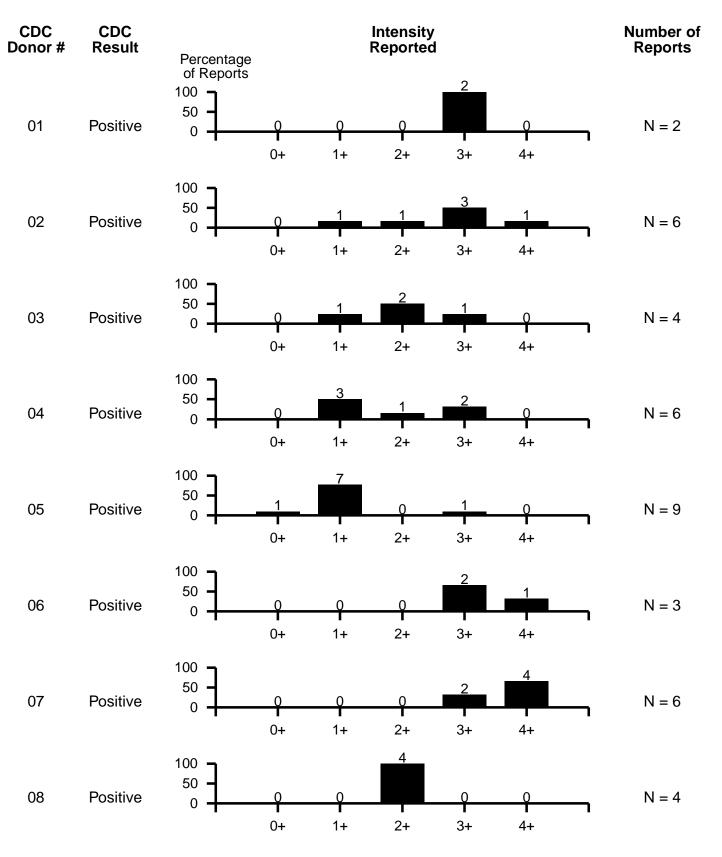


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 26, 1998 shipment

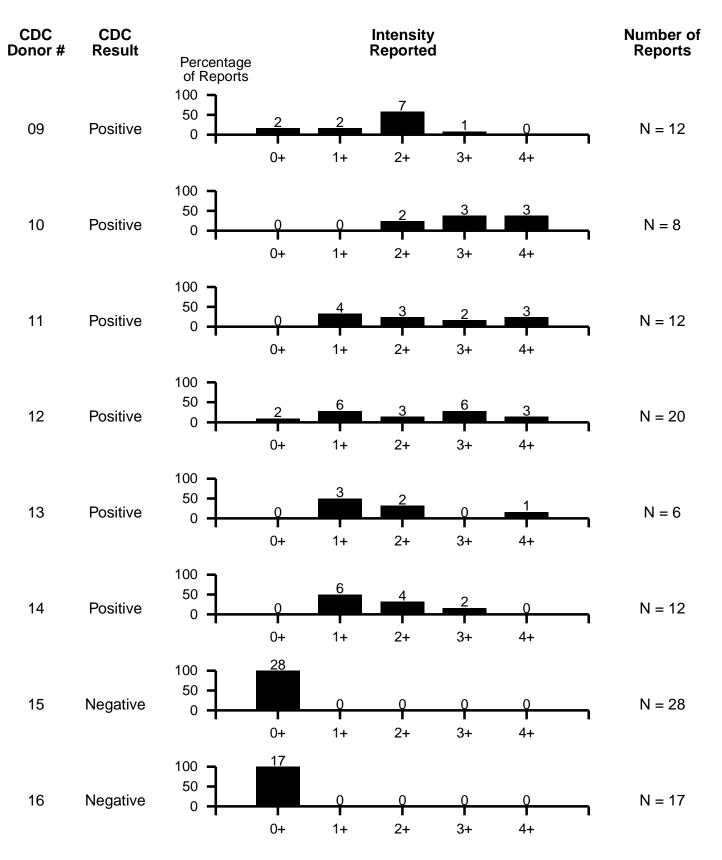
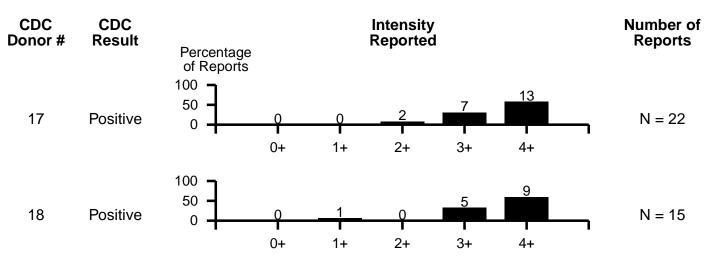
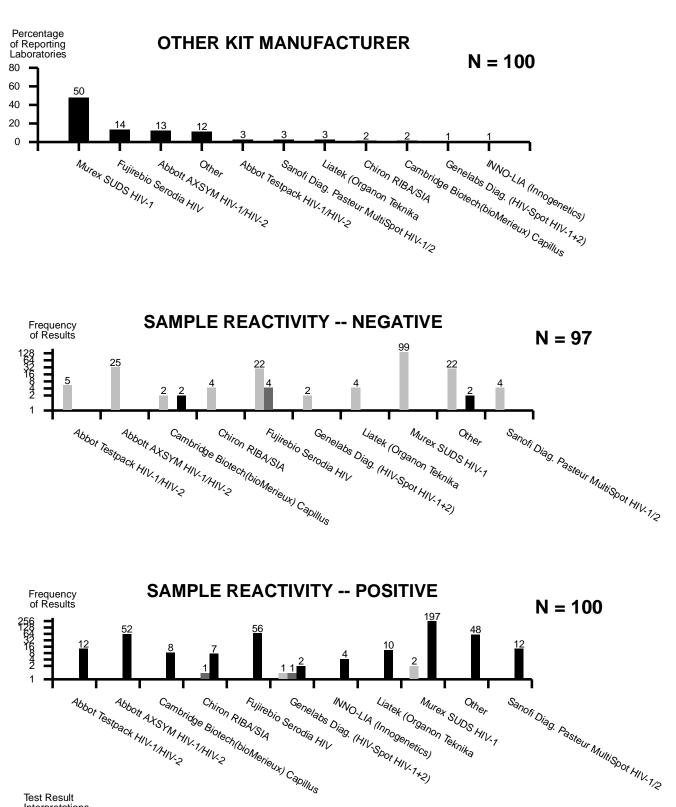
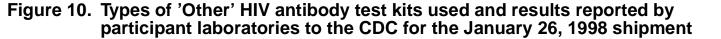


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 26, 1998 shipment







Interpretations