#### 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 25, 1999 Performance Evaluation Testing Results Reported by Participant Laboratories

#### U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



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Public Health Practice Program Office
Division of Laboratory Systems
Atlanta, Georgia 30341-3724



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Report of the January 25, 1999 Human Immunodeficiency Virus Type I (HIV-1) Antibody Performance Evaluation Sample Testing Results Provided by Participant 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 January 25, 1999 Participant Laboratory Shipment

Table 1

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result <sup>2</sup>	Donor HIV Status	E	ratory In IA	•	
					INIT. <sup>3</sup>	FINAL⁴	WB	IIF
Н	H1 H2 H3,H4 H5,H6	17 01 08 15	Positive Indeterminate See Table 2 Negative	Infected Infected Infected Uninfected			<u> </u>	_ _ _
I	11 12 13,14 15, 16	02 18 09 16	See Table 2 Positive See Table 2 Negative	Infected Infected Infected Uninfected	<u> </u>		<u>-</u> - -	_ _ _
J	J1,J4 J2,J5 J3 J6	15 10 17 03	Negative Positive Positive Indeterminate	Uninfected Infected Infected Infected	  	_ _ _		_ _ _
K	K1 K2,K5 K3,K6 K4	04 11 16 18	Positive Positive Negative Positive	Infected Infected Uninfected Infected	<u> </u>	<u> </u>		<u> </u>

**Table 1, Continued** 

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result <sup>2</sup>	Donor HIV Status	Laboratory Interpretation <sup>1</sup> EIA			
						FINAL <sup>4</sup>	WB	IIF
L	L1,L4 L2 L3,L6 L5	15 05 12 17	Negative Positive Positive Positive	Uninfected Infected Infected Infected	<u> </u>	_ _ _	<u> </u>	  
M	M1,M4 M2,M5 M3 M6	13 16 06 18	Positive Negative Positive Positive	Infected Uninfected Infected Infected	  	_ _ _		  
N	N1 N2,N5 N3,N6 N4	17 14 15 07	Positive Positive Negative Positive	Infected Infected Uninfected Infected			<u> </u>	

Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

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.

Initial EIA interpretation

Final EIA interpretation

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

### <u>Table 2.</u> CDC Western Blot (WB) Testing Results for the January 25, 1999 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	H 1	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
	H 2	01	24,51 24 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Indeterminate Indeterminate
	H 3,H 4	08	24,55 24,66,160 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Indeterminate
	H 5,H 6	15	No Bands	All Manufacturers	Negative
ı	I1	02	24 24,120,160 24,160	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Positive Positive
	12	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
	I 3,I 4	09	24,55,160 24,66,160 24	BioRad Cambridge Biotech Epitope/Organon	Positive Positive Indeterminate
	I 5,I 6	16	No Bands	All Manufacturers	Negative
J	J 1,J 4	15	No Bands	All Manufacturers	Negative
	J 2,J 5	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
	J 3	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
	J 6	03	24,51 24 24	BioRad Cambridge Biotech Epitope/Organon	Indeterminate Indeterminate Indeterminate
K	K 1	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
	K 2,K 5	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
	K 3,K 6	16	No Bands	All Manufacturers	Negative
	K 4	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

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

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

<sup>\*</sup> 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	24,32,41,51,65,120,160 24,31,41,51,66,120,160 24,31,41,51,65,120,160	BioRad Cambridge Biotech* Epitope/Organon	Positive Positive Positive
	L3,L6	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
	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	M 1,M 4	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
	M 2,M 5	16	No Bands	All Manufacturers	Negative
	М 3	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
	M 6	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
N	<b>N</b> 1	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
	N 2,N 5	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
	N 3,N 6	15	No Bands	All Manufacturers	Negative
	N 4	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

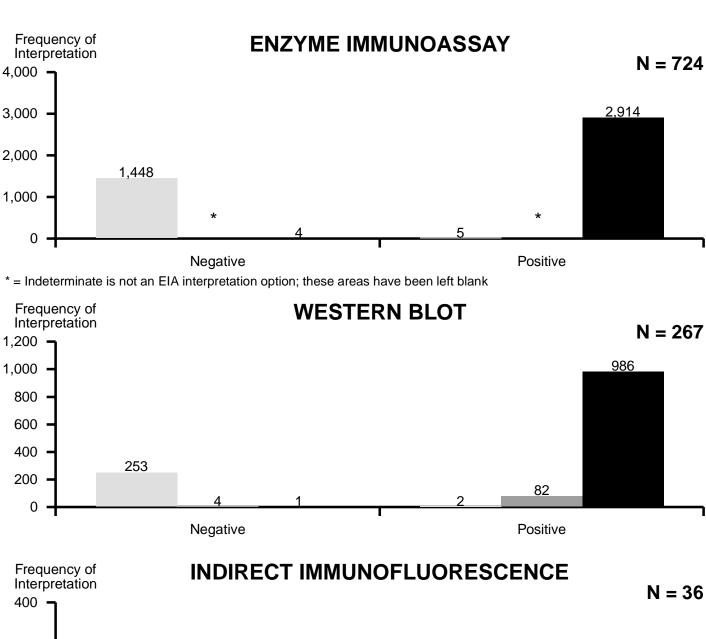
Western blot (WB) result based on band intensity of ≥ 1+ staining.
 The CDC interpretation is consistent with the manufacturer's criteria for interpretation of WB results.

<sup>\*</sup> 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 25, 1999 shipment



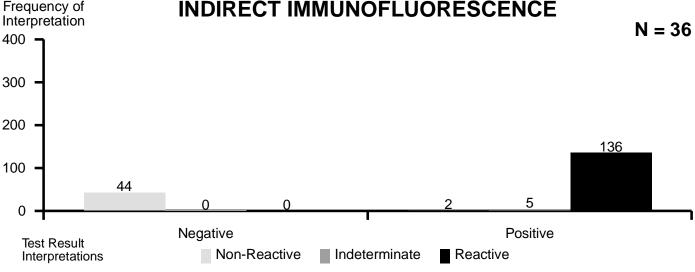


Figure 2. Percentage of HIV-1 participant laboratories, by laboratory type, that reported EIA, WB, and IIF results to the CDC for the January 25, 1999 shipment

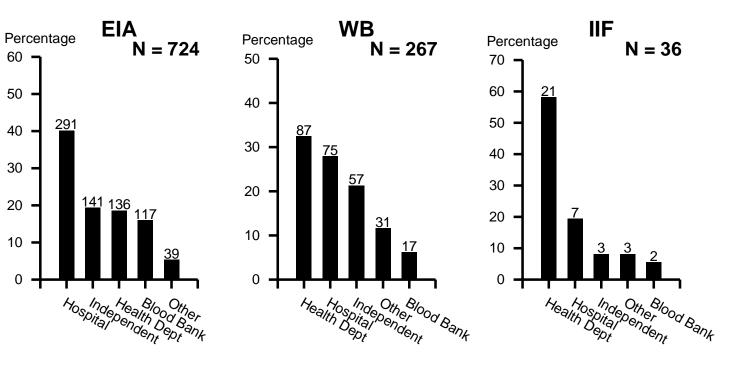


Figure 3. Combination of HIV-1 antibody tests reported by participant laboratories for the January 25, 1999 shipment

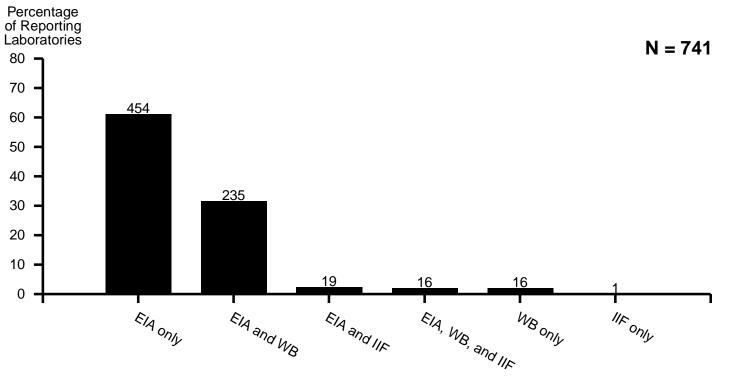


Figure 4. Types of HIV-1 antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the January 25, 1999 shipment

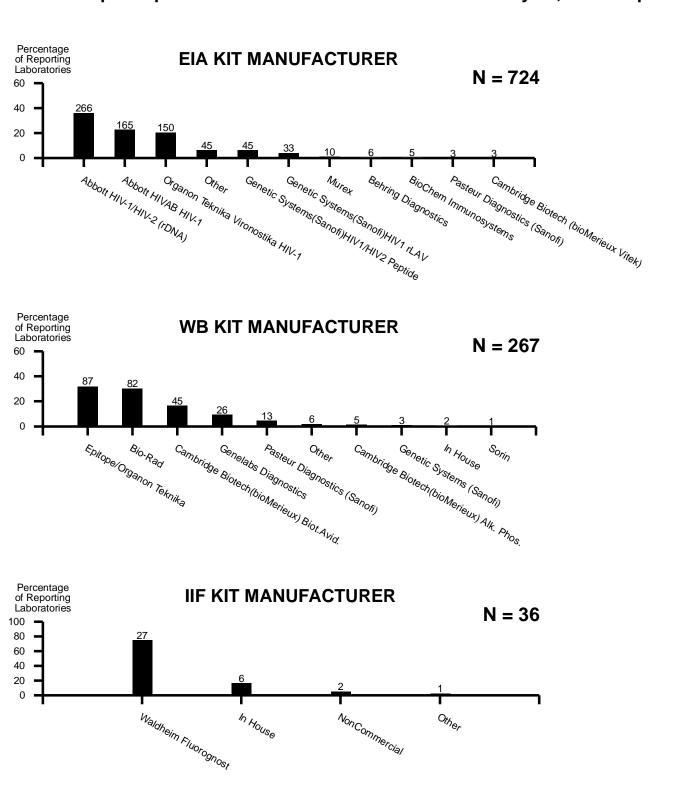
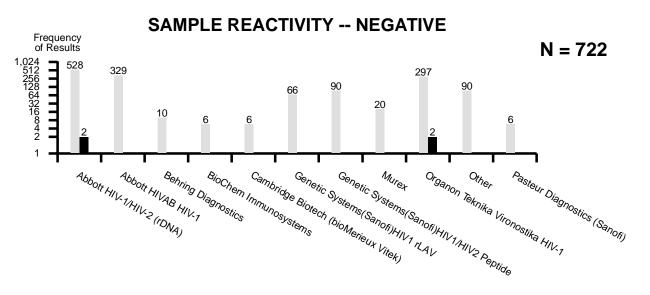
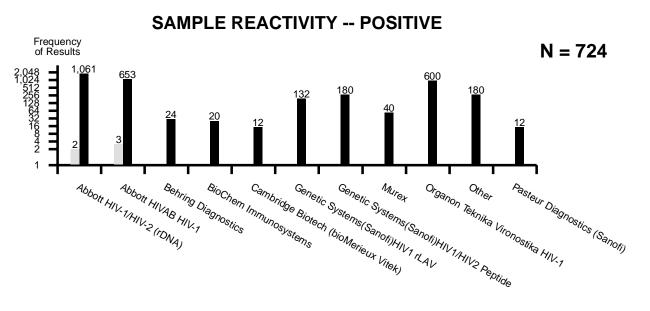


Figure 5. Enzyme immunoassay HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 25, 1999 shipment

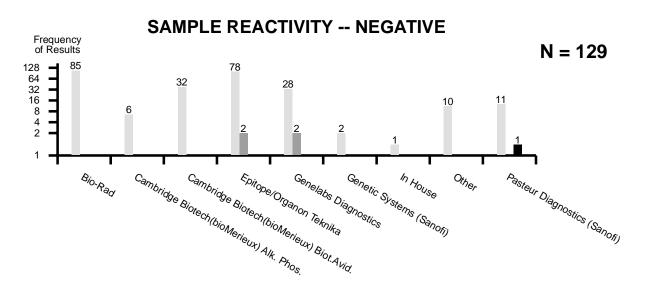


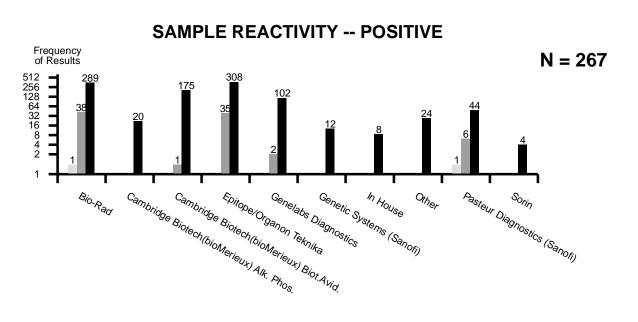


Test Result Interpretations

Non-Reactive Reactive

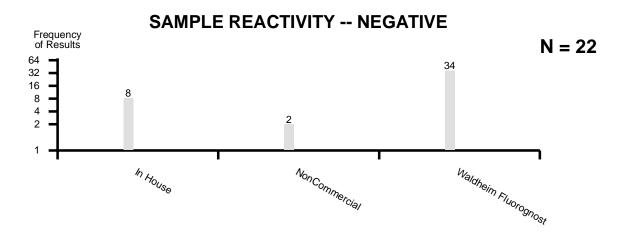
Figure 6. Western blot HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 25, 1999 shipment





Test Result

Figure 7. Indirect immunofluorescence HIV-1 antibody test results, by kit manufacturer, reported by participant laboratories for the January 25, 1999 shipment



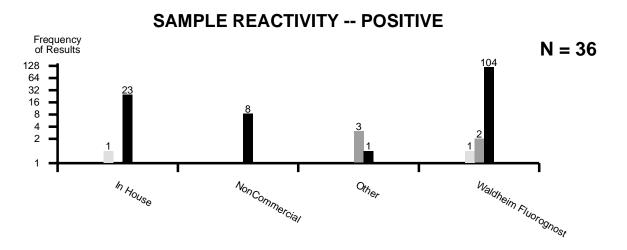




Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 25, 1999 shipment

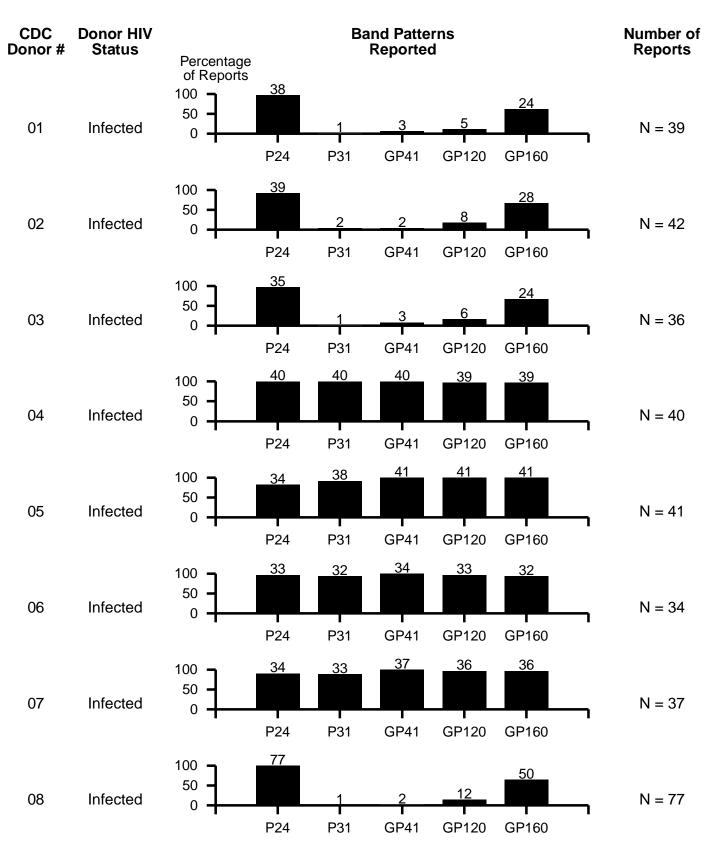


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 25, 1999 shipment

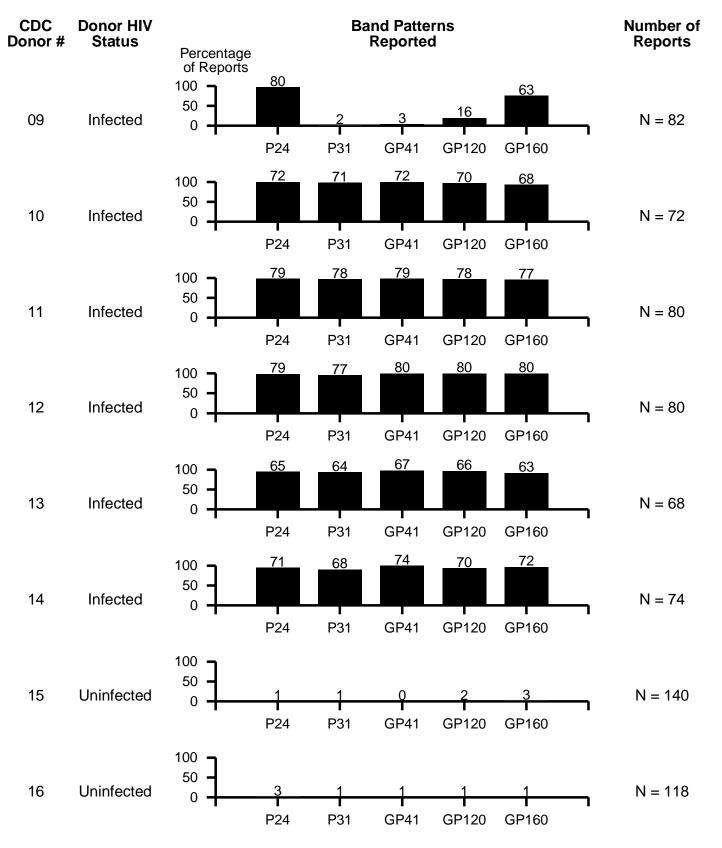


Figure 8. Western blot HIV-1 antibody band patterns reported to CDC by participant laboratories for the January 25, 1999 shipment

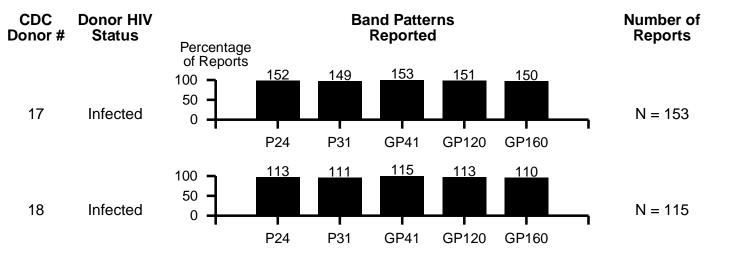


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 25, 1999 shipment

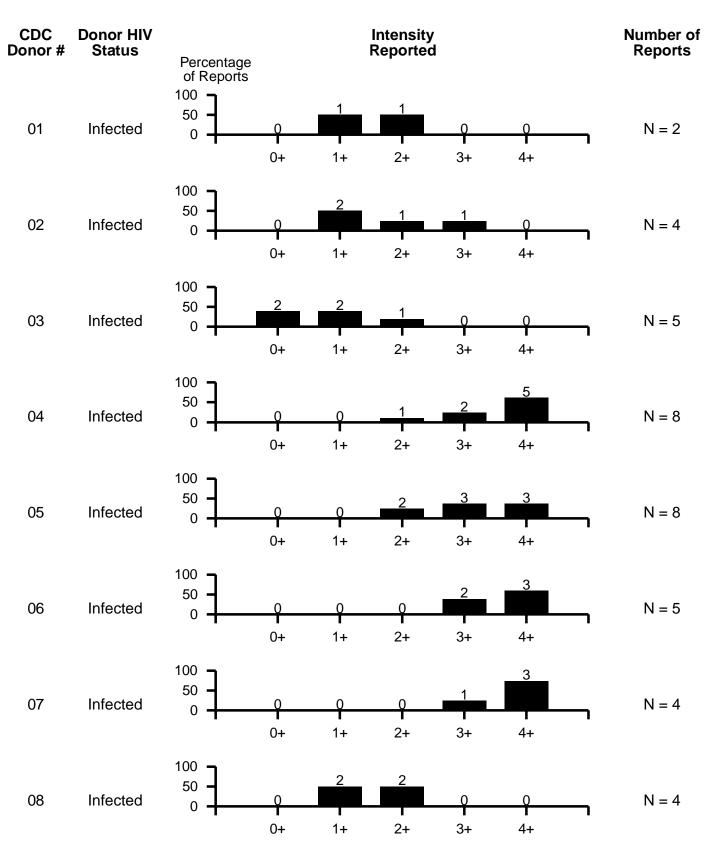


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 25, 1999 shipment

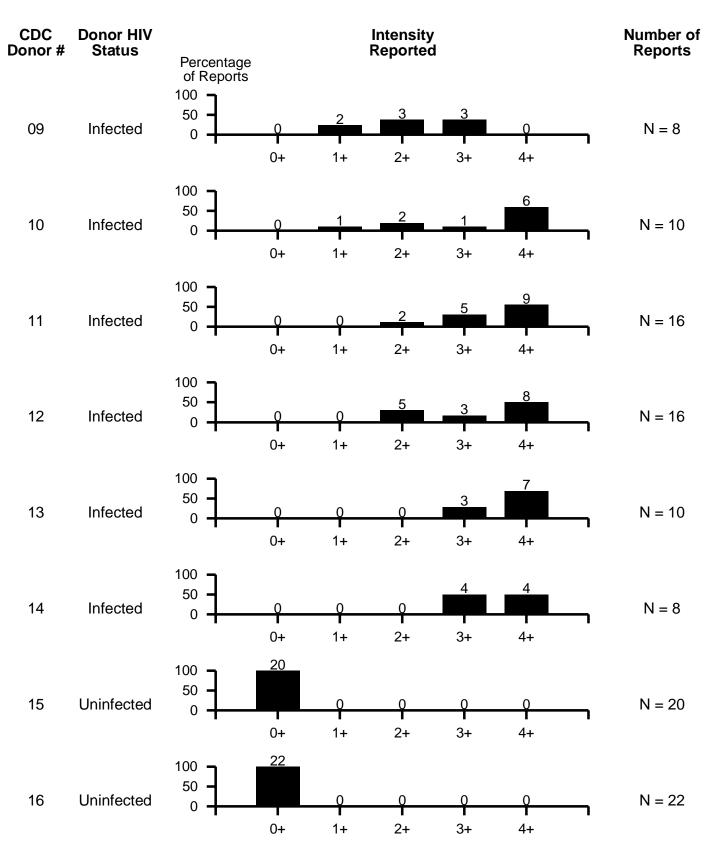


Figure 9. Fluorescence intensity patterns, of HIV-1-infected cells, for IIF results reported to CDC by participant laboratories for the January 25, 1999 shipment

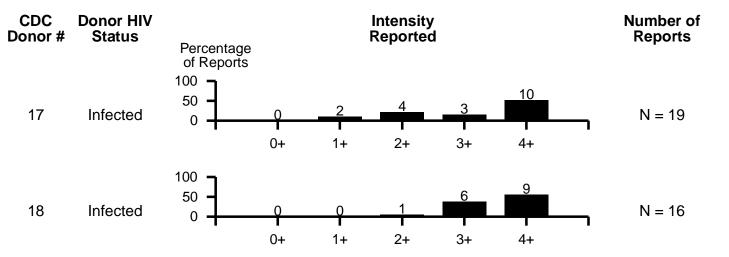


Figure 10. Types of 'Other' HIV antibody test kits used and results reported by participant laboratories to the CDC for the January 25, 1999 shipment

