

**Centers for Disease Control and Prevention  
Model Performance Evaluation Program  
Human Immunodeficiency Virus Type 1 (HIV-1)  
Testing for p24 Antigen**

**Figures Used for the Analysis  
of the September 13, 1999 Performance Evaluation  
Testing Results Reported by Participant Laboratories**



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
Public Health Practice Program Office  
Division of Laboratory Systems  
Atlanta, Georgia 30341**



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

**Report of the September 13, 1999 Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen 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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## **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 kit for a specific test type; therefore, the "N=" may exceed the actual number of laboratories participating in the survey. In figures 1-3 and 5-6, the vertical axis is labeled either as frequency of results or percentage of reporting laboratories; in figure 4, the horizontal axis is labeled as percentage of reporting laboratories. In all figures, the number appearing directly above each bar represents a frequency of results only.

**Centers for Disease Control and Prevention (CDC)  
 Model Performance Evaluation Program  
 Human Immunodeficiency Virus Type 1 (HIV-1) p24 Antigen Testing  
 September 13, 1999 Participant Laboratory Shipment**

**Table 1**

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result <sup>2</sup>	Donor HIV Status	Laboratory Interpretation <sup>1</sup> EIA TESTS		
					QUAL. <sup>3</sup>	NEUT <sup>4</sup>	QUANT <sup>5</sup>
A	A1, A3	4	Positive	Infected	_____	_____	_____
	A2	3	Positive	Infected	_____	_____	_____
	A4	1	Negative	Uninfected	_____	_____	_____
	A5	2	Negative	Uninfected	_____	_____	_____
B	B1	1	Negative	Uninfected	_____	_____	_____
	B2	3	Positive	Infected	_____	_____	_____
	B3,B5	4	Positive	Infected	_____	_____	_____
	B4	2	Negative	Uninfected	_____	_____	_____

<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> Prior to shipment, donor samples were tested using three HIV-1 p24 antigen kits, two of which are licensed by the Food and Drug Administration (FDA). The CDC result is consistent with the manufacturer's criteria for interpretation of results.

<sup>3</sup> p24 Antigen Qualitative Test

<sup>4</sup> p24 Antigen Neutralization (Blocking Antibody) Test

<sup>5</sup> p24 Antigen Quantitation Test

**Centers for Disease Control and Prevention (CDC)  
Model Performance Evaluation Program for  
Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen Testing**

**Table 2. CDC HIV-1 p24 Antigen Testing Results for the September 13, 1999 Participant Laboratory Panel Samples**

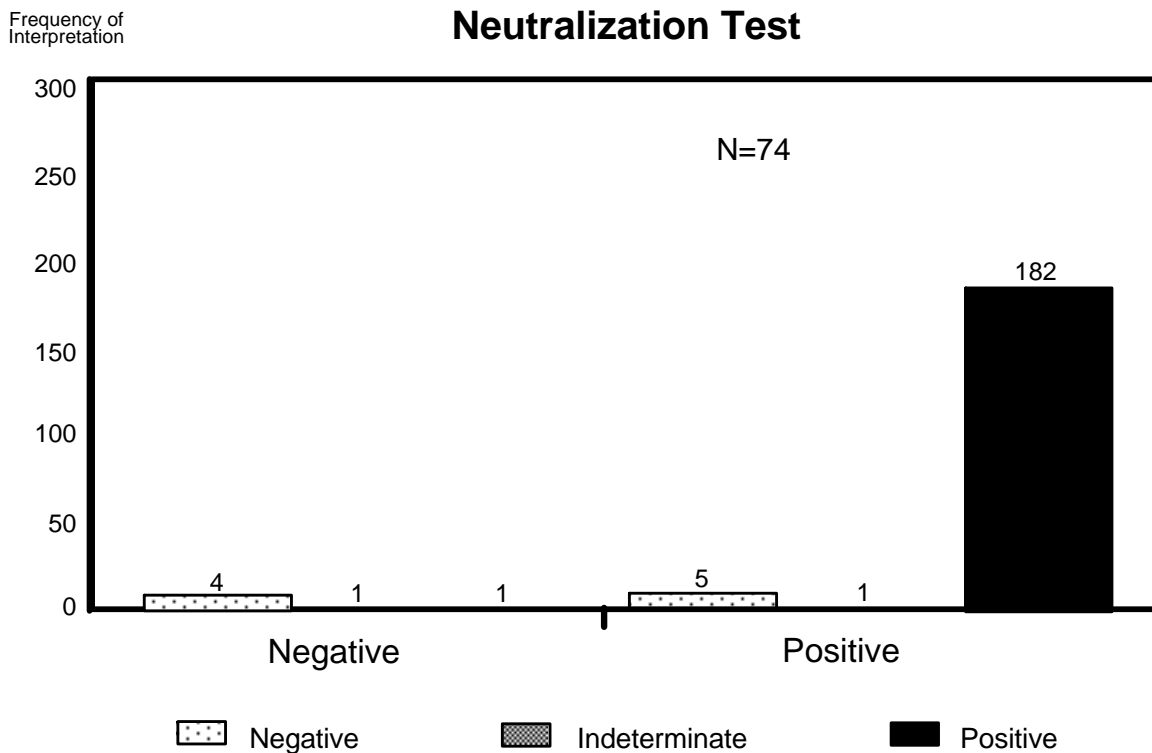
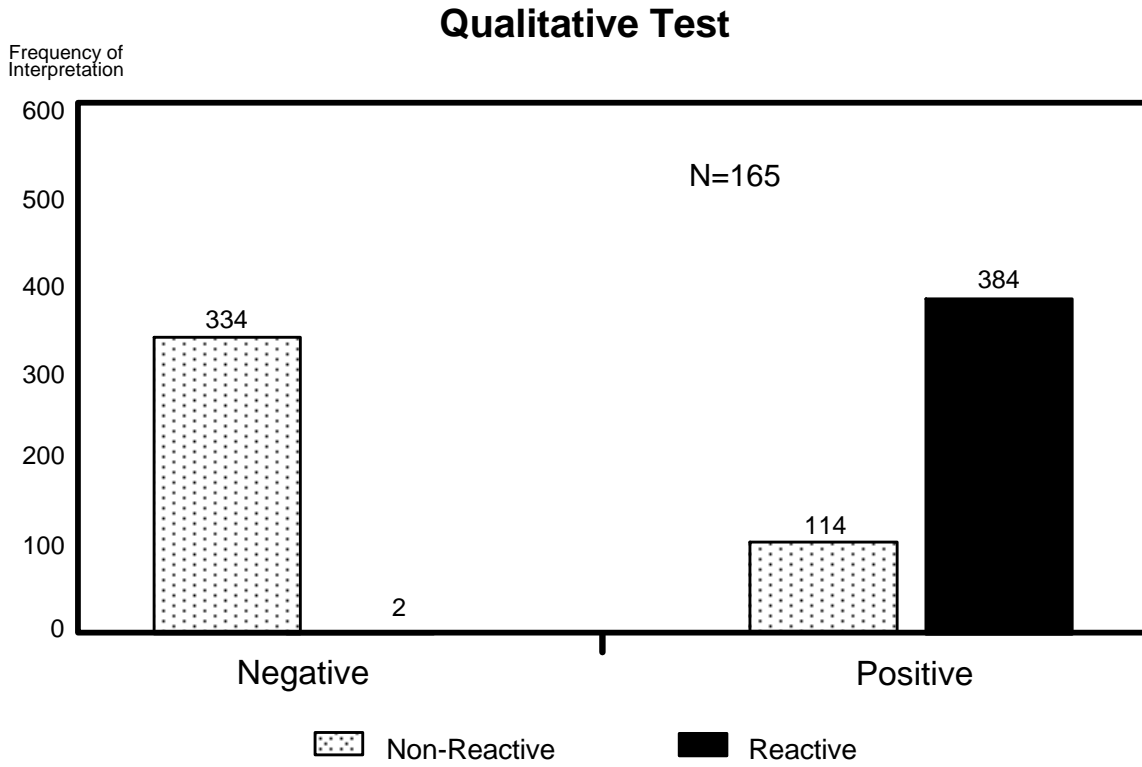
<b>Panel Letter</b>	<b>Vial Label</b>	<b>CDC Donor Number</b>	<b>CDC Test Results <sup>1</sup></b>	<b>Test Kit Manufacturer</b>	<b>CDC Interpretation</b>
<b>A</b>	<b>A1, A3</b>	<b>4</b>	<b>p24 Antigen detected p24 Antigen detected p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb<sup>3</sup> Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Positive Positive Positive</b>
	<b>A2</b>	<b>3</b>	<b>p24 Antigen detected p24 Antigen detected p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Positive Positive Positive</b>
	<b>A4</b>	<b>1</b>	<b>No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Negative Negative Negative</b>
	<b>A5</b>	<b>2</b>	<b>No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Negative Negative Negative</b>
<b>B</b>	<b>B1</b>	<b>1</b>	<b>No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Negative Negative Negative</b>
	<b>B2</b>	<b>3</b>	<b>p24 Antigen detected p24 Antigen detected p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Positive Positive Positive</b>
	<b>B3, B5</b>	<b>4</b>	<b>p24 Antigen detected p24 Antigen detected p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Positive Positive Positive</b>
	<b>B4</b>	<b>2</b>	<b>No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected</b>	<b>Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen</b>	<b>Negative Negative Negative</b>

<sup>1</sup> The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 p24 antigen. Two of these kits are licensed by the Food and Drug Administration (FDA).

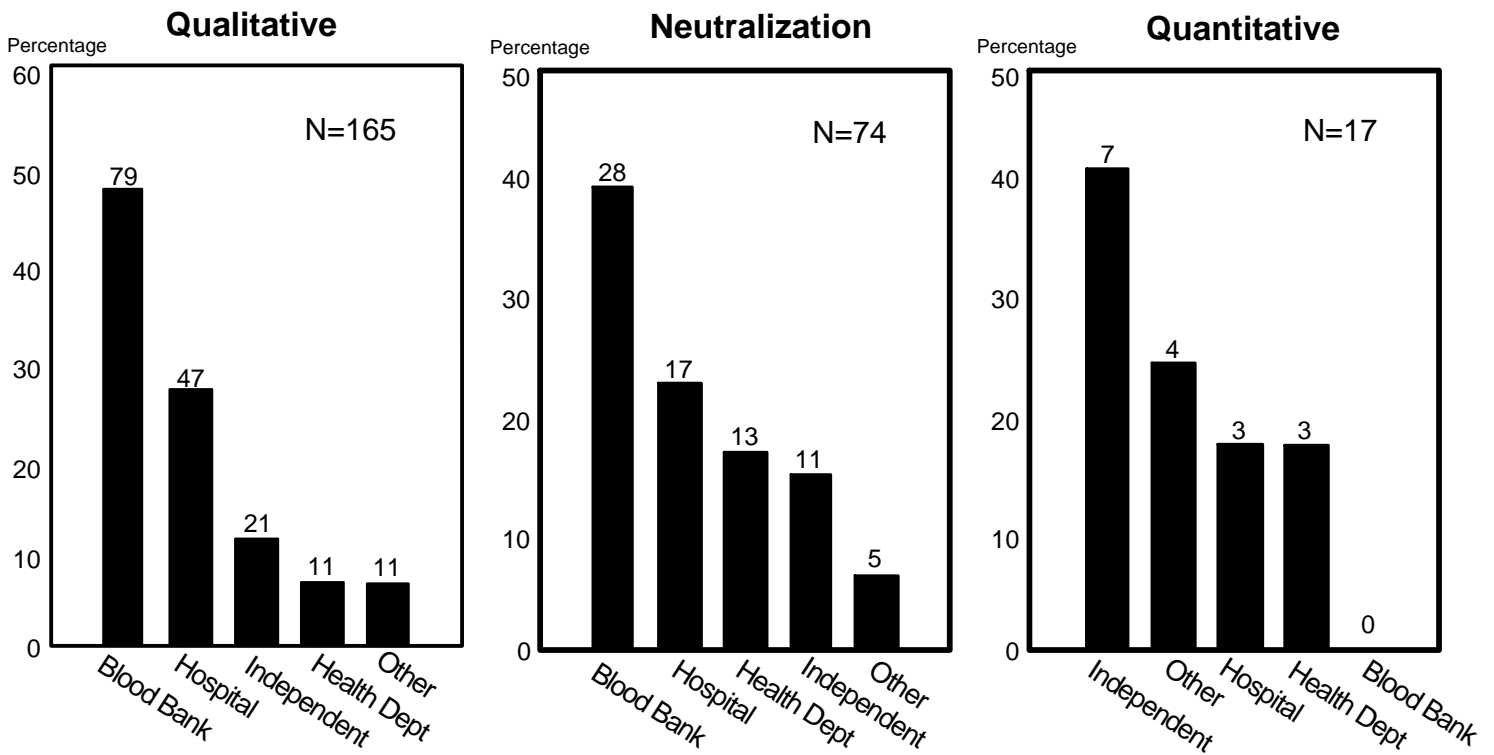
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.  
Positive = Presence of HIV-1 p24 antigen confirmed; Negative = p24 antigen not detected

<sup>3</sup> MAb = monoclonal antibody

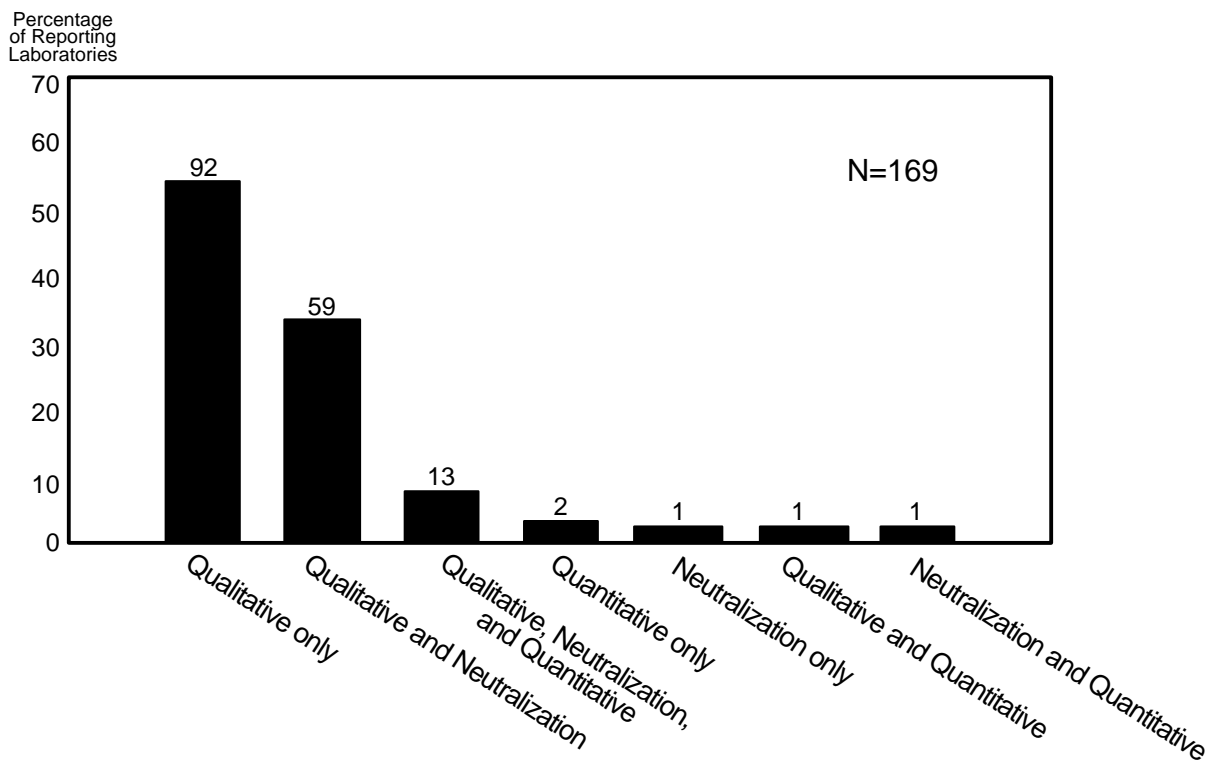
**Figure 1. Frequency of HIV-1 p24 Antigen Test Result Interpretations, by Sample Type (Reactivity), for Qualitative and Neutralization Tests Reported by Participant Laboratories for the September 13, 1999 Shipment**



**Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the September 13, 1999 Shipment**

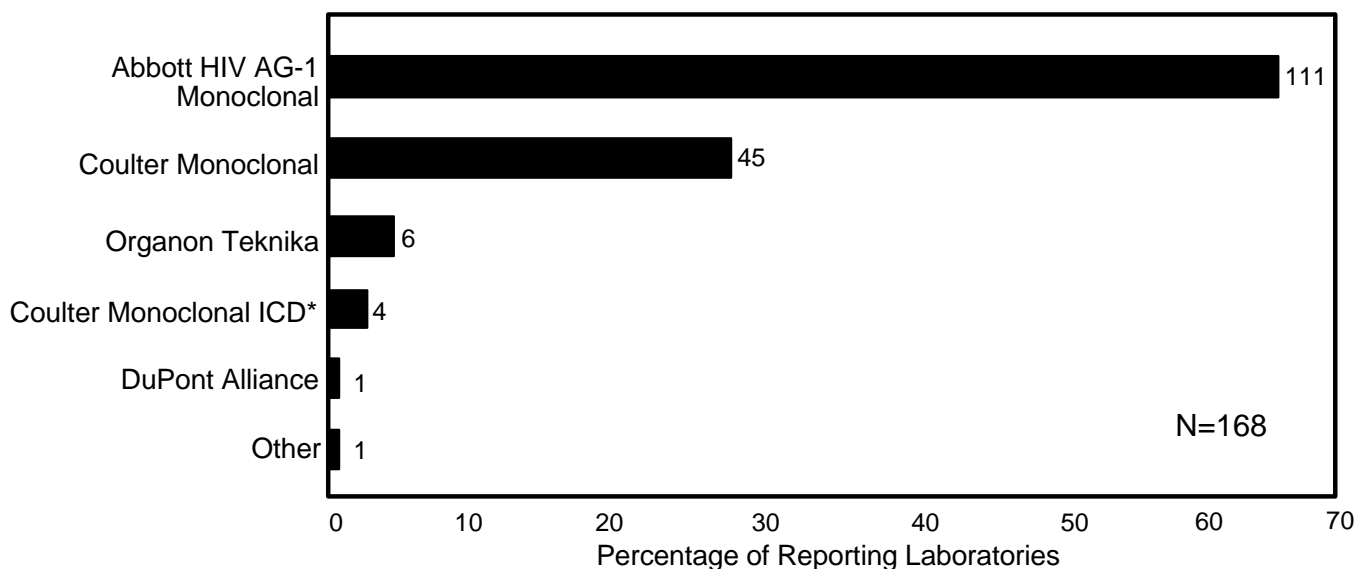


**Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the September 13, 1999 Shipment**

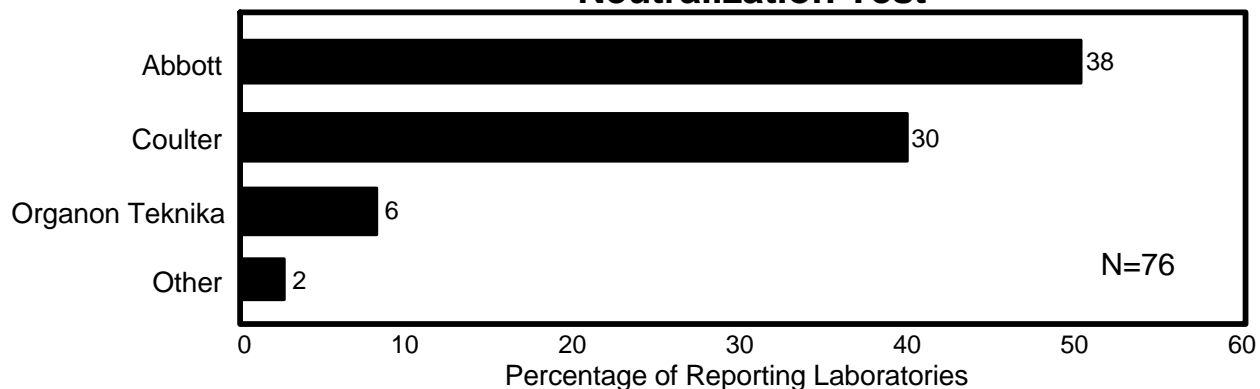


**Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the September 13, 1999 Shipment**

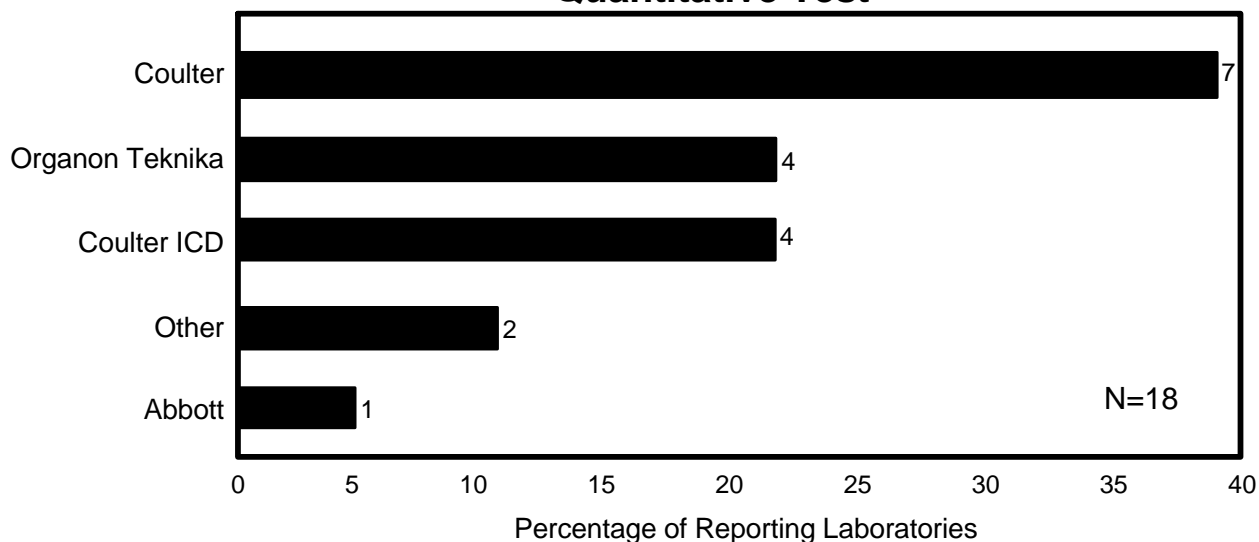
**Qualitative Test**



**Neutralization Test**



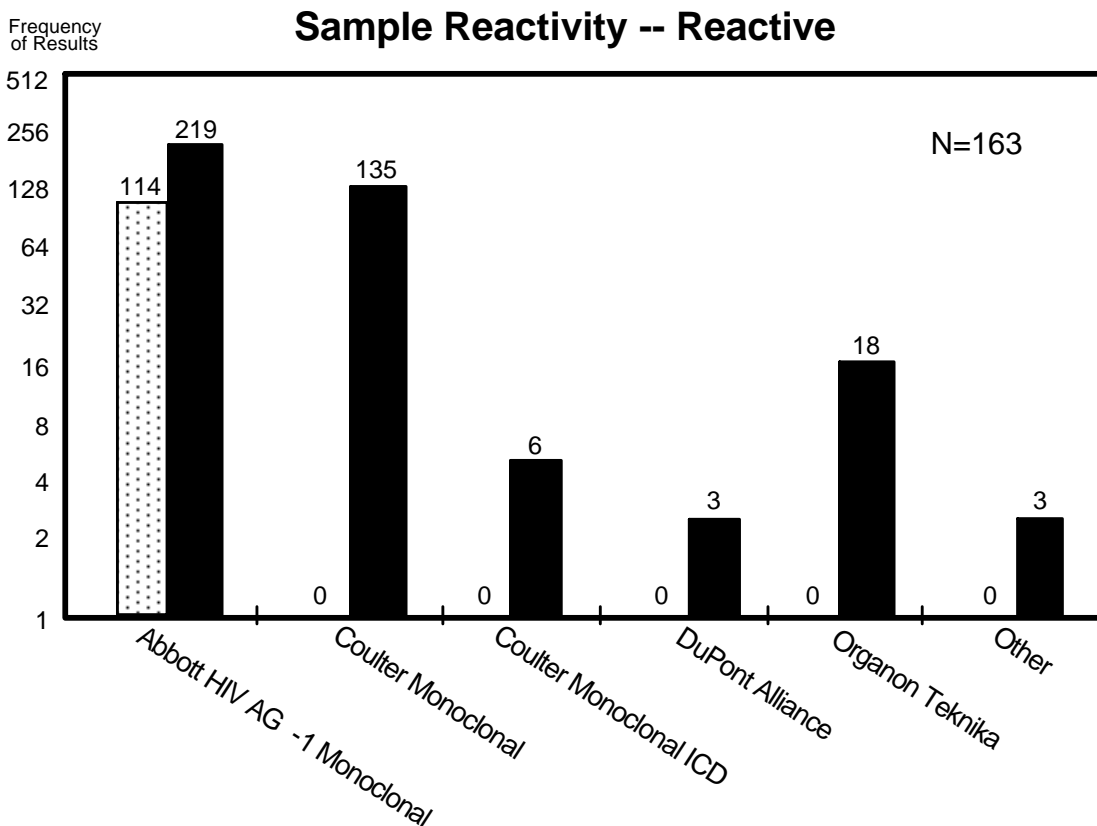
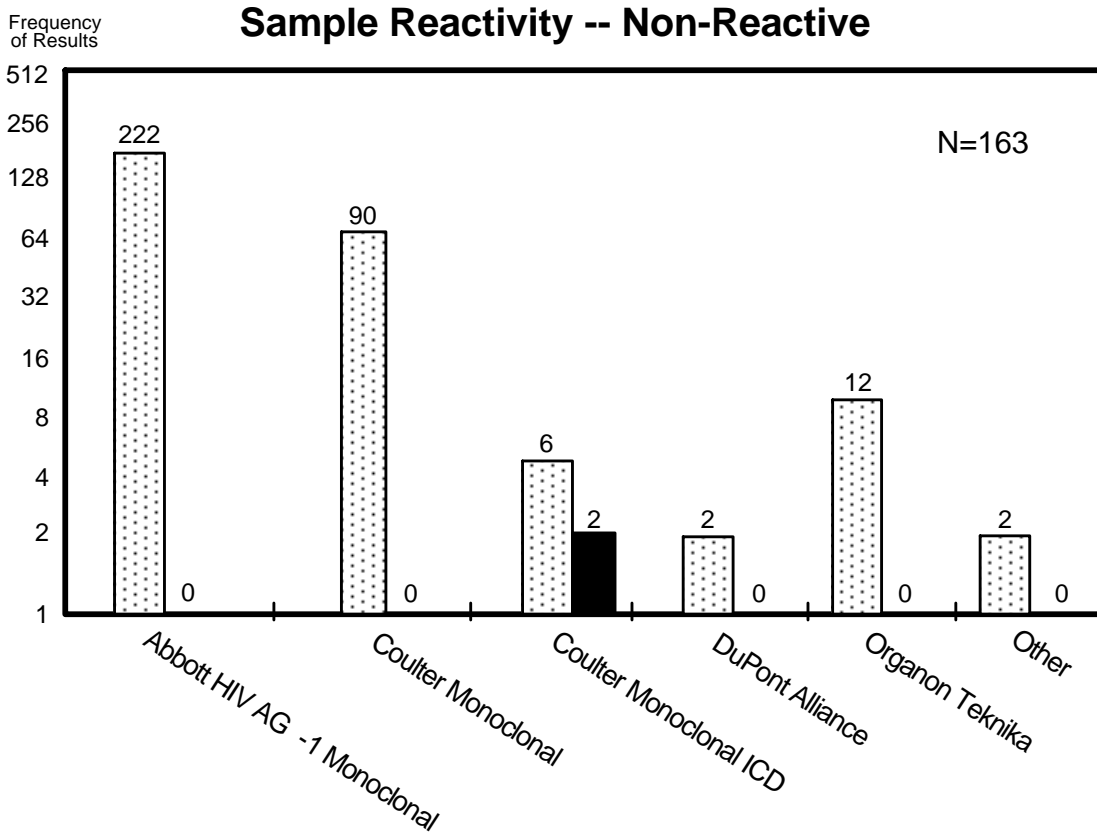
**Quantitative Test**



\*ICD=Immune Complex Dissociation

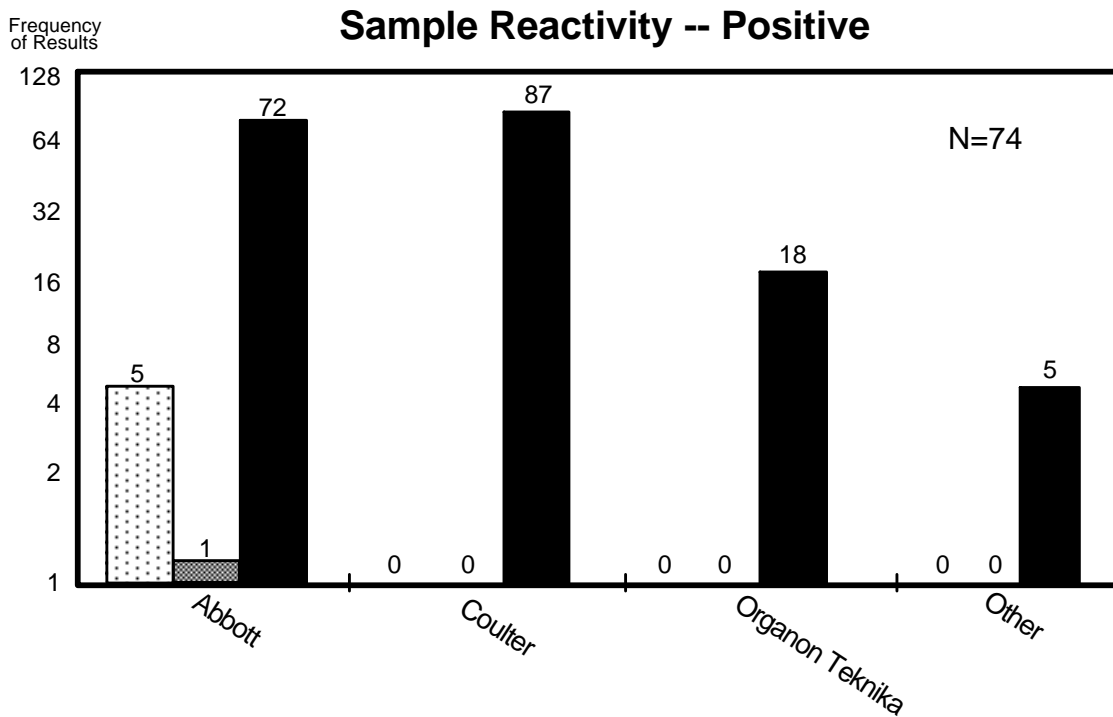
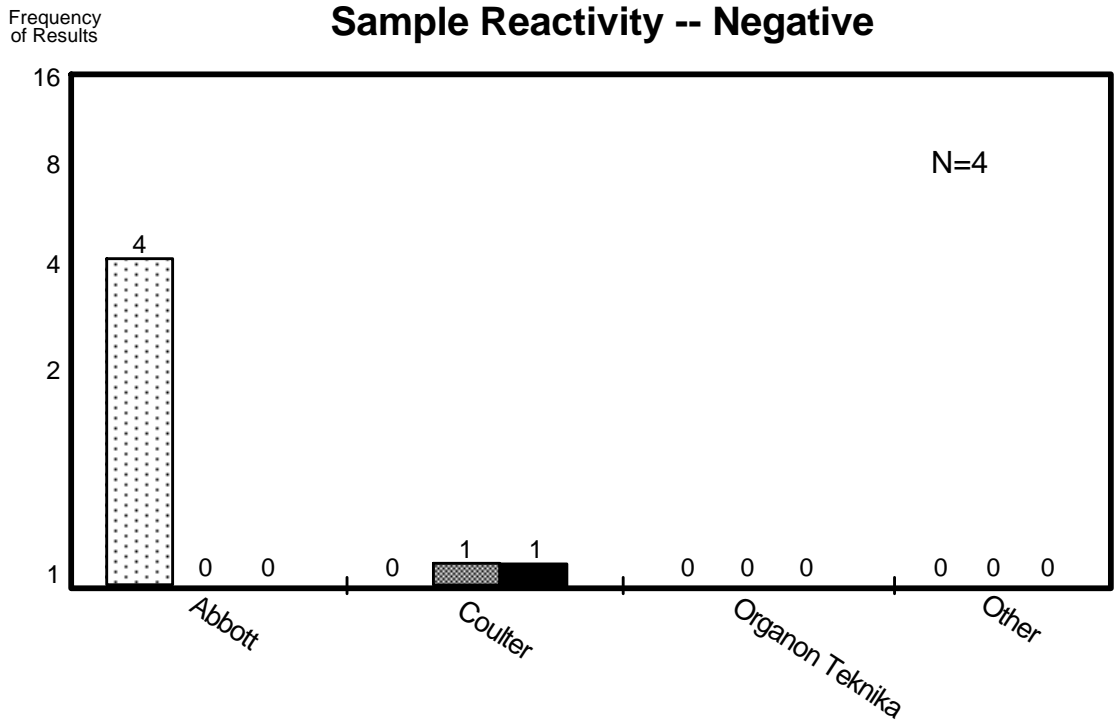


**Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 13, 1999 Shipment**



Non-Reactive
  Reactive

**Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 13, 1999 Shipment**



Negative
  Indeterminate
  Positive

**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 13, 1999 Performance Evaluation Shipment**

**CDC Donor #3  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A2, B2**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	1	64.3	64.3	64.3
	Negative	2	72.7	88.4	104.8
Coulter	Positive	29	68.8	90.7	99.1
Organon Teknika	Positive	6	68.0	93.3	97.0
Other	Positive	1	84.4	84.4	84.4

**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 13, 1999 Performance Evaluation Shipment (Continued)**

**CDC Donor #4**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A1, B3**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	36	77.2	96.4	115.5
	Negative	2	0.0	62.5	125.0
Coulter	Positive	29	85.7	95.0	104.1
Organon Teknika	Positive	6	85.3	95.7	98.7
Other	Positive	2	98.9	105.1	111.3

**CDC Donor #4 - Duplicate**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A3, B5**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	35	75.0	95.8	114.5
	Indeterminate	1	23.5	23.5	23.5
	Negative	1	94.4	94.4	94.4
Coulter	Positive	29	86.0	95.0	104.4
Organon Teknika	Positive	6	85.0	94.6	97.0
Other	Positive	2	97.5	103.5	109.4

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 13, 1999 Performance Evaluation Shipment**

**CDC Donor #3  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A2, B2**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	2.9	2.9	2.9
Coulter	7	24.7	40.3	60.0
Coulter ICD	4	29.1	32.4	34.7
Organon Teknika	3	9.8	9.9	10.0
Other	2	3.4	7.2	11.0

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 13, 1999 Performance Evaluation Shipment (Continued)**

**CDC Donor #4  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A1, B3**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	13.4	13.4	13.4
Coulter	7	69.4	95.7	112.0
Coulter ICD	4	68.0	70.2	77.4
Organon Teknika	4	24.0	25.9	27.9
Other	2	12.4	19.7	27.0

**CDC Donor #4 - Duplicate  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A3, B5**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	13.4	13.4	13.4
Coulter	7	64.7	93.2	120.0
Coulter ICD	4	71.2	74.9	78.2
Organon Teknika	4	16.7	25.7	27.1
Other	2	12.0	19.0	26.0