

**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 March 12, 2001 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 30341-3717**



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Report of the March 12, 2001 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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**Centers for Disease Control and Prevention (CDC)  
 Model Performance Evaluation Program  
 Human Immunodeficiency Virus Type 1 (HIV-1) p24 Antigen Testing  
 March 12, 2001 Participant Laboratory Shipment**

**Table 1**

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result <sup>1</sup>	Donor HIV Status	Laboratory Interpretation <sup>2</sup>		
					EIA TESTS		
					QUAL <sup>3</sup>	NEUT <sup>4</sup>	QUANT <sup>5</sup>
A	A1	1	Negative	Uninfected	_____	_____	_____
	A2	7	Positive	Infected	_____	_____	_____
	A3	2	Negative	Uninfected	_____	_____	_____
	A4, A5	5	Positive	Infected	_____	_____	_____
B	B1, B4	5	Positive	Infected	_____	_____	_____
	B2	1	Negative	Uninfected	_____	_____	_____
	B3	7	Positive	Infected	_____	_____	_____
	B5	2	Negative	Uninfected	_____	_____	_____

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

<sup>2</sup> Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

<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 March 12, 2001 Participant Laboratory Panel Samples**

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results <sup>1</sup>	Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
A	A1	1	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb <sup>3</sup> Coulter HIV-1 p24 Antigen	Negative Negative
	A2	7	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	A3	2	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	A4, A5	5	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
B	B1, B4	5	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B2	1	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	B3	7	P24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B5	2	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative

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

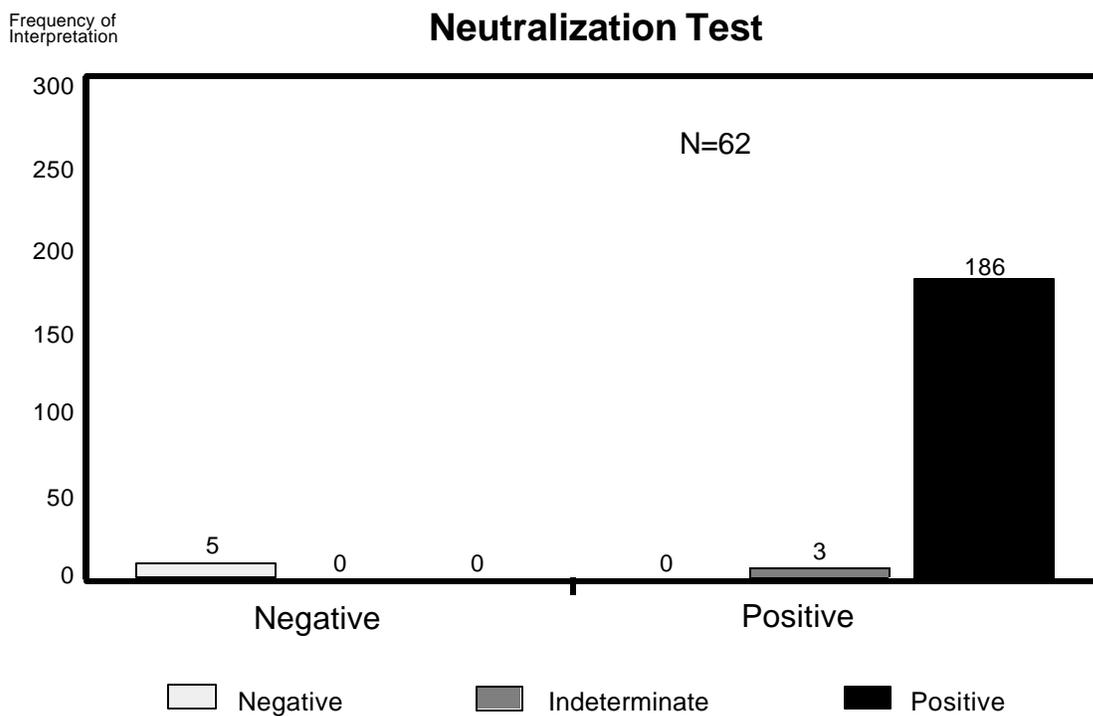
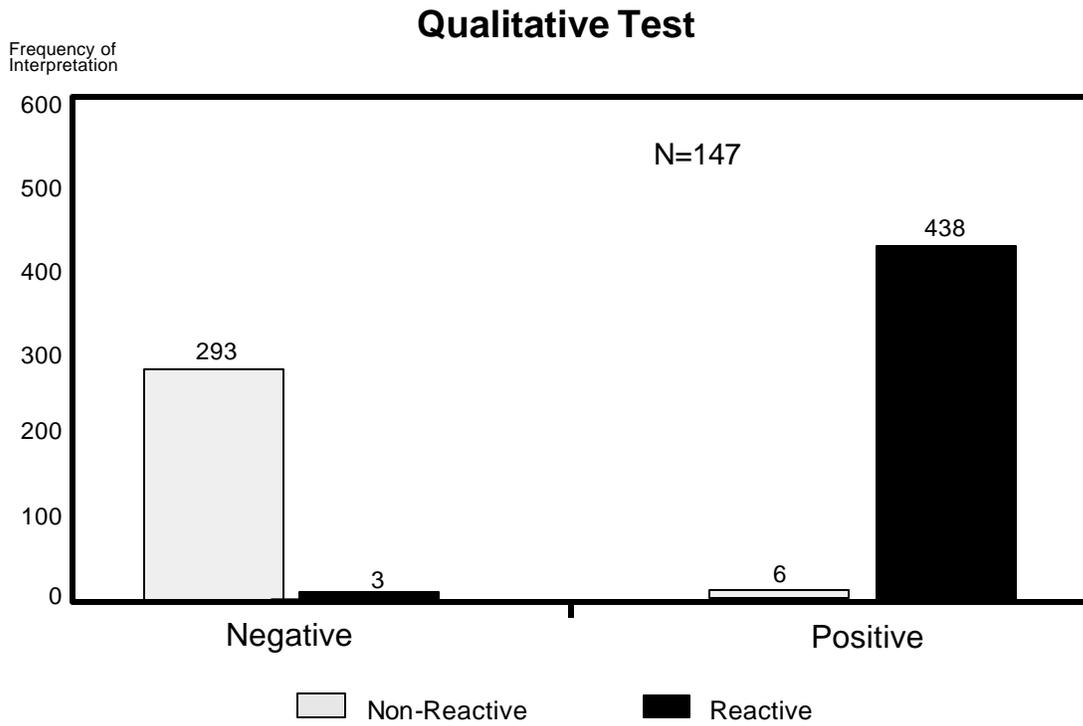
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results. Positive = Presence of HIV-1 p24 antigen confirmed; Negative = p24 antigen not detected.

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

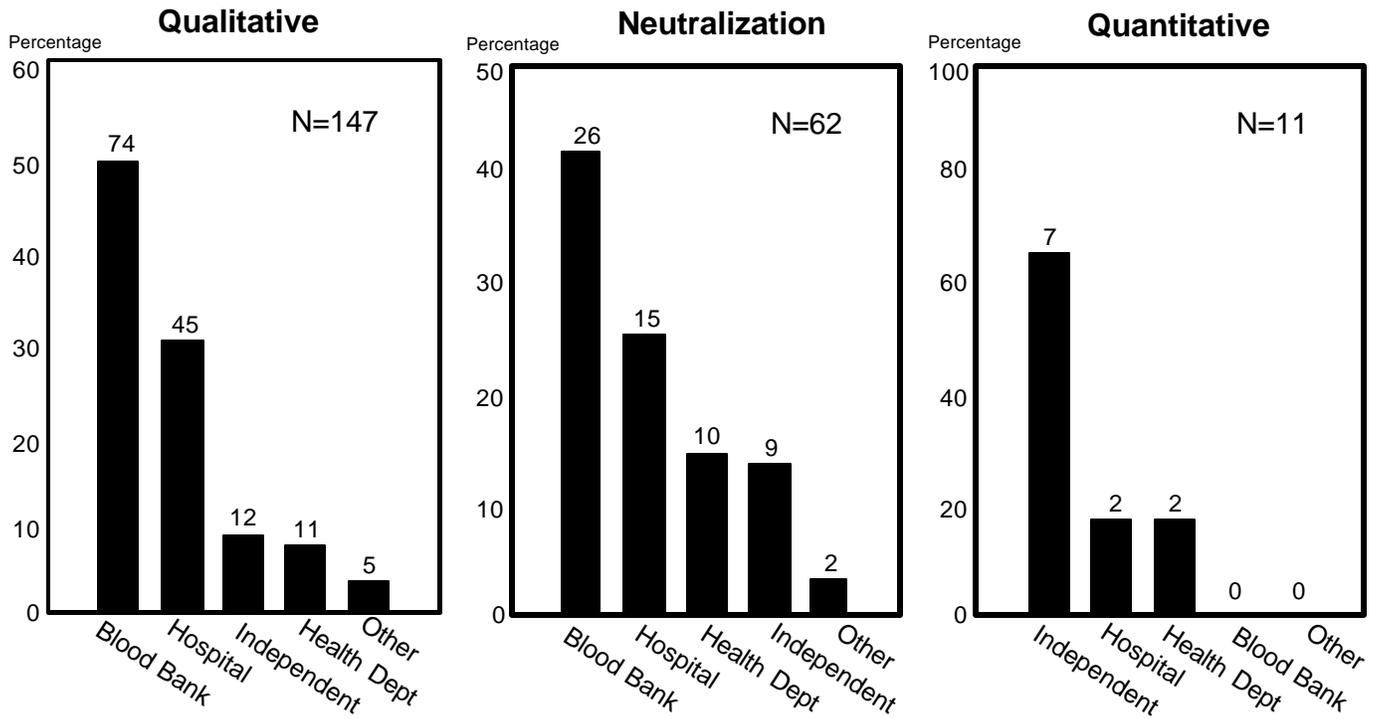
**SUPPLEMENTAL INFORMATION FOR COMPREHENDING  
THE NUMBERS USED TO LABEL FIGURES  
IN THIS REPORT**

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.

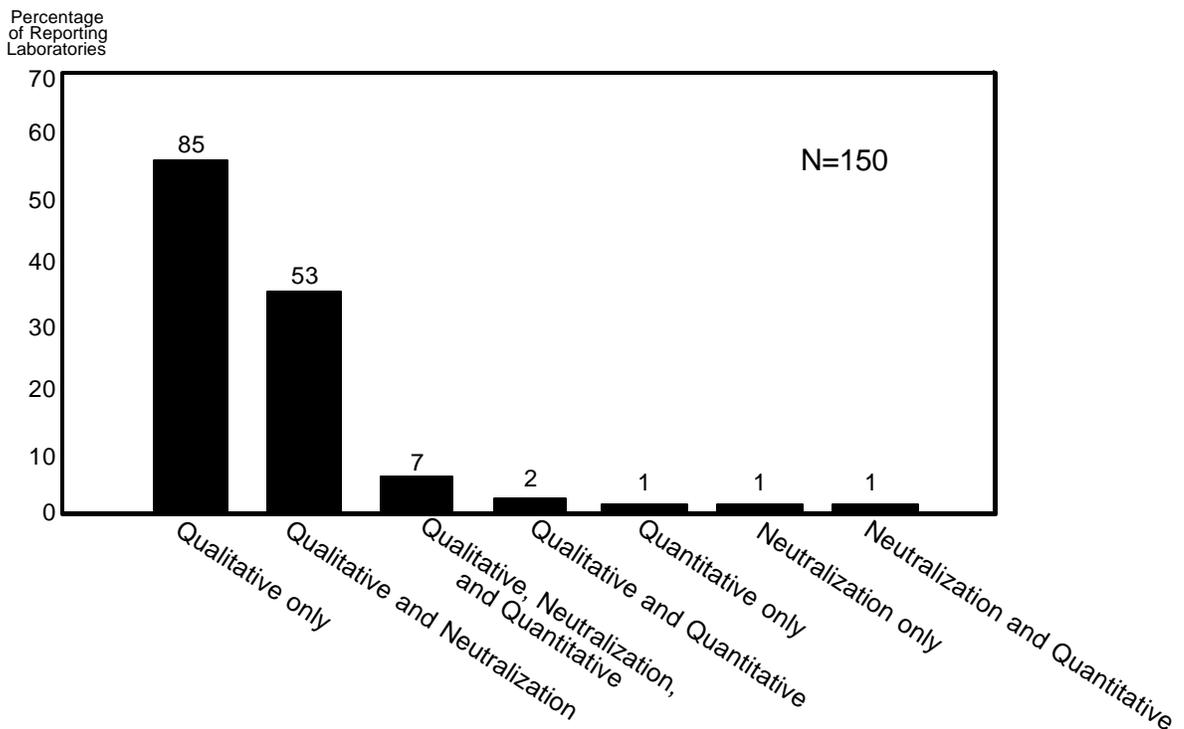
**Figure 1. Frequency of HIV-1 p24 Antigen Test Result Interpretations, by Sample Type (Reactivity), for Qualitative and Neutralization Tests Reported by Participant Laboratories for the March 12, 2001 Shipment**



**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 March 12, 2001 Shipment**

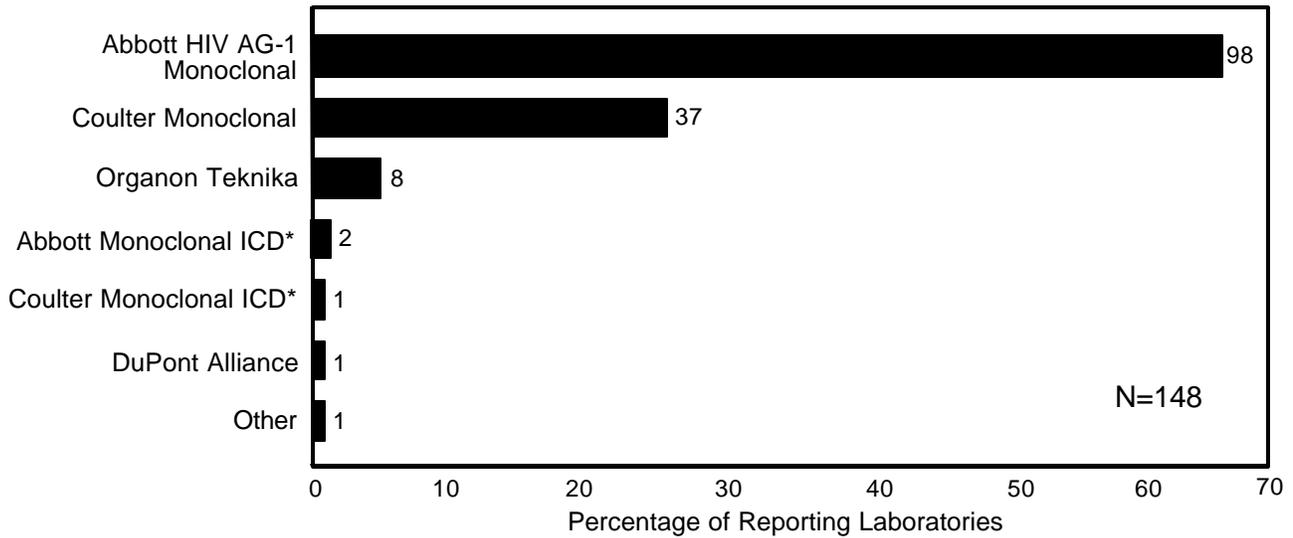


**Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the March 12, 2001 Shipment**

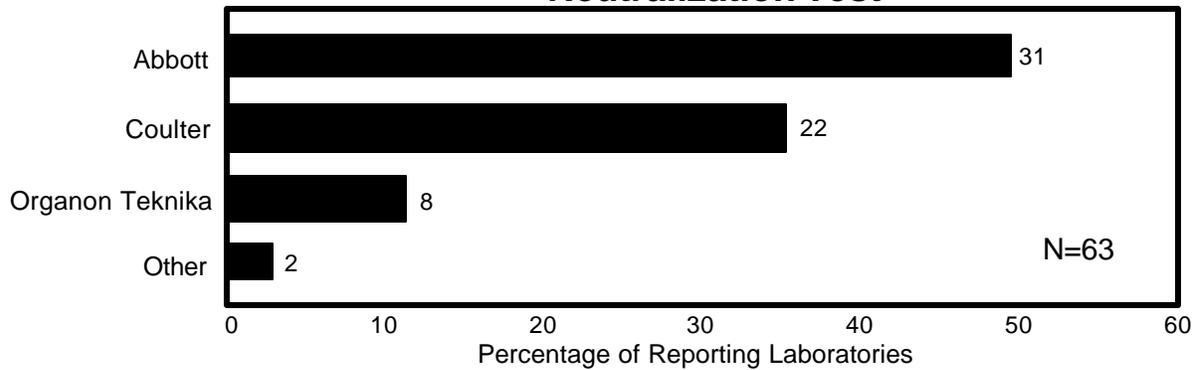


**Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the March 12, 2001 Shipment**

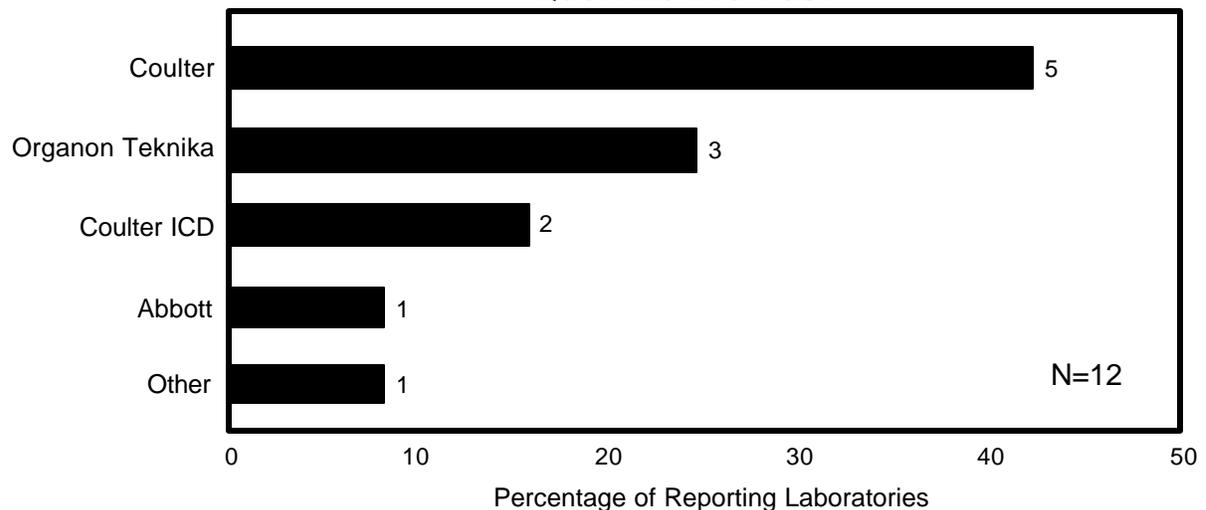
**Qualitative Test**



**Neutralization Test**

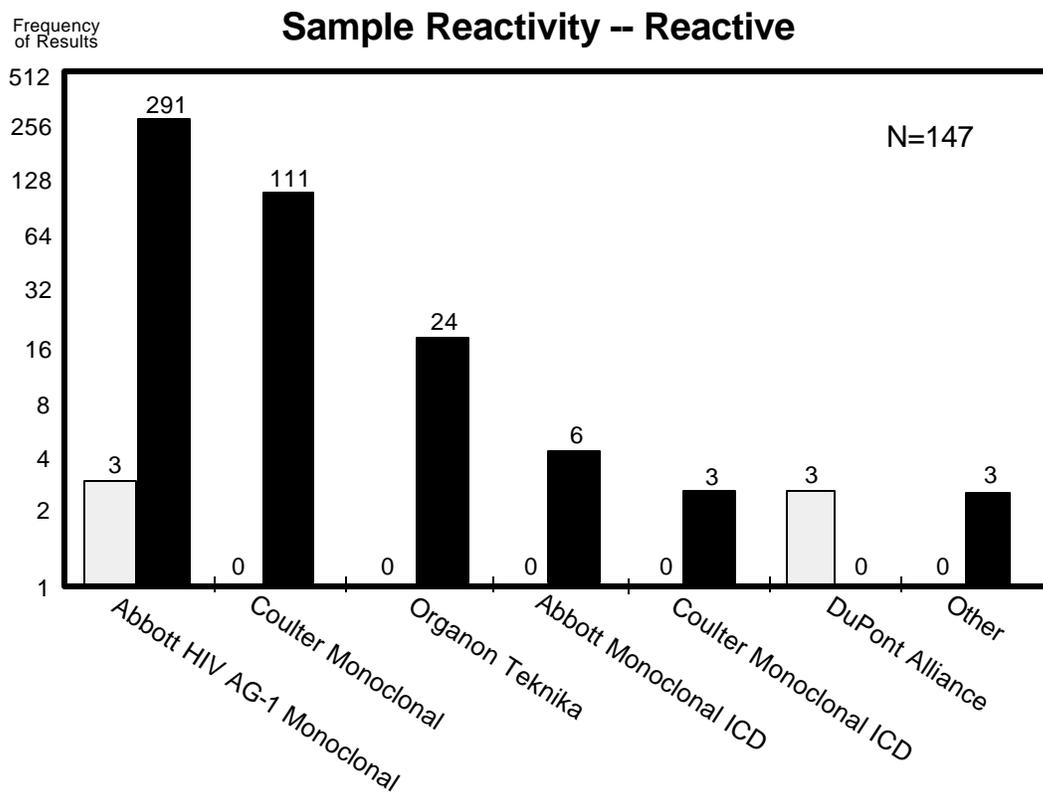
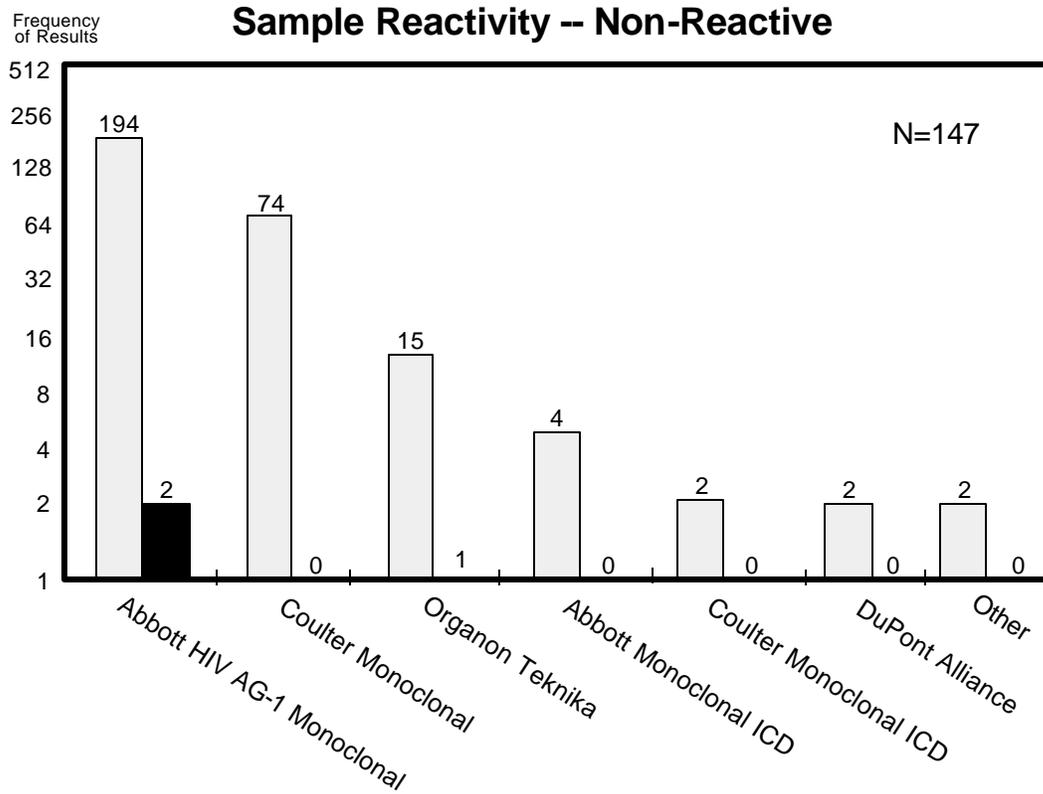


**Quantitative Test**



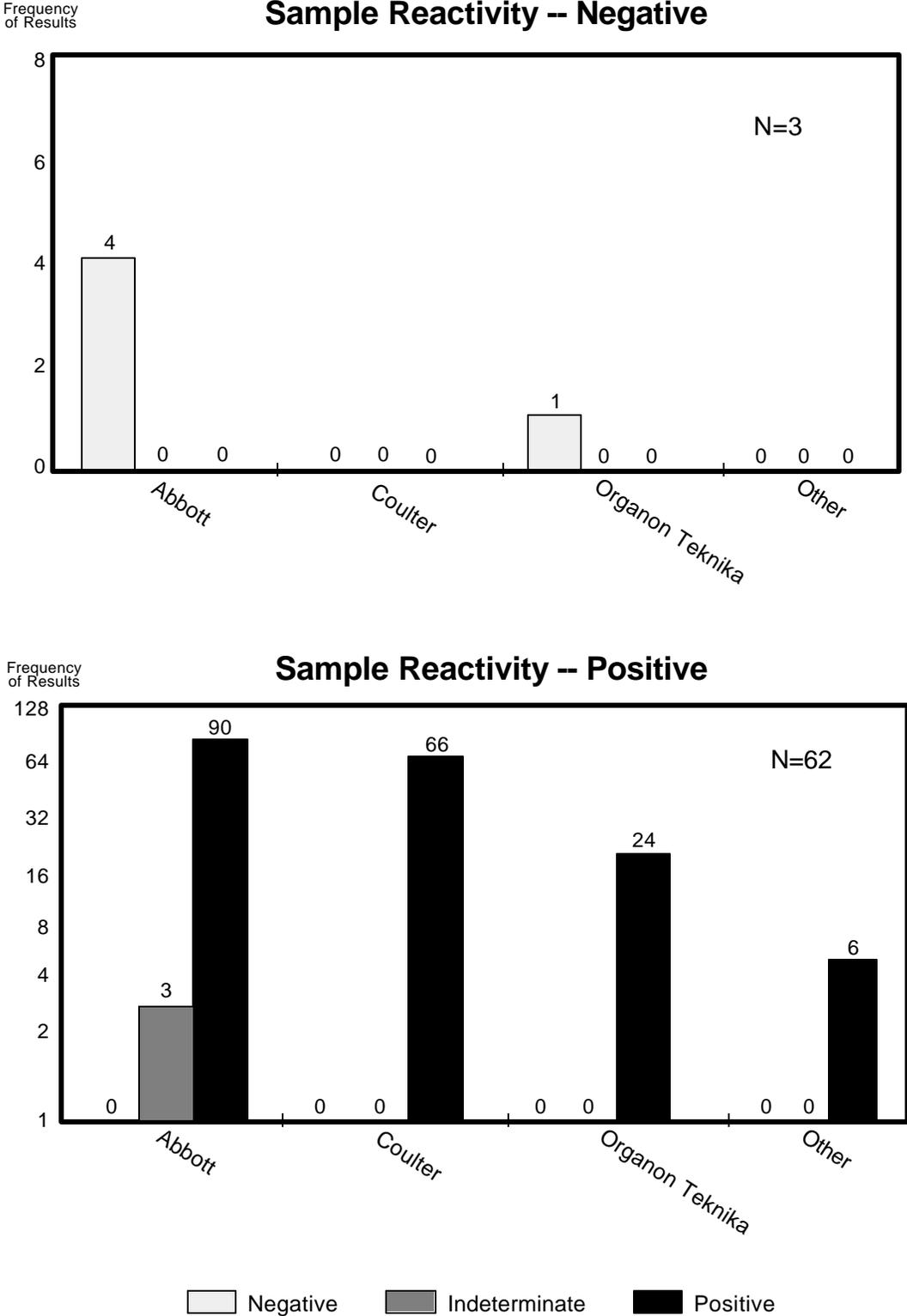
\*ICD=Immune Complex Dissociation

**Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 12, 2001 Shipment**



Non-Reactive
  Reactive

**Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 12, 2001 Shipment**



**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 12, 2001 Performance Evaluation Shipment**

**CDC Donor #5  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A4, B1**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	30	93.5	100.7	107.7
	Indeterminate	1	53.9	53.9	53.9
Coulter	Positive	22	79.1	93.3	111.1
Organon Teknika	Positive	8	70.7	89.1	97.1
Other	Positive	2	100.4	102.4	104.3

**CDC Donor #5 - Duplicate  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A5, B4**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	30	77.9	100.6	112.3
	Indeterminate	1	36.8	36.8	36.8
Coulter	Positive	22	81.5	93.2	203.8
Organon Teknika	Positive	8	65.9	88.1	96.3
Other	Positive	2	100.2	102.8	105.4

**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 12, 2001 Performance Evaluation Shipment (Continued)**

**CDC Donor #7  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A2, B3**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	30	94.4	101.6	105.4
	Indeterminate	1	110.0	110.0	110.0
Coulter	Positive	22	83.5	92.9	101.5
Organon Teknika	Positive	8	74.8	92.8	97.6
Other	Positive	2	98.0	100.7	103.5

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the March 12, 2001 Performance Evaluation Shipment**

**CDC Donor #5  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A4, B1**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	34.6	34.6	34.6
Coulter	5	57.0	82.5	3014.3
Coulter ICD	2	58.9	69.7	80.4
Organon Teknika	3	7.7	67.0	85.5
Other	1	28.7	28.7	28.7

**CDC Donor #5 - Duplicate  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A5, B4**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	31.9	31.9	31.9
Coulter	5	57.0	81.3	2789.7
Coulter ICD	2	53.3	64.7	76.1
Organon Teknika	3	7.5	61.0	90.2
Other	1	30.1	30.1	30.1

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the March 12, 2001 Performance Evaluation Shipment (Continued)**

**CDC Donor #7  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A2, B3**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	22.0	22.0	22.0
Coulter	5	66.5	109.3	7012.0
Coulter ICD	2	76.7	85.6	94.5
Organon Teknika	3	10.2	39.0	58.8
Other	1	27.2	27.2	27.2