

**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 18, 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 September 18, 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  
September 18, 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	3	Positive	Infected	_____	_____	_____
	A2	4	Negative	Uninfected	_____	_____	_____
	A3	5	Negative	Uninfected	_____	_____	_____
	A4, A5	2	Positive	Infected	_____	_____	_____
B	B1	4	Negative	Uninfected	_____	_____	_____
	B2, B5	2	Positive	Infected	_____	_____	_____
	B3	5	Negative	Uninfected	_____	_____	_____
	B4	3	Positive	Infected	_____	_____	_____

<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 September 18, 2001 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<sup>2</sup></b>
A	A1	3	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb <sup>3</sup> Coulter HIV-1 p24 Antigen	Positive Positive
	A2	4	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	A3	5	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	A4, A5	2	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
B	B1	4	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	B2, B5	2	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B3	5	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	B4	3	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive

<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.

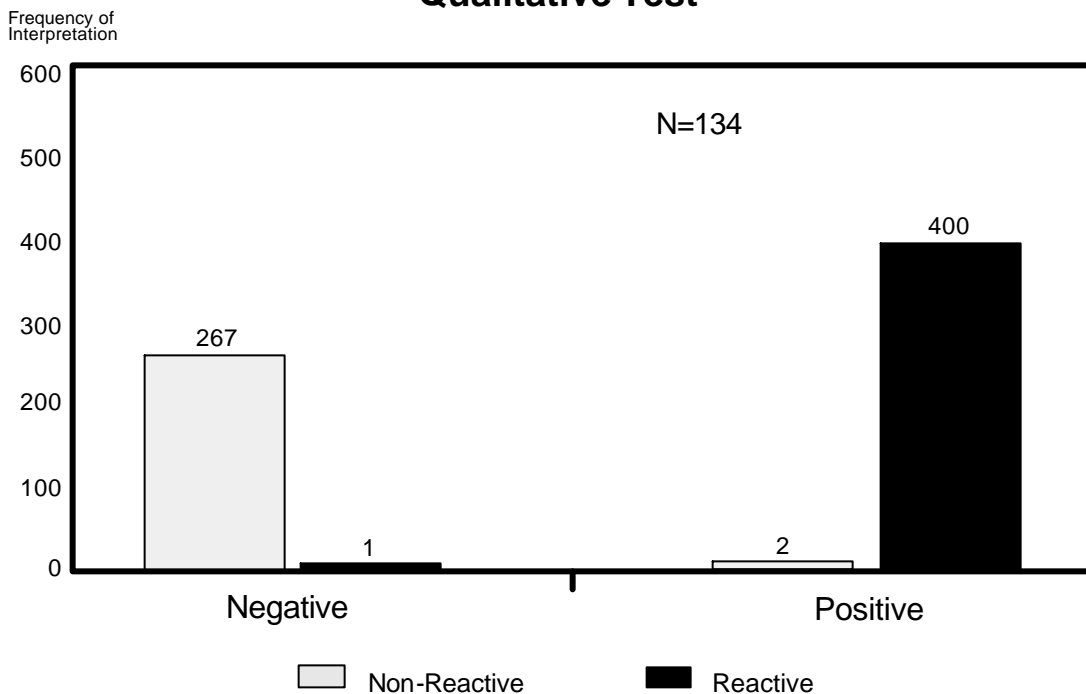
<sup>3</sup> MAb = monoclonal antibody

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

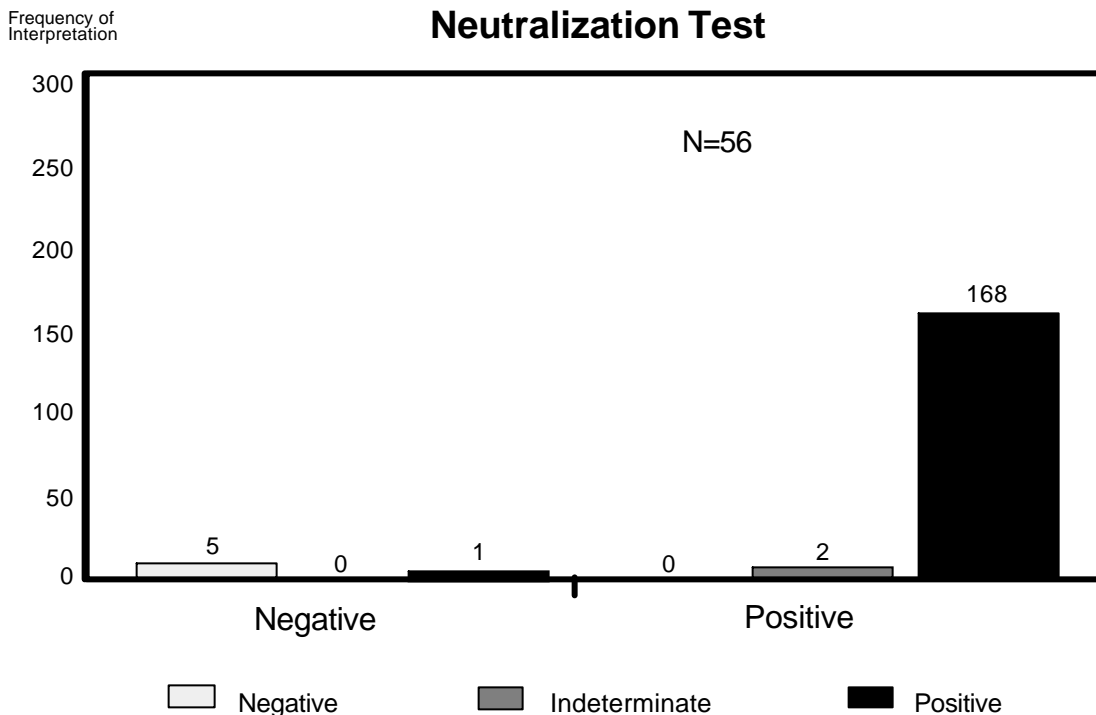
The "N=" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test kit for a specific test type; therefore, the "N=" may exceed the actual number of laboratories participating in the survey. In figures 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 September 18, 2001 Shipment**

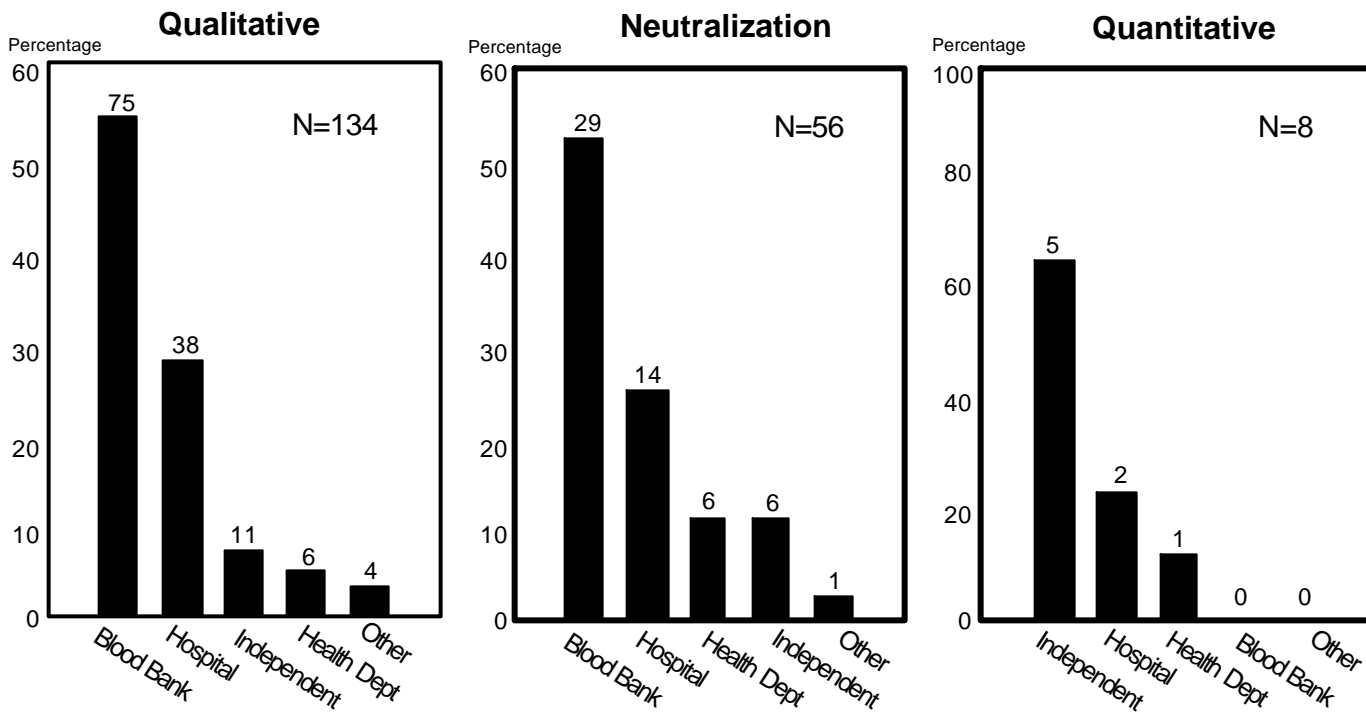
### Qualitative Test



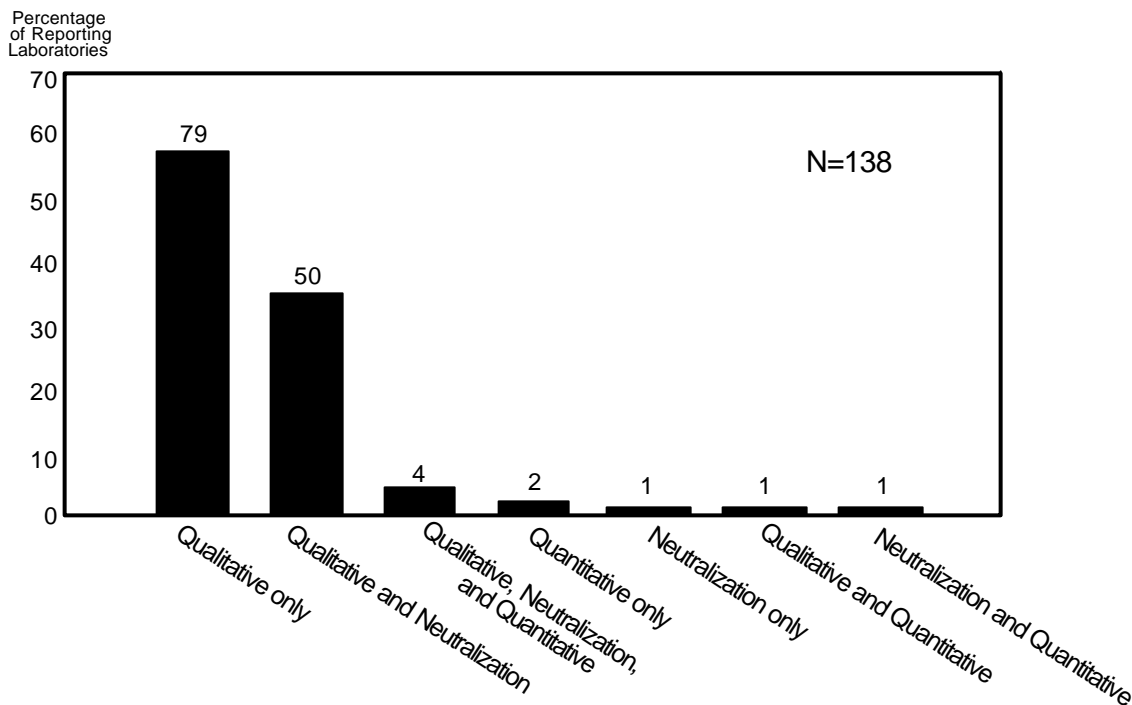
### Neutralization Test



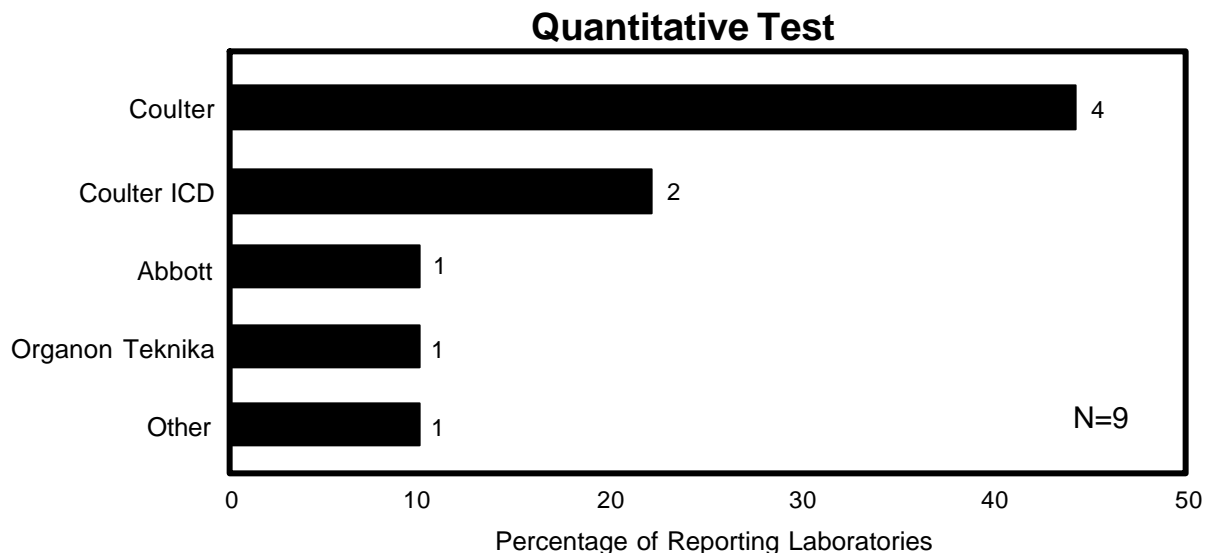
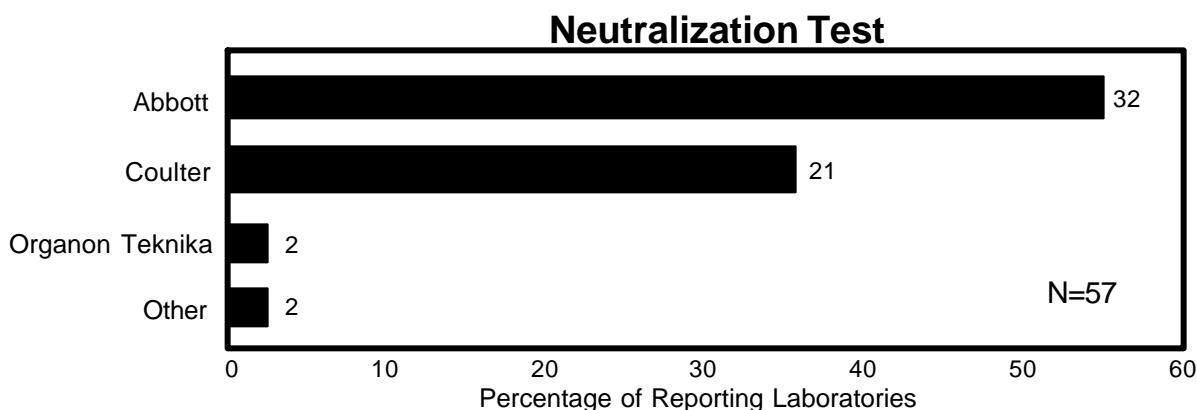
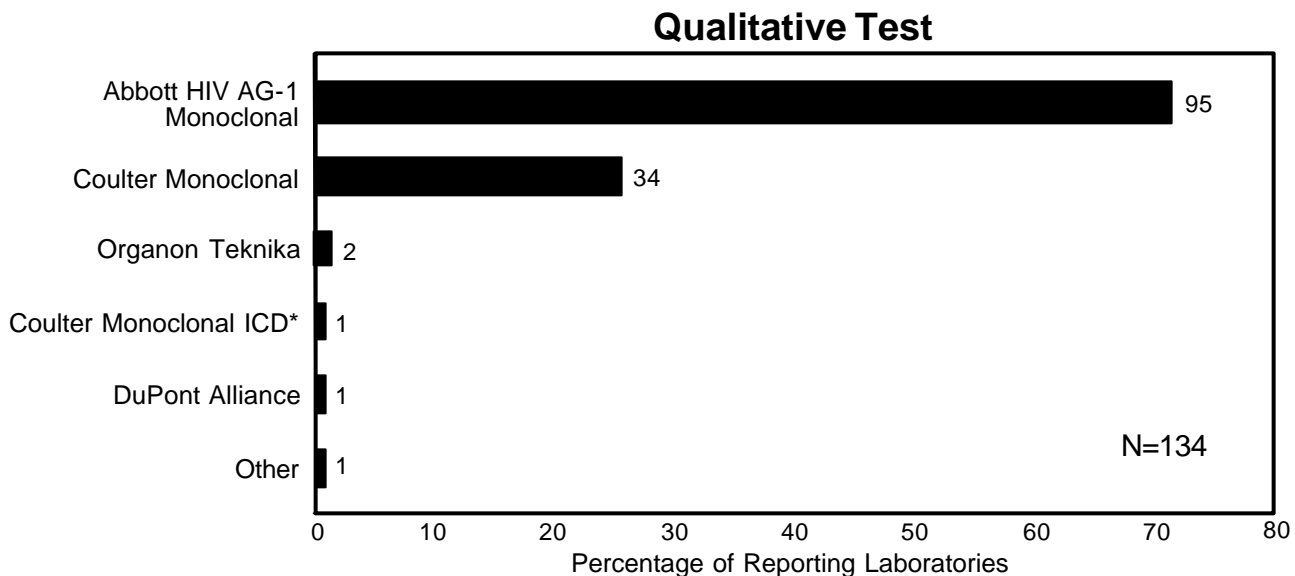
**Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the September 18, 2001 Shipment**



**Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the September 18, 2001 Shipment**



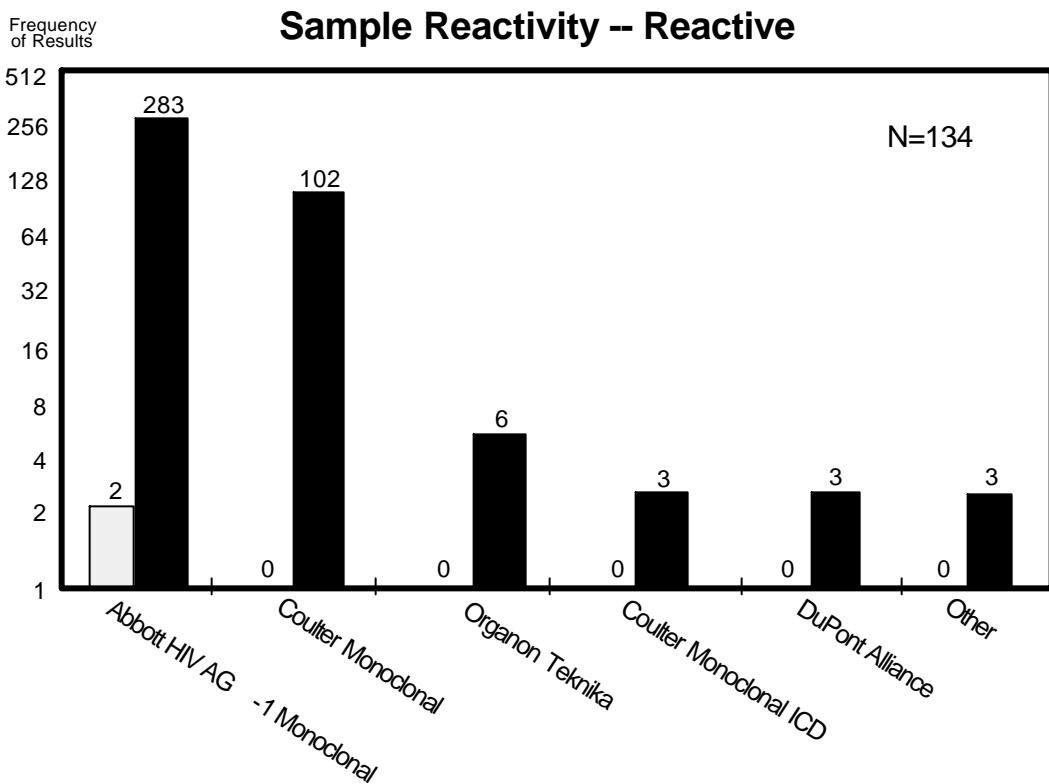
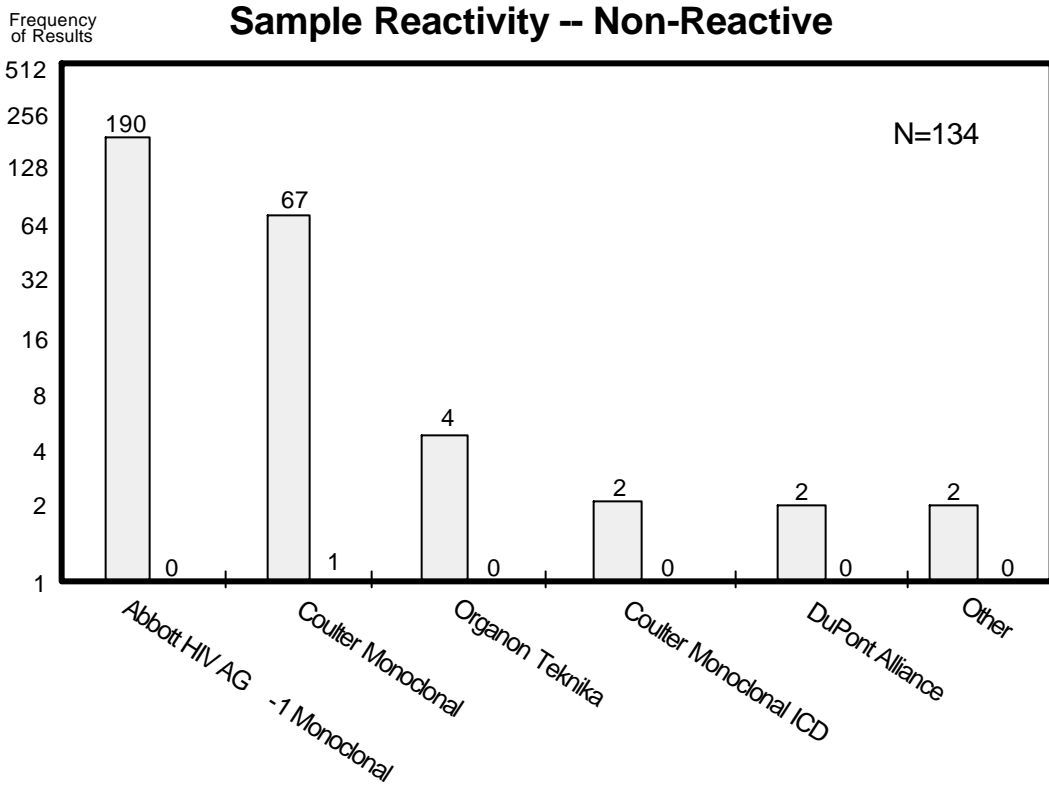
**Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the September 18, 2001 Shipment**



\*ICD=Immune Complex Dissociation

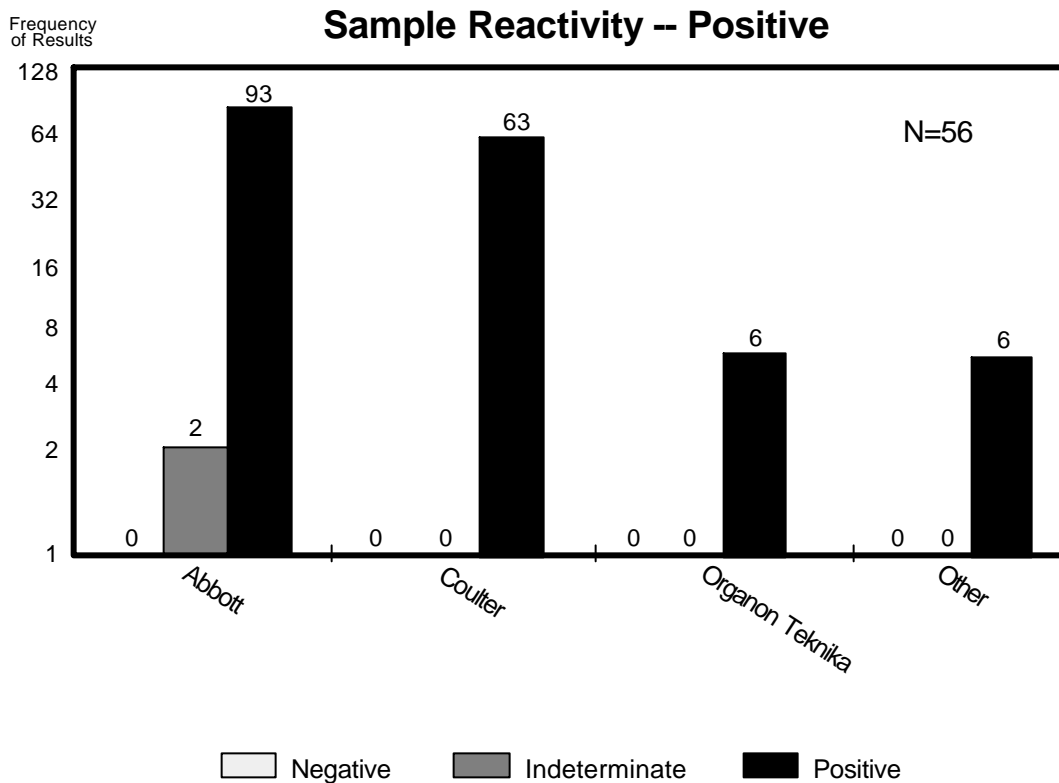
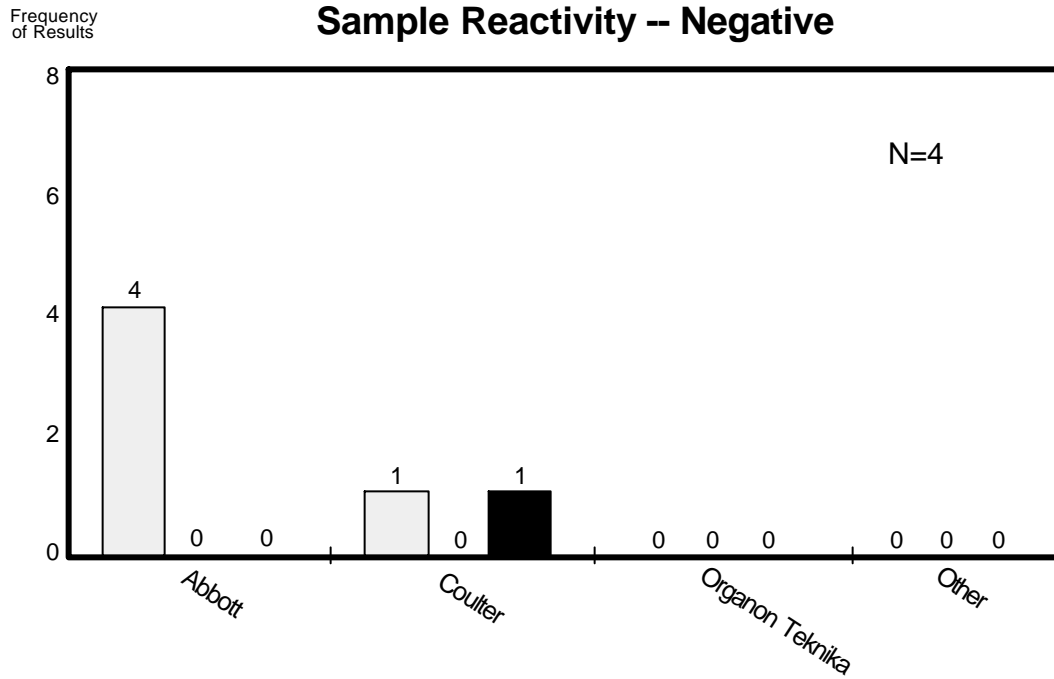


**Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 18, 2001 Shipment**



Non-Reactive
  Reactive

**Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 18, 2001 Shipment**



**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 18, 2001 Performance Evaluation Shipment**

**CDC Donor #2  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A4, B2**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	31	93.3	99.6	102.6
	Indeterminate	1	0.0	0.0	0.0
Coulter	Positive	21	85.0	91.2	101.3
Organon Teknika	Positive	2	95.8	95.8	95.9
Other	Positive	2	99.1	99.9	100.7

**CDC Donor #2 - Duplicate  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A5, B5**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	31	95.1	100.0	118.7
Coulter	Positive	21	82.0	90.9	99.7
Organon Teknika	Positive	2	95.2	95.8	96.3
Other	Positive	2	99.2	100.8	102.4

**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 18, 2001 Performance Evaluation Shipment (Continued)**

CDC Donor #3  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A1, B4

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	31	93.0	99.3	137.7
	Indeterminate	1	10.6	10.6	10.6
Coulter	Positive	21	91.0	95.5	99.0
Organon Teknika	Positive	2	93.0	93.6	94.2
Other	Positive	2	97.2	100.0	102.8

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 18, 2001 Performance Evaluation Shipment**

**CDC Donor #2  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A4, B2**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	39.6	39.6	39.6
Coulter	4	70.2	89.1	103.4
Coulter ICD	2	95.9	97.0	98.1
Organon Teknika	1	51.5	51.5	51.5
Other	1	30.3	30.3	30.3

**CDC Donor #2 - Duplicate  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A5, B5**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	39.8	39.8	39.8
Coulter	4	83.2	85.0	99.2
Coulter ICD	2	92.7	99.2	105.7
Organon Teknika	1	51.5	51.5	51.5
Other	1	28.8	28.8	28.8

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 18, 2001 Performance Evaluation Shipment (Continued)**

**CDC Donor #3  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A1, B4**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	1	20.1	20.1	20.1
Coulter	4	72.9	97.2	105.1
Coulter ICD	2	73.7	84.6	95.4
Organon Teknika	1	35.8	35.8	35.8
Other	1	13.8	13.8	13.8