

**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 June 23, 1997 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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Report of the June 23, 1997 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 for  
Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen Testing**

**Table 1. CDC HIV-1p24 Antigen Testing Results for the June 23, 1997 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, A4	01	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb <sup>3</sup> Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	A2	03	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	A3	02	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	A5	04	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
B	B1	04	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	B2, B5	01	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	B3	03	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	B4	02	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
C	C1, C3	01	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	C2	04	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	C4	03	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	C5	02	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
D	D1	02	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	D2, D4	01	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	D3	04	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	D5	03	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative

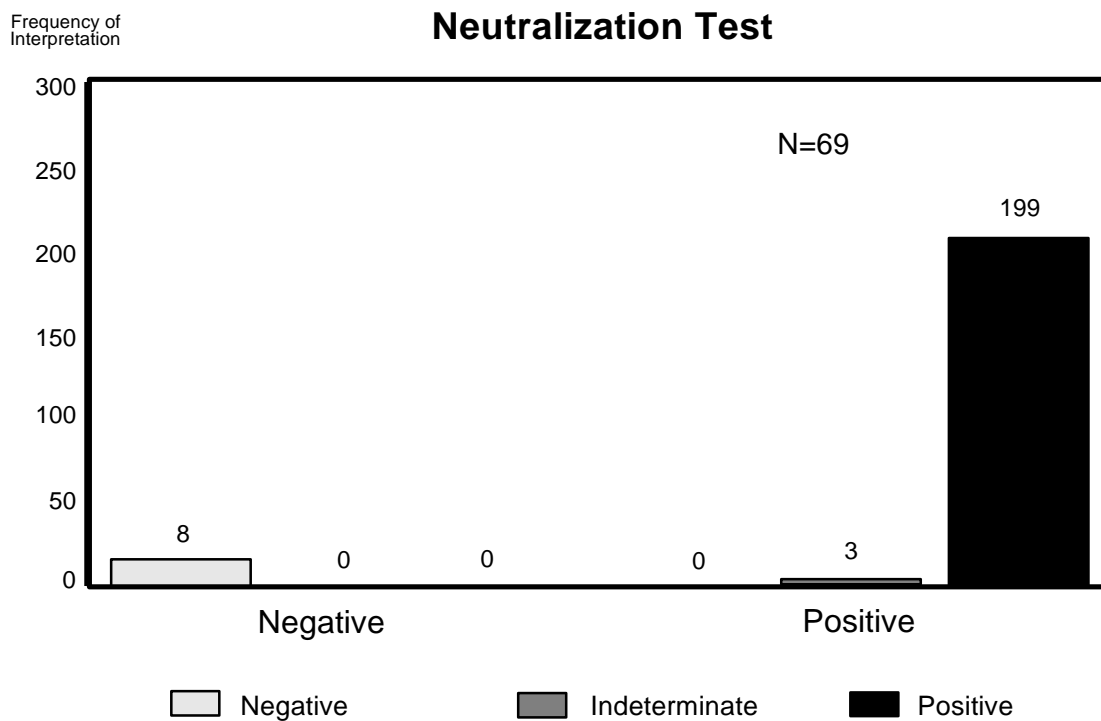
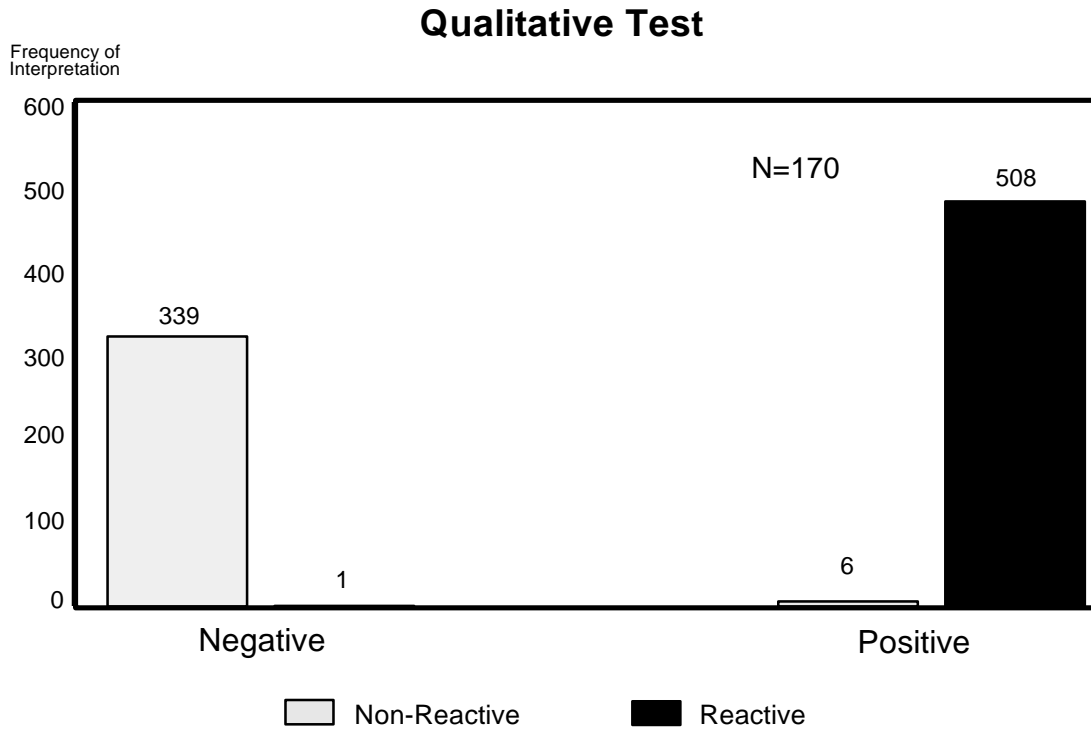
<sup>1</sup> Result based on testing performed in two separate laboratories.

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

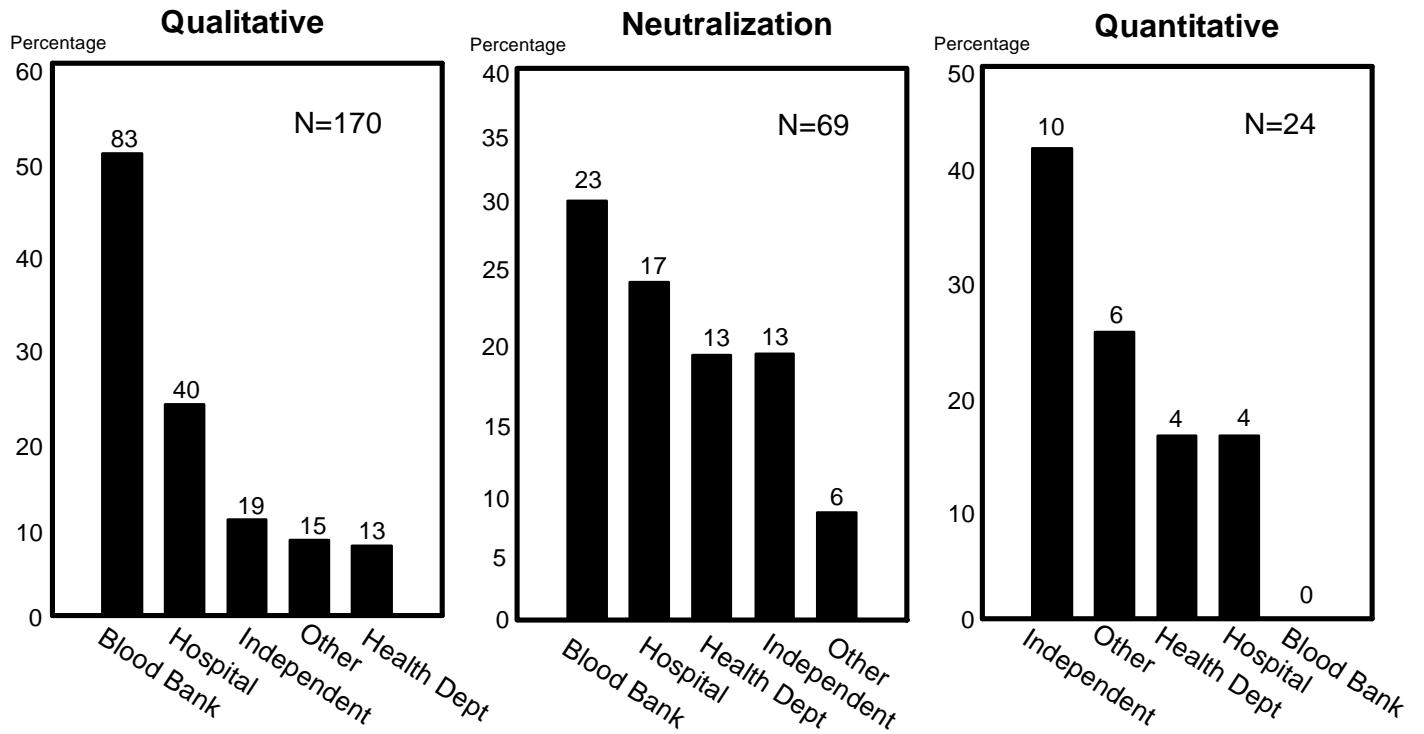
Positive = Presence of HIV-1 p24 antigen confirmed; Negative = p24 antigen not detected

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

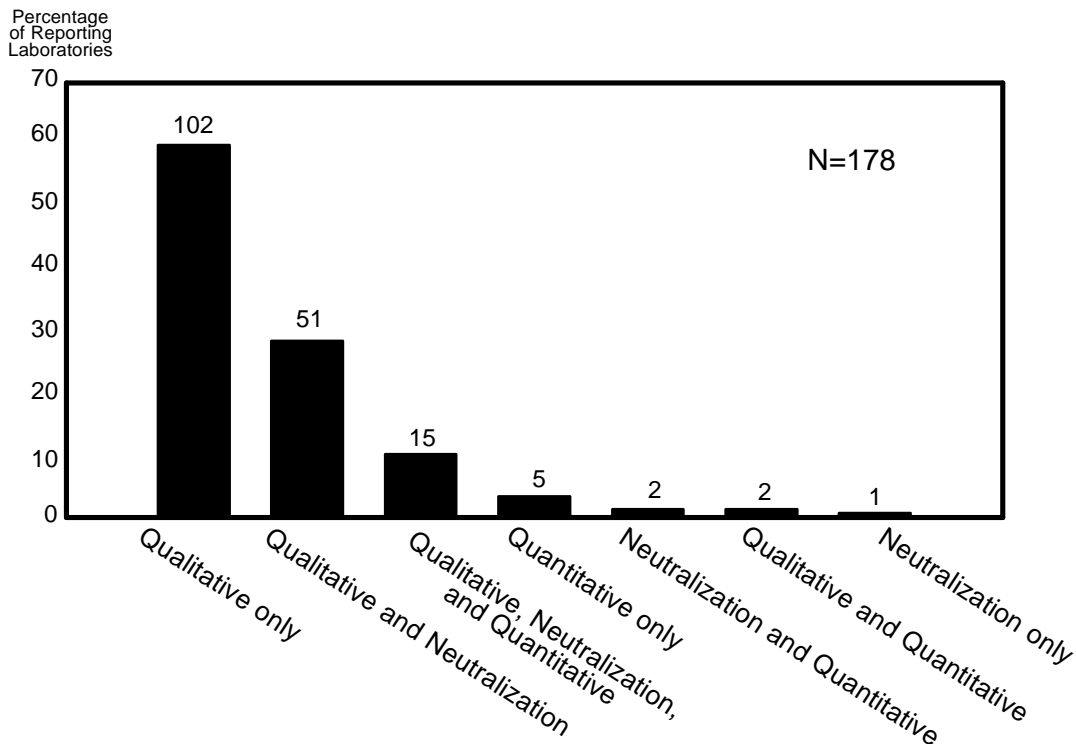
**Figure 1. Frequency of HIV-1 p24 Antigen Test Result Interpretations, by Sample Type (Reactivity), for Qualitative and Neutralization Tests Reported by Participant Laboratories for the June 23, 1997 Shipment**



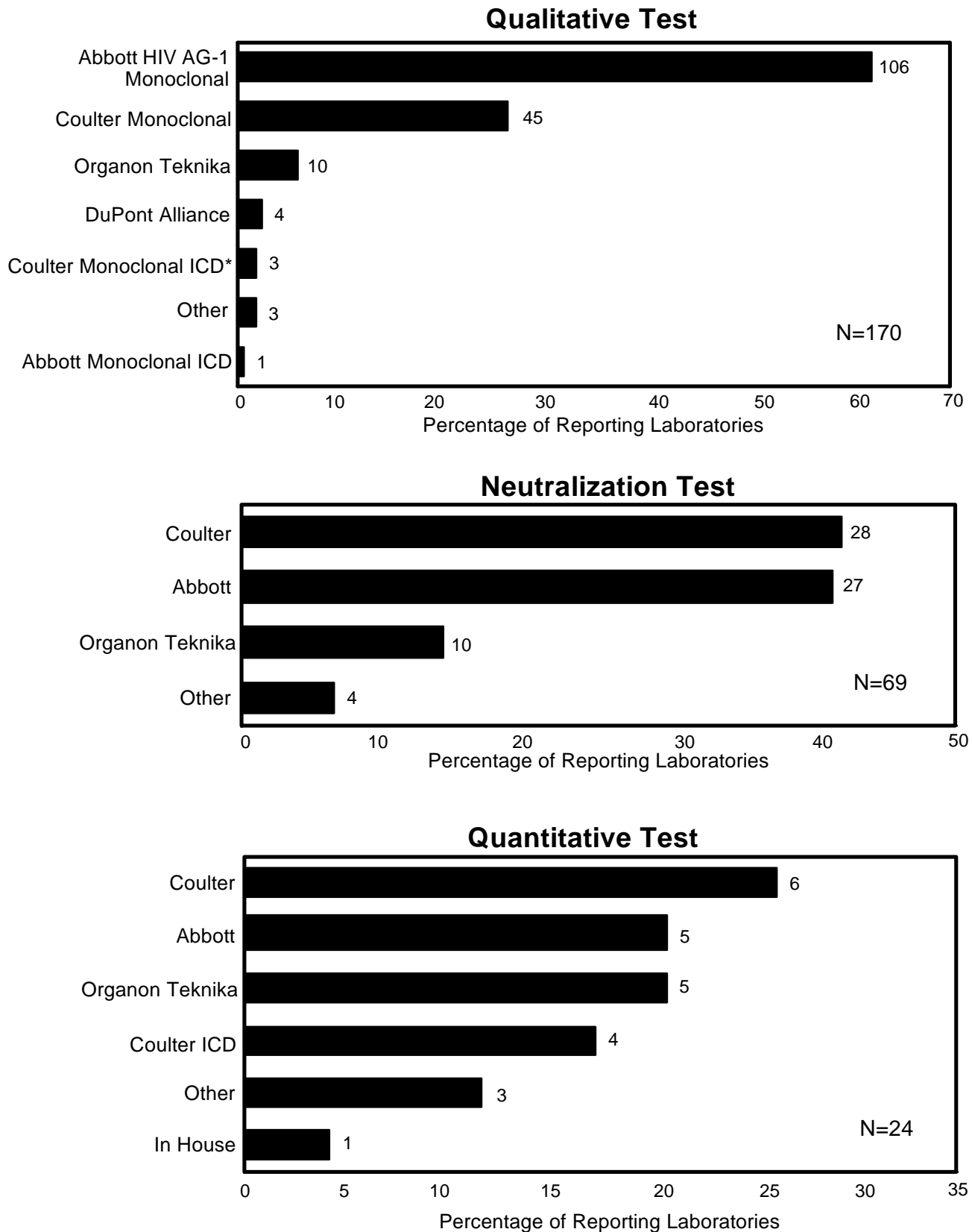
**Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the June 23, 1997 Shipment**



**Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the June 23, 1997 Shipment**

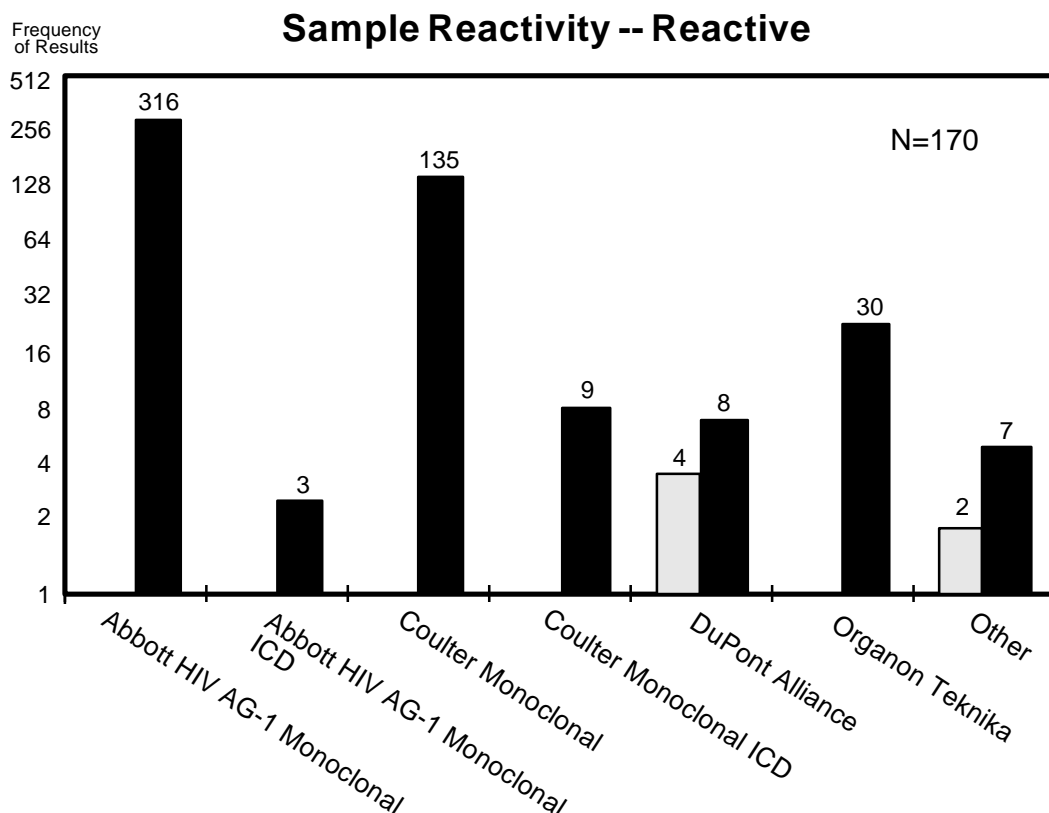
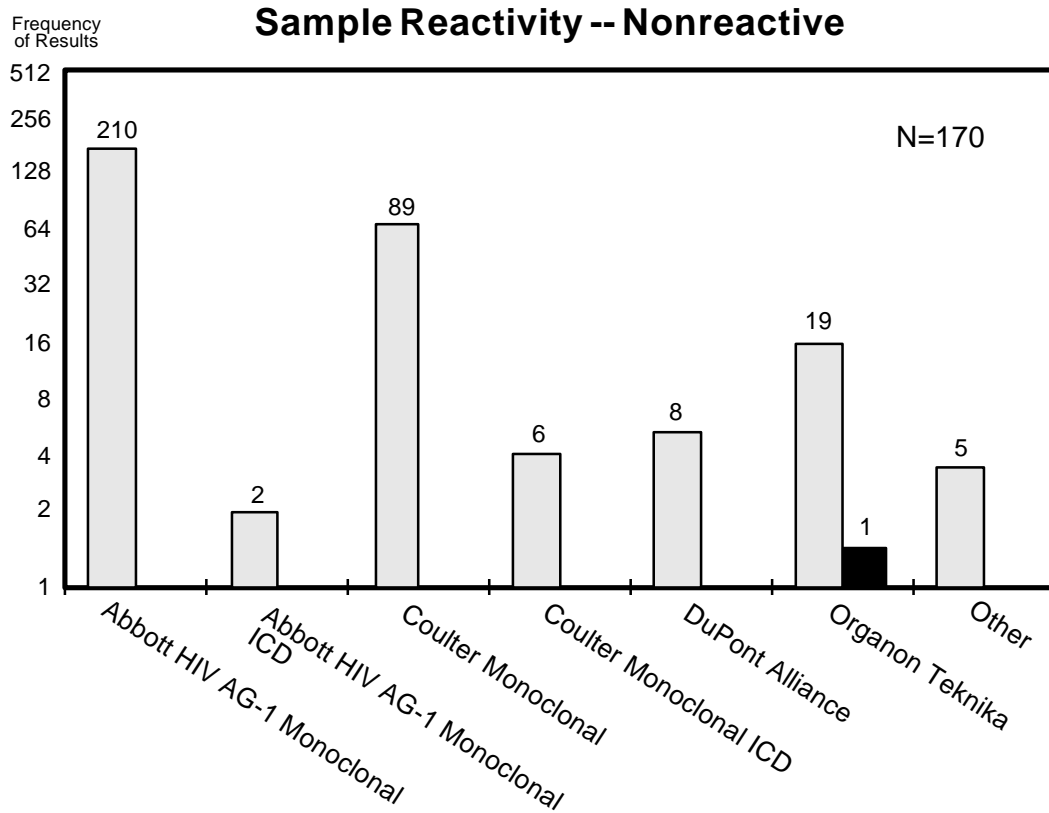


**Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the June 23, 1997 Shipment**



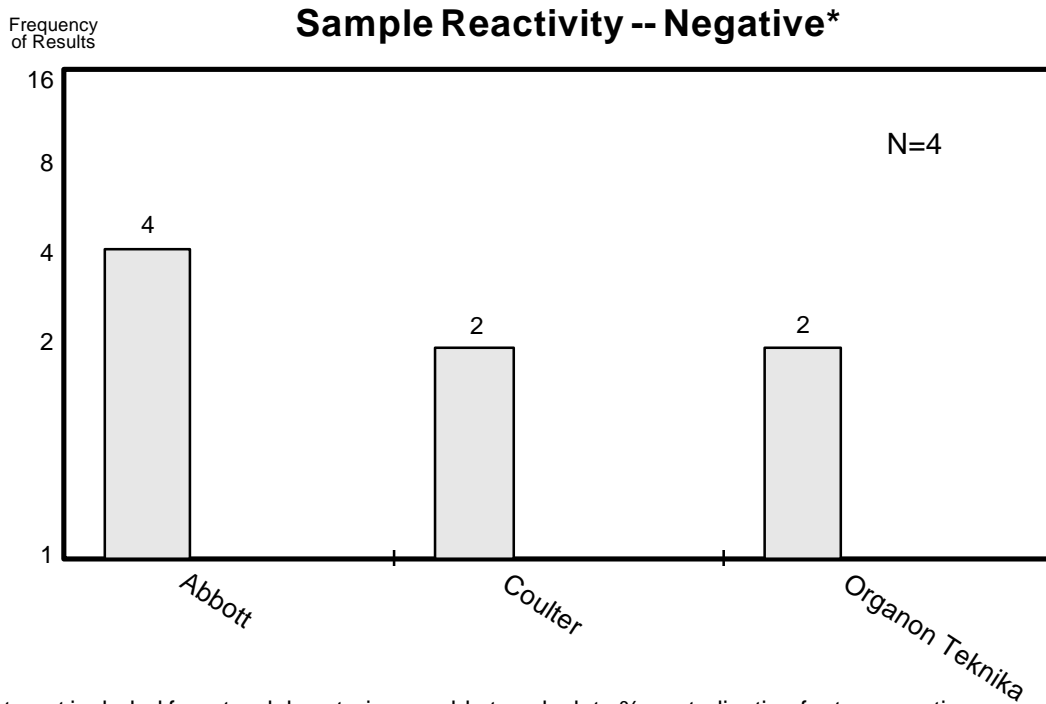
\*ICD=Immune Complex Dissociation

**Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the June 23, 1997 Shipment**

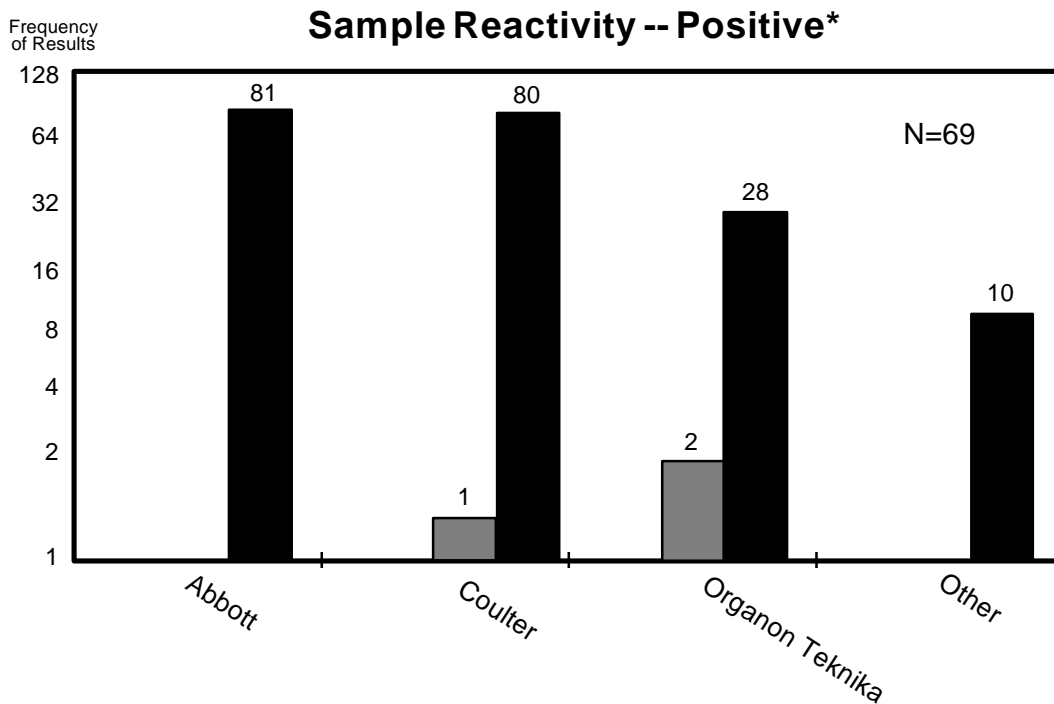


Nonreactive
  Reactive

**Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the June 23, 1997 Shipment**



\*Data not included from two laboratories, unable to calculate % neutralization for two negative donor samples, that reported "Indeterminate" neutralization test interpretations. Likewise, data not included from two laboratories that did not perform neutralization tests on a negative donor sample, but reported "negative" neutralization test interpretations.



\*Data not included from two laboratories, unable to calculate a % neutralization for a qualitative test reactive sample, that reported "Indeterminate" neutralization test interpretations.

Negative
  Indeterminate
  Positive



**Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the June 23, 1997 Performance Evaluation Shipment**

**CDC Donor #1**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A1, B2, C1, D2**

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	27	0	61.8	87.5	103.6
Coulter	27	0	65.4	91.0	100.0
Organon Teknika	10	0	67.0	94.5	96.0
Other	3	0	77.9	99.5	99.6

**CDC Donor #1 - Duplicate**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A4, B5, C3, D4**

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	26	0	64.0	87.1	110.3
Coulter	27	1	0.0	89.6	100.0
Organon Teknika	10	0	69.0	93.9	96.1
Other	3	0	79.1	98.7	99.6

**Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the June 23, 1997 Performance Evaluation Shipment (Continued)**

**CDC Donor #2  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A3, B4, C5, D1**

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	28	0	60.0	95.3	101.0
Coulter	26	0	45.4	91.3	100.0
Organon Teknika	8	2	25.7	63.2	85.3
Other	4	0	85.0	98.1	99.6

**Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the June 23, 1997 Performance Evaluation Shipment**

**CDC Donor #1  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A1, B2, C1, D2**

Test Kit	No. of Results Quantitating p24	No. of Results Not Quantitating p24	Range of Results Reported Concentration (pg/ml)		
			minimum	median	maximum
Abbott	4	0	25.7	85.0	133.0
Coulter	5	0	8.8	20.0	680.0
Coulter ICD	4	0	250.0	421.5	596.3
Organon Teknika	5	0	47.0	69.6	195.0
In House	1	0	85.7	85.7	85.7
Other	3	0	49.5	223.1	331.9

**CDC Donor #1 - Duplicate  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A4, B5, C3, D4**

Test Kit	No. of Results Quantitating p24	No. of Results Not Quantitating p24	Range of Results Reported Concentration (pg/ml)		
			minimum	median	maximum
Abbott	5	0	33.1	119.2	204.0
Coulter	5	0	16.2	20.0	748.0
Coulter ICD	4	0	250.0	423.2	787.0
Organon Teknika	4	0	58.0	69.7	125.0
In House	1	0	86.9	86.9	86.9
Other	3	0	45.8	248.8	330.4

**Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the June 23, 1997 Performance Evaluation Shipment (Continued)**

**CDC Donor #2  
 Donor Status: HIV-1 Infected  
 Panel Vial Labels: A3, B4, C5, D1**

Test Kit	No. of Results Quantitating p24	No. of Results Not Quantitating p24	Range of Results Reported Concentration (pg/ml)		
			minimum	median	maximum
Abbott	4	0	100.0	380.0	635.8
Coulter	5	0	250.0	614.8	1460.8
Coulter ICD	4	0	250.0	423.2	2116.0
Organon Teknika	5	0	80.0	197.7	931.0
In House	1	0			2760.0
Other	3	0	197.1	227.0	283.1