

**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 2, 1998 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
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Report of the March 2, 1998 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-1 p24 Antigen Testing Results for the March 2, 1998
Participant Laboratory Panel Samples**

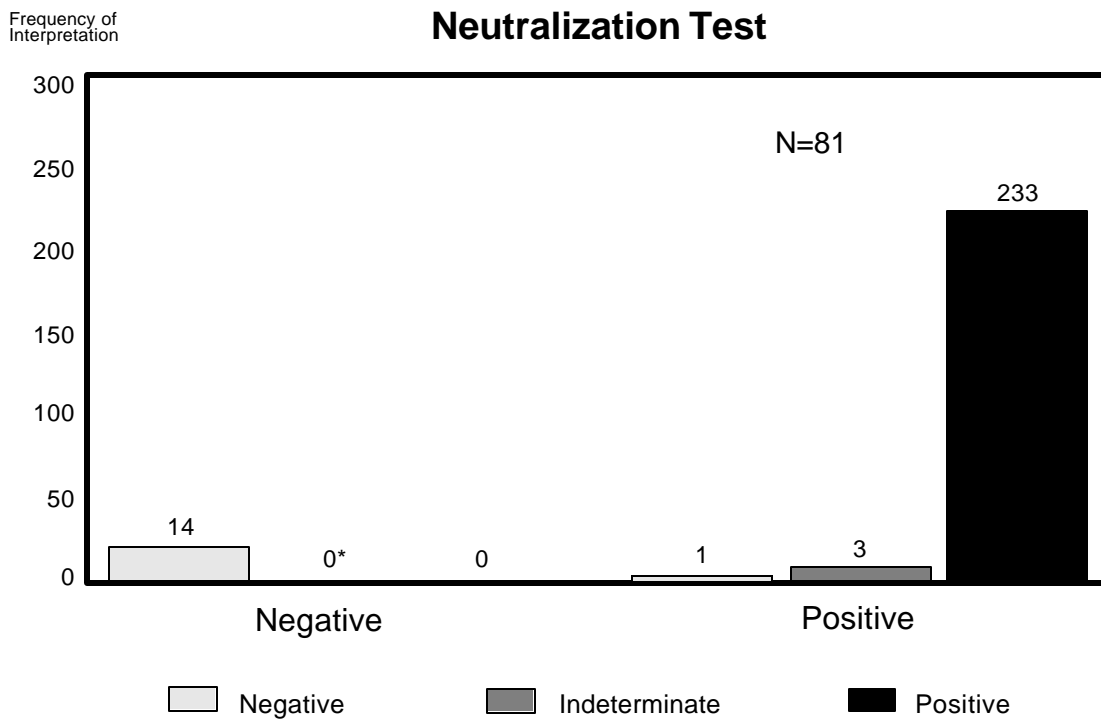
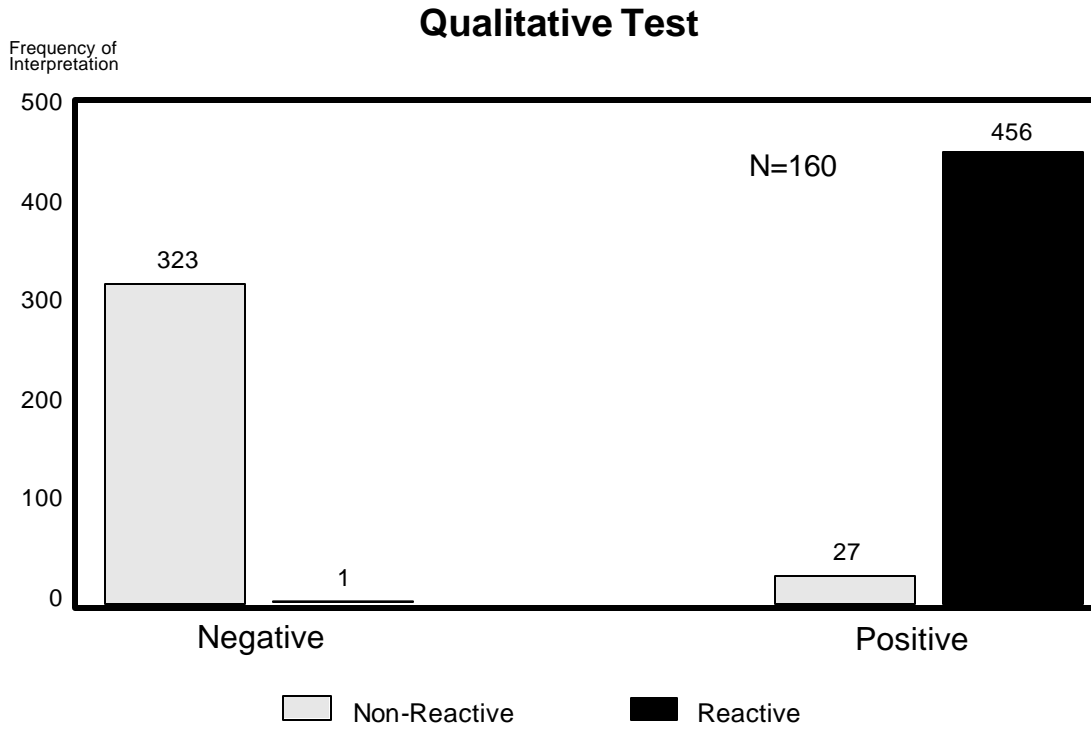
Panel Letter	Vial Label	CDC Donor Number	CDC Test Results ¹	Test Kit Manufacturer	CDC Interpretation ²
E	E1, E5	03	No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb ³ Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	E2, E4	02	p24 Antigen detected p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Positive Positive Positive
	E3	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
F	F1, F2	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
	F3, F5	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
	F4	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
G	G1, G4	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
	G2, G3	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
	G5	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
H	H1	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
	H2, H5	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
	H3, H4	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

¹ Result based on testing performed in two separate laboratories.

² 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

³ 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 March 2, 1998 Shipment



*See comment in analysis.

Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 2, 1998 Performance Evaluation Shipment

**CDC Donor #1
 Donor Status: HIV-1 Infected
 Panel Vial Labels: E3, F4, G5, H1**

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	42	1	44.8	95.5	100.0
Coulter	27	0	62.4	90.0	97.0
Organon Teknika	11	0	56.9	81.2	90.8
Other	1	0	99.4	99.4	99.4

Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 2, 1998 Performance Evaluation Shipment (Continued)

CDC Donor #2
Donor Status: HIV-1 Infected
Panel Vial Labels: E2, F3, G1, H2

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	38	1	50.8	87.5	116.3
Coulter	27	0	62.4	88.6	109.6
Organon Teknika	11	0	86.1	88.1	92.0
Other	1	0	108.4	108.4	108.4

CDC Donor #2 - Duplicate
Donor Status: HIV-1 Infected
Panel Vial Labels: E4, F5, G4, H5

Test Kit	No. of Results Confirming p24	No. of Results Not Confirming p24	Range of Results Reported % Neutralization		
			minimum	median	maximum
Abbott	37	2	0.0	85.5	108.4
Coulter	26	0	68.7	88.4	105.8
Organon Teknika	11	0	78.1	89.4	91.4
Other	1	0	100.0	100.0	100.0

Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the March 2, 1998 Performance Evaluation Shipment

**CDC Donor #1
 Donor Status: HIV-1 Infected
 Panel Vial Labels: E3, F4, G5, H1**

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	333.9	446.4
Coulter	5	0	125.0	598.2	1971.4
Coulter ICD	3	0	250.0	2319.0	2565.0
Organon Teknika	4	0	612.0	700.5	787.8
In House	1	0	276.0	276.0	276.0
Other	3	0	93.7	216.9	741.4

Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the March 2, 1998 Performance Evaluation Shipment (Continued)

CDC Donor #2
Donor Status: HIV-1 Infected
Panel Vial Labels: E2, F3, G1, H2

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	9.8	48.4	130.3
Coulter	5	0	7.8	13.5	203.6
Coulter ICD	2	0	183.1	334.1	485.0
Organon Teknika	4	0	8.4	14.8	69.5
In House	1	0	0.1	0.1	0.1
Other	3	0	5.9	123.4	159.0

CDC Donor #2 - Duplicate
Donor Status: HIV-1 Infected
Panel Vial Labels: E4, F5, G4, H5

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	10.8	47.6	141.7
Coulter	5	0	6.9	13.5	201.6
Coulter ICD	2	0	176.4	197.2	218.0
Organon Teknika	4	0	8.1	12.9	56.9
In House	1	0	0.1	0.1	0.1
Other	3	0	7.5	118.0	140.2

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 2, 1998 Shipment

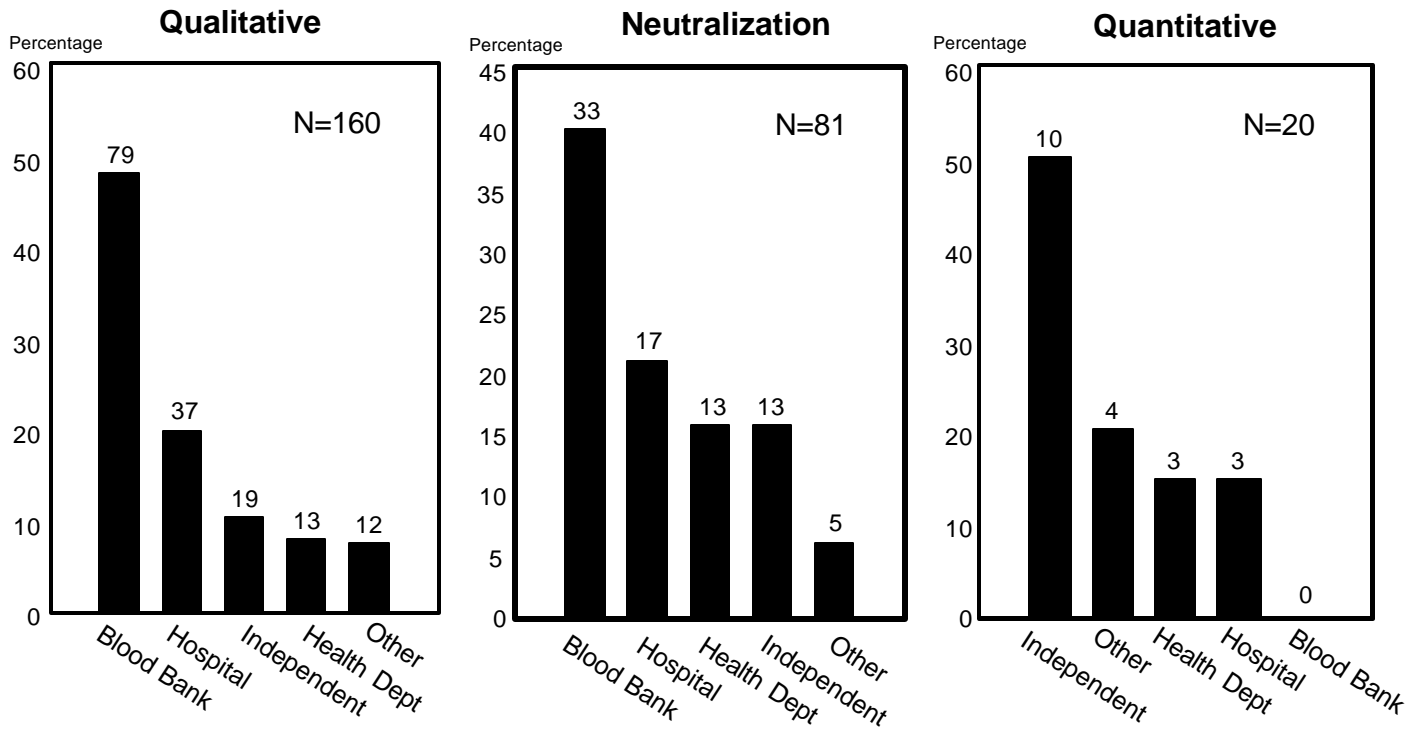


Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the March 2, 1998 Shipment

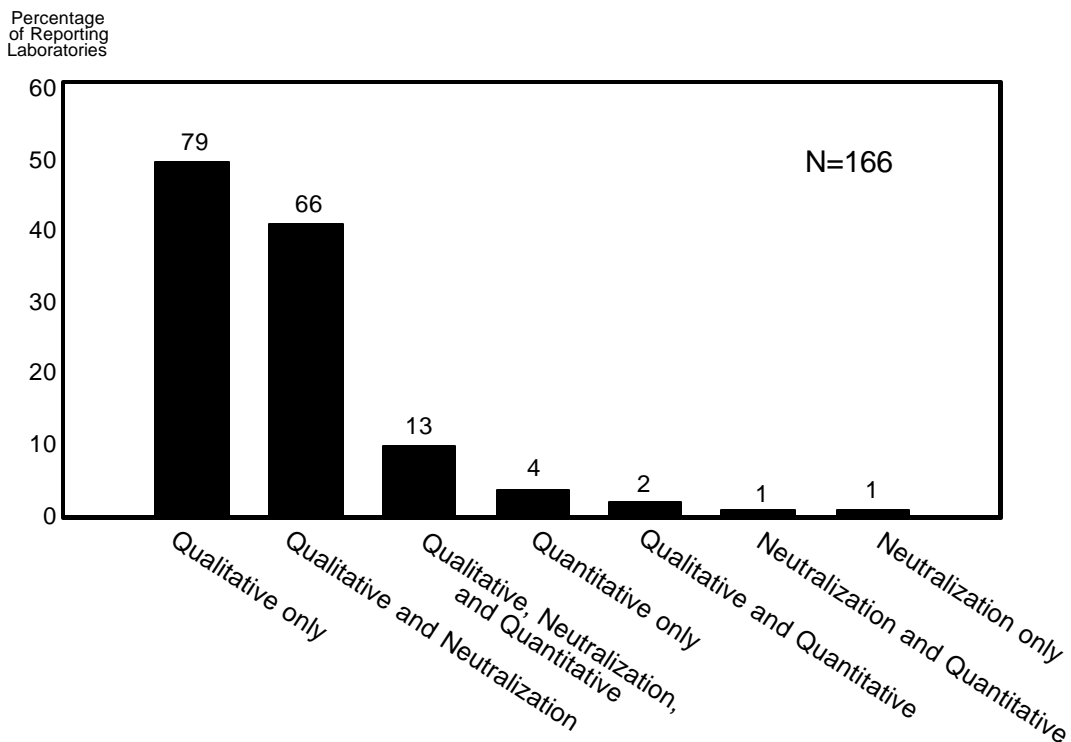
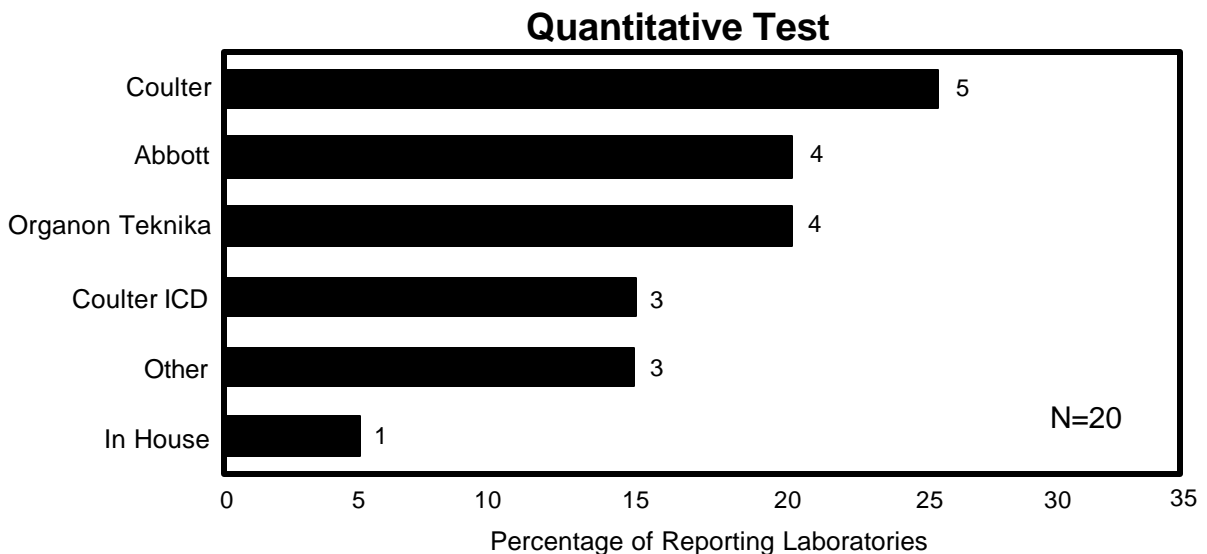
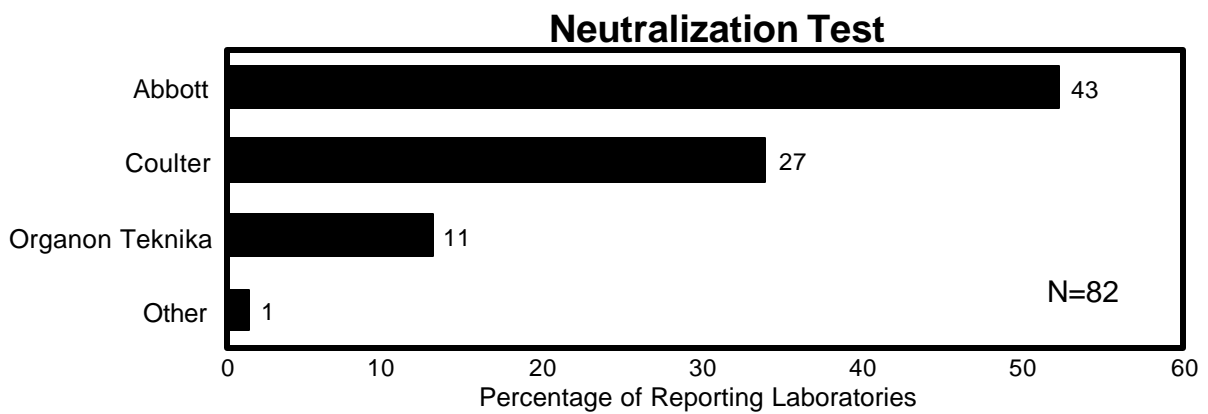
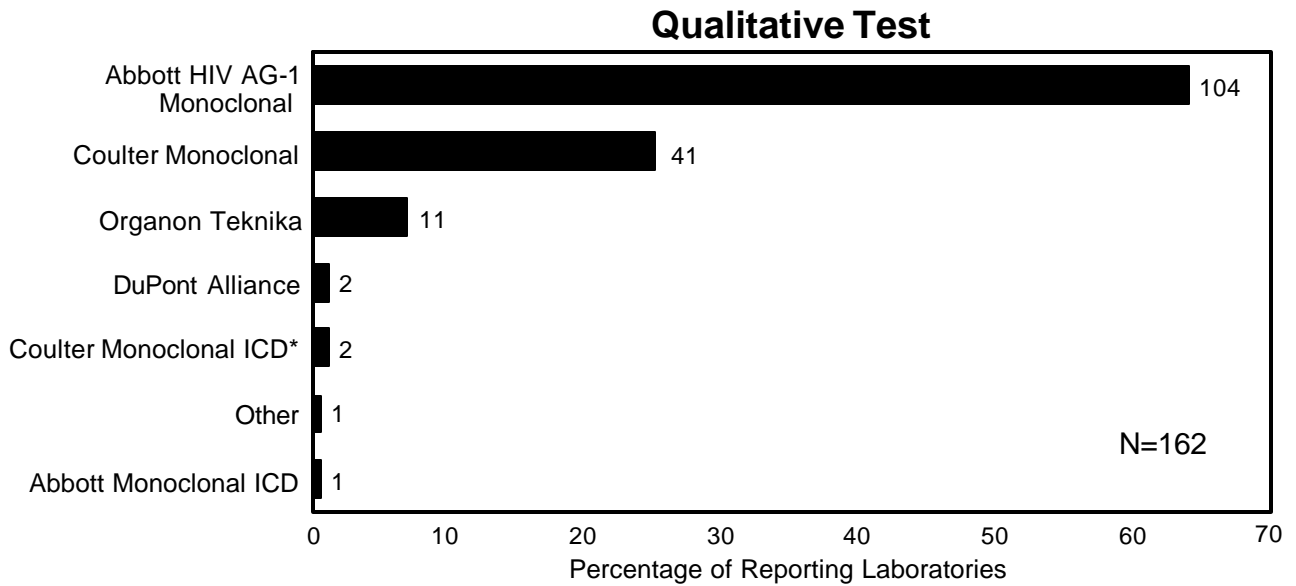
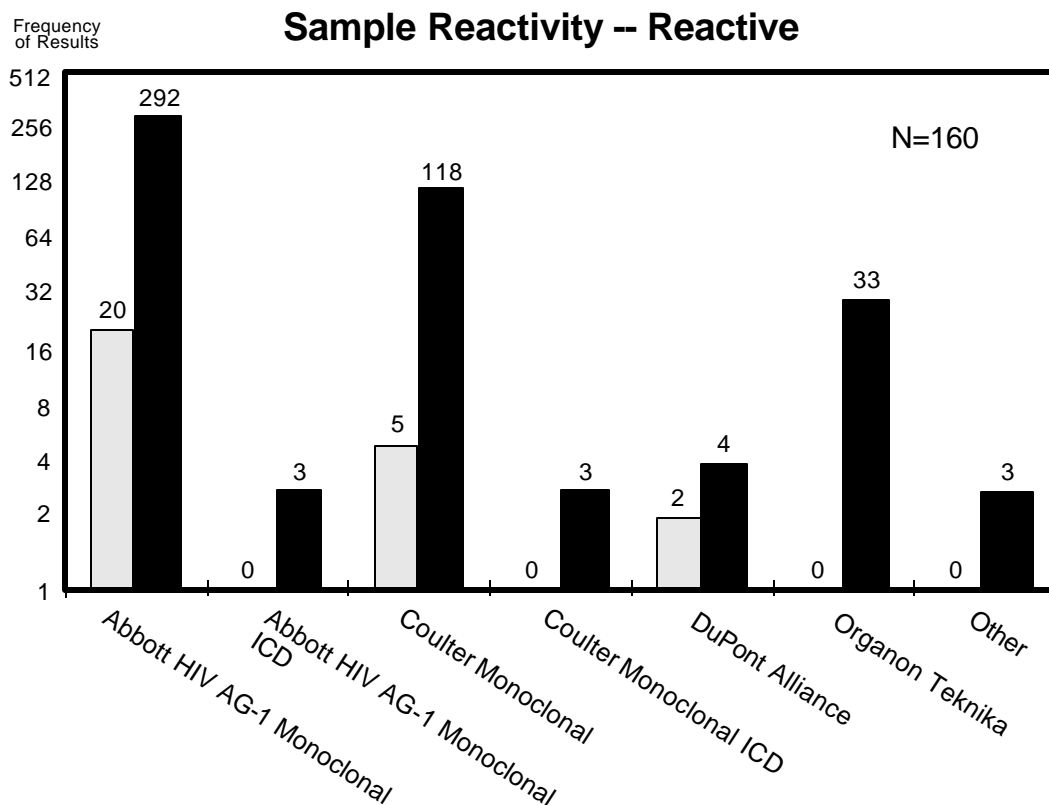
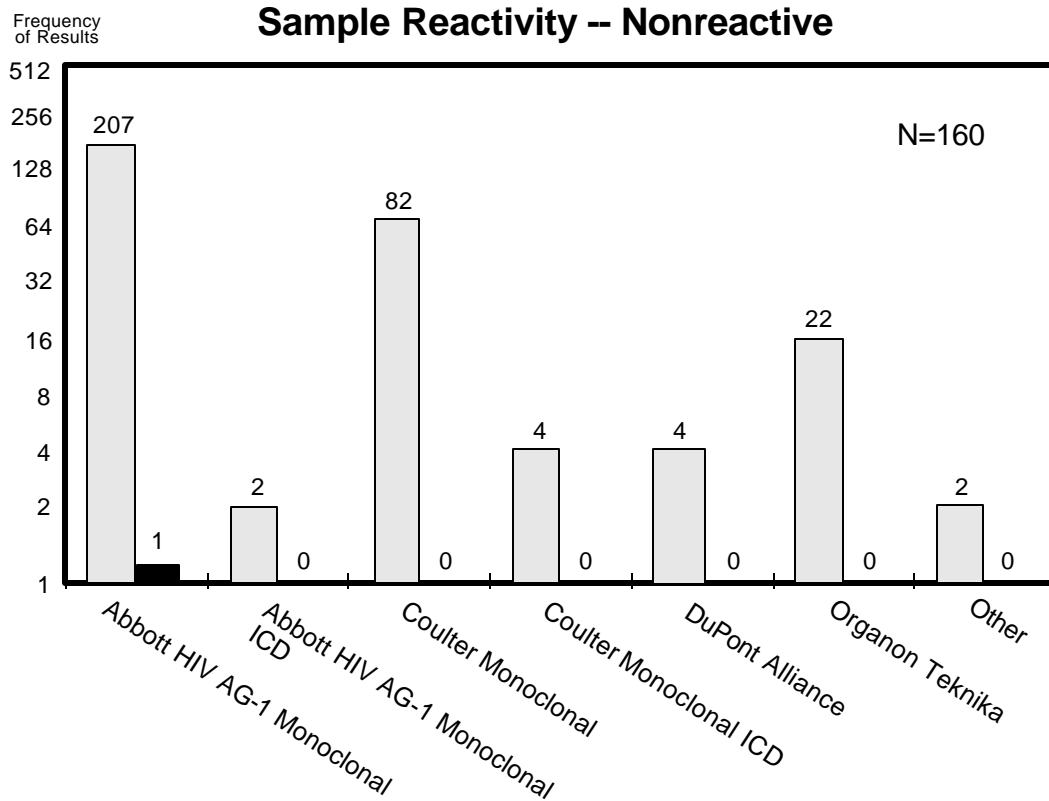


Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the March 2, 1998 Shipment



*ICD=Immune Complex Dissociation

Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 2, 1998 Shipment



Nonreactive
 Reactive

Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 2, 1998 Shipment

