

**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 1, 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 March 1, 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).

The production of this report was coordinated in CDC by:

Public Health Practice Program Office.....Edward L. Baker, M.D., M.P.H., Director
Division of Laboratory Systems.....Robert Martin, Dr. P.H., Director
Laboratory Practice Assessment Branch.....Tina M. St. John, M.D., Acting Chief

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP).....William O. Schalla, M.S., Chief
MPEP HIV-1 Performance Evaluation.....Sharon O. Blumer, M.S.,
HIV-1 Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation
Program by calling (770) 488-8090 or (770) 488-8098.

**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 for
Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen Testing**

Table 1. CDC HIV-1 p24 Antigen Testing Results for the March 1, 1999 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results ¹	Test Kit Manufacturer	CDC Interpretation ²
E	E1, E5	3	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	2	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	1	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	3	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	2	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	1	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	2	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	3	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	1	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	1	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	2	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	3	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 1, 1999, Shipment

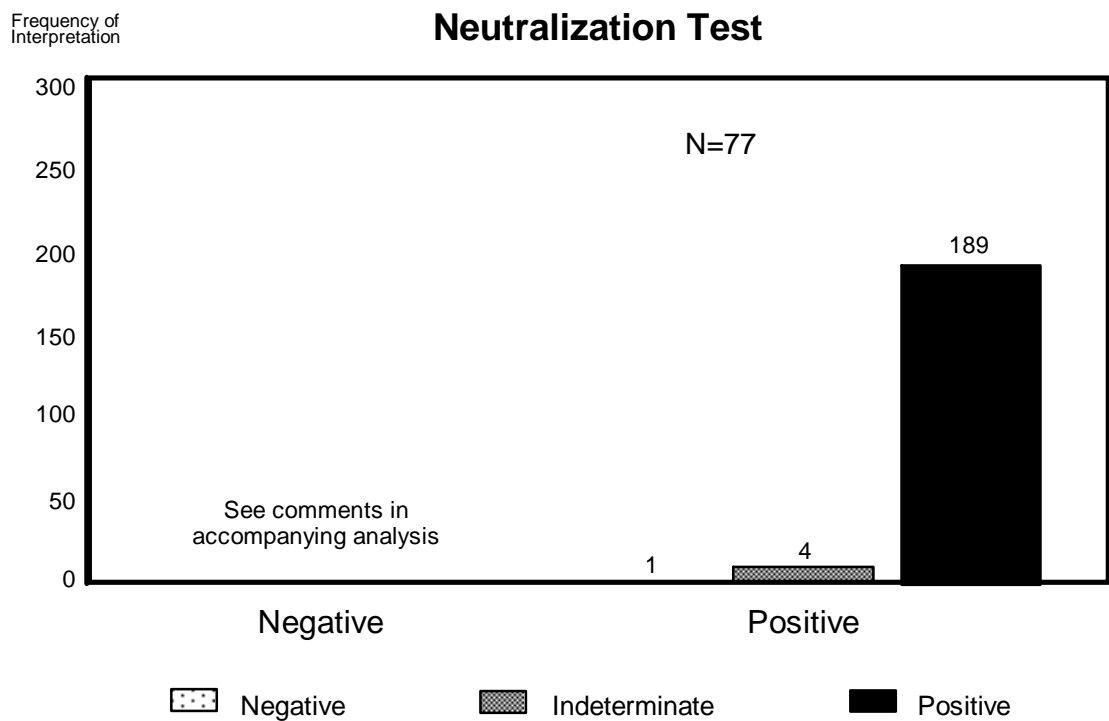
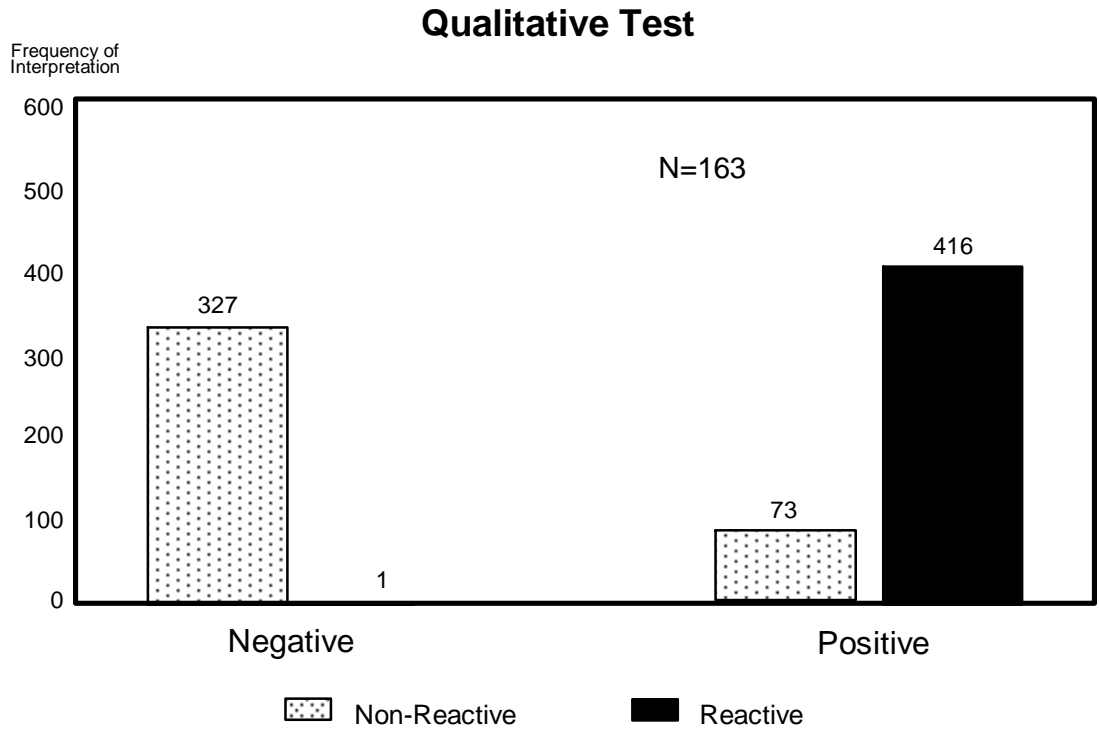


Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the March 1, 1999, Shipment

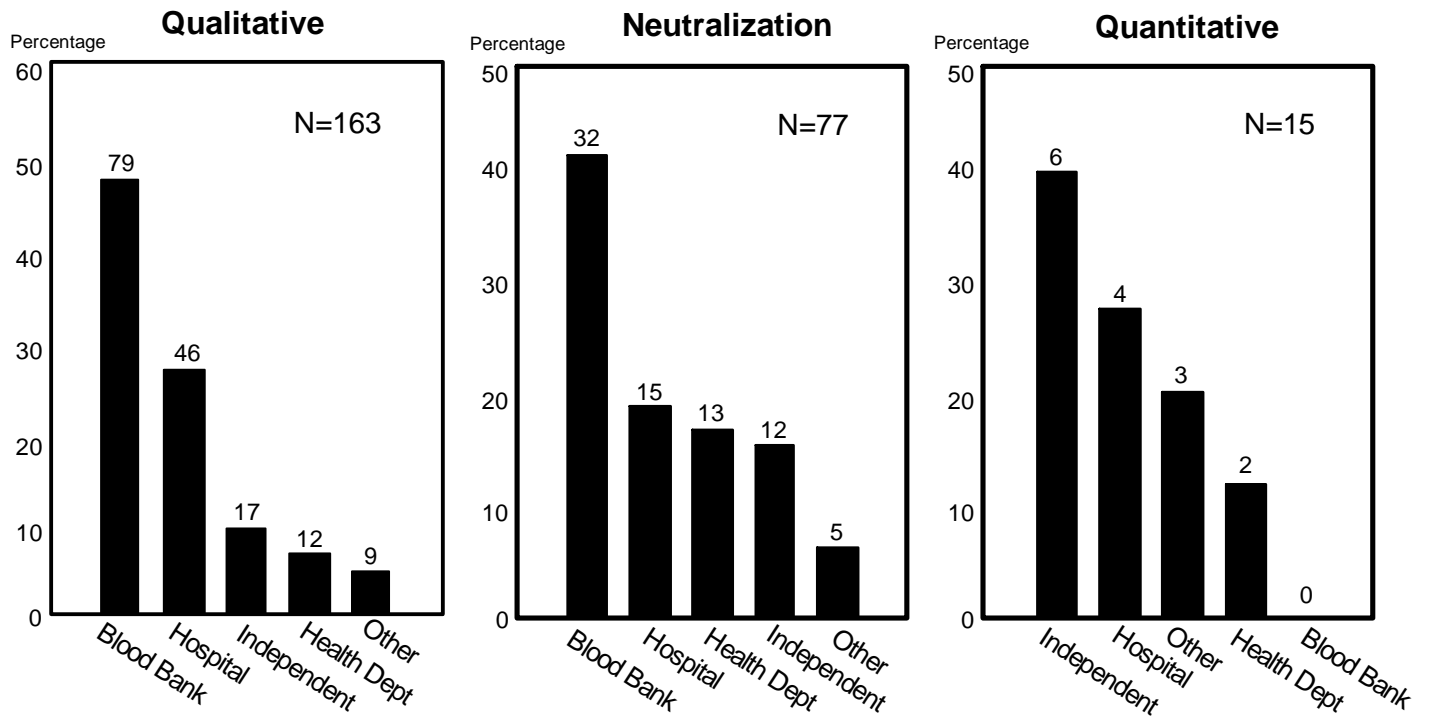


Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the March 1, 1999, Shipment

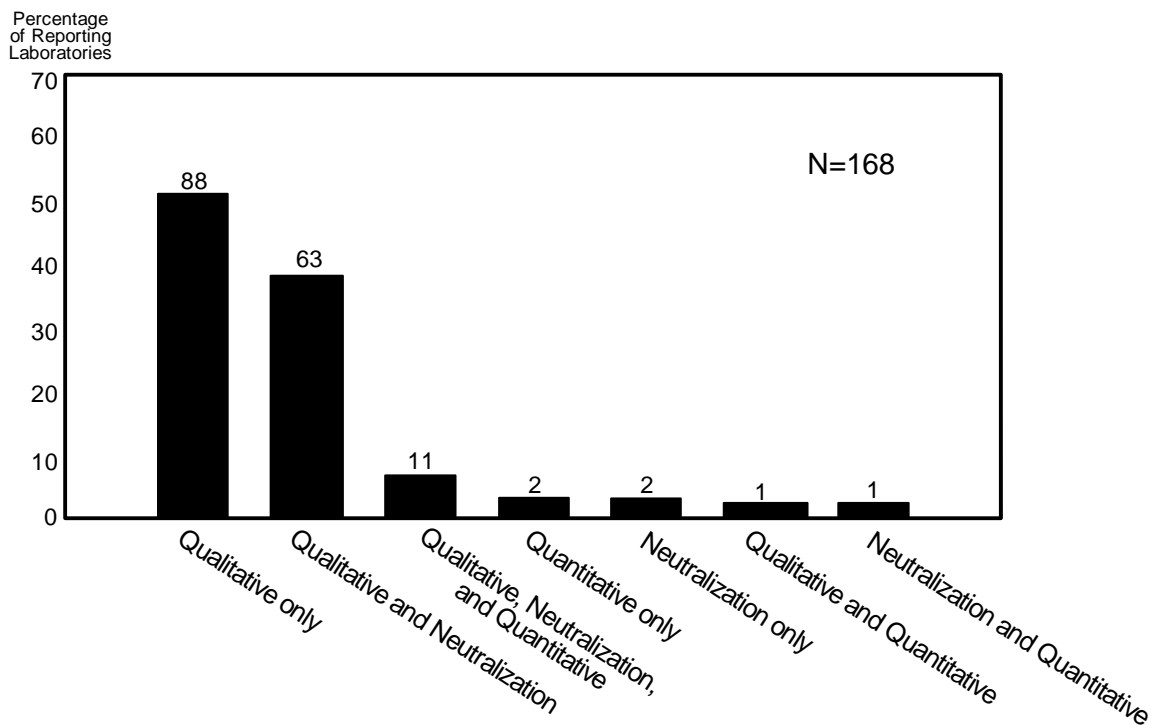
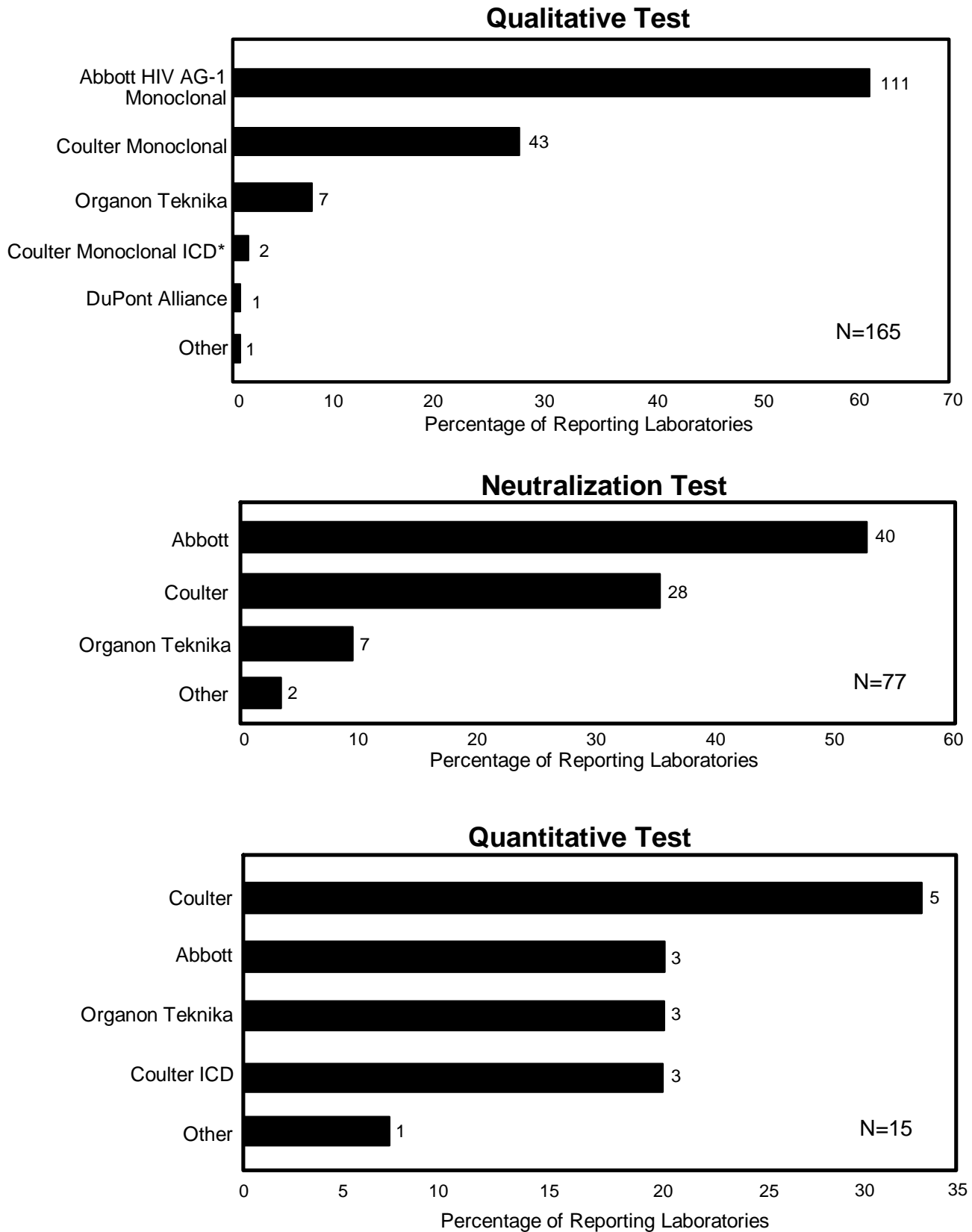
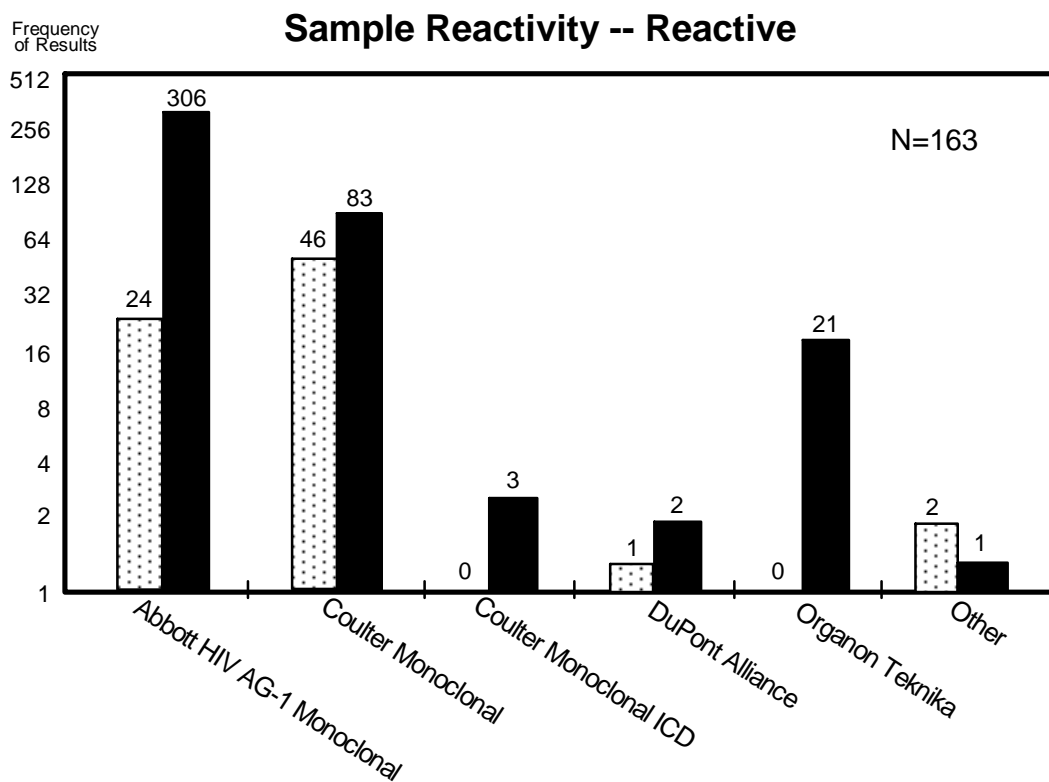
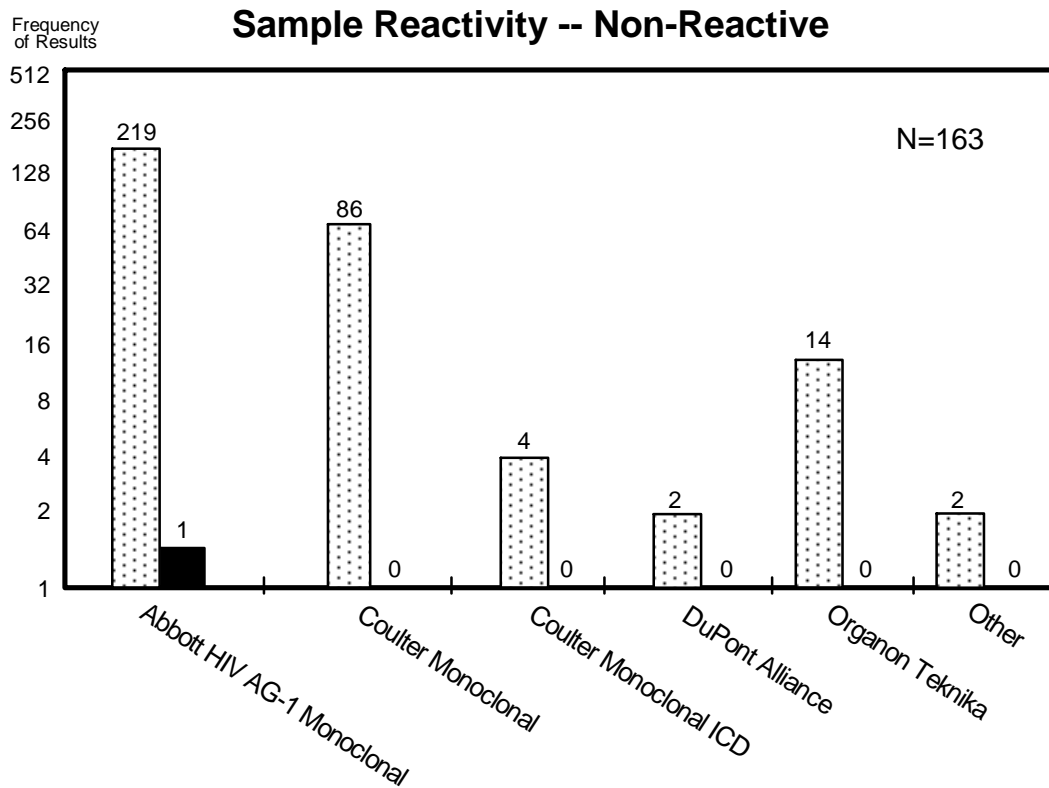


Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the March 1, 1999, Shipment



*ICD=Immune Complex Dissociation

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



Non-Reactive
 Reactive

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

Sample Reactivity -- Negative

See comments in accompanying analysis

Data not included from laboratories that tested negative donor samples but did not provide absorbance values and/or % neutralization calculations. Likewise, data not included from laboratories that did not perform neutralization tests on negative donor samples, but reported "negative" neutralization test interpretations.

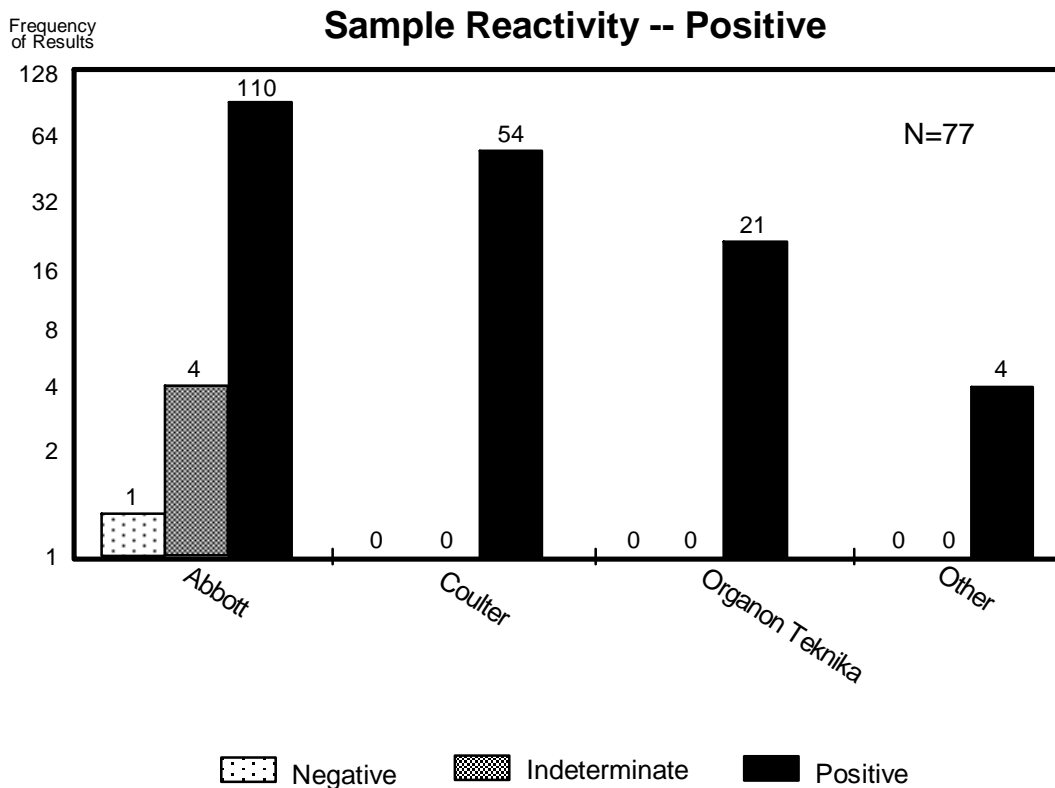


Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 1, 1999, Performance Evaluation Shipment

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

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	40	63.4	87.3	106.4
Coulter	Positive	28	66.3	81.2	96.6
Organon Teknika	Positive	7	80.0	86.0	90.3
Other	Positive	2	99.2	99.6	100.0

Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the March 1, 1999, Performance Evaluation Shipment (Continued)

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

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	35	55.8	72.5	101.7
	Indeterminate	2	18.3	33.6	48.9
Coulter	Positive	14	65.4	83.2	98.3
Organon Teknika	Positive	7	86.4	91.8	94.5
Other	Positive	1	99.6	99.6	99.6

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

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	35	50.0	72.6	92.2
	Indeterminate	2	57.6	65.2	72.9
	Negative	1	90.6	90.6	90.6
Coulter	Positive	12	52.6	83.1	101.5
Organon Teknika	Positive	7	81.7	90.9	92.4
Other	Positive	1	99.6	99.6	99.6

Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the March 1, 1999, Performance Evaluation Shipment

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

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	3	13.4	26.4	61.7
Coulter	5	8.9	27.8	294.4
Coulter ICD	3	274.8	304.0	529.0
Organon Teknika	3	24.6	35.7	64.4
Other	1	77.9	77.9	77.9

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

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

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	3	6.1	17.4	93.8
Coulter	5	9.3	13.0	669.1
Coulter ICD	3	261	606.8	907.0
Organon Teknika	3	12.9	28.9	70.9
Other	1	86.6	86.6	86.6

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

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	3	9.2	17.4	100.0
Coulter	4	2.9	11.9	689.7
Coulter ICD	2	598.1	673.5	749.0
Organon Teknika	3	15.3	27.0	70.7
Other	1	87.5	87.5	87.5