

**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 11, 2000 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**



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 September 11, 2000 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., M.P.H., Director  
.....Thomas L. Hearn, Ph.D., Deputy Director

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.....Marianne K. Simon, M.P.H.,  
HIV-1 Project Coordinator

---

Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-8125 or (770) 488-8098.

**Centers for Disease Control and Prevention (CDC)  
Model Performance Evaluation Program  
Human Immunodeficiency Virus Type 1 (HIV-1) p24 Antigen Testing  
September 11, 2000 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, A4	7	Positive	Infected	_____	_____	_____
	A2	5	Positive	Infected	_____	_____	_____
	A3	1	Negative	Uninfected	_____	_____	_____
	A5	2	Negative	Uninfected	_____	_____	_____
B	B1	1	Negative	Uninfected	_____	_____	_____
	B2, B5	7	Positive	Infected	_____	_____	_____
	B3	5	Positive	Infected	_____	_____	_____
	B4	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 manufacturer's 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 11, 2000 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, A4	7	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb <sup>3</sup> Coulter HIV-1 p24 Antigen	Positive Positive
	A2	5	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	A3	1	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	A5	2	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
B	B1	1	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	B2, B5	7	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B3	5	P24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B4	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).

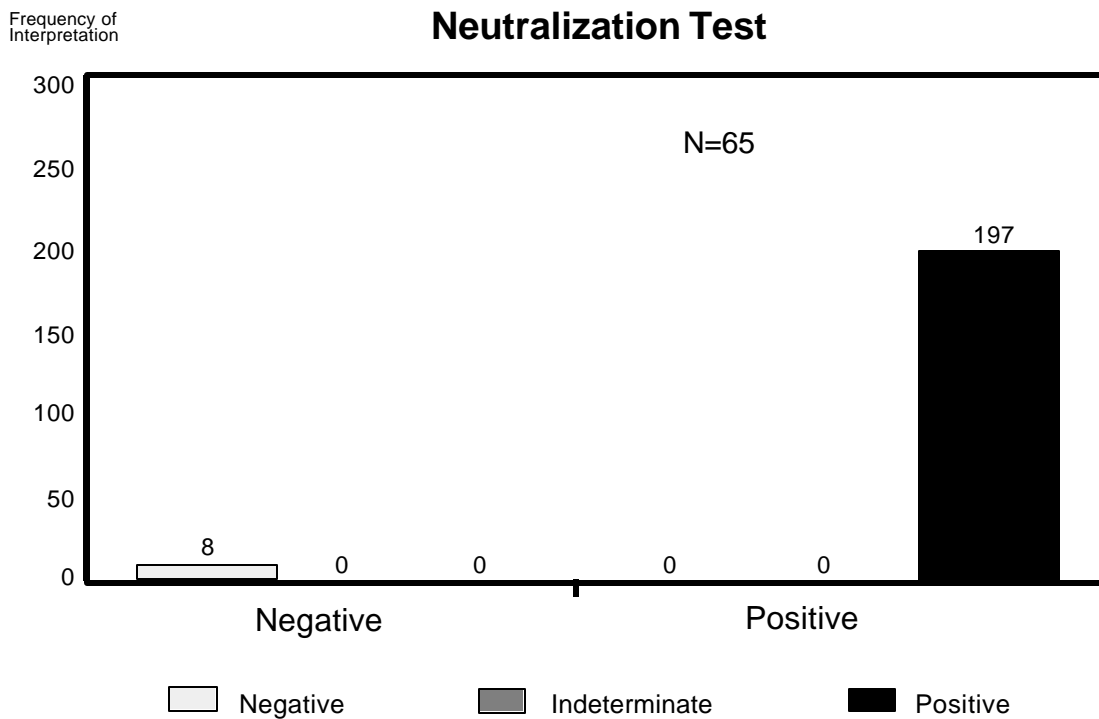
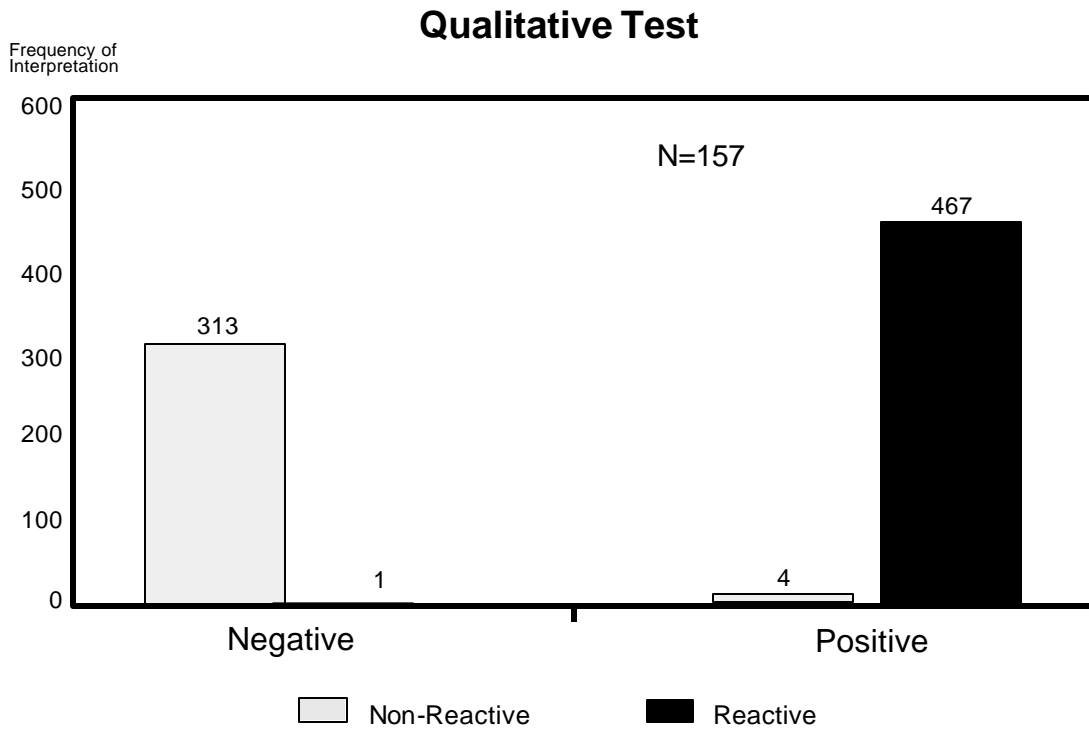
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.  
Positive = Presence of HIV-1 p24 antigen confirmed; Negative = p24 antigen not detected.

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

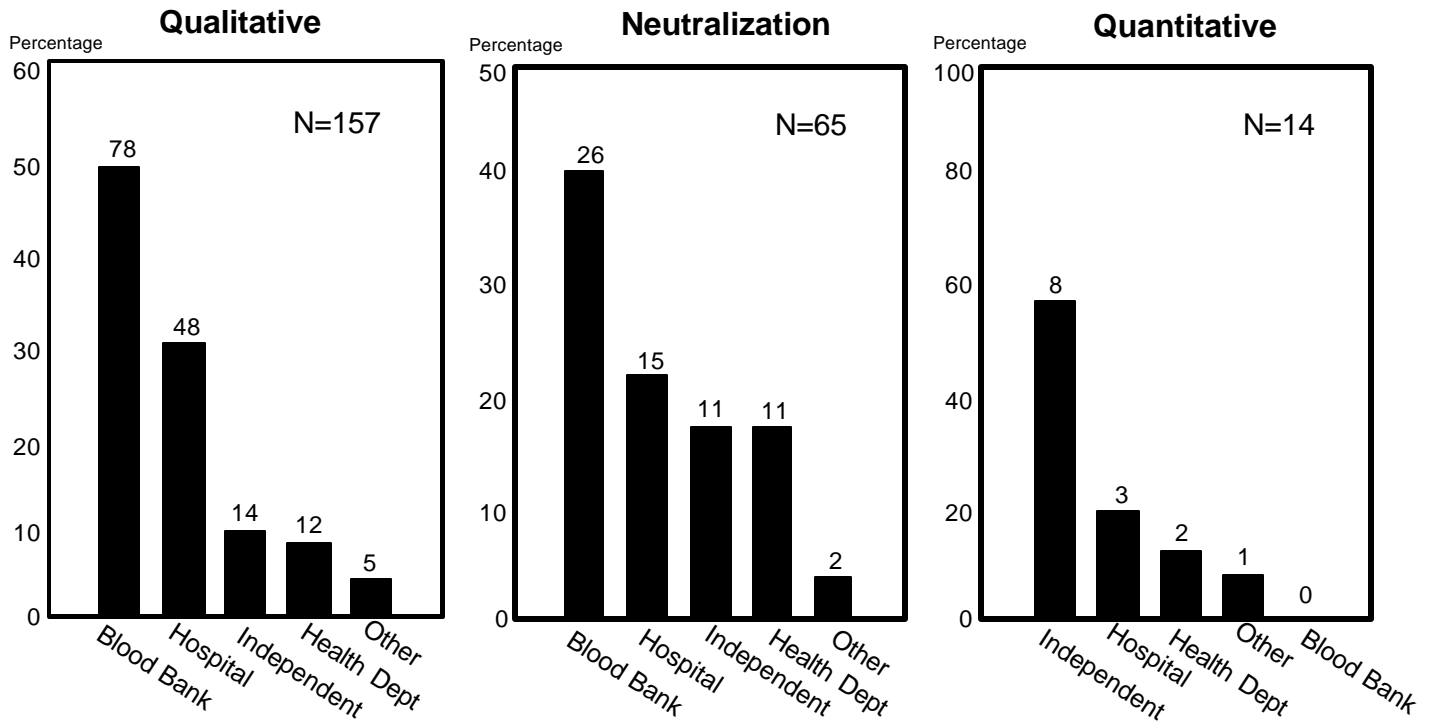
**SUPPLEMENTAL INFORMATION FOR COMPREHENDING  
THE NUMBERS USED TO LABEL FIGURES  
IN THIS REPORT**

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.

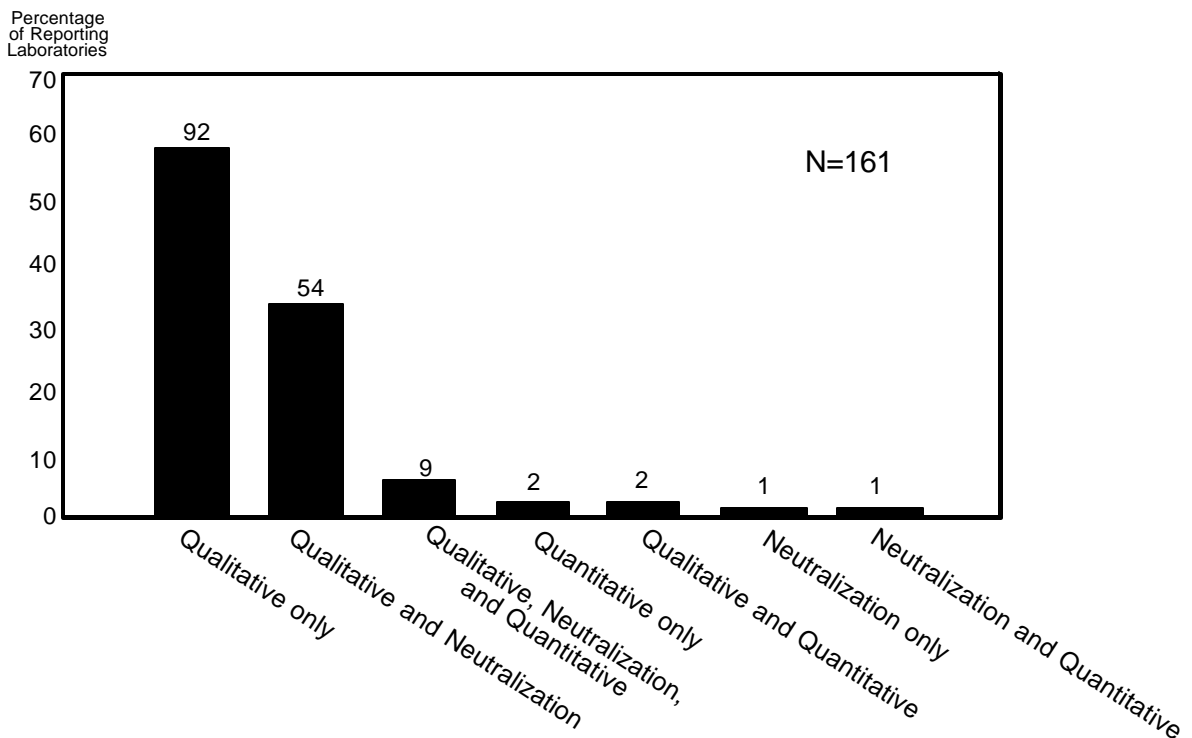
**Figure 1. Frequency of HIV-1 p24 Antigen Test Result Interpretations, by Sample Type (Reactivity), for Qualitative and Neutralization Tests Reported by Participant Laboratories for the September 11, 2000 Shipment**



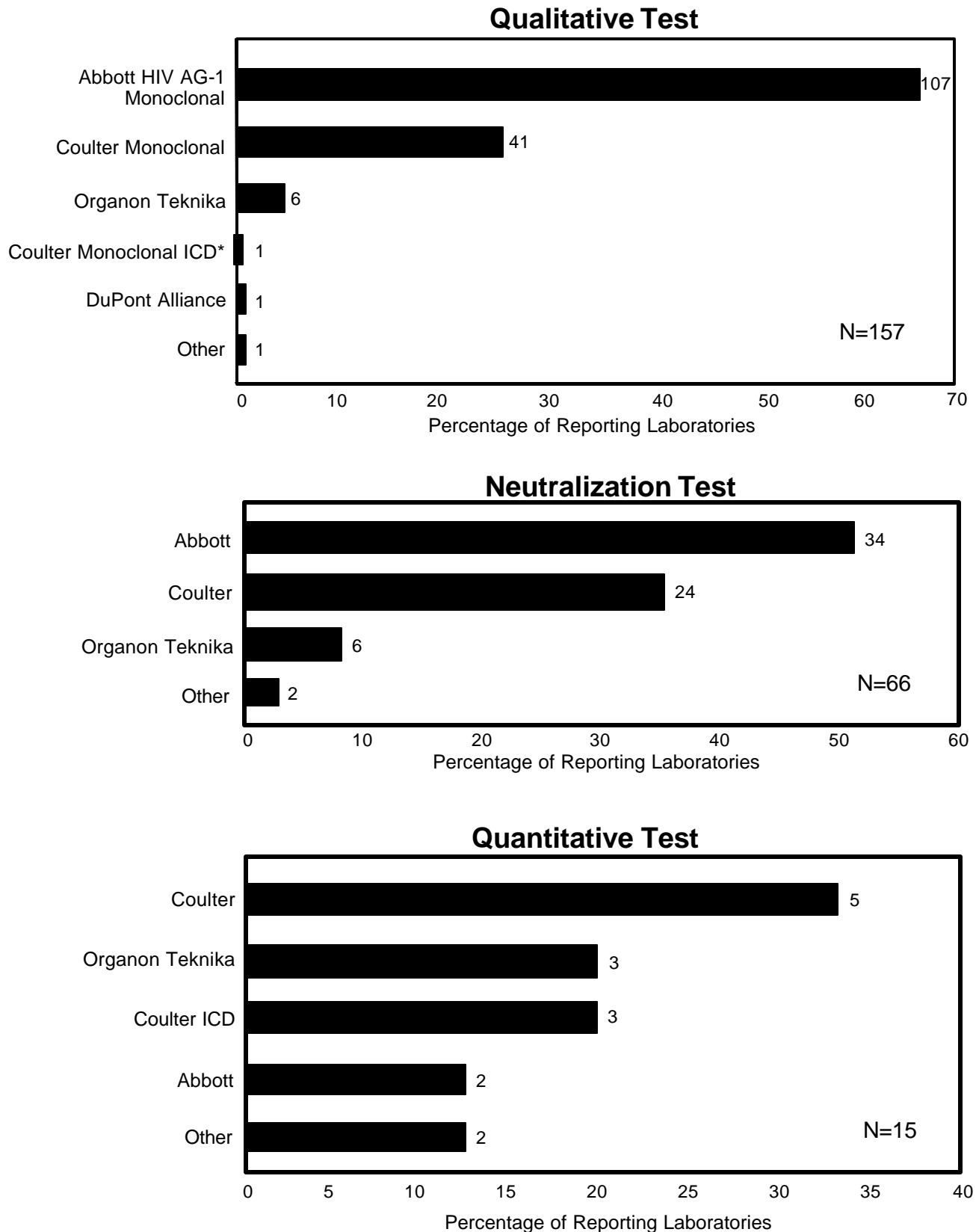
**Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the September 11, 2000 Shipment**



**Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the September 11, 2000 Shipment**



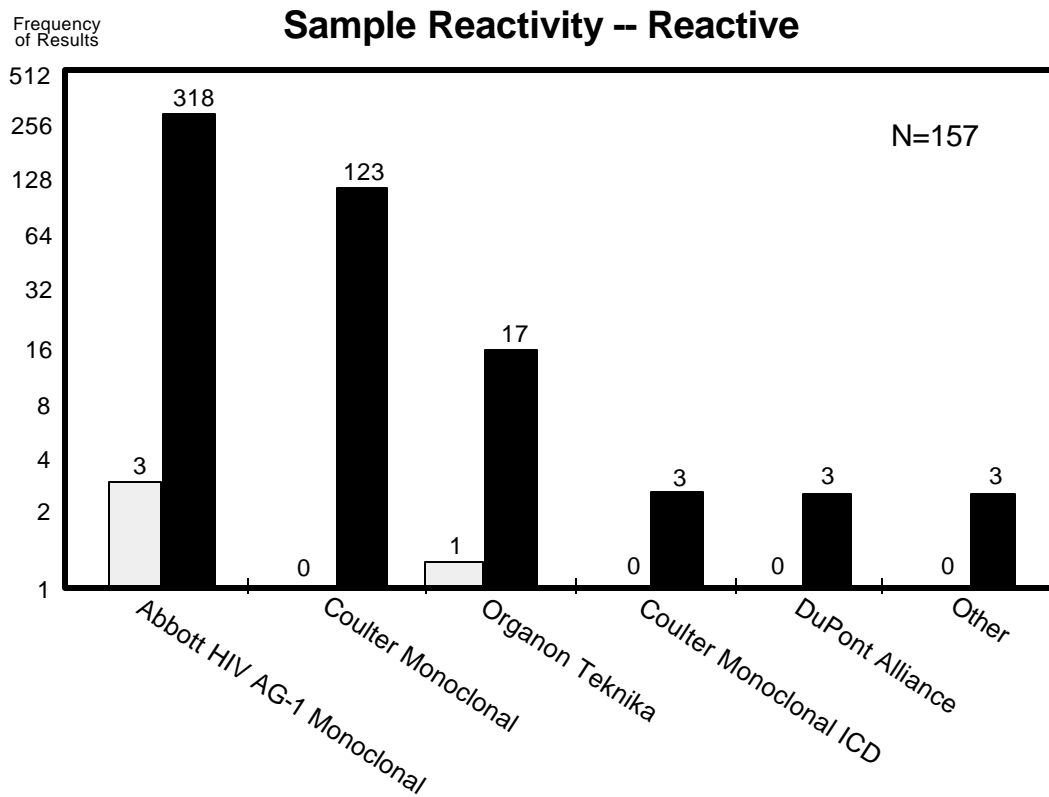
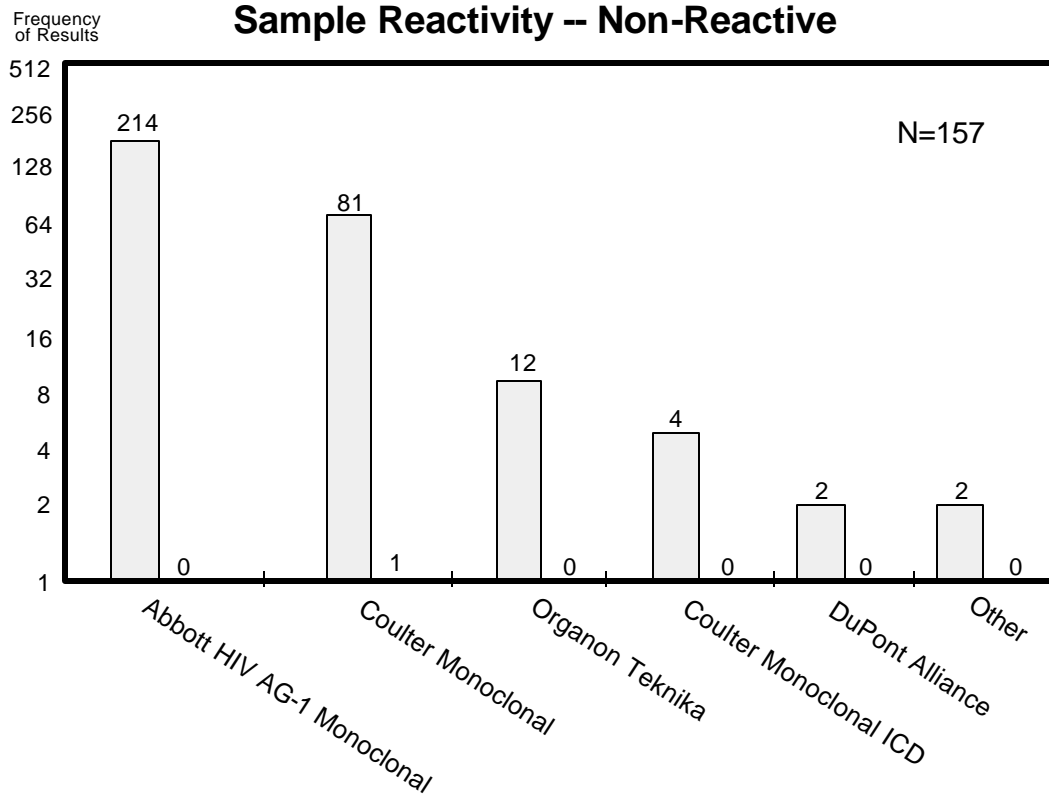
**Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the September 11, 2000 Shipment**



\*ICD=Immune Complex Dissociation

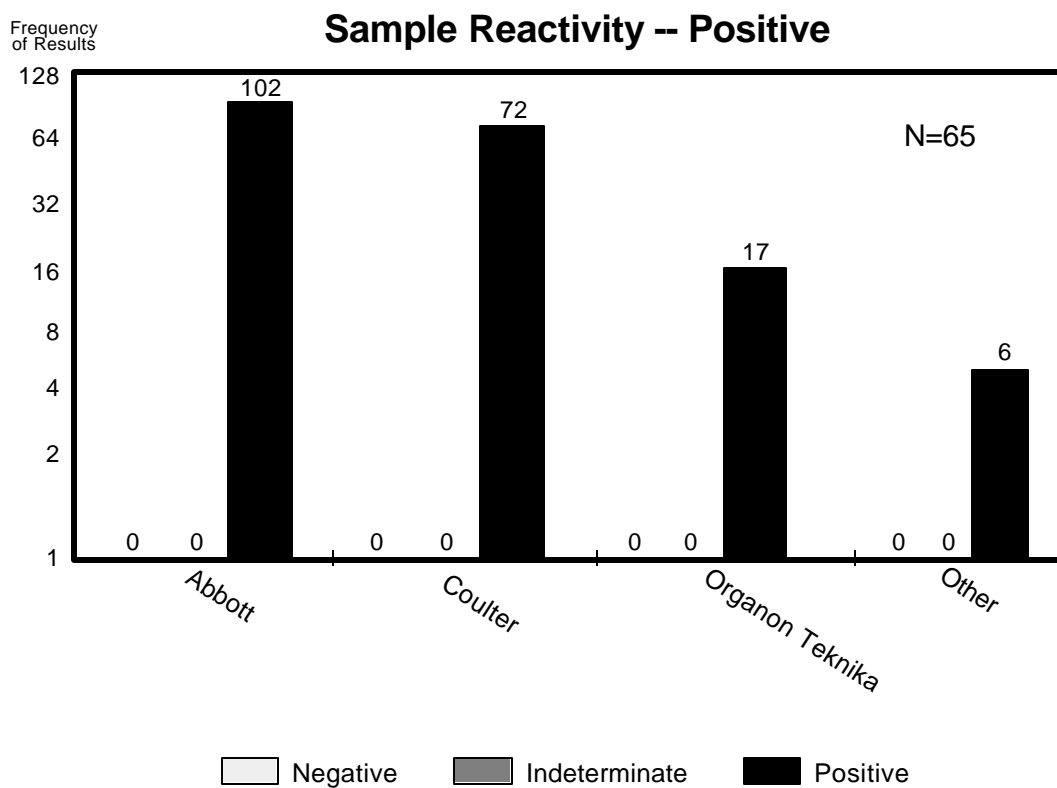
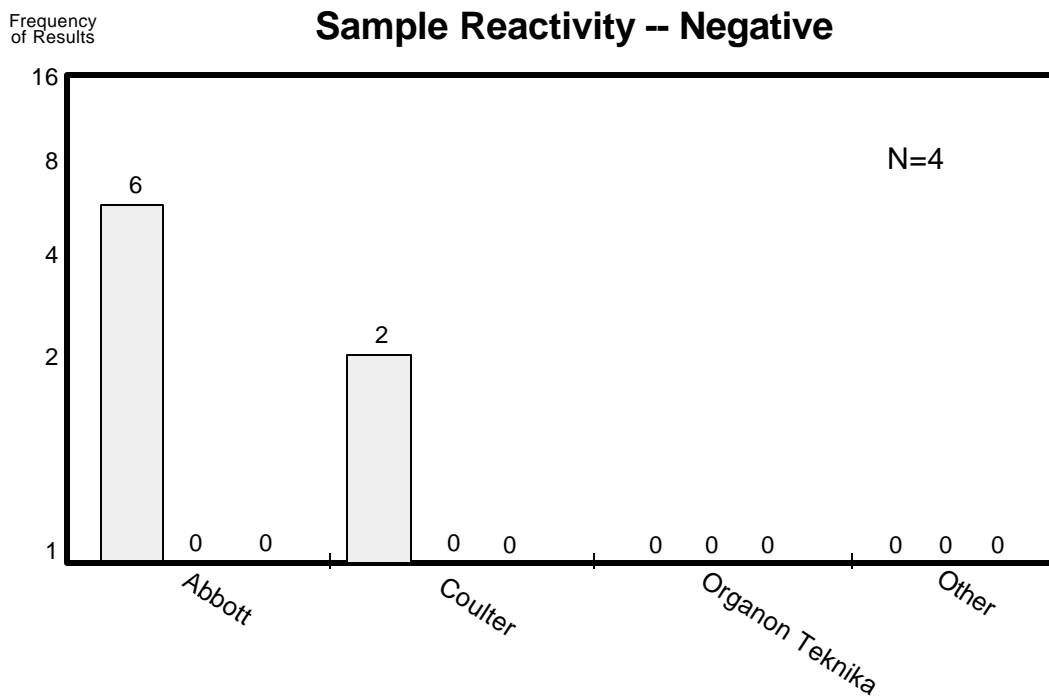


**Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 11, 2000 Shipment**



Non-Reactive
  Reactive

**Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the September 11, 2000 Shipment**



**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 11, 2000 Performance Evaluation Shipment**

**CDC Donor #5  
 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	34	96.6	101.0	108.3
Coulter	Positive	24	76.4	94.6	104.2
Organon Teknika	Positive	6	83.8	90.4	93.9
Other	Positive	2	100.0	101.7	103.4

**Table 3. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the September 11, 2000 Performance Evaluation Shipment (Continued)**

**CDC Donor #7**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A1, B2**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	34	61.2	101.0	108.6
Coulter	Positive	24	81.8	93.2	100.7
Organon Teknika	Positive	5	78.6	93.1	95.9
Other	Positive	2	100.0	102.0	104.0

**CDC Donor #7 - Duplicate**  
**Donor Status: HIV-1 Infected**  
**Panel Vial Labels: A4, B5**

Test Kit	Test Interpretation	No. of Tests	Range of Test Results Reported % Neutralization		
			minimum	median	maximum
Abbott	Positive	34	97.0	100.8	110.3
Coulter	Positive	24	75.0	93.5	101.7
Organon Teknika	Positive	6	82.1	91.7	97.6
Other	Positive	2	100.0	102.3	104.6

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 11, 2000 Performance Evaluation Shipment**

**CDC Donor #5  
 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	2	29.3	32.0	34.6
Coulter	5	26.5	31.5	50.1
Coulter ICD	3	59.9	66.8	70.9
Organon Teknika	3	6.4	19.0	69.5
Other	2	18.6	32.3	46.0

**Table 4. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the September 11, 2000 Performance Evaluation Shipment (Continued)**

**CDC Donor #7  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A1, B2**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	2	17.9	22.8	27.6
Coulter	5	59.8	66.0	83.6
Coulter ICD	3	84.2	88.9	98.8
Organon Teknika	3	9.0	18.8	46.5
Other	2	24.7	31.4	38.0

**CDC Donor #7 - Duplicate  
Donor Status: HIV-1 Infected  
Panel Vial Labels: A4, B5**

Test Kit	No. of Tests	Range of Test Results Reported p24 Antigen Concentration (pg/ml)		
		minimum	median	maximum
Abbott	2	20.0	23.0	26.0
Coulter	5	50.3	67.0	75.7
Coulter ICD	3	83.1	90.2	110.8
Organon Teknika	3	7.1	23.0	46.7
Other	2	16.7	27.4	38.0