

**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 5, 2002 Performance Evaluation
Testing Results Reported by Participant Laboratories**

Report of the March 5, 2002 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
 March 5, 2002 Participant Laboratory Shipment**

Table 1

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result ¹	Donor HIV Status	Laboratory Interpretation ²		
					QUAL ³	NEUT ⁴	QUANT ⁵
A	A1	2	Positive	Infected			
	A2,A4	3	Positive	Infected			
	A3	4	Negative	Uninfected			
	A5	5	Negative	Uninfected			
B	B1,B5	3	Positive	Infected			
	B2	4	Negative	Uninfected			
	B3	2	Positive	Infected			
	B4	5	Negative	Uninfected			

¹ 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.

² Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

³ p24 Antigen Qualitative Test

⁴ p24 Antigen Neutralization (Blocking Antibody) Test

⁵ 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 March 5, 2002 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results¹	Test Kit Manufacturer	CDC Interpretation²
A	A1	2	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb³ Coulter HIV-1 p24 Antigen	Positive Positive
	A2, A4	3	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	A3	4	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	A5	5	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
B	B1, B5	3	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B2	4	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative
	B3	2	p24 Antigen detected p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Positive Positive
	B4	5	No p24 Antigen detected No p24 Antigen detected	Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen	Negative Negative

¹ 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).

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

**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 AN=@ 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 March 5, 2002 Shipment

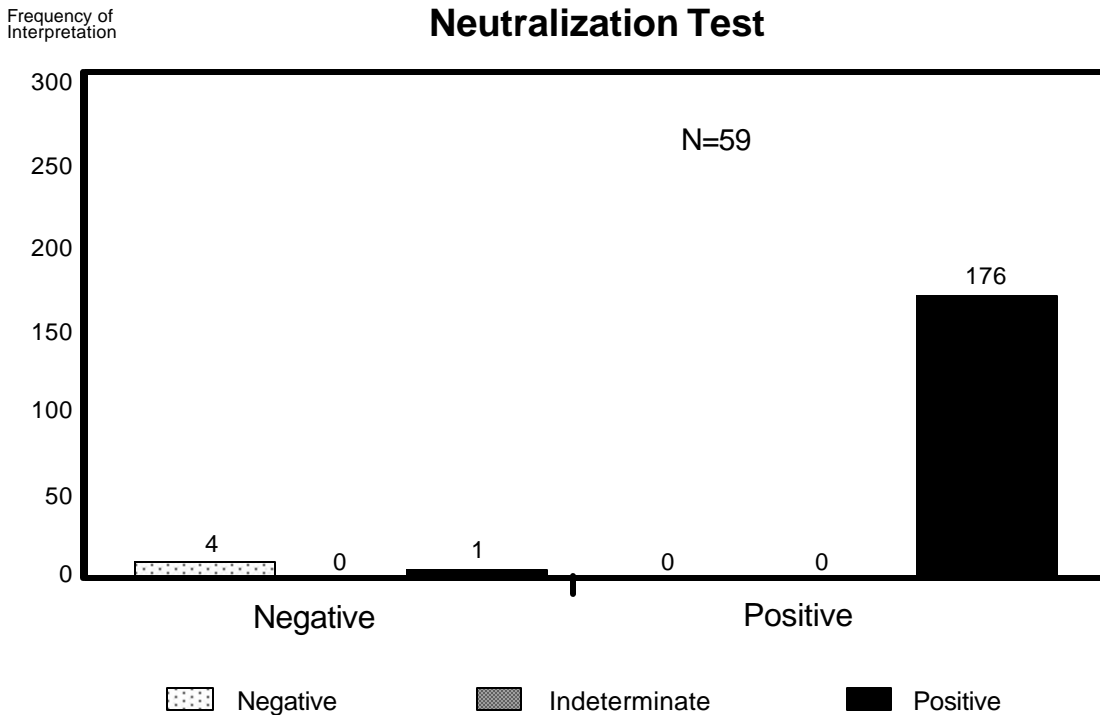
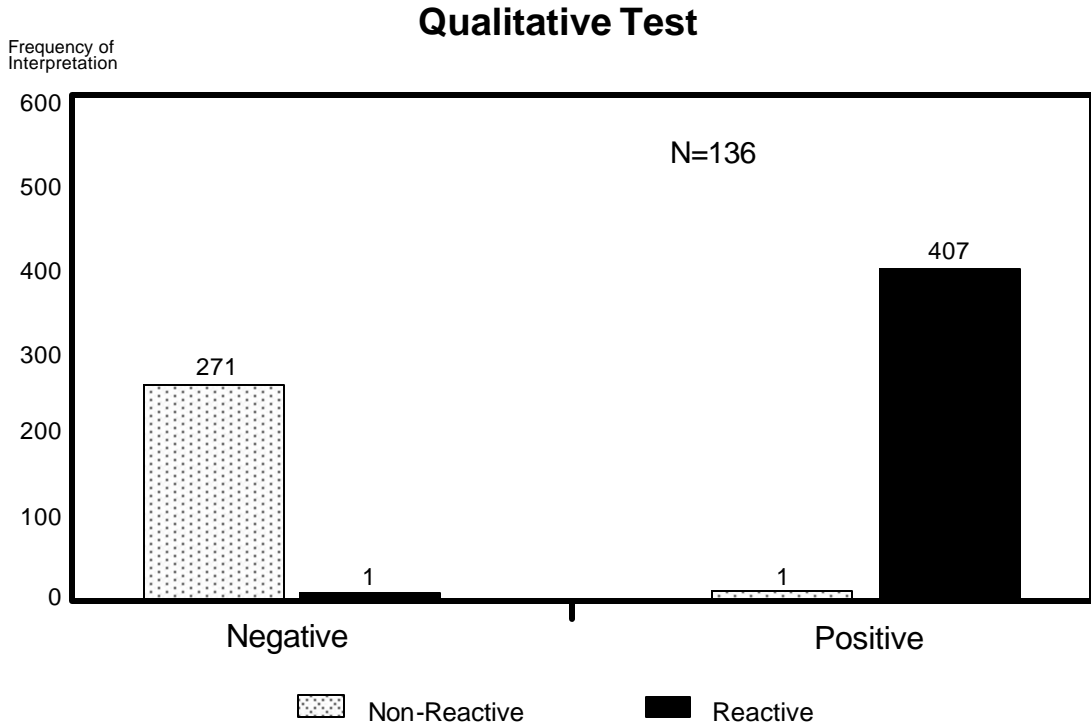


Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the March 5, 2002 Shipment

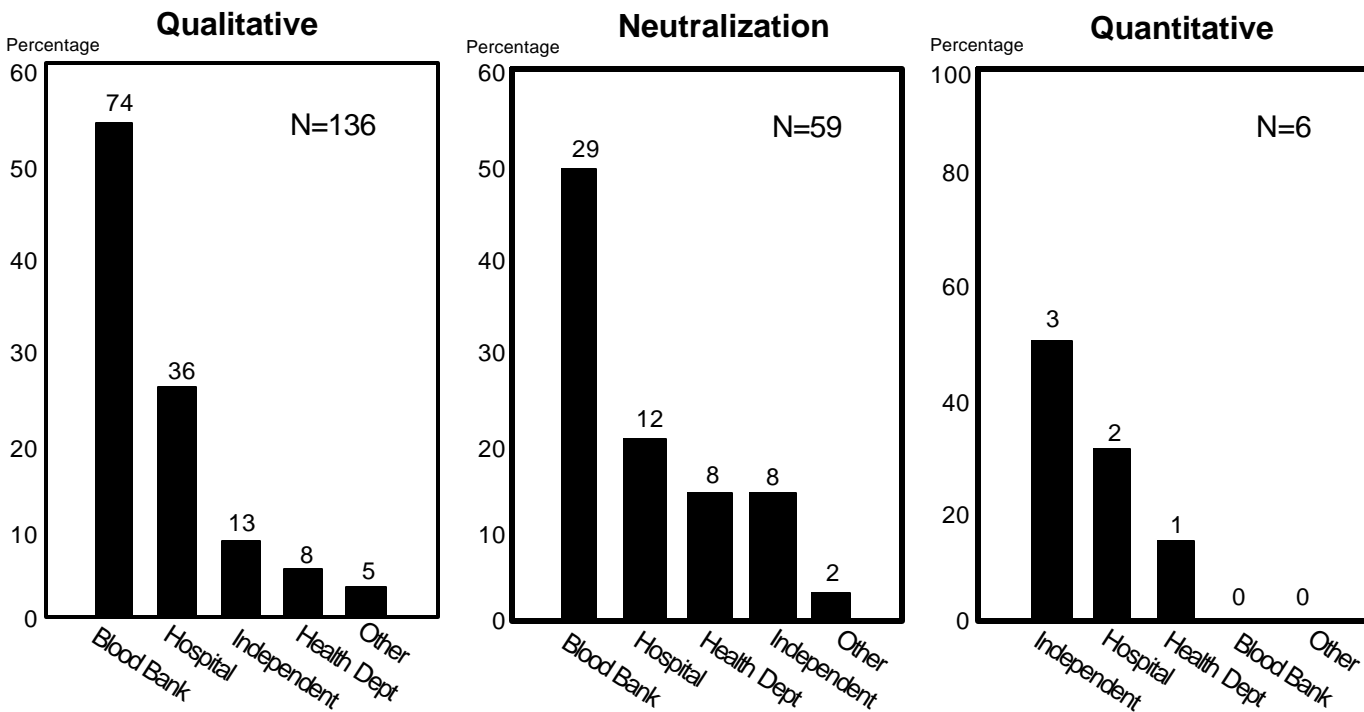


Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the March 5, 2002 Shipment

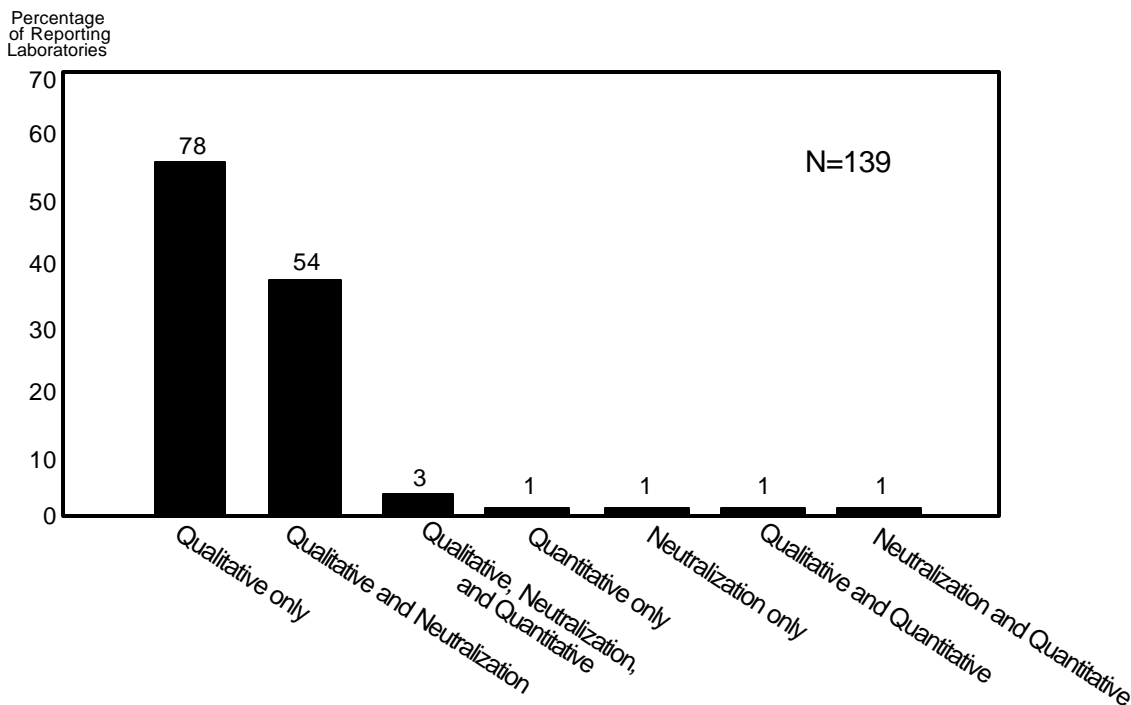
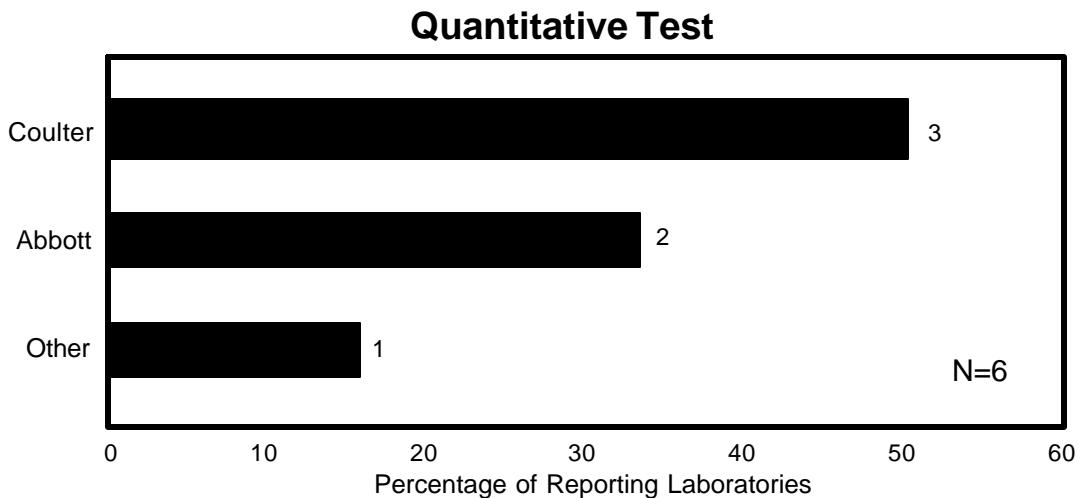
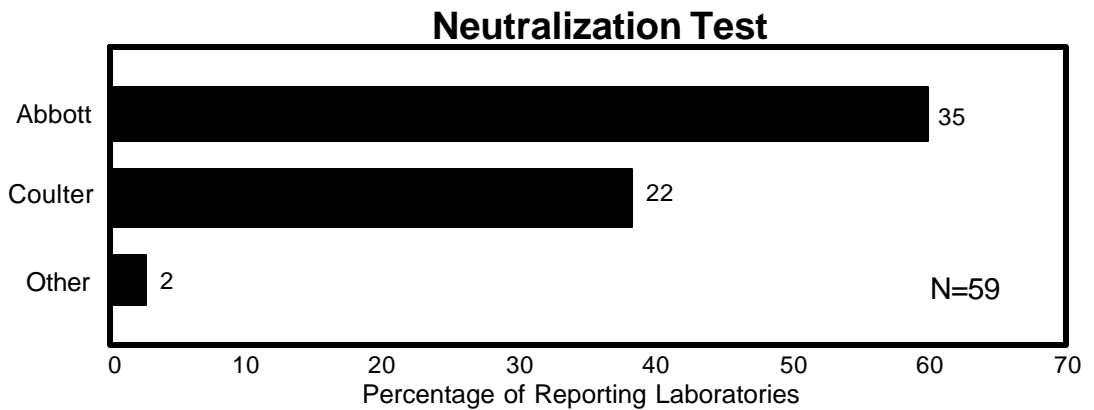
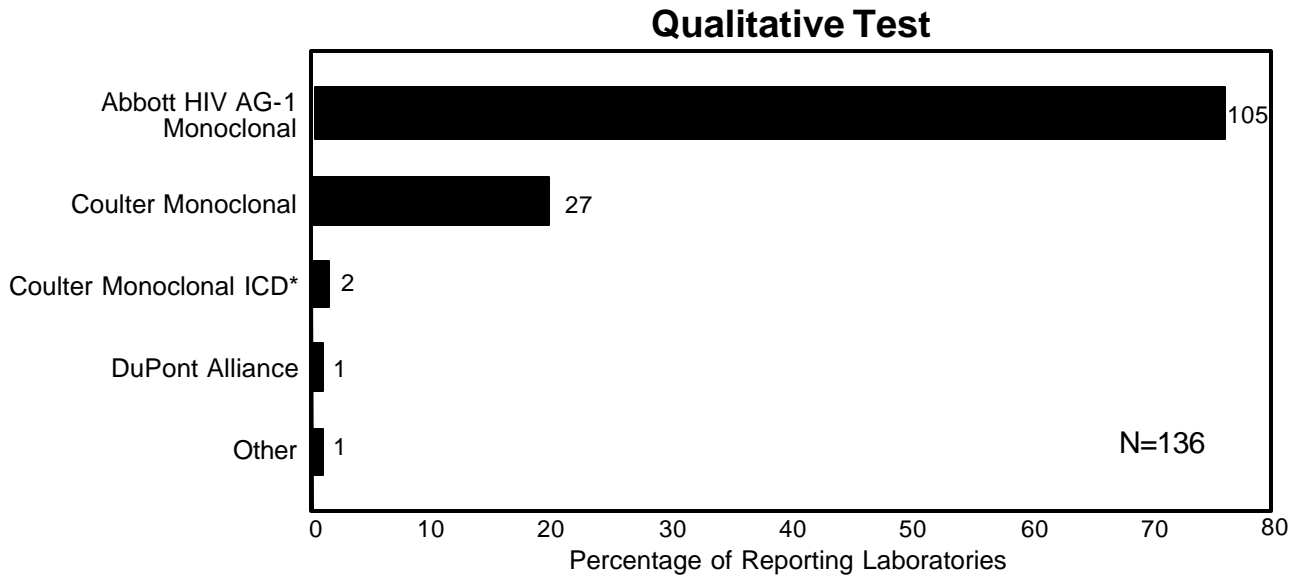
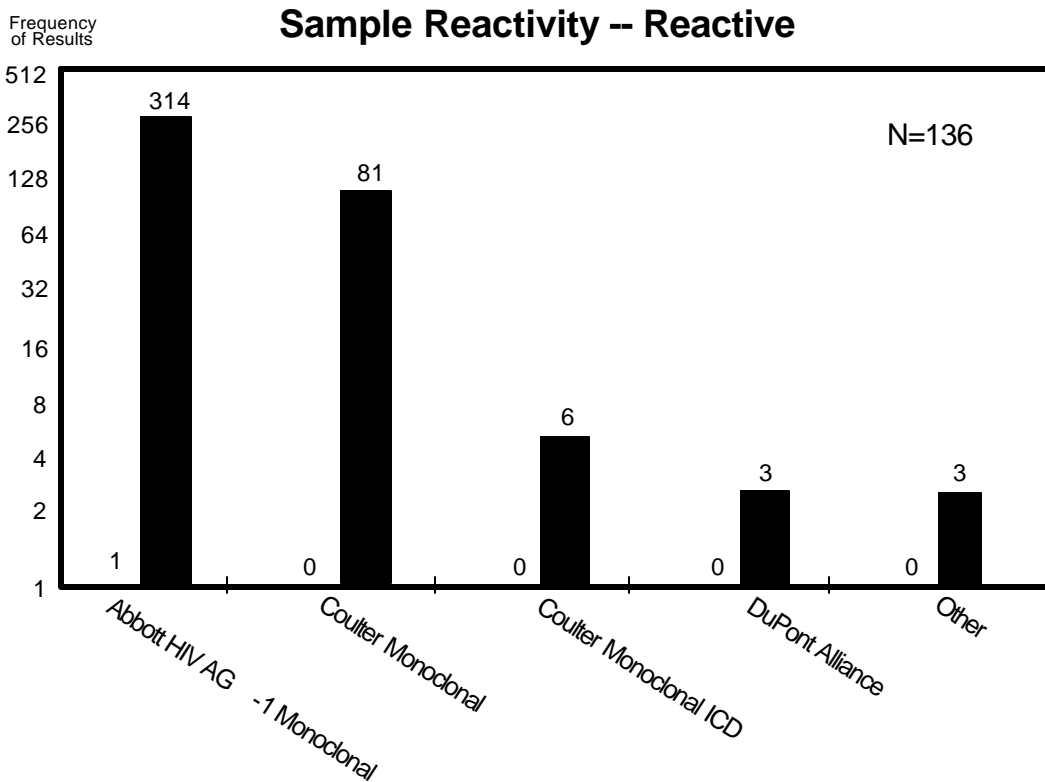
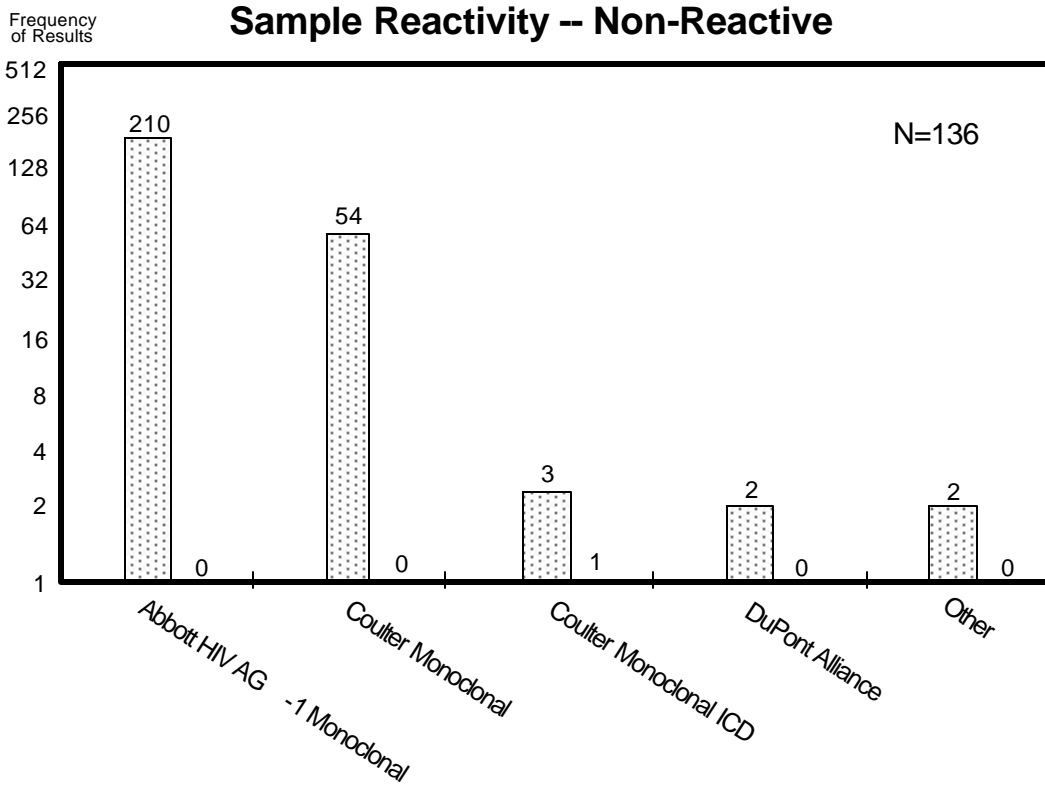


Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the March 5, 2002 Shipment



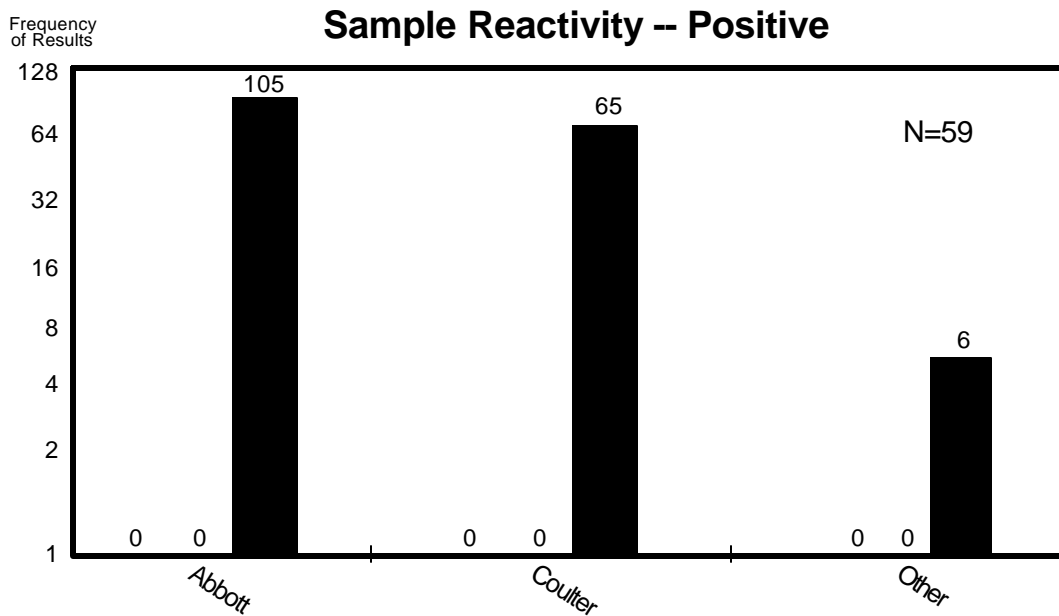
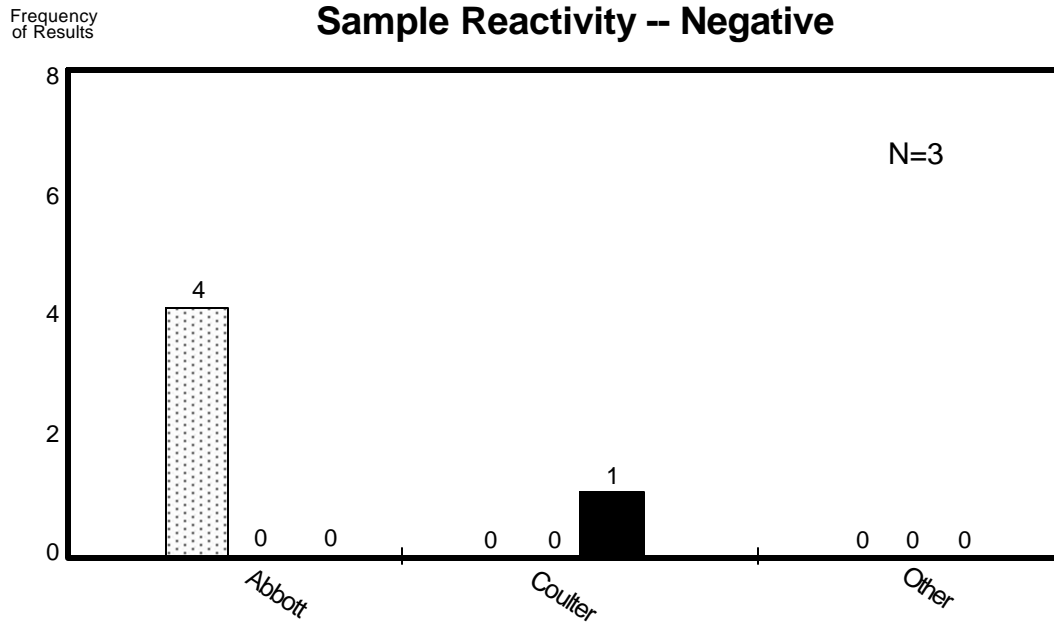
*ICD=Immune Complex Dissociation

Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 5, 2002 Shipment



Non-Reactive
 Reactive

Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the March 5, 2002 Shipment



Negative
 Indeterminate
 Positive