

**Centers for Disease Control and Prevention
Model Performance Evaluation Program
Human Immunodeficiency Virus Type 1 (HIV-1)
Ribonucleic Acid (RNA) Determinations**

**Figures Used for the Analysis
of the June 23, 1997 Performance Evaluation
Testing Results Reported by Participant Laboratories**



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Report of the June 23, 1997 Human Immunodeficiency Virus Type I (HIV-1) Viral Ribonucleic Acid (RNA) Determinations Performance Evaluation Sample Testing Results Provided by Laboratories Participating in the Model Performance Evaluation Program (MPEP), 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) Viral Load Testing**

**Table 1. CDC Viral Load Testing Results for the June 23, 1997
Participant Laboratory Panel Samples**

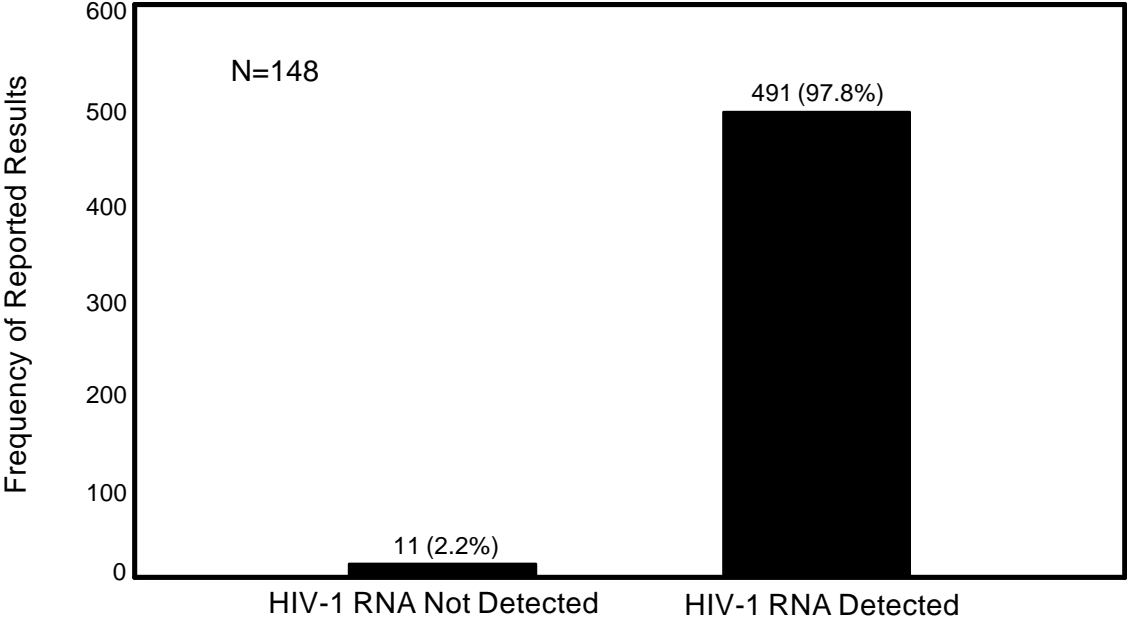
Panel Letter	Vial Label	CDC Donor Number	CDC Test Results ¹	Test Kit Manufacturer	CDC Interpretation ²
A	A1, A4	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	A2	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	A3	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	A5	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
B	B1	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	B2, B5	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	B3	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	B4	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
C	C1, C3	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	C2	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	C4	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	C5	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
D	D1	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	D2, D4	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	D3	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	D5	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative

¹ The CDC results are based on testing provided by two laboratories for each manufacturer's test kit.

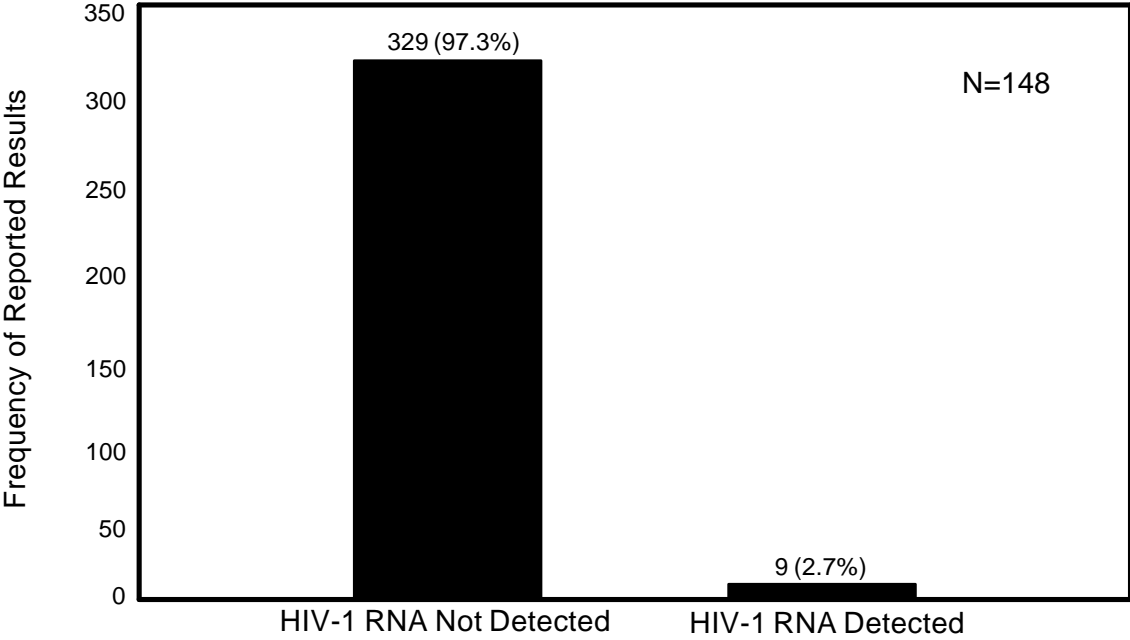
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.

Positive = HIV-1 RNA detected; Negative = HIV-1 RNA not detected (based on lower limits of test kit sensitivity).

Figure 1. Summary of Results Reported by Participant Laboratories for HIV-1 RNA Determinations in the June 1997 shipment



Results of HIV-1 RNA Determinations Reported for the Three HIV-1 Infected Donors with Detectable HIV-1 RNA



Results of HIV-1 RNA Determinations Reported for the Two Non-HIV-1 Infected Donors

Figure 2. Types of Laboratories Performing HIV-1 Viral RNA Determinations in the June 1997 Panel Shipment

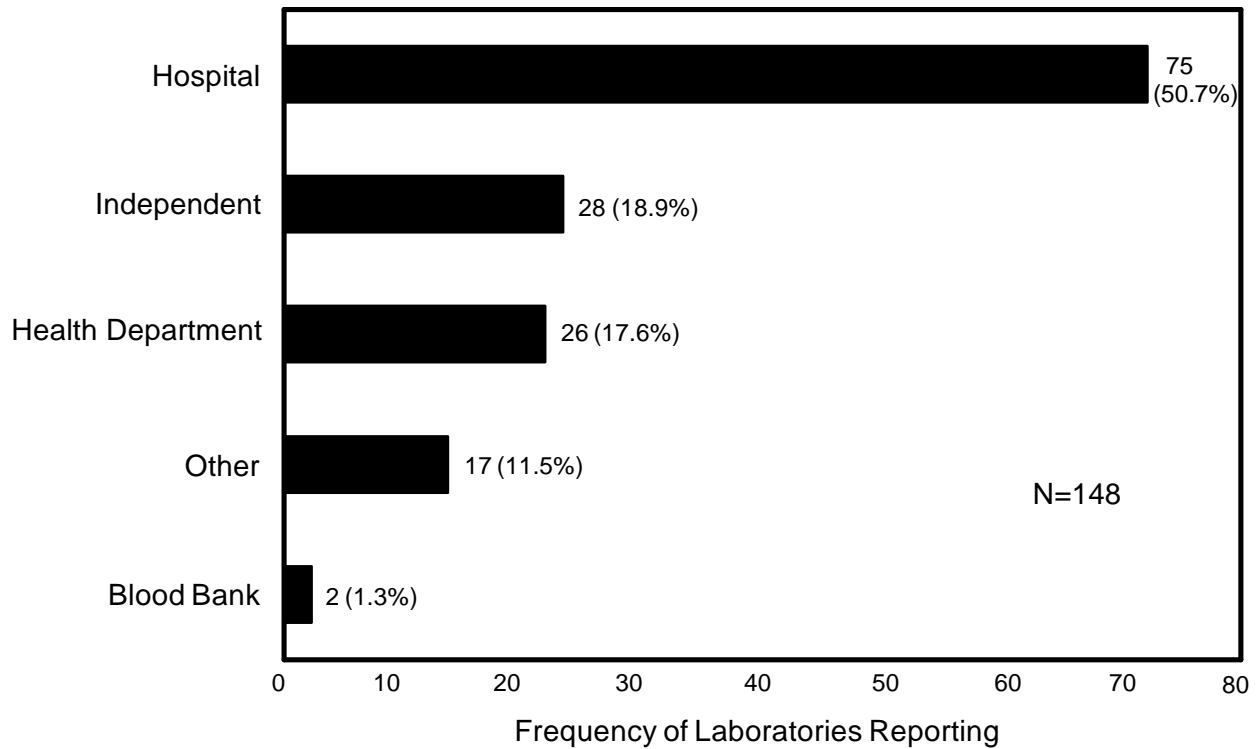


Figure 3. Types of Test Kits Used to Perform HIV-1 Viral RNA Determinations in the June 1997 Panel Shipment

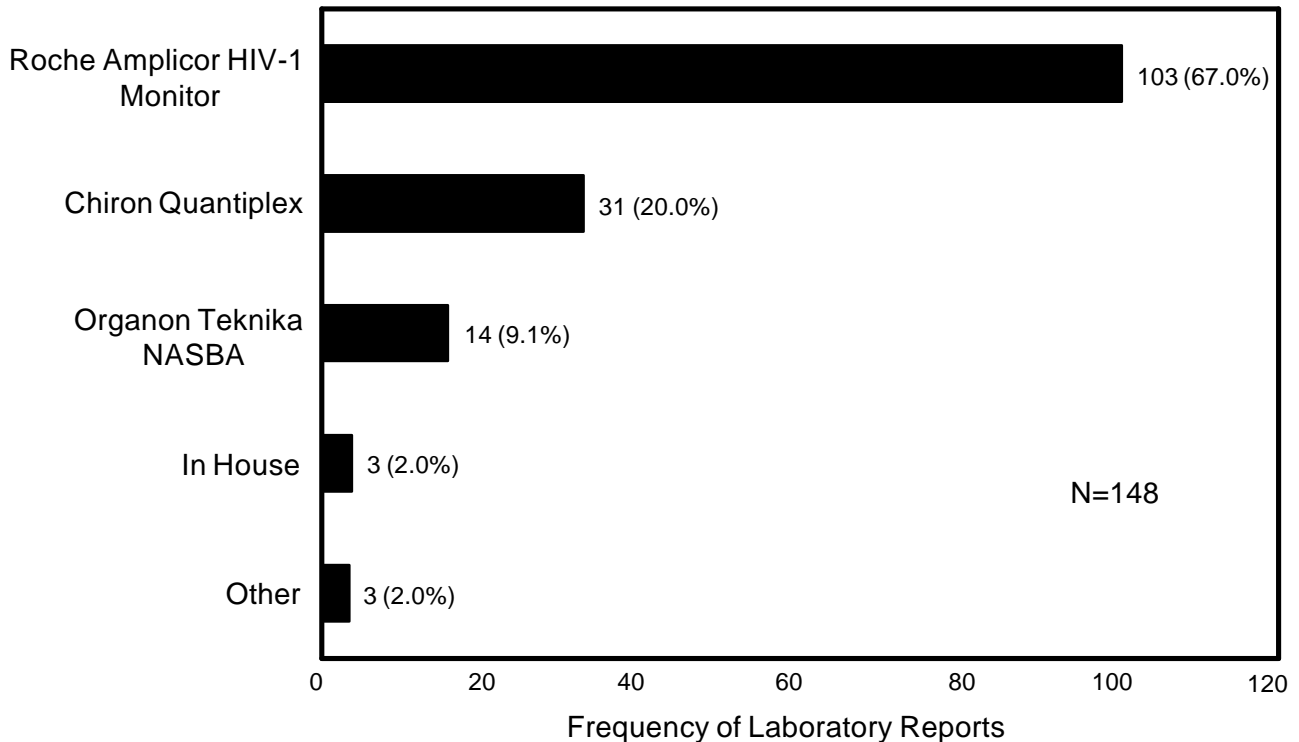


Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1997 Performance Evaluation Shipment.

CDC Donor #1

Donor Status: HIV-1 Infected and HIV-1 RNA Detected

Panel Vial Labels: A1, B2, C1, D2

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Results Reported (RNA copies/ml)		
			minimum	median	maximum
Roche Amplicor HIV-1 Monitor™	111	1	3,423	6,830	16,630
Chiron Quantiplex™	31	1	781	2,295	6,290
Organon Teknika NASBA™	15	1	3,000	11,000	25,000
In House	3	0	500	700	4,184
Other	4	0	1,150	8,850	12,000

CDC Donor #1 Duplicate

Donor Status: HIV-1 Infected and HIV-1 RNA Detected

Panel Vial Labels: A4, B5, C3, D4

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Results Reported (RNA copies/ml)		
			minimum	median	maximum
Roche Amplicor HIV-1 Monitor™	111	1	2,000	6,923	42,188
Chiron Quantiplex™	31	0	615	2,403	4,684
Organon Teknika NASBA™	15	2	2,400	13,000	20,500
In House	3	0	400	600	4,135
Other	4	0	1,700	8,100	10,000

Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1997 Performance Evaluation Shipment.

CDC Donor #2

Donor Status: HIV-1 Infected and HIV-1 RNA Detected

Panel Vial Labels: A3, B4, C5, D1

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Results Reported (RNA copies/ml)		
			minimum	median	maximum
Roche Amplicor HIV-1 Monitor™	109	3	1,300	5,087	15,540
Chiron Quantiplex™	31	1	566	1,963	3,739
Organon Teknika NASBA™	16	1	2,600	8,900	39,000
In House	3	0	600	650	1,945
Other	4	0	680	9,750	13,000

Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1997 Performance Evaluation Shipment.

CDC Donor #3
Donor Status: HIV-1 Non-Infected
Panel Vial Labels: A2, B3, C4, D5

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Results Reported (RNA copies/ml)		
			minimum	median	maximum
Roche Amplicor HIV-1 Monitor™	4	108	<kit sens.	<kit sens.	9,787
Chiron Quantiplex™	0	32	<kit sens.	<kit sens.	<kit sens.
Organon Teknika NASBA™	1	17	<kit sens.	<kit sens.	2,000
In House	0	3	<kit sens.	<kit sens.	<kit sens.
Other	0	4	<kit sens.	<kit sens.	<kit sens.

CDC Donor #4
Donor Status: HIV-1 Non-Infected
Panel Vial Labels: A5, B1, C2, D3

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Results Reported (RNA copies/ml)		
			minimum	median	maximum
Roche Amplicor HIV-1 Monitor™	1	111	<kit sens.	<kit sens.	500
Chiron Quantiplex™	2	30	<kit sens.	<kit sens.	613
Organon Teknika NASBA™	1	17	<kit sens.	<kit sens.	2,500
In House	0	3	<kit sens.	<kit sens.	<kit sens.
Other	0	4	<kit sens.	<kit sens.	<kit sens.