

**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 8, 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**  
**Public Health Practice Program Office**  
**Division of Laboratory Systems**  
**Atlanta, Georgia 30333**



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Report of the June 8, 1998 Human Immunodeficiency virus type I (HIV-1)  
Ribonucleic Acid (RNA) 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) Ribonucleic Acid (RNA) Testing**

**Table 1. CDC HIV-1 RNA Testing Results for the June 8, 1998  
Participant Laboratory Panel Samples**

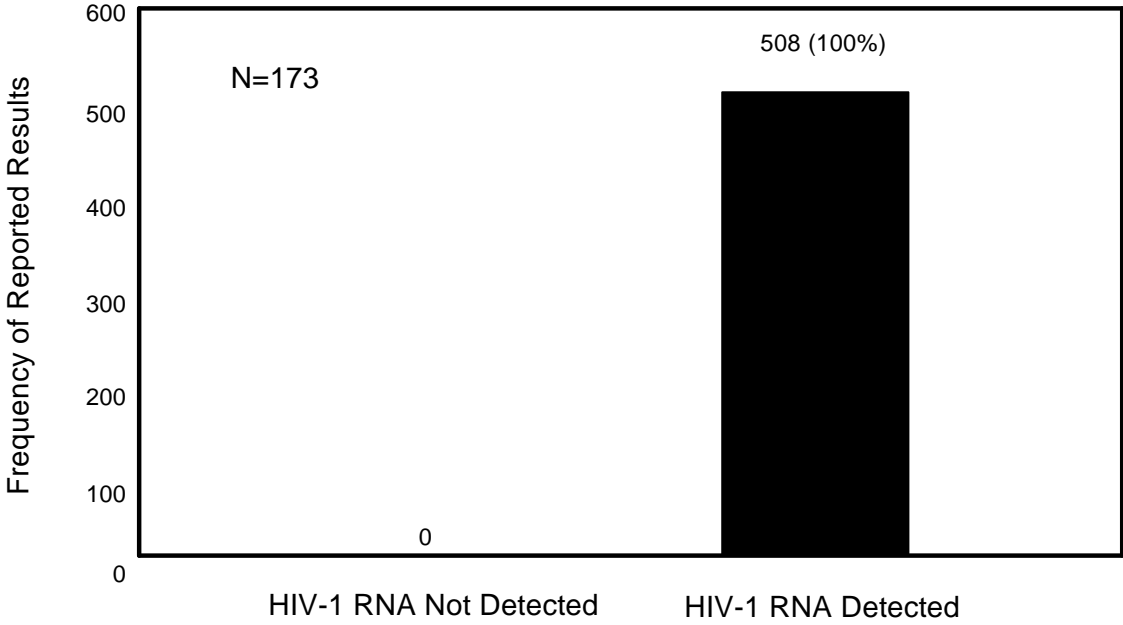
Panel Letter	Vial Label	CDC Donor Number	CDC Test Results <sup>1</sup>	Test Kit Manufacturer	CDC Interpretation <sup>2</sup>
A	A1, A4	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	A2	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	A3	03	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	A5	05	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
B	B1	05	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	B2, B5	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
	B3	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	B4	03	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	05	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	C4	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	C5	03	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Positive Positive Positive
D	D1	03	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	05	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative
	D5	04	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NASBA Chiron Quantiplex	Negative Negative Negative

<sup>1</sup> The CDC results are based on testing provided by two laboratories.

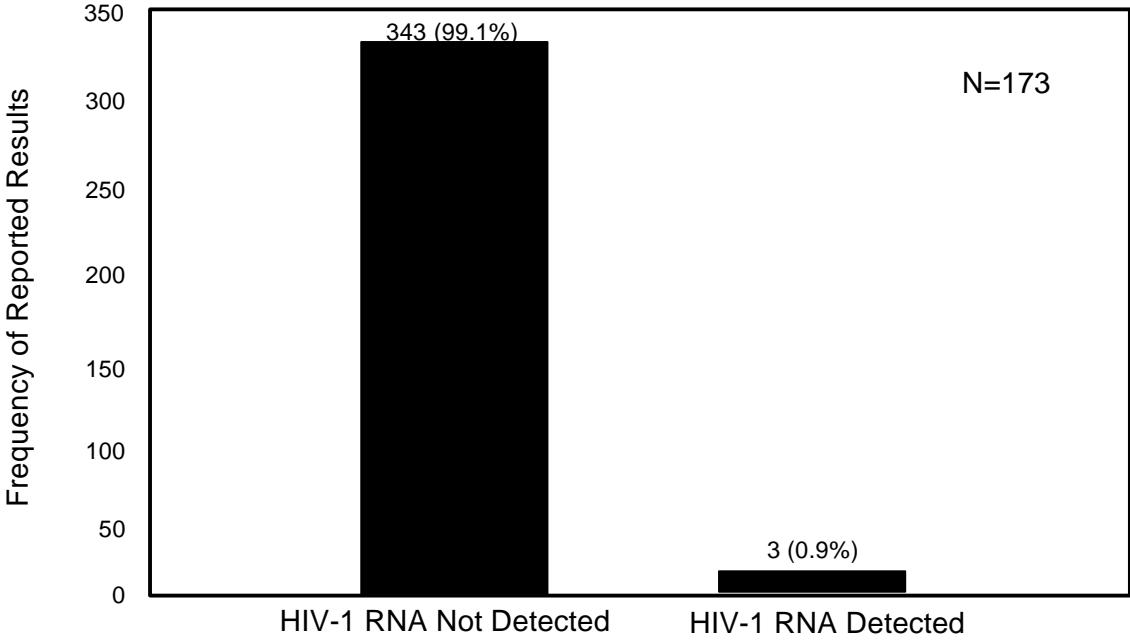
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.

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 1998 Performance Evaluation Shipment



**Results of HIV-1 RNA Determinations Reported for the Three Samples Obtained From Three HIV-1 Infected Donors with Detectable HIV-1 RNA**



**Results of HIV-1 RNA Determinations Reported for the Two Samples Obtained From Two Uninfected Donors**

Figure 2. Types of Laboratories Performing HIV-1 RNA Determinations in the June 1998 Performance Evaluation Shipment

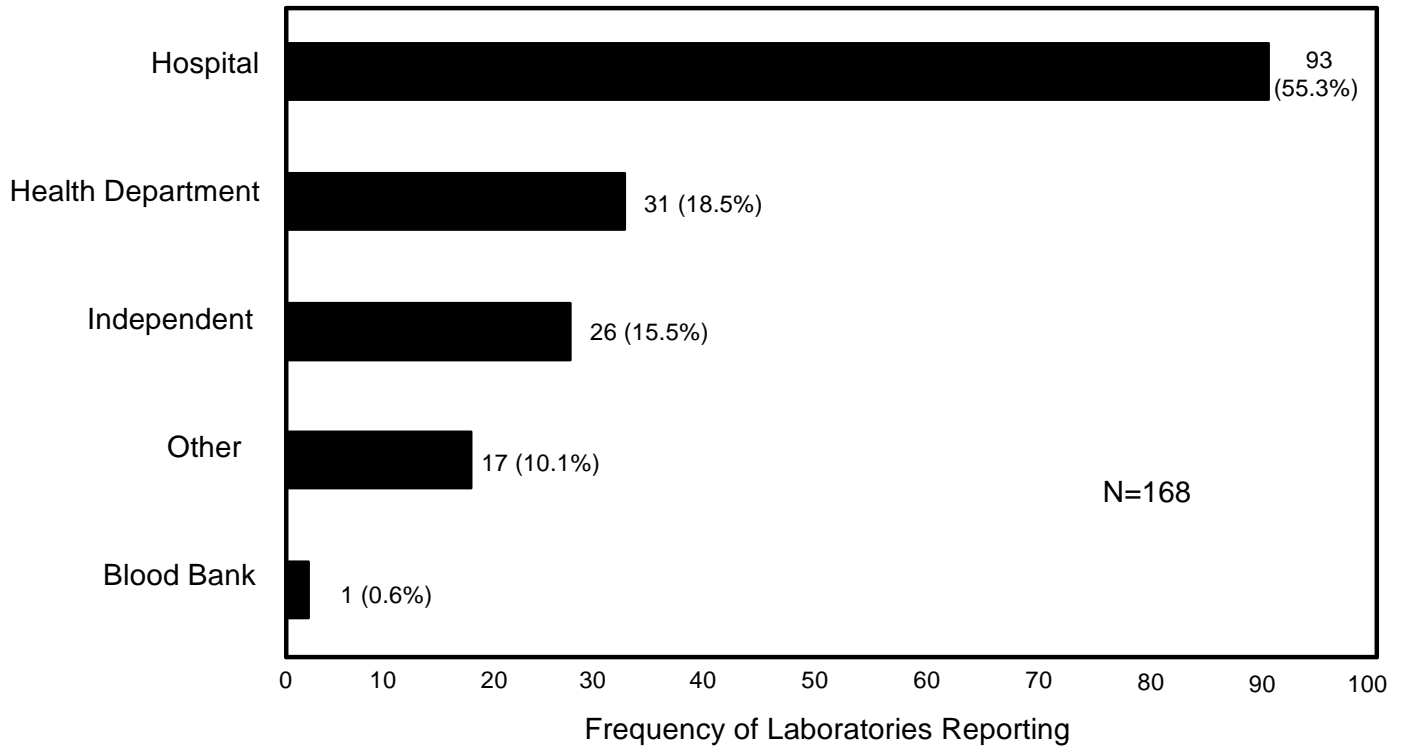
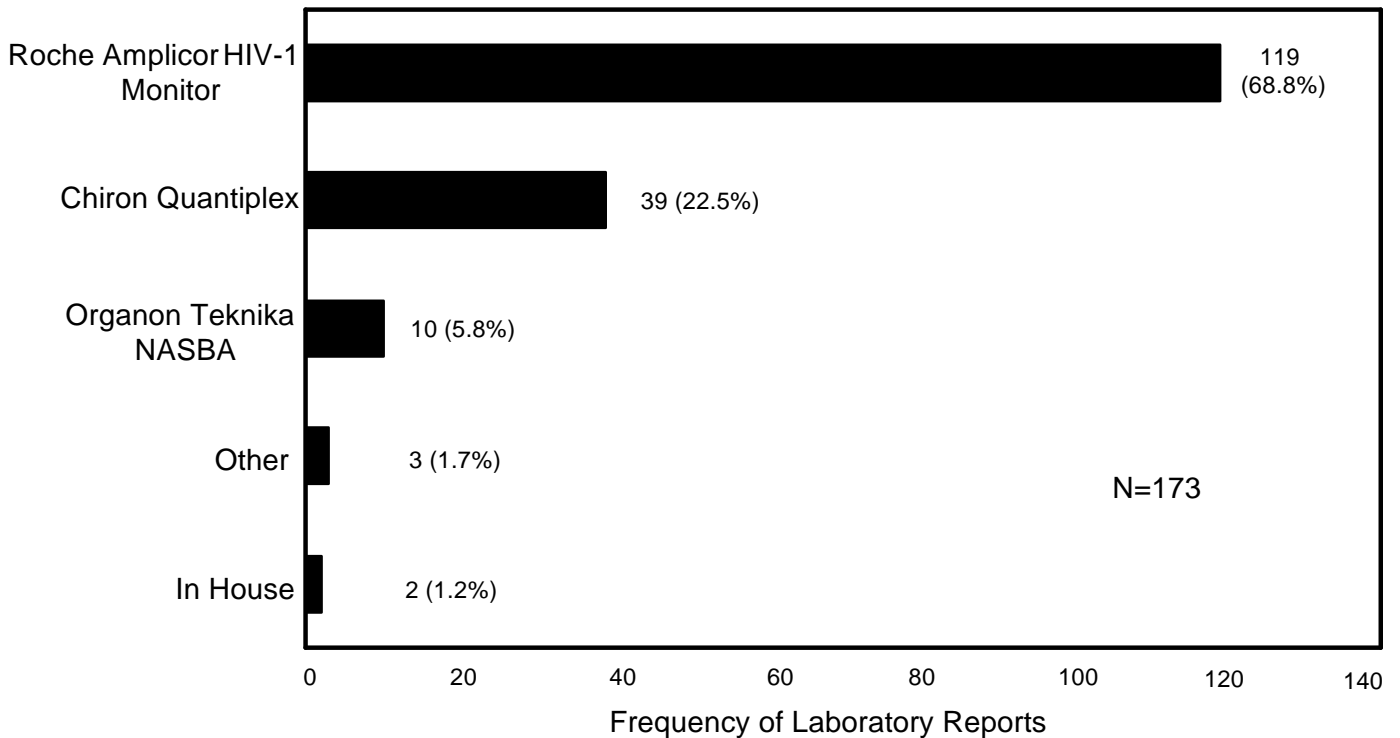


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the June 1998 Performance Evaluation Shipment



**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1998 Performance Evaluation Shipment.**

**CDC Donor #1**

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

**Panel Vial Labels: 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™	69	0	72,821	169,419	489,627
Chiron Quantiplex™	14	0	65,540	93,445	187,800
Organon Teknika NASBA™	5	0	89,000	160,000	360,000
In House	0	0	0	0	0
Other	2	0	14,125	115,524	216,924

**CDC Donor #1 Duplicate**

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

**Panel Vial Labels: 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™	69	0	77,066	169,843	1,291,635
Chiron Quantiplex™	14	0	70,180	95,515	205,500
Organon Teknika NASBA™	5	0	94,000	150,000	180,000
In House	0	0	0	0	0
Other	2	0	20,000	130,203	240,406

**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1998 Performance Evaluation Shipment.**

**CDC Donor #2**

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

**Panel Vial Labels: A1, B2**

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™	50	0	57,281	101,554	304,627
Chiron Quantiplex™	25	0	10,580	29,240	48,390
Organon Teknika NASBA™	5	0	63,000	88,000	100,000
In House	2	0	20,000	43,821	67,643
Other	1	0	172,000	172,000	172,000

**CDC Donor #2 Duplicate**

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

**Panel Vial Labels: A4, B5**

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™	50	0	54,186	104,361	750,000
Chiron Quantiplex™	25	0	4,400	26,900	48,630
Organon Teknika NASBA™	5	0	66,000	74,000	120,000
In House	2	0	25,000	41,818	58,636
Other	1	0	178,000	178,000	178,000

**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1998 Performance Evaluation Shipment.**

**CDC Donor #3**

**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™	108	0*	898	22,766	212,045
Chiron Quantiplex™	39	0	4,128	13,660	31,080
Organon Teknika NASBA™	10	0	20,000	37,125	56,000
In House	2	0	8,800	17,420	26,040
Other	3	0	7,400	41,126	78,000

\* Eleven laboratories reported invalid results. Please refer to discussion in accompanying analysis.

**CDC Donor #4**

**Donor Status: HIV-1 Uninfected**

**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™	1	117	10,497	10,497	10,497
Chiron Quantiplex™	1	38	803	803	803
Organon Teknika NASBA™	0	10	< kit sens.	< kit sens.	< kit sens.
In House	0	2	< kit sens.	< kit sens.	< kit sens.
Other	0	3	< kit sens.	< kit sens.	< kit sens.



**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the June 1998 Performance Evaluation Shipment.**

**CDC Donor #5**  
**Donor Status: HIV-1 Uninfected**  
**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™	0	119	< kit sens.	< kit sens.	< kit sens.
Chiron Quantiplex™	1	38	628	628	628
Organon Teknika NASBA™	0	10	< kit sens.	< kit sens.	< kit sens.
In House	0	2	< kit sens.	< kit sens.	< kit sens.
Other	0	3	< kit sens.	< kit sens.	< kit sens.

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