

**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 February 8, 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 30333**



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Report of the February 8, 1999 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 February 8, 1999 Participant Laboratory Panel Samples**

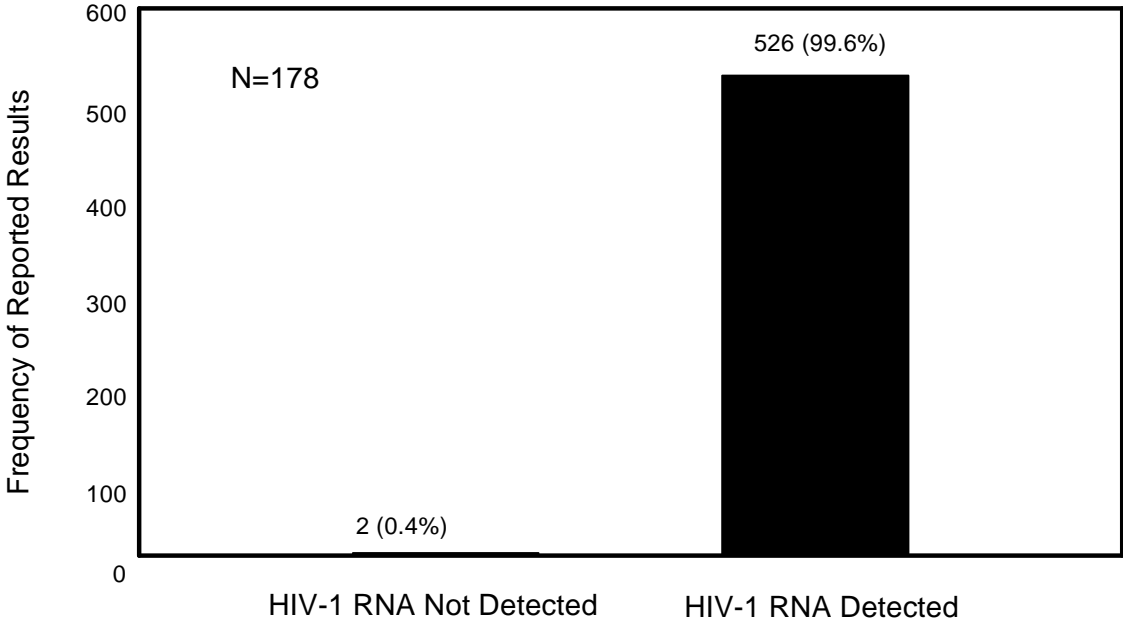
<b>Panel Letter</b>	<b>Vial Label</b>	<b>CDC Donor Number</b>	<b>CDC Test Results <sup>1</sup></b>	<b>Test Kit Manufacturer</b>	<b>CDC Interpretation<sup>2</sup></b>
E	E1, E5	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	E2, E4	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	E3	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
F	F1, F2	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	F3, F5	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	F4	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
G	G1, G4	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	G2, G3	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	G5	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
H	H1	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	H2, H5	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	H3, H4	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative

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

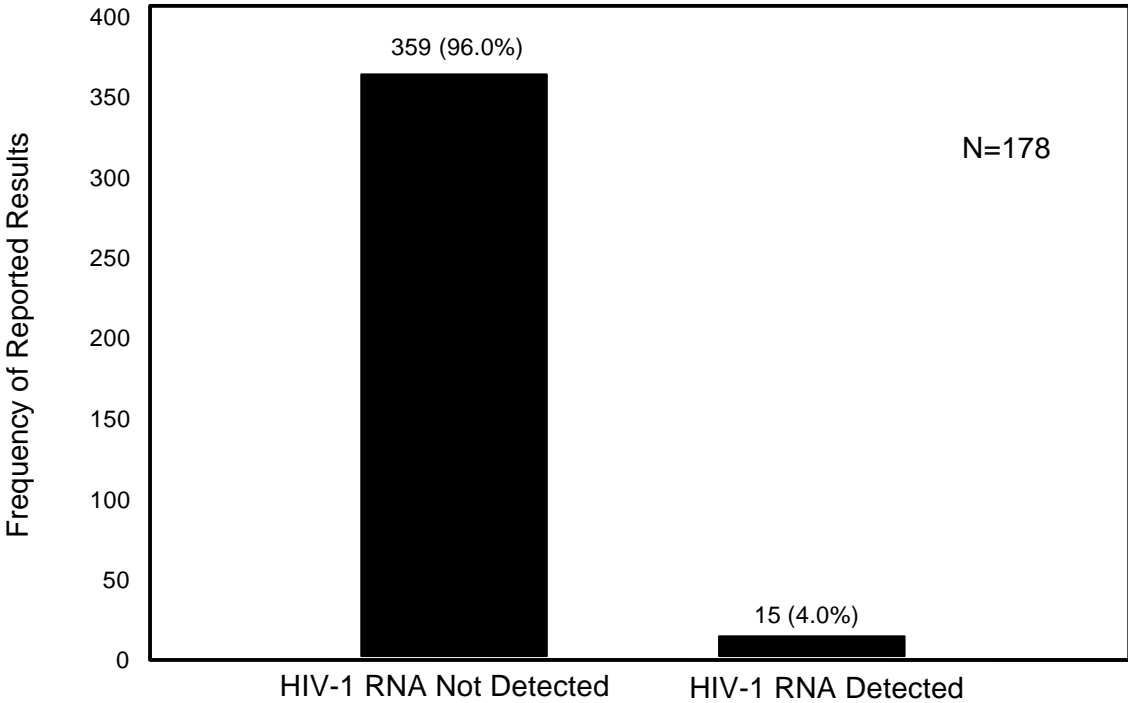
<sup>2</sup> The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.

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 February 1999 Performance Evaluation Shipment



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



**Results of HIV-1 RNA Determinations Reported for the Duplicated Sample Obtained From An Uninfected Donor**

Figure 2. Types of Laboratories Performing HIV-1 RNA Determinations in the February 1999 Performance Evaluation Shipment

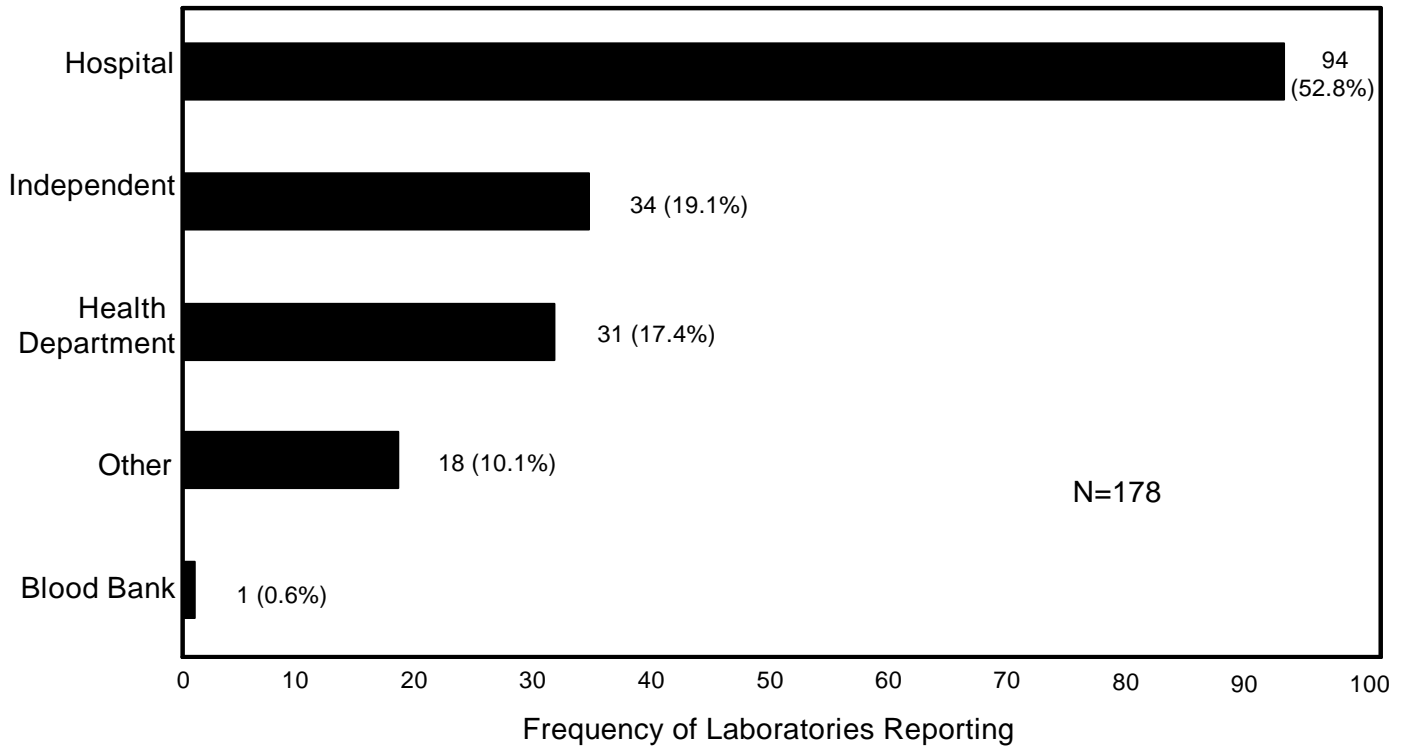
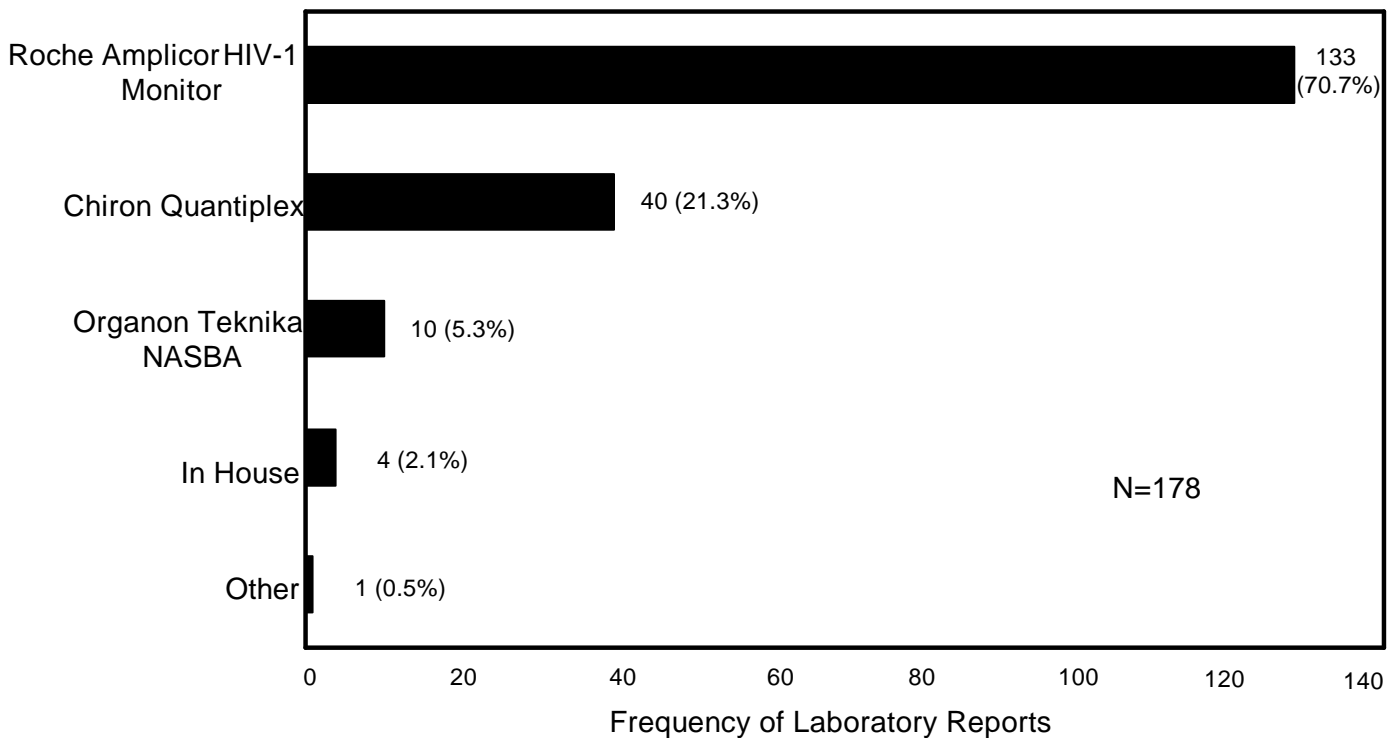


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the February 1999 Performance Evaluation Shipment



**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 1999 Performance Evaluation Shipment.**

**CDC Donor #1**

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

**Panel Vial Labels: G5, H1**

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™	71	0	3,849	118,000	259,018
Chiron Quantiplex™	15	0	63,750	126,515	196,590
Organon Teknika NASBA™	5	0	110,000	125,500	200,000
In House	1	0	5,900	5,900	5,900
Other	1	0	214,416	214,416	214,416

**CDC Donor #2**

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

**Panel Vial Labels: E3, F4**

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™	59	0	33,700	75,196	154,631
Chiron Quantiplex™	25	0	9,247	34,168	66,165
Organon Teknika NASBA™	5	0	45,000	60,000	86,000
In House	3	0	14,017	34,000	111,000
Other	0	0	0	0	0

**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 1999 Performance Evaluation Shipment.**

**CDC Donor #3**

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

**Panel Vial Labels: E2, F3, G1, H2**

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™	146	2	760	14,759	145,693
Chiron Quantiplex™	50	0	4,864	24,797	37,530
Organon Teknika NASBA™	11	0	24,000	35,000	46,000
In House	4	0	3,800	12,178	64,400
Other	2	0	38,382	40,957	45,532

**CDC Donor #3 Duplicate**

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

**Panel Vial Labels: E4, F5, G4, H5**

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™	85	0	3,640	17,682	44,812
Chiron Quantiplex™	30	0	6,961	22,986	34,899
Organon Teknika NASBA™	9	0	23,000	26,000	44,500
In House	4	0	4,412	12,335	71,900
Other	0	0	0	0	0

**Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 1999 Performance Evaluation Shipment.**

**CDC Donor #4**  
**Donor Status: HIV-1 Uninfected**  
**Panel Vial Labels: E1, F1, G2, H3**

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™	6	152	28	445	3,176
Chiron Quantiplex™	4	50	52	67	558
Organon Teknika NASBA™	0	14	<kit sens.*	<kit sens.	<kit sens.
In House	0	6	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

\* = less than kit lower limit sensitivity

**CDC Donor #4 Duplicate**  
**Donor Status: HIV-1 Uninfected**  
**Panel Vial Labels: E5, F2, G3, H4**

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™	3	103	318	510	1,717
Chiron Quantiplex™	2	24	80	94	108
Organon Teknika NASBA™	0	6	<kit sens.*	<kit sens.	<kit sens.
In House	0	2	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

\* = less than kit lower limit sensitivity