

**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 16, 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
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Report of the February 16, 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)**

**Table 1. CDC HIV-1 RNA Testing Results for the February 16, 1998
Participant Laboratory Panel Samples**

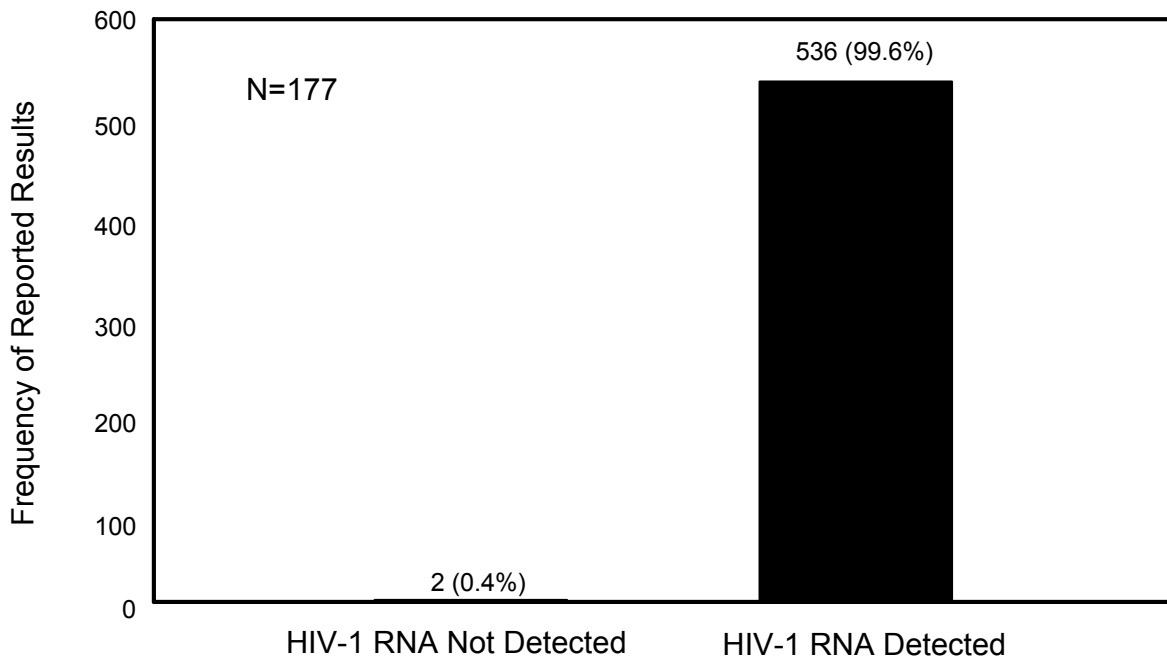
Panel Letter	Vial Label	CDC Donor Number	CDC Test Results ¹	Test Kit Manufacturer	CDC Interpretation ²
E	E1, E5	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen	Negative Negative Negative
	E2, E4	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
	E3	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
F	F1 F2	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Negative Negative Negative
	F3, F5	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
	F4	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
G	G1, G4	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
	G2, G3	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Negative Negative Negative
	G5	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
H	H1	01	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Coulter HIV-1 HIV RNA Chiron Quantiplex	Positive Positive Positive
	H2, H5	02	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Positive Positive Positive
	H3, H4	03	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens(NASBA) Chiron Quantiplex	Negative Negative Negative

¹ Result based on testing performed by two laboratories for each manufacturers' test kit.

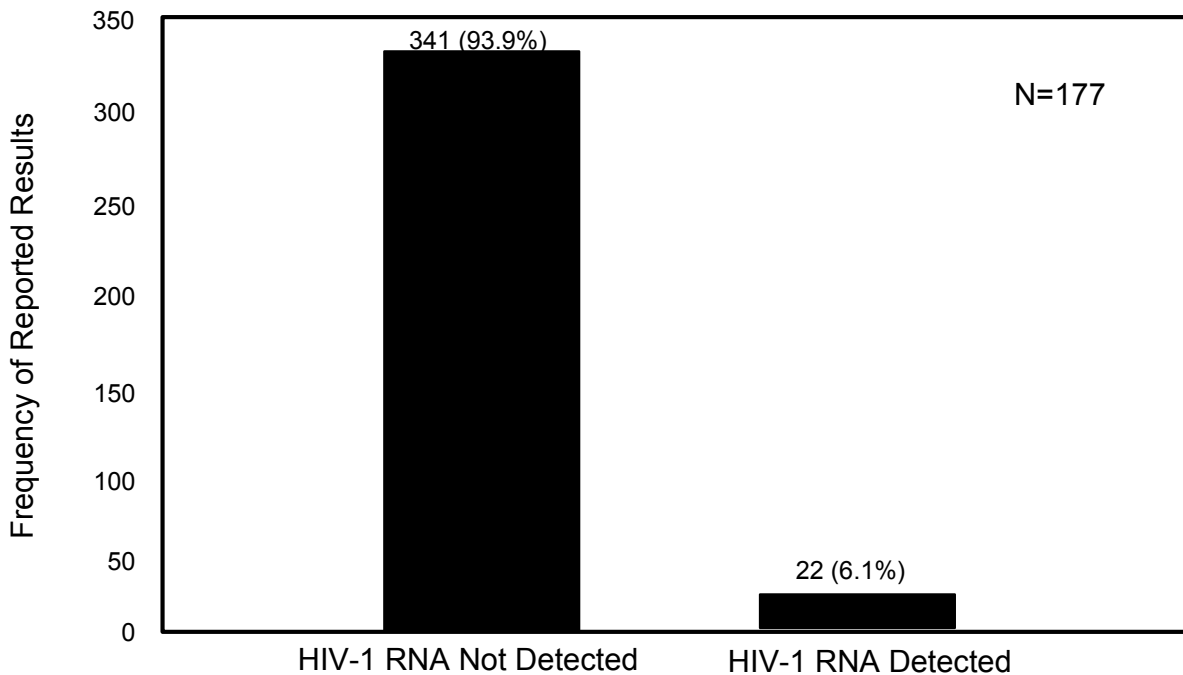
² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.

Positive = HIV RNA detected; Negative = HIV 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 1998 shipment



Results of HIV-1 RNA Determinations Reported for the Three Samples Obtained From Two HIV-1 Infected Donors (One Donor Duplicated) with Detectable HIV-1 RNA



Results of HIV-1 RNA Determinations Reported for the Two Samples Obtained From One Duplicated Non-HIV-1 Infected Donor

Figure 2. Types of Laboratories Performing HIV-1 RNA Determinations in the February 1998 Panel Shipment

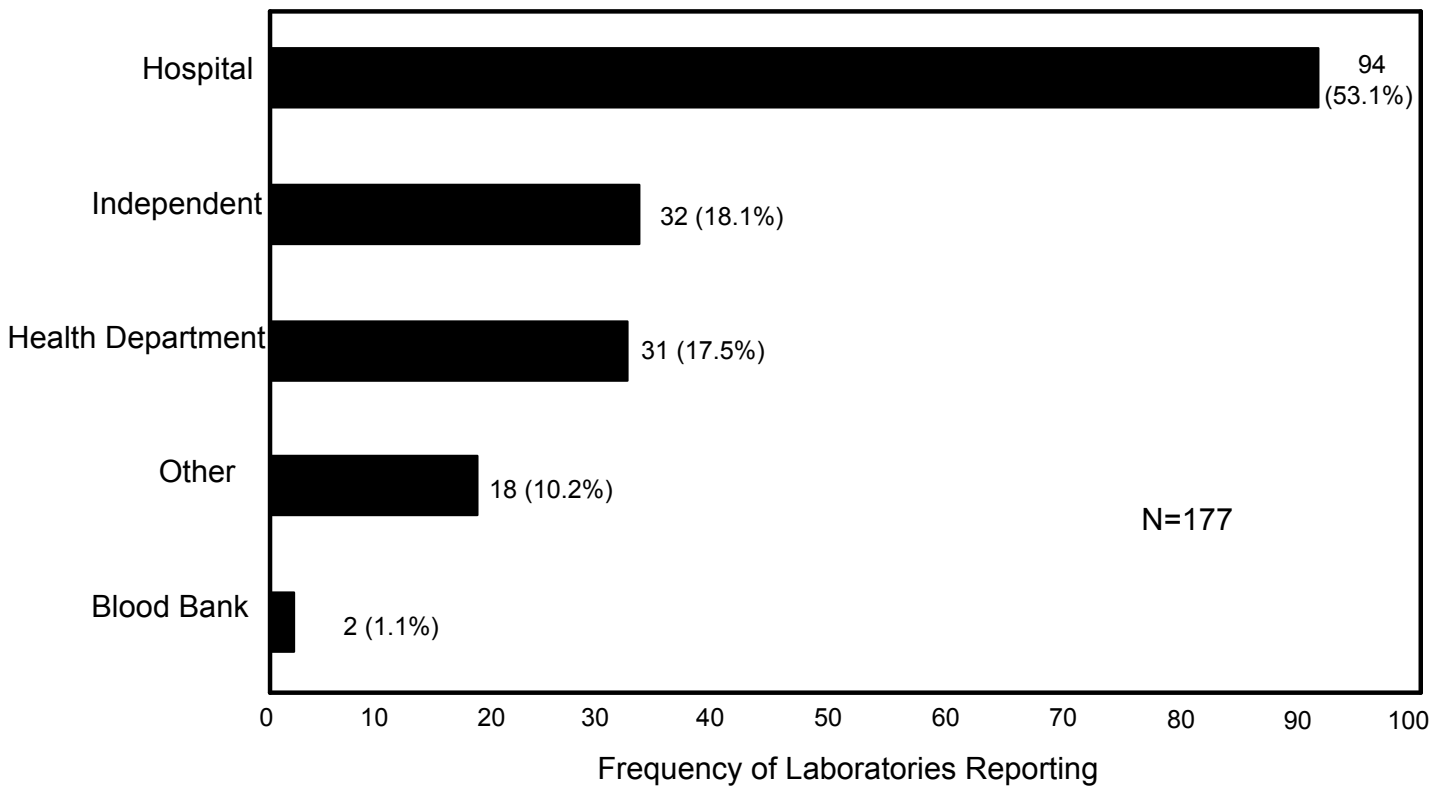


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the February 1998 Panel Shipment

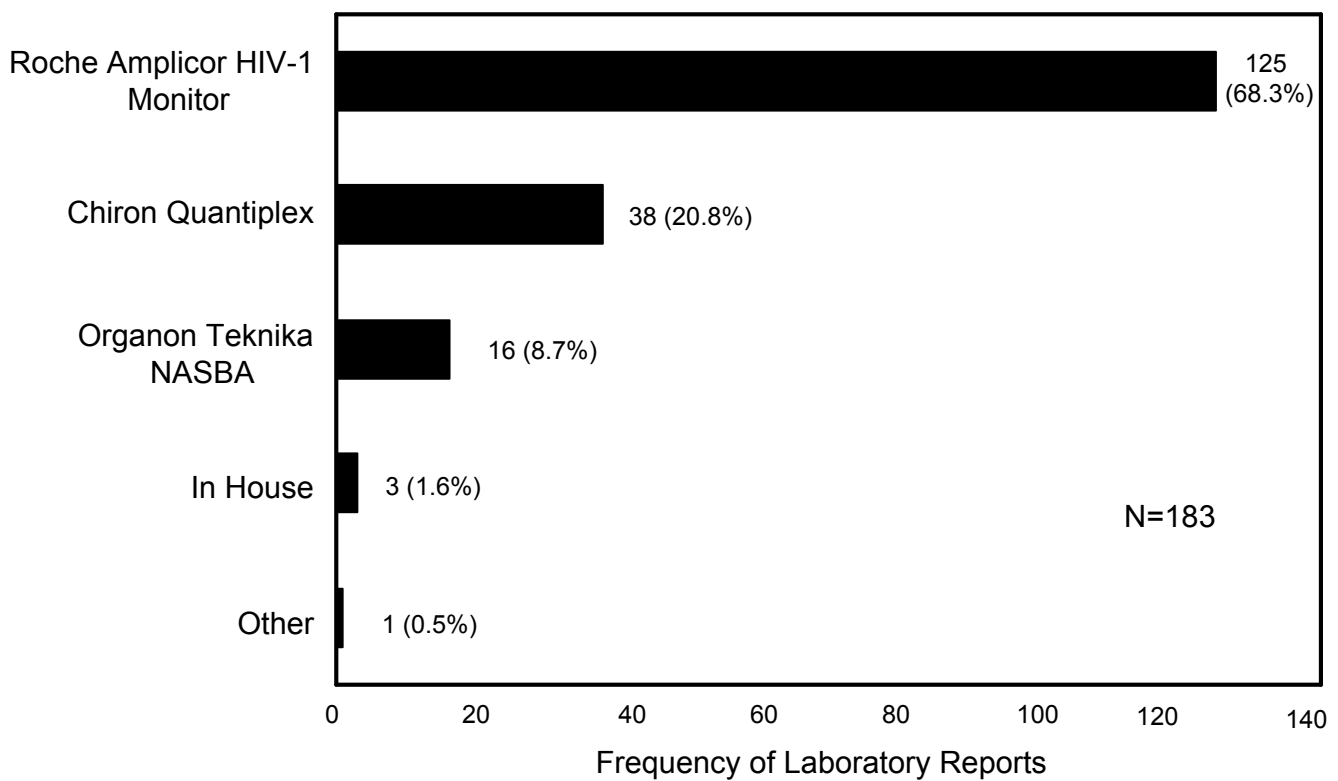


Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 1998 Performance Evaluation Shipment.

CDC Donor #1

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

Panel Vial Labels: E3, F4, 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™	124	0	1,414	5,793	14,784
Chiron Quantiplex™	38	0	148	1,578	6,310
Organon Teknika NASBA™	16	0	7,100	10,000	33,000
In House	3	0	440	1,375	5,627
Other	1	0	6,535	6,535	6,535

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

CDC Donor #2

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™	117	0	1,055	4,290	12,694
Chiron Quantiplex™	38	0	123	1,504	3,520
Organon Teknika NASBA™	16	0	6,600	12,000	22,000
In House	3	0	770	1,150	2,890
Other	1	0	6,119	6,119	6,119

CDC Donor #2 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™	122	1	527	4,307	12,992
Chiron Quantiplex™	37	1	182	1,500	2,415
Organon Teknika NASBA™	16	0	2,400	10,950	18,000
In House	3	0	830	1,855	2,000
Other	1	0	6,787	6,787	6,787

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

CDC Donor #3
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™	5	119	0	299	24,665
Chiron Quantiplex™	6	31	50	850	13,390
Organon Teknika NASBA™	0	16	< 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.

CDC Donor #3 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™	5	119	0	266	492
Chiron Quantiplex™	6	32	50	581	1,852
Organon Teknika NASBA™	0	16	< kit sens.	< kit sens.	< kit sens.
In House	0	3	< kit sens.	< kit sens.	< kit sens.
Other	0	1	< kit sens.	< kit sens.	< kit sens.