

**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
August 15, 2000 Performance Evaluation
Testing Results Reported by Participant Laboratories**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Report of the August 15, 2000 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
 Human Immunodeficiency Virus Type 1 (HIV-1) Ribonucleic Acid (RNA) Testing
 August 15, 2000 Participant Laboratory Shipment**

Table 1. Panel and Vial Designations, CDC Donor Numbers, CDC HIV-1 RNA Test Results, and Donor HIV Status

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result ²	Donor HIV Status	Laboratory Interpretation ¹ and/or Results	
					Test Result	Interpretation
A	A1	5	Negative	Uninfected	_____	_____
	A2, A3	1	Positive	Infected	_____	_____
	A4	3	Negative	Uninfected	_____	_____
	A5	2	Positive	Infected	_____	_____
B	B1, B2	1	Positive	Infected	_____	_____
	B3	3	Negative	Uninfected	_____	_____
	B4	2	Positive	Infected	_____	_____
	B5	5	Negative	Uninfected	_____	_____

¹ Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

² The CDC result was obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA). The CDC result is consistent with the manufacturer's criteria for interpretation of results.

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

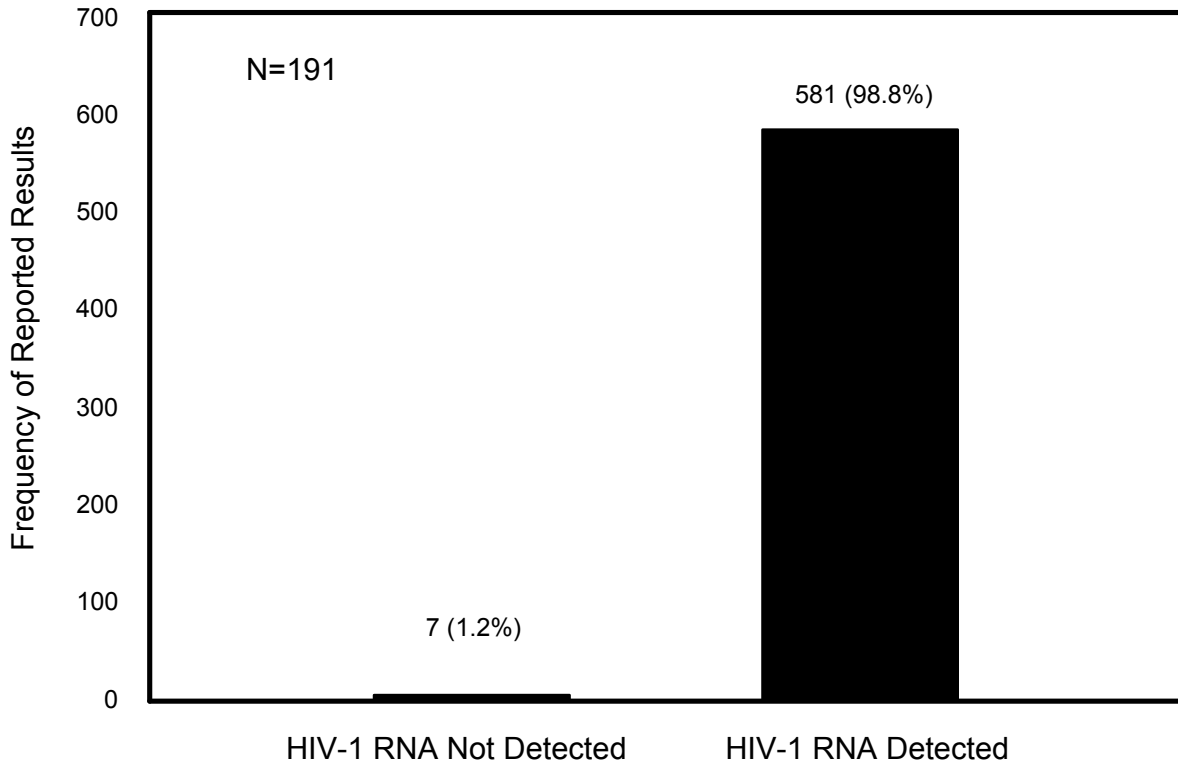
Table 2. CDC HIV-1 RNA Testing Results for the August 15, 2000 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results¹	Test Kit Manufacturer	CDC Interpretation²
A	A1	5	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Negative Negative Negative
	A2, A3	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Positive Positive Positive
	A4	3	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Negative Negative Negative
	A5	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Positive Positive Positive
	B1, B2	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Positive Positive Positive
B	B3	3	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Negative Negative Negative
	B4	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Positive Positive Positive
	B5	5	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex	Negative Negative Negative

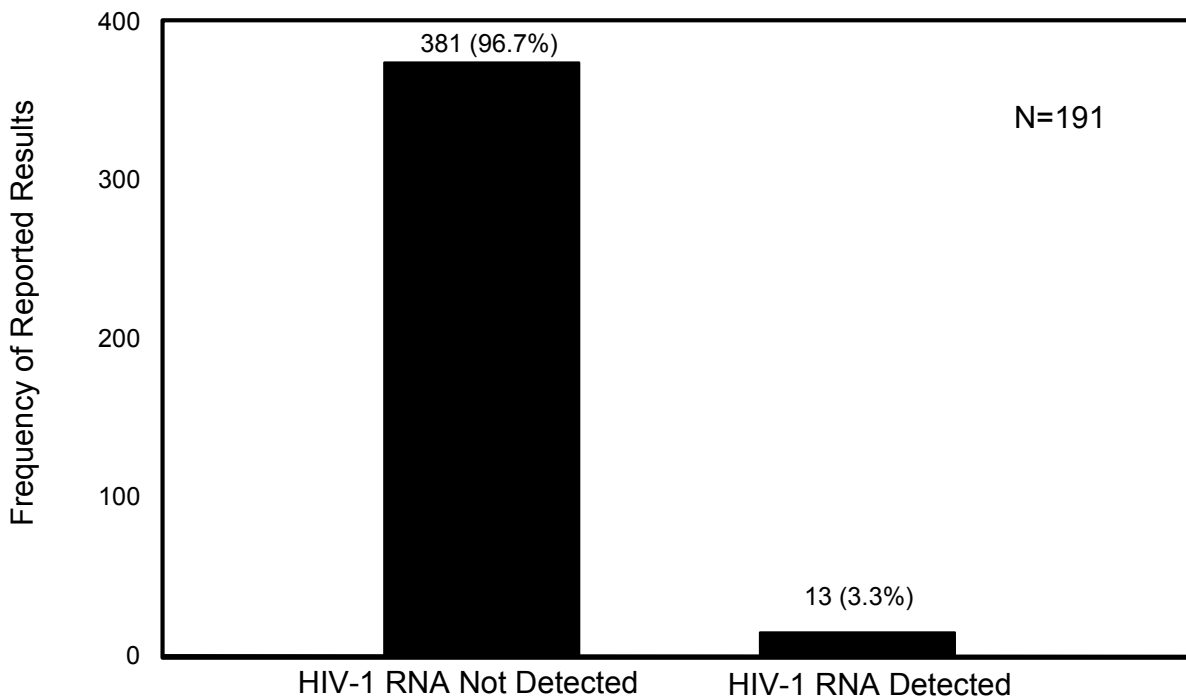
¹The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA).

²The 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 limit of test kit sensitivity).

Figure 1. Summary of Results Reported by Participant Laboratories for HIV-1 RNA Determinations in the August 15, 2000 Performance Evaluation Survey



Results of HIV-1 RNA Determinations Reported for the Three Samples Obtained From Two 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 August 15, 2000 Performance Evaluation Survey

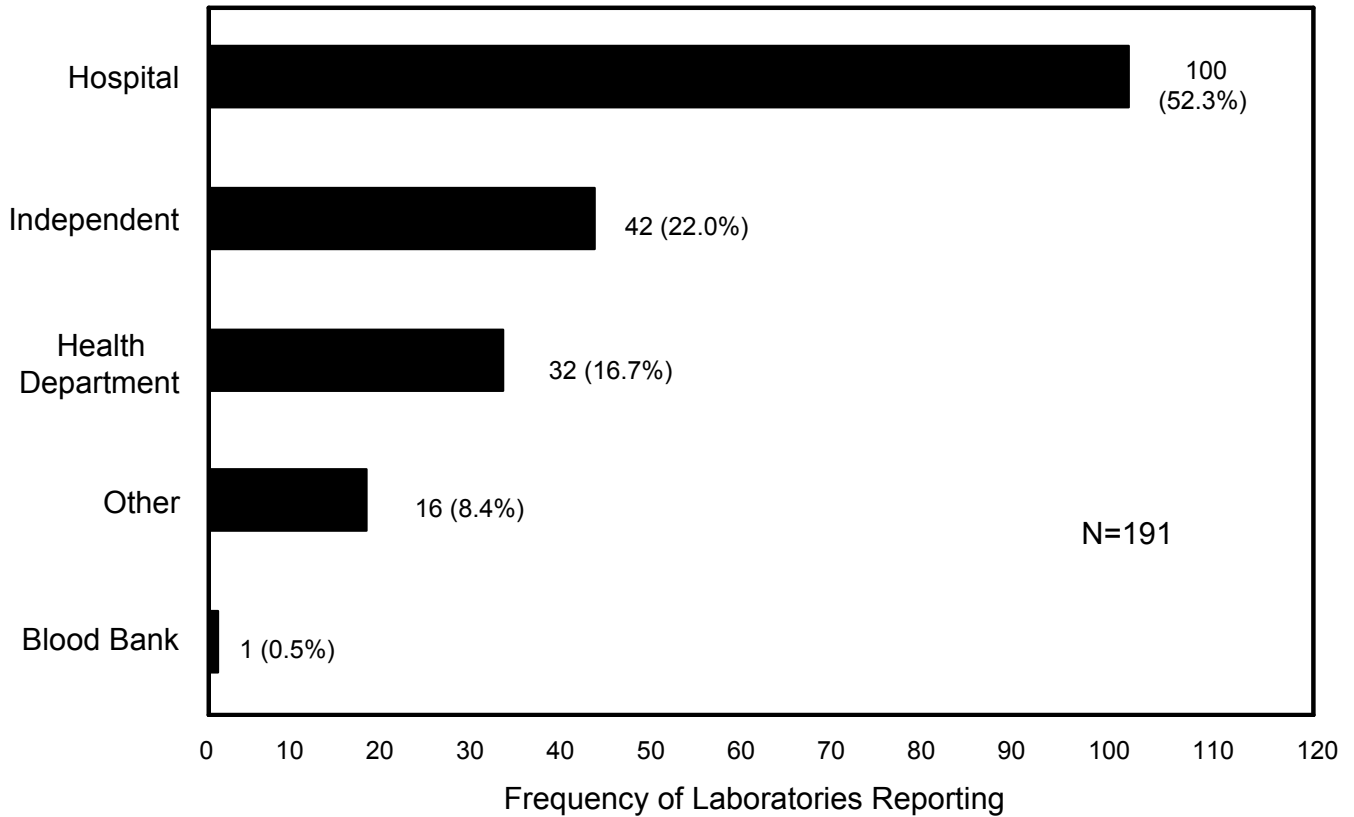


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the August 15, 2000 Performance Evaluation Survey

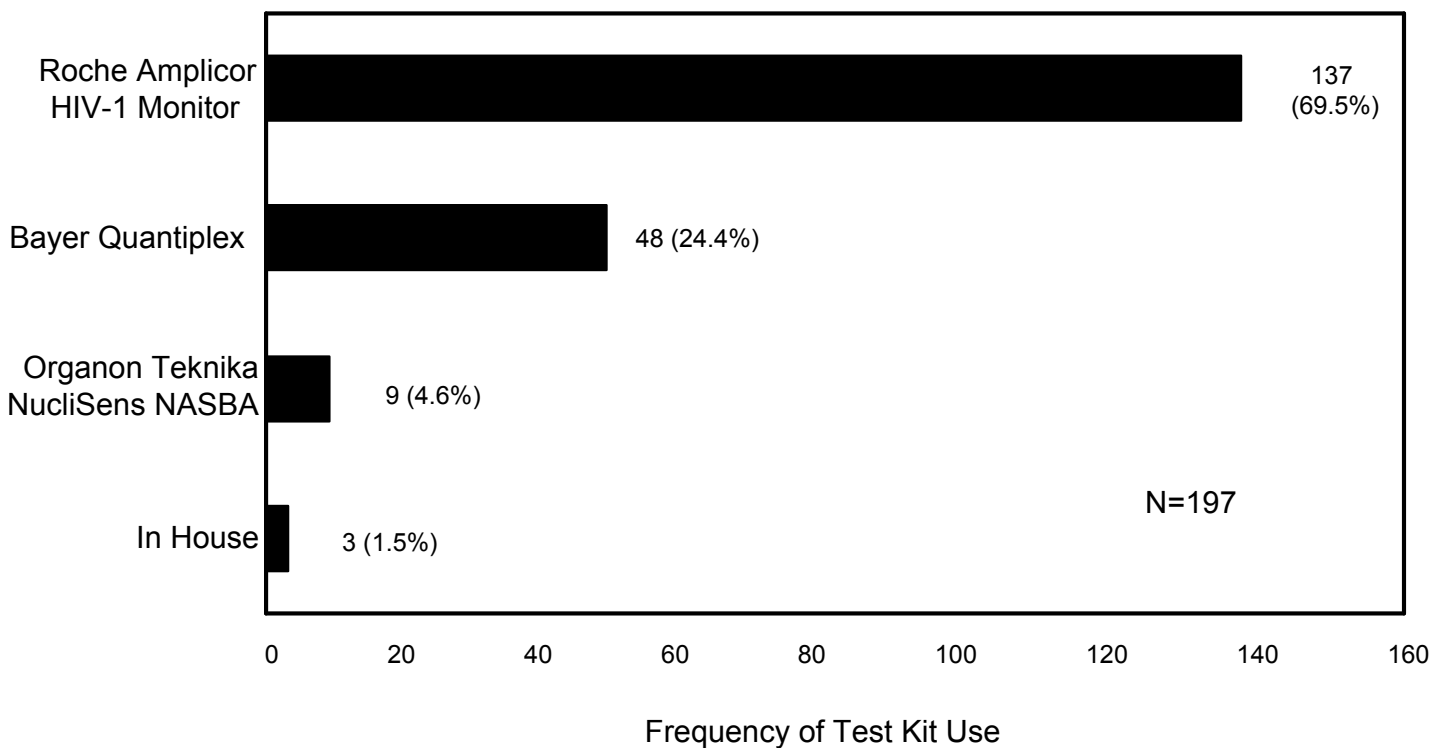


Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 15, 2000 Performance Evaluation Survey.

CDC Donor #1

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

Panel Vial Labels: A2, B1

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™	136	0	6,895	16,787	51,510
Bayer Quantiplex™	48	0	5,561	9,977	15,715
Organon Teknika NucliSens NASBA™	9	0	16,000	29,000	37,000
In House	3	0	7,245	10,468	23,000

CDC Donor #1 Duplicate

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

Panel Vial Labels: A3, 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™	136	0	5,906	17,589	52,993
Bayer Quantiplex™	48	0	6,701	9,095	18,883
Organon Teknika NucliSens NASBA™	9	0	16,000	26,000	38,000
In House	3	0	13,997	15,999	19,000

Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 15, 2000 Performance Evaluation Survey.

CDC Donor # 2

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

Panel Vial Labels: A5, B4

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™	130	6	484	1,159	3,151
Bayer Quantiplex™	48	0	391	597	1,166
Organon Teknika NucliSens NASBA™	8	1	820	1,700	3,800
In House	3	0	403	786	1,100

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Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 15, 2000 Performance Evaluation Survey.

CDC Donor #3
Donor Status: HIV-1 Uninfected
Panel Vial Labels: A4, B3

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	136	1,234	1,234	1,234
Bayer Quantiplex™	3	45	51	52	56
Organon Teknika NucliSens NASBA™	0	9	<kit sens.*	<kit sens.	<kit sens.
In House	0	3	<kit sens.	<kit sens.	<kit sens.

* = less than kit lower limit sensitivity

CDC Donor #5
Donor Status: HIV-1 Uninfected
Panel Vial Labels: A1, 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™	4	133	623	812	13,148
Bayer Quantiplex™	4	44	51	53	61
Organon Teknika NucliSens NASBA™	0	9	<kit sens.*	<kit sens.	<kit sens.
In House	1	2	25	25	25

* = less than kit lower limit sensitivity