

**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 16, 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
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Report of the August 16, 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**

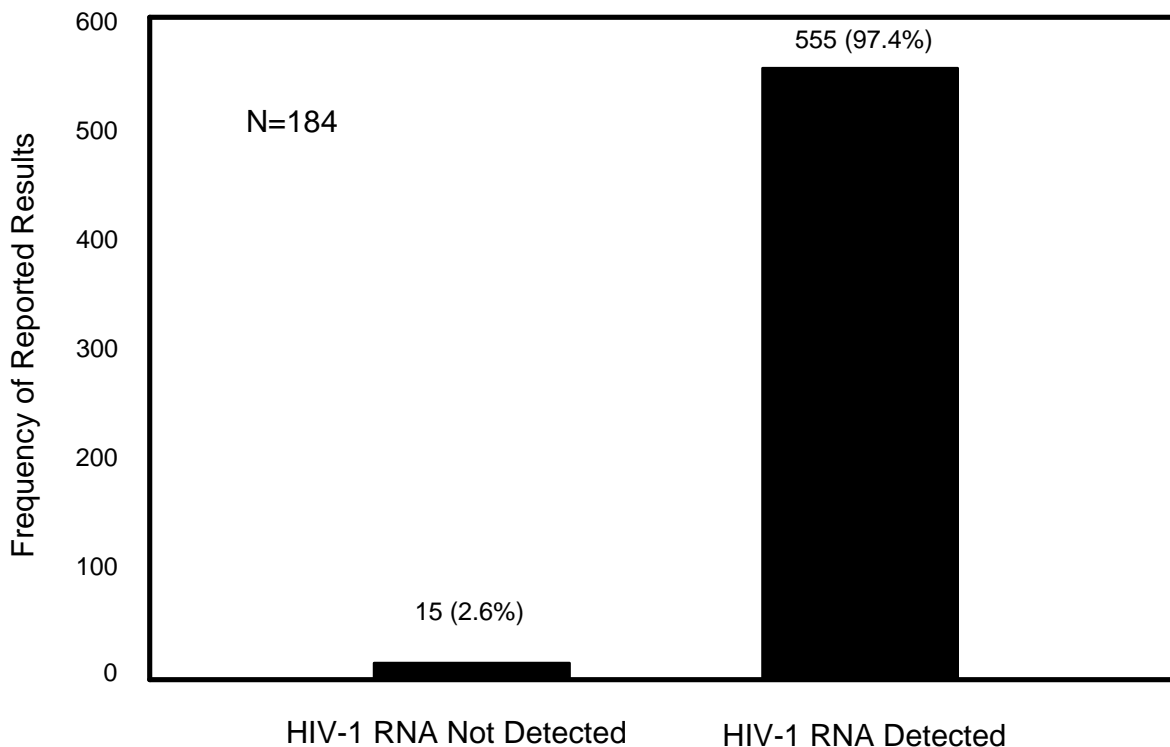
Table 1. CDC HIV-1 RNA Testing Results for the August 16, 1999 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results¹	Test Kit Manufacturer	CDC Interpretation²
A	A1, A2	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	A3	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	A4	3	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	A5	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
B	B1	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	B2, B3	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive
	B4	3	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Negative Negative Negative
	B5	2	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Chiron Quantiplex	Positive Positive Positive

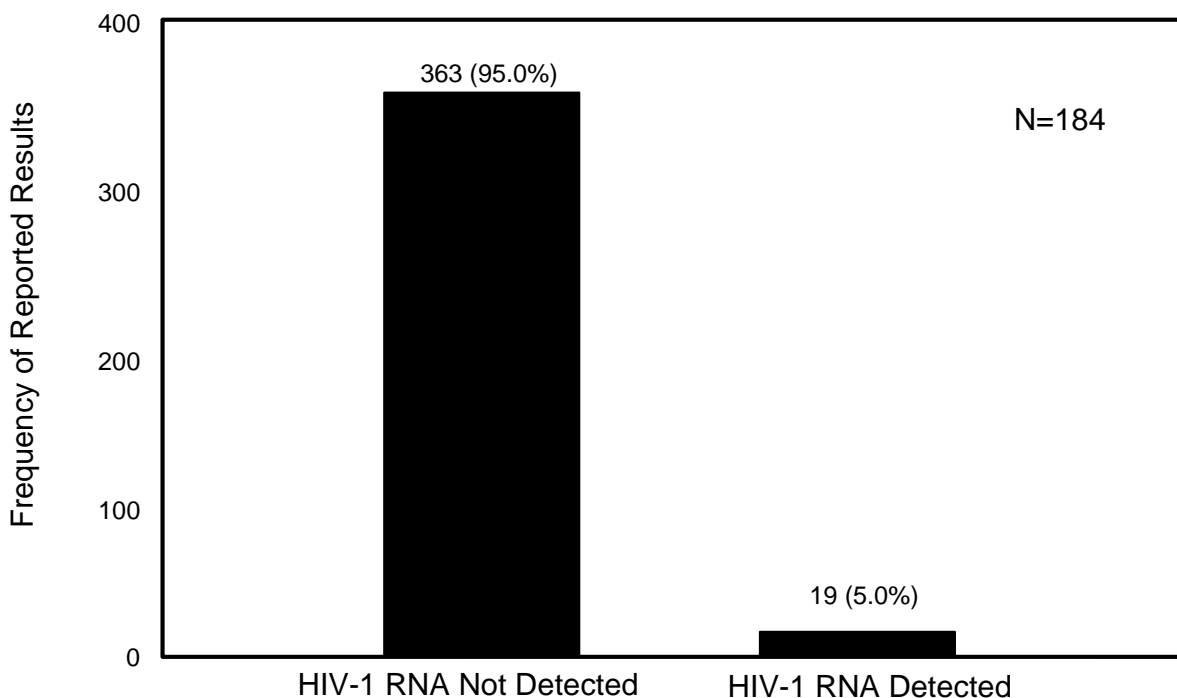
¹The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA).

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 limits of test kit sensitivity).

Figure 1. Summary of Results Reported by Participant Laboratories for HIV-1 RNA Determinations in the August 16, 1999 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 16, 1999 Performance Evaluation Survey

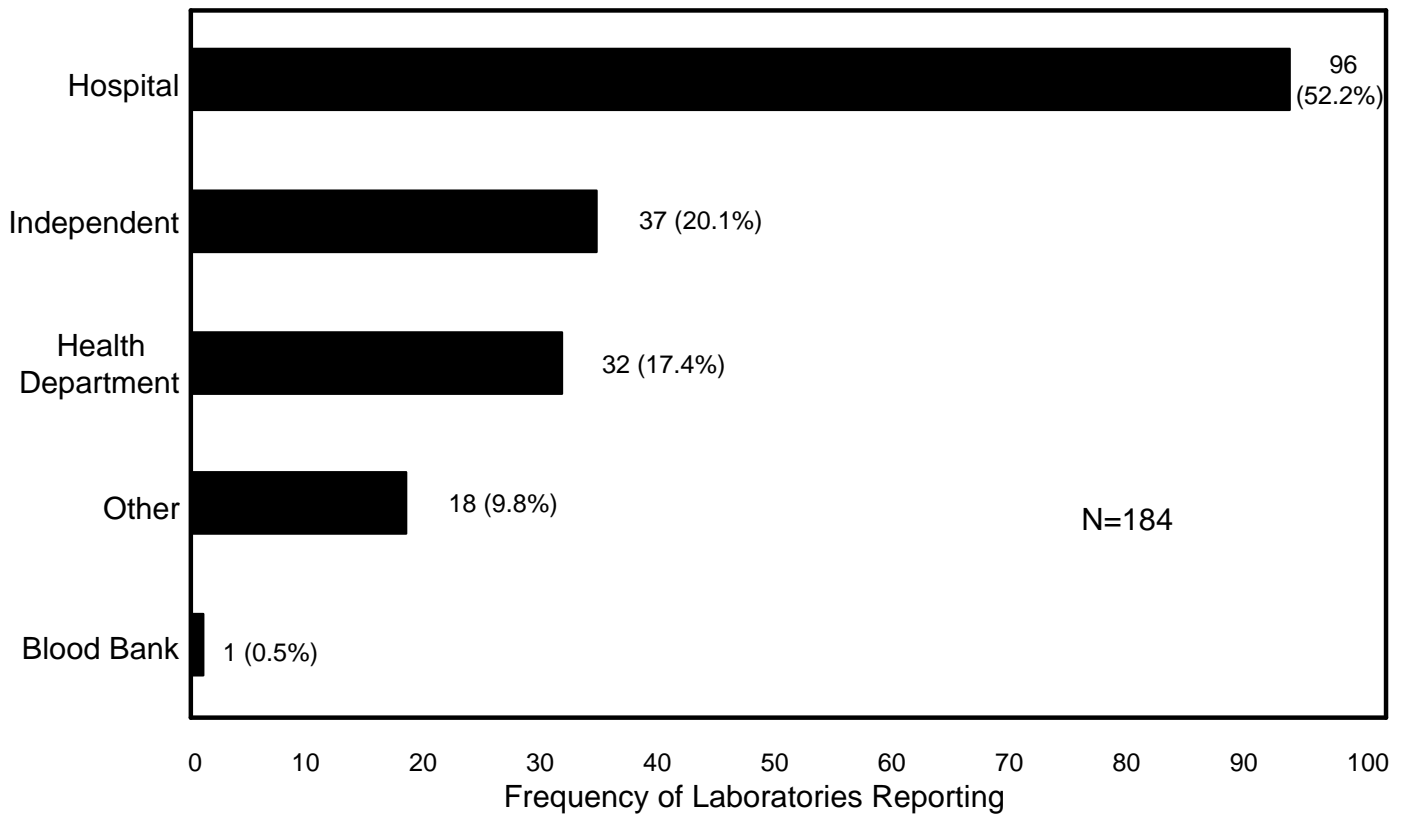


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the August 16, 1999 Performance Evaluation Survey

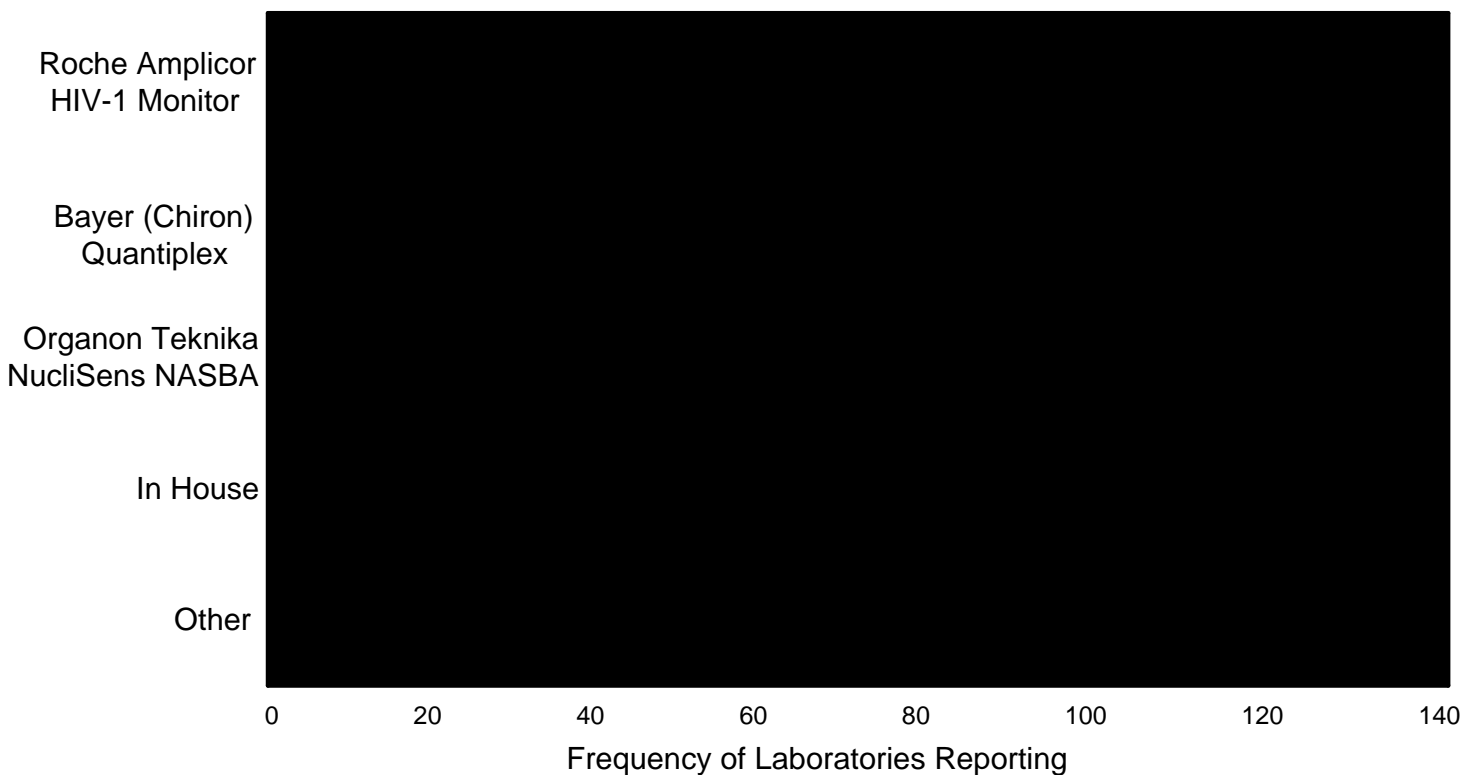


Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 16, 1999 Performance Evaluation Survey.

CDC Donor #1

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™	128	6	418	905	2,166
Bayer (Chiron) Quantiplex™	42	0	265	657	1,196
Organon Teknika NucliSens NASBA™	8	1	590	1,300	1,900
In House	4	0	334	851	1,600
Other	1	0	527	527	527

CDC Donor # 1 (Duplicate)

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

Panel Vial Labels: A2, 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™	129	5	412	880	4,389
Bayer (Chiron) Quantiplex™	42	0	288	668	1,103
Organon Teknika NucliSens NASBA™	7	2	440	1,200	1,300
In House	4	0	432	1,285	1,900
Other	1	0	644	644	644

Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 16, 1999 Performance Evaluation Survey.

CDC Donor #2

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

Panel Vial Labels: A3, 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™	133	1	1,592	11,678	57,400
Bayer (Chiron) Quantiplex™	42	0	2,569	7,883	15,353
Organon Teknika NucliSens NASBA™	9	0	4,300	9,300	14,000
In House	4	0	2,140	14,500	28,817
Other	1	0	9,712	9,712	9,712

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Table 2. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 16, 1999 Performance Evaluation Survey.

CDC Donor #3
Donor Status: HIV-1 Uninfected
Panel Vial Labels: A4, 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™	0	135	<kit sens.*	<kit sens.	<kit sens.
Bayer (Chiron) Quantiplex™	5	37	53	58	255
Organon Teknika NucliSens NASBA™	0	9	<kit sens.	<kit sens.	<kit sens.
In House	0	4	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

* = less than kit lower limit sensitivity

CDC Donor #4
Donor Status: HIV-1 Uninfected
Panel Vial Labels: A5, 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™	1	134	2,801	2,801	2,801
Bayer (Chiron) Quantiplex™	13	29	54	62	147
Organon Teknika NucliSens NASBA™	0	9	<kit sens.*	<kit sens.	<kit sens.
In House	0	4	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

* = less than kit lower limit sensitivity