

**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 14, 2001 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
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Report of the August 14, 2001 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 14, 2001 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, A5	2	Positive	Infected	_____	_____
	A2, A4	5	Negative	Uninfected	_____	_____
	A3	1	Positive	Infected	_____	_____
B	B1, B5	5	Negative	Uninfected	_____	_____
	B2, B4	2	Positive	Infected	_____	_____
	B3	1	Positive	Infected	_____	_____

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**

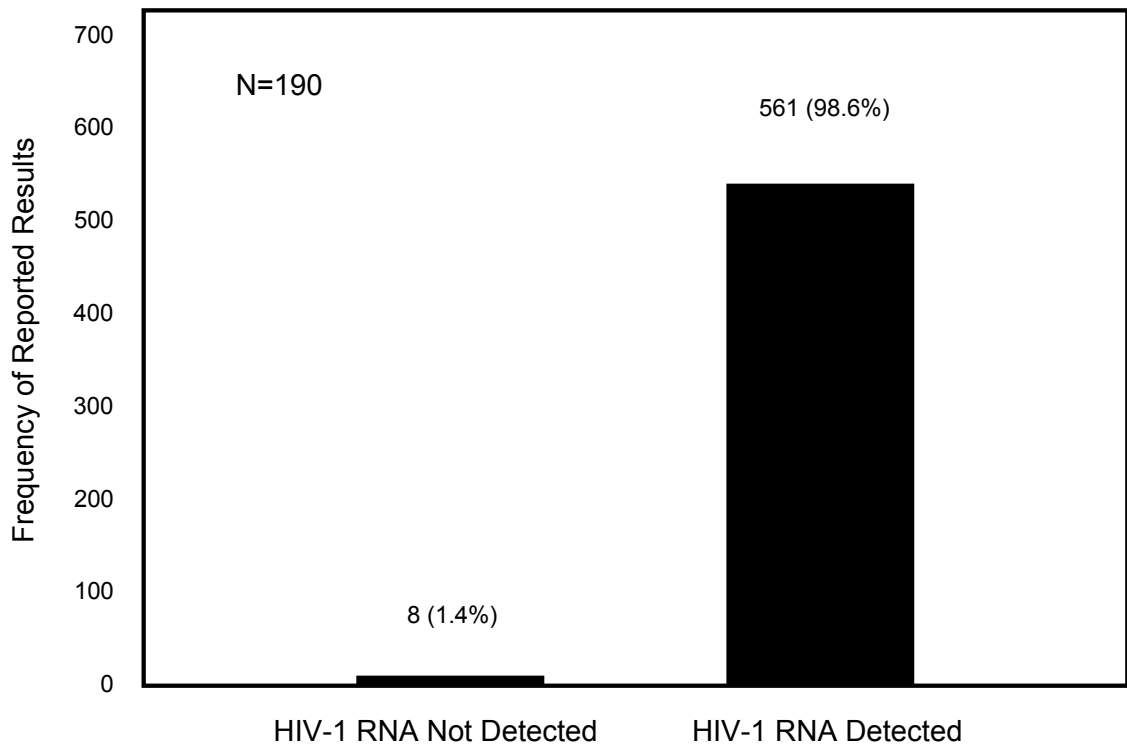
Table 2. CDC HIV-1 RNA Testing Results for the August 14, 2001 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results¹	Test Kit Manufacturer	CDC Interpretation²
A	A1, A5	2	HIV RNA detected	Roche Amplicor Monitor	Positive
			HIV RNA detected	Organon NucliSens	Positive
			HIV RNA detected	Bayer 3.0 Quantitative Assay	Positive
	A2, A4	5	No HIV RNA detected	Roche Amplicor Monitor	Negative
			No HIV RNA detected	Organon NucliSens	Negative
			No HIV RNA detected	Bayer 3.0 Quantitative Assay	Negative
	A3	1	HIV RNA detected	Roche Amplicor Monitor	Positive
			HIV RNA detected	Organon NucliSens	Positive
			HIV RNA detected	Bayer 3.0 Quantitative Assay	Positive
B	B1, B5	5	No HIV RNA detected	Roche Amplicor Monitor	Negative
			No HIV RNA detected	Organon NucliSens	Negative
			No HIV RNA detected	Bayer 3.0 Quantitative Assay	Negative
	B2, B4	2	HIV RNA detected	Roche Amplicor Monitor	Positive
			HIV RNA detected	Organon NucliSens	Positive
			HIV RNA detected	Bayer 3.0 Quantitative Assay	Positive
	B3	1	HIV RNA detected	Roche Amplicor Monitor	Positive
			HIV RNA detected	Organon NucliSens	Positive
			HIV RNA detected	Bayer 3.0 Quantitative Assay	Positive

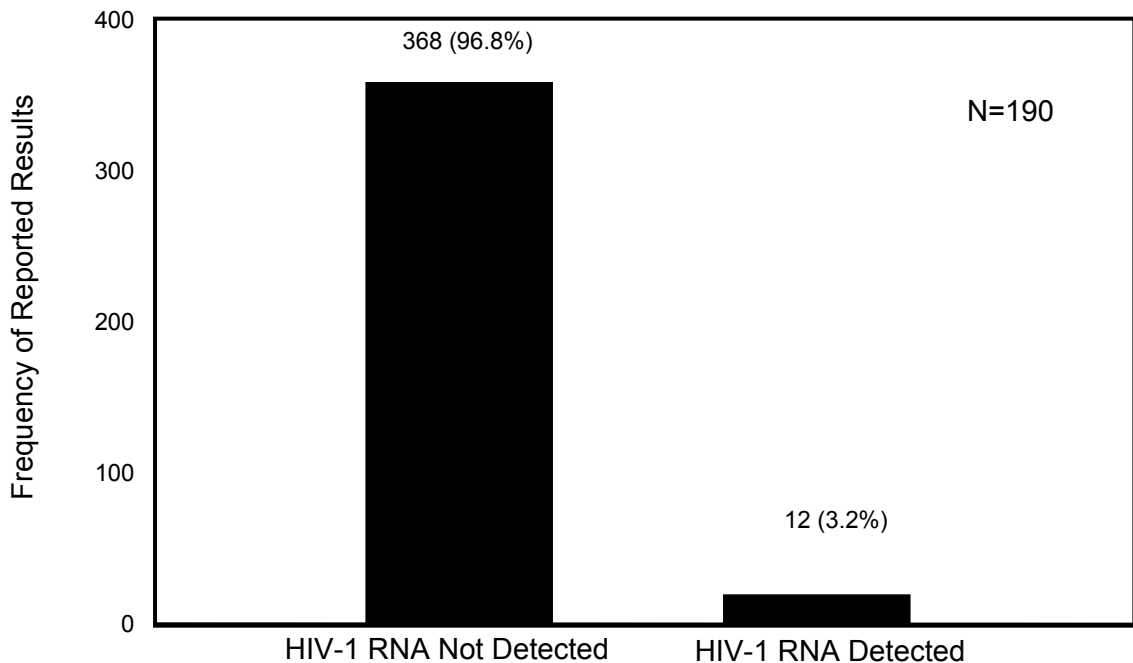
¹The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA).

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 limit of test kit sensitivity).

Figure 1. Summary of Results Reported by Participant Laboratories for HIV-1 RNA Determinations in the August 14, 2001 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 14, 2001 Performance Evaluation Survey

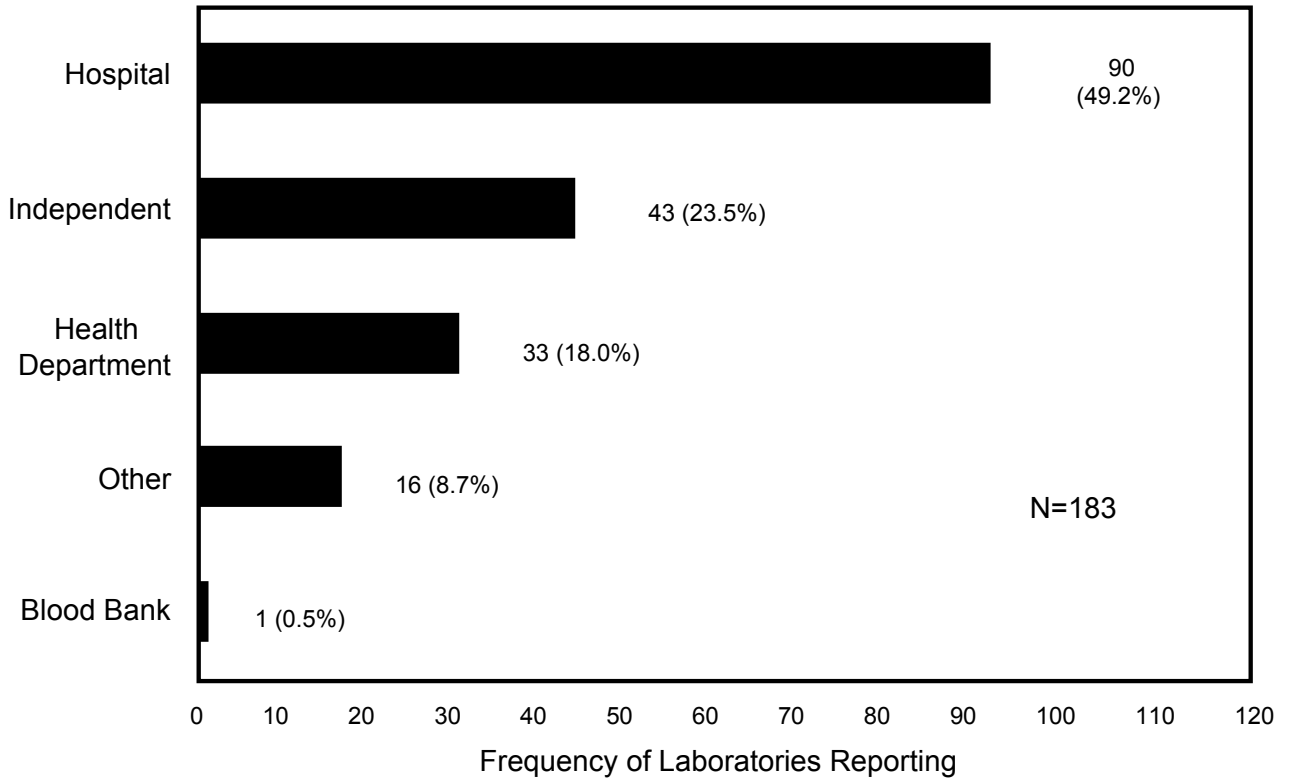


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the August 14, 2001 Performance Evaluation Survey

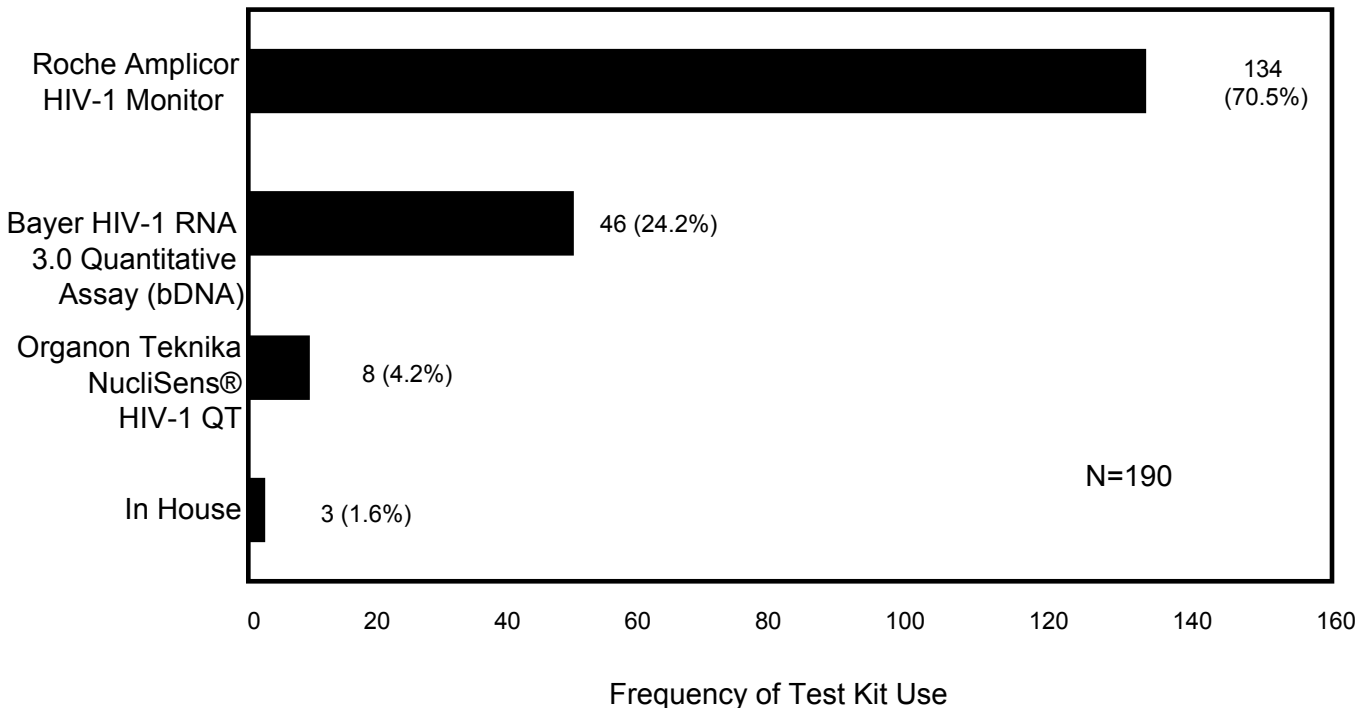


Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 14, 2001 Performance Evaluation Survey.

CDC Donor #1

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

Panel Vial Labels: A3, 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™	127	6	105	1,069	2,853
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	46	0	285	635	1,210
Organon Teknika NucliSens® HIV-1 QT	7	1	480	980	3,400
In House	3	1	467	734	1,000

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Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 14, 2001 Performance Evaluation Survey.

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™	133	0	1,911	20,453	113,296
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	46	0	11,690	19,679	42,706
Organon Teknika NucliSens® HIV-1 QT	8	0	19,373	33,000	52,000
In House	3	0	24,858	29,000	31,500

CDC Donor #2 (Duplicate)

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™	133	0	2,243	20,989	59,400
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	46	0	10,276	20,916	44,071
Organon Teknika NucliSens® HIV-1 QT	8	0	15,646	27,000	34,000
In House	3	0	17,100	31,300	34,000

Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the August 14, 2001 Performance Evaluation Survey.

CDC Donor #5

Donor Status: HIV-1 Uninfected

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™	3	130	2	26,571	27,768
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	3	43	56	68	572
Organon Teknika NucliSens® HIV-1 QT	0	8	<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 (Duplicate)

Donor Status: HIV-1 Uninfected

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™	2	131	433	809	1184
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	4	42	70	82	102
Organon Teknika NucliSens® HIV-1 QT	0	8	<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.

* = less than kit lower limit sensitivity