

**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 22, 2000 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 30341**



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**Report of the February 22, 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  
 February 22, 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 <sup>2</sup>	Donor HIV Status	Laboratory Interpretation <sup>1</sup> and/or Results	
					Test Result	Interpretation
A	A1	4	Negative	Uninfected	_____	_____
	A2	1	Positive	Infected	_____	_____
	A3, A5	2	Positive	Infected	_____	_____
	A4	3	Negative	Uninfected	_____	_____
B	B1, B4	2	Positive	Infected	_____	_____
	B2	4	Negative	Uninfected	_____	_____
	B3	1	Positive	Infected	_____	_____
	B5	3	Negative	Uninfected	_____	_____

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

<sup>2</sup> 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**

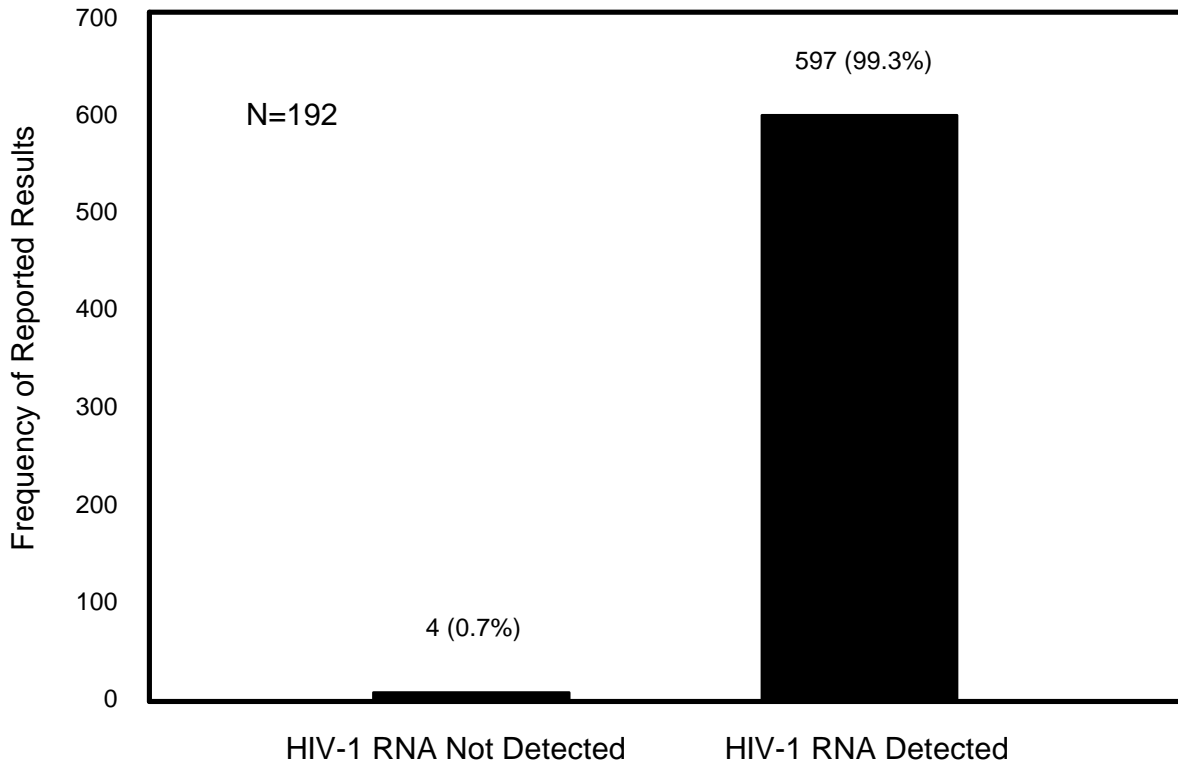
**Table 2. CDC HIV-1 RNA Testing Results for the February 22, 2000 Participant Laboratory Panel Samples**

<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>
<b>A</b>	<b>A1</b>	<b>4</b>	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Negative Negative Negative
	<b>A2</b>	<b>1</b>	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Positive Positive Positive
	<b>A3, A5</b>	<b>2</b>	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Positive Positive Positive
	<b>A4</b>	<b>3</b>	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Negative Negative Negative
<b>B</b>	<b>B1, B4</b>	<b>2</b>	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Positive Positive Positive
	<b>B2</b>	<b>4</b>	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Negative Negative Negative
	<b>B3</b>	<b>1</b>	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Positive Positive Positive
	<b>B5</b>	<b>3</b>	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor Monitor Organon NucliSens Bayer (Chiron) Quantiplex	Negative Negative Negative

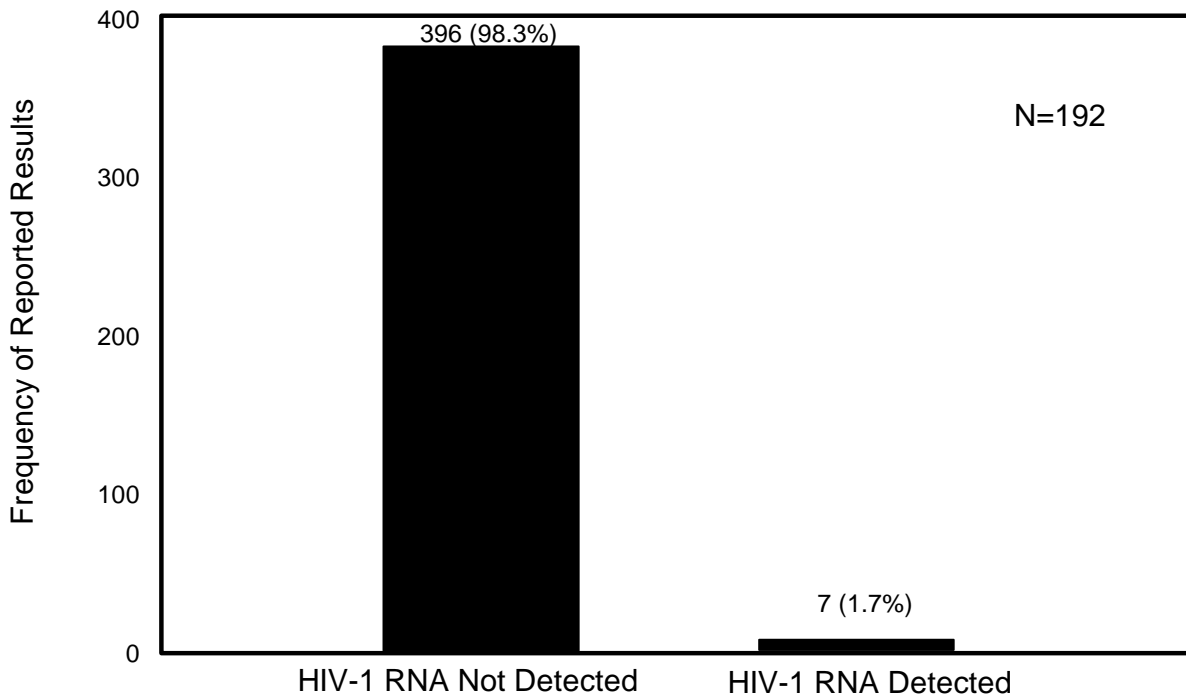
<sup>1</sup>The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA).

<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 22, 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 February 22, 2000 Performance Evaluation Survey

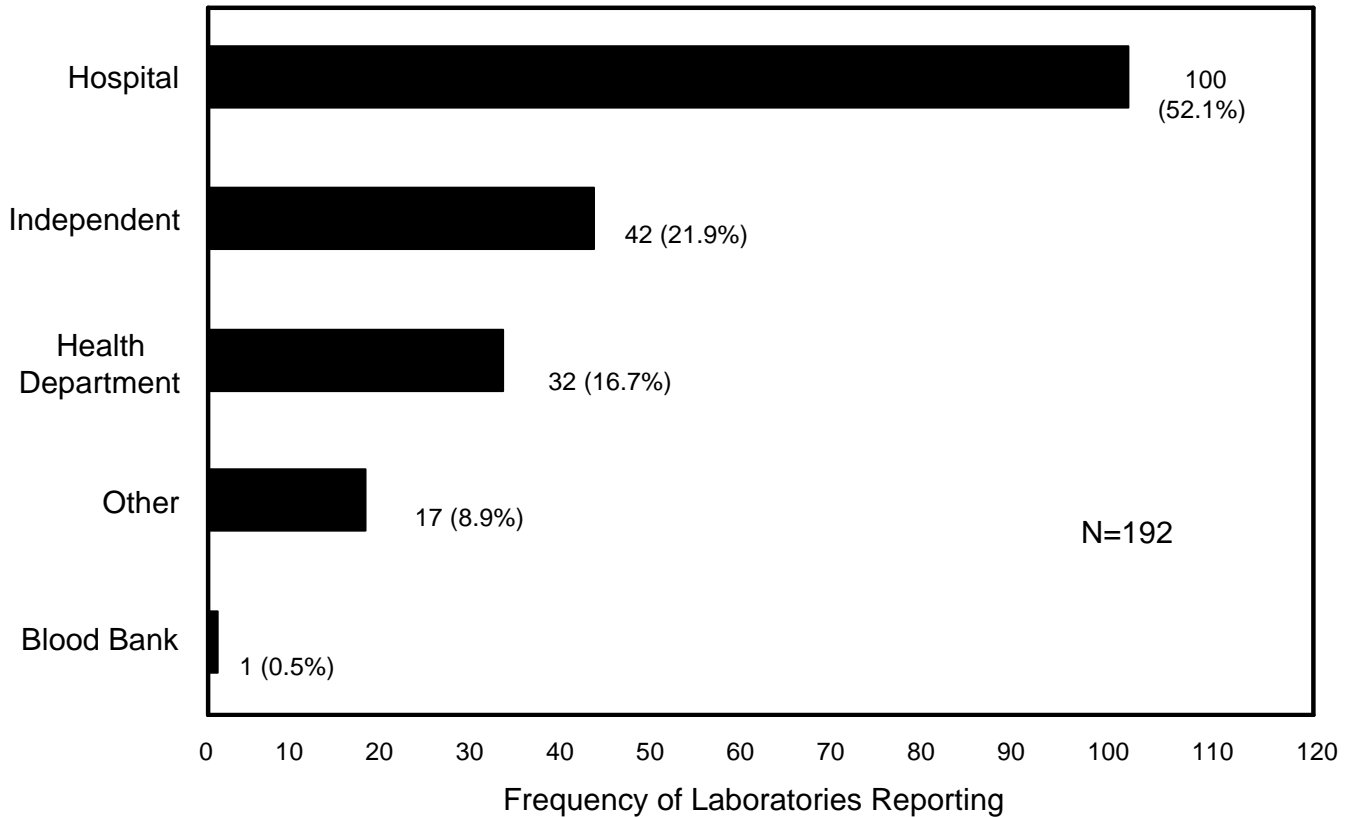
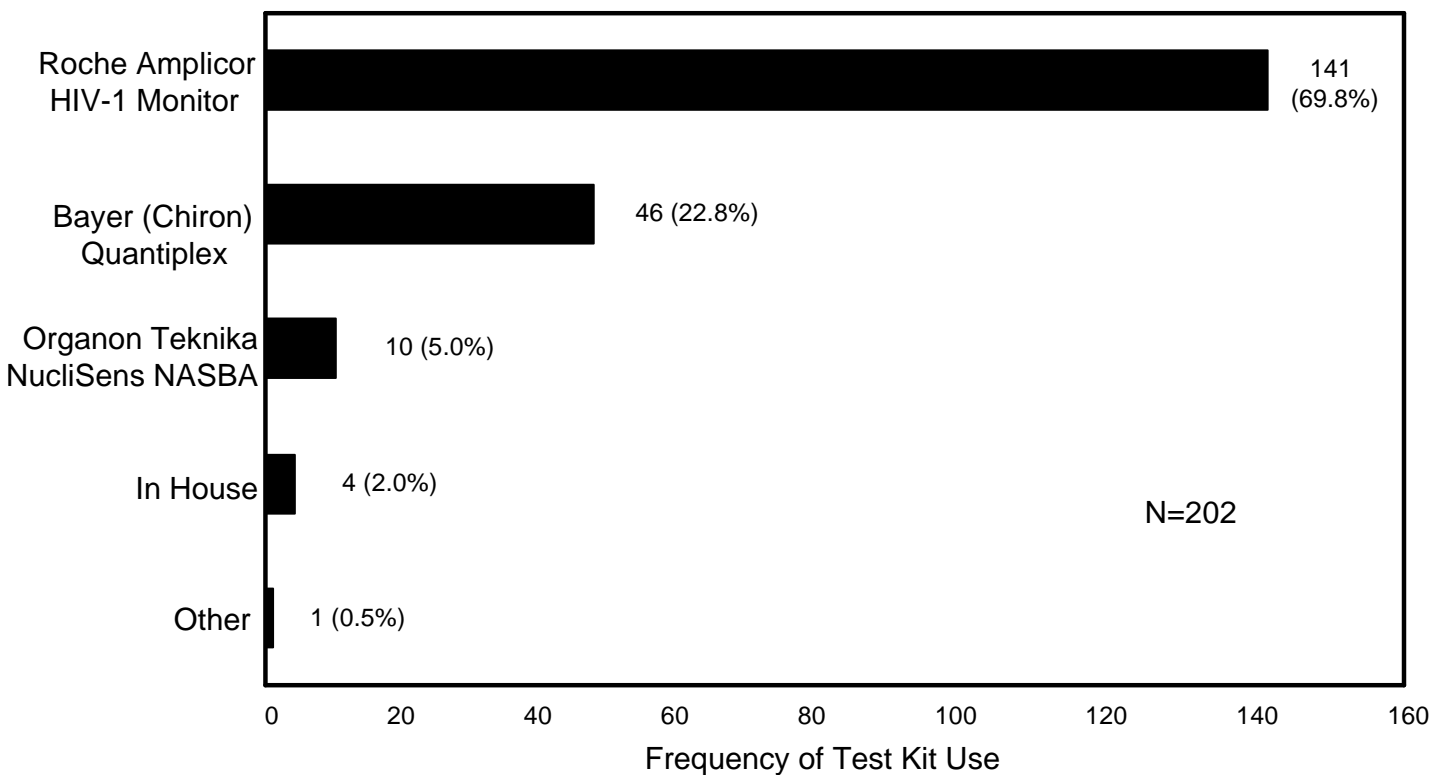


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the February 22, 2000 Performance Evaluation Survey



**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 22, 2000 Performance Evaluation Survey.**

**CDC Donor #1**

**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™	138	2	129	977	2,646
Bayer (Chiron) Quantiplex™	46	0	386	661	3,899
Organon Teknika NucliSens NASBA™	8	2	310	1,000	5,500
In House	4	0	99	613	1,797
Other	1	0	1,115	1,115	1,115

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**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 22, 2000 Performance Evaluation Survey.**

**CDC Donor # 2**

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

**Panel Vial Labels: A3, 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™	140	0	1,295	11,355	40,592
Bayer (Chiron) Quantiplex™	46	0	4,430	8,630	37,671
Organon Teknika NucliSens NASBA™	10	0	6,750	12,000	30,000
In House	4	0	1,633	10,420	23,115
Other	1	0	7,146	7,146	7,146

**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™	138	0	3,635	12,103	32,294
Bayer (Chiron) Quantiplex™	46	0	2,888	8,735	38,918
Organon Teknika NucliSens NASBA™	10	0	7,700	15,000	33,000
In House	4	0	1,332	9,705	19,438
Other	1	0	6,800	6,800	6,800



**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 22, 2000 Performance Evaluation Survey.**

**CDC Donor #3**  
**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™	0	140	<kit sens.*	<kit sens.	<kit sens.
Bayer (Chiron) Quantiplex™	2	44	77	80	82
Organon Teknika NucliSens NASBA™	0	10	<kit sens.	<kit sens.	<kit sens.
In House	1	3	86	86	86
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: 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™	1	140	30	30	30
Bayer (Chiron) Quantiplex™	2	44	66	89	11
Organon Teknika NucliSens NASBA™	1	9	3,200	3,200	3,200
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

