

**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 13, 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  
Division of Laboratory Systems  
Atlanta, Georgia 30341-3717**



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**Report of the February 13, 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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The production of this report was coordinated in CDC by:

Public Health Practice Program Office.....Edward L. Baker, M.D., M.P.H., Director  
Division of Laboratory Systems.....Robert Martin, Dr.P.H., Director  
.....Thomas L. Hearn, Ph.D., Deputy Director

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP).....Barbara A. Slade, M.D., Chief  
MPEP HIV-1 RNA Performance Evaluation.....Michelle B. Kahn, M.S., D.V.M.  
HIV-1 RNA Project Coordinator

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Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-8095 or (770) 488-8137.

**Centers for Disease Control and Prevention (CDC)  
 Model Performance Evaluation Program  
 Human Immunodeficiency Virus Type 1 (HIV-1) Ribonucleic Acid (RNA) Testing  
 February 13, 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 <sup>2</sup>	Donor HIV Status	Laboratory Interpretation <sup>1</sup> and/or Results	
					Test Result	Interpretation
A	A1	1	Positive	Infected	_____	_____
	A2	3	Negative	Uninfected	_____	_____
	A3, A4	2	Positive	Infected	_____	_____
	A5	5	Negative	Uninfected	_____	_____
B	B1	5	Negative	Uninfected	_____	_____
	B2, B3	2	Positive	Infected	_____	_____
	B4	3	Negative	Uninfected	_____	_____
	B5	1	Positive	Infected	_____	_____

<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 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**

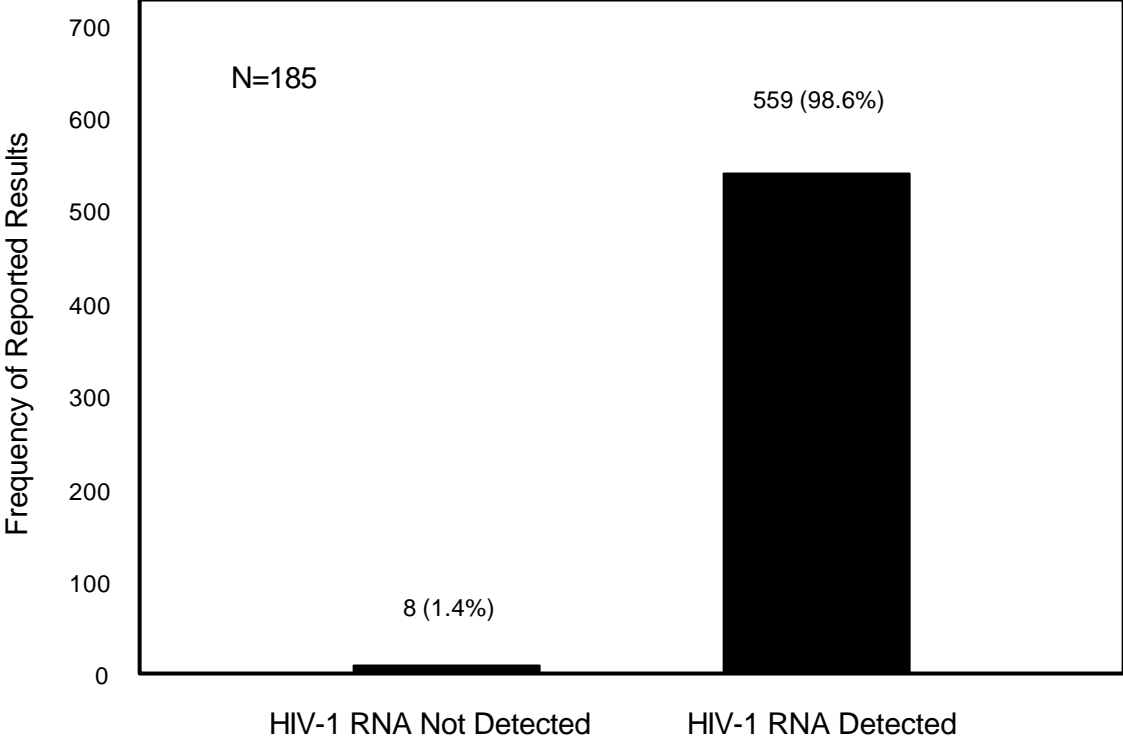
**Table 2. CDC HIV-1 RNA Testing Results for the February 13, 2001 Participant Laboratory Panel Samples**

<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>1</b>	<b>HIV RNA detected HIV RNA detected HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Positive Positive Positive</b>
	<b>A2</b>	<b>3</b>	<b>No HIV RNA detected No HIV RNA detected No HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Negative Negative Negative</b>
	<b>A3,A4</b>	<b>2</b>	<b>HIV RNA detected HIV RNA detected HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Positive Positive Positive</b>
	<b>A5</b>	<b>5</b>	<b>No HIV RNA detected No HIV RNA detected No HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Negative Negative Negative</b>
	<b>B</b>	<b>B1</b>	<b>5</b>	<b>No HIV RNA detected No HIV RNA detected No HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>
	<b>B2,B3</b>	<b>2</b>	<b>HIV RNA detected HIV RNA detected HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Positive Positive Positive</b>
	<b>B4</b>	<b>3</b>	<b>No HIV RNA detected No HIV RNA detected No HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Negative Negative Negative</b>
	<b>B5</b>	<b>1</b>	<b>HIV RNA detected HIV RNA detected HIV RNA detected</b>	<b>Roche Amplicor Monitor Organon NucliSens Bayer Quantiplex</b>	<b>Positive Positive Positive</b>

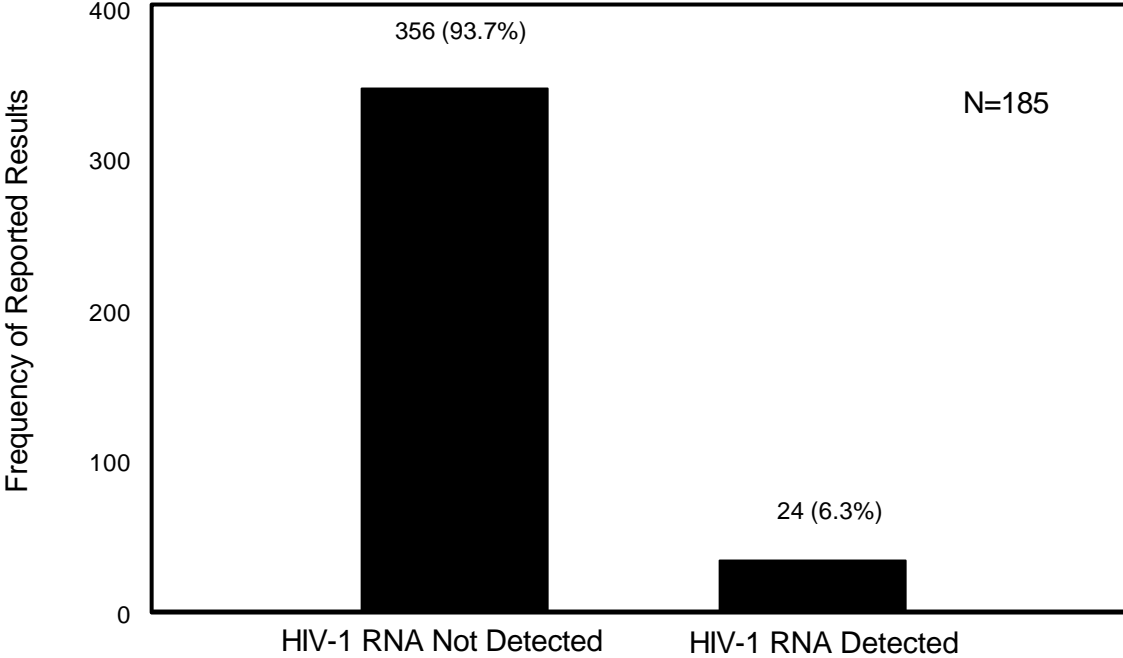
<sup>1</sup>The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. One of these kits is licensed by the Food and Drug Administration (FDA).

<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 limit of test kit sensitivity).

Figure 1. Summary of Results Reported by Participant Laboratories for HIV -1 RNA Determinations in the February 13, 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 February 13, 2001 Performance Evaluation Survey

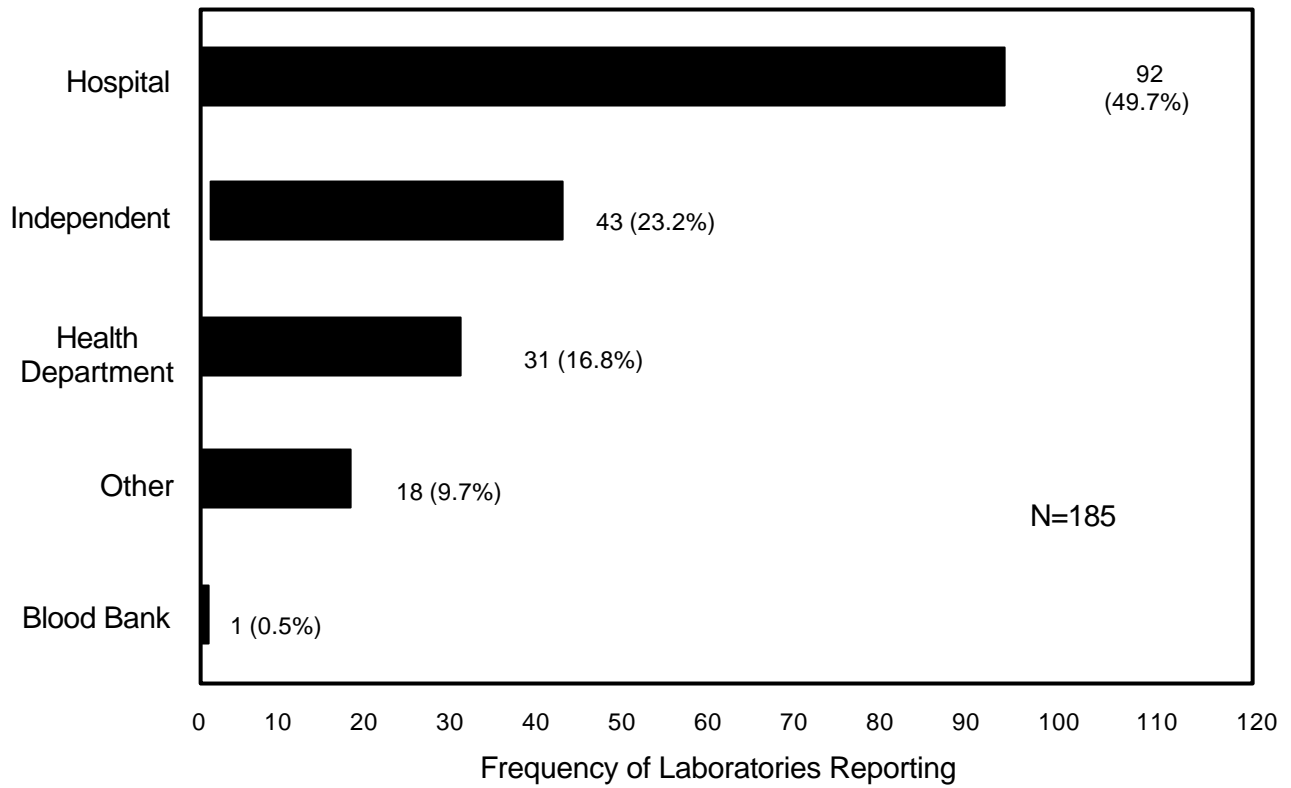
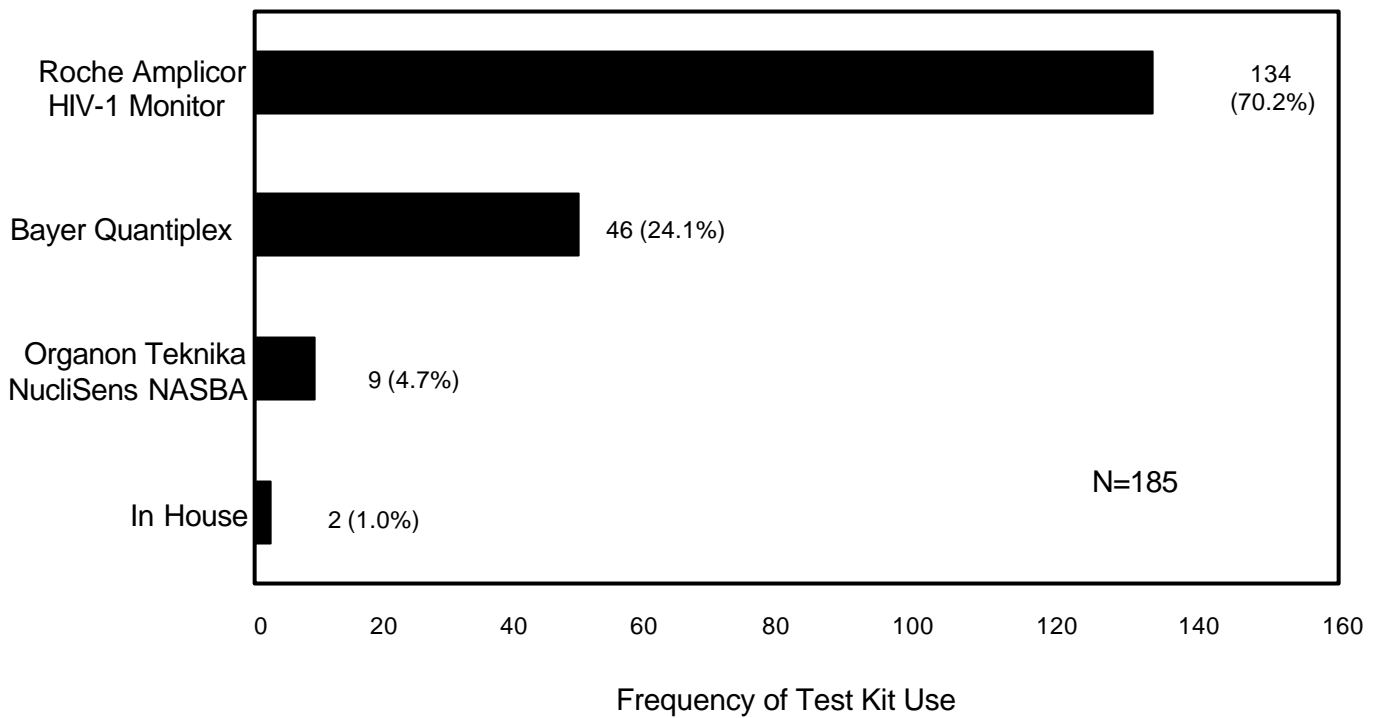


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the February 13, 2001 Performance Evaluation Survey



**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 13, 2001 Performance Evaluation Survey.**

**CDC Donor #1**

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

**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™	132	0	4,532	15,112	54,862
Bayer (Chiron) Quantiplex™	46	0	714	11,022	19,375
Organon Teknika NucliSens NASBA™	8	0	15,000	25,501	44,000
In House	2	0	1,040	16,520	32,000

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**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 13, 2001 Performance Evaluation Survey.**

**CDC Donor # 2**

**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™	128	4	319	976	4,013
Bayer (Chiron) Quantiplex™	46	0	334	689	1,114
Organon Teknika NucliSens NASBA™	8	1	360	1,250	4,600
In House	2	0	230	665	1,100

**CDC Donor #2 (Duplicate)**

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

**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™	128	4	232	1,024	2,324
Bayer (Chiron) Quantiplex™	46	0	336	647	11,886
Organon Teknika NucliSens NASBA™	8	0	190	1,650	7,300
In House	2	0	180	790	1,400



**Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 13, 2001 Performance Evaluation Survey.**

**CDC Donor #3**  
**Donor Status: HIV-1 Uninfected**  
**Panel Vial Labels: A2, 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	133	<kit sens.*	<kit sens.	<kit sens.
Bayer (Chiron) Quantiplex™	7	39	53	58	111
Organon Teknika NucliSens NASBA™	0	8	<kit sens.	<kit sens.	<kit sens.
In House	0	2	<kit sens.	<kit sens.	<kit sens.

\* = less than kit lower limit sensitivity

**CDC Donor #5**  
**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™	0	133	<kit sens.*	<kit sens.	<kit sens.
Bayer (Chiron) Quantiplex™	17	29	51	84	397
Organon Teknika NucliSens NASBA™	0	8	<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