

**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 12, 2002 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**

Report of the February 12, 2002 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).

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).....G. David, Cross, M.S., Acting Chief
MPEP HIV-1 RNA Performance Evaluation.....Michelle B. Kahn, M.S., D.V.M.
HIV-1 RNA Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation Program
by calling (770) 488-8095 or (770) 488-8091.

**Centers for Disease Control and Prevention (CDC)
 Model Performance Evaluation Program
 Human Immunodeficiency Virus Type 1 (HIV-1) Ribonucleic Acid (RNA) Testing
 February 12, 2002 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	1	Positive	Infected	
	A2	4	Negative	Uninfected	
	A3	3	Positive	Infected	
	A4	5	Negative	Uninfected	
B	B1	4	Negative	Uninfected	
	B2	3	Positive	Infected	
	B3, B4	1	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. Two of these kits are 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 12, 2002 Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results¹	Test Kit Manufacturer	CDC Interpretation²
A	A1, A5	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Positive Positive Positive
	A2	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Negative Negative Negative
	A3	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Positive Positive Positive
	A4	5	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Negative Negative Negative
B	B1	4	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT) Bayer 3.0 Quantitative Assay (bDNA)	Negative Negative Negative
	B2	3	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Positive Positive Positive
	B3, B4	1	HIV RNA detected HIV RNA detected HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Positive Positive Positive
	B5	5	No HIV RNA detected No HIV RNA detected No HIV RNA detected	Roche Amplicor HIV-1 Monitor[⌋] bioMérieux NucliSens⁷ HIV-1 QT Bayer 3.0 Quantitative Assay (bDNA)	Negative Negative Negative

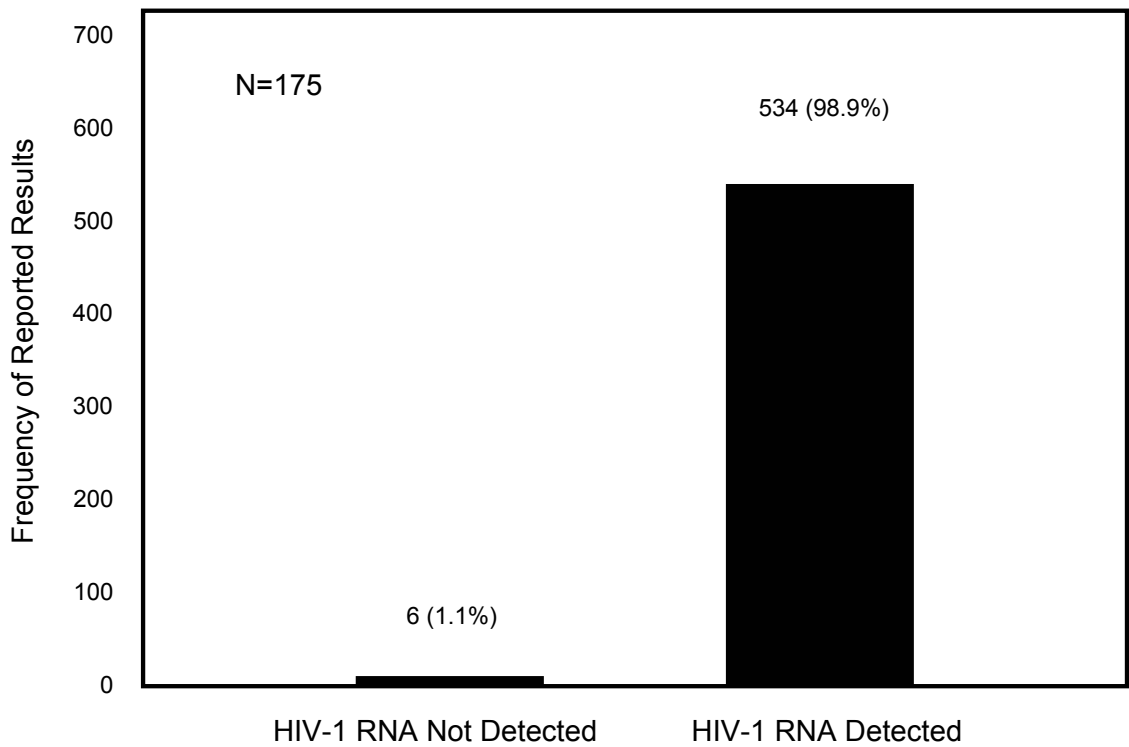
¹The CDC test results were obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. Two of these kits are licensed by the Food and Drug Administration (FDA).

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).

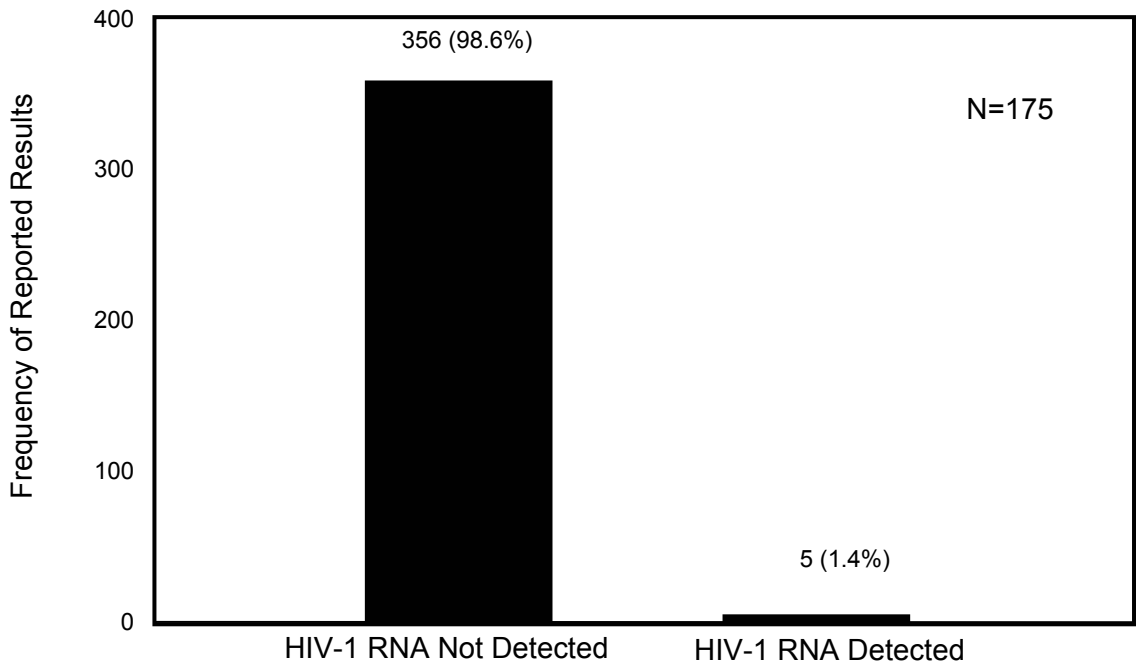
**SUPPLEMENTAL INFORMATION FOR COMPREHENDING
THE NUMBERS USED TO LABEL FIGURES
IN THIS REPORT**

The "N=" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test; therefore, the number of results may exceed the actual number of laboratories providing reports. The number appearing directly above or within each bar represents a frequency of results only.

Figure 1. Summary of Results Reported by Participant Laboratories for HIV-1 RNA Determinations in the February 12, 2002 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 12, 2002 Performance Evaluation Survey

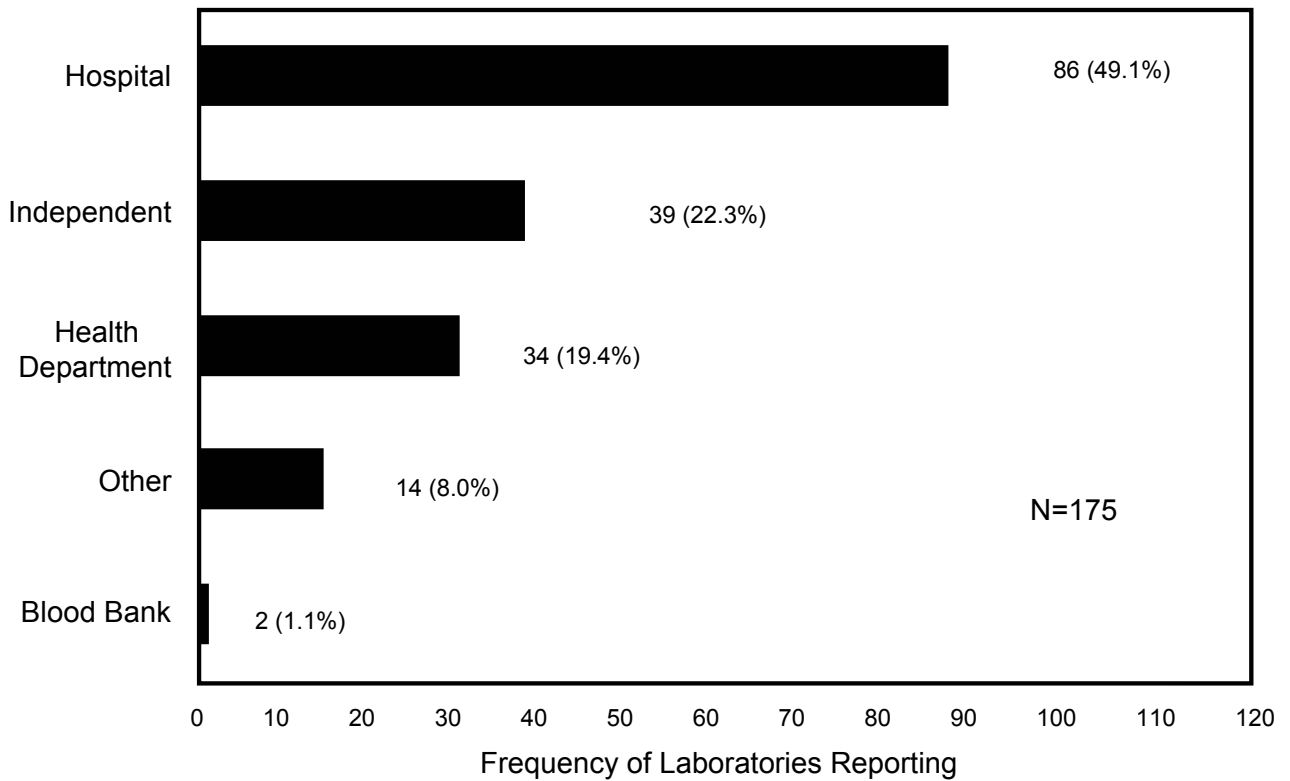


Figure 3. Types of Test Kits Used to Perform HIV-1 RNA Determinations in the February 12, 2002 Performance Evaluation Survey

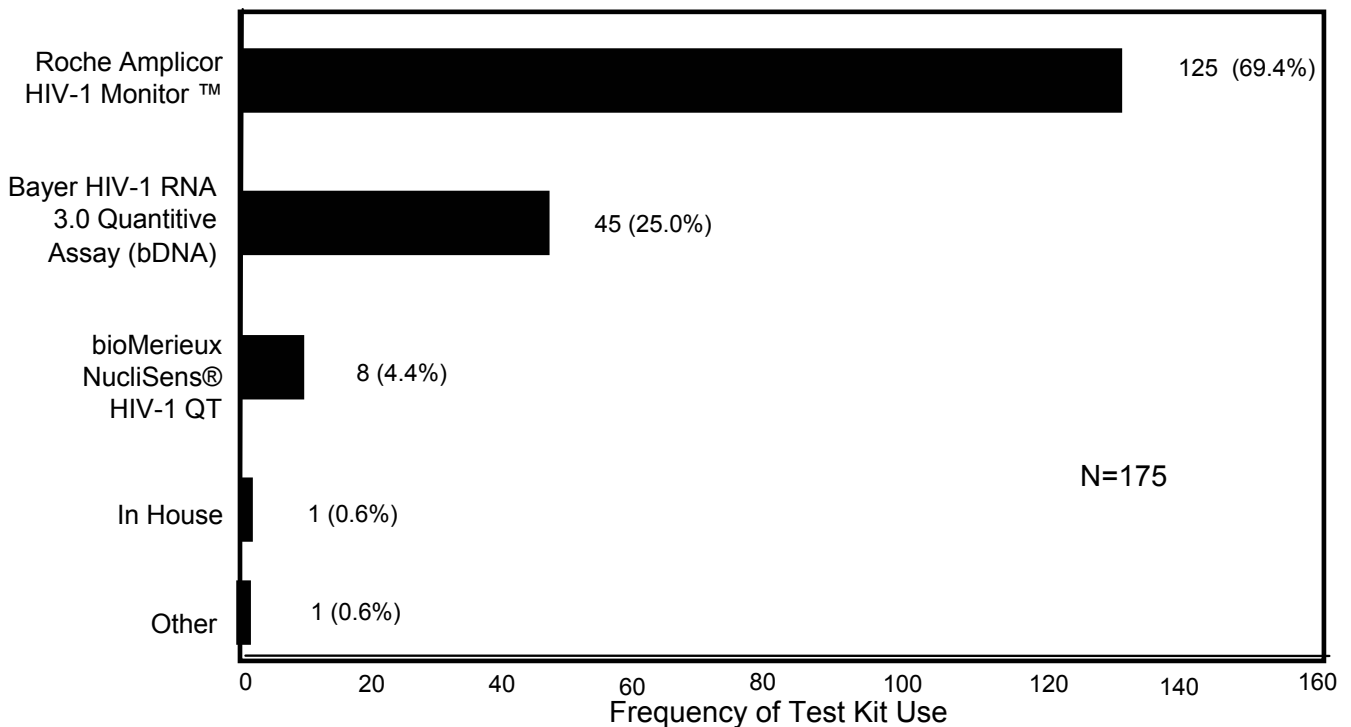


Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 12, 2002 Performance Evaluation Survey.

CDC Donor #1

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

Panel Vial Labels: A1, 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™	122	3	314	1,258	7,117
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	45	0	429	1,281	3,780
bioMérieux NucliSens® HIV-1 QT	8	0	630	960	8,500
In House	1	0	3,400	3,400	3,400
Other	1	0	147	147	147

CDC Donor #1 (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™	122	3	424	1,108	9,703
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	45	0	587	1,240	3,712
bioMérieux NucliSens® HIV-1 QT	8	0	655	950	1,700
In House	1	0	3,100	3,100	3,100
Other	1	0	158	158	158

Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 12, 2002 Performance Evaluation Survey.

CDC Donor # 3

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™	125	0	3,417	13,396	52,591
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	45	0	9,710	15,300	35,488
bioMérieux NucliSens® HIV-1 QT	8	0	15,500	28,500	49,000
In House	1	0	39,000	39,000	39,000
Other	1	0	28,900	28,900	28,900

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Table 3. Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the February 12, 2002 Performance Evaluation Survey.

CDC Donor #4
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™	2	123	90	100	110
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	0	45	<kit sens.*	<kit sens.	<kit sens.
bioMérieux NucliSens® HIV-1 QT	0	8	<kit sens.	<kit sens.	<kit sens.
In House	0	1	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

* = less than kit lower limit sensitivity

CDC Donor #5
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	123	806	5,792	10,778
Bayer HIV-1 RNA 3.0 Quantitative Assay (bDNA)	1	44	196	196	196
bioMérieux NucliSens® HIV-1 QT	0	8	<kit sens.*	<kit sens.	<kit sens.
In House	0	1	<kit sens.	<kit sens.	<kit sens.
Other	0	1	<kit sens.	<kit sens.	<kit sens.

* = less than kit lower limit sensitivity