DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention Model Performance Evaluation Program

Human Immunodeficiency Virus Type 1 Ribonucleic Acid (RNA) Determinations

Report of Results for the Performance Evaluation Survey Conducted in August 2004

CENTERS FOR DISEASE™
CONTROL AND PREVENTION

COORDINATING CENTER FOR HEALTH INFORMATION AND SERVICE
DIVISION OF LABORATORY SERVICES
ATLANTA, GEORGIA

HIV-1 Ribonucleic Acid Testing MPEP August 2004
Report of Results

Report of the August 2004 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 (MPEP), Centers for Disease Control and Prevention (CDC).

Report Production

The production of this report was coordinated in CDC by:

Coordinating Center
for Health Information and Services.....Ed Sondik, Ph.D.,
Blake Caldwell, M.D., M.P.H., Acting Directors

National Center for Health Marketing……Steve L. Solomon, M.D., Acting Director

Office of Public Health Partnerships.....Robert Martin, M.P.H., Dr.P.H., Acting Director

Division of Laboratory Services…….Thomas L. Hearn, Ph.D., Acting Director

Laboratory Practice Evaluation and
Genomics Branch.....Devery Howerton, Ph.D., Chief

Report Content

The content was developed by:

Model Performance Evaluation Program (MPEP).....Laurina O. Williams, Ph.D., M.P.H.
G. David Cross, M.S.,
Co-Managers

MPEP HIV-1 RNA Performance Evaluation.....Suzette A. Park, M.S.
HIV-1 RNA Project Coordinator

Contact Information

Questions about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-8097 or (770) 488-8130.

Table of Contents

TABLES

FIGURES

Overview

Introduction

This report is an analysis of testing results reported by laboratories participating in the Centers for Disease Control and Prevention (CDC) Model Performance Evaluation Program (MPEP) for human immunodeficiency virus type 1 (HIV-1) ribonucleic acid (RNA) determinations performance evaluation specimens sent on August 10, 2004.

Specimen Panels

Each laboratory received a total of five plasma specimens obtained from individual donors (not pooled or diluted with plasma from other donors); three HIV-1 antibody-positive and two HIV-1 antibody-negative specimens.

- Before shipment, the CDC tested each donor with three viral RNA test kits approved by the Food and Drug Administration (FDA).
- One of the HIV-1 antibody-positive plasma specimens, Donor 2, was sent to the participant laboratories in duplicate.
- For the samples designated Donor 2 and Donor 2 Duplicate, the material came from the same plasma but was sent to the laboratories as separate samples under different sample vial designations. The vial designations were A2, A3, B3 and B5.
- Not all laboratories received the same panel of specimens.

Laboratory Response

Of the 190 laboratories receiving specimen panels, 175 (92.1%) reported testing results.

- In general, the percentage of the laboratories reporting results has remained steady at about 90-92% over the last three shipments.
- The majority of the laboratories (126/175, 72%) reported their testing results using the online data entry system.
    - This represents a 4.2% increase in online result reporting as compared to the previous (February 2004) survey (67.8%) and a 28.7% increase as compared to the first time reporting using the online option (43.3%).

Note: We continue to encourage laboratories to use the online option as a method of streamlining the reporting process.

Overview: Significant Findings

Table 1: The following table summarizes the results grouped by test type.

Results Summary

			Positive Donors		Negative Donors		Overall Performance
Method	Total # of labs	Total # of results	Positive	False-negative	Negative	False-positive	(TP+TN/total # results)[3]
Quantitative[1]	168	879	509	19	339	12	96.5%
Qualitative[2]	7	35	35	0	35	0	100%
Total	175	914	530	19	353	12	96.6%

[1] Roche Amplicor HIV-1 Monitor, Bayer Versant HIV-1 RNA 3.0 Assay (bDNA), bioMérieux NucliSens® HIV-1 QT, bioMérieux NucliSens® EasyQ HIV-1 and In-house methods.
[2] Chiron Procleix method
[3] TP, true positives; TN, true negatives.

False-negative Results

The overall quality of testing performance as measured in this survey has decreased compared to the previous shipment.

There were 3.5% (19/549) false-negative interpretations for this shipment compared with 1.9% (11/575) in the previous shipment.

- The average false-negative rate for the past two years (last three shipments) has been approximately 1.5%.

- Eighteen of the nineteen false-negative results were associated with Donor 2, and the other result was reported for Donor 1.
    - It should be noted that Donor 2 (also listed as Donor 2 duplicate) comprised the "low-positive" samples, with a target value of approximately 1,000 RNA copies/ml, whereas Donor 1 had a target value of approximately 15,000 RNA copies/ml.

- Of the 19 false-negatives, 18 were obtained using Roche's Amplicor HIV-1 Monitor® test and one using Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA).

Continued on next page

Overview: Significant Findings, Continued

False-positive Results

The percentage of false-positive results, 3.3% (12/365), reported in this survey was an increase from the previous survey [0.5% (2/384)].

- The average false-positive rate for the past two years (last three shipments) has been approximately 0.8%.
- Of the 12 false-positives reported, four were associated with Donor 3 and eight for Donor 4.
- Nine of the 12 false-positives were reported by laboratories using Roche's Amplicor HIV-1 Monitor® test with a lower limit sensitivity of 400 copies/ml.

Quality Control

A total of 50.8% (87/171) of respondents indicated that they used external quality control materials.

Donor Report

Overview

The Donor Report contains the specimen numbers and donor information for each performance evaluation specimen. Table 2, below, is provided for the participant laboratories to record and compare their results with CDC MPEP results for each performance evaluation specimen.

Table 2 Donor Identification for August 2004 Shipment Specimens

Panel Letter	Vial Label	CDC Donor Number	CDC Test Result[1]	Donor HIV Status	Laboratory Interpretation[2] and/or Results	
					Test Result	Interpretation
A	A1	3	Negative	Uninfected	_____	_____
	A2	2	Positive	Infected	_____	_____
	A3	2	Positive	Infected	_____	_____
	A4	1	Positive	Infected	_____	_____
	A5	4	Negative	Uninfected	_____	_____
B	B1	1	Positive	Infected	_____	_____
	B2	4	Negative	Uninfected	_____	_____
	B3	2	Positive	Infected	_____	_____
	B4	3	Negative	Uninfected	_____	_____
	B5	2	Positive	Infected	_____	_____

[1] The CDC result was obtained after pre-shipment testing with three manufactured kits for determining the presence of HIV-1 RNA. 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.

[2] Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

Continued on next page

Donor Report: CDC HIV-1 RNA Testing Results, Continued

Table 3 CDC HIV-1 RNA Testing Results for the August 10, 2004, Participant Laboratory Panel Samples

Panel Letter	Vial Label	CDC Donor Number	CDC Test Results[1]	Manufacturer Test Kit	CDC Interpretation[2]
A	A1	3	No HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Negative
			No HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Negative
			No HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Negative
	A2, A3	2	HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Positive
			HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Positive
			HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Positive
	A4	1	HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Positive
			HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Positive
			HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Positive
	A5	4	No HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Negative
			No HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Negative
			No HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Negative
B	B1	1	HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Positive
			HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Positive
			HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Positive
	B2	4	No HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Negative
			No HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Negative
			No HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Negative
	B3, B5	2	HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Positive
			HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Positive
			HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Positive
	B4	3	No HIV RNA detected	Roche Amplicor HIV-1 Monitor®	Negative
			No HIV RNA detected	bioMérieux NucliSens® HIV-1 QT	Negative
			No HIV RNA detected	Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA)	Negative

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

[2]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)

Demographics

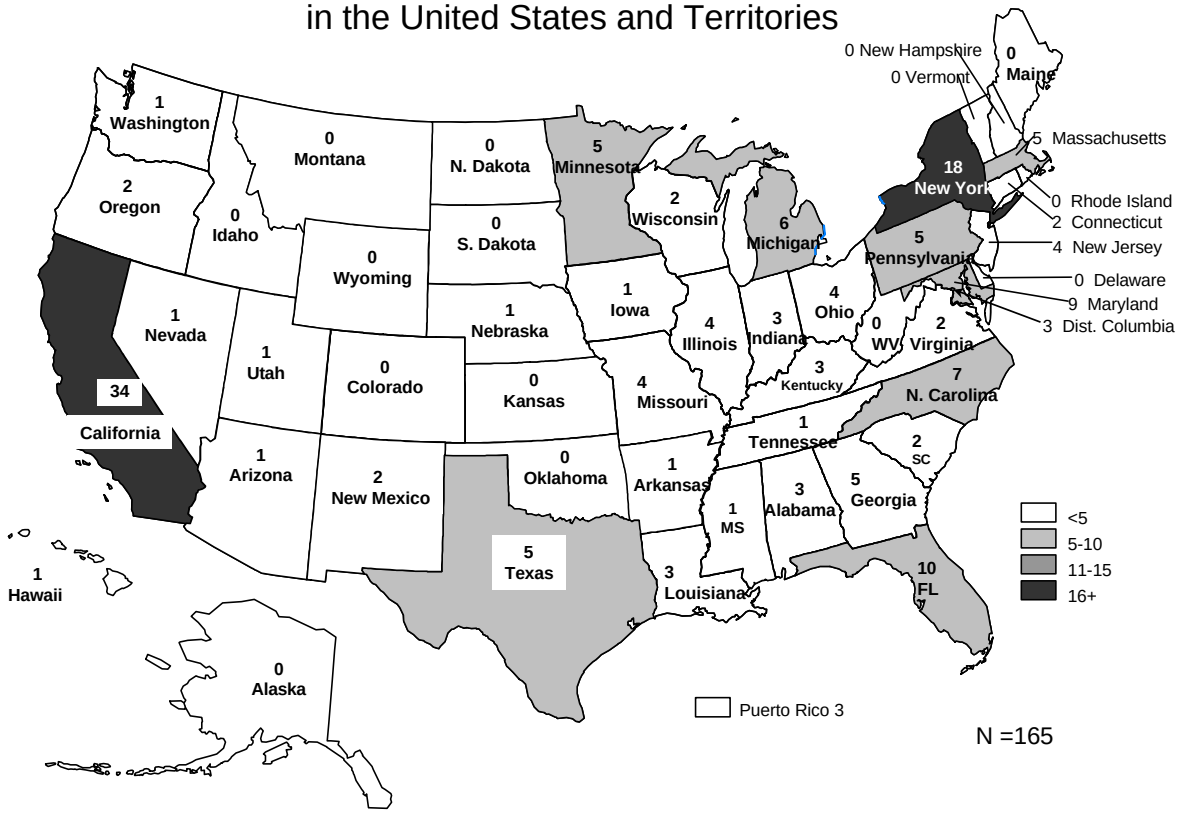
Overview

A total of 175 different laboratories submitted results. Of these:

- 165 were in the United States (domestic) and U.S. associated laboratories ***(Figure 1).***
- 10 testing sites were Canadian laboratories.
- ***Figure 2*** shows the primary classification of laboratories reporting quantitative or qualitative HIV-1 RNA results.
    - Hospital laboratories predominated.

Figure 1

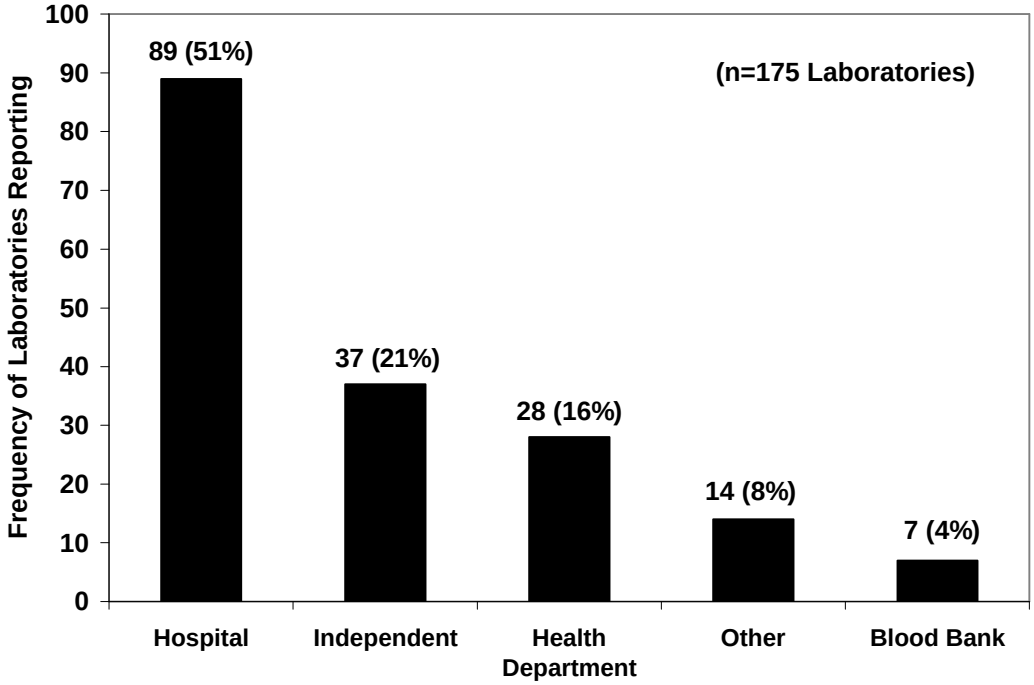
Number of MPEP HIV-1 RNA Laboratories returning results in the United States and Territories



Continued on next page

Demographics, Continued

Figure 2 Types of Participant Laboratories



Kit Types Used by Participants

Overview

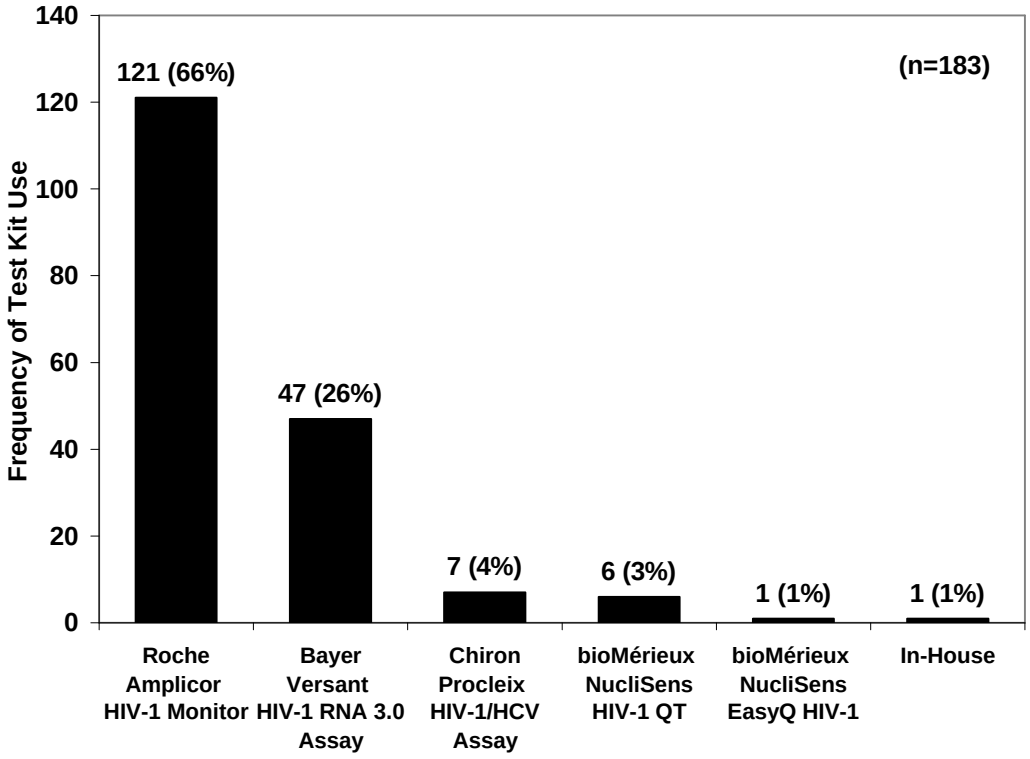
This section describes the types of test kits used by laboratories performing viral RNA quantitative and qualitative determinations.

- Roche's Amplicor HIV-1 Monitor® test kit was used most frequently (121/183, 66.1%) in reporting results.

- Seven of the eight participating laboratories that reported using qualitative RNA testing procedures used the HIV-1/HCV assay, which was developed by Gen-Probe and is marketed by Chiron under the name of Procleix™ HIV-1/HCV Assay. These seven laboratories (3.8%) provided the only qualitative test results reported in this survey. All results were correct using this assay.

Note: The "n=" on Figure 3 represents the number of reported results. For this graph, some laboratories used more than one test kit, therefore, the number of results reported (n =183) exceeds the number of laboratories reporting results (n =175).

Figure 3 Types of Test Kits Used to Perform HIV-1 RNA Determinations



Overall Summary of Results

Overview

There were 12 false-positives (12/365, 3.3%) reported in the current survey, in contrast to two false-positive (2/384, 0.5%) results reported in the previous performance survey (February 2004). The percentage of false-negative results (3.5%, 19/549) reported in this survey was higher from that of the previous survey (1.9%, 11/575).

Table 4: Cumulative Frequencies of Test Results

This table contains the cumulative frequencies of quantitative and qualitative test results for all donor samples reported by the laboratories. Described below is the final test interpretations (positive or negative for HIV-1 RNA) with respect to the donors' status (infected or uninfected) and includes the data for all test kits used.

	Number of Results	Percent Correct	Percent False Negative	Percent False Positive
Infected Donor Samples	549	96.5% (530/549)	3.5% (19/549)	n/a
Uninfected Donor Samples	365	96.7% (353/365)	n/a	3.3% (12/365)
TOTAL RESULTS	914	96.6% (883/914)	***	***

Results by Donor

The distribution by donor of the 12 false-positives quantitative results reported (12/351, 3.4%) and the 19 false-negative quantitative results (9/528, 3.6%) is shown in the table below.

Donor 1, (HIV-1 infected, high-positive)	1 false-negative
Donor 2, (HIV-1 infected, low-positive)	7 false-negative
Donor 2 Duplicate, (HIV-1 infected, low-positive)	11 false-negative
Donor 3, (HIV-1 negative)	4 false-positives
Donor 4, (HIV-1 negative)	8 false-positives

Note: Donor 2 comprised the "low-positive" samples, with a target value of approximately 1,000 RNA copies/ml, whereas Donor 1 had a target value of approximately 15,000 RNA copies/ml.

Overall Summary of Results: Test Kit Lower Limit Sensitivities

Test Kit Lower Limit Sensitivities

There was variability in the Lower Limit Sensitivities (LLS) reported by the laboratories that used commercially manufactured quantitative HIV-1 RNA test kits. Table 5 below shows the false-negative and false-positive results as they relate to the kit manufacturer and the LLS.

- Sixteen of the nineteen false-negative results were obtained using Roche's Amplicor HIV-1 Monitor® test; fourteen of these reports specified using a LLS of 400 copies/mL (two reports did not specify a LLS).

- Nine of the twelve false-positive results were also obtained using Roche's Amplicor HIV-1 Monitor® test and all of these reports specified using a LLS of 400 copies/mL.

Table 5:

LLS Results by Kit Manufacturer

			LLS[‡] for FP			LLS for FN	
Manufacturer	**Total # of Results**	**FP[*]**	**Freq**	**LLS**	**FN[†]**	**Freq**	**LLS**
Roche Amplicor HIV-1 Monitor	604	9 (1.5%)	9	400	16 (2.7%)	14 2	400 missing
Bayer Versant HIV-1 RNA 3.0 Assay (bDNA)	235	3 (1.3%)	2 1	75 50	1 (0.4%)	1	75
bioMérieux NucliSens HIV-1 QT	30	0			1 (3.3%)	1	400
bioMérieux NucliSens® EasyQ HIV-1	5	0			1 (20.0%)	1	400
In House	5	0			0		
Total	879	12 (1.4%)			19 (2.2%)		

[*]FP, False-positives
[†]FN, False-negatives
[‡]LLS, Lower Limit Sensitivity Used (copies/ml)

Continued on next page

Overall Summary of Results: Test Kit Lower Limit Sensitivities,
Continued

Test Kit Lower Limit Sensitivities (Continued)

The lower limit sensitivities of the reported quantitative kits ranged from 25 RNA copies/ml to 400 copies/ml.

Table 6 displays the lower limit sensitivities reported by the participating laboratories, by type of test kit used. For each test kit, the percentage of the total reported results for each specified lower limit sensitivity is shown, and "n" is the number of sample results reported using that test kit.

Table 6

Manufacturer Test Kit (n = number of reports)	Lower Limit Sensitivity Used (copies/ml)	Percent of Reports (n)
Roche Amplicor HIV-1 Monitor® (n = 604)	25	1% (5)
	50	35% (214)
	200	1% (5)
	400	56% (340)
	not indicated	7% (40)
Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA) (n= 235)	25	2% (5)
	50	15% (35)
	75	83% (195)
bioMérieux NucliSens® HIV-1 QT (n= 30)	25	33% (10)
	160	33% (10)
	250	17% (5)
	400	17% (5)
bioMérieux NucliSens® EasyQ HIV-1 (n=5)	400	100% (5)
In-House (n= 5)	100	100% (5)

Quantitative and Qualitative Test Aggregate Results

Aggregate Test Results

Tables 7 through 10 show the aggregate participant laboratories' testing results for each donor sample by test kit manufacturer.

Description: Tables 7-10

- Result columns provide the totals for the number of results reported detecting HIV-1 RNA and not detecting HIV-1 RNA.

For the quantitative results:

- The absolute minimum and maximum reported values of RNA copies/ml are given irrespective of the different kits' lower limit sensitivities.
- Also included for the quantitative results are the 25%, 50% (median) and 75% quartiles for those samples that had detectable RNA levels.

Description: Table 8A and 8B, Duplicate Sample

- For this performance survey shipment, Donor 2, an HIV-1 infected donor, was duplicated in each panel to provide the participant laboratories an opportunity to evaluate their intra-shipment reproducibility.
- For the samples designated Donor 2 and Donor 2 Duplicate, the material came from the same plasma but was sent to the laboratories as separate samples under different sample vial designations.
- Table 8A shows the laboratory test results reported for Donor 2.
- Table 8B shows results for the duplicated specimen, Donor 2 Duplicate.

Continued on next page

Quantitative and Qualitative Test Aggregate Results, Continued

Table 7 Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for Donor #1

Donor Status:
HIV-1 Infected and HIV-1 RNA Detected
Panel Vial Labels: A4, B1

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Quantitative Results Reported (RNA copies/ml)				
			minimum	maximum	25% Quartile	Median (50%)	75% Quartile
Roche Amplicor HIV-1 Monitor	120	1	2110	23400	4060	**5300**	7140
Bayer Versant HIV-1 RNA 3.0 Assay	47	0	1166	12412	3857	**4263**	5021
bioMérieux NucliSens HIV-1 QT	6	0	2300	8300	2700	**4100**	4700
Chiron Procleix	7	0	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens EasyQ HIV-1	1	0	6200	6200	n/a	**n/a**	n/a
In House	1	0	14000	14000	14000	**14000**	14000

Table 8A Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for Donor #2

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 Quantitative Results Reported (RNA copies/ml)				
			minimum	maximum	25% Quartile	Median (50%)	75% Quartile
Roche Amplicor HIV-1 Monitor	114	7	129	4890	573	**854**	1180
Bayer Versant HIV-1 RNA 3.0 Assay	47	0	222	1849	666	**890**	1045
bioMérieux NucliSens HIV-1 QT	6	0	130	1000	250	**690**	810
Chiron Procleix	7	0	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens EasyQ HIV-1	1	0	420	420	n/a	**n/a**	n/a
In House	1	0	200	200	200	**200**	200

Continued on next page

Quantitative and Qualitative Test Aggregate Results, Continued

Table 8B Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for Donor #2 Duplicate

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 Quantitative Results Reported (RNA copies/ml)				
			minimum	maximum	25% Quartile	Median (50%)	75% Quartile
Roche Amplicor HIV-1 Monitor	113	8	117	4162	542	**747**	1238
Bayer Versant HIV-1 RNA 3.0 Assay	46	1	311	1988	726	**846**	1019
bioMérieux NucliSens HIV-1 QT	5	1	180	1100	205	**525**	960
Chiron Procleix	7	0	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens EasyQ HIV-1	0	1	450	450	n/a	**n/a**	n/a
In House	1	0	430	430	430	**430**	430

Table 9 Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for Donor #3

Donor Status:
HIV-1 Uninfected and HIV-1 RNA Not Detected
Panel Vial Labels: A1, B4

Test Kit	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Quantitative Results Reported (RNA copies/ml)				
			minimum	maximum	25% Quartile	Median (50%)	75% Quartile
Roche Amplicor HIV-1 Monitor	4	117	0	3570	0	**810**	3570
Bayer Versant HIV-1 RNA 3.0 Assay	0	47	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens HIV-1 QT	0	6	n/a	n/a	n/a	**n/a**	n/a
Chiron Procleix	0	7	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens EasyQ HIV-1	0	1	n/a	n/a	n/a	**n/a**	n/a
In House	0	1	n/a	n/a	n/a	**n/a**	n/a

Quantitative and Qualitative Test Aggregate Results, Continued

Table 10 Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for the Donor #4

Donor Status:
HIV-1 Uninfected and HIV-1 RNA Not Detected
Panel Vial Labels: A5, B2

	No. of Results Detecting RNA	No. of Results Not Detecting RNA	Range of Quantitative Results Reported (RNA copies/ml)				
Test Kit			**minimum**	**maximum**	**25% Quartile**	**Median (50%)**	**75% Quartile**
Roche Amplicor HIV-1 Monitor	5	115	0	2820	0	**1861**	2820
Bayer Versant HIV-1 RNA 3.0 Assay	3	44	55	155	55	**87**	155
bioMérieux NucliSens HIV-1 QT	0	6	n/a	n/a	n/a	**n/a**	n/a
Chiron Procleix	0	7	n/a	n/a	n/a	**n/a**	n/a
bioMérieux NucliSens EasyQ HIV-1	0	1	n/a	n/a	n/a	**n/a**	n/a
In House	0	1	n/a	n/a	n/a	**n/a**	n/a

HIV Positive Donors' Results in Histogram Format

Histogram of HIV-1 RNA Quantitative Determinations

Histograms depicting the aggregate results of RNA copies/ml for the two HIV positive donors are shown in Figures 4 and 5 below. Figure 4 depicts the quantitative results for Donor 1 and Figure 5 depicts the results for Donor 2 and Donor 2 duplicate.

Figure 4 Histogram of HIV-1 RNA Quantitative Determinations for Donor 1

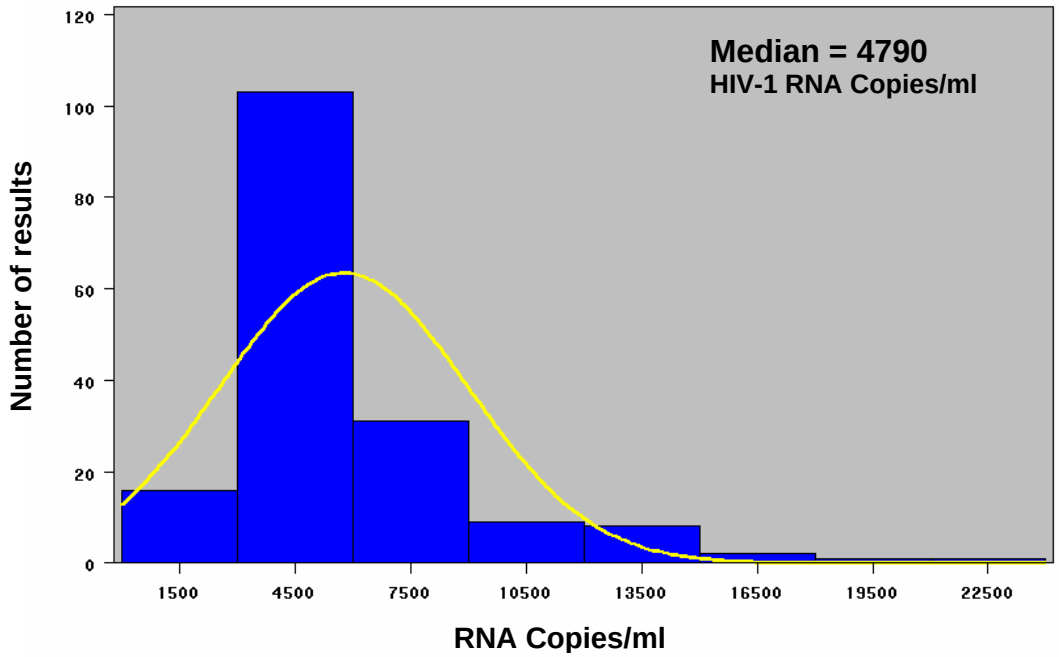
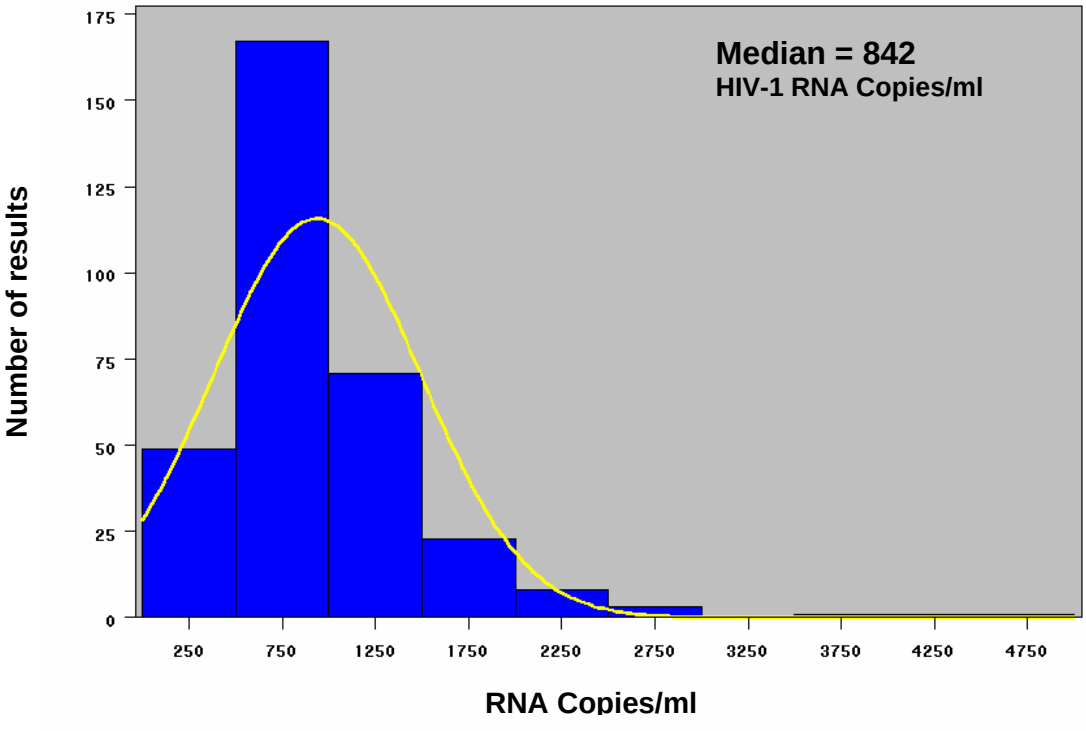


Figure 5 Histogram of HIV-1 RNA Quantitative Determinations for Donor 2



Conclusion

Overall Performance

The results of this performance evaluation shipment for quantitative and qualitative HIV-1 RNA determinations showed that the relative number of false-positive and false negative results, when compared with the previous performance surveys, has increased.

The overall performance in this survey was 96.6%, representing overall decreased accuracy compared with recent shipments.

Shipment Date	Overall Performance
February 2003	98.7%
August 2003	99.0%
February 2004	98.6%
August 2004	96.6%

False-negative Rate

The false-negative rate for this shipment was 3.5%, well above the average, 1.5%, of the false-negative rates in the previous three shipments.

Shipment Date	% False-negative
February 2003	0.9%
August 2003	1.6%
February 2004	1.9%
August 2004	3.5%

There were a total of 19 false-negative interpretations reported for HIV-1 RNA positive samples in this shipment.

- One laboratory reported a false-negative interpretation for Donor 1 (10,000 copies/ml).
- Seventeen different laboratories reported false-negative interpretations for Donor 2 or Donor 2 duplicate (identical "low-positive" samples with a target value of 1,000 copies/ml).
    - Of these 17, one laboratory reported false-negative interpretations for both samples.
    - Sixteen laboratories reported discordant results, i.e., a false-negative interpretation for one sample and a correct positive interpretation for the other sample.

Continued on next page

Conclusion, Continued

False-positive Rate

The rate of false-positive interpretations was also higher in this shipment; 3.3% compared with the average of 0.8% over the past three shipments.

Shipment Date	% False-positive
February 2003	1.9%
August 2003	0%
February 2004	0.5%
August 2004	3.3%

- Four out of eight laboratories reported false-positives results on both negative donors 3 and 4.

External Quality Control (QC)

Of the 175 laboratories reporting results in this survey:

- 97.7% (171/175) provided information on external QC materials
  - 49.1% (84/171) did not use external QC samples
  - 50.8% (87/171) indicated that they used external QC materials. The sources of their external QC materials were as follows:

Commercial Material	62.1% (54/87)
In-House material	35.6% (31/87)
Both Commercial and In-House Material	2.3% (2/87)