

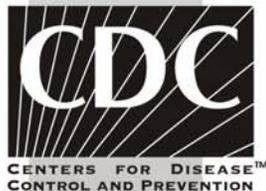


**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**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 during February 2006**



**Coordinating Center for Infectious Diseases  
Division of Laboratory Systems  
Atlanta, Georgia**

# Report of the February 2006 Human Immunodeficiency Virus Type 1 (HIV-1) Ribonucleic Acid (RNA) Determinations

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Report of the February 2006 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).

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## Overview

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### 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 performed using specimens sent on February 7, 2006.

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### Specimen panels

Each laboratory received a total of five specimens. All were plasma specimens obtained from individual donors (not pooled or diluted with plasma from other donors). Overall, the shipment contained three HIV-1 antibody-positive and two HIV-1 antibody-negative samples.

- 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 for this shipment were A1, A3, B2 and B5.
  - Not all laboratories received the same panel of samples. Each laboratory received either Panel A or B.
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### Laboratory response

Of the 190 laboratories receiving sample panels, 173 (91%) reported testing results.

- The percentage of the laboratories reporting results increased from 84% for the August 2005 shipment to 91% for this shipment.
  - The majority of the laboratories (123/173, 71%) reported their testing results using the online data entry system.
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## Overview: Significant Findings

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### Results Summary

The following table summarizes the results grouped by test type and HIV positive and negative donors. The overall quality of testing performance in this survey was 96.5%, the same overall performance as in the previous survey.

**Table 1:**

Method	Total # of labs	Total # of results	Results for Positive Donors		Results for Negative Donors		Overall Performance
			Positive	False-negative	Negative	False-positive	(TP+TN/ total # results) <sup>3</sup>
Quantitative <sup>1</sup>	166	874	499	25	343	7	96.3%
Qualitative <sup>2</sup>	7	35	21		14		100%
Total	173	909	520	25	357	7	96.5%

<sup>1</sup> 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.

<sup>2</sup> Chiron Procleix method

<sup>3</sup> TP, true positives; TN, true negatives.

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### False-negative results

The false negative rate increased in this survey from what was observed in the previous survey.

- There were 4.6% (25/545) false-negative interpretations reported for this shipment, compared to 3.5% (18/517) reported for plasma samples in the previous shipment.
- Of the 25 false-negatives reported, 23 were obtained using Roche's Amplicor HIV-1 Monitor® test, and two using Roche's Amplicor HIV-1 Monitor® UltraSensitive test.

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## Overview: Significant Findings, Continued

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**False-positive results** The percentage of false-positive results, 1.9% (7/364), reported in this survey is less than the previous survey false-positive rate for Plasma MPEP samples of 3.5% (12/346).

- Of the seven false-positives reported, four were associated with Donor 3 and three with Donor 4.
- Three of the seven false-positives were reported by laboratories using Roche's Amplicor Monitor® test with a reported lower limit sensitivity (LLS) of 400 copies/ml.
- Three of the seven false-positives were reported by laboratories using Roche's Amplicor Monitor® UltraSensitive test with reported lower limit sensitivity (LLS) of 50 copies/ml.
- One of the false-positives was reported by a laboratory using Bayer Versant HIV-1 RNA 3.0 Assay (bDNA) with lower limit sensitivity (LLS) of 75 copies/ml.

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**Quality control** A total of 56.1% (97/173) of respondents indicated that they used external quality control materials.

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# Donor Report

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**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.

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**Table 2 Donor Identification for February 2006 Shipment Specimens**

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

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<sup>1</sup> 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.

<sup>2</sup> Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

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# Donor Report: CDC HIV-1 RNA Testing Results

**Table 3** CDC HIV-1 RNA Testing Results for the February, 2006, Participant Laboratory Panel Samples

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

# Laboratory Demographics and Methods

## Overview

A total of 173 different laboratories submitted results. Of these:

- the 162 United States and U.S. associated laboratories are depicted in *Figure 1*.
- 11 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 Participant Laboratories in the United States and Territories**



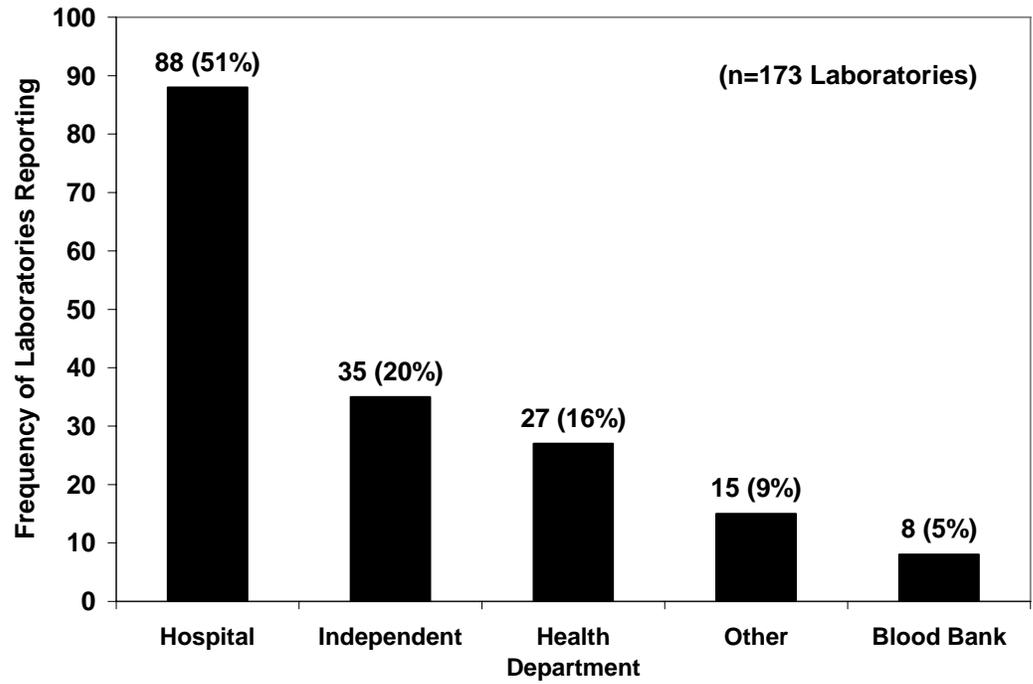
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## Laboratory Demographics and Methods, Continued

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Figure 2:

Types of  
Participant  
Laboratories



# Kit Types Used by Participants

## Overview

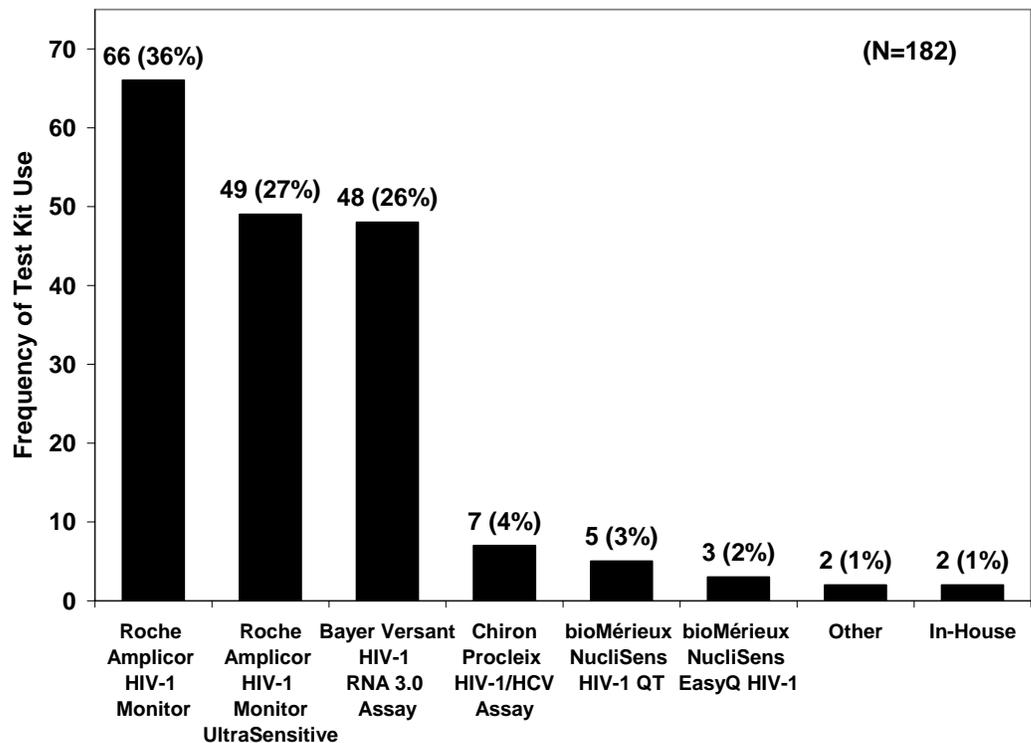
This section describes the types of test kits used by laboratories performing viral RNA quantitative and qualitative determinations in this survey.

- Roche’s Amplicor HIV-1 Monitor<sup>®</sup> test kit was used most frequently (66/182, 36.3%) in reporting results.
- All of the 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 Procleix<sup>™</sup> HIV-1/HCV Assay.

Note: The “N=” in 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 =182) exceeds the number of laboratories reporting results (n =173).

**Figure 3:**

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



## Summary of Results

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### Overview

There were seven false-positives (7/364, 1.9%) reported in the current survey, less than the 12 false-positive (12/346, 3.5%) results reported in the previous performance survey (August 2005). The percentage of false-negative results (4.6%, 25/545) reported for plasma MPEP donors 1 and 2 in this survey was more than that of the previous survey (3.5%, 18/517).

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### Summary of participant results

Table 4 contains the cumulative frequencies of quantitative and qualitative test results for all donor samples reported by participants. This table describes 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.

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**Table 4:**

**Cumulative frequencies of test results**

	<b>Number of Results</b>	<b>Percent Correct</b>	<b>Percent False Negative</b>	<b>Percent False Positive</b>
<b>Infected Donor Samples</b>	545	95.4% (520/545)	4.6% (25/545)	n/a
<b>Uninfected Donor Samples</b>	364	98.1% (357/364)	n/a	1.9% (7/364)
<b>TOTAL RESULTS</b>	909	96.5% (877/909)	***	***

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## Summary of Results, Continued

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### Test kit lower limit sensitivities

Table 5 shows the false-positive and false-negative results categorized by kit type and lower limit sensitivities.

Table 6 shows the variability in the lower limit sensitivities reported by the laboratories using commercially manufactured quantitative HIV-1 RNA test kits. The lower limit sensitivities of the reported quantitative kits ranged from 25 RNA copies/ml to 400 copies/ml. 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.

### False Negative Results

Twenty-five false-negative results were reported using the following test kits and LLS:

- Twenty of the 25 false-negative results were reported for Donor 1, the low-positive donor.
- Twenty-three were reported by laboratories using Roche’s Amplicor HIV-1 Monitor® test; the reported LLS associated with this result was 400 copies/ml, and
- Two reported using Roche’s Amplicor HIV-1 Monitor® UltraSensitive test; the reported LLS associated with this result was 50 copies/ml, and

### False Positive Results

Seven false-positives results were reported using the following test kits and LLS:

- Three false positive results were reported using Roche’s Amplicor HIV-1 Monitor® test; the reported LLS associated with these results was 400 copies/ml, and
- Three false positive results were reported using Roche’s Amplicor HIV-1 Monitor® UltraSensitive test; the reported LLS associated with these results was 50 copies/ml, and
- One of the seven false positive results were obtained using Bayer Versant HIV-1 RNA 3.0 Assay; the reported LLS associated with this result was 75 copies/ml.

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## Summary of Results, Continued

**Table 5:**

**LLS Results  
by Kit  
Manufacturer**

Manufacturer	Total # of Results	FP*	LLS <sup>‡</sup> for FP		FN <sup>†</sup>	LLS for FN	
			# of Results	LLS		# of Results	LLS
Roche Amplicor HIV-1 Monitor	330	3 (0.9%)	3	400	23 (6.7%)	23	400
Roche Amplicor HIV-1 Monitor UltraSensitive	244	3 (1.2%)	3	50	2 (0.4%)	2	50
Bayer Versant HIV-1 RNA 3.0 Assay (bDNA)	240	1 (0.4%)	1	75	0		
bioMérieux NucliSens HIV-1 QT	25	0			0		
bioMérieux NucliSens® EasyQ HIV-1	15	0			0		
In House	10	0			0		
Other	10	0			0		
Total	874	7 (0.8%)			25 (2.9%)		

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

**Table 6:  
Test Kit Lower  
Limit  
Sensitivities**

Manufacturer Test Kit (n = number of reports)	Lower Limit Sensitivity Used (copies/ml)	Percent of Reports (n) for each kit type
<b>Roche Amplicor HIV-1 Monitor® (n = 330)</b>	50	3% (10)
	100	2% (5)
	400	94% (310)
	not indicated	2% (5)
<b>Bayer Versant® HIV-1 RNA 3.0 Assay (bDNA) (n= 235)</b>	50	11% (25)
	75	85% (205)
	not indicated	4% (10)
<b>bioMérieux NucliSens® HIV-1 QT (n= 25 )</b>	25	20% (5)
	160	40% (10)
	200	20% (5)
	250	20% (5)
<b>bioMérieux NucliSens® EasyQ HIV-1 (n= 15)</b>	25	67% (10)
	80	33% (5)
<b>Roche Amplicor HIV-1 Monitor® UltraSensitive (n= 245)</b>	40	2% (5)
	50	94% (230)
	100	2% (5)
	not indicated	2% (5)
<b>In-House (n= 10)</b>	30	50% (5)
	100	50% (5)
<b>Other (n= 10)</b>	50	100% (10)

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## Summary of Results, Continued

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### Results by donor

Of the 7 false-positive quantitative results reported (7/350, 2.0%), four were associated with Donor 3 and three with Donor 4. Out of the 25 false-negatives reported for donors 1 and 2, 20 were associated with Donor 1, none were associated with Donor 2 and five were associated with Donor 2 duplicate.

Donor 1 (HIV-1 infected, low-positive)	20 false-negative
Donor 2 (HIV-1 infected, high-positive)	0 false-negative
Donor 2 Duplicate (HIV-1 infected, high-positive)	5 false-negative
Donor 3 (HIV-1 negative)	4 false-positives
Donor 4 (HIV-1 negative)	3 false-positives

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## Quantitative and Qualitative Test Aggregate Results

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

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**Description: Tables 9-12** 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** Table 8A shows the laboratory test results reported for Donor 2 and table 8B shows results for the duplicated specimen, Donor 2 Duplicate.

- 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.
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## 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, 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
Bayer Versant HIV-1 RNA 3.0 Assay	48	20	194	1035	367	<b>449</b>	506
bioMérieux NucliSens HIV-1 QT	5		440	2000	620	<b>1400</b>	1900
bioMérieux NucliSens HIV-1 QT EasyQ	3		1800	4400	1800	<b>2800</b>	4400
Roche Amplicor HIV-1 Monitor	46		219	2648	474	<b>554</b>	656
Roche Amplicor HIV-1 Monitor UltraSensitive	49		159	1770	354	<b>427</b>	561
In House	2		809	2400	809	<b>1605</b>	2400
Other	2		404	688	404	<b>546</b>	688

**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: A1, B2**

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
Bayer Versant HIV-1 RNA 3.0 Assay	48		1012	14241	6561	<b>7867</b>	8764
bioMérieux NucliSens HIV-1 QT	5		18000	23000	18000	<b>20000</b>	21000
bioMérieux NucliSens HIV-1 QT EasyQ	3		5600	28000	5600	<b>25000</b>	28000
Roche Amplicor HIV-1 Monitor	66		1020	22800	6180	<b>8375</b>	10500
Roche Amplicor HIV-1 Monitor UltraSensitive	48		1000	43500	5075	<b>8345</b>	11100
In House	2		12193	36000	12193	<b>24097</b>	36000
Other	2		9427	12900	9427	<b>11164</b>	12900

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## 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 Detection RNA	Range of Quantitative Results Reported (RNA copies/ml)				
			minimum	maximum	25% Quartile	Median (50%)	75% Quartile
Bayer Versant HIV-1 RNA 3.0 Assay	48		1071	17798	7070	<b>8087</b>	9121
bioMérieux NucliSens HIV-1 QT	5		16000	79000	16000	<b>22000</b>	24000
bioMérieux NucliSens HIV-1 QT EasyQ	3		1100	30000	1100	<b>20000</b>	30000
Roche Amplicor HIV-1 Monitor	63	3	1030	28505	5305	<b>8640</b>	10100
Roche Amplicor HIV-1 Monitor UltraSensitive	47	2	1035	33700	5722	<b>6840</b>	10500
In House	2		9199	39000	9199	<b>24100</b>	39000
Other	2		8955	12700	8955	<b>10828</b>	12700

**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: A2, 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
Bayer Versant HIV-1 RNA 3.0 Assay	1	47	104	104	104	<b>104</b>	104
bioMérieux NucliSens HIV-1 QT		5	n/a	n/a	n/a	n/a	n/a
bioMérieux NucliSens HIV-1 QT EasyQ		3	n/a	n/a	n/a	n/a	n/a
Roche Amplicor HIV-1 Monitor	1	65	400	400	400	<b>400</b>	400
Roche Amplicor HIV-1 Monitor UltraSensitive	2	47	n/a	n/a	n/a	n/a	n/a
In House		2	n/a	n/a	n/a	n/a	n/a
Other		2	n/a	n/a	n/a	n/a	n/a

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## Quantitative and Qualitative Test Aggregate Results, Continued

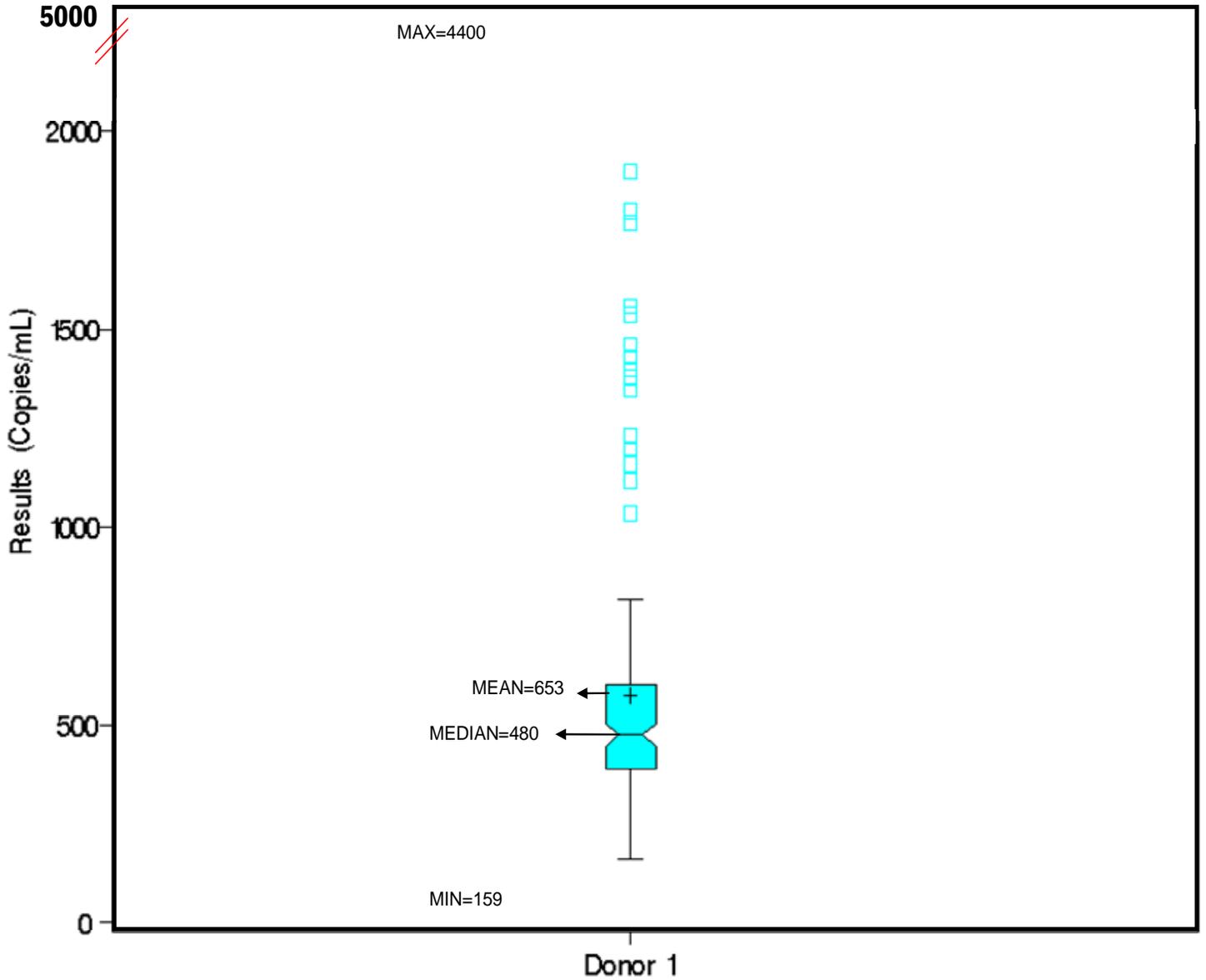
**Table 10** Results of the HIV-1 RNA Determinations Reported by Participant Laboratories for Donor #4  
**Donor Status: HIV-1 Uninfected and HIV-1 RNA Not Detected**  
**Panel Vial Labels: A5, B4**

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
Bayer Versant HIV-1 RNA 3.0 Assay		48	n/a	n/a	n/a	n/a	n/a
bioMérieux NucliSens HIV-1 QT		5	n/a	n/a	n/a	n/a	n/a
bioMérieux NucliSens HIV-1 QT EasyQ		3	n/a	n/a	n/a	n/a	n/a
Roche Amplicor HIV-1 Monitor	2	64	400	400	400	<b>400</b>	400
Roche Amplicor HIV-1 Monitor UltraSensitive	1	48	50	1338	50	<b>694</b>	1338
In House		2	n/a	n/a	n/a	n/a	n/a
Other		2	n/a	n/a	n/a	n/a	n/a

# Distribution of Quantitative Results by Sample

**Figure 4:**  
**Box plot –**  
**Donor 1**

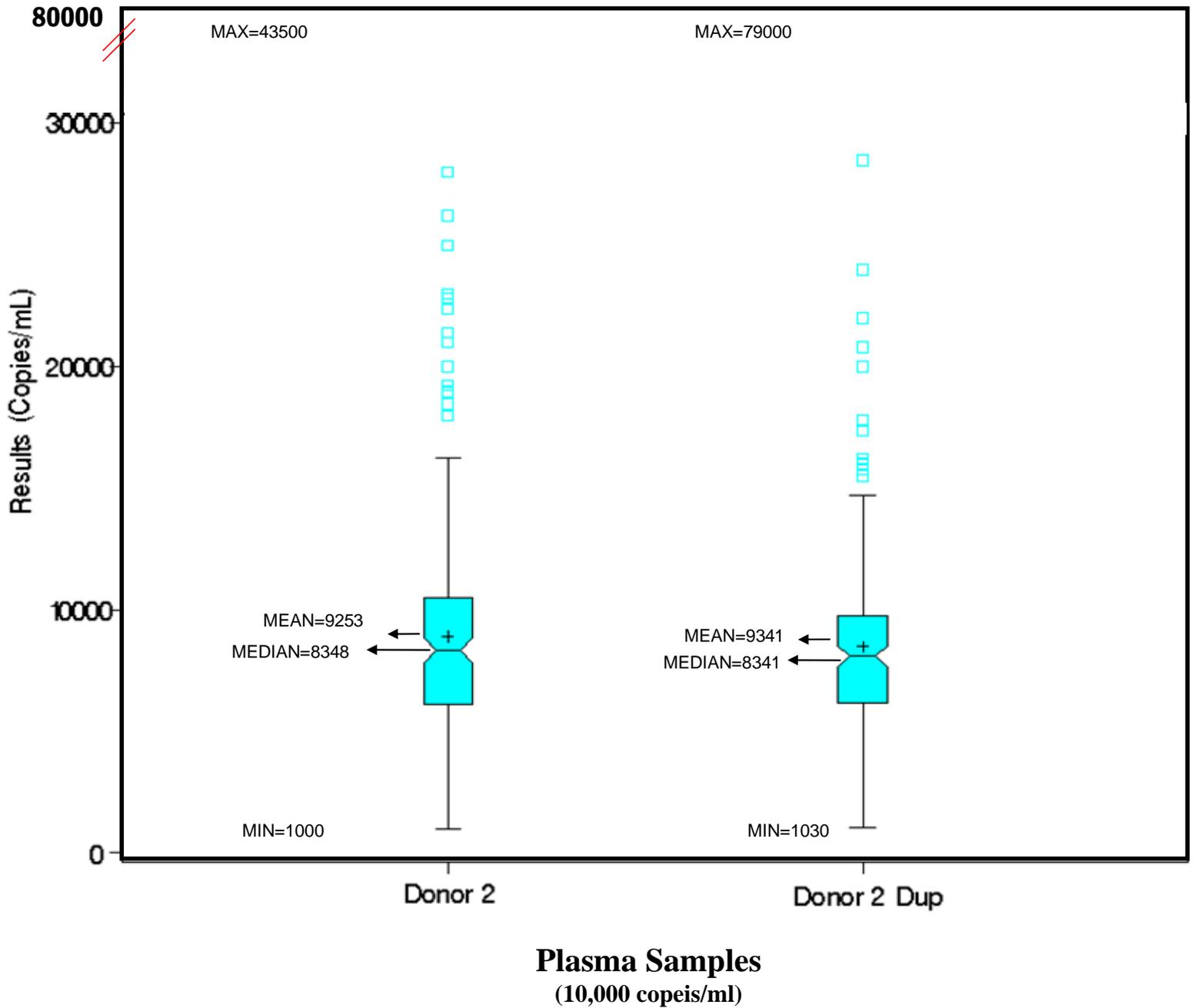
This box plot depicts results for Donor 1, the low level positive sample with a target value of 1,000 copies/ml.



**Plasma Samples**  
**(1,000 copies/ml)**

## Distribution of Quantitative Results by Sample, Continued

**Figure 5:** This box plot shows results for Donor 2 and Donor 2 Duplicate, high level positive samples with target values of 10,000 copies/ml.  
**Box plot – Donor 2 and 2 duplicate**



## Discussion

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### **Overall performance**

The overall performance in this survey was 96.5%, the same overall performance as the last shipment in August 2005 (96.5%) for plasma samples.

There were a total of 25 false-negative interpretations reported for HIV-1 RNA positive samples Donor 1, Donor 2, and Donor 2 duplicate in this shipment.

- Twenty unique laboratories reported 20 false-negative interpretations for Donor 1 (1,000 copies/ml). Laboratories could report multiple results if they used more than one method.
- Five unique laboratories reported false-negative interpretations for Donor 2 duplicate (identical to donor 2, "high-positive" samples with a target value of 10,000 copies/ml).

There were a total of 7 false-positive interpretations reported for HIV-1 RNA negative samples Donor 3 and Donor 4 in this shipment.

- There were four reported false-positives results on negative Donor 3 and three false-positive results on Donor 4.
- Five unique laboratories reported false-positive interpretations for either Donor 3 or Donor 4.

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## Discussion, Continued

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### External Quality Control (QC)

Of the 173 laboratories reporting results in this survey:

- 98.8% (171/173) provided information on external QC materials\*
  - 43% (74/171) reported they did not use external QC samples
  - 57% (97/171) indicated that they used external QC materials. The source of their external QC materials are as follows:

Commercial Material	62% (60/97)
In-House material	35% (34/97)
Both Commercial and In-House Material	3% (3/97)

\* External QC materials are quality control materials in which laboratories use IN ADDITION to controls, standards or calibrators that are included in their manufacturer's kit.

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