

# Comparison of the APTIMA® HIV-1 Quant Assay to the COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0

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## Abstract

### Background:

The APTIMA HIV-1 Quant Assay is a fully automated quantitative assay being developed on the PANTHER System and based on real-time Transcription-Mediated Amplification technology. This assay is intended for monitoring HIV-1 viral load in plasma specimens using a 0.5 mL sample.

### Methods:

A cohort of 245 clinical specimens from University of Athens Medical School was tested using the COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 (Roche Assay) and the APTIMA HIV-1 Quant Assay (APTIMA Assay). The specimens included subtypes A, B, C and G as well as circulating recombinant forms of HIV-1.

### Results:

Using a lower limit of quantitation for the APTIMA Assay of 30 copies/mL, 175 specimens gave results quantifiable for both assays. The correlation between the two assays was excellent (0.98), with a slope of 1.06 and an intercept of -0.13. Sixty-nine specimens gave results that were either detectable but not quantifiable or not detectable in at least one assay. Thirty were not detectable in both assays and 14 were detectable in both assays. The APTIMA Assay detected 13 specimens that were undetectable with the Roche Assay. There were 12 specimens that were detectable with the Roche Assay and undetectable with the APTIMA Assay. One specimen was above the upper limit of quantitation (10,000,000 copies/mL).

### Conclusion:

The APTIMA HIV-1 Quant Assay gave comparable viral load results when compared to the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0. The sensitivity of the APTIMA HIV-1 Quant Assay is similar to that of the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0.

## Assay Procedure

The APTIMA HIV-1 Quantitative Assay Reagents and plasma samples are loaded into the PANTHER System (Figure 1) reagent and sample bays (Figure 2).

The PANTHER System processes 0.5 mL of sample through target capture, amplification, and real-time detection in the presence of an internal control.

The assay has 1 negative control and two positive controls (1 low and 1 high concentration)

### KEY FEATURES OF PANTHER SYSTEM

- Full automation from sample to result
- Random sample loading eliminating the need for batching samples together to perform the assay
- Continuous access to change reagents, samples, and consumables
- Small instrument foot print
- 2.5 hrs to first result
- 100 tests results in 4.5 hours
- 500 test results in <11 hours



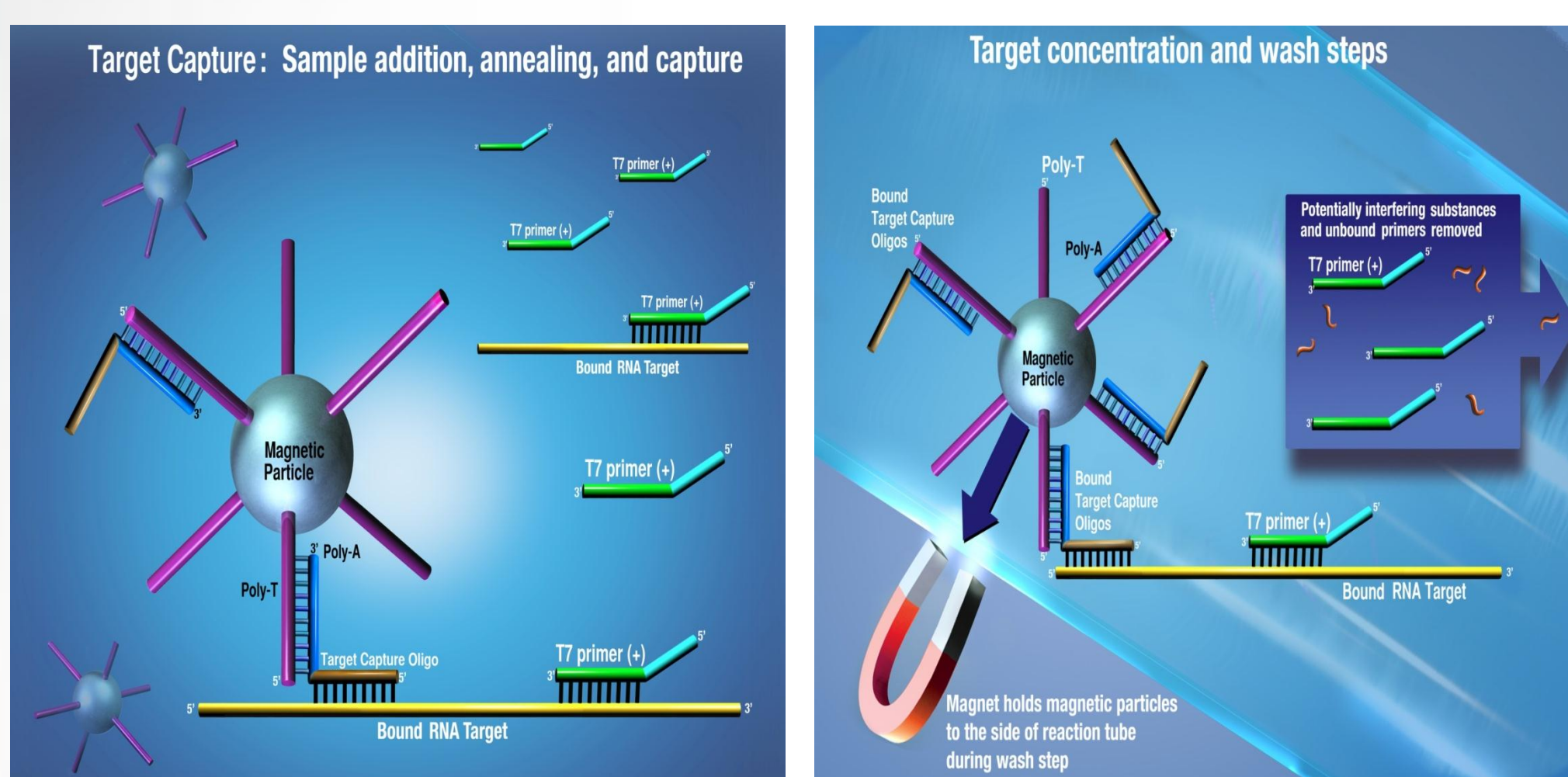
Figure 1. PANTHER System



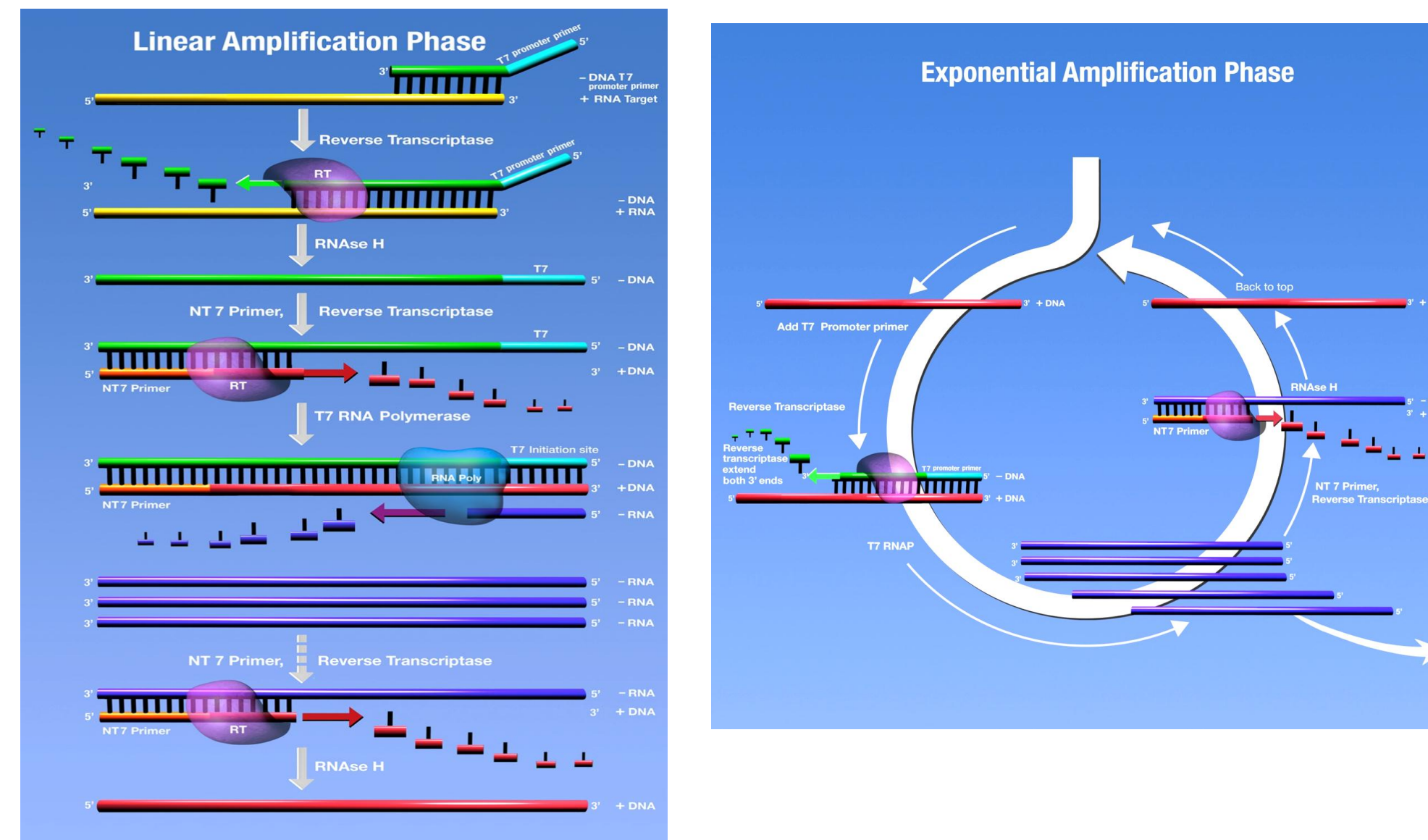
Figure 2. PANTHER Reagent and Sample bay

## Assay Technology

### Target Capture



### Transcription-Mediated Amplification



### Real-time Signal Generation

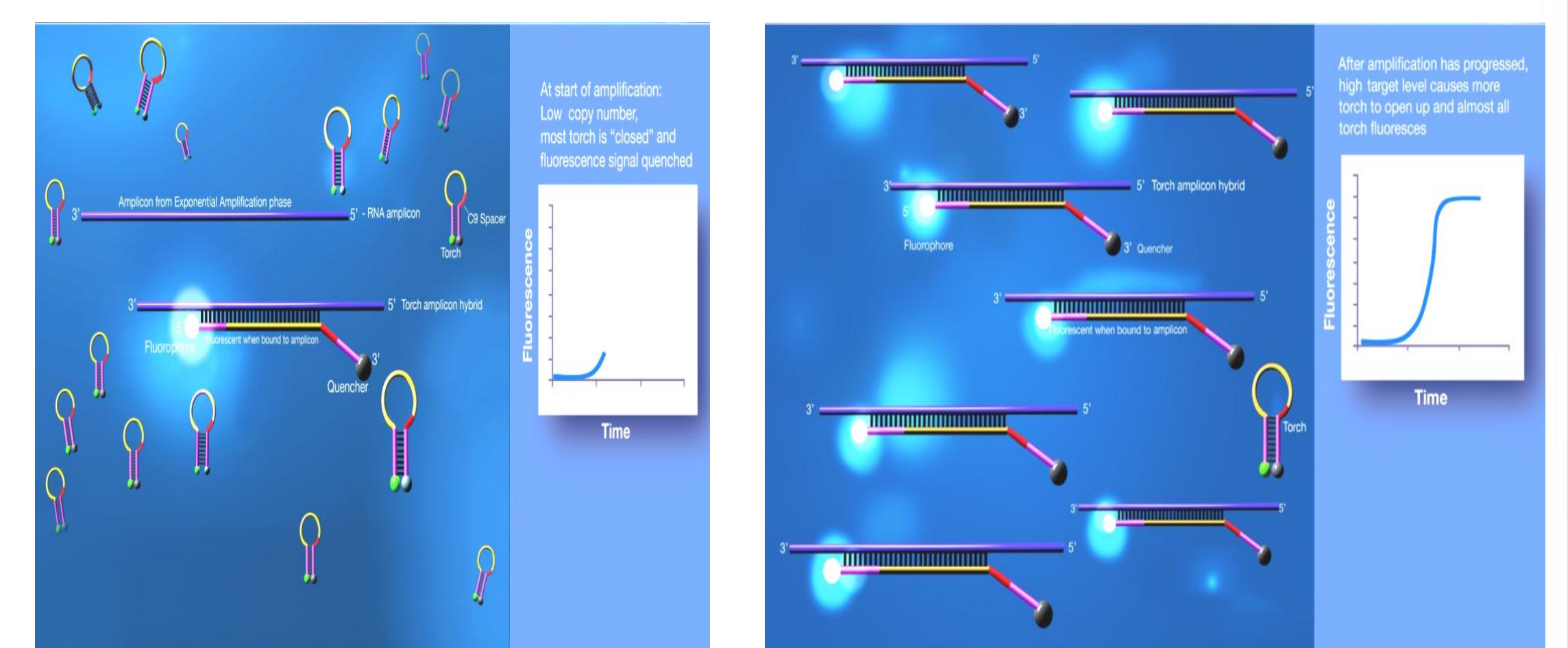


Figure 3. The APTIMA HIV-1 Quantitative Assay uses Gen-Probe's real-time Transcription-Mediated Amplification technology

## Assay Performance

### Method Comparison

A cohort of 245 clinical specimens was tested using the Roche Assay and the APTIMA Assay. The APTIMA Assay results were generated at Gen-Probe. The Roche results were generated at the University of Athens. The results are shown as scatter plots in Figures 4 and 5 for those samples giving quantitative results in both assays

Figure 4. Comparison of APTIMA and Roche Assays using All Clinical Sample Data

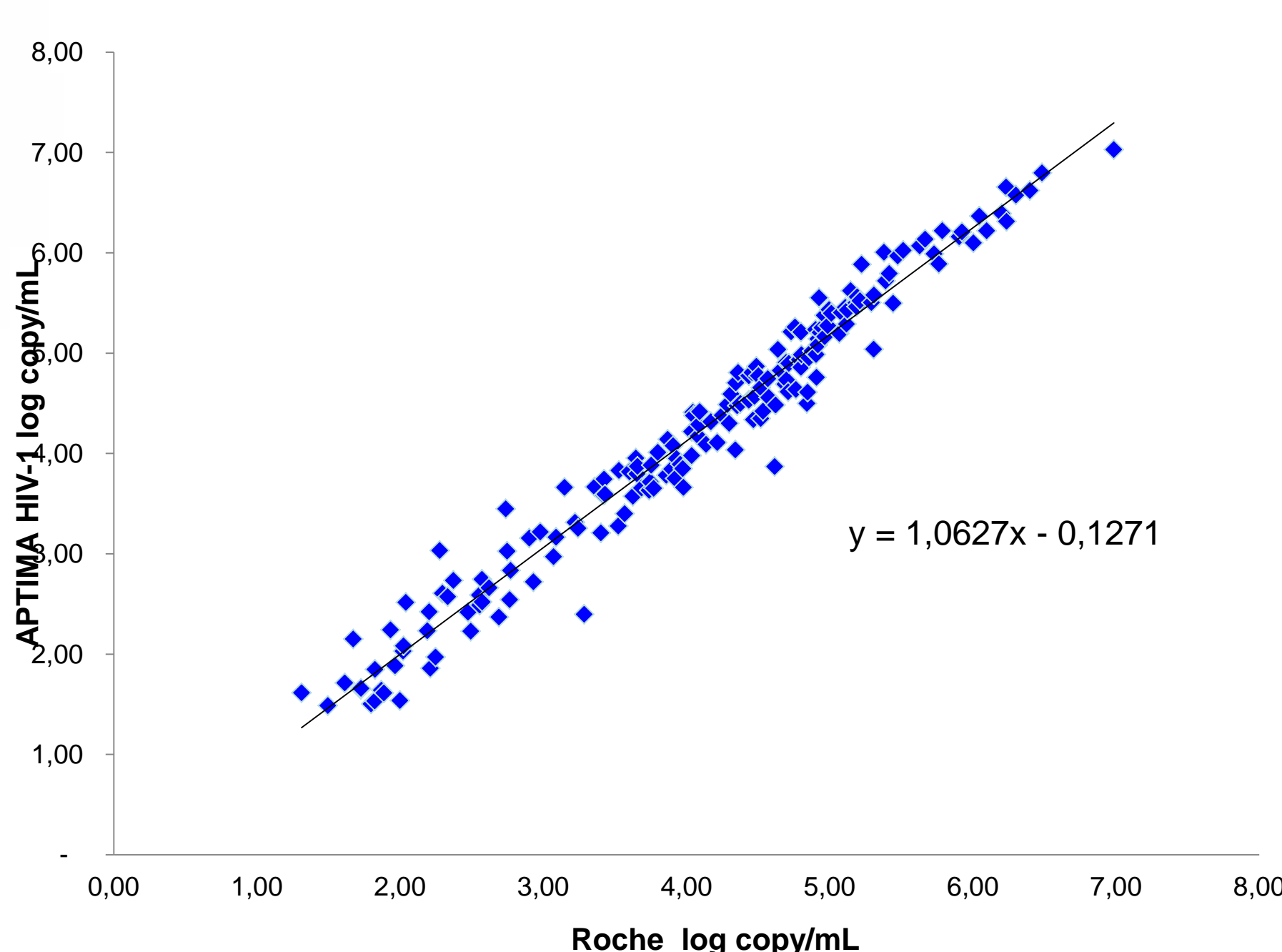
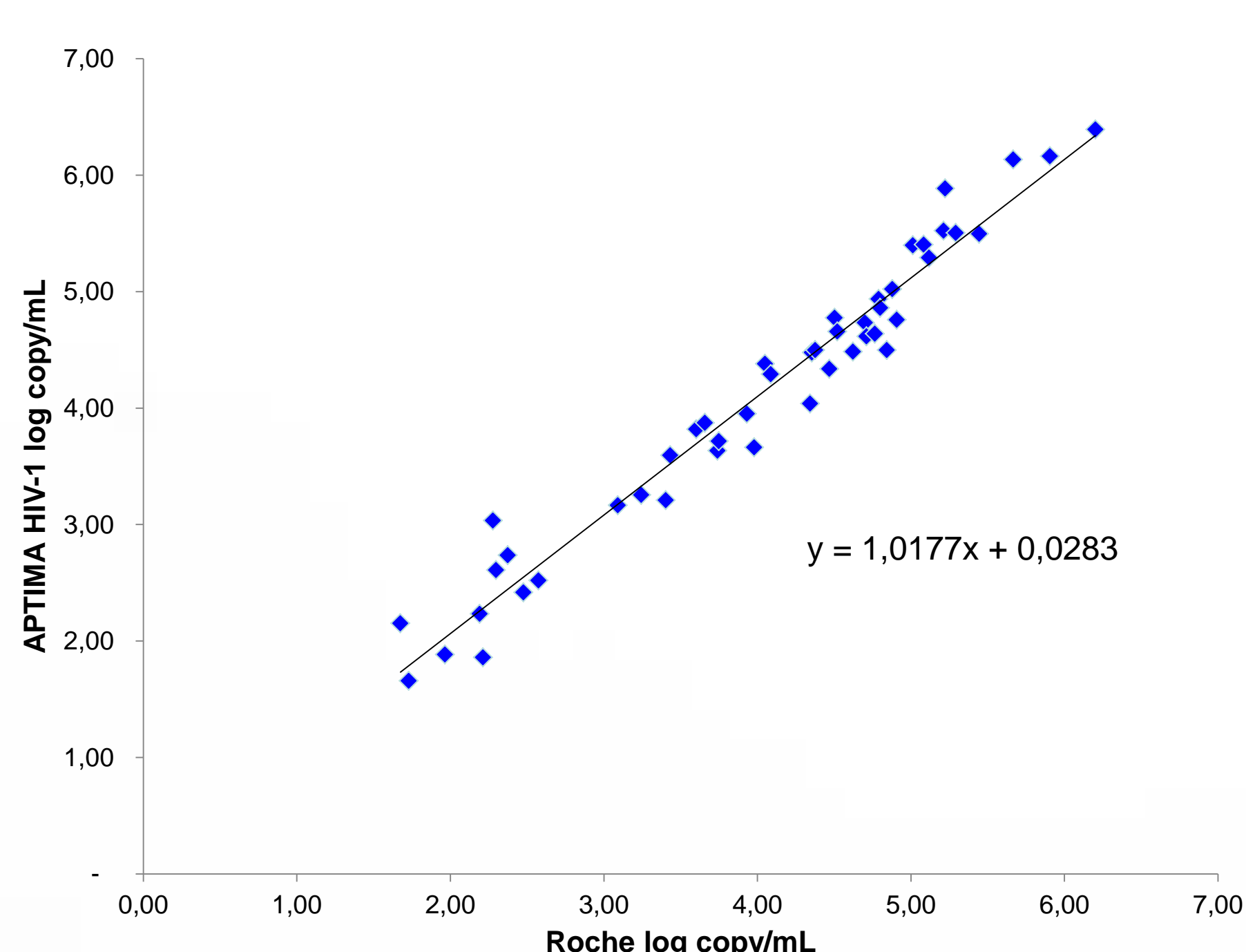


Figure 5. Comparison of APTIMA and Roche Assays using Subtype B Clinical Sample Data



### Limit of Detection

The WHO panel (HIV-1 Subtype B, batch # 97/650) was diluted in negative plasma to concentrations of 0, 5, 10, 15, 20, 25, 30 & 40 IU/mL. A total of 90 replicates were run at Gen-Probe using three PANTHER Systems and 3 reagent lots to generate data at each concentration. The results are shown in Table 1.

Table 1: Estimate of APTIMA HIV-1 Quant Lower Limit of Detection using Dilutions of the WHO standard

IU/mL	Instrument 1			Instrument 2			Instrument 2			Total		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	average	N	Number positive
0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	89	0
5	70.0%	50.0%	50.0%	60.0%	44.4%	40.0%	20.0%	70.0%	60.0%	51.6%	89	46
10	80.0%	90.0%	90.0%	80.0%	70.0%	50.0%	90.0%	100.0%	80.0%	81.1%	90	73
15	100.0%	80.0%	100.0%	100.0%	90.0%	70.0%	100.0%	100.0%	100.0%	93.3%	90	84
20	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	97.8%	90	88
25	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%	90.0%	97.8%	89	87
30	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	98.9%	90	89
40	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	89	89

### Sensitivity

Sixty-nine specimens gave results that were either detectable but not quantifiable or not detectable in at least one assay. The results are shown on Table 2. Samples with detectable results were designated as positive and those where target was not detected designated negative for the assay used

Table 2. Comparison of Clinical Samples using the APTIMA and Roche HIV Assays

ROCHE		APTIMA	
		-	+
	-	14	13
	+	12	30

Probit analysis of the data estimated the concentration at which the APTIMA HIV-1 Quant Assay detects 95% of samples is 17.6IU/mL (IU is approximately 1 copy).

## Conclusions

The APTIMA HIV-1 Quant Assay gave comparable viral load results when compared to the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0. The sensitivity of the APTIMA HIV-1 Quant Assay is similar to that of the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0.

The APTIMA HIV-1 Quantitative assay is a good candidate for monitoring HIV-1 viral load in HIV-1 infected patients.

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