



# Ability of the Genprobe APTIMA HIV-1 RNA Qualitative Assay to Confirm Reactive Rapid HIV Screening Tests

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J. Heffelfinger,<sup>1</sup> K. Delaney,<sup>1</sup> M. Owen,<sup>1</sup> D. Candal,<sup>1</sup> S. Kennedy,<sup>1</sup> A. Uniyal,<sup>2</sup> P. Kerndt,<sup>2</sup> B. Branson<sup>1</sup>

<sup>1</sup>Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, Atlanta, GA, USA

<sup>2</sup>Los Angeles County Department of Health Services, Sexually Transmitted Diseases Program, Los Angeles, CA, USA

J. D. Heffelfinger, MD, MPH  
CDC, MS: E-46  
1600 Clifton Road NE  
Atlanta, GA 30333  
Email: jzh7@cdc.gov



## Background

- In 2006, the Centers for Disease Control and Prevention (CDC) published revised recommendations for HIV testing in healthcare settings calling for routine, voluntary HIV screening for all persons age 13-64 years in healthcare settings
- Taking advantage of advances in HIV testing technology will facilitate implementation of CDC's revised recommendations
- Rapid HIV tests make testing feasible in a variety of clinical and nonclinical settings, but reactive test results need to be confirmed
- In October 2006, the Food and Drug Administration (FDA) approved the Genprobe APTIMA HIV-1 RNA Qualitative Assay to confirm HIV-1 infection in persons with specimens repeatedly reactive for HIV-1 antibodies; however, APTIMA is not currently approved to confirm single reactive rapid HIV test results

## Objective

To assess the performance of the APTIMA HIV-1 RNA Qualitative assay to confirm single reactive rapid HIV test results.

## Methods

- We assessed the performance of APTIMA using specimens collected during a study evaluating rapid HIV tests at 2 clinical sites in Los Angeles
- From June 2003—September 2003, persons  $\geq 18$  years known to be HIV-infected (some on antiretroviral therapy [ART]) were recruited to provide specimens for rapid HIV testing and confirmatory testing
- From June 2003—August 2005, persons  $\geq 18$  years who were not already known to be HIV-infected and who sought HIV testing at the two sites were offered rapid testing; confirmatory testing was performed on specimens from persons with reactive rapid test results
- Rapid HIV testing using up to 6 different rapid HIV test kits was conducted on fingerstick whole blood and/or oral fluid specimens
- Confirmatory testing was conducted using enzyme immunoassay and Western blot

## Methods (continued)

- All participants also provided anti-coagulated whole blood and serum specimens
- Remnant serum and plasma specimens were stored frozen at the Los Angeles County Health Department Laboratory and transferred to CDC at the completion of the study
- Frozen remnant plasma specimens were tested with Aptima at CDC
- When plasma was available, the Roche 1.5 Ultrasensitive HIV-1 RNA (Amplicor) assay was used to test specimens with discordant APTIMA and Western blot results

## Results

- 280 (4.9%) of 5,754 persons screened were Western blot positive and considered newly diagnosed with HIV infection
- APTIMA confirmed ~85% of all reactive RT results from HIV-infected persons
- APTIMA was reactive for 270 (97.1%) of 278 newly diagnosed vs. 370 (78.2%) of 473 previously diagnosed HIV-infected persons ( $p < 0.001$ )
- Of persons with a prior HIV diagnosis, APTIMA was reactive for 101 (98.1%) persons not on ART vs. 269 (72.7%) persons on ART ( $p < 0.001$ )
- The performance of APTIMA did not differ by type of rapid HIV test used
- APTIMA correctly resolved all 38 specimens from HIV-uninfected persons who had reactive RT results and negative Western blot results

Figure 1. Flow diagram of testing algorithm used in this study.

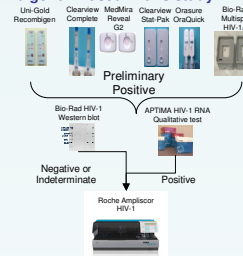


Figure 2. Sensitivity of APTIMA among persons with prior and new HIV diagnoses.

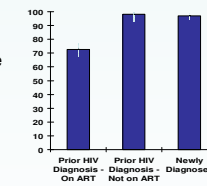


Table 1. Sensitivity of APTIMA for confirmation of HIV-1 infection by type of rapid HIV test kit.

Rapid HIV Test Kit	Number of persons			Sensitivity of APTIMA (%)
	Reactive	Non-reactive	Total	
Uni-Gold Recombigen	148	1	149	99.3%
Clearview Complete	148	1	149	99.3%
MedMira Renal G2	148	1	149	99.3%
Clearview Renal Stat-Pak	148	1	149	99.3%
OraQuick	148	1	149	99.3%
OraSure OraQuick	148	1	149	99.3%
Bio-Rad Multispot HIV-1/2	148	1	149	99.3%
Total	888	6	894	99.3%

## Results (continued)

- APTIMA correctly identified 5 specimens with reactive rapid test results and indeterminate or negative Western blot results as reactive
- Of 16 specimens that had negative rapid HIV test results and negative Western blot results but reactive APTIMA results, 12 were available for testing with Amplicor
  - Median HIV viral load of specimens with quantified Amplicor results: 175,903 (range: 294-631,290) copies/mL
- The specificity of APTIMA among almost 5,500 HIV-uninfected persons was 100%

## Limitations

- Because Amplicor test was not performed on all specimens with reactive APTIMA results, it is possible that one or more of the untested specimens were from HIV-uninfected persons
- Since persons who were not already known to be HIV-infected were screened with rapid HIV tests and not asked about ART use, it is possible that we have underestimated the sensitivity of APTIMA for persons not taking ART
- Because this study pre-dated FDA-approval of APTIMA, handling and processing of specimens did not necessarily conform to suggested procedures outlined in the APTIMA package insert to preserve HIV RNA in plasma specimens; this may have led to an underestimation of the sensitivity of APTIMA

## Conclusions

- We found that APTIMA could be used to confirm single reactive RT results in persons without prior HIV diagnosis
  - Among persons with no prior HIV diagnosis, APTIMA confirmed HIV infection for >97% of specimens that had single reactive rapid HIV test results
  - APTIMA failed to confirm 28% of rapid HIV test results on specimens from persons taking ART
- When APTIMA test results are negative, other serologic methods and/or testing follow-up specimens collected would be required to confirm or rule out HIV infection

Table 2. Amplicor results for specimens with negative rapid HIV test results and negative Western blot results but reactive APTIMA results.

Specimen ID	Rapid HIV Test Result	Western Blot Result	APTIMA Result	Amplicor Result
1	Negative	Negative	Reactive	Reactive
2	Negative	Negative	Reactive	Reactive
3	Negative	Negative	Reactive	Reactive
4	Negative	Negative	Reactive	Reactive
5	Negative	Negative	Reactive	Reactive
6	Negative	Negative	Reactive	Reactive
7	Negative	Negative	Reactive	Reactive
8	Negative	Negative	Reactive	Reactive
9	Negative	Negative	Reactive	Reactive
10	Negative	Negative	Reactive	Reactive
11	Negative	Negative	Reactive	Reactive
12	Negative	Negative	Reactive	Reactive
13	Negative	Negative	Reactive	Reactive
14	Negative	Negative	Reactive	Reactive
15	Negative	Negative	Reactive	Reactive
16	Negative	Negative	Reactive	Reactive