JCM Accepts, published online ahead of print on 17 June 2009
J. Clin. Microbiol. doi:10.1128/JCM.00119-09

JCM00119-09 Version 2

Assessment of the Ability of a Fourth Generation Immunoassay for HIV Antibody and p24 Antigen to Detect both Acute and Recent HIV Infection in a High-Risk Setting

Mark W. Pandori[1], John Hackett Jr.[2] Brian Louie[1], Ana Vallari[2], Teri Dowling[1], Sally Liska[1], Jeffrey D. Klausner[1,3]

1. San Francisco Department of Public Health, San Francisco, CA, USA
2. Abbott Diagnostics, Abbott Park, IL, USA
3. University of California at San Francisco, San Francisco, CA, USA

Corresponding Author: Mark Pandori
San Francisco Department of Public Health
101 Grove St. Room 412
San Francisco, CA, 94102
Phone: (415) 554-2800
FAX: (415) 431-0651

Abstract

An immunoassay (IA) that simultaneously detects both antibody to HIV and HIV p24 antigen (ARCHITECT® HIV Ag/Ab Combo) was evaluated for its ability to detect HIV infection using a panel of specimens collected from individuals recently infected with HIV-1. This IA was found to be capable of detecting the majority (89%) of infections, including 79.5% of those considered as acute infections based on the presence of HIV RNA and the lack of detectable antibody to HIV. Substantial improvements in detection of recent infections by the ARCHITECT® HIV Ag/Ab Combo relative to previous generation IAs as well as the capacity to detect acute infections have important implications for HIV prevention strategies.

Immunoassays (IA) for the detection of HIV-specific antibodies have been in continual development since the incipience of the HIV pandemic. The recent success of IgG and IgM-sensitive antibody tests (third generation assays) in narrowing the window period of HIV diagnosis has been notable (2, 4, 5, 7, 10, 32). However IA designed to detect antibody alone will not be able to identify individuals with acute infection who have not yet begun to produce HIV-specific antibodies. Attempts to detect acutely-infected individuals have mostly involved RNA-detection algorithms using pooled HIV antibody-negative specimens. Such efforts have yielded significant returns in detection of recent HIV infection in certain communities (6, 16, 18, 22, 24). Evidence suggests that these individuals are at greatest risk for transmission of HIV and contribute disproportionately to the ongoing epidemic (17, 19, 20, 25). However, the use of RNA-based detection methods is expensive, laborious and can be operationally daunting. Moreover, in most cases the time to results ranges from 7-14 days. This amount of time is less than ideal from an HIV prevention perspective. An alternative to the detection of acute HIV infections using RNA-based methods is to utilize antigen-antibody combination tests, also known as “fourth generation” IA (12, 23, 26). Fourth generation assays simultaneously function as both third generation IA (for the detection of IgG and IgM antibody) and capture IA for the direct detection of p24 antigen (the most abundant protein of HIV virions). Because fourth generation IA are standard immunoassays, they are easy to perform, relatively inexpensive, and easily automated. At the time of preparation of this article, fourth generation IA are not FDA-cleared within the United States, but their use and performance in other locations worldwide has been well-

documented (1, 3, 12-15, 21, 23, 26–31). However, given the paucity of data available on performance of fourth generation assays relative to HIV RNA detection algorithms in the diagnostic setting, it is of considerable interest from a public health perspective to assess the ability of these assays to detect acute HIV infections.

In the present study, performance of the ARCHITECT® HIV Ag/Ab Combo (HIV Combo; Abbott Diagnostics, Wiesbaden, Germany; available for sale outside of the United States only) was assessed. The HIV Combo is a chemiluminescent magnetic microparticle-based immunoassay run on an automated random access instrument. The assay is designed to detect HIV-1 (group M, O and N) and HIV-2. Specimens with signal to cut-off (S/CO) values of 1.0 or greater are considered reactive. HIV Combo performance was evaluated on specimens from 64 recently infected individuals (tested in San Francisco, CA) identified based on an HIV-1 RNA testing algorithm (all specimens were HIV-1 RNA positive). This highly characterized panel, collected over a five year period, consists of a range of specimen types, including specimens from acutely infected individuals (HIV RNA-positive/no detectable HIV antibody; $n = 35$), individuals reactive on a single antibody test ($n = 7$), and individuals who are reactive on multiple, but not all antibody tests ($n = 22$) evaluated (10, 11). Sequence analysis was performed on sixty of the panel members. All were infected with subtype B virus (data not shown). The 64-member panel, interspersed with an additional 31 control specimens, was blinded prior to testing in HIV Combo. The 31 controls were known HIV antibody-positive (n = 16) and negative (n = 15) specimens.

As shown in Table 1, 57 of the 64 specimens from recently-infected individuals were found to be reactive in the HIV Combo assay. Amongst the 57 specimens found reactive by the HIV Combo were 28 of the 35 previously determined to contain no detectable HIV antibody by any other antibody-based method evaluated. These data confirm the ability of the HIV Combo to detect HIV antigen and therefore provide a reactive (positive) result, even when antibody to HIV is not detectable. Moreover, these data demonstrate that the HIV Combo assay is able to identify acutely infected individuals in the majority of the cases where antibody testing fails to do so. HIV Combo detected all 7 specimens reactive on only one of the antibody tests as well as all 22 reactive by multiple but not all antibody tests. The HIV Combo assay found all of the positive controls to be reactive and all negative controls to be non-reactive.

Seven of the 64 panel members were non-reactive in the HIV Combo assay. These specimens (A, E, G, H, J, N, and BJ) are notable because each was found to be uniformly non-reactive for HIV antibody while being shown to contain measurable viral RNA. Of interest, the HIV-1 RNA levels measured in these specimens were relatively low (mean = 7,716 copies/ml; median = 6,373 copies/ml; range 1,177 to 14,062 copies/ml). Of the antibody-negative specimens detected by the HIV Combo, the lowest RNA value was 30,734 copies/ml, while the highest RNA value for a specimen not detected by HIV Combo was 14,062 copies/ml. These data suggest that the limit of detection for the HIV Combo assay, with regard to virus detection, is between 14,000 and 30,000 RNA copies/ml. This is consistent with recent estimates for this assay based on analysis of multiple cultured viral isolates (8). Additionally, these data provide further

evidence that the HIV Combo non-reactive specimens are derived from individuals who were so recently infected with HIV at the time of collection, that they had not yet mounted an antibody response. This supposition is substantiated by data obtained from follow-up specimens, available for 5 of the 7 individuals, where viral RNA levels dramatically increased between the first and second visit and antibodies to HIV had become detectable (data not shown).

The HIV Combo assay's ability to detect HIV antigen empowers the test with the capacity to detect recent HIV infections during the antibody-negative window period. In the present study, it detected approximately 89% of infected individuals who had been missed by an initial antibody-screening test (Table 2). With regard to specimens from acutely infected individuals that were initially screened and missed by a third generation IA, HIV Combo detected 6 out of 7 (85.7%). For specimens from acutely infected individuals who were initially screened by a rapid, Point-of-care test or first generation IA, HIV Combo detected 51 of 57 (89.5%). Thus, the incremental yield in detection of recently-infected individuals by HIV Combo relative to immunoassays currently used in the U.S. is substantial. These data, combined with the relatively low cost and lower labor requirements as compared to RNA-based testing argue that fourth generation IA will be a useful addition to available HIV diagnostic tests. This may be particularly true for regions where there exists some reasonable concern about the detection of recent, window period infections (i.e. high risk, high incidence populations). However it should be recognized that performance of fourth-generation assays vary substantially with respect to p24 antigen sensitivity, antibody sensitivity, HIV group/subtype detection, and

specificity (9, 14). Comparative evaluations have revealed that the HIV Combo assay is among the most sensitive for detection of p24 antigen across genetically divergent strains and has high specificity (14). Thus, viral RNA detection levels observed for HIV Combo likely are not directly translatable to all fourth generation assays. For communities of high HIV incidence where a significant percentage of tested, infected individuals might be within the antibody negative window period it is reasonable to consider the possibility that ARCHITECT HIV Ag/Ab Combo, with automation and high throughput, may be an appropriate replacement for testing algorithms that combine HIV RNA testing with antibody screening.

Acknowledgements

We thank the HIV Counseling and Testing staff at the San Francisco City Clinic for technical assistance. We thank Abbott Diagnostics for providing kits and testing services in support of this study and Teresa Lukaszewska for her technical support. J.H.Jr. and A.V. are employees of Abbott Laboratories.

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Tables

Table 1. Summary of assay performances with specimens from acutely and recently infected individuals.

Table 2. Percentages of acute/recent specimens from Table 1 found positive by different assay methods.

Table 1: Comparative HIV detection test results with acute infection panel

ID	Initial Test Screen	1st/2ND Gen. EIA S/C Avg	1st/2ND Gen. EIA Result	WB	3rd Gen. EIA S/C Avg	3rd Gen. EIA Result	OQ RT	UG RT	SR RT	MS RT	Viral Load copies/ml	4th Gen IA S/CO	4th Gen IA Result
A	1st Gen EIA	0.351	NR	I	0.127	NR	N	N	N	N	5770†	**0.37**	**NR**
B	1st Gen EIA	0.602	NR	I	0.955	NR	N	N	N	N	≥500,000†	**611.12**	**R**
C	1st Gen EIA	0.440	NR	I	≥14.658	R	N	R	N	N	12183†	**1.62**	**R**
E	1st Gen EIA	0.368	NR	I	0.233	NR	N	N	N	N	6373†	**0.65**	**NR**
F	1st Gen EIA	0.329	NR	I	13.433	R	N	R	N	R1	≥500,000†	**85.73**	**R**
G	1st Gen EIA	0.317	NR	N	0.084	NR	N	N	N	N	12852†	**0.74**	**NR**
H	1st Gen EIA	0.338	NR	I	0.109	NR	N	N	N	N	14062†	**0.68**	**NR**
I	1st Gen EIA	0.646	NR	I	≥14.658	R	R	R	R	R1	≥500,000†	**67.70**	**R**
J	1st Gen EIA	0.358	NR	N	0.106	NR	N	N	N	N	3921†	**0.23**	**NR**
K	1st Gen EIA	0.346	NR	N	4.574	R	N	R	N	N	≥500,000†	**43.92**	**R**
L	1st Gen EIA	0.373	NR	N	0.175	NR	N	R	N	N	≥500,000†	**39.55**	**R**
M	OQ RT-FS	0.344	NR	N	1.5327	R	N	N	N	N	≥500,000†	**368.21**	**R**
N	1st Gen EIA	0.337	NR	N	0.113	NR	N	N	N	N	1177†	**0.21**	**NR**
O	OQ RT-FS	0.301	NR	N	0.127	NR	N	N	N	N	≥500,000†	**61.32**	**R**
P	1st Gen EIA	0.755	NR	N	≥14.658	R	N	R	N	R1	≥500,000†	**136.62**	**R**
Q	1st Gen EIA	0.311	NR	N	0.277	NR	N	N	N	N	43173†	**1.80**	**R**
R	OQ RT-FS	0.642	NR	I	0.117	NR	N	N	N	N	30734†	**2.05**	**R**
S	1st Gen EIA	0.406	NR	N	13.276	R	N	R	N	R1	≥500,000†	**219.97**	**R**
T	OQ RT-OF	0.401	NR	N	4.929	R	N	N	N	N	≥500,000†	**268.30**	**R**
U	OQ RT-FS	0.325	NR	N	0.195	NR	N	N	N	N	≥500,000†	**317.71**	**R**
V	OQ RT-FS	0.512	NR	N	0.198	NR	N	N	N	N	≥500,000†	**20.53**	**R**
W	1st Gen EIA	0.504	NR	I	≥12.403	R	N	R	N	R1	≥500,000†	**121.68**	**R**
Y	OQ RT-FS	0.340	NR	N	≥12.590	R	N	N	N	N	≥500,000†	**237.06**	**R**
Z	1st Gen EIA	0.378	NR	N	0.201	NR	N	N	N	N	102288†	**2.09**	**R**
AA	1st Gen EIA	0.343	NR	N	0.327	NR	N	N	N	N	327333†	**6.34**	**R**
AB	1st Gen EIA	0.373	NR	N	0.189	NR	N	N	N	N	≥500,000†	**168.87**	**R**
AC	OQ RT-FS	0.396	NR	I	0.280	NR	N	N	N	N	≥500,000†	**35.93**	**R**
AD	1st Gen EIA	0.426	NR	N	0.371	NR	N	N	N	N	≥500,000†	**132.59**	**R**
AE	OQ RT-FS	0.369	NR	N	0.145	NR	N	N	N	N	389850†	**12.24**	**R**
AF	OQ RT-FS	0.761	NR	I	0.907	NR	N	R	N	R1	413186†	**13.89**	**R**
AG	3rd Gen EIA	0.436	NR	I	0.165	NR	N	N	N	N	446770†	**19.21**	**R**
AH	3rd Gen EIA	0.371	NR	N	0.195	NR	N	N	N	N	358030†	**10.66**	**R**
AJ	OQ RT-FS	0.6	NR	N	1.528	R	N	N	N	N	≥500,000†	**24.25**	**R**
AK	OQ RT-FS	0.6	NR	N	0.147	NR	N	N	N	N	427490†	**3.45**	**R**
AM	OQ RT-FS	0.41	NR	N	0.187	NR	N	N	N	N	≥500,000†	**309.58**	**R**
AN	OQ RT-OF	0.33	NR	N	0.17	NR	N	N	N	N	≥500,000†	**17.55**	**R**
AO	3rd Gen EIA	0.45	NR	N	9.634	R	N	N	N	N	≥500,000†	**22.83**	**R**
AP	3rd Gen EIA	0.34	NR	N	≥12.834	R	N	R	N	R1	≥500,000†	**131.50**	**R**
AR	OQ RT-OF	0.45	NR	N	0.097	NR	N	N	N	N	≥500,000†	**10.57**	**R**
AS	3rd Gen EIA	0.48	NR	I	≥14.641	R	R	R	R	R1	≥500,000†	**24.74**	**R**
AT	OQ RT-OF	0.40	NR	N	0.174	NR	N	N	N	N	≥500,000†	**176.23**	**R**
AU	OQ RT-OF	1.48	R	P	13.09	R	R	R	R	R1	109,211	**31.35**	**R**
AV	OQ RT-OF	0.5	NR	N	0.271	NR	N	N	N	N	333,066	**5.68**	**R**
AW	OQ RT-OF	5.82	R	P	12.496	R	R	R	R	R1	335	**14.33**	**R**
AX	OQ RT-OF	0.36	NR	N	1.554	R	N	R	N	N	≥10,000,000	**360.32**	**R**
AY	OQ RT-OF	0.45	NR	N	0.215	NR	N	N	N	N	69,599	**1.46**	**R**
AZ	OQ RT-OF	0.59	NR	P	9.454	R	R	R	R	R1	2,915,309	**80.82**	**R**
BA	OQ RT-OF	0.31	NR	N	13.205	R	N	R	N	R1	518,434	**9.13**	**R**
BB	3rd Gen EIA	0.32	NR	N	0.16	NR	N	N	N	N	317,609	**3.81**	**R**
BC	OQ RT-OF	6.65	R	P	≥13.943	R	R	R	R	R1	13,204	**77.09**	**R**
BD	OQ RT-FS	0.5	NR	P	10.7	R	R	R	R	R1	8,887,199	**128.99**	**R**
BE	OQ RT-FS	0.38	NR	I	0.243	NR	N	N	N	N	≥10,000,000	**132.66**	**R**
BF	OQ RT-OF	0.34	NR	N	5.443	R	N	N	N	N	≥10,000,000	**430.39**	**R**
BG	OQ RT-OF	5.69	R	P	≥13.514	R	R	R	R	R1	468,809	**12.66**	**R**
BH	OQ RT-OF	0.35	NR	N	0.232	NR	N	N	N	N	9,289,006	**80.34**	**R**
BI	OQ RT-FS	2.93	R	P	10.564	R	R	R	R	R1	355	**3.99**	**R**
BJ	3rd Gen EIA	0.346	NR	I	0.123	NR	N	N	N	N	9,855	**0.71**	**NR**
BK	OQ RT-OF	0.294	NR	N	0.403	NR	N	N	N	N	650,629	**6.08**	**R**
BL	OQ RT-OF	5.13	R	P	≥14.493	R	R	R	R	R1	752	**199.51**	**R**
BM	OQ RT-FS	0.326	NR	N	0.345	NR	N	N	N	N	4,589,912	**44.06**	**R**
BN	OQ RT-FS	2.959	R	I	1.18	R	R	N	R	R1	4,571,787	**48.35**	**R**
BO	OQ RT-FS	0.22	NR	N	0.168	NR	N	N	N	N	1,531,891	**18.05**	**R**
BP	OQ RT-FS	1.015	R	N	4.139	R	N	R	N	R1	≥10,000,000	**136.82**	**R**
BQ	OQ RT-FS	0.15	NR	N	0.539	NR	N	N	N	N	3,427,483	**14.92**	**R**

1st Gen. EIA - BioMérieux Vironostika HIV-1 Microelisa
2nd Gen. EIA - BioRad Genetic Systems rLAV HIV-1 EIA
3rd Gen. EIA - BioRad Genetic Systems HIV-1/2 plus O EIA
4th Gen. IA - Abbott Architect HIV Ag/Ab Combo
WB - BioRad Genetic Systems HIV-1 Western Blot
OQ RT-OF - OraQuick Rapid Test - Oral Fluid
OQ RT-FS - OraQuick Rapid Test - Fingerstick

OQ-RT - Oraquick Advance HIV-1/2 rapid test
UG -RT - Uni-Gold Recombigen HIV-1 rapid test
SP-RT - Stat Pak HIV-1/2 rapid test
MS-RT - Multi-SpotHIV-1/2 rapid test
† viral load determined by Siemens Versant HIV-1 RNA v. 3.0 (otherwise tested by Abbott RealTime HIV-1)

R - Reactive
NR - NonReactive
R1 - Reactive for HIV-1
P - Positive
N - Negative
I - Indeterminate

Table 2: Comparative Test Method Detection Rates

Method	% Detected
1st/2nd Generation IA	12.5
HIV-1 Western Blot	12.5
OraQuick Advance HIV-1/2 Rapid Test	17.2
Stat-Pak HIV-1/2 Rapid Test	17.2
Multi-Spot HIV-1/2 Rapid Test	28.1
Uni-Gold HIV-1 Rapid Test	34.4
3rd Generation IA	42.2
4th Generation IA	89.1