DEVELOPMENT OF A NEW LATEX-BASED LATERAL-FLOW ASSAY FOR RAPID DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS

Ganga Kanaujia, Javan Esfandiari, David Greenwald, Konstantin Lyashchenko, and Rena Greenwald
Chembio Diagnostic Systems, Inc., Medford, NY

OBJECTIVE

Despite of valuable efforts in the field of HIV diagnosis, early detection of infection remains a problem. Several screening and confirmatory tests are available in the market but most of them have low sensitivity when evaluated with seroconversion panels. We have developed a new rapid test prototype based on recombinant antigens of HIV-1 and HIV-2 that can detect both IgM and IgG antibodies at earlier stages of infection

Methods

Over 40 recombinant antigens and synthetic peptides of HIV1/2 from different sources were screened by MAPIA (multi-antigen print immunoassay, for more details, see our separate poster). Figure 2. Commercially available HIV1/2 serum panels were used to identify most potent antigenic reagents. A cocktail of antigens was conjugated to blue latex particles, immobilized on membrane, and test strips were made. A blue line visible on the strip figure 1within 15 minutes after sample application indicated a positive result. Test performance was evaluated with several seroconversion as well as low titer HIV-1 serum panels (Boston Biomedica, Inc.).

Results

Based on MAPIA studies, we selected recombinant gp41 and gp120 for HIV-1, and gp36 for HIV-2 antibody detection. We have also incorporated a multiepitope chimeric HIV1/2 antigen which had a superior sensitivity. The rapid test showed 100% agreement with Abbott HIV1/2 EIA and 99.5% specificity, based on testing 241 HIV-negative blood bank sera. Table 1,2, and 3

Conclusions

We developed a new latex-based lateral-flow test prototype. Its sensitivity was found to be equal to that of Abbott HIV1/2 EIA and greater than the sensitivity of western blot assays when used with seroconversion panels. The rapid test is an excellent alternative to conventional HIV antibody testing methods, especially for detection of recent HIV infections in remote areas.

Figure 1.

Table 1. HIV-1 Low Titer Performance Panel (BBI PRB107)

	Western Blot Bio-Rad Western Blot		HIV 1/2 Rapid Test	HIV EIA Tests Gen Sys	Abbott
Member ID	Band Pattern	Result	Chembio	HIV 1/2	HIV 1/2
PRB107-1	No Bands	NEG	POS	0.4	6.6
PRB107-2	24,55	IND	POS	1.0	3.7
PRB107-3	No Bands	NEG	POS	0.3	4.5
PRB107-4	No Bands	NEG	POS	1.0	9.7
PRB107-5	No Bands	NEG	NEG	0.1	0.1
PRB107-6	No Bands	NEG	POS	2.4	7.3
PRB107-7	No Bands	NEG	POS	0.3	1.0
PRB107-8	No Bands	NEG	POS	1.8	7.1
PRB107-9	No Bands	NEG	POS	0.3	2.4
PRB107-10	No Bands	NEG	POS	2.5	3.5
PRB107-11	24, 55, 160	POS	POS	7.0	3.3
PRB107-12	No Bands	NEG	POS	0.1	5.0
PRB107-13	24	IND	POS	0.4	3.3
PRB107-14	24, 160	POS	POS	7.0	14.3
PRB107-15	24	IND	POS	6.4	2.7

Assay	Total Reactive Samples
Abbott	14/15
Chembio	14/15
Gen SYS EIA	8/15
Western Blot	2/15

Table 2. HIV-1 Low Titer Performance Panel (BBI PRB108)

	Western Blot Bio-Rad Western Blot		Rapid Tests Determine	SUDS	Chembio	HIV EIA Tests Gen Sys	Abbott
Member ID	Band Pattern	Result	Result	Result	Results	HIV 1/2	HIV 1/2
PRB108-1	24,55,160	POS	POS	POS	POS	3.9	10.4
PRB108-2	No Bands	NEG	NEG	NEG	NEG	0.2	0.2
PRB108-3	160	IND	POS	POS	POS	3.2	9.3
PRB108-4	41,120,160	POS	POS	NEG	POS	8.1	15.7
PRB108-5	24,41,55,120,160	POS	POS	POS	POS	6.2	4.8
PRB108-6	160	IND	POS	NEG	POS	4.4	6.4
PRB108-7	24,160	POS	POS	POS	POS	2.2	7.3
PRB108-8	24,160	POS	POS	POS	POS	5	11
PRB108-9	24,160	POS	POS	NEG	POS	2.1	11.8
PRB108-10	24	IND	POS	NEG	POS	0.5	9.6
PRB108-11	24,160	POS	POS	POS	POS	8.2	10.1
PRB108-12	No Bands	NEG	NEG	NEG	POS	0.1	2.8
PRB108-13	24	IND	POS	POS	POS	0.3	13.1
PRB108-14	No Bands	NEG	POS	NEG	POS	0.3	9.6
PRB108-15	160	IND	POS	NEG	POS	7.7	16.2

Assay	Total Reactive Samples
Abbott	14/15
Chembio	14/15
Determine	13/15
Gen SYS EIA	10/15
Western Blot	7/15
SUDS	7/15

Specificity:

241 Blood Bank Sera non-reactive HIV samples tested. 240 Negative results

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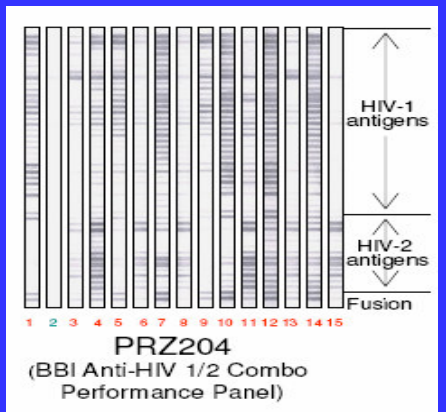
Table 3. Seroconversion Panels

Panel	Sample	Days Between Bleeds	Western Blot Bio-Rad	HIV EIA Gen Sys	HIV Rapid Test Chembio	HIV EIA Abbott
PRB-904	3		Neg	Neg	Neg	Neg
	4	28	Pos	Pos	Pos	Pos
PRB-910	2		Neg	Neg	Neg	Neg
	3	17	Pos	Pos	Pos	Pos
PRB-914	1		Ind	Neg	Pos	Pos
	2	4	Ind	Pos	Pos	Pos
	3	3	Ind	Pos	Pos	Pos
	4	18	Pos	Pos	Pos	Pos
PRB-916	4		Neg	Neg	Neg	Neg
	5	15	Pos	Pos	Pos	Pos
PRB-919	1		Neg	Neg	Neg	Neg
	2	9	Pos	Neg	Pos	Pos
	3	2	Pos	Pos	Pos	Pos
PRB-927	1		Neg	Neg	Neg	Neg
	2	28	Neg	Neg	Pos	Pos
	3	5	Neg	Neg	Pos	Pos
	4	2	Neg	Neg	Pos	Pos
	5	5	Pos	Pos	Pos	Pos
PRB-930	2		Neg	Neg	Neg	Neg
	3	4	Neg	Neg	Pos	Pos
	4	3	Ind	Pos	Pos	Pos
PRB-931	5		Neg	Neg	Neg	Neg
	6	13	Neg	Neg	Pos	Pos
	7	5	Ind	Pos	Pos	Pos
	8	2	Pos	Pos	Pos	Pos
PRB-934	1		Neg	Neg	Neg	Neg
	2	7	Ind	Neg	Pos	Pos
	3	4	Ind	Pos	Pos	Pos
PRB-938	2		Neg	Neg	Neg	Neg
	3	6	Ind	Neg	Pos	Pos
PRB-944	4		Neg	Neg	Neg	Neg
	5	5	Ind	Neg	Pos	Pos
	6	2	Ind	Neg	Pos	Pos
Total Reactive Samples	33		8/33	12/33	23/33	23/33

Figure 2. Evaluation of HIV antigens by MAPIA



For questions or comments please contact:
Ganga Kanaujia, Ph.D.
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road, Medford, NY 11763
Tel: (631)924-1135
Fax: (631)924-6033
E-mail: GKanaujia@chembio.com
Web: www.chembio.com