



An assessment of the seroconversion sensitivity of ImmunoFlow HIV1-HIV2 rapid test device

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Background and Description of the Assay

ImmunoFlow HIV1-HIV2 (Figure 1) is manufactured by Core Diagnostics and is an immunochromatographic rapid test for the detection of antibodies to HIV-1 and/or HIV-2 in human serum/plasma. Antigens representing HIV-1 and HIV-2 are coated on the membrane as two separate bands in the test region. Although the kit has two specific bands the kit instructions state that between the two HIV types there can be between 30 and 70% cross reactivity. The third band on the test device comprises the assay control.

Following the addition of test serum to the well, the sample flows through the device membrane assembly. The coloured conjugate (HIV-1/-2 specific recombinant antigen conjugated to colloidal gold) complexes with HIV antibodies, if present in the sample. The complex moves further down the membrane to the test region where it is immobilised by the HIV-1/-2 antigens that are coated on the membrane. This leads to the formation of a coloured band which represents a positive reaction. Absence of colour in this region indicates a negative reaction. The unreacted conjugate then moves further down the membrane to the control region where it is immobilised by the anti-rabbit antibodies coated on the membrane to form a coloured band. The control band serves to validate the test results. Table 1 includes a summary of the assay information.

Figure 1: ImmunoFlow rapid test device

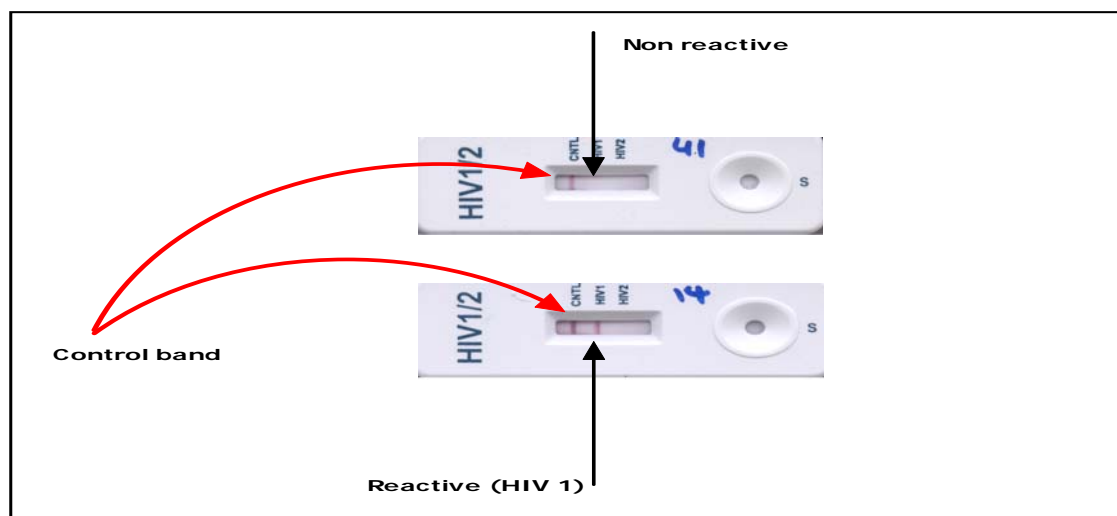


Table 1: Assay information

General	
Assay name	ImmunoFlow HIV1-HIV2
Manufacturer	Core Diagnostics
Product number	IF-110022
Number of tests in one pack	25
Specimen volume (for dilution)	25µl
Kit instruction version number	Version EnI-05/2006

Presentation	
Assay type	Immunochromatographic
Device coating description	Strips coated with HIV1 and HIV2 specific antigen and goat anti rabbit IgG along with HIV specific antigen and rabbit IgG gold conjugate
Sample running buffer	Tris buffer with 1.5% Tween ₂₀ and 0.1% sodium azide

Stages	
	Add one drop (25µl) of serum/plasma to sample well
	Add two drops of sample running buffer
	Wait 15 minutes (as currently stated in the kit insert)
	Visual reading of results

Evaluation Method

The ability of ImmunoFlow HIV1-HIV2 Rapid Test Device (Lot 48014) to detect early HIV infection was assessed by testing 29 commercial seroconversion panels totalling 169 specimens. Each seroconversion panel is a defined series of specimens from an individual undergoing HIV seroconversion which has been tested by many other HIV assays¹. Replicates of eight quality control samples were also included in the assessment to identify which are suitable for monitoring assay reactivity (Table 2).

Evaluation testing was carried out according to the manufacturer's instructions. All results were read visually after 30 minutes by three readers who independently recorded their scores using separate results sheets. The following scoring system was applied:

- 0 = No reactivity
- 1 = Uncertain reactivity
- 2 = Weak, but definite reaction
- 3 = Medium reactivity
- 4 = Strong reactivity

The mean of the three scores (consensus) was taken as the final result. The results are shown in Table 6 in the Appendix.

Table 2: Specimen panel for the evaluation of ImmunoFlow HIV1/2

Sample Category	Number of specimens
<i>1. HIV seroconversion panels (n=169; 29 panels)</i>	
PRB912	6
PRB914	5
PRB916	6
PRB917	5
PRB919	3
PRB922	4
PRB923	13
PRB924	8
PRB925	6
PRB926	6
PRB927	5
PRB928	5
PRB929	7
PRB930	4
PRB931	9
PRB932	9
PRB333	3
PRB934	3
PRB935	7
PRB937	6
PRB938	3
PRB939	5
PRB940	8
PRB941	6
PRB942	4
PRB943	6
PRB944	4
PRB945	7
PRB948	6
<i>2. Quality control samples (n=8)</i>	
HPA-HIV1 QC1	1
HPA-HIV1 QC2	1
HPA-HIV1 QC3	1
HPA-HIV1 QC4	1
HPA-HIV1 QC5	1
HPA-HIV2 QC2	1
HPA-HIV2 QC3	1
NIBSC Monitor a-HIV2	1
Total (number of samples tested)	177
Notes: BBI = Boston Biomedica Inc; BCP = BioClinical Partners Inc (Zeptometrix); HPA = Health Protection Agency, Colindale UK; NIBSC = National Institute for Biological Standards and Controls	

Results

Seroconversion panels: Immunoflow compared with HIV antibody-only laboratory-based assays; 19 panels

The seroconversion sensitivity for Immunoflow HIV-1/HIV-2 rapid test device was directly compared with CE marked antibody-only laboratory based assays by testing against 19 seroconversion panels. An aggregate sensitivity score was obtained for each kit by summing the total number of reactive samples. The most sensitive kit detected primary HIV infection earlier and had the highest aggregate score. Immunoflow was found to be marginally less sensitive than laboratory based antibody-only tests giving a score of 46 compared with a range of 47 to 53 for ten antibody-only kits. Immunoflow was more sensitive than Western Blot, score 17 (Table 3a).

Table 3a: Combined seroconversion panel scores: Laboratory based antibody-only assays compared with Immunoflow rapid test device (19 Panels)

HIV assay	Product number	Cumulative score *	Rank
		(PRB916-948 n=109)	
Genscreen HIV1/2 EIA (v2)	72279	53	1
Murex HIV 1.2.O	GE94/95	51	2
Biotest Anti-HIV TETRA ELISA	807 008	50	3=
Vitros <i>ECi</i> Anti-HIV 1+2	124-1850	50	3=
Access HIV 1/2 NEW	34020	50	3=
AxSYM HIV 1/2 gO	3D41-20	49	6
IMx HIV-1/HIV-2 III Plus	8C98	48	7=
Ortho HIV-1/HIV-2 ELISA Test System	932380	48	7=
Enzygnost Anti-HIV1/2 Plus	OQFK 12/13	47	9=
Vironostika HIV Uni-Form II <i>plus O</i>	84018	47	9=
ImmunoFlow HIV	IF-110022	46	11
Western Blot	77018090	17	12

Table 3a shows an addition of positive scores (consensus results) for Immunoflow HIV1-HIV2 RTD compared with antibody-only HIV assays (including Vitros *ECi* HIV-1/HIV-2) and HIV Western blot (Cambridge) tested against nineteen seroconversion panels

Seroconversion panels: Immunoflow compared with other rapid tests, 7 panels

The seroconversion sensitivity for Immunoflow HIV-1/HIV-2 rapid test device was directly compared with other rapid test devices by testing against a subset of seven seroconversion panels. ImmunoFlow, Determine HIV-1/2 (Abbott Diagnostics) and Core HIV 1&2 (Core Diagnostics) gave equivalent scores of 22.

Table 3b: Combined seroconversion panel scores: Rapid Test Devices

	Lot Number	PRB 917M n = 6	PRB922 n = 4	PRB927 n = 5	PRB930 n = 4	PRB940 n = 8	PRB941 n = 6	PRB945 n = 6	Cumulative score PRB917- 947 n = 44
Abbott Determine™ HIV-1/2	3932OU100-2	3	3	3	2	6	3	2	22
Core HIV 1&2	41018A	3	2	3	2	6	3	3	22
ImmunoFlow HIV1/2	48014	3	3	3	2	6	3	2	22

Note: * The score was calculated by summing the number of positive samples for each of the seroconversion panels.

Table 3b shows an addition of positive scores (consensus results) for ImmunoFlow HIV1-HIV2 RTD compared with two other HIV rapid tests (Core HIV1/2 RTD and Determine™ HIV1/2) tested against seven seroconversion panels

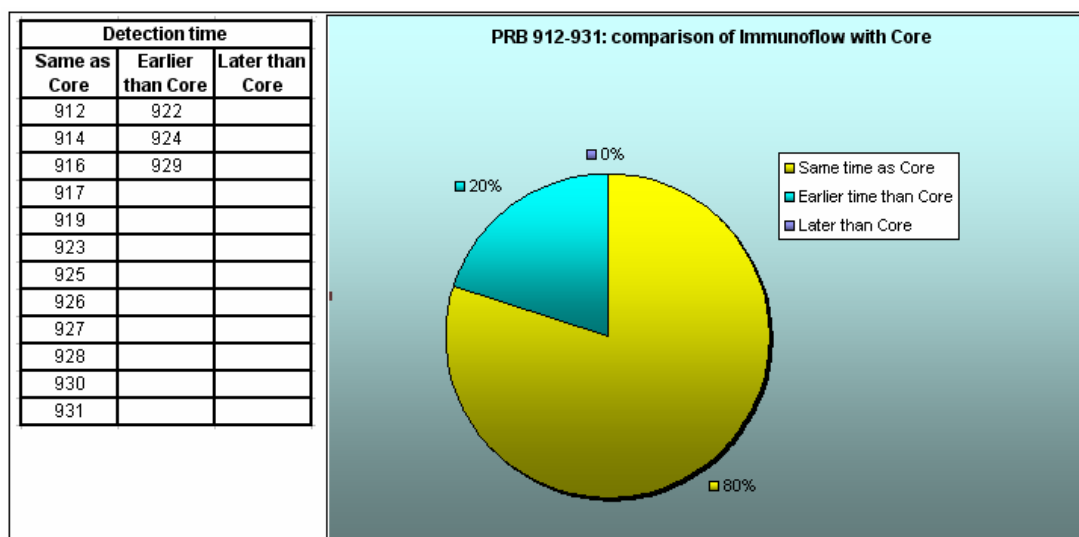
Seroconversion panels: Immunoflow HIV1/HIV2 compared with Core HIV-1/2, 15 panels; PRB912 - 931

In total, Immunoflow HIV-1/HIV-2 was directly compared Core HIV-1/2 for 15 seroconversion panels and these were grouped into three categories:

1. Panels detected by Immunoflow at the **same time** Core
2. Panels detected **earlier** than Core
3. Panels detected **later** than Core

The results show that HIV antibody was detected by Immunoflow at the same time as Core HIV1/2 for the majority (80%) of the panels, earlier than Core for 20% of the panels, and later than Core for none of panels.

Figure 4a: Panels PRB 912-931 and their time categories for this evaluation



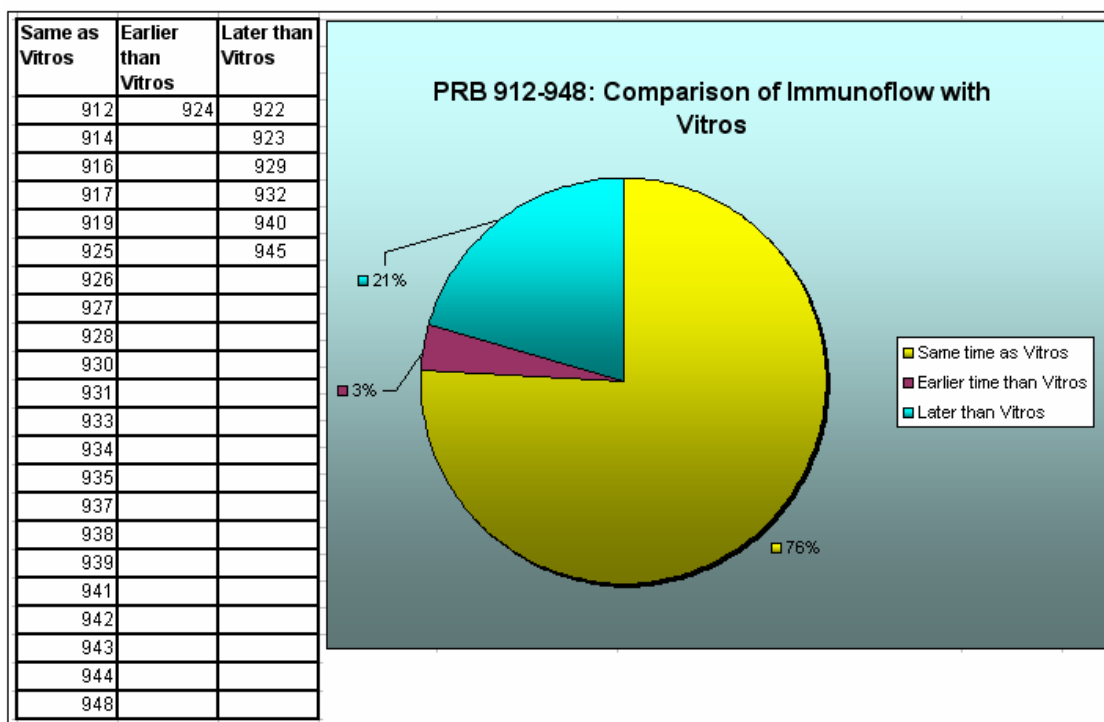
Seroconversion panels (ImmunoFlow compared with Vitros (29 panels

ImmunoFlow HIV-1/HIV-2 was directly compared Vitros ECI HIV-1/2 for 29 seroconversion panels and these were grouped into three categories:

- 1 Panels detected by ImmunoFlow at the **same time** Vitros
- 2 Panels detected **earlier** than Vitros
- 3 Panels detected **later** than Vitros

ImmunoFlow detected HIV antibody at the same time as the Vitros for 76% of the panels and earlier than the Vitros for 3% of the panels. Twenty-one percent of the panels were detected later than the Vitros by ImmunoFlow

Figure 4b: Panels PRB 912-948 and their time categories for this evaluation Compared with Core



Quality Control Reagents

Our findings suggest that HPA HIV1QC1 is the most suitable anti-HIV1 control for in-use monitoring of ImmunoFlow HIV1/2 (Table 5). The kit produced a score of 2 when tested against this control. This is within the range of possible reactions and provides a means to monitor run-to-run variation.

Table 5: Control results on ImmunoFlow HIV1/2

	consensus HIV1	consensus HIV2
HIV1QC1	2	0
HIV1QC2	0	0
HIV1QC3	0	0
HIV1QC4	0	0
HIV1QC5	1	0
HIV2QC2	0	2
HIV2QC3	0	0
NIBSC Monitor a-HIV 2	1	1

Technical Appraisal

The ImmunoFlow HIV1/2 was quick and easy to use and required approximately one hour to test twenty devices. The device has the advantage that it can be stored at room temperature.

The kit instructions would benefit from the following changes:

1. A suggested maximum number of tests per run
2. Reading time of results at 30 minutes as opposed to the 15 minute option (subject to other specificity and sensitivity trial results undertaken at 30 minutes). The results in this evaluation were obtained following 30 minutes incubation as agreed with the supplier.

Conclusions

When directly compared with two other CE-marked rapid test devices (Core and Determine) for seven seroconversion panels, Immunoflow was found to have an equivalent order of seroconversion sensitivity. Immunoflow was marginally less sensitive than laboratory based antibody-only assays for detecting seroconversion (against 20 panels), but this is generally the case for all HIV rapid tests. The Immunoflow seroconversion score of 46 in this comparison, against a range of 47 to 53 for ten antibody-only kits is only a small difference.

When directly compared to Core HIV using 15 seroconversion panels, Immunoflow detected seroconversion at the same time or earlier for all panels. Immunoflow detected seroconversion at the same time or earlier than Vitros for 79% of 29 panels.

Diagnostic specificity and sensitivity values are not included in this report as testing was only carried out on seroconversion panels. We recommend that this is undertaken as part of a larger study involving both negative and positive samples and according to the 30 minute incubation time. Subject to favourable findings in these studies, Immunoflow is suitable for use as a part of an HIV testing algorithm or in healthcare settings where there is limited access to equipment or ancillary reagents.

Acknowledgements

We would like to thank Fu Li and Laura Dean for reading the device results for this evaluation

References

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2. **Dean L, Perry K**, (2003): An assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device.
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3. **Kenny C, Giles RE, Perry K, Parry J** (1999): An evaluation of VITROS *ECi* HIV 1 + 2 automated immunoassay (product code 124 1850)
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Appendix

Table 6: Panels 912-922.

HIV seroconversion panel results for Immunoflow, Core, Western Blot, and Vitros

Panel ID	Days since first bleed	ImmunoFlow Consensus	Immunoflow HIV1/2	Core Consensus	Core HIV 1&2 +/-	Western Blot - Ortho Cambridge	Vitros ECI
PRB912-01	0	3	POS	2	POS	NEG	19.8
PRB912-02	9	4	POS	4	POS	POS	26.2
PRB912-03	14	4	POS	4	POS	POS	29.9
PRB912-04	16	4	POS	4	POS	POS	29.2
PRB912-05	28	4	POS	4	POS	POS	33.6
PRB912-06	30	4	POS	4	POS	POS	33.7
PRB914-01	0	3	POS	2	POS	IND	24.8
PRB914-02	4	3	POS	2	POS	POS	23.2
PRB914-03	7	3	POS	1	IND	POS	27.3
PRB914-04	25	3	POS	2	POS	POS	44.5
PRB914-05	31	3	POS	2	POS	POS	44
PRB916-01	0	0	NEG	0	NEG	NEG	0.08
PRB916-02	4	0	NEG	0	NEG	NEG	0.07
PRB916-03	9	0	NEG	0	NEG	NEG	0.08
PRB916-04	15	0	NEG	0	NEG	NEG	0.08
PRB916-05	30	4	POS	4	POS	POS	26.3
PRB916-06	35	4	POS	4	POS	POS	26.8
PRB917-01	0	0	NEG	0	NEG	IND	0.08
PRB917-02	53	0	NEG	0	NEG	IND	0.07
PRB917-03	57	0	NEG	0	NEG	IND	0.11
PRB917-05	65	4	POS	2	POS	IND	25.2
PRB917-06	67	4	POS	2	POS	IND	26.6
PRB917-07	72	NT	NT	NT	NT	NT	NT
PRB919-01	0	0	NEG	0	NEG	NEG	0.34
PRB919-02	9	4	POS	4	POS	POS	56.2
PRB919-03	11	4	POS	4	POS	POS	50.3
PRB922-01	0	0	NEG	0	NEG	NEG	4.14
PRB922-02	4	3	POS	0	NEG	NEG	31.7
PRB922-03	7	3	POS	3	POS	NEG	38.4
PRB922-04	11	3	POS	1	IND	POS	24.4

Table 6 continued: Panels 923-928.

HIV seroconversion panel results for Immunoflow, Core, Western Blot, and Vitros

Panel ID	Days since first bleed	Immunoflow Consensus	Immunoflow HIV1/2	Core Consensus	Core HIV 1&2 +/-	Western Blot - Ortho Cambridge	Vitros ECI
PRB923-01	0	0	NEG	0	NEG	NEG	0.07
PRB923-02	7	0	NEG	0	NEG	NEG	0.08
PRB923-03	12	0	NEG	0	NEG	NEG	0.08
PRB923-04	14	0	NEG	0	NEG	NEG	0.08
PRB923-05	28	0	NEG	0	NEG	NEG	0.08
PRB923-06	30	0	NEG	0	NEG	NEG	0.09
PRB923-07	35	0	NEG	0	NEG	NEG	0.09
PRB923-08	37	0	NEG	0	NEG	NEG	0.07
PRB923-09	47	0	NEG	0	NEG	NEG	4.12
PRB923-10	84	4	POS	2	POS	IND	24.4
PRB923-11	86	4	POS	2	POS	IND	24.8
PRB923-12	145	4	POS	3	POS	POS	57.8
PRB923-13	161	4	POS	4	POS	POS	56.4
PRB924-01	0	0	NEG	0	NEG	NEG	0.1
PRB924-02	2	0	NEG	0	NEG	NEG	0.09
PRB924-03	8	0	NEG	0	NEG	NEG	0.1
PRB924-04	10	0	NEG	0	NEG	NEG	0.1
PRB924-05	26	3	POS	0	NEG	NEG	0.09
PRB924-06	33	3	POS	2	POS	NEG	32.5
PRB924-07	35	3	POS	2	POS	NEG	34.5
PRB924-08	40	3	POS	1	IND	POS	26.3
PRB 925-01	0	0	NEG	0	NEG	NEG	0.1
PRB 925-02	10	0	NEG	0	NEG	NEG	0.09
PRB 925-03	18	0	NEG	0	NEG	NEG	0.08
PRB 925-04	22	0	NEG	0	NEG	NEG	0.09
PRB 925-05	44	3	POS	3	POS	IND	28
PRB 925-06	49	3	POS	3	POS	IND	29.9
PRB 926-01	0	0	NEG	0	NEG	NEG	0.07
PRB 926-02	0	0	NEG	0	NEG	NEG	0.07
PRB 926-03	7	0	NEG	0	NEG	NEG	0.08
PRB 926-04	9	0	NEG	0	NEG	NEG	0.08
PRB 926-05	27	4	POS	4	POS	POS	57.4
PRB 926-06	32	4	POS	4	POS	POS	47.8
PRB927-01	0	0	NEG	0	NEG	NEG	0.09
PRB927-02	28	0	NEG	0	NEG	NEG	0.46
PRB927-03	33	3	POS	2	POS	NEG	34.2
PRB927-04	35	4	POS	4	POS	POS	34.3
PRB927-05	40	4	POS	4	POS	POS	35.8
PRB928-01	0	0	NEG	0	NEG	NEG	0.08
PRB928-02	111	2	POS	2	POS	NEG	14.3
PRB928-03	120	4	POS	3	POS	POS	28.1
PRB928-04	125	4	POS	3	POS	POS	31.6
PRB928-05	130	4	POS	3	POS	POS	37.8

Table 6 continued: Panels 929-931.

HIV seroconversion panel results for Immunoflow, Core, Western Blot, and Vitros

Panel ID	Days since first bleed	Immunoflow Consensus	Immunoflow HIV1/2	Core Consensus	Core HIV 1&2 +/-	Western Blot - Ortho Cambridge	Vitros ECI
PRB929-01	0	0	NEG	0	NEG	NEG	0.08
PRB929-02	4	0	NEG	0	NEG	NEG	0.08
PRB929-03	14	0	NEG	0	NEG	NEG	0.07
PRB929-04	18	0	NEG	0	NEG	NEG	0.1
PRB929-05	21	0	NEG	1	IND	NEG	5.44
PRB929-06	25	4	POS	2	NEG	POS	44
PRB929-07	28	4	POS	4	NEG	POS	54.7
PRB930-01	0	0	NEG	0	NEG	NEG	0.08
PRB930-02	3	0	NEG	0	NEG	NEG	0.13
PRB930-03	7	3	POS	2	POS	NEG	25.6
PRB930-04	10	4	POS	3	POS	IND	55.6
PRB931-01	0	0	NEG	0	NEG	NEG	0.09
PRB931-02	2	0	NEG	0	NEG	NEG	0.1
PRB931-03	7	0	NEG	0	NEG	NEG	0.08
PRB931-04	9	0	NEG	0	NEG	NEG	0.07
PRB931-05	15	0	NEG	0	NEG	NEG	0.07
PRB931-06	28	4	POS	4	POS	NEG	40.3
PRB931-07	33	4	POS	4	POS	POS	33.2
PRB931-08	35	4	POS	2	POS	POS	28.8
PRB931-09	42	4	POS	3	POS	POS	29.2

Table 6 continued: Panels 932-939.

HIV seroconversion panel results for Immunoflow, Western Blot, and Vitros

Panel ID	Days since first bleed	Immunoflow Consensus	Immunoflow HIV1/2	Western Blot - Ortho Cambridge	Vitros ECI
PRB932-01	0	0	NEG	NEG	0.07
PRB932-02	3	0	NEG	NEG	0.07
PRB932-03	13	0	NEG	NEG	0.09
PRB932-04	27	1	IND	NEG	8.06
PRB932-05	34	4	POS	POS	53.9
PRB932-06	50	3	POS	POS	19.3
PRB932-07	78	2	POS	POS	16.2
PRB932-08	163	2	POS	POS	20.3
PRB932-09	194	3	POS	POS	27.5
PRB933-01	0	0	NEG	neg	0.08
PRB933-02	21	3	POS	IND	32
PRB933-03	27	4	POS	POS	41.6
PRB934-01	0	0	NEG	IND	0.75
PRB934-02	7	3	POS	POS	15.8
PRB934-03	11	3	POS	POS	10.2
PRB935-01	0	0	NEG	neg	0.07
PRB935-02	10	0	NEG	neg	0.09
PRB935-03	16	0	NEG	neg	0.09
PRB935-04	21	0	NEG	neg	0.1
PRB935-05	24	0	NEG	neg	0.08
PRB935-06	28	0	NEG	neg	0.08
PRB935-07	43	3	POS	POS	23.6
PRB937-02	7	0	NEG	neg	0.06
PRB937-03	9	0	NEG	neg	0.07
PRB937-04	14	0	NEG	neg	0.06
PRB937-05	16	0	NEG	neg	0.11
PRB937-06	21	2	POS	neg	2.81
PRB938-01	0	0	NEG	neg	0.07
PRB938-02	3	0	NEG	neg	0.09
PRB938-03	9	3	POS	IND	12.5
PRB939-05	0	0	NEG	neg	0.07
PRB939-06	2	0	NEG	neg	0.07
PRB939-07	7	0	NEG	neg	0.09
PRB939-08	9	0	NEG	neg	0.44
PRB939-09	89	4	POS	POS	45.2

Table 6 continued: Panels 940-948.

HIV seroconversion panel results for Immunoflow, Western Blot, and Vitros

Panel ID	Days since first bleed	Immunoflow Consensus	Immunoflow HIV1/2	Western Blot - Ortho Cambridge	Vitros ECI
PRB940-01	0	0	NEG	neg	0.07
PRB940-02	7	0	NEG	neg	1.05
PRB940-03	11	3	POS	neg	18.3
PRB940-04	15	3	POS	IND	29.1
PRB940-05	18	2	POS	IND	26.3
PRB940-06	22	2	POS	IND	21.5
PRB940-07	25	2	POS	IND	16
PRB940-08	29	3	POS	IND	15.4
PRB941-01	0	0	NEG	neg	0.1
PRB941-02	4	0	NEG	neg	0.08
PRB941-03	9	0	NEG	neg	0.1
PRB941-04	18	3	POS	IND	18
PRB941-05	21	3	POS	IND	17.7
PRB941-06	25	3	POS	IND	17.8
PRB942-01	0	0	NEG	neg	0.07
PRB942-02	2	0	NEG	neg	0.07
PRB942-03	9	0	NEG	neg	0.08
PRB942-04	14	0	NEG	neg	0.07
PRB943-01	0	0	NEG	neg	0.06
PRB943-02	5	0	NEG	neg	0.07
PRB943-03	7	0	NEG	neg	0.07
PRB943-04	12	0	NEG	neg	0.07
PRB943-05	14	0	NEG	neg	0.38
PRB943-06	19	4	POS	neg	30.2
PRB943-07	21	4	POS	IND	38.9
PRB944-01	0	0	NEG	neg	0.08
PRB944-02	2	0	NEG	neg	0.06
PRB944-03	7	0	NEG	neg	0.11
PRB944-04	9	0	NEG	neg	0.48
PRB944-05	14	3	POS	IND	25
PRB944-06	16	3	POS	POS	23.8
PRB945-01	0	0	NEG	neg	0.07
PRB945-02	3	0	NEG	neg	0.06
PRB945-03	7	0	NEG	neg	0.06
PRB945-04	13	1	IND	neg	3
PRB945-05	15	4	POS	neg	25.6
PRB945-06	20	4	POS	POS	57.7
PRB948-01	0	0	NEG	neg	0.07
PRB948-02	18	0	NEG	neg	0.07
PRB948-03	20	0	NEG	neg	0.07
PRB948-04	23	0	NEG	neg	0.07

Table 7: Seroconversion panel scores for Immunoflow and laboratory based antibody-only assays

HIV assay	Product number	The number of positive samples and the number of days from initial bleed to first reactive sample (shown in parentheses)							Score (PRB916-927)
		PRB916	PRB917M	PRB919	PRB922	PRB924	PRB925	PRB927	
		n=6	n=6	n=3	n=4	n=8	n=6	n=5	
Genscreen HIV1/2 EIA (v2)	72279	2 (30)	3 (65)	3 (0)	4 (0)	3 (33)	2 (44)	4 (28)	21
Murex HIV 1.2.O	GE94/95	2 (30)	3 (65)	2 (9)	4 (0)	3 (33)	2 (44)	4 (28)	20
Biotest Anti-HIV TETRA ELISA	807 008	2 (30)	3 (65)	3 (0)	4 (0)	3 (33)	2 (44)	4 (28)	21
Access HIV 1/2 NEW	34020	2 (30)	3 (65)	2 (9)	4 (0)	3 (33)	2 (44)	4 (28)	20
Vitros ECI Anti-HIV 1+2	124-1850	2 (30)	3 (65)	2 (9)	4 (0)	3 (33)	2 (44)	3 (33)	19
AxSYM HIV 1/2 gO	3D41-20	2 (30)	3 (65)	2 (9)	4 (0)	3 (33)	2 (44)	3(33)	19
IMx HIV-1/HIV-2 III Plus	8C98	2 (30)	3 (65)	2 (9)	3 (4)	3 (33)	2 (44)	4 (28)	19
Ortho HIV-1/HIV-2 ELISA Test System	932380	2 (30)	3 (65)	2 (9)	3 (4)	3 (33)	2 (44)	3 (33)	18
Enzygnost Anti-HIV1/2 Plus	OQFK 12/13	2 (30)	3 (65)	2 (9)	3 (4)	3 (33)	2 (44)	4 (28)	19
Vironostika HIV Uni-Form II plus O	84018	2 (30)	3 (65)	2 (9)	3 (4)	3 (33)	2 (44)	4 (28)	19
ImmunoFlow HIV	IF-110022	2 (30)	3 (65)	2 (9)	3 (4)	4 (26)	2 (44)	3(33)	19
Western Blot	77018090	2(30)	0(67)	2(9)	1(11)	1(40)	0(49)	2(35)	8

PRB917M: members 04 and 07 no longer available. Member 07 was scored as positive for kits that detected seroconversion in earlier members

HIV assay	Product number	The number of positive samples and the number of days from initial bleed to first reactive sample (shown in parentheses)								Score (PRB929-941)	Cumulative score (PRB916 - 941)
		PRB929	PRB930	PRB932	PRB937	PRB938	PRB939	PRB940	PRB941		
		n=7	n=4	n=9	n=6	n=3	n = 5	n = 8	n=6		
Genscreen® HIV1/2 EIA (v2)	72279	2 (25)	2 (7)	6 (27)	1 (21)	1 (9)	2 (9)	6 (11)	3 (18)	23	44
Murex HIV 1.2.O	GE94/95	3 (21)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	23	43
Biotest Anti-HIV TETRA ELISA	807 008	2 (25)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	22	43
Access® HIV 1/2 NEW	34020	2 (25)	2 (7)	6 (27)	1 (21)	1 (9)	2 (9)	6 (11)	2 (21)	22	42
Vitros ECI Anti-HIV 1+2	124-1850	3 (21)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	7 (7)	3 (18)	24	43
AxSYM® HIV 1/2 gO	3D41-20	3 (21)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	23	42
IMx® HIV-1/HIV-2 III Plus	8C98	2 (25)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	22	41
Ortho® HIV-1/HIV-2 ELISA Test System	932380	3 (21)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	23	41
Enzygnost® Anti-HIV1/2 Plus	OQFK 12/13	2 (25)	2 (7)	6 (27)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	22	41
Vironostika® HIV Uni-Form II plus O	84018	3 (21)	2 (7)	5 (34)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	22	41
ImmunoFlow HIV	IF-110022	2 (25)	2 (7)	5 (34)	1 (21)	1 (9)	1 (89)	6 (11)	3 (18)	21	40
Western Blot	77018090	2(25)	0(10)	5 (34)	1(43)	0(9)	1 (89)	0(29)	0(25)	9	19

HIV assay	Product number	The number of positive samples and the number of days from initial bleed to first reactive sample (shown in parentheses)				Score (PRB943-6240)	Cumulative score (PRB916-948)
		PRB943	PRB944	PRB945	PRB948		
		n=7	n = 6	n=6	n=4		
Genscreen HIV1/2 EIA (v2)	72279	2 (19)	4 (7)	3 (13)	0 (>23)	9	53
Murex HIV 1.2.O	GE94/95	3 (14)	2 (14)	3 (13)	0 (>23)	8	51
Biotest Anti-HIV TETRA ELISA	807 008	2 (19)	2 (14)	3 (13)	0 (>23)	7	50
Access HIV 1/2 NEW	34020	2 (19)	3 (9)	3 (13)	0 (>23)	8	50
Vitros ECI Anti-HIV 1+2	124-1850	2 (19)	2 (14)	3 (13)	0 (>23)	7	50
AxSYM HIV 1/2 gO	3D41-20	2 (19)	2 (14)	3 (13)	0 (>23)	7	49
IMx HIV-1/HIV-2 III Plus	8C98	2 (19)	2 (14)	3 (13)	0 (>23)	7	48
Ortho HIV-1/HIV-2 ELISA Test System	932380	2 (19)	2 (14)	3 (13)	0 (>23)	7	48
Enzygnost Anti-HIV1/2 Plus	OQFK 12/13	2 (19)	2 (14)	2 (15)	0 (>23)	6	47
Vironostika HIV Uni-Form II plus O	84018	2 (19)	2 (14)	2 (15)	0 (>23)	6	47
ImmunoFlow HIV	IF-110022	2 (19)	2 (14)	2 (15)	0 (>23)	6	46
Western Blot	77018090	0(21)	1(16)	1(20)	0(23)	2	17