

An assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device.

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May 2003

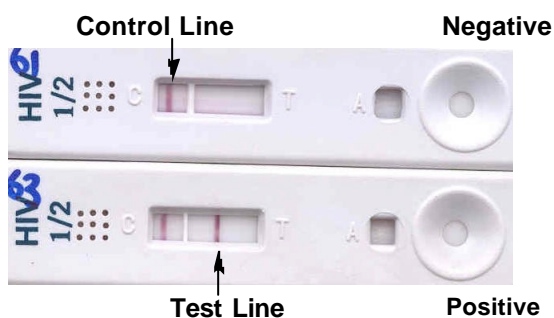
Summary

Core diagnostics HIV 1&2 is a rapid chromatographic immunoassay for the qualitative detection of anti-HIV 1 and anti-HIV 2 in whole blood, serum or plasma. Thirty seroconversion panels comprising 168 members were tested to assess the ability of Core HIV 1&2 to detect early HIV infection. The kit was more sensitive than an indirect and peptide immunoassay and had similar sensitivity to antigen sandwich ELISA's.

Description of the assay

Core HIV 1&2 (Figure 1) is an immunochromatographic rapid test for the detection of antibodies to HIV 1 and/or HIV 2. Antigens representing HIV-1 and HIV-2 are coated on the membrane in the test region and anti-rabbit antiserum in the control region. As the test sample flows through the membrane assembly within the test device the coloured, HIV1/2 specific recombinant antigen, colloidal gold conjugate complexes with HIV antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilised by the HIV 1/2 antigens that are coated on the membrane leading to the formation of a coloured band which represents a positive reaction. No colour in this region indicates a negative reaction. The unreacted conjugate then moves further down the membrane and is subsequently immobilised by the anti-rabbit antibodies coated on the membrane at the control region, forming a coloured band. This band serves to validate the test results.

Figure 1: Core HIV 1&2 Rapid Test Device



Evaluation method

The evaluation panel totalled 168 specimens from 30 commercial seroconversion panels (Table 1). These specimens were tested using Lot 41018A of the Core HIV 1&2 rapid test device.

All results were read visually by three readers who

independently recorded their scores using separate results sheets. The following scoring system was applied:

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

The mean of the three scores was taken as the final result.

Results

Seroconversion & performance panel sensitivity

The ability of the Core HIV 1&2 to detect HIV, was assessed by using 30 seroconversion panels. It was possible to make a limited comparison with four other rapid test devices covering eight panels. Core HIV 1&2 performed well in these tests and was ranked second behind Abbott Determine HIV 1/2 with a score of 24 out of 44 (Table 2).

A chart showing the full results and a comparison with three HIV 1&2 ELISA's and an HIV-1 western blot can be found in Annex 1-4.

Conclusion

The Core HIV 1&2 rapid test device is particularly suited for use in situations that require no electricity, refrigeration, ancillary reagents or sophisticated equipment. It could also be used for point of care screening and as part of the HIV testing algorithm in several health care settings such as small hospital laboratories, sexually transmitted disease clinics and student health and emergency care settings. The Core HIV 1&2 was quick and easy to use and could be stored at room temperature. When comparing its sensitivity at seroconversion, the test was ranked at the upper end of the range of rapid test devices. It was also more sensitive than an indirect ELISA, Innostest HIV-1+2 (M 421) and in the same order of sensitivity as the antigen sandwich ELISA's, Murex HIV 1+2 (VK 84/85) and Vitros ECi anti HIV 1+2 (124-1850).

References

1. Giles RE, Gollapalli M, Perry KR, Parry JV, Mortimer PP (1998): Thirteen anti-HIV screening simple/rapid test devices *Medical Devices Agency evaluation report: MDA/98/27*
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3. Giles RE, Ogunade O, Burgess C, Perry KR, Parry JV (2000): Sero•Strip® HIV-1/2
Medical Devices Agency evaluation report: MDA/2000/02

4. Donovan L, Perry KR, Burgess C, Kenny C, Lewis K, Parry JV (2001) Know HIV 1+2 ProPac
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An assessment of ExpresScreen HIV rapid test device.
Private report.

Acknowledgments

I would like to thank Michelle Cole and Rachel White for the important part they played in this evaluation.

Table 1: Specimen panel tested by lot 41018A

Sample category	Number
1. HIV seroconversion panels	
BBi: PRB912	6
BBi: PRB914	5
BBi: PRB916	6
BBi: PRB917	5
BBi: PRB919	3
BBi: PRB922	4
BBi: PRB923	13
BBi: PRB924	8
BBi: PRB925	6
BBi: PRB926	6
BBi: PRB927	5
BBi: PRB928	5
BBi: PRB929	7
BBi: PRB930	4
BBi: PRB931	9
BBi: PRB933	3
BBi: PRB934	3
BBi: PRB935	7
BBi: PRB937	6
BBi: PRB938	3
BBi: PRB939	5
BBi: PRB940	8
BBi: PRB941	6
BBi: PRB942	4
BBi: PRB943	7
BBi: PRB944	6
BBi: PRB945	6
BBi: PRB946	4
BBi: PRB947	4
BBi: PRB948	4
TOTAL (number of tests)	168
Notes:	
BBi = Boston Biomedica Inc;	

Table 2: Detection of 8 seroconversion panels by five Simple/Rapid test devices

Product name	PRB 917 n = 7	PRB922 n = 4	PRB927 n = 5	PRB930 n = 4	PRB940 n = 8	PRB941 n = 6	PRB945 n = 6	PRB947 n = 4	Cumulative score PRB917- 947 n = 44
Abbott Determine™ HIV-1/2	4	3	3	2	6	3	2	3	26
Core HIV 1&2	2	2	3	2	6	3	3	3	24
Know HIV 1+2 Propac	2	2	2	0	5	1	1	1	14
ExpresScreen HIV	3	2	2	0	5	1	0	0	13
Sero•Strip® HIV-1/2	1	1	0	0	4	0	0	0	6

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

Annex 1: PRB912 – PRB924

Assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device

Panel ID	Days since first bleed	Reader 1	Reader 2	Reader 3	Consensus	Core HIV 1&2 +/-	Innotest HIV 1+2 ELISA	Murex HIV 1+2 ELISA	Vitros Eci Anti-HIV 1+2	Western Blot - Ortho Cambridge
PRB912-01	0	2	2	2	2	+	0.23	1.31	19.80	neg
PRB912-02	9	4	4	4	4	+	5.96	≥10.79	26.20	POS
PRB912-03	14	4	4	4	4	+	5.48	≥10.79	29.90	POS
PRB912-04	16	4	4	4	4	+	5.93	≥10.79	29.20	POS
PRB912-05	28	4	4	4	4	+	7.22	≥10.79	33.60	POS
PRB912-06	30	4	4	4	4	+	7.54	≥10.79	33.70	POS
PRB914-01	0	2	2	2	2	+	1.36	≥11.32	24.80	Ind
PRB914-02	4	2	2	2	2	+	1.42	≥11.32	23.20	POS
PRB914-03	7	2	0	1	1	Trace	1.49	≥11.32	27.30	POS
PRB914-04	25	2	2	2	2	+	3.26	≥11.32	44.50	POS
PRB914-05	31	2	2	2	2	+	3.07	≥11.32	44.00	POS
PRB916-01	0	0	0	0	0	-	0.20	0.27	0.08	neg
PRB916-02	4	0	0	0	0	-	0.21	0.27	0.07	neg
PRB916-03	9	0	0	0	0	-	0.22	0.26	0.08	neg
PRB916-04	15	0	0	0	0	-	0.18	0.25	0.08	neg
PRB916-05	30	3	4	4	4	+	4.84	8.85	26.30	POS
PRB916-06	35	3	4	4	4	+	6.25	≥10.79	26.80	POS
PRB917-01	0	0	0	0	0	-	0.20	0.45	0.08	Ind
PRB917-02	53	0	0	0	0	-	0.17	0.68	0.07	Ind
PRB917-03	57	0	0	0	0	-	0.19	0.45	0.11	Ind
PRB917-05	60	2	2	3	2	+	1.59	≥8.85	25.20	Ind
PRB917-06	67	2	2	2	2	+	2.17	≥8.85	26.60	Ind
PRB919-01	0	0	0	0	0	-	0.18	0.27	0.34	neg
PRB919-02	9	4	4	4	4	+	2.43	3.90	56.20	POS
PRB919-03	11	4	4	4	4	+	2.78	3.59	50.30	POS
PRB922-01	0	0	0	0	0	-	0.37	2.50	4.14	neg
PRB922-02	4	0	0	0	0	-	2.38	≥8.85	31.70	neg
PRB922-03	7	3	4	2	3	+	5.05	≥8.85	38.40	neg
PRB922-04	11	2	0	1	1	+	5.79	≥8.85	24.40	POS
PRB923-01	0	0	0	0	0	-	0.19	0.31	0.07	neg
PRB923-02	7	0	0	0	0	-	0.19	0.26	0.08	neg
PRB923-03	12	0	0	0	0	-	0.09	0.29	0.08	neg
PRB923-04	14	0	0	0	0	-	0.20	0.30	0.08	neg
PRB923-05	28	0	0	0	0	-	0.19	0.31	0.08	neg
PRB923-06	30	0	0	0	0	-	0.18	0.31	0.09	neg
PRB923-07	35	0	0	0	0	-	0.20	0.28	0.09	neg
PRB923-08	37	0	0	0	0	-	0.20	0.34	0.07	neg
PRB923-09	47	0	0	1	0	-	0.18	1.39	4.12	neg
PRB923-10	84	3	2	2	2	+	5.05	≥11.32	24.40	Ind
PRB923-11	86	3	2	2	2	+	4.94	≥11.32	24.80	Ind
PRB923-12	145	4	3	3	3	+	7.22	≥11.32	57.80	POS
PRB923-13	161	4	4	4	4	+	7.29	≥11.32	56.40	POS
PRB924-01	0	0	0	0	0	-	0.34	0.28	0.10	neg
PRB924-02	2	0	0	0	0	-	0.24	0.28	0.09	neg
PRB924-03	8	0	0	0	0	-	0.25	0.25	0.10	neg
PRB924-04	10	0	0	0	0	-	0.22	0.26	0.10	neg
PRB924-05	26	0	0	0	0	-	0.25	0.29	0.09	neg
PRB924-06	33	2	2	2	2	+	0.44	4.86	32.50	neg
PRB924-07	35	2	2	2	2	+	0.95	5.54	34.50	neg
PRB924-08	40	1	1	1	1	+	2.55	4.62	26.30	POS

Key: Ind = Indeterminate
 = Negative
 = Not tested

Annex 2: PRB925 – PRB931

Assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device

Sample ID	Days since first bleed	Reader 1	Reader 2	Reader 3	Consensus	Core HIV 1&2 +/-	Innotest HIV 1+2 ELISA	Murex HIV 1+2 ELISA	Vitros Eci Anti-HIV 1+2	Western Blot - Ortho Cambridge
PRB925-01	0	0	0	0	0	-	0.21	0.27	0.10	neg
PRB925-02	10	0	0	0	0	-	0.17	0.30	0.09	neg
PRB925-03	18	0	0	0	0	-	0.17	0.24	0.08	neg
PRB925-04	22	0	0	0	0	-	0.17	0.34	0.09	neg
PRB925-05	44	3	3	3	3	+	1.26	≥ 11.07	28.00	Ind
PRB925-06	49	3	3	3	3	+	3.66	≥ 11.07	29.90	Ind
PRB926-01	0	0	0	0	0	-	0.18	0.33	0.07	neg
PRB926-02	2	0	0	0	0	-	0.03	0.35	0.07	neg
PRB926-03	7	0	0	0	0	-	0.12	0.33	0.08	neg
PRB926-04	9	0	0	0	0	-	0.06	0.33	0.08	neg
PRB926-05	27	4	4	4	4	+	7.48	≥9.20	57.40	POS
PRB926-06	32	4	4	3	4	+	6.92	≥9.20	47.80	POS
PRB927-01	0	0	0	0	0	-	0.03	0.35	0.09	
PRB927-02	28	0	0	0	0	-	0.02	0.50	0.46	
PRB927-03	33	2	2	2	2	+	1.36	6.94	34.20	
PRB927-04	35	4	4	4	4	+	4.19	8.28	34.30	
PRB927-05	40	4	4	4	4	+	6.80	8.35	35.80	
PRB928-01	0	0	0	0	0	-	0.03	0.34	0.08	neg
PRB928-02	111	2	1	2	2	+	0.59	3.83	14.30	neg
PRB928-03	120	4	3	3	3	+	5.45	≥9.20	28.10	POS
PRB928-04	125	4	3	3	3	+	6.12	≥9.20	31.60	POS
PRB928-05	130	4	3	3	3	+	6.81	≥9.20	37.80	POS
PRB929-01	0	0	0	0	0	-	0.04	0.53	0.08	neg
PRB929-02	4	0	0	0	0	-	0.07	0.44	0.08	neg
PRB929-03	14	0	0	0	0	-	0.04	0.46	0.07	neg
PRB929-04	18	0	0	0	0	-	0.05	0.44	0.10	neg
PRB929-05	21	1	0	1	1	Trace	0.04	1.17	5.44	neg
PRB929-06	25	2	2	2	2	+	0.05	≥9.20	44.40	POS
PRB929-07	28	4	4	4	4	+	0.80	≥9.20	54.70	POS
PRB930-01	0	0	0	0	0	-	0.08	0.46	0.08	neg
PRB930-02	3	0	0	0	0	-	0.08	1.38	0.13	neg
PRB930-03	7	2	2	2	2	+	1.14	5.09	25.60	neg
PRB930-04	10	3	4	3	3	+	3.74	≥9.20	55.60	ind
PRB931-01	0	0	0	0	0	-	0.08	0.41	0.09	neg
PRB931-02	2	0	0	0	0	-	0.07	0.35	0.10	neg
PRB931-03	7	0	0	0	0	-	0.08	0.33	0.08	neg
PRB931-04	9	0	0	0	0	-	0.08	0.37	0.07	neg
PRB931-05	15	0	0	0	0	-	0.07	0.38	0.07	neg
PRB931-06	28	4	4	4	4	+	2.90	≥9.20	40.30	neg
PRB931-07	33	4	4	4	4	+	4.02	≥9.20	33.20	POS
PRB931-08	35	2	2	2	2	+	4.56	≥9.20	28.80	POS
PRB931-09	42	3	2	3	3	+	5.79	≥9.20	29.20	POS

Key: Ind = Indeterminate
 = Negative
 = Not tested

Annex 3: PRB933 – PRB942

Assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device

Sample ID	Days since first bleed	Reader 1	Reader 2	Reader 3	Consensus	Core HIV 1&2 +/-	Innotest HIV 1+2 ELISA	Murex HIV 1+2 ELISA	Vitros Eci Anti-HIV 1+2	Western Blot - Ortho Cambridge
PRB933-01	0	0	0	0	0	-	0.06	0.42	0.08	neg
PRB933-02	21	3	2	3	3	+	0.24	≥9.20	32.00	Ind
PRB933-03	27	2	2	2	2	+	5.96	≥9.20	41.60	POS
PRB934-01	0	0	0	0	0	-	0.07	0.47	0.75	Ind
PRB934-02	7	2	2	3	2	+	4.01	2.06	15.80	POS
PRB934-03	11	2	2	2	2	+	4.37	3.18	10.20	POS
PRB935-01	0	0	0	0	0	-	0.06	0.44	0.07	neg
PRB935-02	10	0	0	0	0	-	0.07	0.38	0.09	neg
PRB935-03	16	0	0	0	0	-	0.06	0.28	0.09	neg
PRB935-04	21	0	0	0	0	-	0.06	0.38	0.10	neg
PRB935-05	24	0	0	0	0	-	0.05	0.35	0.08	neg
PRB935-06	28	0	0	0	0	-	0.05	0.36	0.08	neg
PRB935-07	43	2	2	2	2	+	3.15	6.45	23.60	POS
PRB937-01	0	0	0	0	0	-	0.02	0.48	0.06	neg
PRB937-02	7	0	0	0	0	-	0.03	0.40	0.07	neg
PRB937-03	9	0	0	0	0	-	0.02	0.67	0.06	neg
PRB937-04	14	0	0	0	0	-	0.02	0.45	0.11	neg
PRB937-05	16	0	0	0	0	-	0.02	1.23	2.81	neg
PRB937-06	21	2	2	2	2	+	0.02	0.45	0.07	neg
PRB938-01	0	0	0	0	0	-	0.02	0.44	0.09	neg
PRB938-02	3	0	0	0	0	-	0.11	3.14	12.50	ind
PRB938-03	9	2	1	2	2	+	0.02	0.39	0.07	neg
PRB939-05	0	0	0	0	0	-	0.03	0.36	0.07	neg
PRB939-06	2	0	0	0	0	-	0.03	0.36	0.09	neg
PRB939-07	7	0	0	0	0	-	0.03	0.38	0.44	neg
PRB939-08	9	0	0	0	0	-	8.00	2.19	45.20	POS
PRB939-09	89	4	4	4	4	+	0.03	0.34	0.07	neg
PRB940-01	0	0	0	0	0	-	0.04	0.41	1.05	neg
PRB940-02	7	0	0	0	0	-	0.07	2.84	18.30	neg
PRB940-03	11	2	2	2	2	+	1.61	3.38	29.10	ind
PRB940-04	15	2	2	2	2	+	2.45	2.23	26.30	ind
PRB940-05	18	2	2	2	2	+	3.67	2.23	21.50	ind
PRB940-06	22	3	2	3	3	+	4.34	3.58	16.00	ind
PRB940-07	25	2	2	2	2	+	4.80	5.59	15.40	ind
PRB940-08	29	2	2	2	2	+	0.04	0.33	0.10	neg
PRB941-01	0	0	0	0	0	-	0.05	0.34	0.08	neg
PRB941-02	4	0	0	0	0	-	0.04	0.36	0.10	neg
PRB941-03	9	0	0	0	0	-	0.15	7.60	18.00	ind
PRB941-04	18	3	2	2	2	+	1.01	7.25	17.70	ind
PRB941-05	21	2	1	2	2	+	2.97	≥9.43	17.80	ind
PRB941-06	25	2	2	2	2	+	0.03	0.38	0.07	neg
PRB942-01	0	0	0	0	0	-	0.03	0.36	0.07	neg
PRB942-02	2	0	0	0	0	-	0.03	0.39	0.08	neg
PRB942-03	9	0	0	0	0	-	0.03	0.35	0.07	neg
PRB942-04	14	0	0	0	0	-				neg

Key: Ind = Indeterminate

= Negative

= Not tested

Annex 4: PRB943 – PRB948

Assessment of the seroconversion sensitivity of Core Diagnostics HIV 1&2 rapid test device

Sample ID	Days since first bleed	Reader 1	Reader 2	Reader 3	Consensus	Core HIV 1&2 +/-	Innotest HIV 1+2 ELISA	Murex HIV 1+2 ELISA	Vitros Eci Anti-HIV 1+2	Western Blot - Ortho Cambridge
PRB943-01	0	0	0	0	0	-	0.03	0.38	0.06	neg
PRB943-02	5	0	0	0	0	-	0.03	0.41	0.07	neg
PRB943-03	7	0	0	0	0	-	0.02	0.34	0.07	neg
PRB943-04	12	0	0	0	0	-	0.04	0.41	0.07	neg
PRB943-05	14	1	0	0	0	-	0.03	0.56	0.38	neg
PRB943-06	19	4	4	3	4	+	0.03	5.66	30.20	neg
PRB943-07	21	4	4	4	4	+	0.05	≥9.43	38.90	Ind
PRB944-01	0	0	0	0	0	-	0.04	0.43	0.08	neg
PRB944-02	2	0	0	0	0	-	0.03	0.35	0.06	neg
PRB944-03	7	0	0	0	0	-	0.02	0.41	0.11	neg
PRB944-04	9	0	0	0	0	-	0.02	0.61	0.48	neg
PRB944-05	14	2	2	2	2	+	0.20	3.69	25.00	Ind
PRB944-06	16	2	2	2	2	+	0.69	5.09	23.80	POS
PRB945-01	0	0	0	0	0	-	0.04	0.36	0.07	neg
PRB945-02	3	0	0	0	0	-	0.02	0.35	0.06	neg
PRB945-03	7	0	0	0	0	-	0.03	0.38	0.06	neg
PRB945-04	13	2	1	1	1	Trace	0.03	2.65	3.00	neg
PRB945-05	15	3	2	2	2	+	0.03	≥9.43	25.60	neg
PRB945-06	20	4	4	4	4	+	0.63	≥9.43	57.70	POS
PRB946-01	0	0	0	0	0	-	0.04	0.37	0.06	neg
PRB946-02	4	0	0	0	0	-	0.04	0.36	0.07	neg
PRB946-03	7	0	0	0	0	-	0.04	0.40	0.06	neg
PRB946-04	11	0	0	0	0	-	0.04	0.53	0.14	neg
PRB947-01	0	0	0	0	0	-	0.02	0.37	0.06	neg
PRB947-02	9	2	2	2	2	+	0.03	4.93	10.80	Ind
PRB947-03	11	2	2	2	2	+	0.04	≥9.43	14.30	Ind
PRB947-04	20	4	3	2	3	+	0.51	≥9.43	15.90	POS
PRB948-01	0	0	0	0	0	-	0.02	0.68	0.07	neg
PRB948-02	18	0	0	0	0	-	0.02	0.37	0.07	neg
PRB948-03	20	0	0	0	0	-	0.02	0.34	0.07	neg
PRB948-04	23	0	0	0	0	-	0.02	0.40	0.07	neg
Cumulative score of all positives from 168 specimens						73	52	78	77	60
Key: Ind = Indeterminate										
= Negative										
= Not tested										