



An assessment of the seroconversion sensitivity of ImmunoFlow HCV rapid test device (Core Diagnostics)

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Background and Description of the Assay

ImmunoFlow HCV is manufactured by Core Diagnostics and is an immunochromatographic rapid test for the detection of HCV antibodies in human serum/plasma. The test device is coated with antigens representing Core, NS3, NS4 and NS5. The second band on the test device is coated with reagent control. At the time of this evaluation, ImmunoFlow was not CE marked

Following the addition of test serum and sample buffer to the well, the sample flows through the device membrane assembly region. As the test sample flows through the membrane assembly the coloured, Protein-A, colloidal gold conjugate complexes with HCV antibodies in the sample. This complex moves further along the membrane to the test region where it is immobilised by the HCV specific recombinant 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-Protein-A antibodies coated on the membrane at the control region, forming a coloured band. This band serves to validate the test results.

Figure 1: ImmunoFlow rapid HCV test device



Table 1: Assay information

<i>General</i>	
<i>Assay name</i>	<i>ImmunoFlow HCV</i>
<i>Manufacturer</i>	<i>Core Diagnostics</i>
<i>Product number</i>	<i>HCV- 120025</i>
<i>Number of tests in one pack</i>	<i>25</i>
<i>Specimen volume</i>	<i>5µl</i>
<i>Kit instruction version number</i>	<i>Not provided</i>
<i>Presentation</i>	
<i>Assay type</i>	<i>ImmunoChromatographic</i>
<i>Device coating description</i>	<i>Strips coated with anti-Protein-A along with HCV antigens and Protein-A gold conjugate</i>
<i>Sample running buffer</i>	<i>Tris buffer with 1.5% Tween₂₀ and 0.1% sodium azide</i>
<i>Stages</i>	
<i>Add (5µl) of serum/plasma to sample well</i>	
<i>Add two drops of sample running buffer</i>	
<i>Wait 15 minutes (as currently stated in the kit insert)</i>	
<i>Visual reading of results</i>	

Evaluation Method

The ability of ImmunoFlow HCV Rapid Test Device (Lot 52001) to detect HCV antibody early was assessed by testing 30 commercial seroconversion panels totalling 220 specimens. Replicates of an HPA quality control samples was also included in the assessment to identify if it was suitable for monitoring assay reactivity (Table 2).

Evaluation testing was carried out according to the manufacturer's instructions. All results were read visually after 15 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 the table in the Appendix.

Table 2a: Specimen panel for the evaluation of ImmunoFlow HCV

Sample Category	Number of specimens
<i>1. HCV seroconversion panels (30 panels)</i>	
PHV 901	11
PHV 904	7
PHV 905	9
PHV 906	7
PHV 907	7
PHV 908	13
PHV 909	3
PHV 910	5
PHV 911	5
PHV 912	3
PHV 913	4
PHV 914	9
PHV 915	4
PHV 916	8
PHV 917	10
BCP 6211	4
BCP 6212	9
BCP 6213	12
BCP 6214	13
BCP 6215	4
BCP 6216	7
BCP 6222	8
BCP 6224	6
BCP 6227	7
BCP 6229	8
BCP 9041	8
BCP 9044	6
BCP 9045	8
BCP 9046	5
BCP 9047	10
<i>4. Quality control samples (n=1)</i> HPA HCV QC1	1 x 3
Total (number of tests)	223
Notes:	
BBI = Boston Biomedica Inc; BCP = BioClinical Partners Inc (Zeptometrix); HPA = Health Protection Agency, Colindale UK	

Results

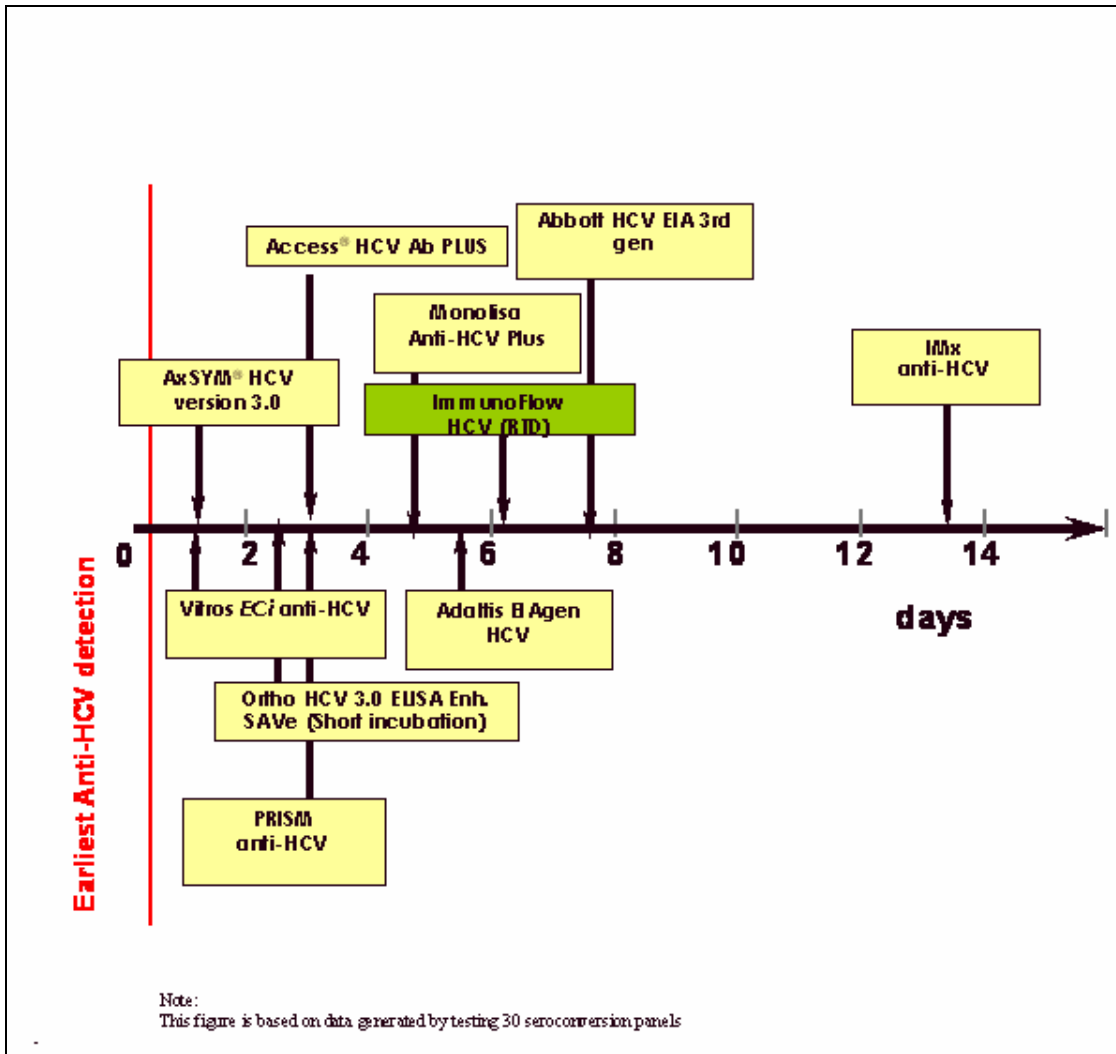
Seroconversion sensitivity: Comparative timing of detection

Using a method that assigns the most sensitive test “time zero” and any test less sensitive test a positive value; we found that that ImmunoFlow HCV detected HCV infection on average 5.16 days later than the most sensitive antibody-only assay (Vitros ECi anti-HCV). ImmunoFlow HCV detected 1.5 days earlier than the Abbott HCV EIA and 7.5 days earlier than the IMX anti-HCV.

Table 2b: Comparative timing of detection

Anti-HCV assay	Product number	Assay type	Overall delay in detecting seroconversion compared with the most sensitive assay		
			Range (days)	Mean (days)	Median (days)
Vitros ECi anti-HCV	1318450	Ab-only	0 - 7	1.0	0.0
AxSYM HCV	3B44-20	Ab-only	0 -10	1.05	0.0
Ortho HCV 3.0 SAvE	9307401	Ab-only	0 - 9	2.21	0.0
PRISM HCV	6A52-48	Ab-only	0 - 10	2.95	0.0
Access HCV Ab plus	34330	Ab-only	0 - 12	2.95	0.0
Monolisa anti-HCV plus	72312	Ab-only	0 - 20	4.63	3.0
Adaltis EIAgen HCV Ab	071064	Ab-only	0 - 25	5.74	3.0
ImmunoFlow HCV	HCV-120025	Ab-only	0 - 44	6.16	6.0
Abbott HCV EIA 3 rd gen	7A16-23	Ab-only	0 - 41	7.63	5.0
IMX anti-HCV	3A99-20	Ab-only	0 - 151	13.63	4.0

Notes:
The upper limits of the bleeds are top some extent influenced by the bleeds



KEY:

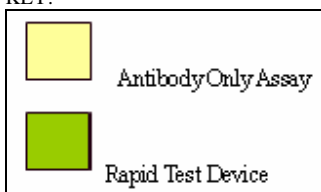


Figure 2: The mean time delay (days) of the detection of anti-HCV kits on the basis of testing 30 seroconversion panels. ImmunoFlow HCV detected anti-HCV on average 6.6 days later than AxSym HCV. ImmunoFlow detected anti HCV 1.5 days earlier than the Abbott HCV EIA 3rd generation and 7.5 days earlier than the IMx anti-HCV

Quality Control Reagents

HPA HCVQC1 was not detected and therefore it is not a suitable anti-HCV control for in-house monitoring of ImmunoFlow HCV (Table 3).

Table 3: Control results on ImmunoFlow HCV

	Reader 1	Reader 2	Reader 3	Consensus
HCVQC1	0	0	0	0

Technical Appraisal

The ImmunoFlow HCV was quick and easy to use and required approximately one hour to test twenty devices.

The kit instructions would benefit from including a suggested maximum number of tests per run

Conclusions

When directly compared with nine other antibody only EIAs, Immunoflow was found to be at the lower end of seroconversion sensitivity. Seven of the nine assays were more sensitive, varying from five days more sensitive (Vitros and AxSYM HCV) to just 0.4 days more sensitive (Adaltis HCV). Abbott HCV 3rd generation and IMx HCV were less sensitive.

To date this is the only HCV rapid test that we have assessed to such an extent (30 seroconversion panels) and the results provide a level of reassurance that this rapid test can reach the order of sensitivity of some EIAs. However, the analysis does not include a comparison with HCV antibody/antigen assays which are now providing a higher benchmark.

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. Subject to favourable findings in these studies, Immunoflow is suitable for use as a part of an HCV 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 Christine Burgess for reading the device results for this evaluation

Appendix

Seroconversion panels: ImmunoFlow compared with HCV laboratory-based Immunoassays; 30 panels

Sample ID	Days since first bleed	Reader 1	Reader 2	Reader 3	Consensus score	ImmunoFlow Status	Ortho HCV 3.0 ELISA / enhanced SAbve	AxSYM® HCV version 3.0	Access HCV Ab PLUS	Monolisa anti-HCV Plus	RIBA HCV 3.0
PHV901-01	0	0	0	0	0	NEG	0.05	0.36	0.05	0.16	NEG
PHV901-02	65	0	0	0	0	NEG	0.00	0.22	0.04	0.12	NEG
PHV901-03	97	3	3	3	3	POS	6.79	56.88	5.11	6.37	POS
PHV901-04	99	3	2	3	3	POS	6.80	50.17	5.41	6.59	POS
PHV901-05	104	3	3	4	3	POS	7.56	57.23	5.84	6.93	POS
PHV901-06	106	3	3	3	3	POS	7.52	57.67	5.74	6.98	POS
PHV901-07	131	4	3	4	4	POS	≥ 9.09	75.67	8.33	8.49	POS
PHV901-08	139	3	3	3	3	POS	≥ 9.09	65.99	8.22	8.31	POS
PHV901-09	159	4	4	4	4	POS	≥ 9.09	70.80	8.50	8.70	POS
PHV901-10	166	4	4	4	4	POS	≥ 9.09	69.65	8.29	8.71	POS
PHV901-11	203	4	4	4	4	POS	≥ 9.09	95.90	9.20	9.26	POS
PHV904-01	0	0	0	0	0	NEG	0.02	0.24	0.04	0.07	NEG
PHV904-02	2	0	0	0	0	NEG	0.02	0.14	0.03	0.08	NEG
PHV904-03	7	0	0	0	0	NEG	0.26	0.91	0.21	0.33	NEG
PHV904-04	9	0	0	0	0	NEG	1.47	2.26	0.89	1.24	NEG
PHV904-05	14	0	0	0	0	NEG	4.19	11.30	2.24	3.31	EQV
PHV904-06	21	0	0	0	0	NEG	6.38	18.13	3.47	5.20	EQV
PHV904-07	23	1	2	2	2	POS	6.78	26.58	3.87	6.65	EQV
PHV905-01	0	0	0	0	0	NEG	0.02	0.17	0.03	0.04	NEG
PHV905-02	4	0	0	0	0	NEG	0.03	0.14	0.03	0.04	NEG
PHV905-03	7	0	0	0	0	NEG	0.04	0.23	0.09	0.07	NEG
PHV905-04	11	0	0	0	0	NEG	0.83	0.84	0.37	0.35	EQV
PHV905-05	14	Not tested	Not tested	Not tested	Not tested	NT	1.37	1.33	0.63	0.66	EQV
PHV905-06	18	0	0	0	0	NEG	2.39	2.44	0.81	1.43	EQV
PHV905-07	21	1	2	1	1	IND	3.77	5.27	1.94	2.99	POS
PHV905-08	25	3	3	3	3	POS	7.18	29.08	5.56	6.04	POS
PHV905-09	28	4	3	4	4	POS	8.41	46.18	6.39	6.31	POS
PHV906-01	0	2	2	2	2	POS	2.42	14.52	3.24	1.98	EQV
PHV906-02	2	3	2	3	3	POS	2.73	21.34	4.13	3.89	EQV
PHV906-03	7	3	3	3	3	POS	2.24	32.82	5.23	6.00	POS
PHV906-04	10	4	3	3	3	POS	4.59	38.30	5.52	6.58	POS
PHV906-05	14	4	3	4	4	POS	4.14	44.97	6.46	6.96	POS
PHV906-06	17	3	3	3	3	POS	5.69	47.36	6.87	8.80	POS
PHV906-07	21	4	3	4	4	POS	6.06	54.35	7.19	7.99	POS
PHV907-01	0	0	0	0	0	NEG	0.07	0.21	0.02	0.05	NEG
PHV907-02	4	0	0	0	0	NEG	0.07	0.23	0.02	0.08	NEG
PHV907-03	7	0	0	0	0	NEG	0.07	0.29	0.02	0.04	NEG
PHV907-04	13	2	2	2	2	POS	0.27	0.50	1.27	0.15	EQV
PHV907-05	18	3	2	3	3	POS	1.75	3.16	3.29	0.88	EQV
PHV907-06	21	3	2	3	3	POS	2.90	8.70	3.95	1.29	POS
PHV907-07	164	4	3	3	3	POS	8.19	49.52	9.55	7.83	N/K
PHV908-01	0	0	0	0	0	NEG	0.06	0.15	0.02	0.05	NEG
PHV908-02	3	0	0	0	0	NEG	0.05	0.17	0.02	0.04	NEG
PHV908-03	5	0	0	0	0	NEG	0.06	0.22	0.04	0.06	NEG
PHV908-04	11	0	0	0	0	NEG	0.62	1.44	0.39	0.11	NEG
PHV908-05	13	0	0	0	0	NEG	0.73	2.35	0.61	0.17	POS
PHV908-06	19	1	2	1	1	IND	2.19	7.42	1.93	0.84	POS
PHV908-07	25	2	3	3	3	POS	3.82	22.03	3.99	4.50	POS
PHV908-08	27	3	3	3	3	POS	4.69	32.98	4.54	5.57	POS
PHV908-09	32	3	3	4	3	POS	5.80	48.61	5.40	7.31	POS
PHV908-10	35	3	3	4	3	POS	6.34	59.07	5.68	7.42	POS
PHV908-11	41	3	3	4	3	POS	7.16	55.19	6.14	8.05	POS
PHV908-12	45	3	3	4	3	POS	7.21	55.66	5.90	8.48	POS
PHV908-13	48	4	3	4	4	POS	7.02	56.30	5.97	8.57	POS
PHV909-01	0	0	0	0	0	NEG	0.12	0.18	0.41	0.12	NEG
PHV909-02	28	0	0	0	0	NEG	2.93	0.66	4.65	2.42	EQV
PHV909-03	30	0	0	0	0	NEG	2.87	0.86	4.45	2.43	EQV
PHV910-01	0	0	0	0	0	NEG	0.02	0.16	0.05	0.21	NEG
PHV910-02	4	0	0	0	0	NEG	0.08	0.26	0.26	0.40	NEG
PHV910-03	8	2	2	2	2	POS	2.97	2.73	3.30	0.47	POS
PHV910-04	11	4	3	4	4	POS	4.79	11.09	5.57	2.19	POS
PHV910-05	15	4	3	4	4	POS	6.13	23.33	7.00	3.12	POS
PHV911-01	0	0	0	0	0	NEG	0.03	0.20	NEG	0.04	NEG
PHV911-02	3	0	0	0	0	NEG	0.03	0.21	NEG	0.05	NEG
PHV911-03	14	2	2	2	2	POS	1.51	3.00	POS	1.04	POS
PHV911-04	21	4	4	4	4	POS	6.87	31.75	POS	6.94	POS
PHV911-05	24	4	4	4	4	POS	7.20	49.07	POS	8.94	POS
PHV912-01	0	0	0	0	0	NEG	0.17	0.51	0.22	0.30	NEG
PHV912-02	4	0	0	0	0	NEG	0.12	0.60	0.22	0.28	NEG
PHV912-03	7	4	3	4	4	POS	9.71	12.58	8.78	8.05	EQV

Key: EQV = EQUIVOCAL

Appendix

Seroconversion panels: Immunoflow compared with HCV laboratory-based Immunoassays; 30 panels

Sample ID	Days since first bleed	0	2	1	Consensus score	ImmunoFlow Status	Ortho HCV 3.0 ELISA / enhanced SAVE	AxSYM® HCV version 3.0	Access HCV Ab PLUS	Monolisa anti-HCV Plus	RIBA HCV 3.0
PHV913-01	0	0	0	0	0	NEG	0.04	0.19	0.10	0.10	NEG
PHV913-02	2	0	0	0	0	NEG	0.12	0.22	0.65	0.34	NEG
PHV913-03	7	0	2	1	1	IND	1.50	0.41	3.65	2.99	EQV
PHV913-04	9	2	2	2	2	POS	1.69	0.60	3.43	2.90	EQV
PHV914-01	0	0	0	0	0	NEG	0.01	0.19	0.02	0.03	NEG
PHV914-02	5	0	0	0	0	NEG	0.02	0.16	0.02	0.04	NEG
PHV914-03	9	0	0	0	0	NEG	0.03	0.19	0.03	0.04	NEG
PHV914-04	12	0	0	0	0	NEG	0.06	0.63	0.16	0.08	NEG
PHV914-05	16	0	0	0	0	NEG	1.16	1.37	2.18	0.75	EQV
PHV914-06	19	0	1	0	0	NEG	2.05	1.76	3.08	1.56	EQV
PHV914-07	24	2	2	2	2	POS	4.50	5.42	5.41	4.48	EQV
PHV914-08	30	3	3	3	3	POS	6.84	18.90	6.53	5.40	POS
PHV914-09	33	4	3	4	4	POS	7.63	22.57	7.11	5.30	POS
PHV915-01	0	0	0	0	0	NEG	0.03	0.44	0.09	0.14	NEG
PHV915-02	5	0	0	0	0	NEG	0.24	1.50	0.28	0.47	EQV
PHV915-03	12	0	0	0	0	NEG	0.85	4.19	0.65	0.86	EQV
PHV915-04	14	1	2	1	1	IND	2.21	9.16	0.97	1.44	EQV
PHV916-01	0	0	0	0	0	NEG	0.02	0.25	0.04	0.08	NEG
PHV916-02	2	0	0	0	0	NEG	0.02	0.21	0.04	0.09	NEG
PHV916-03	7	0	0	0	0	NEG	0.02	0.19	0.04	0.12	NEG
PHV916-04	9	0	0	0	0	NEG	0.01	0.23	0.04	0.11	NEG
PHV916-05	16	0	0	0	0	NEG	0.11	1.57	0.17	0.10	NEG
PHV916-06	19	0	2	1	1	IND	0.87	5.33	0.58	0.27	NEG
PHV916-07	23	3	2	3	3	POS	2.79	14.59	1.83	1.22	POS
PHV916-08	28	3	3	3	3	POS	3.13	21.53	2.89	2.18	POS
PHV917-01	0	0	0	0	0	NEG	0.02	0.20	0.03	NOT TESTED	NEG
PHV917-02	13	0	0	0	0	NEG	0.02	0.29	0.04	NOT TESTED	NEG
PHV917-03	20	0	0	0	0	NEG	0.01	0.28	0.03	NOT TESTED	NEG
PHV917-04	22	0	0	0	0	NEG	0.01	0.26	0.03	NOT TESTED	NEG
PHV917-05	85	3	2	3	3	POS	5.16	38.09	5.89	NOT TESTED	POS
PHV917-06	131	3	3	3	3	POS	4.89	24.94	5.33	NOT TESTED	POS
PHV917-07	135	3	3	3	3	POS	5.24	29.18	5.67	NOT TESTED	POS
PHV917-08	138	2	2	3	2	POS	5.72	34.47	6.70	NOT TESTED	POS
PHV917-09	146	4	3	4	4	POS	6.72	55.85	8.41	NOT TESTED	POS
PHV917-10	152	4	3	4	4	POS	6.83	59.41	8.44	NOT TESTED	POS
BCP6211-37	0	0	0	0	0	NEG	0.01	0.14	0.06	0.02	NEG
BCP6211-38	2	0	0	0	0	NEG	1.54	3.66	0.83	0.72	EQV
BCP6211-39	7	3	2	3	3	POS	4.61	20.41	1.95	2.53	POS
BCP6211-40	9	3	2	3	3	POS	5.37	38.39	3.18	4.08	POS
BCP6212-01	0	0	0	0	0	NEG	0.02	0.15	0.02	0.05	NEG
BCP6212-02	12	0	0	0	0	NEG	1.08	3.49	0.40	0.07	NEG
BCP6212-03	14	0	0	0	0	NEG	1.49	6.09	0.74	0.08	NEG
BCP6212-04	23	2	2	2	2	POS	4.12	21.11	3.81	0.36	EQV
BCP6212-05	26	3	2	3	3	POS	4.80	23.62	5.07	0.53	EQV
BCP6212-06	32	3	2	3	3	POS	5.03	21.51	4.84	1.29	EQV
BCP6212-07	37	1	2	2	2	POS	4.75	20.88	4.59	1.48	EQV
BCP6212-08	53	3	2	3	3	POS	8.62	39.87	6.77	7.00	EQV
BCP6212-09	55	3	3	3	3	POS	≥ 9.01	42.14	7.12	7.45	EQV
BCP6213-01	0	0	0	0	0	NEG	0.03	0.86	0.03	0.07	NEG
BCP6213-02	2	0	0	0	0	NEG	0.03	0.79	0.03	0.04	NEG
BCP6213-03	8	0	0	0	0	NEG	0.03	0.85	0.03	0.03	NEG
BCP6213-04	11	0	0	0	0	NEG	0.03	0.91	0.04	0.03	NEG
BCP6213-05	15	0	0	0	0	NEG	0.02	0.76	0.03	0.04	NEG
BCP6213-06	18	0	0	0	0	NEG	0.03	0.91	0.03	0.06	NEG
BCP6213-07	28	0	0	0	0	NEG	0.02	0.92	0.03	0.07	NEG
BCP6213-08	30	0	0	0	0	NEG	0.01	0.88	0.03	0.08	NEG
BCP6213-09	35	0	0	0	0	NEG	0.04	0.96	0.05	0.09	NEG
BCP6213-10	37	0	0	0	0	NEG	0.82	2.54	0.42	0.26	NEG
BCP6213-11	43	3	2	4	3	POS	4.97	32.52	4.26	3.85	POS
BCP6213-12	46	3	2	3	3	POS	5.53	34.12	4.69	3.79	POS
BCP6214-01	0	0	0	0	0	NEG	0.01	0.25	0.03	0.05	NEG
BCP6214-02	2	0	0	0	0	NEG	0.02	0.20	0.02	0.06	NEG
BCP6214-03	8	0	0	0	0	NEG	0.00	0.20	0.02	0.04	NEG
BCP6214-04	10	0	0	0	0	NEG	0.02	0.15	0.02	0.07	NEG
BCP6214-05	16	0	0	0	0	NEG	0.02	0.17	0.02	0.07	NEG
BCP6214-06	18	0	0	0	0	NEG	0.02	0.23	0.02	0.02	NEG
BCP6214-07	23	0	0	0	0	NEG	0.03	0.90	0.05	0.03	NEG
BCP6214-08	25	0	1	1	1	IND	0.08	2.77	0.14	0.05	NEG
BCP6214-09	30	3	2	3	3	POS	1.23	18.97	1.00	0.28	EQV
BCP6214-10	32	3	3	3	3	POS	3.02	19.43	1.95	1.13	EQV
BCP6214-11	49	4	3	4	4	POS	7.47	71.97	6.31	7.05	POS
BCP6214-12	53	4	3	4	4	POS	7.94	73.93	6.46	7.77	POS
BCP6214-13	56	4	4	4	4	POS	7.75	72.96	6.28	8.22	POS
BCP6215-01	0	0	0	0	0	NEG	0.03	0.15	0.02	0.04	NEG
BCP6215-02	3	0	0	0	0	NEG	0.04	0.18	0.02	0.05	NEG
BCP6215-03	10	0	0	0	0	NEG	0.03	0.19	0.10	0.05	NEG
BCP6215-04	20	3	3	4	3	POS	3.24	3.62	3.24	1.90	EQV
BCP6216-01	0	0	0	0	0	NEG	0.02	0.38	0.04	0.08	NEG
BCP6216-02	3	0	0	0	0	NEG	0.02	0.40	0.03	0.09	NEG
BCP6216-03	8	0	0	0	0	NEG	0.03	0.48	0.04	0.06	NEG
BCP6216-04	10	0	0	0	0	NEG	0.07	0.25	0.03	0.04	NEG
BCP6216-05	15	0	0	0	0	NEG	0.05	0.36	0.03	0.06	NEG
BCP6216-06	17	0	0	0	0	NEG	0.03	0.27	0.04	0.06	NEG
BCP6216-07	23	0	0	0	0	NEG	2.37	1.50	2.62	0.49	EQV

Key: EQV = EQUIVOCAL

Appendix

Seroconversion panels: Immunoflow compared with HCV laboratory-based Immunoassays: 30 panels

Sample ID	Days since first bled	Reader 1	Reader 2	Reader 3	Consensus score	ImmunoFlow Status	Ortho HCV 3.0 ELISA / enhanced SAve	AxSYM® HCV version 3.0	Access HCV Ab PLUS	Monolisa anti-HCV Plus
BCP6222-01	0	0	0	0	0	NEG	0.01	0.19	0.04	0.02
BCP6222-02	2	0	0	0	0	NEG	0.01	0.17	0.03	0.03
BCP6222-03	17	0	0	0	0	NEG	0.01	0.20	0.04	0.03
BCP6222-04	19	0	0	0	0	NEG	0.01	0.16	0.04	0.02
BCP6222-05	14	0	0	0	0	NEG	0.00	0.16	0.04	0.04
BCP6222-06	26	0	0	0	0	NEG	0.00	0.20	0.03	0.06
BCP6222-07	36	0	0	0	0	NEG	0.09	0.58	0.29	0.14
BCP6222-08	40	0	0	0	0	NEG	1.66	6.71	2.65	1.15
BCP6224-01	0	0	0	0	0	NEG	NOT TESTED	0.19	0.04	0.05
BCP6224-02	3	0	0	0	0	NEG	NOT TESTED	0.21	0.04	-0.03
BCP6224-03	7	0	0	0	0	NEG	NOT TESTED	0.19	0.04	0.03
BCP6224-04	11	0	0	0	0	NEG	NOT TESTED	0.30	0.08	0.04
BCP6224-05	19	0	0	0	0	NEG	NOT TESTED	2.32	1.17	0.91
BCP6224-06	22	0	0	0	0	NEG	NOT TESTED	3.27	1.74	1.56
BCP6227-01	0	0	0	0	0	NEG	0.00	0.63	Not Tested	Not Tested
BCP6227-02	22	0	0	0	0	NEG	0.00	0.63	Not Tested	Not Tested
BCP6227-03	24	0	0	0	0	NEG	0.00	0.52	Not Tested	Not Tested
BCP6227-04	42	0	0	0	0	NEG	0.00	0.56	Not Tested	Not Tested
BCP6227-05	46	0	0	0	0	NEG	0.00	0.53	Not Tested	Not Tested
BCP6227-06	74	2	2	2	2	POS	2.10	1.75	Not Tested	Not Tested
BCP6227-07	76	3	2	2	2	POS	2.52	1.64	Not Tested	Not Tested
BCP6229-01	0	0	0	0	0	NEG	0.03	0.55	Not Tested	Not Tested
BCP6229-02	3	0	0	0	0	NEG	0.02	0.54	Not Tested	Not Tested
BCP6229-03	7	0	0	0	0	NEG	0.02	0.51	Not Tested	Not Tested
BCP6229-04	10	0	0	0	0	NEG	0.02	0.53	Not Tested	Not Tested
BCP6229-05	17	0	0	0	0	NEG	0.53	0.89	Not Tested	Not Tested
BCP6229-06	20	0	0	0	0	NEG	0.87	1.37	Not Tested	Not Tested
BCP6229-07	24	0	0	0	0	NEG	1.71	1.50	Not Tested	Not Tested
BCP6229-08	28	1	2	2	2	POS	3.98	3.69	Not Tested	Not Tested
BCP9041-01	0	0	0	0	0	NEG	0.00	0.14	0.02	0.09
BCP9041-02	24	0	0	0	0	NEG	0.01	0.18	0.03	0.05
BCP9041-03	27	0	0	0	0	NEG	0.01	0.14	0.03	0.05
BCP9041-04	31	0	0	0	0	NEG	0.01	0.18	0.03	0.04
BCP9041-05	62	1	2	1	1	IND	7.30	21.87	5.70	5.68
BCP9041-06	64	2	2	2	2	POS	8.03	28.60	6.30	6.07
BCP9041-07	69	3	2	3	3	POS	8.21	45.28	6.85	6.16
BCP9041-08	71	4	3	4	4	POS	8.78	60.66	7.46	6.26
BCP9044-01	0	0	0	0	0	NEG	0.01	0.16	0.03	0.08
BCP9044-02	4	0	0	0	0	NEG	0.02	0.15	0.03	0.05
BCP9044-03	17	0	0	0	0	NEG	0.02	0.18	0.04	0.06
BCP9044-04	21	0	0	0	0	NEG	0.32	1.51	0.27	0.22
BCP9044-05	25	0	0	0	0	NEG	1.86	7.70	1.16	1.13
BCP9044-06	29	2	2	1	2	POS	3.16	20.11	1.76	1.87
BCP9045-01	0	0	0	0	0	NEG	0.02	0.13	0.03	0.03
BCP9045-02	2	0	0	0	0	NEG	0.02	0.11	0.03	0.04
BCP9045-03	7	0	0	0	0	NEG	0.00	0.13	0.03	0.05
BCP9045-04	9	0	0	0	0	NEG	0.00	0.14	0.02	0.04
BCP9045-05	26	0	0	0	0	NEG	0.00	0.11	0.03	0.03
BCP9045-06	32	0	0	0	0	NEG	0.03	0.28	0.06	0.07
BCP9045-07	37	0	0	0	0	NEG	1.60	4.02	1.05	0.73
BCP9045-08	41	0	0	0	0	NEG	2.35	6.80	1.46	2.40
BCP9046-01	0	0	0	1	0	NEG	0.00	0.14	0.05	0.06
BCP9046-02	69	4	4	4	4	POS	9.13	97.01	9.03	5.68
BCP9046-03	72	4	4	4	4	POS	8.85	84.89	9.35	5.33
BCP9046-04	76	4	4	4	4	POS	7.96	87.20	9.25	4.95
BCP9046-05	79	4	4	4	4	POS	8.96	83.07	9.15	5.25
BCP9047-01	0	0	0	0	0	NEG	0.10	0.17	0.07	0.09
BCP9047-02	2	0	0	0	0	NEG	0.12	0.16	0.07	0.12
BCP9047-03	10	0	0	0	0	NEG	0.09	0.15	0.10	0.10
BCP9047-04	12	0	0	0	0	NEG	0.05	0.16	0.06	0.07
BCP9047-05	19	0	0	0	0	NEG	0.10	0.14	0.07	0.12
BCP9047-06	21	0	0	0	0	NEG	0.09	0.16	0.06	0.16
BCP9047-07	28	1	1	1	1	IND	1.51	10.06	1.79	0.73
BCP9047-08	30	2	2	3	2	POS	3.92	38.14	4.57	4.12
BCP9047-09	35	3	3	4	3	POS	7.36	61.66	6.31	5.89
BCP9047-10	37	3	3	4	3	POS	6.77	62.47	6.25	6.45