



Blood and Transplant



Evaluation of Abbott Architect HCV Assay Product code 6C37

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Introduction

The Microbiological Diagnostics Assessment Service (HPA_MiDAS) in conjunction with the National Transfusion Microbiology Reference Laboratory (NTMRL), North London Blood Centre carried out evaluations of six assays for the Abbott Architect i2000SR analyser. The object of the evaluations was to assess the ability of the Architect HBsAg, HIV Ag/Ab combo, Anti-HCV, Rubella IgG, anti-CMV and Syphilis TP assays to detect serological evidence of each respective marker in human serum and plasma specimens. The analyser was installed at the NTMRL where all testing took place.

The results of the evaluation of the Anti-HCV assay are presented in this report. The kits were tested against a panel of serum/plasma samples found to be either reactive or unreactive by relevant screening assays used in Europe. In addition, several sequential blood collections from individuals undergoing seroconversion for the relevant marker (chosen to compare directly with a range of other assays), and national quality control samples were incorporated in this evaluation.

Abbott Diagnostics provided all equipment, reagents and consumables required for this evaluation. They were responsible for the training of the operators in the use of the analyser and for the installation and ongoing maintenance and repair of any faulty equipment.

HPA-MiDAS staff were responsible for the testing of the evaluation panel which consisted of HBsAg positive and weakly positive samples, seroconversion panels and quality control samples. NTMRL staff were responsible for the specificity testing of a panel of ante-natal samples.

Description of the assay

The Abbott Architect anti-HCV assay is a two-step sandwich chemiluminescent microparticle immunoassay (CMIA) for the detection of antibody to HCV in human serum or plasma. Anti-HCV present in the sample binds to HCV antigen (*E. coli* and yeast recombinant) coated paramagnetic particles. After a wash step, a murine anti-IgG/anti-IgM acridinium-labelled conjugate is added. Following a further wash step, pre-trigger solution (hydrogen peroxide) and trigger solution (sodium hydroxide) are added. The resulting chemiluminescent reaction is measured in relative light units (RLUs) which are directly proportional to the amount of anti-HCV present in the sample. Further assay information is shown in Table 1.

The assay was evaluated to determine its ability to detect anti-HCV. The Architect Anti-HCV assay was run on the i2000SR analyser at the NTMRL. HPA-MiDAS provided a sensitivity panel which was interspersed with anti-HCV negative specimens. The main specificity testing panel was undertaken by NTMRL, comprising specimens from blood donors and from antenatal patients. In addition NTMRL also tested the NBS HCV Lot Release Testing Panel.

Table 1: Assay information

General	
Assay name	Architect Anti-HCV
Manufacturer/UK agent	Abbott Diagnostics
Product number	6C37
Number of tests per pack	100 / 500
Sample volume (including 'dead volume')	150µL
Presentation	
Assay type	Two-step chemiluminescent sandwich immunoassay
Solid phase	Paramagnetic microparticles coated with HCV antigen (<i>E. coli</i> & yeast recombinant))
Conjugate	Acridinium-labelled anti-IgG and anti-IgM (murine)
Substrate	Pre-trigger - hydrogen peroxide solution Trigger - sodium hydroxide solution
Negative control	1
Positive control	1
Reading wavelength	n/a - chemiluminescent
Cut-off computation	Calibrator 1 mean RLU x 0.074
Equivocal zone	None
Stages	
Preparation/sample well loading	5 minutes
Specimen volume (excluding 'dead volume')	20µL
Incubation status	37°C
Sampling time - 1 sample	1 minute
Total time to completion (from initial loading of first sample)*	
- 1 sample	30 minutes
- 10 samples	34 minutes
- 100 samples	60 minutes
Additional equipment requirement	
Centrifuge	
Latex/nitrile gloves & personal protective equipment	

Note: * These data were observed timings by the evaluator.
Information provided by Abbott Laboratories: Throughput 100 tests per hour for the first hour and 200 tests per hour after the first result is generated.

Evaluation panel and method

A total of 2366 samples were included in the evaluation panel, Table 2.

The main specificity study was carried out by the NTMRL, for which 1007 blood donors' specimens were tested. The specimens had been previously screened and found negative for anti-HCV by Abbott PRISM Anti-HCV assay, product code 06A52.

NTMRL also tested 1015 ante-natal patients' samples which had not previously been screened for anti-HCV. Additionally, a panel of 15 samples which comprised the NBS Lot Release Testing panel were tested. Twelve of the 15 samples were anti-HCV positive and three were negative.

The evaluation panel used by the HPA-MiDAS totalled 329 specimens. Two hundred and fifteen specimens were from anti-HCV positive samples. These samples were supplied by Boston Biomedical Inc and had been reactive in one or more of the following assays: Ortho HCV 3.0, PRISM HCV and Roche HCV 2.0. Twenty anti-HCV negative blood donors specimens were sourced from NTMRL. Thirteen seroconversion panels from commercial sources and, additionally, two quality control samples, from the HPA and NIBSC, were included in the panel.

The method described in the kit insert was strictly followed. Abbott Architect is a fully automated analyser; all processing steps are performed on the instrument. The Architect assay parameters are factory set and defined in the system software.

A daily maintenance program is followed each day, the steps for which are prompted on the display screen. Principally, Probe Conditioning Solution and sodium hypochlorite solution are loaded onto the analyser by the operator and the analyser completes the program automatically. A weekly maintenance program is also required in which the sample, reagent and wash probes are cleaned with cotton-wool swabs soaked in distilled water and the air filters are cleaned.

Prior to running the analyser, test reagents, pre-trigger solution, trigger solution, wash buffer and reaction vessels are loaded onto the analyser and automatically primed and loaded as appropriate. The latter two may also be added when the analyser is in 'running' mode.

Prior to running a new batch of an assay, a calibration must first be performed. The calibrator is provided in a dropper bottle and an appropriate volume is placed into a sample cup and loaded onto the analyser. The calibration is valid for all subsequent tests using that particular lot number; it is not time limited. For the Anti-HCV assay, one calibrator is supplied which is run in triplicate. The mean of the triplicate RLU results x 0.074 is calculated to provide the cut-off for the lot number.

Two anti-HCV kit controls are provided by Abbott; the negative control is non-reactive for anti-HCV and has a S/CO ≤ 0.60 , the positive control is reactive for anti-HCV and has a S/CO range of 1.71 to 5.13. These should be run immediately after the calibration has been performed to ensure the correct readings are obtained and it is then recommended that they are run at least once within every 24 hours that the test is in use.

Specimens may be loaded in their primary tubes, if suitable for the analyser, or aliquotted into Architect sample cups. Sample processing is initiated by the loading of the samples onto the analyser. The reactions occur in the following processing sequence: -

- A reaction mixture is formed combining, sample, microparticles and specimen diluent in the reaction vessel.
- After the first incubation is complete, the reaction mixture undergoes a wash step. A magnetic field is applied to retain the paramagnetic microparticles within the reaction vessel during the wash procedure.
- The anti-IgG/anti-IgM-acridinium conjugate is then added and a further incubation takes place.
- Following a second wash step, pre-trigger (hydrogen peroxide) and trigger (sodium hydroxide) solutions are added to the reaction vessel
- The resultant chemiluminescent signal is measured and expressed as Relative Light Units.

The Architect Anti-HCV assay results are calculated as ratios of the sample RLU / cut-off value (S/CO). A specimen with a S/CO value <1 is considered non-reactive and a S/CO value ≥ 1 reactive for anti-HCV.

The time taken from loading a sample to obtaining a result was 30 minutes for the Anti-HCV assay. Subsequent results are obtained approximately every 18 seconds, assuming continuous loading of samples. (18 seconds is a set cycle time and does not vary.)

Table 2: Evaluation panel

Sample category	Number	
<u>NTMRL, NBS</u>		
1. Anti-HCV negative		
Blood donor specimens	1007	
Ante-natal patients' specimens	1013	
2. Anti-HCV positive		
Ante-natal patients' specimens	2	
3. Lot release testing panel		
	15	
<u>HPA-MiDAS</u>		
1. Anti-HCV negative		
Screen unreactive blood donor sera (freshly collected)	20	
2. Anti-HCV positive		
Screen reactive and confirmed anti-HCV positive	215	
3. HCV seroconversion panels		
BBi: PHV904	7	
BBi: PHV906	7	
BBi: PHV909	3	
BBi: PHV911	5	
BBi: PHV913	4	
BBi: PHV914	9	
BBi: PHV915	4	
BBi: PHV916	8	
BBi: PHV917	10	
BcP6214	13	
BcP6222	8	
BcP9041	8	
BcP9044	6	
4. Quality control samples		
HPA: HCV-QC1	3x	1
NIBSC HCV Working Standard	3x	1
TOTAL (number of specimens)	2366	
Notes:		
BBi = Boston Biomedica Inc (Seracare Inc);		
BcP = BioClinical Partners Inc (Zeptomatrix)		
HPA = Health Protection Agency		
NIBSC = National Institute for Biological Standards and Control.		

Specificity

One thousand and seven blood donors' specimens were tested in the Architect Anti-HCV assay, lot number 48229HN00, by NTMRL.

One thousand and five of the 1007 samples were nonreactive in the Architect Anti-HCV assay to give a specificity of 99.80% (95% confidence interval 99.3-100%), Table 3.

Two of the blood donors' samples were initially reactive (S/CO 1.12 and 1.15) and were again reactive when repeat tested in duplicate, repeat reactive rate 0.20% (95% confidence interval 0.02-0.71%). The samples gave low S/CO ratios in the Architect Anti-HCV assay; these are shown in Table 4, along with the results of further testing.

NTMRL also tested 1015 ante-natal patients' samples that had not been previously screened by the NBS for HCV antibodies. Specificity on the specimens has therefore not been calculated as their anti-HCV status was unknown. Three of the 1015 specimens were initially reactive and again reactive after retesting by the Architect Anti-HCV assay. Two of the three specimens were confirmed as reactive in two other assays and one was unreactive by the two assays, Table 4.

Table 3: Specificity (blood donors' specimens)

	Number tested	Number initially positive	Specificity (95% confidence interval)	Mean S/CO	Median S/CO	Range S/CO
Anti-HCV negative specimens	1007	2	99.80 (99.3-100%)	0.07	0.05	0.03-1.15

Table 4: S/CO results of five repeatedly reactive samples

Specimen		Architect Anti-HCV		Biorad Monolisa	Innogenetics	Inno-Lia	Ortho
Category	Number	Initial	Repeat	HCV Ag/Ab Ultra	HCV Ab IV	HCV Score	HCV Riba III
Blood donor	D0526	1.12	1.15 / 1.21	0.334 / 0.325	0.175 / 0.166	NT	NT
Blood donor	D0749	1.15	1.17 / 1.30	0.131 / 0.124	0.018 / 0.004	NT	NT
Ante-natal	483	1.79	1.95 / 1.97	0.112 / 0.113	0.846 / 0.861	NT	NT
Ante-natal	9	8.37	9.54 / 9.62	3.813 / 3.726	3.887 / 3.806	Positive	Positive
Ante-natal	295	14.00	14.44 / 14.61	6.390 / 6.546	4.058 / 4.136	Positive	Positive

Twenty-one anti-HCV negative samples were interspersed among the anti-HCV positive samples when tested by the HPA-MiDAS and all were negative in the assay, Table 5.

Table 5: Specificity (HPA-MiDAS results)

	Number tested	Number initially positive	Mean S/CO	Median S/CO	Range S/CO
Anti-HCV negative specimens	21	0	0.08	0.06	0.04-0.25

Sensitivity

215 anti-HCV positive specimens were tested by the Architect Anti-HCV assay, lot number 48229HN00. All 215 specimens were detected by the assay to give a sensitivity of 100% (95% confidence interval 98.3-100%), Table 6.

Table 6: Sensitivity

	Number tested	Number initially reactive	Sensitivity (95% confidence interval)	Mean S/CO	Median S/CO	Range S/CO
Anti-HCV Positive Specimens	215	215	100% (98.3-100%)	13.13	13.63	3.98-16.46

One of the 215 anti-HCV specimens gave a low S/CO values of 3.98 when tested in the Architect Anti-HCV assay. For comparison, the results obtained by HPA-MiDAS in previous evaluations of other anti-HCV assays also show low S/CO values in the majority of cases, Table 7.

Table 7: Results of testing of low positive sample

MiDAS results							Original BBI result
Architect Anti-HCV	Monolisa HCV Ag/Ab	Murex HCV Ag/Ab	Adaltis HCV	Access HCV Ab plus	AxSYM HCV 3.0	Vitros HCV Eci	Ortho HCV 3.0
S/CO	OD/CO	OD/CO	OD/CO	S/CO	S/CO	S/CO	OD/CO
3.98	2.684	1.602	3.12	2.16	5.24	7.64	4.525

Results of testing of NBS Lot Release Panel

Fifteen samples that comprise the NBS Anti-HCV Lot Release Panel were tested at NTMRL. The panel consists of three anti-HCV negative and 12 anti-HCV positive specimens, with a range of reactivities. The status of the specimens was correctly identified by the Architect Anti-HCV assay and with the expected ratios, Table 8.

Table 8: Results for NBS Lot Release Testing Panel

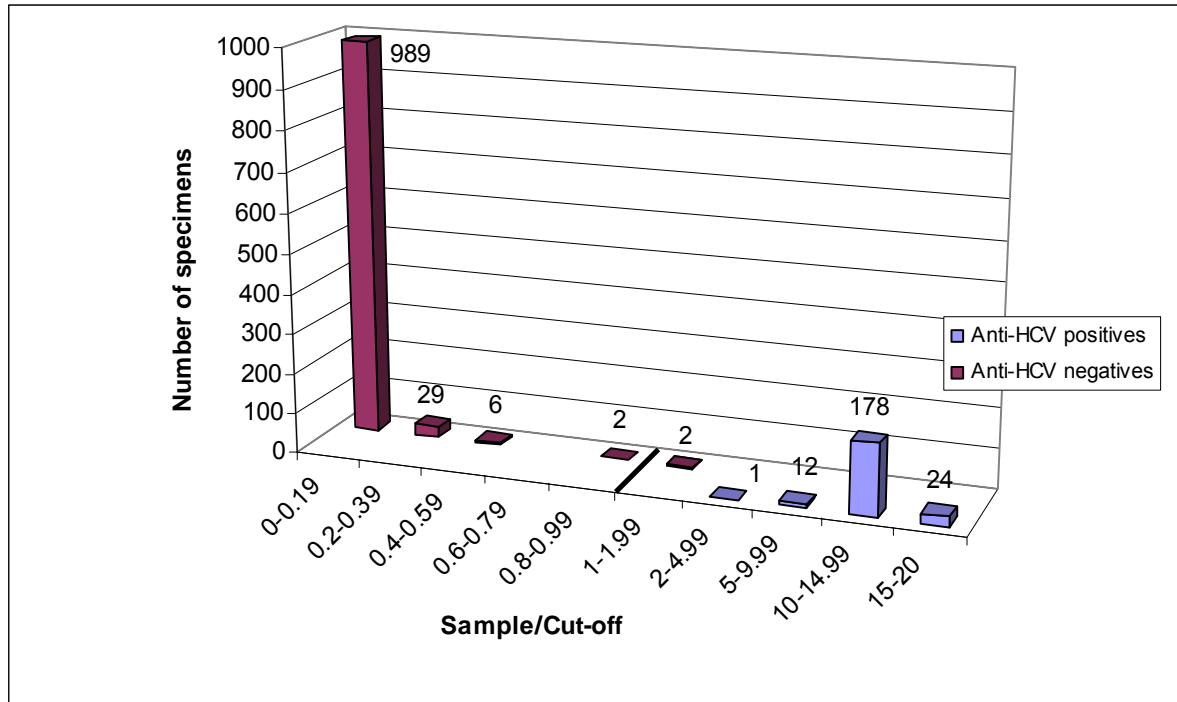
Panel/Ctrl Member	Expected Ratio	Expected Result	Architect Anti-HCV	
			S/CO	Result
1	>1.5	Positive	3.03	Positive
2	>1	Positive	1.52	Positive
3	>1	Positive	1.65	Positive
4	>1	Positive	2.28	Positive
5	>2	Positive	4.70	Positive
6	>1.5	Positive	3.51	Positive
7	<0.2	Negative	0.06	Negative
8	>0.4	Negative	0.98	Negative
9	>1	Positive	2.03	Positive
10	>1	Positive	2.17	Positive
11	>2	Positive	3.87	Positive
12	>3.5	Positive	7.02	Positive
13	<0.2	Negative	0.06	Negative
14	>1	Positive	1.99	Positive
15	>1	Positive	2.03	Positive

Distribution of initial reactivities

The distribution of reactivities for the total of 1028 anti-HCV negative and 217 anti-HCV positive samples is shown in Figure 1. Assays with good discrimination have few or no samples wrongly classified and few reactions close to the cut-off.

For the anti-HCV negative specimens, the Architect Anti-HCV assay gave two initial reactive results which were again reactive on retesting. No false negative results were observed and the majority of the positives gave high reactivities

Figure 1. Distribution of initial reactivities



Note. The sample/cut-off axis is not continuous

Seroconversion sensitivity

Thirteen commercial seroconversion panels were tested. Of the 92 specimens represented by the 13 panels, 46 were detected by the Architect Anti-HCV assay. Complete data for the thirteen panels are available for six other assays, two of which are combined antigen and antibody detection assays. In a comparison with these six assays, the Architect Anti-HCV assay was joint 4th most sensitive overall and joint 2nd most sensitive when compared to the antibody-only detection assays, Table 9 and Appendix Tables 12, 13 and 14.

Table 9: Comparative seroconversion sensitivity based on 13 HCV panels

HCV assay	Product number	Cumulative score *	Rank
		(PHV904-9044) n=92	
Murex HCV Ag/Ab Combination	4J24-01	78	1
Monolisa HCV AgAb ULTRA (cut-off = 1.0)	72558	74	2
Vitros <i>ECi</i> anti-HCV	131 8450	47	3
Architect Anti-HCV	6C37-20	46	4
AxSYM® HCV version 3.0	3B44-20	46	4
Access® HCV Ab PLUS	34330	42	6
Adaltis EIAGEN HCV Ab	071064	39	7

Note: The total for each assay was calculated by summing the correct positive reactions for each of the panels. A higher score suggests higher sensitivity.

Timing of detection

For each panel, the number of days delay in detection of HCV antigen/anti-HCV was compared with one combined HCV antigen and antibody detection assay, four HCV antibody-only detection assays and with PCR.

The median detection time for the Architect Anti-HCV kit was 19 days which would rank the assay as joint fifth, however the assay was joint 2nd most sensitive, with 3 days delay, when compared to HCV antibody-only detection assays, Table 10 and Figure 1a. The median delay is not affected in the same way as the mean delay which can be strongly influenced by outlying results from seroconversion panels for which the interval between the last negative and the first positive specimen is long. This can give rise to an artefact due to the timing of blood collection.

When compared for mean values, the Architect Anti-HCV detected anti-HCV, on average, 22.77 days later than PCR, however the assay detected seroconversion less than one day later than the two most sensitive antibody-only detection assays, mean values 0.69 and 0.39 days respectively, Table 10 and Figure 1b.

Table 10: Delay in detection of seroconversion

Assay	Product code	Delay in detecting seroconversion in each panel compared with the most sensitive assay		
		Range	Median	Mean
PCR	NA	0 - 0	0	0.0
Murex HCV Ag/Ab Combination	4J24-01	0 - 17	0	2.38
Monolisa HCV AgAb ULTRA (cut-off = 1.0)	72558	0 - 25	0	4.15
AxSYM® HCV version 3.0	3B44-20	0 - 72	16	22.08
Vitros ECi anti-HCV	131 8450	0 - 72	19	22.38
Architect Anti-HCV	6C37-20	0 - 72	19	22.77
Access® HCV Ab PLUS	9307401	0 - 72	23	23.62
Adaltis EIAGEN HCV Ab	071064	0 - 72	23	25.23

Notes: The upper limit of the range is, to some extent, influenced by the intervals between bleeds for any individual panel. The mean and median values provide a better general guide to each assay's ability to detect seroconversion. When an assay failed to detect seroconversion in a panel it was given an arbitrary extra 3 days delay for that panel.

Time 0 = earliest detection of HCV infection by any screening assay.

Figure 1a: Timing of detection for HCV assays (median values)

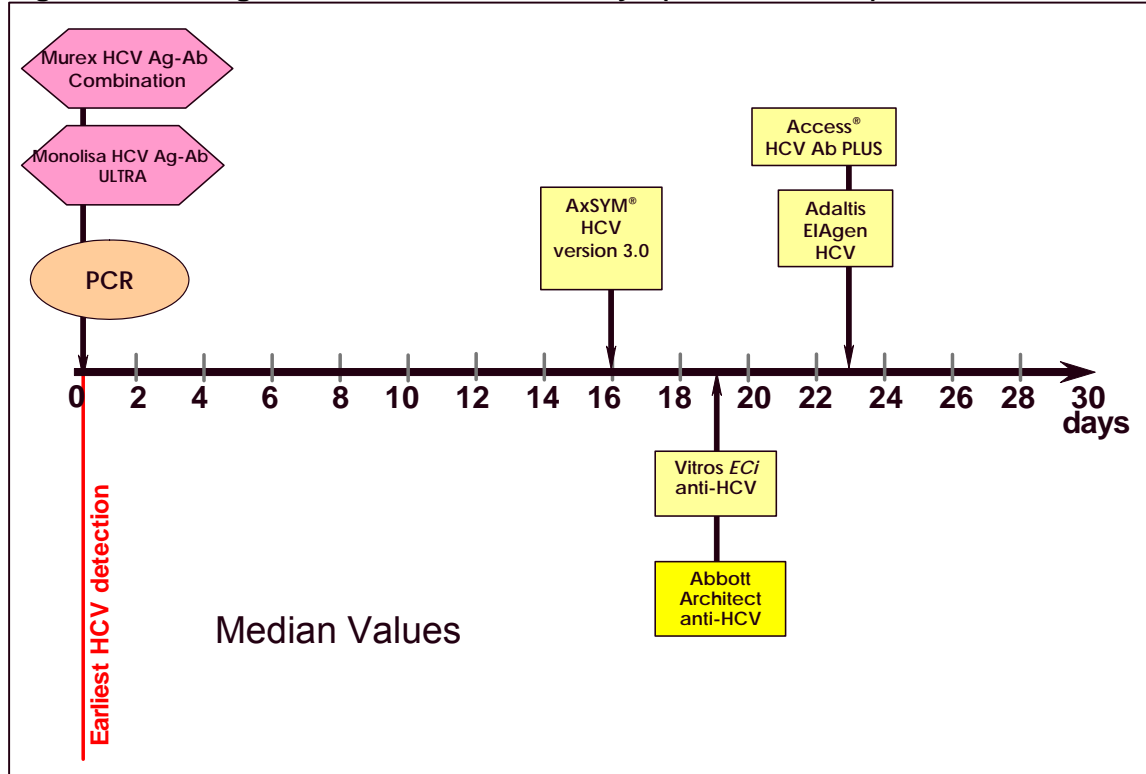
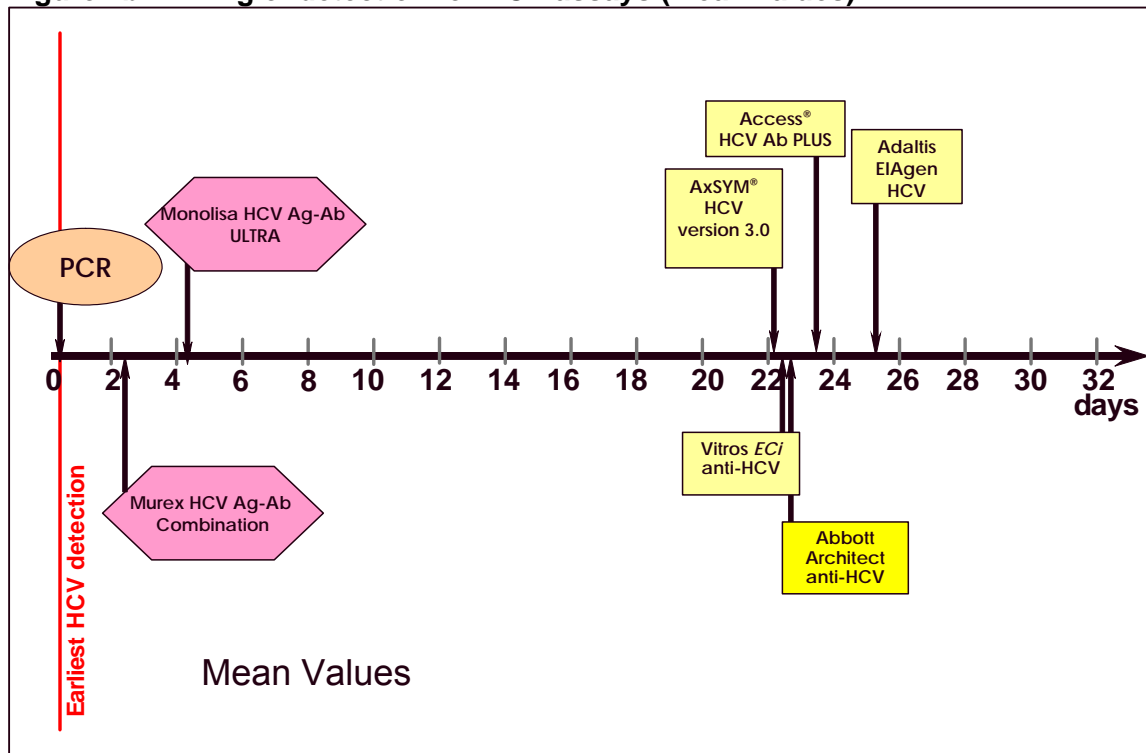


Figure 1b: Timing of detection for HCV assays (mean values)



Lot comparison

A subset of the main evaluation panel was tested in a second lot of the assay (Lot number 50104HN00). Forty anti-HCV positive specimens, 20 negative specimens, six HCV seroconversion panels and two quality control samples were compared, Tables 11a-d and *Appendix Table 14*. The S/CO results obtained from both lots were similar for the positive, negative and quality control samples. For the six seroconversion panels, Lot 1 detected 19 and lot 2 detected 20 of the total of 45 samples.

Table 11a: Comparison of two lots of Architect HCV tested against 40 anti-HCV positive samples

Anti-HCV Positive	Lot 1	Lot 2
	48229HN00	50104HN00
Number tested	40	40
Number reactive	40	40
Mean	12.65	12.80
Range	3.04-16.07	2.79-16.05

Table 11b: Comparison of two lots of Architect HCV tested against 20 anti-HCV negative samples

Anti-HCV negative	Lot 1	Lot 2
	48229HN00	50104HN00
Number tested	20	20
Number initial reactive	0	0
Mean	0.08	0.08
Range	0.04-0.25	0.04-0.23

Table 11c: Comparison of two lots of Architect HCV tested against 6 seroconversion panels

Panel (number of samples)	Number reactive	
	Lot 1	Lot 2
	48229HN00	50104HN00
PHV904 (7)	4	4
PHV911 (5)	3	3
PHV913 (4)	2	2
6214 (13)*	5	6
6222 (8)	1	1
9041 (8)	4	4
Total (45)	19	20

Note. *The results of panel member 6214-8 were close to the cut-off for both lot numbers (0.99 and 1.07).

Table 11d: Comparison of two lots of Architect HCV tested against two quality control samples

Quality control sample	Lot 1. 48229HN00				Lot 2. 50104HN00			
	Test 1	Test 2	Test 3	Mean	Test 1	Test 2	Test 3	Mean
NIBSC working standard	4.17	4.29	4.58	4.35	4.13	3.94	4.24	4.10
HPA QC1	3.73	3.64	3.90	3.76	3.50	3.50	3.37	3.45

A quality control sample/statistical assay control should be chosen to have a reactivity within the linear dynamic range of the assay. Our findings suggest that both controls tested would be suitable for use in the Architect Anti-HCV assay.

Conclusions

The Architect anti-HCV assay had an initial and repeat reactive rate of 0.2%, whereby two of the 1007 anti-HCV blood donors specimens were repeatedly weakly reactive with S/CO values of 1.12 - 1.3.

All 215 anti-HCV positive samples tested were reactive in the assay to give a sensitivity of 100%. The majority of specimens were strongly positive with just one sample giving a S/CO value of less than 5.

Thirteen commercial seroconversion panels were tested. In a comparison with six other assays (two of which were combined antigen-antibody detection assays), the Architect Anti-HCV assay was joint 4th most sensitive overall and joint 2nd most sensitive when compared to the antibody-only detection assays. When assessed for the delay in seroconversion detection, the Architect Anti-HCV assay was joint 4th most sensitive when based on the median value for all seven assays compared but 2nd when compared with antibody-only detection assays.

A small lot comparison was undertaken in which both lots of the Architect HBsAg assay gave very similar S/CO results for positive, negative and quality control samples tested. For the six seroconversion panels, Lot 1 detected 19 and lot 2 detected 20 of the total of 45 samples, however the S/CO values for the discordant sample were both very close to the cut-off (panel number 6214-08, S/CO 0.99 and 1.07).

Appendix

Table 12: Comparative results of seroconversion panels

HCV assay	Product number	The number of positive samples and the number of days from initial bleed to first reactive sample (shown in parentheses)												Score *	
		PHV904	PHV906	PHV909	PHV911	PHV913	PHV914	PHV915	PHV916	PHV917	6214	6222	9041		9044
Genotype		1a	1b	3	1a	2b	2b	2b	2b	2b	1	NK	NK	NK	
Number in panel		n=7	n=7	n=3	n=5	n=4	n=9	n=4	n=8	n=10	n=13	n=8	n=8	n=6	n=92
Murex HCV Ag/Ab Combination	4J24-01	1 (14)	7 (0)	3 (0)***	5 (0)	4 (0)	9 (0)	0 (>14)	8 (0)	9 (13)	13 (0)	6 (17)	7 (24)	6 (0)	78
Monolisa HCV AgAb ULTRA (cut-off = 1.0)	72558	4 (9)	7 (0)	3 (0)	5 (0)	4 (0)	9 (0)	2 (12)	7 (2)	9 (13)	6 (25)	6 (17)	6 (27)	6 (0)	74
Vitros <i>ECi</i> anti-HCV	131 8450	4 (9)	7 (0)	2 (28)	3 (14)	3 (2)	5 (16)	2 (12)	3 (19)	6 (85)	5 (30)	1 (40)	4 (62)	2 (25)	47
Architect Anti-HCV	6C37-20	4 (9)	7 (0)	2 (28)	3 (14)	2 (7)	5 (16)	2 (12)	3 (19)	6 (85)	5 (30)	1 (40)	4 (62)	2 (25)	46
AxSYM® HCV version 3.0	3B44-20	4 (9)	7 (0)	0 (>30)	3 (14)	0 (>9)	5 (16)	3 (5)	4 (16)	6 (85)	6 (25)	1 (40)	4 (62)	3 (21)	46
Adaltis EIAGEN HCV Ab	071064	3 (14)	7 (0)	2 (28)	3 (14)	3 (2)	5 (16)	0 (>14)	2 (23)	6 (85)	3 (49)	0 (>40)	4 (62)	1 (29)	39
Access® HCV Ab PLUS	34330	3 (14)	7 (0)	2 (28)	3 (14)	2 (7)	5 (16)	0 (>14)	2 (23)	6 (85)	5 (30)	1 (40)	4 (62)	2 (25)	42
Ortho HCV 3.0 with Enh SAVE (Short inc.)	9307401	4 (9)	7 (0)	2 (28)	3 (14)	2 (7)	5 (16)	1 (14)	2 (23)	NT	5 (30)	1 (40)	4 (62)	2 (25)	NA
PRISM™ HCV	6A5248	4 (9)	NT	2 (28)*	NT	0 (>9)*	3 (24)*	2 (12)*	NT	NT	5 (30)*	1 (40)	4 (62)*	2 (25)*	NA
Monolisa anti-HCV Plus	72312	4 (9)	7 (0)	2 (28)	3 (14)	2 (7)	4 (19)	1 (14)	2 (23)	NT	4 (32)	1 (40)	4 (62)	2 (25)	NA
Abbott IMx	3A99-20	3 (14)	5 (7)	0 (>30)	2 (21)	0 (>9)	3 (24)	2 (12)	NT	NT	3 (49)	0 (>40)	4 (62)	2 (25)	NA
Abbott anti-HCV 3rd gen EIA	7A16-23	3 (14)	4 (10)	2 (28)	3 (14)	2 (7)	4 (19)	0 (>14)	NT	NT	3 (49)	0 (>40)	4 (62)	1 (29)	NA

Notes:
 NT = not tested. NS = not scored, all panels had not been tested by the assay.
 * PRISM results were extracted from BBI / BCP data sheets
 **The total for each assay was calculated by summing the correct positive reactions for each of the panels. A higher score suggests higher sensitivity.
 The number in parenthesis is the number of days from the initial bleed to the first positive sample
 *** Panels marked began positive but had one or more negative results later on in the panel

Table 13: Architect HCV results of seven seroconversion panels tested by Lot 1, 48229HN00.

Panel	S/CO	Panel	S/CO
PHV906-1	7.58	PHV917-01	0.06
PHV906-2	8.03	PHV917-02	0.06
PHV906-3	8.87	PHV917-03	0.06
PHV906-4	9.26	PHV917-04	0.06
PHV906-5	10.32	PHV917-05	9.85
PHV906-6	10.59	PHV917-06	8.57
PHV906-7	11.17	PHV917-07	8.56
PHV909-1	0.16	PHV917-08	9.08
PHV909-2	1.73	PHV917-09	11.22
PHV909-3	2.29	PHV917-10	10.83
PHV914-01	0.05	9044-01	0.05
PHV914-02	0.05	9044-02	0.04
PHV914-03	0.05	9044-03	0.06
PHV914-04	0.17	9044-04	0.98
PHV914-05	1.84	9044-05	4.74
PHV914-06	3.28	9044-06	6.31
PHV914-07	5.69		
PHV914-08	7.48		
PHV914-09	8.47		
PHV915-01	0.14		
PHV915-02	0.70		
PHV915-03	2.33		
PHV915-04	4.57		
PHV916-01	0.11		
PHV916-02	0.11		
PHV916-03	0.11		
PHV916-04	0.12		
PHV916-05	0.74		
PHV916-06	2.59		
PHV916-07	5.77		
PHV916-08	7.35		

Table 14: Architect HCV results for six seroconversion panels tested by both Lot 1, 48229HN00, and Lot 2, 50104HN00

Panel	S/CO	
	Lot 1 48229	Lot 2 50104
PHV904-01	0.06	0.06
PHV904-02	0.05	0.05
PHV904-03	0.49	0.45
PHV904-04	2.16	1.97
PHV904-05	6.02	5.94
PHV904-06	7.75	7.47
PHV904-07	7.79	7.82
PHV911-01	0.13	0.14
PHV911-02	0.15	0.16
PHV911-03	2.71	2.58
PHV911-04	8.85	9.27
PHV911-05	10.09	9.94
PHV913-01	0.13	0.13
PHV913-02	0.41	0.41
PHV913-03	3.27	3.20
PHV913-04	3.42	3.01
6214-01	0.10	0.10
6214-02	0.09	0.09
6214-03	0.09	0.09
6214-04	0.08	0.08
6214-05	0.08	0.08
6214-06	0.09	0.09
6214-07	0.34	0.29
6214-08	0.99	1.07
6214-09	3.88	3.85
6214-10	5.16	5.26
6214-11	11.77	11.56
6214-12	11.43	11.91
6214-13	11.46	11.33

Panel	S/CO	
	Lot 1 48229	Lot 2 50104
6222-01	0.06	0.06
6222-02	0.06	0.06
6222-03	0.05	0.06
6222-04	0.05	0.06
6222-05	0.05	0.06
6222-06	0.05	0.05
6222-07	0.43	0.41
6222-08	5.31	5.42
9041-01	0.04	0.04
9041-02	0.05	0.04
9041-03	0.04	0.04
9041-04	0.04	0.04
9041-05	10.92	11.12
9041-06	12.12	12.16
9041-07	13.11	13.05
9041-08	13.64	13.55