



# Evaluation of Adaltis EIAgen HCV Ab

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## Background and Description of the Assay

Adaltis EIAGEN HCV Ab is a two-step enzyme immunoassay for the detection of Hepatitis C virus (HCV) infection in human serum and plasma. The microplate wells are coated with HCV specific antigens which capture anti-HCV antibodies in the sample. Upon completion of the assay, the development of colour indicates the presence of HCV, while no colour development suggests the absence of HCV. The assay includes Sample and Reagent Addition Monitoring; thus the addition of samples and reagents can be measured colorimetrically. The assay was evaluated to determine its ability to detect HCV.

The assay carries a CE mark and therefore has undergone testing described in the Common Technical Specification for Annex IIa related products and according to the European Union In-vitro Diagnostic Medical Device Directive. This means that the kit has been already been tested against 400 HCV positive specimens including a range of subtypes, 5300 negative specimens and 30 seroconversion panels. This evaluation builds on the work already done for CE marking by providing comparative performance information on a range of kits with a particular focus on seroconversion timing. The panel is moderately sized, recognising that a large number of specimens have already been tested as part of the CE Marking process.

This report specifically relates to the kit version and lot numbers supplied for this evaluation. We cannot guarantee that these will reflect the performance of other lot numbers or subsequent versions. Laboratories should always validate and monitor assay performance as part of an ongoing quality control program.

Further assay information is shown in Table 1.

**Table 1: Assay Information**

<b>General</b>	
Assay name	EIAGEN HCV Ab Kit
Manufacturer / UK agent	Adaltis Italia S.p.A
Product number	071064 / 071065 / 071067
Number of tests in one pack	192 / 960 / 96
Specimen volume	10µL

<b>Presentation</b>	
Assay type	Two-step Sandwich ELISA
Solid phase	12 x 8 microtitre plate wells
Coating	Core peptide, recombinant NS3, NS4 and NS5 peptides
Conjugate	Horseradish peroxidase conjugated goat polyclonal anti-human IgG and IgM
Substrate	TMB
Controls per plate	6 + a blank well
Negative control	3
Calibrator	2
Positive control	1
Reading wavelength	450 / 630
Cut-off computation	Mean [Neg control] +0.35
Equivocal zone	OD/CO 0.9 - 1.1

<b>Stages</b>	
Preparation / sample well loading	30 minutes
Prewash of reaction plate	n/a
Incubation status	Static
Sample incubation	45 minutes 37°C
Conjugate incubation	45 minutes 37°C
Number of washes	5
Substrate incubation (time/temp)	15 minutes 18-25°C
Reading	5 minutes
Total incubation times	105 minutes
Approximate time to completion	135 minutes
Number of optional procedures	none

<b>Additional equipment required</b>	
Incubator, type not specified (*Dry incubator)	
Microplate spectrophotometer (* EL 808)	
Micropipettes: 40 - 200µL, 200 - 1000µL & 2 - 10mL	
Multichannel pipettes: 50 - 300µL	
Disposable tips	
Reagent troughs and bottles	
Measuring cylinder	
Distilled water	

<b>Notes:</b>	
* Equipment used in this evaluation.	

## Evaluation Panel and Method

The evaluation panel consisted of 608 specimens (Table 2). Of these, 200 specimens were from HCV negative blood donors, 200 from HCV positive subjects, 205 from twenty-six commercial seroconversion panels and three quality control samples. 133 specimens were tested against a second kit lot (Table 3).

The method described in the kit insert was strictly followed. Briefly, 200µL of sample diluent followed by 10µL of specimens or controls and 50µL of assay diluent was added to each of the microplate wells. The wells were incubated at 37°C for 45 minutes then washed five times. 100 µL of conjugate was added to all wells, which were then incubated for 45 minutes at 37°C. The plate was washed five times then 100µL of substrate was added to each of the wells. The microplate was incubated for 15 minutes at room temperature (18 – 24°C). Finally the stop solution was added and the plates were read at 450/630nm.

**Table 2: Evaluation panel (Lot 060604)**

Sample category	Number
<b>1. Anti-HCV negative</b>	200
<b>2. Anti-HCV positive</b>	200
<b>3. HCV seroconversion panels</b>	
BBI: PHV901	11
BBI: PHV904	7
BBI: PHV905	9
BBI: PHV906	7
BBI: PHV907	7
BBI: PHV908	13
BBI: PHV909	3
BBI: PHV910	5
BBI: PHV911	5
BBI: PHV913	4
BBI: PHV914	9
BBI: PHV915	4
BBI: PHV916	8
BBI: PHV917	10
BCP6211	10
BCP6212	9
BCP6213	12
BCP6214	13
BCP6215	4
BCP6216	7
BCP6222	8
BCP6229	8
BCP9041	8
BCP9044	6
BCP9045	8
BCP9047	10
<b>4. Quality control samples</b>	
HPA: HCV-QC1	3x 1
NIBSC HCV BWS	3x 1
NIBSC HCV BWS 1 in 8	3x 1
<b>TOTAL (number of specimens)</b>	<b>608</b>

**Notes:**

BBI = Boston Biomedica Inc; BCP = BioClinical Partners Inc (Zeptometrix)  
 HPA = Health Protection Agency  
 NIBSC = National Institute for Biological Standards and Control.

**Table 3: Batch 2 evaluation panel (Lot: 051002)**

Sample category	Number	
1. Anti-HCV negative	40	
2. Anti-HCV positive	40	
3. HCV seroconversion panels		
BBI: PHV914	13	
BBI: PHV917	8	
BCP6214	10	
BCP9045	9	
BCP9047	10	
4. Quality control samples		
HPA: HCV-QC1	3x	1
NIBSC HCV BWS	3x	1
NIBSC HCV BWS 1 in 8	3x	1
<b>TOTAL (number of specimens)</b>	<b>133</b>	

**Notes:**

BBI = Boston Biomedica Inc; BCP = BioClinical Partners Inc (Zeptometrix)  
 HPA = Health Protection Agency  
 NIBSC = National Institute for Biological Standards and Control.

## Specificity Findings

Of the 200 HCV negative blood donor specimens there were three initially reactive specimens (Figure 2). These specimens were repeated in duplicate and were all negative. A repeat reactive rate of 0% (95% confidence interval, 0 – 1.8%) was therefore observed (Table 4).

Appendix 1 shows a table of false positive rates for 14 previously evaluated HCV screening kits.

**Table 4: Specificity of Adaltis EIAgen HCV Ab**

HCV negative blood donors	Number tested	Number reactive		Range OD/CO	Mean OD/CO	Median OD/CO	Specificity
Stored < 6 mths	200	Initial	3	0.02 - 1.328	0.204	0.133	98.5%
		Repeat	0	0.02 - 0.945	0.195	0.133	100%

## Sensitivity Findings (routine positives)

All of the 200 randomly selected HCV positive specimens were detected by the assay. A sensitivity of 100% (95% confidence interval, 98.2 – 100%) was therefore observed (Table 5, Figure 1). The majority (95%) of specimens tested had OC/CO values of >7.0, a small proportion showed weak reactivity (OD/CO <5.0) in this assay. Further details of these five specimens can be seen in Appendix 3.

Appendix 2 shows a table of sensitivities for 14 previously evaluated HCV screening kits.

**Table 5: Sensitivity of Adaltis EIAgen HCV Ab**

	Number tested	Number initially negative	Number repeatedly negative	Range OD/CO	Mean OD/CO	Median OD/CO
<b>Anti -HCV Positive Specimens</b>	200	0	0	1.69 - 10.16	9.41	9.71

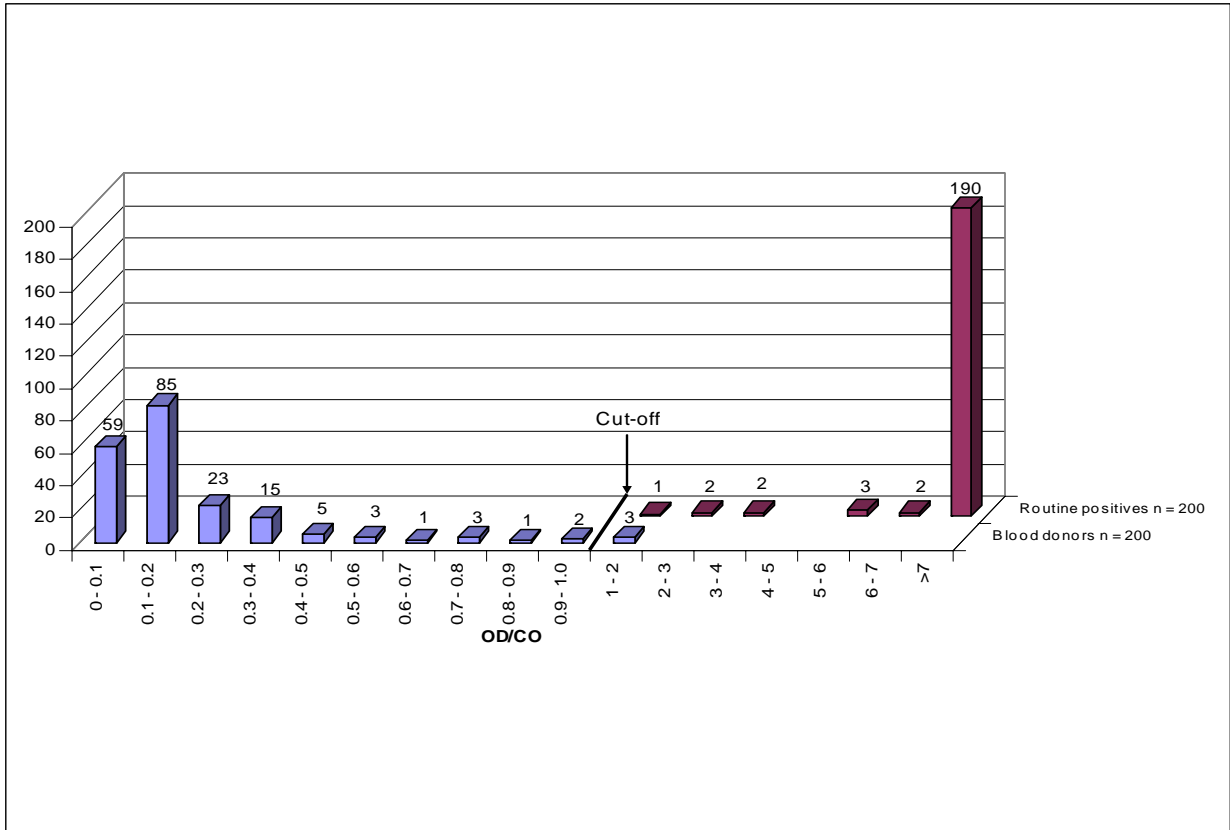


Figure 1: Distribution of initial reactivities

### Seroconversion Sensitivity: Aggregate scores

The ability of the Adaltis EIAGEN HCV Ab assay to detect early antibody in 19 seroconversion panels was compared with previous evaluation results for eight other antibody-only HCV kits and one HCV Ag/Ab kits. Adaltis EIAGEN HCV Ab found 53 out of 164 specimens to be reactive and was ranked 9th out of the eleven HCV kits making it the second most sensitive manual antibody-only assay (Table 6, Appendix 4).

It was also possible to compare results of 25 panels with four more HCV EIAs. In this case Adaltis EIAGEN HCV Ab found 75 out of 197 specimens to be reactive and was ranked 5th out of the five HCV kits (Table 7, Appendix 5).

**Table 6: Combined Seroconversion Scores (19 panels)**

Kit Name	Product Number	Lot Number	Aggregate score* (19 panels, n = 164 )
PCR	NA	NA	130
Monolisa HCV AgAb ULTRA (cut-off = 1.0)	72558	5B1513	108
Vitros <i>ECi</i> anti-HCV	131 8450	0100	72
AxSYM HCV version 3.0	3B44-20	65113LU00	70
Ortho HCV 3.0 with Enh SAVe (Short inc.)	9307401	GECV028	66
Access HCV Ab PLUS	34330	194822	64
PRISM HCV	6A5248	10143 HP00	63
Monolisa anti-HCV Plus	72312	6C501.U	55
<b>Adaltis EIAGEN HCV Ab</b>	<b>071064</b>	<b>060604</b>	<b>53</b>
IMx	3A99-20	12220 HP00	47
Abbott anti-HCV 3rd gen EIA	7A16-23	12027 HP00	47

Notes:  
\*The score was calculated by summing the correct positive reactions for each of the panels. A higher score suggests higher sensitivity.

**Table 7: Combined seroconversion scores (25 panels)**

Kit Name	Product Number	Lot Number	Aggregate score* (25 panels, n = 197 )
PCR	NA	NA	181
Monolisa HCV AgAb ULTRA (cut-off = 1.0)	72558	5B1513	152
Vitros <i>ECi</i> anti-HCV	131 8450	0100	99
AxSYM® HCV version 3.0	3B44-20	65113LU00	98
Access® HCV Ab PLUS	34330	194822	85
<b>Adaltis EIAGEN HCV Ab</b>	<b>071064</b>	<b>060604</b>	<b>75</b>

Notes:  
\*The score was calculated by summing the correct positive reactions for each of the panels. A higher score suggests higher sensitivity.

## Seroconversion Sensitivity: Comparative timing of detection

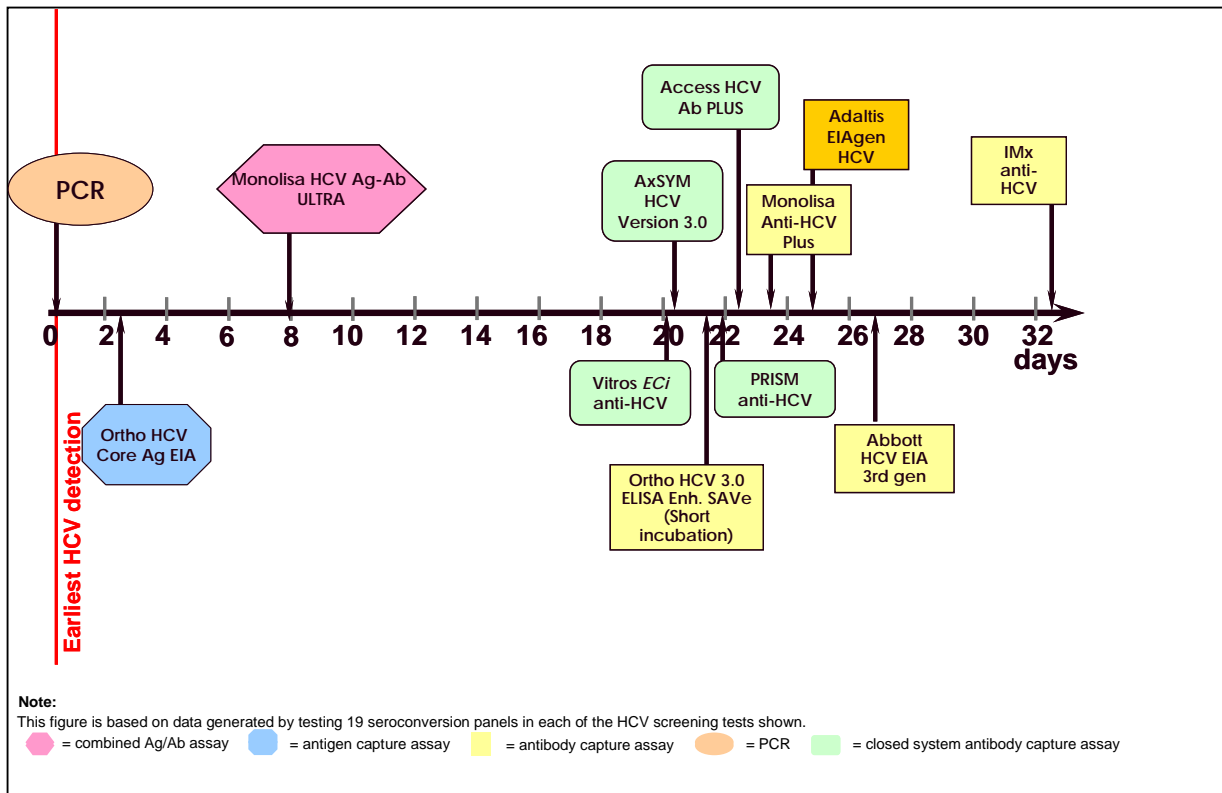
Using a method that assigns the most sensitive test “time zero” and any test less sensitive a positive value we found that Adaltis EIAGEN HCV Ab detected HCV infection on average 4.7 days later than the most sensitive antibody-only HCV kit (Vitros ECi anti-HCV) and less than a day later than a manually performed antibody-only HCV kit (Monolisa anti-HCV plus EIA). The kit detected infection 24.3 days later than the most sensitive method, PCR and 16.8 days later than the most sensitive combined antigen/antibody kit (Table 8, Figure 2).

The median detection time for Murex HCV Ag/Ab Combination was 0 days which was 20 days earlier than any other antibody-only HCV kit. 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.

**Table 8: 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)
PCR	N/A	PCR	0 - 9	0.5	0
Ortho HCV Ag EIA**	933255	Ag-only	0 - 23	2.5	0
Monolisa HCV Ag-Ab (1.0 threshold)	72558	Ag-Ab	0 - 35	8.0	0
Vitros <i>ECi</i> anti-HCV	1318450	Ab-only	0 - 38	20.1	20
AxSYM HCV version 3.0	3B44-20	Ab-only	0 - 38	20.2	20
Ortho HCV 3.0 ELISA Enhanced SAVE (short procedure)	9307401	Ab-only	0 - 41	21.3	20
PRISM anti-HCV	6A52-48	Ab-only	0 - 41	22.0	23
Access HCV Ab PLUS	34330	Ab-only	0 - 41	22.2	23
Monolisa anti-HCV Plus EIA	72312	Ab-only	3 - 41	23.7	25
<b>Adaltis EIAGEN HCV Ab</b>	<b>071064</b>	<b>Ab-only</b>	<b>0 - 49</b>	<b>24.8</b>	<b>26</b>
Abbott HCV EIA 3rd generation	7A16-23	Ab-only	0 - 53	26.7	28
IMx HCV	3A99-20	Ab-only	3 - 164	32.7	26

**Notes:**  
 The upper limit of the range and the mean are, to some extent, influenced by the intervals between bleeds. When any assay failed to detect seroconversion by the last sample available in a panel, an arbitrary extra  
 \*\* It should be noted that a number of panels tested on Ortho HCV EIA began positive but then became negative. This is not taken into account when calculating the time taken to detect the first positive.



**Figure 2: Mean Delay of HCV Detection.** Adaltis EIAGEN HCV Ab detected HCV infection on average 24.8 days later than PCR. There is a possibility that if earlier samples were available for some seroconversion panels PCR may detect infection earlier (this will also apply to Ag-Ab ELISAs).

### Batch Comparison

Two batches of Adaltis EIAGEN HCV Ab were tested to examine variation. The comparison showed that there was no difference in the number of reactive specimens detected by the two batches.

**Table 9: Batch Comparison**

Specimen Category	Number of specimens	Number of reactive specimens	
		Batch Number	
		060604	051002
HCV positive	40	40	40
HCV negative blood donors	40	0	0
PHV914	9	5	5
PHV917	10	6	6
6214	13	3	3
9045	8	0	0
9047	10	3	3
HPA HCV QC1	3	3	3
NIBSC BWS	3	3	3
NIBSC BWS 1 in 5	3	0	0
<b>Total</b>	<b>139</b>	<b>63</b>	<b>63</b>

## Quality Control

Three quality control reagents were each tested in triplicate to identify a suitable control to run throughout the evaluation. Both HPA HCV QC1 and the NIBSC British Working Standard would be suitable to use as internal quality control reagents for this assay. A suitable control is one that has an OD reading that is approximately 2 to 3 times higher than the cut-off. For this evaluation, HPA HCV QC1 was included at the beginning, middle and end of each test plate.

**Table 10: Quality Control Reagents**

QC sample ID	Batch number	Adaltis EIAGEN HCV							
		Batch number: 06064				Batch number: 051002			
		OD/CO 1	OD/CO 2	OD/CO 3	Mean	OD/CO 1	OD/CO 2	OD/CO 3	Mean
HPA HCV QC1	05/B438-01	6.23	3.09	3.73	4.35	3.1664	3.4145	2.8929	3.16
NIBSC Anti-HCV (BWS)	02/238-003-WIL	2.74	2.42	2.32	2.49	1.8806	1.6297	1.9398	1.82
NIBSC Anti-HCV 1 in 8	02/240-003-WIL	0.35	0.36	0.36	0.36	0.3412	0.3863	0.3186	0.35

## Conclusion

Adaltis EIAGEN HCV Ab showed 100% sensitivity and specificity when tested against a small number of routine positive and negative specimens.

The seroconversion sensitivity of the kit was in the same order of sensitivity as other antibody-only HCV kits, and similar to the manually performed Monolisa anti-HCV PLUS EIA. Compared to the most sensitive antibody-only kit (Vitros *Eci* anti-HCV) it had a delay of 4.7 days. As expected, there was a longer delay (approximately 19 days) when compared to newer Ag/Ab EIAs. A comparison of two batches of the kit showed 100% equivalence of performance on 139 specimens tested.

Overall the test was easy to use, had short incubation times and reagents that were clearly labelled. Sample addition monitoring also added to the simplicity of the test.

**Appendix 1: False positive rates for 14 previously evaluated HCV screening kits**

Assay	Product code	Number tested	Number initially reactive (IR)	Initial reactive rates (95% confidence intervals)	Number repeatedly reactive (RR)	Repeat reactive rates (95% confidence intervals)
Monolisa <sup>®</sup> anti-HCV Plus v2 Lot 9M512T	72317/18	1232*	0	0.00% (0 – 0.3%)	0	0.00% (0 – 0.3%)
Monolisa <sup>®</sup> anti-HCV Plus v2 Lot 9M513U	72317/18	1056*	0	0.00% (0 – 0.3%)	0	0.00% (0 – 0.3%)
Access <sup>®</sup> HCV Ab PLUS	34330	373	2	0.54% (0.1 - 1.9%)	0	0.00% (0 - 1.0%)
Ortho <sup>®</sup> HCV 3.0 ELISA enh. SAVe (standard incubation - MiDAS data)	9307401	262	0	0.00% (0 – 1.4%)	0	0.00% (0 – 1.4%)
<b>Adaltis EIAGEN HCV Ab</b>	<b>071064</b>	<b>200</b>	<b>3</b>	<b>1.50%</b> <b>(0.3 - 4.3%)</b>	<b>0</b>	<b>0.00%</b> <b>(0 - 1.8%)</b>
Monolisa HCV Ag-Ab ULTRA	72558	200	0	0.00% (0 - 1.8%)	0	0.00% (0 - 1.8%)
Abbott HCV EIA 3rd generation	7A16-23	199	0	0.00% (0 – 1.8%)	0	0.00% (0 – 1.8%)
Access <sup>®</sup> HCV	34310	181	2	1.10% (0.1 – 3.9%)	0	0.00% (0 – 2.0%)
AxSYM <sup>®</sup> HCV version 3.0	3B44-20	377	3	0.80% (0.2 – 2.3%)	0	0.00% (0 – 1.0%)
Ortho <sup>®</sup> HCV 3.0 ELISA enh. SAVe (short incubation)	9307401	1993*	2	0.10% (0 – 0.4%)	1	0.10% (0 – 0.3%)
PRISM <sup>™</sup> anti-HCV	6A52-48	9743*	20	0.20% (0.1 – 0.3%)	17	0.20% (0.1 – 0.3%)
Monolisa <sup>®</sup> anti-HCV Plus EIA (version 1)	72312	2090*	10	0.48% (0.20 – 0.90%)	6	0.29% (0.10 – 0.60%)
IMx <sup>®</sup> HCV	3A99-20	176	4	2.27% (0.6 – 5.7%)	1	0.57% (0 – 3.1%)
Vitros <i>ECi</i> anti-HCV	1318450	310	2	0.65% (0.08 – 2.31%)	2	0.65% (0.08 – 2.31%)
<b>Note:</b> * = data from blood centre specificity evaluations						

**Appendix 2: Sensitivity for 14 previously evaluated HCV screening assays**

Assay	Product code	Number tested	Number positive (Sensitivity)	95% confidence interval %	Range S/CO	Mean S/CO	Median S/CO
Access <sup>®</sup> HCV Ab PLUS	34330	499	499 (100%)	99.3 - 100	1.09 - 11.32	9.28	9.85
Vitros ECI anti-HCV	1318450	433	433 (100%)	99.2 - 100	4.17 - 38.2	27.07	26.00
AxSYM <sup>®</sup> HCV version 3.0	3B44-20	500	500 (100%)	99.3 - 100	1.92 - 138.32	79.76	86.94
Ortho <sup>®</sup> HCV 3.0 ELISA enhanced SAve (standard incubation)	9307401	215	215 (100%)	98.3 - 100	1.34 - 5.03	4.88	4.99
Ortho <sup>®</sup> HCV 3.0 ELISA enhanced SAve (short incubation)	9307401	215	215 (100%)	98.3 - 100	1.06 - 9.12	8.71	9.09
<b>Adaltis EIAgen HCV Ab</b>	<b>071064</b>	<b>200</b>	<b>200 (100%)</b>	<b>98.2 - 100</b>	<b>1.69 - 10.16</b>	<b>9.41</b>	<b>9.71</b>
Monolisa HCV Ag-Ab ULTRA	72558	200	200 (100%)	98.2 - 100	2.00 - 7.73	6.61	6.88
PRISM <sup>™</sup> anti-HCV	6A52-48	114	114 (100%)	96.8 - 100	1.22 - 6.47	4.59	4.75
IMx <sup>®</sup> HCV	3A99-20	103	103 (100%)	96.5 - 100	1.84 - 54.22	31.15	30.26
Monolisa <sup>®</sup> anti-HCV Plus version 1	72312	101	101 (100%)	96.4 - 100	1.21 - 10.65	8.50	8.73
Monolisa <sup>®</sup> anti-HCV Plus version 2 lot 9M512T	72317/18	40	40 (100%)	91.2 - 100	7.09 - 12.43	9.95	10.01
Monolisa <sup>®</sup> anti-HCV Plus version 2 lot 9M513U	72317/18	40	40 (100%)	91.2 - 100	8.00 - 13.10	11.06	11.35
Abbott HCV EIA 3rd generation	7A16-23	230	228 (99.1%)	96.9 - 99.9	0.19 - 6.49	4.68	4.62
Access <sup>®</sup> HCV	34310	177	175 (98.9%)	96.0 - 99.9	0.32 - 447.73	132.67	129.78

**Appendix 3: Further test results for five weakly reactive specimens in Adaltis EIAgen HCV Ab**

Sample ID	SOURCE	Adaltis EIAgen HCV Ab OD/CO	Murex HCV AgAb Combination OD/CO	Monolisa HCV AgAb ULTRA OD/CO	Vitros Eci anti-HCV S/CO	Access HCV Ab Plus S/CO
00-10314	BBI	1.6852	3.2199	6.0477	13.4	6.49
00-10413	BBI	3.1077	1.8613	5.2959	16.9	4.96
00-10421	BBI	2.3039	6.0745	6.8831	17.3	5.51
00-10488	BBI	2.9776	3.7612	3.7924	Not tested	2.76
00-10495	BBI	3.1202	1.602	2.6837	7.64	2.16

**Appendix 4: Combined seroconversion scores (19 panels)**

Panel	Number of specimens in panel	PCR	Monolisa HCV AgAb ULTRA (cut off = 1.0)	Vitros ECI anti-HCV	AxSYM® HCV version 3.0	Ortho HCV 3.0 with Enh SAVE (Short inc.)	Access® HCV Ab PLUS	PRISM™ HCV	Monolisa anti-HCV Plus	Adaltis EIAGEN HCV Ab	IMx	Abbott anti-HCV 3rd gen EIA
PHV901	11	10 (65)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)
PHV904	7	6 (0)	4 (9)	4 (9)	4 (9)	4 (9)	3 (14)	4 (9)	4 (9)	3 (14)	3 (14)	3 (14)
PHV907	7	7 (0)	7 (0)	4 (13)	3 (18)	3 (18)	4 (13)	2 (21)*	2 (21)	4 (13)	1 (164)	2 (21)
PHV908	13	13 (0)	9 (13)	9 (13)	10 (11)	8 (19)	8 (19)	8 (19)*	7 (25)	7 (25)	3 (41)	5 (32)
PHV909	3	3 (0)	3 (0)	2 (28)	0 (>30)	2 (28)	2 (28)	2 (28)*	2 (28)	2 (28)	0 (>30)	2 (28)
PHV910	5	5 (0)	5 (0)	3 (8)	3 (8)	3 (8)	3 (8)	3 (8)*	2 (11)	3 (8)	2 (11)	3 (8)
PHV913	4	4 (0)	4 (0)	3 (2)	0 (>9)	2 (7)	2 (7)	0 (>9)*	2 (7)	3 (2)	0 (>9)	2 (7)
PHV914	9	9 (0)	9 (0)	5 (16)	5 (16)	5 (16)	5 (16)	3 (24)*	4 (19)	5 (16)	3 (24)	4 (19)
PHV915	4	4 (0)	2 (12)	2 (12)	3 (5)	1 (14)	0 (>14)	2 (12)*	1 (14)	0 (>14)	2 (12)	0 (>14)
6212	9	9 (0)	6 (23)	8 (12)	8 (12)	8 (12)	6 (23)	8 (12)*	4 (32)	3 (37)	8 (12)	2 (53)
6213	12	9 (11)	3 (37)	3 (37)	3 (37)	2 (43)	2 (43)	2 (43)*	2 (43)	2 (43)	2 (43)	2 (43)
6214	13	13 (0)	6 (25)	5 (30)	6 (25)	5 (30)	5 (30)	5 (30)*	4 (32)	3 (49)	3 (49)	3 (49)
6215	4	4 (0)	4 (0)	1 (20)	1 (20)	1 (20)	1 (20)	1 (20)*	1 (20)	0 (>20)	1 (20)	1 (20)
6216	7	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)*	0 (>23)	1 (23)	0 (>23)	1 (23)
6222	8	2 (17)	6 (17)	1 (40)	1 (40)	1 (40)	1 (40)	1 (40)	1 (40)	0 (>40)	0 (>40)	0 (>40)
9041	8	7 (24)	6 (27)	4 (62)	4 (62)	4 (62)	4 (62)	4 (62)*	4 (62)	4 (62)	4 (62)	4 (62)
9044	6	6 (0)	6 (0)	2 (25)	3 (21)	2 (25)	2 (25)	2 (25)*	2 (25)	1 (29)	2 (25)	1 (29)
9045	8	8 (0)	8 (0)***	2 (37)	2 (37)	2 (37)	2 (37)	2 (37)*	1 (41)	0 (>41)	2 (37)	0 (>41)
9047	10	10 (0)	10 (0)	4 (28)	4 (28)	4 (28)	4 (28)	4 (28)*	3 (30)	3 (30)	4 (28)	3 (30)
<b>Total**</b>	<b>164</b>	<b>130</b>	<b>108</b>	<b>72</b>	<b>70</b>	<b>66</b>	<b>64</b>	<b>63</b>	<b>55</b>	<b>53</b>	<b>47</b>	<b>47</b>
PHV905	9	9 (0)	6 (11)	5 (14)	5 (14)	5 (14)	3 (21)	NT	4 (18)	3 (21)	2 (25)	2 (25)
PHV906	7	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	NT	7 (0)	7 (0)	5 (7)	4 (10)
PHV911	5	5 (0)	5 (0)	3 (14)	3 (14)	3 (14)	3 (14)	NT	3 (14)	3 (14)	2 (21)	3 (14)
PHV916	8	8 (0)	7 (2)	3 (19)	4 (16)	2 (23)	2 (23)	NT	2 (23)	2 (23)	NT	NT
PHV917	10	9 (13)	9 (13)	6 (85)	6 (85)	NT	6 (85)	NT	NT	6 (85)	NT	NT
6211	10	13 (140)	10 (150)	3 (182)	3 (182)	3 (182)	2 (186)	NT	2 (186)	1 (189)	0 (>189)	2 (186)
Product Number	NA	NA	72558	131 8450	3B44-20	9307401	34330	6A5248	72312	071064	3A99-20	7A16-23
Lot Number	NA	NA	5B1513	0100	65113LU00	GECV028	194822	10143 HP00	6C501.U	060604	12220 HP00	12027 HP00

**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

**Appendix 5: Combined seroconversion scores (25 panels)**

Panel	Number of specimens in panel	PCR	Monolisa HCV AgAb ULTRA (cut-off = 1.0)	Vitros Eci anti-HCV	AxSYM® HCV version 3.0	Access® HCV Ab PLUS	Adaltis EIAGEN HCV Ab
PHV901	11	10 (65)	9 (97)	9 (97)	9 (97)	9 (97)	9 (97)
PHV904	7	6 (0)	4 (9)	4 (9)	4 (9)	3 (14)	3 (14)
PHV905	9	9 (0)	6 (11)	5 (14)	5 (14)	2 (21)	3 (21)
PHV906	7	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
PHV907	7	7 (0)	7 (0)	4 (13)	3 (18)	4 (13)	4 (13)
PHV908	13	13 (0)	9 (13)	9 (13)	10 (11)	7 (19)	7 (25)
PHV909	3	3 (0)	3 (0)	2 (28)	0 (33)	2 (28)	2 (28)
PHV910	5	5 (0)	5 (0)	3 (8)	3 (8)	3 (8)	3 (8)
PHV911	5	5 (0)	5 (0)	3 (14)	3 (14)	3 (14)	3 (14)
PHV913	4	4 (0)	4 (0)	3 (2)	0 (312)	2 (7)	3 (2)
PHV914	9	9 (0)	9 (0)	5 (16)	5 (16)	5 (16)	5 (16)
PHV915	4	4 (0)	2 (12)	2 (12)	3 (5)	0 (>14)	0 (>14)
PHV916	8	8 (0)	7 (2)	3 (19)	4 (16)	2 (23)	2 (23)
PHV917	10	9 (13)	9 (13)	6 (85)	6 (85)	6 (85)	6 (85)
6211	10	13 (140)	10 (150)	3 (182)	3 (182)	2 (186)	1 (189)
6212	9	9 (0)	6 (23)	8 (12)	8 (12)	6 (23)	3 (37)
6213	12	9 (11)	3 (37)	3 (37)	3 (37)	2 (43)	2 (43)
6214	13	13 (0)	6 (25)	5 (30)	6 (25)	5 (30)	3 (49)
6215	4	4 (0)	4 (0)	1 (20)	1 (20)	1 (20)	0 (>20)
6216	7	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)
6222	8	2 (17)	6 (17)	1 (40)	1 (40)	1 (40)	0 (>40)
9041	8	7 (24)	6 (27)	4 (62)	4 (62)	4 (62)	4 (62)
9044	6	6 (0)	6 (0)	2 (25)	3 (21)	2 (25)	1 (29)
9045	8	8 (0)	8 (0)**	2 (37)	2 (37)	2 (37)	0 (>41)
9047	10	10 (0)	10 (0)	4 (28)	4 (28)	4 (28)	3 (30)
<b>Score*</b>	<b>197</b>	<b>181</b>	<b>152</b>	<b>99</b>	<b>98</b>	<b>85</b>	<b>75</b>
<b>Product Number</b>	<b>NA</b>	<b>NA</b>	<b>72558</b>	<b>131 8450</b>	<b>3B44-20</b>	<b>34330</b>	<b>071064</b>
<b>Lot Number</b>	<b>NA</b>	<b>NA</b>	<b>5B1513</b>	<b>0100</b>	<b>65113LU00</b>	<b>194822</b>	<b>060604</b>

Notes:

\*The score 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



November 28<sup>th</sup> 2006

Dr. Keith Perry  
Microbiological Diagnostics Assessment Service  
61, Colindale Avenue  
London NW9 5HT

**Re: Report, Evaluation of Adaltis EIAGEN HCV Ab**

Dear Dr. Perry,

First and foremost, we would like to thank you for giving us the opportunity to comment on this report. We would also like to mark our appreciation to Ms. Dean for the quality of her work and her availability throughout this evaluation.

We are pleased with the results that you obtained, particularly for the 100% sensitivity and specificity obtained with the 2 groups of 200 specimens. The excellent accuracy you observed and the 100% equivalence also observed between the two batches tested confirm our internal results and our other external evaluations. Finally, your conclusion about the user-friendliness and the suitability of our kit is also well appreciated.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Michel Houde".

**Michel Houde Ph.D.**

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