CE
0344

Anti-HCV Elisa

4.0

KAPG4NAE3

DIAsource ImmunoAssays S.A. - Rue de l'Industrie, 8 - B-1400 Nivelles - Belgium

LOT : 110330/1

Anti-HCV Elisa V 4.0.

CE 0344

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For in-vitro qualitative detection of Antibody to Hepatitis C virus (anti-HCV) in human serum or plasma

KAPG4NAE3

IN VITRO DIAGNOSTIC USE

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1) INTENDED USE

Anti-HCV Elisa V 4.0 is a forth generation enzyme immunoassay diagnostic kit for in-vitro qualitative detection of Antibody to Hepatitis C virus (anti-HCV) in human serum or plasma.

2) DESIGN THEORY/ BRIEF DESCRIPTION OF THE PRODUCT

Anti-HCV Elisa V 4.0 adopts the "direct sandwich principle" as the basis for the assay to detect antibodies to Hepatitis C virus (anti-HCV). It is a forth generation enzyme immunoassay kit, which uses recombinant HCV antigens (Core, NS3 and NS5 antigens) for the detection of Antibody to Hepatitis C virus (anti-HCV) in human serum or plasma.[*1-3] These antigens, which are reactive with the predominant antibodies of HCV, constitute the solid phase antigenic absorbent. When human serum or plasma is added to the well, the HCV antigens and Anti-HCV will form complexes on the wells if Anti-HCV is present in the specimen. The wells are washed to remove the unbound materials. The diluted HCV Ag•HRPO Conjugate is added to the well and results in the formation of (HCV) • (Anti-HCV) • (HCV Ag•HRPO) complex. After washing out the unbound conjugate, TMB substrate solution is added for color development. The intensity of color development is proportional to the amount of antibodies present in the specimen. The reaction processes are summarized as follows:

A. Specimen (containing Anti-HCV):

1. Plate (HCV Antigens) + Specimen (containing Anti-HCV) → plate (HCV Antigen)•Anti-HCV
2. Wash to remove the unbound materials.
3. Plate (HCV Antigen) •Anti-HCV + HCV Ag•HRPO → Plate (HCV Antigen)•Anti-HCV•HCV Ag•HRPO complex
4. Wash to remove the unbound materials.
5. Plate (HCV Antigen) •Anti-HCV•HCV Ag•HRPO complex + TMB Solution → light blue to blue color
6. Light blue to blue color + Stop Solution → light yellow to yellow color, measured at 450nm with a selected reference wavelength within 620 to 690nm[*4]

B. Specimen (without human Anti-HCV):

1. Plate (HCV Antigens) + Specimen (without Anti-HCV) → plate (HCV Antigen)
2. Wash to remove the unbound materials.
3. Plate (HCV Antigen) + HCV Ag•HRPO → plate (HCV Antigen)------ No complex will form
4. Wash to remove the unbound materials.
5. Plate (HCV Antigen) + TMB Solution (colorless) → colorless
6. colorless + Stop Solution → colorless, measured at 450nm with a selected reference wavelength within 620 to 690nm[*4]

3) DESCRIPTION OF PROVIDED MATERIALS & PRODUCT CODE SYSTEM

- **Item 1 - 7 on the following reagent table should be refrigerated at +2 to +8°C. Washing Solution D (20X) and Stop Solution can be stored at +2 to +30°C.**

ITEMS	Components	Description	Qt. per 96 tests
(1)	HCV Antigens Plate	Microtiter plate coated with HCV antigens.	1 plate
(2)	Ag | HRP | CONC Conc. HCV Ag•HRPO Conjugate	Contained HCV Ag•Peroxidase (Horseradish) in buffer with Bovine serum. Preservatives: 0.005 % Sodium azide and 0.05 % Enzyme stabilizer.	1bottle, 1.8 ml
(3)	CONTROL | H Anti-HCV Positive Control	Inactivated human plasma positive for Anti-HCV. Preservative: 0.099 % Sodium azide.	1 bottle, 2.0 ml
(4)	CONTROL | L Hepatitis C Negative Control	Normal human plasma non-reactive for Antibody to HCV. Preservative: 0.099 % Sodium azide.	1 bottle, 3.0 ml

(5)	CONJ | BUF Conjugate Diluent	PB-buffer with Bovine serum and Tween-20. Preservatives: 0.005 % Sodium azide and 0.05 % Enzyme stabilizer	1bottle, 24 ml
(6)	CHROM | TMB | CONC Chromogenic TMB concentrate	3, 3', 5, 5'-tetramethylbenzidine (TMB) in an organic base.	1 bottle, 12 ml
(7)	SUB | BUF Substrate Buffer	Citric acid buffer with Urea Hydrogen Peroxidase	1 bottle, 12 ml
(8)	WASH | SOLN | CONC Conc. Washing Solution D (20X)	Phosphate buffer with Tween-20.	1 bottle 110 ml
(9)	STOP | SOLN Stop Solution	Stop Solution	1 bottle 12 ml

● **OTHER MATERIALS REQUIRED, BUT NOT PROVIDED**

ITEMS	Components
(1)	50µl, 100µl and 200µl, 1-ml micropipettes and tips are needed.
(2)	Water-bath at 37 +/- 1° or incubator at 37 +/- 1°.
(3)	Tubes for specimen dilution.
(4)	Plate washing equipment.
(5)	ELISA Microwell Reader: Dual wavelength 450nm with 620-690nm as reference wavelength[*4], bandwidth 10nm.
(6)	Purified water: distilled or deionized water.
(7)	Fully automatic EIA micro-plate analyzer is optional. User should validate the automatic EIA micro-plate analyzer in combination with the kit.
(8)	Adhesive slip

4) INSTRUCTIONS FOR USE

4.1) Warnings

4.1.1) This reagent kit is for professional use only.
4.1.2) This reagent kit is for *in vitro* diagnosis only.
4.1.3) Bring all kit reagents and samples to room temperature (+20 to +30°C) and mix carefully before use.
4.1.4) Do not use reagent past its expiration date.
4.1.5) Do not interchange reagents between different lots.
4.1.6) Do not put pipette in mouth.
4.1.7) Do not smoke or eat in areas where specimens or reagents are handled.
4.1.8) All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols.
4.1.9) Potential infectious specimens and non-acid containing spills or leakages should be wiped up thoroughly with 5% sodium hypochlorite or treated in accordance with your practice for potential bio-hazard control.
4.1.10) Prior to dispose the waste of used specimens and kit reagents as general waste; it should be treated in accordance with your treatment practice of potential bio-hazardous waste or treated as follows:
Both liquid and solid waste should be autoclaved at 121°C for at least 30 minutes.
Solid waste can also be incinerated.
Non-acidic liquid waste can be treated with sodium hypochlorite diluted to a final concentration of 1%.
Acidic liquid wastes must be neutralized before treatment with sodium hypochlorite as mentioned above and should stand for 30 minutes to obtain effective disinfection.
4.1.11) Stop Solution is an irritant to skin, eyes, respiratory tract and mucous membranes. Avoid contact of the Stop Solution with skin and mucous membranes. In case of contact, flush immediately with abundant amounts of water.
In case of inhalation, find fresh air immediately and seek medical advice in case of pain.
4.1.12) Chromogenic TMB concentrate contains organic solvent, which is flammable. Chromogenic TMB concentrate contains dimethyl sulfoxide, an irritant to skin and mucous membranes.
4.1.13) Although all human sourced material are tested free from HBsAg and Anti-HIV and inactivated at 56°C for one hour, the reagent should still be handled as potential infectious material. *[5]

4.2) Specimen Collection and Storage

4.2.1) Either serum or plasma can be used with this diagnostic kit. Whole blood specimens should be separated as soon as possible in order to avoid hemolysis. Any particulates (e.g. fibrin clots, erythrocytes) contained in the specimen should be removed prior to use.
4.2.2) Specimens must be stored at +2 to +8°C and avoided heat-inactivation to minimize deterioration. For long-term storage, they should be frozen below -20°C. Storage in self-defrosting freezer is not recommended.
4.2.3) Frozen specimens must be thoroughly thawed and mixed homogenously before test.
4.2.4) Avoid multiple freeze-thaw procedures.
4.2.5) Incompletely coagulated sera and microbial-contaminated specimens should not be used.

4.3) Reagents Storage

4.3.1) The kit must be stored at +2 to +8°C. Do not freeze.
4.3.2) Strips of the plate should be used within one month once the original aluminum foil bag is opened. The unused strips should be kept in the aluminum foil bag and taped the opening tightly.
4.3.3) Return reagents to +2 to +8°C immediately after use.
4.3.4) Washing Solution D (20X) Concentrate can be stored at room temperature to avoid crystallization, because the kits are stored and shipped at +2 to +8°C. If the crystal has been precipitated before use, warm up the solution in 37°C water bath till crystal dissolved.

4.4) Plate Washing Procedure

4.4.1) Preparation of washing solution:
Dilute Washing Solution D (20X) Concentrate with distilled or de-ionized water to 1:20 dilution. Do not use tap water.
4.4.2) Plate washing:
(a) For plate washer with overflow aspirating function: 6 cycles with at least 0.5ml washing buffer per well per cycle.
Or
(b) For plate washer without overflow aspirating function: 8 cycles with at least 0.35ml washing buffer per well per cycle.
4.4.3) Blot dry by inverting the plate and tapping firmly onto absorbent paper. Too much residual wash buffer will cause false results.
WARNING
Improper washing will cause false results.

4.5) Test Procedure

4.5.1) Bring all reagents and specimens to room temperature (+20 to 30°C) before assay. Adjust water bath or incubator to 37 ± 1 °C.
4.5.2) Preparation **of Diluted Conjugate**
1. Use only clean container to avoid contamination.
2. Prepare diluted conjugate by making 1:20 dilution of Conc. HCV Ag•HRPO conjugate with conjugate diluent, or following Conjugate Preparation Chart below. Swirl gently to mix thoroughly and avoid foaming.
3. Excess diluted conjugate solution should be discarded after use.

Conjugate Preparation Chart:

Number of Wells used	Volume of Conjugate Diluent needed (ml)	Volume of Conc. HCV Ag• HRPO conjugate needed (µl)
8	1	50
16	2	100
24	3	150
32	4	200
40	5	250
48	6	300
56	7	350
64	8	400
72 - 80	9	450
81 - 96	10	500

4.5.3) Reserve one well for blank.
Do not add any specimen or specimen diluent into the well for blank.
4.5.4) Prepare the needed number of wells, including 1 well for Blank, 3 wells for Negative Control, 2 wells for Positive Control, and 1 well for each Specimen.
4.5.5) Sample input:
4.5.5.1) Add 100µl of Positive Control, Negative Control and specimen to each appropriate well of HCV Antigens Plate.
4.5.5.2) Mix well by tapping the plate gently.
NOTE: Use a new pipette tip after each sampling to avoid cross-contamination.

4.5.6) Seal the Plate with an Adhesive Slip.
4.5.7) Incubate the plate in a 37 ± 1 °C water bath or circulative incubator for 60 minutes.
NOTE: Do not stack plates.
4.5.8) At the end of the incubation period, remove carefully the adhesive slip and discard.
4.5.9) Wash the plate according to section §4.4. Plate Washing Procedure.
4.5.10) Add 100µl of the Diluted Conjugate in each well, except the blank.
4.5.11) Seal the plate with an Adhesive Slip.
4.5.12) Incubate the Plate in a 37 ± 1 °C water bath or circulative incubator for 30 minutes.
4.5.13) Repeat step 4.5.8) and 4.5.9)
4.5.14) Select one of the following methods for color development:
A. Mix equal volumes of Chromogenic TMB concentrate and Substrate Buffer in a clean container immediately prior to use. Add 100µl of the mixture solution to each well including the blank.
B. Add 50µl of Chromogenic TMB concentrate first, and then add 50µl of Substrate Buffer into each well including the blank. Carefully mix well.
NOTE: Chromogenic TMB concentrate should be colorless to light blue; otherwise, it should be discarded. The mixture of Chromogenic TMB concentrate and Substrate Buffer should be used within 30 minutes after mix. The mixture should be avoided from intense light.
4.5.15) Seal the plate with an Adhesive Slip and incubate at 37 ± 1°C for 15 minutes.
4.5.16) Stop the reaction by adding 100µl of Stop Solution to each well including the blank.
4.5.17) Determine the absorbance of Controls and test specimens within 15 minutes, measured at 450nm with a selected reference wavelength within 620 to 690nm[*4].
Use the blank well to blank the spectrophotometer.
NOTE: The color of the blank should be colorless to light yellowish; otherwise, the test results are invalid. Substrate blank : absorbance value must be less than 0.100 OD.

4.6) Calculation of Tested Data

4.6.1) Calculation of the NCx (Mean Absorbance of Negative Control).
Example:

Sample No.	Absorbance
1	0.045
2	0.060
3	0.051

NCx = (0.045+0.060+0.051) / 3 = 0.052

NCx must be ≤ 0.200, otherwise the test is invalid.

4.6.2) Calculation of PCx (Mean Absorbance of Positive Control)
Example:

Sample No.	Absorbance
1	1.510
2	1.826

PCx = (1.510 + 1.826) /2 = 1.668

PCx must be ≥ 0.600, otherwise the test is invalid.

4.6.3) Calculation of **P-N Value**
P-N = PCx **-** NCx
Example:
P - N = 1.668 – 0.051 = 1.617
P - N Value must be ≥ 0.400, otherwise the test is invalid.

4.6.4) Calculation of the **Cutoff Value**
Cutoff Value = NCx + 0.100
Example:
Cutoff Value = 0.053+0.100 = 0.153

4.6.5) Calculate the cut-off index of the specimens
Cutoff Index
=Sample OD Value / Cutoff Value
Example:
Sample Value is 0.596
Cutoff Index = 0.596/0.153 = 3.895
4.6.6) Gray Zone: Cut-off index = 1.000 ~ 1.500

4.7) Quality Control of the Test Run

4.7.1) **NCx must be ≤ 0.100, otherwise the test is invalid.**

4.7.2) **PCx must be ≥ 0.600, otherwise the test is invalid.**

4.7.3) **P-N Value must be ≥ 0.500, otherwise the test is invalid.**
NOTE: Negative Control: absorbance value must be less than or equal to 0.200 after subtracting the blank.

4.8) Result Interpretation

4.8.1) Specimens with **CUTOFF INDEX < 1.000** are considered **NON-REACTIVE** by the criteria of DIAsource's Anti-HCV Elisa V 4.0.

4.8.2) Specimens with **CUTOFF INDEX ≥ 1.000** are considered as initially **REACTIVE**. They should be **RETESTED** in duplicate.
If both **CUTOFF INDEXES** of the duplicate are **GREATER** than 1.500, the specimen is considered to be repeatedly **REACTIVE** for Anti-HCV by the criteria of DIAsource ImmunoAssays SA's Anti-HCV Elisa V 4.0.
Specimens repeatedly reactive in the Anti-HCV Elisa V 4.0 should be further tested by additional, more specific tests.

4.8.3) Initially reactive specimens, of which both **CUTOFF INDEXES** of the duplicate retest are **LESS** than **1.000**, will be considered **NON-REACTIVE** for Anti-HCV.

4.8.4) If one of the two **CUTOFF INDEXES** of the duplicate is **GREATER** than **1.000** but **LESS** than **1.500**, the specimen may be interpreted as **QUESTIONABLE** and this individual should be monitored in follow up samples, or additional more specific tests should be used.

4.8.5) If one of the **CUTOFF INDEX** of the duplicate is **GREATER** than **1.500** and the other one is **LESS** than **1.000**, this indicates unusual experimental **error**. The test should be repeated again.

4.9) Troubleshooting

If the result cannot be reproduced, please do your own preliminary troubleshooting by checking the possibilities listed below:
4.9.1) Improper washing procedure.
4.9.2) Contaminated with positive specimen.
4.9.3) Add wrong volume of sample, conjugate or substrates.
4.9.4) The well rim is contaminated with conjugate.
4.9.5) Improper specimen such as hemolyzed serum or plasma, specimen containing precipitate and specimen not being mixed well before use.
4.9.6) Wrong incubation time or temperature.
4.9.7) Obstructed or partial obstructed washer aspirate/dispense head and needles.
4.9.8) Insufficient aspiration.

4.10) Limitations and Interferences

4.10.1) This reagent kit is to be used for un-pooled human serum or plasma only.
4.10.2) The reagent kit has not been validated for use with cadaveric samples.
4.10.3) Specimens with very low level of Anti-HCV may not consistently repeat positive. In this case, it is recommended to test follow-up samples.
4.10.4) Anti-HCV negative result does not preclude the possibility of infection with HCV.
4.10.5) Non-repeatable false positive results may occur due to non-specific binding of the sample and conjugate to the wall of the well(s).
4.10.6) Potential Interfering Substances: there is no significant influence on Anti-HCV Elisa V 4.0.

4.11) Storage Conditions and Stability

Kit/components	Storage condition	State	Stability
Anti-HCV Elisa V 4.0 KIT	+2 to +8°C	Original	18 months
		Once open	1 month
Anti-HCV Positive Control	+2 to +8°C	Original	18 months
		Once open	1 month
Hepatis C Negative Control	+2 to +8°C	Original	18 months
		Once open	1 month
HCV Antigens Plate	+2 to +8°C	Original	18 months
		Once open	1 month
Conc. HCV Antigen•HRPO Conjugate Solution	+2 to +8°C	Original	18 months
		Once open	1 month
		Once open	1 month
Conc. HCV Antigen•HRPO Conjugate Solution	Room temp.	Diluted	6 hours
	+2 to +8°C	Diluted	2 days
Conjugate Diluent	+2 to +8°C	Original	18 months

		Once open	1 month
Washing Solution D Concentrate (20X)	Room temp.	Original	24 months
		Once open	1 month
20X Diluted Washing Solution	Room temp.	Diluted	2 days
	+2 to +8°C	Diluted	1 week
Chromogenic TMB concentrate	+2 to +8°C	Original	24 months
		Once open	1 month
Substrate Buffer	+2 to +8°C	Original	24 months
		Once open	1 month
TMB Substrate Solution Mixture	Room temp.	Mixture	6 hours
Stop Solution	Room temp.	Original	24 months
		Once open	1 month

4.12) Performance Characteristics

4.12.1) Analytical Specificity

Potential Interfering Substances: There is no significant influence on Anti-HCV Elisa V 4.0.

Potential Interfering Substances	n tests	n reactive	n non-reactive
Serum with interfering substances in fixed ratios (Triglycerides, hemoglobin, bilirubin, monoclonal IgG and IgM, and rheumatoid factor)	50 tests	0	50
Inhibition panels (EDTA, hemoglobin, triglyceride, bilirubin, and heparin)	14 negative samples 14 positive samples	0 14	14 0
Anticoagulant Panels (Serum, EDTA plasma, heparinized plasma, and citrated plasma)	25 negative samples 25 positive samples	0 25	25 0
Total	128 tested samples	39	89

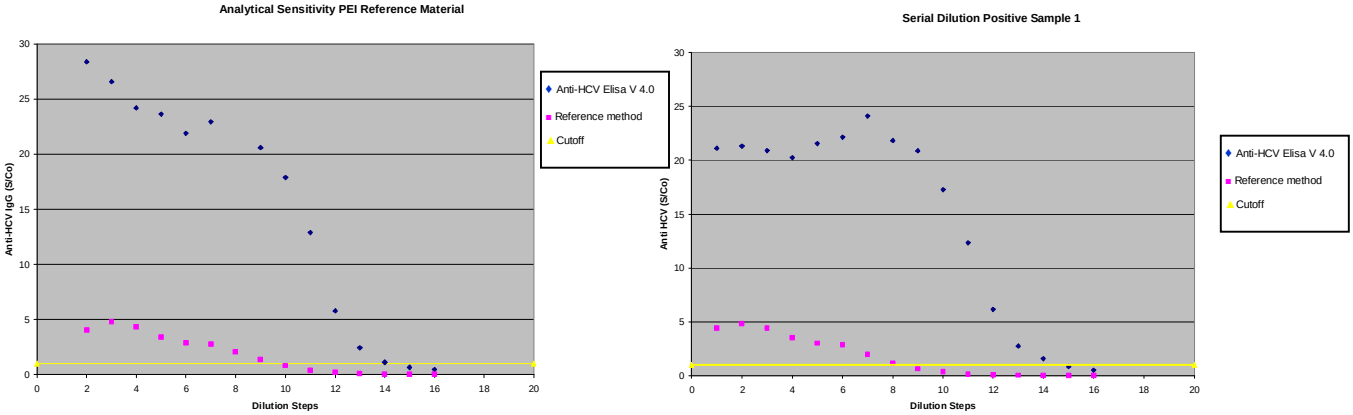
4.12.2) Clinical Specificity

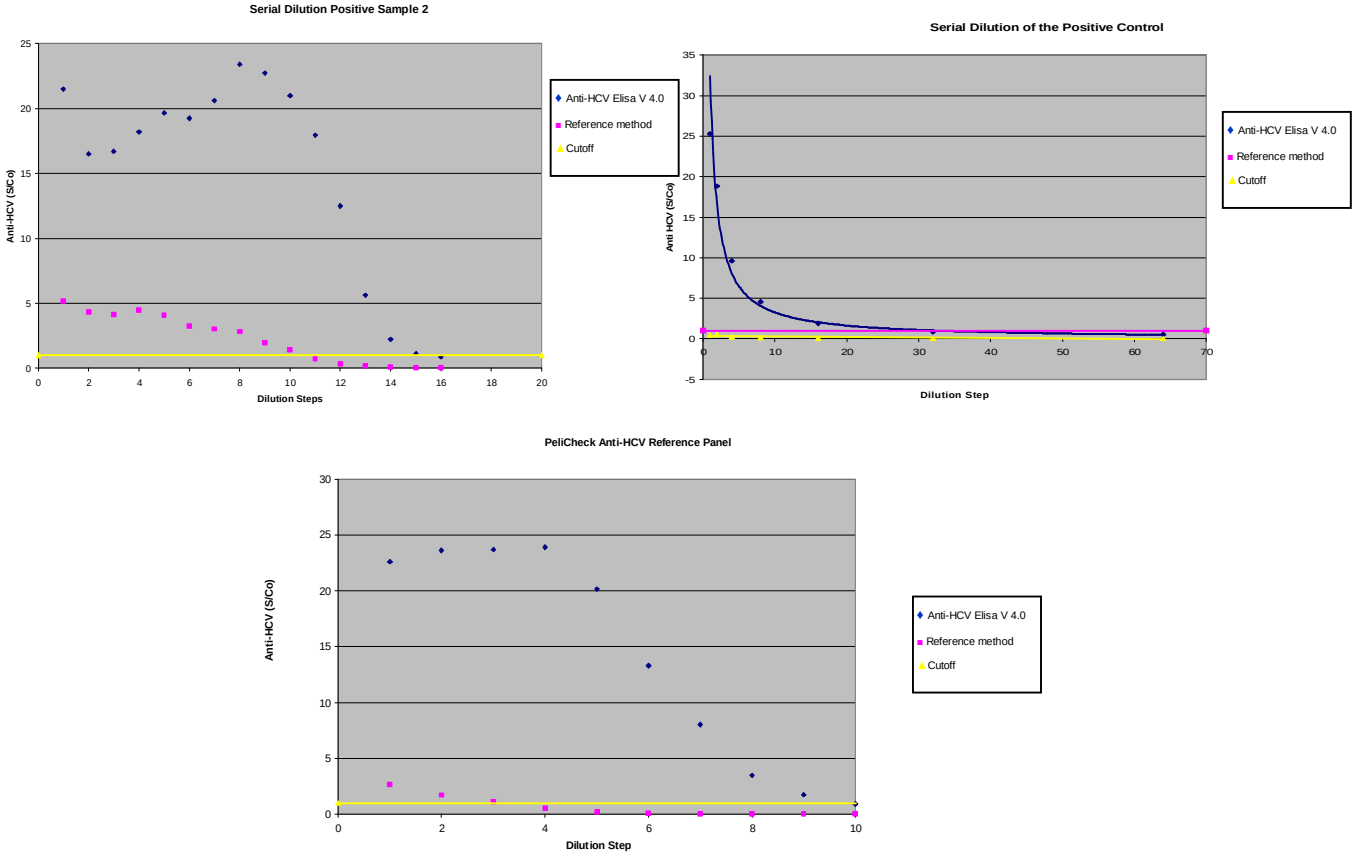
Clinical specificity = 5356/5369 = 99.8 %

Potential Interfering Substances	n tests	n reactive	n non-reactive	Specificity
Blood donors	5169	12	5157	99.77 %
Clinical / hospital specimens	200	1	199	99.5 %
Potentially cross-reacting serum / plasma specimens	100	0	100	100 %
Total	5369	13	5356	99.8 %

4.12.3) Analytical Sensitivity

The analytical sensitivity of Anti-HCV Elisa V 4.0 assay is higher than the comparison test.



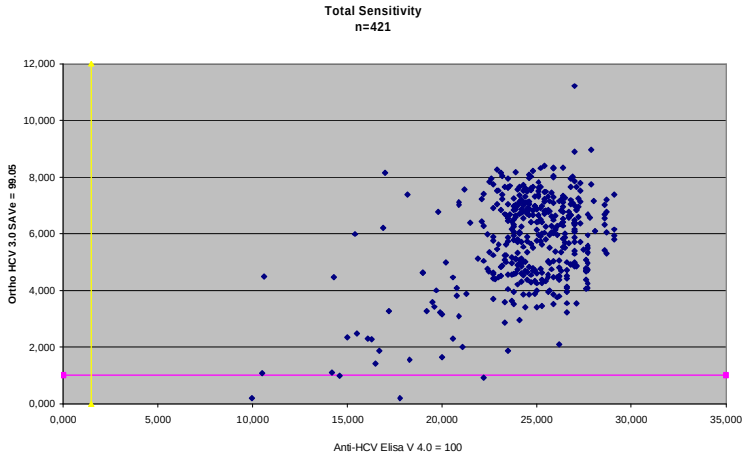


4.12.4) Clinical Sensitivity

1. HCV infected individuals :

The diagnostic sensitivity of the DIAsource ImmunoAssays SA Anti-HCV Elisa V 4.0 was determined to be 100 %.

421 of 421 positive samples including 20 samples per genotype for genotypes 1a – 4a and 5 samples for genotype 6 were tested and confirmed reactive for HCV antibodies.



2. Commercial seroconversion panels :

Anti-HCV Elisa V 4.0 assay showed a higher seroconversion sensitivity in comparison with the chosen reference method which is CE-marked anti-HCV ELISA.

The total number of tested samples from the 22 seroconversion panels amounted to 198. Sixty three (63) of these samples were tested reactive with Anti-HCV Elisa V 4.0 assay, whereas only 44 of these samples were found to be reactive with the reference method.

4.12.5) Precision

1. Intra-assay Reproducibility

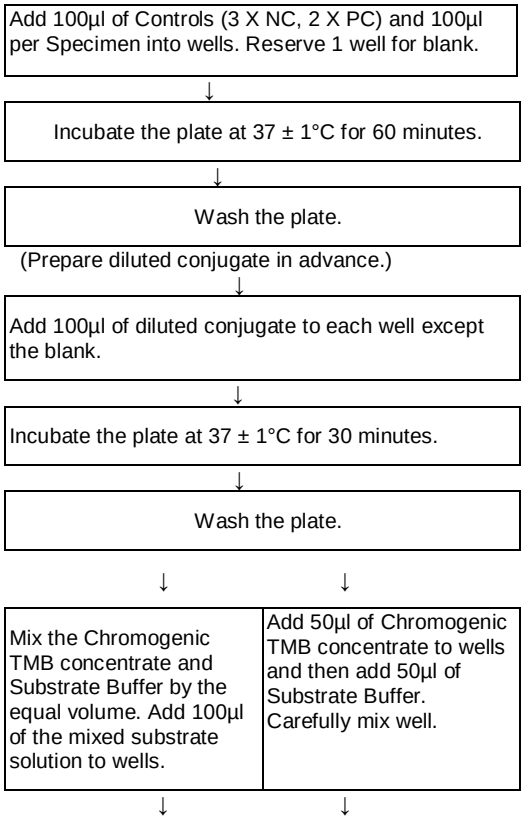
CUTOFF INDEX	Positive Serum 1		Positive Serum 2		Positive Control	
	Mean	CV (%)	Mean	CV (%)	Mean	CV (%)
Day 1	4.49	7.22	9.01	5.94	21.79	4.91
Day 2	4.16	13.06	8.54	9.41	21.44	4.23
Day 3	5.07	5.24	10,64	9,27	21,70	3,08
Mean	**4.57**	**8.51**	**9.40**	**8.21**	**21.64**	**4.07**

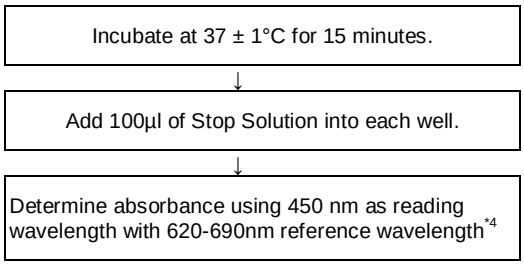
2. Total Imprecision

Lot C68332PT		CUTOFF INDEX			
Run-No	Run Date	NC	PS1	PS2	PC
1	15/7/08	0.31	5.03	10.70	22.50
2	18/7/08	0.30	4.52	7.83	23.56
3	18/7/08	0.30	4.83	9.58	21.16
4	21/7/08	0.29	5.72	10.40	21.38
5	22/7/08	0.33	4.91	8.82	20.72
6	22/7/08	0.33	4.53	10.10	17.25
7	23/7/08	0.27	3.79	6.39	16.86
8	23/7/08	0.34	4.21	8.08	18.42
9	24/7/08	0.29	5.03	7.96	20.59
10	24/7/08	0.35	4.59	8.48	20.59
MEAN		**0.31**	**4.73**	**8.83**	**20.30**
SD		**0.03**	**0.52**	**1.36**	**2.17**
CV		**8.34**	**11.05**	**15.34**	**10.69**

Lot C68333PT		CUTOFF INDEX			
Run-No	Run Date	NC	PS1	PS2	PC
1	19/8/08	0,33	5,63	10,05	20,08
2	19/8/08	0,25	4,96	10,50	18,10
3	20/8/08	0,29	5,62	10,50	21,48
4	21/8/08	0,34	4,05	9,49	20,05
5	21/8/08	0,33	5,31	10,20	19,36
6	22/8/08	0,31	5,34	8,97	19,08
7	22/8/08	0,31	5,39	9,16	19,72
8	25/8/08	0,25	4,31	8,64	18,79
9	25/8/08	0,30	5,74	10,60	21,10
10	26/8/08	0,27	6,03	11,30	20,83
MEAN		**0,30**	**5,15**	**9,94**	**19,86**
SD		**0,03**	**0,63**	**0,85**	**1,07**
CV		**10,82**	**12,22**	**8,51**	**5,39**

4.13) Flow chart of the test procedure





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*2 Claets H, Volckaerts A, De Beenhouwer H, Vermylen C. (1992) Association of hepatitis C virus carrier state with the occurrence of hepatitis C virus core antibodies. J. Med. Virol. 36:259-264.
*3 Beach MJ, et al. (1992) Temporal relationship of hepatitis C virus RNA and antibody responses following experimental infection of chimpanzee. J Med. Virol. 36:226-237.
*4 The reference wavelength of spectrometer could be 620nm to 690nm. However, user should validate the spectrometer in combination with this kit before use.
*5 Incomplete inactivation of hepatitis B virus after heat treatment at 60°C for 10 hours, J. Infect. Dis. 138:242-244.
*6 The supplier is: VQC-AcroMetrix: Jan Steenstraat 1,NL-1816 CT Alkmaar, The Netherlands. Type 7 is available in lyophilised or liquid format. The catalogue numbers are S2233 (lyophilised format) and S2058 (liquid format).
*7 National Inst. For Biological Standards & Control (NIBSC), Blabche Lane South Mimms Potters Bar Herts EN6 3QG, UK; Anti-HCV British Working Standard, Product Code: 02/238-004.

Revision date : 2011-03-30

	Used symbols
	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
CONTROL	Control
I V D	In vitro diagnostic medical device
	Manufacturer
	Contains sufficient for <n> tests
WASH SOLN CONC	Wash solution concentrated
CAL 0	Zero calibrator
CAL N	Calibrator #
CONTROL N	Control #
Ag 125I	Tracer
Ab 125I	Tracer
Ag 125I CONC	Tracer concentrated
Ab 125I CONC	Tracer concentrated
	Tubes
INC BUF	Incubation buffer
ACETONITRILE	Acetonitrile
SERUM	Serum
DIL SPE	Specimen diluent
DIL BUF	Dilution buffer
ANTISERUM	Antiserum
IMMUNOADSORBENT	Immunoadsorbent
DIL CAL	Calibrator diluent
REC SOLN	Reconstitution solution
PEG	Polyethylene glycol
EXTR SOLN	Extraction solution
ELU SOLN	Elution solution
GEL	Bond Elut Silica cartridges
PRE SOLN	Pre-treatment solution
NEUTR SOLN	Neutralization solution
TRACEUR BUF	Tracer buffer
	Microtiterplate
Ab HRP	HRP Conjugate
Ag HRP	HRP Conjugate
Ab HRP CONC	HRP Conjugate concentrate
Ag HRP CONC	HRP Conjugate concentrate
CONJ BUF	Conjugate buffer
CHROM TMB CONC	Chromogenic TMB concentrate
CHROM TMB	Chromogenic TMB solution
SUB BUF	Substrate buffer
STOP SOLN	Stop solution
INC SER	Incubation serum
BUF	Buffer
Ab AP	AP Conjugate
SUB PNPP	Substrate PNPP
BIOT CONJ CONC	Biotin conjugate concentrate
AVID HRP CONC	Avidine HRP concentrate
ASS BUF	Assay buffer
Ab BIOT	Biotin conjugate
Ab	Specific Antibody
SAV HRP CONC	Streptavidin HRP concentrate
NSB	Non-specific binding
2nd Ab	2nd Antibody
ACID BUF	Acidification Buffer
DIST	Distributor