

bi-x-act[®]
of FINLAND

Anti-HCV ELISA 96 and
480 Well Plate Test Kit



Productcodes: 2HCV96
2HCV480



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1) Intended Use

Anti-HCV ELISA Test, 3.0 is an 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 Test 3.0 adopts the second antibody "sandwich principle" as the basis for the assay to detect Antibody to Hepatitis C virus (anti-HCV). It is an enzyme immunoassay kit, which uses recombinant HCV antigens (core, NS3, NS4 and NS5 antigens) for the detection of Antibody to Hepatitis C virus (anti-HCV) in human serum or plasma^{*1-3}. These antigens constitute the solid phase. 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 Anti-Human-IgG•HRPO Conjugate is added to the well and results in the formation of (HCV) • (Anti-HCV) • (Anti-human- IgG•HRPO) complex. After washing out the unbound conjugate, TMB substrate solution is added for color development. The intensity of color development is proportionate 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 + Anti-h IgG•HRPO → Plate (HCV Antigen)•Anti-HCV• Anti-h IgG•HRPO complex
4. Wash to remove the unbound materials.
5. Plate (HCV Antigen)•Anti-HCV• Anti-h IgG•HRPO complex + TMB Solution → light blue to blue color
6. Light blue to blue color + 2N H₂SO₄ → 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) + Anti-h IgG•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+ 2N H₂SO₄ → colorless, measured at 450nm with a selected reference wavelength within 620 to 690nm^{*4}

3) Description of Provided Materials & Product Code System

- Item 1 - 8 on the following reagent table should be refrigerated at +2 to +8°C .
Washing Solution D (20X) and 2N H₂SO₄ can be stored at +2 to +30°C.

ITEMS	Components	Description	Qt. per 96 tests	Qt. per 480 tests
(1)	HCV Antigens Plate	Microtiter plate coated with HCV antigens.	1 plate	5 plates
(2)	Conc. Anti-h-IgG•HRPO Conjugate	Contained anti-h IgG (Goat) •Peroxidase (Horseradish) in buffer with Bovine serum. Preservatives: 0.01% Thimerosal and 0.003% Gentamycin.	1bottle, 2 ml	1 bottle, 5 ml
(3)	Anti-HCV Positive Control	Inactivated human plasma positive for Anti-HCV. Preservative: 0.1% Sodium azide.	1 bottle, 0.5 ml	1 bottle, 3 ml

(4)	Hepatitis C Negative Control	Normal human plasma non-reactive for Anti-HCV. Preservative: 0.1% Sodium azide.	1 bottle, 0.5 ml	1 bottle, 3 ml
(5)	Specimen Diluent	Specimen Diluent C: Tris-buffer with Bovine serum and Tween-20. Preservative: 0.1% sodium azide.	1 bottle 30 ml	1 bottle 100 ml
(6)	Conjugate Diluent	Tris-buffer with Bovine serum and Tween-20. Preservatives: 0.01% Thimerosal and 0.003% Gentamycin.	1 bottle, 20 ml	1 bottle, 100 ml
(7)	TMB Substrate Solution A	0.6 mg/ml of 3, 3', 5, 5'-tetramethylbenzidine (TMB) in an organic base.	1 bottle, 10 ml	1 bottle, 35 ml
(8)	TMB Substrate Solution B	Citric Acid Buffer containing 0.03% H ₂ O ₂ .	1 bottle, 10 ml	1 bottle, 35 ml
(9)	Conc. Washing Solution D (20X)	Phosphate buffer with Tween-20.	1 bottle 100 ml	1 bottle 400ml
(10)	2N H ₂ SO ₄	2N sulfuric acid	1 bottle 12 ml	1 bottle 50 ml

• **ACCESSORIES: (provided as needed)**

ITEMS	Components
(11)	Adhesive slips
(12)	Absorbent pads
(13)	Black cover

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

ITEMS	Components
(1)	10µl, 100µl and 200µl, 1-ml micropipettes and tips are needed.
(2)	Incubator
(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.

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 nonacid 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) 2N Sulfuric Acid is an irritant to skin, eyes, respiratory tract and mucous membranes. Avoid contact of the 2N sulfuric acid 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) TMB substrate solution A contains organic solvent, which is flammable. TMB substrate solution A 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) **WARNING**
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 1:21 dilution of Conc. anti-h-IgG•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. anti-Human-IgG• 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, 2 wells for Negative Control, 3 wells for Positive Control, and 1 well for each Specimen.

4.5.5) Sample input:

4.5.5.1) Add 200µl Specimen Diluent to each appropriate well assigned for specimens and controls in HCV Antigens Plate. The controls should also be diluted in specimen diluent!

4.5.5.2) Add 10µl of Positive Control, Negative Control and specimen to each appropriate well.

4.5.5.3) 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 $37 \pm 1^\circ\text{C}$ water bath or circuited 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 100 μl 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 $37 \pm 1^\circ\text{C}$ water bath or circulated 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 TMB Substrate Solution A and B in a clean container immediately prior to use. Add 100 μl of the mixture solution to each well including the blank.

B. Add 50 μl of TMB Substrate Solution A first, and then add 50 μl of TMB Substrate Solution B into each well including the blank. Carefully mix well.

NOTE: TMB Substrate Solution A should be colorless to light blue; otherwise, it should be discarded. The mixture of TMB Substrate Solution A and B should be used within 30 minutes after mix. The mixture should be avoided from intense light.

4.5.15) Cover the plate with a black cover and incubate at room temperature for 30 minutes.

4.5.16) stop the reaction by adding 100 μl of 2N H_2SO_4 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.

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

$$\text{NCx} = (0.045 + 0.060) / 2 = 0.053$$



NCx must be ≤ 0.2 , 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
3	1.305

$$\text{PCx} = (1.510 + 1.826 + 1.305) / 3 = 1.547$$



PCx must be ≥ 0.6 , otherwise the test is invalid.

4.6.3) Calculation of P-N Value

$$\text{P-N} = \text{PCx} - \text{NCx}$$

Example:

$$\text{P-N} = 1.547 - 0.053 = 1.494$$

⚠ P - N Value must be ≥ 0.4 , otherwise the test is invalid.

4.6.4) Calculation of the **Cutoff Value**

$$\text{Cutoff Value} = \text{NCx} + (\text{PC x})/4$$

Example:

$$\text{Cutoff Value} = 0.053 + 0.25 \times 1.547 = 0.053 + 0.387 = 0.440$$

4.6.5) calculate the cut-off index of the specimens

Cutoff Index

$$= \text{Sample OD Value} / \text{Cutoff Value}$$

Example:

Sample Value is 0.596

$$\text{Cutoff Index} = 0.596 / 0.440 = 1.355$$

4.6.6) Gray Zone: Cut-off index = 1.0 ~ 1.5

4.7) **⚠ Quality Control of the Test Run**

4.7.1) **NCx must be ≤ 0.2 , otherwise the test is invalid.**

4.7.2) **PCx must be ≥ 0.6 , otherwise the test is invalid.**

4.7.3) **P-N Value must be ≥ 0.4 , 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 < 1.0** are considered **NON-REACTIVE** by the criteria of EKOWEB's ANTI-HCV ELISA TEST, 3.0.

4.8.2) Specimens with **CUTOFF INDEX ≥ 1.0** are considered as initially **REACTIVE**. They should be **RETESTED** in duplicate.

If both **CUTOFF INDEXES** of the duplicate are **GREATER** than 1.5, the specimen is considered to be repeatedly **REACTIVE** for Anti-HCV by the criteria of Ekoweb's Anti-HCV ELISA Test.

Specimens repeatedly reactive in the Anti-HCV ELISA Test 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 **1.0**, will be considered **NON-REACTIVE** for Anti-HCV.

4.8.4) If one of the two **CUTOFF INDEXES** of the duplicate is **GREATER** than **1.0** but **LESS** than **1.5**, 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 **1.5** and the other one is **LESS** than **1.0**, 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: EIA test results on HCV-negative patients.

Panel	n tested	n reactive	n questionabl e	n non- reactive
		S/CO > 1.2	1.0 < S/CO < 1.2	S/CO < 1.0
Negative patient panel (Mononucleosis)	299	0	1	298
Risk panel (other hepatitis)	49	1	1	47
Risk panel (hemophilia)	44	2	0	42
Total	392	3	2	387

4.11) Storage Conditions and Stability

Kit/components	Storage condition	State	Stability
Anti-HCV ELISA Test, 3.0 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
HCV Negative Control	+2 to +8°C	Original	18 months
		Once open	1 month
HCV Ag Plate	+2 to +8°C	Original	18 months
		Once open	2 months
Anti-h IgG•HRPO Conjugate Solution	+2 to +8°C	Original	18 months
		Once open	1 month
Specimen Diluent	+2 to +8°C	Original	18 months
		Once open	1 month
Conjugate Diluent	+2 to +8°C	Original	18 months
		Once open	1 month
Concentrated Washing Solution D (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
TMB Substrate Solution A	+2 to +8°C	Original	18 months
		Once open	1 month
TMB Substrate solution B	+2 to +8°C	Original	18 months
		Once open	1 month
2N Sulfuric Acid	Room temp.	Original	24 months
		Once open	1 month

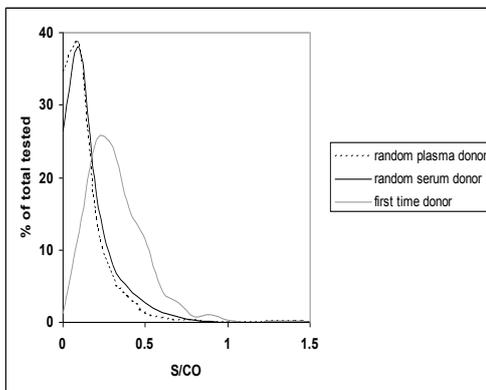
4.12) Performance Characteristics

4.12.1) Clinical Specificity

	n. Tested	n. nonreactive
Serum samples from blood donors	2571	2566
Plasma samples from blood donors	1368	1363
samples from first time blood donors	1122	1114
Negative patient panel (Mononucleosis)	299	298
Risk panel (other hepatitis)	49	47
Risk panel (hemophilia)	44	42
<i>Total</i>	<i>5453</i>	<i>5430</i>

Clinical Specificity = 5430/5453 = 99.6 %.

Figure 1. The distribution of sample cut-off ratios (S/CO) of random and first time donors tested in the Ekoweb Anti-HCV ELISA.



4.12.2) Analytical Sensitivity and Reproducibility

1. Analytical sensitivity and reproducibility of ELISA as determined in 76 runs with the run control sample PeliSpy type 7*6.

Dilution	n	avg	95% C.I.	min	max
1:128	76	1.68	1.19 2.17	1.19	2.42

2. Three (1:100 diluted) genotype panels [Teragenix genotype panels HCVGTP-001b (S10011), (S10019) and (S10020)] were tested in Anti-HCV ELISA Test and show that the assay was as sensitive as the results obtained with another CE-marked anti-HCV ELISA.
3. Sensitivity to NIBSC Working standard for anti-HCV (02/238)^{*7}: S/Co \geq 1.0
4. Sensitivity to NIBSC Anti-HCV genotype 1 high titer working standard (99/608-1)^{*8}: S/Co \geq 1.0

4.12.3) Clinical Sensitivity

1. Fifteen sero-conversion panels were tested in the Anti-HCV ELISA Test and another CE-marked anti-HCV ELISA to compare the performance of the test with the reference test in the early phase of the HCV-infection. The Anti-HCV ELISA Test was on average 1 day later than the reference assay. The Anti-HCV ELISA Test can be considered equally sensitive as the reference assay when the long sampling interval of 13 days in one of the panels was excluded from the comparison.
2. In addition to the panels, 531 HCV-positive patients were tested in the Anti-HCV ELISA Test assay.

	n. Tested	n. Reactive
Samples	531	531
Total	531	531

Clinical Sensitivity = 531/531 = 100 %.

4.12.4) Detectability of genotypes

Different genotypes of HCV have been tested in the Anti-HCV ELISA Test assay. The results show, that the Anti-HCV ELISA Test detects efficiently anti-HCV reactivity against the genotypes 1,2,3,4, 5 and 6.

4.12.5) Precision

1. Intra-run precision for PC:
CV \leq 15%
2. Intra-run precision for panel 2
CV \leq 15%
3. Inter-run precision (intermediate) for PC: CV \leq 25%
4. Inter-run precision (intermediate) for panel 2: CV \leq 25%

4.12.6) Linearity and Traceability

1. VQC Batch Release Panel (PELICHECK anti-HCV Reference Panel S2007 or S2259)
LOD (lowest limit of detection): at least 128X dilution.
2. COI of NIBSC Working Standard for anti-HCV (02/238)^{*7} or equivalent \geq 1.0
3. COI of NIBSC anti-HCV genotype 1 high titer working standard (99/608-1) or equivalent \geq 1.0

4.12.7) Antibody Excess/High-dose hook effect

To test the antibody excess/high-dose hook effect 3 serum samples with a very high – Anti-HCV titer (OD > 3) were tested in serial dilution with the Anti-HCV ELISA Test assay. No antibody excess / high-dose hook effect was observed.

4.13) Flow chart of the test procedure

Add 200µl of specimen diluent to each well in HCV Antigens Plate except the blank.
Add 10µl of Controls (2 X NC, 3 X PC) and 10µl per Specimen into wells.
Reserve 1 well for blank.



Incubate the plate at $37 \pm 1^\circ\text{C}$ for 60 minutes.



Wash the plate.

(Prepare diluted conjugate in advance.)



Add 100µl of diluted conjugate to each well except the blank.



Incubate the plate at $37 \pm 1^\circ\text{C}$ for 30 minutes.



Wash the plate.



Mix the TMB Substrate Solution A and B by the equal volume. Add 100µl of the mixed substrate solution to wells.	Add 50µl of TMB Substrate Solution A to wells and then add 50µl of TMB Substrate Solution B. Carefully mix well.
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Incubate at RT for 30 minutes.



Add 100µl of 2N H_2SO_4 into each well.



Determine absorbance using 450 nm as reading wavelength with 620-690nm reference wavelength^{*4}

5) Bibliography

- *1 Abe K, Inchauspe C, Shikate T, and Prince AM. (1992) Three different patterns of hepatitis C virus infection on chimpanzees. *Hepatology*, 15:690.
- *2 Claets H, Volckaerts A, De Beenhouwer H, Vermeylen 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.
- *8 National Inst. For Biological Standards & Control (NIBSC), Blabche Lane South Mimms Potters Bar Herts EN6 3QG, UK; Anti-Hepatitis C Virus (genotype 1), Product Code: 99/608.