

Evaluation results of some commercially available anti-HCV test kits used in countries with limited resources

Assay Evaluation

Table 4 -B-

General Characteristics and Operational Aspects of the Test Kits Evaluated (1)

B-Nr. (working No.)	10ICBS/03	11ICBS/03	12ICBS/03	13ICBS/03	14ICBS/03	15ICBS/03	16ICBS/03	17ICBS/03	18ICBS/03
Product name	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	Anti-HCV Antibody ELISA Kit	Anti-HCV EIA-96	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	LG HCD 3.0 Plus 96T	LSU-ICMRT EIA-Spex Screening Assay for Antibody to Hepatitis C virus (HCV)	HCV IgG ELISA Kit	HCV ELISA Test Kit	Hepatitis C (anti-HCV) ELISA
Manufacturer	SiNo-American Biotechnology Company (SABC)	Biocell Co., Ltd.	General Biologicals (Tianjin) Co., Ltd.	Beijing Kinghawk Pharmaceutical Co., Ltd.	LG Life Sciences, Ltd.	LSU-ICMRT Costa Rica	Zhongshan Bio-tech Co., Ltd.	InTec Products, Inc.	Wiener Laboratorios S.A.I.C.
Catalogue No.	DE03012	Ref#2212:96 test	4NAE5	S-02	n.a.	None	S19990045	ITP23001	1483251
Lot No:	20021201	20021023	20020801	20021101	HCM3001	02-03	20021213	2003020801	212539
Number of tests per kit	96	96	96	96	96	672	96	96	96
Method	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA
Microtiterplate or Stripes	Microtiterplate	Microwell stripes	Microtiterplate	Microtiterplate	Microtiterplate	12x56 Microwell stripes	Microwell stripes	Microtiterplate	Microwell stripes
Assay format	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection	Indirect Ab detection
Antigens coated on the solid phase	"HCV recombinant antigens"	Core, NS3, NS4, NS5	Core, NS4 synthetic peptides, NS3 and NS5 recombinant antigens	"Purified recombinant HCV antigens"	Core/NS3 FP, E1/E2/NS4 FP, NS5	Synthetic polypeptide: 2 core epitopes, and 1 NS4	"Purified recombinant HCV antigens from the structural and Non-structural region"	"Recombinant HCV antigens from the core and NS-zone"	Core, NS3, NS4, NS5 recombinant
Conjugated Antibody	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG (goat)	Anti-human IgG (goat)	Anti-human IgG (goat)
Wave length	450 (660)	450	450	450 (630)	450 (620 or 650)	450	450	450 (630)	450 (620)
Blank	Sample diluent-conjugate-substrate	Sample diluent-conjugate-substrate	Substrate	Sample diluent-substrate	Sample diluent-substrate	No Blank	Sample diluent-substrate	Sample diluent-conjugate-substrate	No blank
Controls in the kit	Negative and positive control	Negative and positive control	Negative and positive control	Negative and positive control	Negative and positive control	Negative, positive control and weak positive control	Negative and positive control	Negative and positive control	Negative and positive control
Sample size	10 µl	5 µl	10 µl	10 µl	10 µl	10 µl	10 µl	10 µl	10 µl
Cut-off definition	0,05 + 0,08 * PCx	NCx * 2,5 if NCx < 0,05; 0,05 * 2,5	NCx + 0,1* PCx	PCx * 0,13 + NCx if NCx < 0,02: NCx = 0,02	NCx+0,4 [NCx>=0,000]	NCx + 0,250	0,05 + 0,15 [NC<0,05]	2,8 * NCx if NCx < 0,05: 2,8 * 0,05	NCx + 0,150
Specimen type	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma	Serum/plasma

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Incubation time in minutes sample/conjugate/substrate	30/30/20	20/15/10	30/15/15	20/20/10	60/30/30	20/20/15 (10-20)	30/20/10	25/25/10	30-35/20-25/1
Incubation temperature in °C	37/37/37	37/37/37	37/37/RT	37/37/37	37/37/15-30	40/RT/RT (RT 18-25°C; 22,5 °C used as RT)	37/37/37	37/37/37	37/37/RT 22,5 °C used as RT
Pre-dilution required	No	No	No	No	No	No	No	No	No
Equipment required	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 1ml, 5ml; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipette 10µl; Multichannel pipette for 50, 100µl and 200µl; Water bath, Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer
Specific accessory reagents required	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	water ad inject, PBS-Buffer pH 7.2-7.5	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water
Storage conditions in °C	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8	2 - 10
Shelf life at recommended storage conditions	n.a.	6 months	10 months	n.a.	12 months	6 months	6 months	n.a.	n.a.
Expiry date	01.12.2003	23.04.2003	11.06.2003	01.05.2003	24.01.2004	18.08.2003	12.06.2003	08.02.2004	12.2003
Stability/robustness of packaging (2)	Very good	Very good	Very good	Very good	Very good	Very good	Very good	Very good	Good
Clarity of instructions for use	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.
Instructions for use in English	Yes	No	No	No	Yes	No	No	Yes	No
Clarity of labelling	"Lot" and "Exp." printed on package, but not no. and date not shown;	Declaration of lot, exp.date on package and reagent bottles not in English; reagent name on bottle not in English	Declaration of lot, exp.date on package and bottles not in English; wrong volume on conjugate bottle (not 150µl); reagent names on bottles not in English	Declaration of lot, exp.date on package not in English; no volume declaration on bottle	O.K.	Distilled water in the bag with the stripes (not air-tight closed); no volume declaration on bottles	Name of reagents on bottles not in English	No exp.date and lot no. and volume declaration on reagent bottles	O.K.

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Remarks						<p>With a substrate incubation time of 15 min half of the negative controls were invalid;</p> <p>With a incubation time of 10 min all negative controls were within the acceptable specification.</p> <p>It appears that the substrate incubation times given as 10-20 min. must be narrowed</p>			

Footnote:

1.) The information in this table are is derived from the package leaflet and the labelling on the kit boxes

2.) Very good/good= plastic coated cardboard box with very good/good stability; fair = card board box of good stability; poor/very poor = simple card board box flexible and not water resistant

Abbreviations:

n.a. = not applicable, n.t. not tested

RT: room temperature

ELISA enzyme-linked immunosorbent assay

NC: negative control

PC: positive control

x: mean