

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

Assay Evaluation

Table 4 -C-

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

B-Nr. (working No.)	19ICBS/03	20ICBS/03	21ICBS/03	22ICBS/03	23ICBS/03	24ICBS/03	25ICBS/03	26ICBS/03	27ICBS/03
Product name	GENEDIA HCV Rapid LF	Dong-A HCV 3.0	Umelisa HCV 3ra Generacion	ImuNo-RÁPIDO HCV	HepaScreen	Anti-HCV ELISA	Anti-HCV ELISA	Immunoenzyme Test-System for Detection of Antibodies to Hepatitis C Virus (Anti-HCV)	HCV- DCM
Manufacturer	GreenCross Life Science Corp.	Dong-A Pharmaceutical Co., Ltd.	TecNosuma International S.A.	WAMA Diagnóstica	BiotechNologitzeska ja Kompanija Bioservis	IMBIO	Union-DiagNostisches-System	NPP Akwapast	Medizinische Biologische Union
Catalogue No.	0483-200-10-0	HCVF96N	D9307-07	621040-R	n.a.	P 93/160/17	n.a.	n.a.	n.a.
Lot No:	483003	2911	030304	305031AA	52-0554	09-130503	3-0303	2/07	11 bzw. 10
Number of tests per kit	5 x 10			40	2 x 96	2 x 96	2 x 96	96	2 x 96
Method	Rapid	ELISA	ELISA	Rapid	ELISA	ELISA	ELISA	ELISA	ELISA
Microtiterplate or Stripes	Immuno-chromatographic lateral flow through	Microwell stripes	opaque plates	Dot / Spot	Microtiterplate	Microtiterplate	Microtiterplate	Microwell stripes	Microtiterplate
Assay format	Direct 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	Core, NS3, NS4, NS5	"Mixture of recombinant HCV antigens"		"Mixture of synthetic proteins and recombinant HCV antigens"	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	?
Conjugated Antibody	n.a.	Anti-human IgG		Protein A Gold	?	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG
Wave length	Visual reading	492 (650)		Visual reading	450	450 (620-690)	450 (620-680)	450	450
Blank	n.a.	No blank	n.t.	n.a.	Air blank	Air blank	Air blank	No blank	Air 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 and positive control	Negative and positive control	Negative and positive control	Negative and positive control
Sample size	20 µl	10 µl		30 µl	50 µl	20 µl	70 µl	30 µl	20 µl
Cut-off definition	Visual reading	NCx + 0,4	NCx + 0,20	visual reading	NCx + 0,20	NCx + 0,15	NCx + 0,18	NCx + 0,2 if PC < 2,0 then NCx + 0,1 * PCx	NCx + 0,2 if PC < 2,0 then NCx + 0,1 * PCx
Specimen type	Whole blood/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	Until absorbance completed/ read after 30 minutes	60/30/15-30		No incubation time	30/30/20	30-40(35)/30-40(35)/10-15(13)	60/30/30	40/20/15	45/30/15
Incubation temperature in °C	RT Not specified 22,5 °C used as RT	37/37/RT RT Not specified 22,5 °C used as RT		RT RT Not specified, 22,5 °C used as RT	37/37/RT (20-25°C) 22,5 °C used as RT	37/37/RT (18-25°C)	37/37/RT (20-24°C) 22,5 °C used as RT	37/37/RT (18-22°C) 22,5 °C used as RT	37/37/RT 22,5 °C used as RT
Pre-dilution required	No	No		No	No	No	No	No	No
Equipment required	Micropipette 20 µl	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer		Micropipette 30 µl	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	pipettes 10µl; multichannel pipette for 50 and 200µl; incubator; reader Tecan; vessels for reagent (preparation: graduated cylinder 1L), timer, washer
Specific accessory reagents required	Distilled or deionized water	No		No	Distilled or deionized water and 1 mmol H2SO4	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water
Storage conditions in °C	2 - 30	2 - 8		2 - 8	4 - 12	2 - 8	4 - 8	4 - 8	2 - 10
Shelf life at recommended storage conditions	18 months	n.a.	n.a.	12 months	6 months	6 months	6 months	n.a.	n.a.
Expiry date	4/11/2004	09.10.2003	12.2003	05.2004	20.09.2003	13.11.2003	28.09.2003	01.2004	27.05.2003
Stability/robustness of packaging (2)	Very good	Fair	Fair	Very good	Poor	Poor	Fair	Poor	Poor
Clarity of instructions for use	O.K.	description blank missing	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.
Instructions for use in English	Yes	No	No	No	No	No	No	No	No
Clarity of labelling	O.K.	Korean		O.K.	No volume declaration or exp.date on bottles; No English lot, exp. date on package;	Test name, declaration of lot, exp.date on package and reagent bottles not in English; reagent name on bottle not in English	Test name, declaration of lot, exp.date on package and reagent bottles not in English; reagent name on bottle not in English	Box without labelling only the single components labelled	Test name, declaration of lot, exp.date on package and reagent bottles not in English; reagent name on bottle not in English

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Remarks					Stopping solution (H ₂ SO ₄) not provided must be prepared by oneself				

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