

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

Assay Evaluation

Table 4 -E-
General Characteristics and Operational Aspects of the Test Kits Evaluated (1)

B-Nr. (working No.)	38ICBS/04	39ICBS/04	40ICBS/04	41ICBS/04	42ICBS/04	43ICBS/05	44ICBS/05	45ICBS/05
Product name	Entebe Anti HCV Dipstick	Acon HCV	Anti HCV-EIA-Avicenna	Detect-HCV	I+Lab Anti-HCV Test	SERODIA-HCV	bioelisa HCV	Assure HCV rapid test
Manufacturer	Laboratorium Hepatika Mataram	Acon Laboratories, Inc., Spain	Avicenna Medical Center, Russia	Adaltis Inc., Montreal, Canada	I+MED Laboratories Co., LTD. Thailand	Fujirebio Inc., Tokyo	Biokit S.A.	Genelabs Diagnostics
Catalogue No. Lot No:	n.a. MTR099	ICH-301 HCV40502	O2EM93-2 04.54C	HCA-702B 4770052	n.a. 470049	n.a. AG40706	3000-1117 L-1804	43531-020 DJ4002
Number of tests per kit	48	50	192	192	25	100	96	20
Method	Rapid	Rapid	ELISA	ELISA	Rapid	PA	ELISA	Rapid
Microtiterplate or Stripes	Comb	Stripes	Microtiterplates	Microtiterplates	Stripes	Microtiterplates	Microtiterplates	Stripes
Assay format	dipping	immuno-chromatic	Indirect Ab detection	Indirect Ab detection	immuno-chromatic	Aglutination	Indirect Ab detection	immuno-chromatic
Antigens coated on the solid phase	synthetic core	recombinant HCVantigenes	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	recombinant HCVantigenes	gelatine particles, sensitized with recombinant c22-3 and c200	Core, NS3, NS4, NS5	recombinant HCVantigenes
Conjugated Antibody	Protein A gold	Protein A coated particles	Protein A	anti-humanIgG	Protein G coated particles	n.a.	anti-humanIgG	Protein A coated particles
Wave length	Visual reading	visual reading	450nm/620nm	450nm/620nm	visual reading	visual reading	450nm/620nm	n.a.
Blank	n.a.	n.a.	conjugate-control	sample diluent	n.a.	n.a.	no	n.a.
Controls in the kit	yes	control-line	Negative and positive control	Negative and positive control	control-line	control particles and positive control	Negative and positive control	control-line
Sample size	100µl	n.a.	10µl	20µl	10µl	25µl	10µl	5µl
Cut-off definition	Visual reading	n.a.	0,1Xc+Nc	NCx+0,082	n.a.	n.a.	NCx+0,3	n.a.
Specimen type	serum/plasma	serum/plasma	serum/plasma	serum/plasma	serum/plasma	serum/plasma	serum/plasma	serum/plasma
Incubation time in minutes sample/conjugate/substrate	30' / - / 30'	10' / - / -	15' / 15' / 15'	60' / 30' / 30'	15-20' / - / -	2h' / - / -	60' / 30' / 30'	10' / - / -
Incubation temperature in °C	RT (20-25°C)	Room temperature	37/18-25	37/18-25	15-30	15-30	37/18-25	15-30
Pre-dilution required	yes, well dilution	no	Yes (well dilution)	yes, well dilution or tube dilution	no	yes (well dilution)	yes (well dilution)	no
Equipment required	measuring cylinder	timer	Micropipettes 10µl, 200µl, 1000µl.; measuring cylinders; Incubator, washer, reader	Micropipettes 10µl, 200µl; Pipetts 1ml, 5ml, 10ml; Measuring cylinders; timer, washer, incubator, reader	timer	Microtiterplates Micropipettes 25µl; Pipettes 1ml, 5ml, 10ml; tray mixer and viewer (optional)	Multichannelpipettes, micropipettes; washer, Incubator, reader	timer
Specific accessory reagents required	Distilled or deionized water	no	Distilled or deionized water	Distilled or deionized water	no	no	Distilled or deionized water, sulphuric acid (2N or 4N)	no
Storage conditions in °C	2-8	2-30	2-8	2-8	15-30	2-10	2-8	2-30
Shelf life at recommended storage conditions	12months after manufacturing	until expiration date	until expiration date	until expiration date	until expiration date	until expiration date	until expiration date	until expiration date
Expiry date	04-2005	05-2006	12.07.2005	03-2005	5/10/2006	07-2005	9/25/2005	7/12/2006
Stability/robustness of packaging (2)	good	fair	fair	good	good	fair	good	good
Clarity of instructions for use	fair	good	ok/good	good	good	good	good	good
Instructions for use in English	yes, after insisting	yes	yes	yes	yes	yes	yes	yes
Clarity of labelling	good	good	good	good	good	good	good	good

B-Nr. (working No.)	381CBS/04	391CBS/04	401CBS/04	411CBS/04	421CBS/04	431CBS/05	441CBS/05	451CBS/05
Product name	Entebe Anti HCV Dipstick	Acon HCV	Anti HCV-EIA- Avicenna	Detect-HCV	i+Lab Anti-HCV Test	SERODIA-HCV	bioelisa HCV	Assure HCV rapid test
Remarks	drawings in the instruction manual to make the procedure clearer				No catalogue -number on package	No catalogue -number on package		
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