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

Assay Evaluation

Table 4 -D-

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

B-Nr. (working	28ICBS/03	29ICBS/03	30ICBS/03	31ICBS/03	32ICBS/03	33ICBS/04	34ICBS/04	35ICBS/04	36ICBS/05	37ICBS/05
Product name	**Anti-HCV ELISA-G**	**RecombiBest anti-HCV- Strip**	**Anti-HCV ELISA**	**Hepa-Scan Hepatitis C Virus Card Test**	**Hepa-Scan HCV ELISA**	**Signal HCV Flow Through Anti-HCV Spot / Immunodot Test Kit**	**InNova HCV ELISA Test Kit**	**HCV Microlisa**	**HCV Tri-Dot (Rapid)**	**Hep-CheX C**
Manufacturer	**Institut Pastera Sankt-Petersburg**	**Vector-Best**	**Radiopreparat**	**Bhat Bio-Tech India (P) Ltd.**	**Bhat Bio-Tech India (P) Ltd.**	**SPAN Diagnostics Ltd.**	**SPAN Diagnostics Ltd.**	**J. Mitra & Co. Ltd.**	**Biotech Inc. under license of J. Mitra & Co. Ltd., New Dehli**	**Xcyton Diagnostics Ltd. marketed by Qualigens Fine Chemicals**
Catalogue No.	**n.a.**	**D-0701**	**ELISA-HCV-96**	**n.a.**	**n.a.**	**25972A**	**25979**	**HC023096**	**n.a.**	**None**
Lot No:	**41**	**656-809**	**8080503**	**7731025**	**21931111**	**4806**	**4225**	**ECV12093**	**HCD31008**	**HCV/10/03**
Number of tests per kit	96	96	96	50	12x8	50	96	96	100	96
Method	ELISA	ELISA	ELISA	Rapid	ELISA	Rapid	ELISA	ELISA	Rapid	ELISA
Microtiterplate or Stripes	Microtitreplate	Microtitreplate	Microtitreplate	Immuno-chromatograpic lateral flow	Microwell stripes	Spot / immuno-dot flow through	Microwell Strips	Microwell Strips	Dot/spot	12x8 Microwell stripes
Assay formate	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	Indirect Ab detection
Antigens coated on the solid phase	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	?	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	"Immunodominant epitopes of structural and Non-structural HCV proteins"
Conjugated Antibody	Anti-human IgG	Anti-human IgG	Anti-human IgG	Protein A gold	Protein A HRP	Protein A gold	Anti-human IgG	Anti-human IgG	Protein A gold	rabbit anti-human IgG
Wave length	450 or 492	450	450	Visual reading	450	Visual reading	450	450 (620-630)	Visual reading	450 (630)
Blank	Substrate + control	Buffer	No	n.a.	Sample diluent-conjugate-substrate	n.a.	Air blank	Diluent/conjugate/substrate/stopping solution	n.a.	Diluent/conjugate/substrate/stopping solution
Controls in the kit	Negative and positive control	Negative and positive control	Negative and positive control	Control line	Negative and positive control	Control spot	Negative and positive control	Negative and positive control	Control dot	Negative and positive control
Sample size	10 µl	20 µl	100 µl	10 µl	5 µl	2 drops (~100µl)	10 µl	20 µl	1 drop (~50µl)	5 µl
Cut-off definition	1. 0,2 + NCx * 1,4 (450) 2. 0,18 + NCx * 1,2	NCx + 0,2 if PC <2,0: NCx + 0,1 * PCx	NCx + 0,1	Visual reading	(0,1 * PCx) + NCx	Visual reading	NCx + 0,225	0,1 * PCx + 0,1 (not blank adjusted)	Visual reading	NCx + 0,150
Specimen type	Serum/plasma	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	30/15/15	30/30/20	40/30/20	5 - 20 min.	90/30/30	2 - 10 min.	30/30/30	30/30/30	No time specified	30/30/10
Incubation temperature in °C	37/37/RT	37/37/RT	42/40/RT (20°C)	unclear RT (22,5 °C) used	RT/RT/RT (20-30°C) 22,5°C used	unclear RT? 22,5°C used	RT (20-30°C)/RT/RT 22,5°C used as RT	37/37/RT	RT (20-25°C)	RT/RT/RT
Pre-dilution required	No	No	No	No	No	No	No	Yes (tube dilution)	No	Yes (well dilution)
Equipment required	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipette 10µl	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	No	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	No	Mcropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer
Specific accessory reagents required	Destilled or deionized water	Destilled or deionized water	Destilled or deionized water	No	Destilled or deionized water	No	Destilled or deionized water	Destilled or deionized water	No	Destilled or deionized water
Storage conditions in °C	10	2 -10	4	2 - 30	2 - 8	2 - 8	2 - 8	4 - 8	4 - 8	2 - 8
Shelf life at recommended storage conditions	n.a.	n.a.	n.a.	18 months	12 months	12 months	12 months	12 months	12 months	12 months
Expiry date	09.2003	OPD version 28.11.2003 TMB version (??)	08.11.2003	31.4.05	38291	38321	38138	38230	38260	38291
Stability / robustness of packaging (2)	Poor	Poor	Poor	Very good	Very good	Very good	Very good	Very good	Very good	Very good
Clarity of instructions for use	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.
Instructions for use in English	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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Clarity of labelling	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	Test name, declaration of lot, exp.date on package and reagent bottles not in English; reagent name on bottle not in English	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.
Remarks		Two different versions provided: 1. With OPD as chromogen (450 nm) 2. With TMB as chromogen (492 nm) the two versions were also different in the cut-off calculation As a result the performance is different too. Conjugate must be adjusted lot-specific (a-value) Expiry date torn off from the box!!						Possibly the cut-off as given in the instructions for use is not optimal. By using 0,1 * PCx + actual blank (instead of + 0,1) the sensitivity was improved without losing specificity		

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