

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

Assay Evaluation

Table 4 -A-

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

B-Nr. (working No.)	1ICBS/03	2ICBS/03	3ICBS/03	4ICBS/03	5ICBS/03	6ICBS/03	7ICBS/03	8ICBS/03	General
Product name	GENEDIA HCV Rapid	GENEDIA HCV ELISA 3.0	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	QuickNow Anti-HCV Diagnostic Kit (ELISA)	HCV ELISA Anti-HCV Antibody ELISA Kit	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	Anti-HCV Ab EIA Kit
Manufacturer	GreenCross Life Science Corp.	GreenCross Life Science Corp.	Shanghai Feilong Medical Diagnostic Articles Co., Ltd.	Shanghai SIIC Kehua Biotech Co., Ltd.	Shanghai Rongsheng Biotech Co., Ltd.	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	GBI Biotech (Beijing) Co., Ltd.	Shanghai Fortune Long March-Trace Medical Science Co., Ltd.	Beijing Goldenweikai Medical Biotechnology Co., Ltd.
Catalogue No.	3320-200-10-6	E 3120-096	06	KH-T-07	2101	S20010014	Product license No.	P/N 32096	E11001
Lot No.	3320043	3120053	20021101	20020922	20021121	C20021111	20021022	20020918	20021101
Number of tests per kit	20	96	96	96	96	96	96	96	96
Method	Rapid	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA	ELISA
Microtiterplate or Stripes	Immuno-chromatographic flow through	12x8 Microwell stripes	12x8 Microwell stripes	Microtiterplate	Microwell stripes	Microwell stripes	Microtiterplate	Microwell stripes	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
Antigens coated on the solid phase	Core, NS3, NS4, NS5, E2, NS3NS4Core fusionprotein	Recombinant and synthetic peptid antigens	Core, NS3, NS4, NS5	Core, NS3, NS4, NS5	"Recombinant HCV antigen"	"Highly purified HCV antigens"	"HCV-specific recombinant antigens"	"Mixture of HCV antigens corresponding to core and NS3"	"Recombinant multi-region HCV fused proteins"
Conjugated Antibody	Protein A Gold	Goat-anti-human IgG	Goat-anti-human IgG	Goat-anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG	Anti-human IgG	anti-human Mab (murine)
Wave length	Visual reading	450 ( 620 )	450 ( 620 )	492 (620)	450	450 (630)	450 ( 630 )	450	450 ( 630 )
Blank	n.a.	Air blank	Specimen diluent-conjugate-substrate	Sample diluent-conjugate-substrate	Specimen diluent - substrate	Substrate	Diluent solution-conjugate-substrate	Sample diluent-conjugate-substrate (Not prescribed)	Sample diluent-conjugate-substrate
Controls in the kit	Control line	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	1 drop (~50µl)	10 µl	10 µl	10 µl	10 µl	10 µl	10 µl	10 µl	10 µl
Cut-off definition	Visual reading	NCx + 0,3	PCx *4% + 0,1	PCx * 10% + NCx	NCx + 0,1 if NC<0,05: 0,05 + 0,1	NCx + 0,12 if NC<0,02: 0,02 + 0,12	NCx + 0,15 if NC<0,03: 0,15 + 0,03	NCx + 0,1 if NC<0,05: 0,05 + 0,1	if NC<0,05: 0,05 + 0,15
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	Until absorbance completed (4-7 minutes)	60/30/30	30/30/10	30/30/10	30/30/10	30/20/10	30/30/10	25/25/10	30/20/15
Incubation temperature in °C	Room temp. (RT) 22,5 °C used	37/37/RT 22,5°C used as RT	37/37/37	37/37/37	37/37/37	37/37/37	37/37/37	37/37/37	37/37/37
Pre-dilution required	No	No	No	No	No	No	No	No	No
Equipment required	No	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 200µl; disposable tips, Incubator; Reader, Measuring cylinder - 100 ml, Timer, Washer	Micropipettes 10µl, 200µl; Multichannel pipette for 50 and 100µl; disposable tips, Incubator; Reader, Measuring cylinder - 100 ml, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer	Micropipettes 10µl, 100µl; Multichannel pipette for 50 and 100µl; Incubator; Reader, Measuring cylinder - 1 L, Timer, Washer
Specific accessory reagents required	No	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	Distilled or deionized water	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	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8	2 - 8
Shelf life at recommended storage conditions	14 months	15 months	6 months	6 months	12 months	6 months	n.a.	6 months	6 months
Expiry date	18.02.2004	10.02.2004	01.05.2003	22.03.2003	21.05.2003	02.05.2003	22.04.2003	18.03.2003	30.04.2003
Stability/ robustness of packaging (2)	Very good	Very good	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.
Instructions for use in English	Yes	Yes	No	No	No	No	No	No	No
Clarity of labelling	O.K.	O.K.	O.K.	Labelling in Chinese, lot no., expiry date on package in English	Labelling in Chinese, lot no., expiry date on package in English	Labelling in Chinese, lot no., expiry date on package in English	O.K.	"Lot" and "Exp." printed on package, but not no. and date not shown;	Declaration of lot, exp. date on package not in English; no volume declaration on reagent bottles
Remarks									

**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