

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

Table 3 - Performance of the Test Kits Evaluated

Manufacturer (in alphabetic order)	Product Name	Method	Sensitivity Mean % (1)	Specificity % (2) [Using 181 members of Negative Panel]	Seroconversion Mean day delay
Acon Laboratories, Inc.	Acon HCV	Rapid	93.50	100.00	16.67
Adaltis Inc., Montreal, Canada	Detect-HCV	ELISA	99.50	99.45	16.67
Avicenna Medical Center, Russia	Anti HCV-EIA-Avicenna	ELISA	100.00	97.79	16.00
Beijing Goldenweikai Medical Biotechnology Co., Ltd.	Anti-HCV Ab EIA Kit	ELISA	100.00	100.00	22.67
Beijing Kinghawk Pharmaceutical Co., Ltd.	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	99.50	100.00	20.33
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HCV ELISA Anti-HCV Antibody ELISA Kit	ELISA	100.00	100.00	15.67
Bhat Bio-Tech India (P) Ltd.	Hepa-Scan Hepatitis C Virus Card Test	Rapid	91.50	100.00	14.67
Bhat Bio-Tech India (P) Ltd.	Hepa-Scan HCV ELISA	ELISA	91.50	100.00	23.67
Biocell Co., Ltd.	Anti-HCV Antibody ELISA Kit	ELISA	99.50	99.45	14.67
Biokit S.A.	bioelisa HCV	ELISA	99.50	100.00	15.67
Biotech Inc. under license of J. Mitra & Co. Ltd., New Dehli	HCV Tri-Dot (Rapid)	Rapid	99.50	100.00	26.00
Biotechnologitzeskaja Kompanija Bioservis	HepaScreen	ELISA	99.00	100.00	14.00
Centro Internacional de Investigacion y Adiestramiento Medico de la Universidad del Estado de Lousiana (LSU-ICMRT) Costa Rica	LSU-ICMRT EIA-Spep Screening Assay for Anti-HCV	ELISA	98.00	99.45	17.67
Dong-A Pharmaceutical Co., Ltd.	Dong-A HCV 3.0	ELISA	99.00	100.00	12.33
Fujirebio Inc., Tokyo	SERODIA-HCV	PA	100.00	100.00	14.00
GBI Biotech (Beijing) Co., Ltd.	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	100.00	100.00	17.67
General Biologicals (Tianjijin) Co. Ltd.	Anti-HCV EIA-96	ELISA	99.50	99.45	3.00
GreenCross Life Science Corp.	GENEDIA HCV Rapid	Rapid	96.50	99.45	20.67

Manufacturer (in alphabetic order)	Product Name	Method	Mean % (1)	Specificity % (2) [Using 181 members of Negative Panel]	Mean day delay
GreenCross Life Science Corp.	GENEDIA HCV ELISA 3.0	ELISA	99.00	100.00	17.33
GreenCross Life Science Corp.	GENEDIA HCV Rapid LF	Rapid	86.00	98.90	22.67
i+MED Laboratories Co., LTD. Thailand	i+Lab Anti-HCV Test	Rapid	22.50	100.00	30.33
IMBIO	Anti-HCV ELISA	ELISA	99.50	100.00	16.67
Institut Pastera Sankt-Petersburg	Anti-HCV ELISA-G	ELISA	100.00	N/A	16.67
InTec Products, Inc.	HCV ELISA Test Kit	ELISA	100.00	97.79	14.33
J. Mitra & Co. Ltd.	HCV Microlisa	ELISA	94.00	100.00	23.33
Laboratorium Hepatika Mataram	Entebe Anti HCV Dipstick	Rapid	95.00	100.00	14.67
LG Life Sciences, Ltd.	LG HCD 3.0 Plus 96T	ELISA	100.00	100.00	10.67
Medizinische Biologische Union	HCV- DCM	ELISA	99.50	99.45	17.67
MP Biomedicals Asia Ltd. (Genelabs)	Assure HCV Rapid Test	Rapid	99.00	100.00	20.50
NPP Akwapast	Immunoenzyme Test-System for Detection of Anti-HCV	ELISA	99.00	N/A	17.67
Radiopreparat	Anti-HCV ELISA	ELISA	98.00	100.00	17.33
Shanghai Feilong Medical Diagnostic Articles Co., Ltd.	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	100.00	100.00	7.67
Shanghai Fortune Long March-Trace Medical Science Co., Ltd.	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	99.00	98.90	22.67
Shanghai Rongsheng Biotech Co., Ltd.	QuickNow Anti-HCV Diagnostic Kit (ELISA)	ELISA	100.00	98.34	8.67
Shanghai SIIC Kehua Biotech Co., Ltd.	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	100.00	100.00	9.67
Sino-American Biotechnology Company (SABC)	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	ELISA	100.00	100.00	6.67
SPAN Diagnostics Ltd.	Signal HCV Flow Through Anti-HCV Spot / Immunodot Test Kit	Rapid	98.00	99.45	23.67
SPAN Diagnostics Ltd., marketed by Stimulus Specialty Diagnostics, Ltd.	Innova HCV ELISA Test Kit	ELISA	99.50	100.00	21.00
Tecnosuma International S.A.	Umelisa HCV 3ra Generacion	ELISA	99.00	100.00	17.67
Union-Diagnostisches-System	Anti-HCV ELISA	ELISA	99.50	99.45	13.67

Manufacturer (in alphabetic order)	Product Name	Method	Mean % (1)	Specificity % (2) [Using 181 members of Negative Panel]	Mean day delay
Vector-Best	RecombiBest anti-HCV- Strip (TMB)	ELISA	99.50	N/A	20.33
Vector-Best	RecombiBest anti-HCV- Strip (OPD)	ELISA	100.00	99.45	17.67
WAMA Diagnóstica	Imuno-RÁPIDO HCV	Rapid	99.50	98.90	14.67
Wiener Laboratories S.A.I.C.	Hepatitis C (anti-HCV) ELISA	ELISA	100.00	99.45	9.67
Xcyton Diagnostics Ltd. marketed by Qualigens Fine Chemicals	Hep-CheX C	ELISA	87.50	99.45	27.00
Zhongshan Bio-tech Co., Ltd.	HCV IgG ELISA Kit	ELISA	100.00	99.45	10.33
Abbott Co. & KG (3) (4)	Abbott HCV 3.0	ELISA	100.00	100.00	6.67
Ortho Clinical Diagnostics, Inc. USA (3)	Vitros Anti-HCV	ELISA	100.00	100.00	2.00
Ortho Clinical Diagnostics Inc. USA	Ortho HCV 3.0 with Enhanced SAVE	ELISA	100.00	100.00	4.67
Abbott Co & KG (3)	Abbott Architect Anti-HCV	ELISA	100.00	99.45	2.00
Bayer HealthCare LLC (3)	Advia Centaur HCV	ELISA	100.00	100.00	2.00
Abbott Co & KG (3)	AxSYM HCV 3.0	ELISA	100.00	100.00	2.00
Abbott Co & KG (3)	PRISM HCV	ELISA	100.00	100.00	4.67
Murex Biotech Ltd. (3)	Murex HCV version 4.0	ELISA	100.00	100.00	5.67

Notes:

N/A: Not available (quantity of test kits supplied were not sufficient to test)

PA; particle agglutination assays

(1) Using the ICBS HCV Positive Master Panel which is composed of 200 members distributed among all major known genotypes resourced by ICBS from varied geographic zones (See table 2-a).

(2) Specificity evaluated using only 181 samples which were verified for their negative status

(3) These assays are not part of the evaluation. Results are shown for comparison only.

(4) This assay is no longer produced by Abbott