InTec HCV Rapid Test Assay Evaluations

International Red Cross – Germany

Summary: The design, numbers and nature of samples analysed in this study are in compliance with the common technical specification (CTS) for list A of In Vitro Diagnostic Devices and therefore should be considered as a valid part of the CE certification requirements based on DIRECTIVE 98/79/EC. Different HCV genotypes are well detected by the Advance Quality Rapid Anti-HCV test.

Test	Sensitivity	Specificity
InTec Rapid Anti-HCV Test	**99.7%**	**99.8%**

INSERM / Paris –France

Summary: The InTec Rapid Anti-HCV Test is easy and rapid to perform. It uses only 10 µL sample volume, making it an ideal test for remote settings and the use of alternative matrices, such as fingerstick whole blood. Our results indicate that the Advanced Quality™ Rapid Anti-HCV Test RDT can be confidently used in its indications. **(S. Chevaliez, J M Pawlotsky) 396 subjects**, included in study: (i) 178 HCV-seropositive patients with chronic HCV infection (group A), all of whom had detectable anti-HCV antibodies (ii) 26 HCV-seropositive patients with resolved HCV infection, all of whom had detectable anti-HCV antibodies, and (iii) 192 HCV-seronegative individuals, with no detectable anti-HCV antibodies or HCV RNA. All HCV genotypes from 1-6 covered.

Test	Sensitivity	Specificity
InTec Rapid Anti-HCV Test	**99%**	**99%**

Onom Foundation – Mongolia

Summary: The InTec Rapid Anti-HCV RDT came second to OraSure in an extensive study involving 10 HCV RDTs in Mongolia. The study was performed under supervision of US CDC. Considering the high cost of OraSure device (x5 common device), we can make a claim that among those affordable tests, the InTec HCV RDT was number one in terms of performance and quality.

Test	Sensitivity	Specificity
Orasure (Serum)	100%	100%
InTec Rapid Anti-HCV Test	**100%**	**97.83%**
Abbott – Abon	100%	87.8%
Abbott – SD Bioline	98.9%	97.82%
Others (Pooled Average)	98.71%	95.86%

Hepatitis Network – Iran

Summary: In this study, **1788 inmates** were tested for hepatitis C antibody (HCV Ab) using HCV RDT on both finger stick blood and venous blood and results were compared with ELISA in an accredited laboratory. The overall results show InTec HCV RDT was able to detect all patients with sufficient antibody titres easily and efficiently. **Those border line samples not detected by InTec RDT and detected by ELISA, turned out to be PCR negative, non-viremic patients.**
Considering the facts above we conclude that InTec HCV RDT can effectively detect all patients who had adequate antibody immune response to HCV exposure and therefore can be used as a useful tool in screening in inmates in prison setting. **The results from finger-stick blood and whole blood were 100% concordant** (S M Alavian, H Sharafi)

Paul Ehrlich-Institute

Summary: Sensitivity of the InTec Anti-HCV rapid test was evaluated using 20 commercial HCV seroconversion panels. From these data it can be concluded that the sensitivity of the ADVANCED Quality Anti-HCV rapid test in early infection is similar to or even better than that of current CE-marked Anti-HCV screening tests. From this data set the conclusion can be drawn that the InTec HCV ADVANCED Quality rapid test detects early HCV infection at similar sensitivity as current Anti-HCV screening tests.

Comparator Assays: ADVIA CENTAUR Anti-HCV, ARCHITECT Anti-HCV Reagent Pack, INNOTEST HCV Ab IV, Ortho HCV 3.0 ELISA Test system with Enhanced SAVe, PRISM HCV, CHIRON RIBA HCV 3.0 SIA.