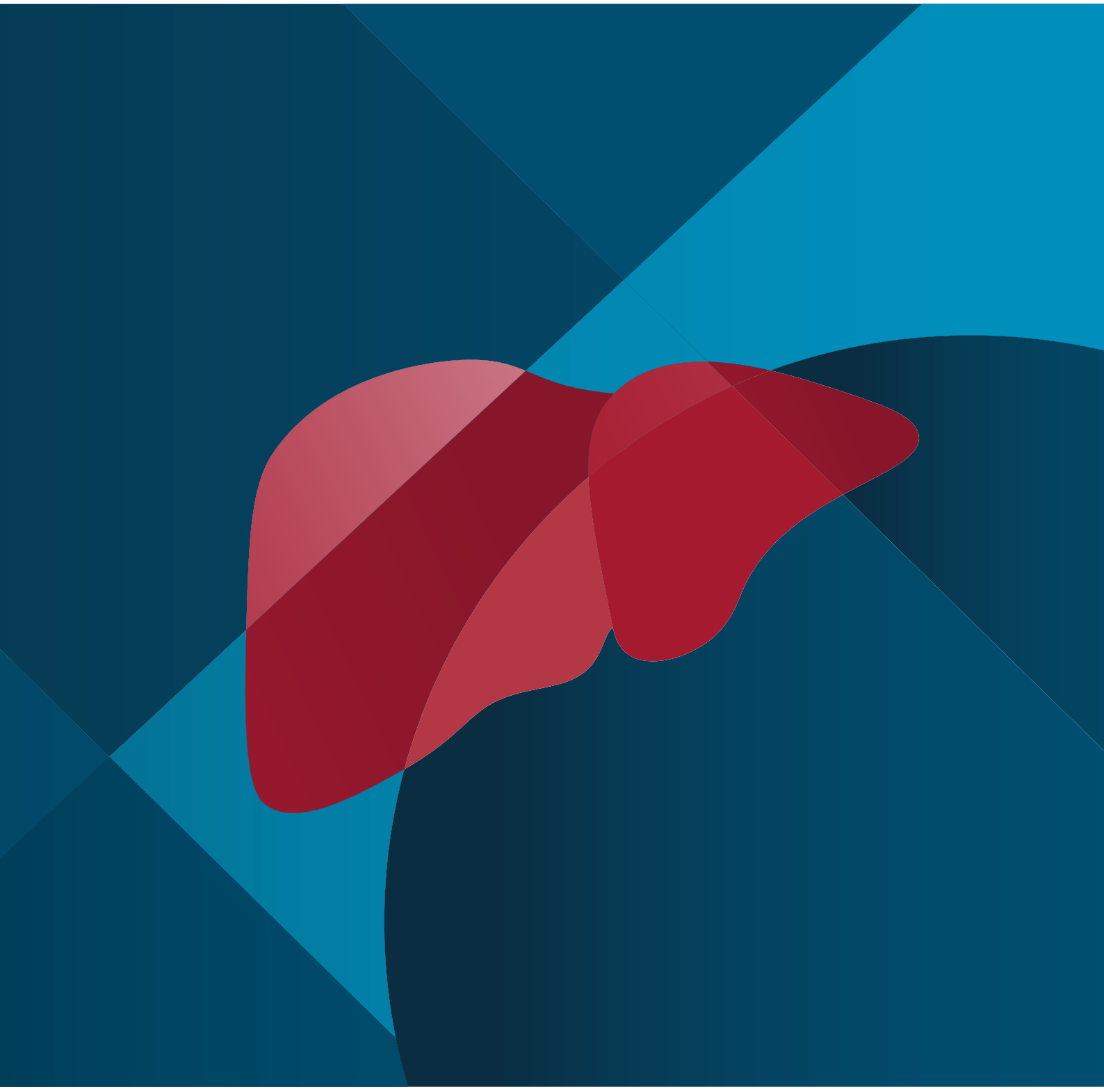
Unitaid
Innovation in Global Health



HEPATITIS C DIAGNOSTICS TECHNOLOGY LANDSCAPE

MAY 2019

This report was prepared by Cambridge Healthcare Research Limited (Cambridge, United Kingdom), in collaboration with Olawale Ajose, Cherise Scott, and Karin Timmermans (Unitaid). All reasonable precautions have been taken by the authors to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall Unitaid or the World Health Organization be liable for damages arising from its use.

HEPATITIS C DIAGNOSTICS TECHNOLOGY LANDSCAPE

MAY 2019

Abbreviations and acronyms

Ab	antibody
Ag	antigen
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
AST	aspartate aminotransferase
°C	degree Celsius
cAg	core antigen
cDNA	complementary DNA
CE-IVD	European Conformity-in vitro diagnostic certified
CIA	chemiluminescence assay
CLEIA	chemiluminescent enzyme immunoassay
CLIA	chemiluminescent immunoassay
cm	centimetre
CMIA	chemiluminescent microparticle immunoassay
CMV	cytomegalovirus
CPA	Cross Priming Amplification
CT/NG	*Chlamydia trachomatis/Neisseria gonorrhoeae*
DAA	direct acting antivirals
DBS	dried blood spot
DNA	deoxyribonucleic acid
ECL	electrochemiluminescense
EDTA	ethylenediaminetetraacetic acid
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay
FDA	Food and Drug Administration (United States)
fmol	femtomoles
g	gram
GSM	global system for mobile communications
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HPV	human papillomavirus
ID	identification
IFN	interferon

IgG	immunoglobulin G
IgM	immunoglobulin M
in	inch
IU	Standardized International Unit
IVD	in vitro diagnostic
kg	kilogram
kPCR	kinetic polymerase chain reaction
L	litre
LIMS	laboratory information management system
LiPA	line probe assay
LIS	laboratory information system
LLOD	lower limit of detection
LLOQ	lower limit of quantification
mL	millilitre
mm	millimetre
MRSA	methicillin-resistant Staphylococcus aureus
MTB	*Mycobacterium* tuberculosis
N/A	not applicable
NAT	nucleic acid-based test/nucleic acid amplification test
ng	nanogram
NS3	non-structural 3 region of the HCV genome
NS4	non-structural 4 region of the HCV genome
NS5	non-structural 5 region of the HCV genome
PCR	polymerase chain reaction
peg-IFN-riba	PEGylated-interferon-ribavirin
POC	point of care
qPCR	real-time polymerase chain reaction
QS	quantitative standard
RDT	rapid diagnostic test
RIBA	recombinant immunoblot assay
RIF	rifampicin
RNA	ribonucleic acid
RT	reverse transcriptase
RUO	research use only
SMS	short message service
SVR	sustained virological response
TB	tuberculosis
TBC	to be confirmed
TMA	transcription-mediated amplification
UPS	uninterruptible power supply
US$	United States dollar
US-IVD	United States-in vitro diagnostic certified
USB	universal serial bus
UTR	untranslated region (of the HCV genome)
µL	microlitre
WHO	World Health Organization

Contents

Introduction

The World Health Organization (WHO) estimates that in 2015, there were 1.75 million new hepatitis C virus (HCV) infections, bringing the total number of infected people to 71 million globally [*1*]. Most infections are caused by unsafe health-care procedures and injection drug use [*2*]. HCV infection is estimated to account for over 400 000 deaths each year [*2*], with most people being unaware that they are infected, resulting in HCV infection becoming known as the "silent pandemic" [*3*][*4*]. Due to the cost of testing and treating HCV, few individuals living in resource-limited settings have access to either.

Although generic versions of direct acting antivirals (DAAs) are now available in low-income settings, the use of DAAs is still limited [*5*][*6*]. It is hoped that the wider availability of DAAs will continue to reduce the cost and complexity of the HCV testing continuum, and reduce adverse events, ultimately improving patient outcomes. Genotyping may also not be required in areas where the epidemiological profile shows the presence of a single HCV genotype [*2*]. In addition, the arrival of pan-genotypic DAA regimens may further reduce, or even obviate, the need for genotyping, reducing the complexity and cost of HCV testing and ultimately expanding access to treatment.

Companies are still developing and improving methods to diagnose, genotype and monitor HCV viral load and as more diagnostic tests/platforms are introduced, it is hoped that access to testing for HCV patients, from screening through to cure, will be improved further. It is also important to highlight the nucleic acid-based/nucleic acid amplification tests (NATs) that are in development for a range of infectious diseases, for use at or near the point of care (POC), without the requirement for expensive laboratory infrastructure. These, in particular, promise to expand access to testing. In addition, there is a significant effort to develop HCV core antigen (HCV cAg) assays that could be used at the POC, and that could potentially be carried out effectively at a lower cost than NAT POC tests [*7*].

This report examines the range of platforms/tests currently available for HCV testing, from screening, to confirmation and genotyping, fibrosis staging and treatment monitoring. Finally, it reviews the progress of the pipeline of tests/platforms for HCV that are planned to be delivered at, or near, the POC.

Methodology and acknowledgements

The material in this landscape was gathered by the authors from publicly available information, published and unpublished reports and prospectuses, and interviews with developers and manufacturers. Photos appearing in this landscape were obtained directly from the manufacturer or from the manufacturer's publicly available website. Unless otherwise noted, the prices for diagnostic equipment and reagents cited in this report were obtained directly from manufacturers. The material is current through May 2018. In several cases, relevant devices in early stages of development were excluded from the report, following explicit requests by the developers.

This Hepatitis C diagnostics technology landscape was compiled by Cambridge Healthcare Research Limited, Cambridge, United Kingdom.

Comments and suggestions from the following reviewers are gratefully acknowledged: Philippa Easterbrook (World Health Organization), Emmanuel Fajardo (Médecins Sans Frontières), Francesco Marinucci (FIND), Rich Thayer (Halteres Associates), Mickey Urdea (Halteres Associates), Lara Vojnov (World Health Organization).

Disclaimer

Although all efforts have been made to ensure that the current report provides an accurate, clear and comprehensive overview of the HCV diagnostics landscape, some devices may not have been identified. In some cases, relevant devices in early stages of development were excluded from the report, on request of the developers.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by Unitaid.

Overview of types of HCV tests

Screening (serological testing)

Detecting HCV infection generally begins with serological testing to detect the presence of anti-hepatitis C virus (HCV) antibodies, HCV antigen, or both. Antibodies to HCV can be detected in the blood, usually within 2–3 months after infection with HCV [8]. Tests for detecting anti-HCV antibodies commonly include laboratory-based enzyme immunoassays (EIAs) or chemiluminescence assays (CIAs) or non-laboratory-based rapid diagnostic tests (RDTs). Antibody testing does not establish whether the patient is currently infected with HCV, since 15–45% of people spontaneously clear HCV infection, and anti-HCV antibodies persist throughout life in these individuals [9]. In addition, anti-HCV antibodies can show up in the blood of newborns, but do not necessarily mean that the newborn is infected with HCV, as most often these are the mothers antibodies that have been passed on to the baby before birth [10]. Therefore, antibody testing only identifies whether the person has at some point been exposed to HCV. As mentioned, antibody testing is also unable to detect recent infection, as the immune system may not yet have produced anti-HCV antibodies. Furthermore, a lowered immune response, for example, in someone coinfected with HIV, could lead to diminished antibody levels, thereby potentially preventing HCV infection from being detected by a serological test [11]. In many resource-limited settings, HCV often remains undiagnosed until a patient presents at a health-care facility with cirrhosis or hepatocellular carcinoma.

Confirmation of viraemic infection

It is estimated that 15–45% of people infected with HCV will clear the virus spontaneously, usually within 6 months of exposure [9]. These individuals remain HCV seropositive, while the remaining individuals go on to develop chronic HCV infection [12]–[15]. About 20–30% of those with persistent viraemia develop liver fibrosis and are at risk of cirrhosis, liver failure and hepatocellular carcinoma [16]. In HCV patients coinfected with HIV, these more serious conditions progress more rapidly, with cirrhosis onset approximately threefold sooner in coinfected patients [17]. Following an HCV seropositive test result, HCV infection should, therefore, be confirmed via a nucleic acid-based test/nucleic acid amplification test (NAT) for HCV RNA (either quantitative or qualitative).

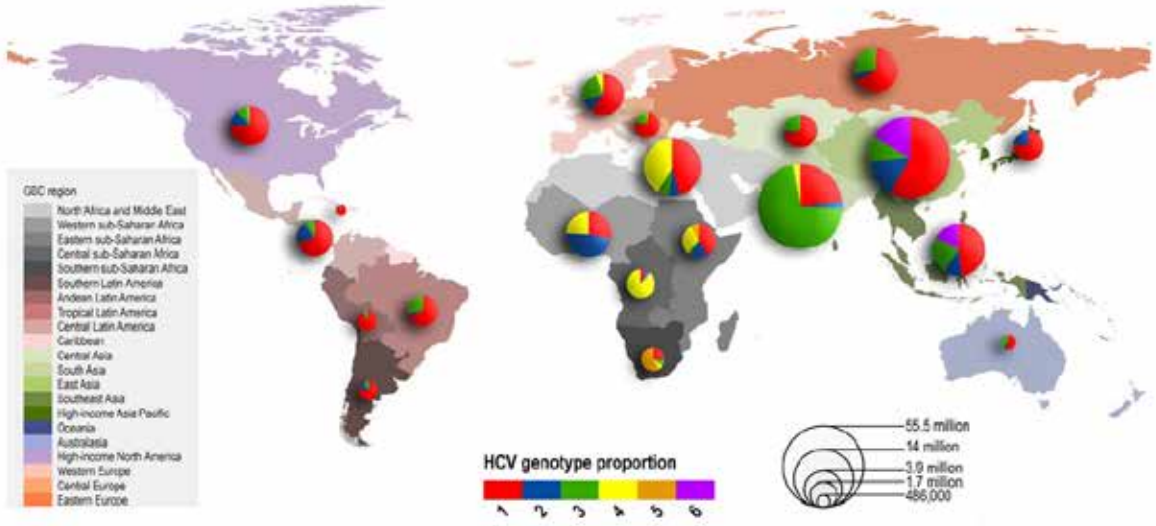
As access to NAT-based assays is restricted in resource-limited settings, HCV core antigen (HCV cAg) assays can be considered as an alternative to NATs for the diagnosis of viraemic HCV infection, especially where HCV cAg testing has been shown to have comparable clinical sensitivity to NAT technologies. The commercially available and pipeline NAT-

based assays for detecting and quantifying HCV RNA, as well as assays based on HCV cAg detection, are described in detail later in this report.

Genotyping

There are at least six major genotypes of HCV (genotypes 1 to 6), which can be divided into 67 subgroups, and there are significant geographical differences in the distribution of genotypes [18][19]. An overview of global trends of HCV genotype prevalence is portrayed in Figure 1 [20].

FIGURE 1.
PREVALENCE OF HCV GENOTYPES 1 TO 6 BY GLOBAL BURDEN OF DISEASE REGION



Note: Size of pie charts are proportional to the number of seroprevalent cases estimated by Hanafiah et al. [*21*].

Though the availability of pan-genotypic DAAs may significantly reduce the need for genotyping, determining the HCV genotype will still be important when pan-genotypic DAAs are not available or not recommended. Genotyping assays are based on four different technologies: real-time polymerase chain reaction (qPCR); line probe assay (LiPA); DNA chip; and DNA sequencing. These tests are expensive, complex and require well-resourced laboratories with well-trained and qualified staff. Although genotyping assays are reviewed in more detail later in this report, they are difficult to perform and currently not recommended for use in most resource-limited settings.

Assessment of the stage of liver disease

Assessing the degree of liver fibrosis is important for the clinical management of HCV-infected patients. Where necessary, patients with cirrhosis should be prioritized for treatment, as they have increased risk of hepatocellular carcinoma and liver failure. Additionally, the presence or absence of cirrhosis may influence the selection or duration of the treatment regimen [*2*][*22*][*23*]. Treatment of HCV infection should be commenced before the onset of decompensated disease, since medical management is more complicated and some HCV medicines can precipitate liver failure and death if administered at this point [*2*][*22*][23]. Although recent clinical trials showed that DAAs may be used in much later stages of liver fibrosis (e.g. liver cirrhosis) than IFN-based therapies [*24*], liver staging is a useful method to prioritize which patients most urgently require treatment, especially in resource-limited settings [*2*][*22*].

Generally, patients with less advanced fibrosis have more favourable treatment outcomes, as measured by increased, sustained virologic responses (SVRs), than those with more advanced fibrosis[1]. Liver biopsy has long been considered the gold standard for staging liver disease, but it is an invasive procedure and can have certain drawbacks that include: serious complications (pain, bleeding, possible perforation of other organs); sampling error; need for special expertise in interpreting results; and cost [*17*][*25*]. This has led to alternative ways to determine the extent of liver fibrosis by non-invasive means [*22*][*26*][27]. The World Health Organization (WHO) recommends using clinical criteria and/or non-invasive tests (NITs) [*2*]. Clinical criteria include: development of portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy); coagulation, or liver insufficiency (jaundice); and other features of advance liver disease/cirrhosis such as: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema, and oedema. In resource-limited settings, WHO recommends that aminotransferase/platelet ratio index (APRI) or FIB-4[2] be used for the assessment of hepatic fibrosis rather than other non-invasive tests that require more resources such as elastography or FibroTest (a six biomarker blood test). This recommendation was made on the assumption that liver biopsy was not a feasible option. WHO makes a recommendation for the use of FibroScan (i.e. a transient elastography test) where it is available and if it is not prohibitively expensive, as it is more accurate than APRI and FIB-4.

Assessment of HCV treatment response

Traditionally, it was recommended to regularly assess the response to treatment through detection of HCV viraemia/monitoring of HCV viral load levels using NATs [*28*][*29*]–[*31*]. This has become less necessary with the introduction of DAAs, due to the relative infrequency of viral breakthrough and because the rate of viral load decline does not correlate with SVR [*2*].

[1] For patients treated with peg-IFN-riba, SVR is generally defined as undetectable HCV load 24 weeks after the completion of therapy (HCV level below the LLOD [<50 IU/mL]) using first-generation viral load assays) [*116*]. For patients on triple-therapy regimens (peg-IFN-riba with either telaprevir or boceprevir), SVR is defined as an HCV RNA level of <25 IU/mL at 24 weeks after the end of treatment [*117*].

[2] APRI = [(AST (IU/L)/AST_ULN (IU/L))×100]/platelet count (109/L). FIB-4 = age (yr) x AST (IU/L)/platelet count (109/L) x [ALT (IU/L)1/2].

Additionally, viral load is undetectable after 4 weeks of treatment in most patients treated with DAAs. This is particularly important due to the high cost and relative unavailability of NAT testing for HCV RNA in lower-income settings [*28*].

Where ribavirin-containing or IFN-based regimes are used, viral load would be normally measured after 4 weeks of treatment to assess the efficacy of the treatment and to decide whether treatment should be stopped, or shortened. In addition, at 12 and/or 24 weeks after the completion of treatment, viral load is measured again to test for SVR [*28*].

HCV RNA testing can still be challenging in resource-limited settings, given the infrastructure, level of platform sophistication and trained personnel required to perform these tests on laboratory-based instruments [*28*]. In addition, the frequent visits to health facilities required by HCV patients on current treatment regimens are difficult in such settings, especially if testing cannot be substantially decentralized. This problem could be eased by commercially available point-of-care (POC) devices capable of carrying out HCV NATs.

Toxicity monitoring

Toxicity monitoring for HCV patients on treatment can be challenging in resource-limited settings. Basic chemistry testing (ALT and creatinine) is generally available in mid-level laboratory facilities; however, haematology testing, other than haemoglobin (e.g. complete blood count), can be difficult. The technology options available for multiparameter chemistry and haematology testing range from manual to semi-automated to fully automated low- and high-throughput laboratory-based instruments. Several low-volume, robust, automated technology analysers designed for low-end laboratories are widely available and are becoming the standard. Similarly, semi-automated spectrophotometers for chemistry analysis have been placed in some low-end laboratories although POC chemistry and haematology platforms/tests are not always available. Access to toxicity monitoring could be expanded by using the diagnostic platforms being rolled out for other infectious diseases such as HIV [*32*], but as DAAs are much safer, the complexity of monitoring for adverse events has been reduced [*22*]. Despite this, hepatotoxicity is a major adverse effect of first-line TB agents, and there is the concern that HCV and/or HIV coinfection could increase the risk of anti-TB agent drug-induced hepatotoxicity [*33*].

Considerations for selecting a diagnostic platform

An HCV serological assay (antibody or antibody/antigen) using either RDT or laboratory-based immunoassay formats (EIA, ECL or CLIA) that meets the required minimum safety, quality and performance standards is recommended to test for serological evidence of past or present infection in adults and children (>18 months of age[3]) [*2*]. Although there are no minimum performance criteria for either EIAs or RDTs, and false-negative HCV antibody tests have been reported in HIV-infected people who are often seronegative with HCV infection, RDTs are still an important means of testing for HCV infection, performing reasonably well when used correctly and at relatively low cost [*2*][*34*]–[*37*]. In addition, WHO recommends that any assay should meet the performance criteria for stringent regulatory authorities [*2*]. Since chemistry and haematology testing is generally regimen based in HCV care, and because there are already several technologies available for use at the POC, these tests are not considered in detail in this report. Similarly, both biomarker testing and non-invasive testing are available for fibrosis staging. Of the remaining tests currently required in the continuum of testing for HCV, the tests that are likely to present the most persistent access challenges currently are genotyping tests (to the extent they continue to be necessary under available treatment regimens), confirmatory testing and monitoring for HCV treatment efficacy and cure. Increasing the availability of high-quality POC technologies for these tests, as well as POC screening tests, has the greatest potential to improve HCV diagnosis and treatment monitoring [*2*].[4] This report focuses on RDTs for screening of HCV, genotyping platforms/assays and molecular and antigen testing for both confirmation of HCV and treatment monitoring.

[3] HCV infection can be confirmed in children under 18 months only by virological assays to detect HCV RNA, because transplacental maternal antibodies remain in the child's bloodstream until 18 months of age, making test results from serology assays ambiguous.

[4] A systematic review assessing the impact of POC CD4 testing on linkage to HIV care identified that POC testing significantly increased the likelihood of a person having their CD4 count measured and receiving a result. Time to being tested was also significantly reduced by a median of 9 days. Evidence for increased treatment initiation was mixed [*118*]. Self-testing has increased the uptake of HIV testing in people not reached by other existing HIV testing services, thus this type of testing could potentially also have a significant impact on people with HCV [*119*] [*120*].

The report examines: (i) the laboratory-based and/or POC or near-POC platforms currently available; and (ii) the laboratory-based and POC technologies needed or in the pipeline for each test category.

Laboratory-based testing in resource-limited settings

The clear majority of tests available today in resource-limited settings, other than disposable rapid tests, were created for high-income settings, where laboratory-based diagnostics are operated by well-trained technicians on sophisticated instrumentation that is expensive, often run in standard high-throughput formats (such as 96-well formats) and require dedicated laboratory infrastructure. Additionally, these instruments rely on a complex medical infrastructure that requires extensive sample transport networks to collect samples from multiple hospitals and clinics. These systems also rely on complex patient tracking mechanisms, which enable doctors and hospitals to return results to patients within days. Generally, these platforms require additional investment to be adapted for low-resource settings, where access, cost, infrastructure, environmental factors, supply chain logistics and issues such as "lost to follow-up"[5] are significant barriers to increasing case detection rates. In addition, there are many settings where high-throughput platforms will not be required.

Laboratory infrastructure

Many of the HCV testing platforms described in this report are laboratory based and most require infrastructure such as continuous power and climate control/air-conditioning. For example, some laboratory-based HCV viral load platforms based on nucleic acid technology may require multiple dedicated rooms in a laboratory.[6] Each room should have minimal dust and preferably would be temperature controlled (air-conditioned in hot climates and heated in cold climates). The rooms would be needed to accommodate the different stages of the testing process: Room 1 would be dedicated to receipt of the patient sample and sample extraction (most of which is done in a biosafety cabinet). Room 2 (which could be reduced to a Clean-Air Box in Room 1, if space is limited) would be used to prepare the reagents, which are prone to contamination. Finally, Room 3, which may become contaminated through the test process, would be dedicated to amplification and detection of the virus and results processing. To avoid contamination, workflow should proceed from Room 1 to Room 2 to Room 3. Each room would need to have sufficient dedicated bench space. Furthermore, test reagents requiring cold storage would need to be kept at between 4 °C and 8 °C. And, as mentioned above, a steady current would be required so that the electrical test equipment is not damaged.

[5] It should be noted that "lost to follow-up" is not unique to low-resource settings.

[6] For example, the Roche Molecular Diagnostics COBAS® AmpliPrep/COBAS® TaqMan® platform requires one room; the Abbott *m*2000 requires two rooms. Newer NAT platforms under development typically require only a single room.

Sample transport networks and the use of dried blood spot

Many HCV tests described in this report require venous blood collection, processing (centrifuging) of that blood to obtain plasma or serum within a certain timeframe and cold-chain storage of specimens by trained personnel. Given the complexity of many HCV test platforms, especially those used for genotyping and for qualitative and quantitative detection of HCV RNA, such testing is currently carried out in more advanced laboratories, which are often not available in resource-limited settings, although POC technologies in the pipeline have the potential to change this. However, currently, this means that patient samples must be transported from urban, peri-urban and rural settings to the laboratory for processing. This is done using sample transport networks in-country, taking advantage of courier or similar services to take samples to the laboratory and to return results at a later time point. But, frequently, inefficiencies lead to lengthy delays in returning sample results to patients and lead to patients being lost to follow-up. Therefore, the ability to use dried blood spot (DBS) samples for HCV testing performed at central laboratories is an important consideration in the implementation of the testing because it greatly simplifies the transport of samples, providing enhanced stability and ease of use for health-care workers. The use of DBS may reduce the costs associated with sample collection, storage and transportation, staff costs by facilitating task-shifting to lay workers, and by allowing batch testing in a centralized laboratory [*28*].[7] In addition, as has been demonstrated in Uganda by the adoption of this model for DBSs for early infant HIV diagnosis, improved mapping of hub-and-spoke transport systems for facilities can help to greatly improve efficiencies and turnaround times [*38*]. In this model, the "hub" is a central health facility serving as a central specimen collection point for multiple referring sites termed "spokes", and then from the hub, specimens are transported to a central laboratory for testing; as such, for this model to work, hubs, spokes and testing laboratories must be optimally mapped by geographic information systems to give the shortest feasible distances and reduce delivery times. Innovative technologies such as results reporting mechanisms (SMS printers, information and communications technologies) as well as sample preservation media are also starting to play an important role in helping to strengthen these networks.

Updated systematic reviews and meta-analyses have been carried out to assess the diagnostic accuracy and impact of using DBS specimens, compared with venous blood specimens, for HCV serological testing and NAT. Eighteen studies were included for HCV antibody [*39*]–[*56*] and nine studies for HCV RNA [*42*][*52*][*53*][*57*]–[*62*] the results of which are shown in Table 1. A number of studies stored DBS specimens at room temperature, and although these storage conditions did not affect accuracy and HCV RNA could still be detected, quantitative signals were reduced over time in two of the studies [*42*][*57*].

[7] DBS involves the transfer of fingerstick or heelstick blood to chromatography paper. The sample is dried and sent to a laboratory where RNA can be extracted from the sample and tested for the presence of HCV infection. Processing dried blood samples can be laborious, and several machines are available to automate the extraction process.

TABLE 1.

Summary of diagnostic performance of DBS specimens for serological and NAT testing

	DBS for anti-HCV	DBS for HCV RNA
No. of included studies	18 (SR), 14 (meta-anal)	9 (SR & meta-anal)
Total sample size	4524	1250
Overall pooled sensitivity (95% CI)	98% [94-99]	96.0% [93.4-97.6]
Overall pooled specificity (95% CI)	99% [97-100]	97.7% [94.7-99.0]
Impact of storage	Storage at -20 °C associated with less variation compared to RT	Better result at -20 °C compared to RT; conflicting results re deterioration of sample at RT
Impact of duration of storage	Accuracy not affected if RT for ≤3 days (1 study) or ≤6 days (another study) or ≤60 days (another study)	Conflicting results re deterioration over time

DBS: dried blood spot; meta-anal: meta-analysis; RT: room temperature; SN: sensitivity; SP specifity; SR: systematic review

[1]HBV DNA testing is not recomanded for ruling out HBV infection if HBsAg is positive. HBV DNA detection can be used to explore occult HBV infection in persons testing for HBaAg. A large proportion of HBV-infected persons have a low HBV replication level (inactive carriers).

Source: Adapted from Guidelines on hepatitis B and C testing 2017 [*2*].

The latest WHO recommendations state that DBS specimens for HCV antibody serological testing[8] may be considered in certain settings including: where there are either no facilities or expertise to take venous or whole blood specimens; or where quality RDTs are not available or their use is not feasible; or the patient has poor venous access (e.g. drug treatment programmes or prisons). Use of DBS to test for viraemic HCV infection may be considered where: there is a lack of access to sites or nearby facilities for NAT testing; or timely delivery of specimens to a laboratory for testing is not possible; or where a person has poor venous access [*28*]. The guidelines development group [*28*] did not make a recommendation for the use of DBS specimens to assess response to treatment due to the lack of suitable studies in the literature. Preliminary evidence does suggest that DBS could be used for this purpose [*28*].

Placement and setting of diagnostics

Given that testing access, cost, infrastructure, environmental factors, supply chain and other issues such as “loss to follow-up” are significant barriers to increasing case detection rates and treatment in resource-limited settings, it is generally believed that the introduction of appropriate, robust POC diagnostics for HCV can improve access to testing in developing

[8]A well-functioning laboratory specimen referral network and system for return of results should be in place to maximize the impact of DBS specimens. There are currently few assays where the manufacturer’s instructions state that DBS specimens are validated for use. Therefore, current use of DBS specimens would be considered “off-label”, unless otherwise noted in the package inserts.

countries. Due to the requirement of nucleic acid amplification to detect HCV RNA to confirm whether a person has active HCV infection, complex devices have typically been required. Reliable, accurate, practical and affordable near-patient tests will be vital to expand HCV testing so that anyone requiring treatment can be identified, particularly in low-income settings. POC technologies for viral HCV include emerging highly portable NAT-based tests for diagnosis and monitoring. These devices are capable of performing qualitative and quantitative molecular testing outside of the conventional laboratory setting. They tend to be easier to use than laboratory-based NAT assays as they are highly automated and require minimal training. Ideally, they can be operated on either battery or conventional power sources and do not require phlebotomy. Typically, a result can be acquired within 1–2 hours, but may take 1 day with sample queuing. This technology includes cartridge-based HCV RNA assays, which can be used with existing diagnostic platforms for HIV or TB. HCV cAg POC platforms are also in development, offering the potential of more rapid infection diagnosis,[9] alone or when combined with an HCV antibody RDT. In addition, NAT platforms with improved turnaround times are also in development.

In this report, the setting of use for each of the technologies, both laboratory based and those intended for use at, or near, the point of patient care, is considered. There are several laboratory-based technologies for HCV that are suited only for higher-level facilities; on the other hand, POC technologies may be used at all laboratory levels. It is important that countries review the operational characteristics of diagnostic platforms/devices when selecting which platforms to implement and at which level of the laboratory system to implement them.[10] These characteristics include the following: type of technology (including whether for laboratory or POC) and output (sensitivity and specificity);[11] throughput and turnaround time; sample required; protocol complexity; reagent stability; cost of instrumentation and cost per test for reagents; instrumentation power supply; if instrument based, the size of the instrument; supplies required from parties other than the manufacturer of the instrument/test (e.g. vortex, pipettes, etc.); connectivity options; training required, environmental conditions, service and support network, need for internet for system monitoring/calibration/maintenance, and other factors.

These operational characteristics are set out in Appendix 1 for each of the platforms currently available for HCV viral load testing, and where sufficient information is available from the developer, for platforms in the pipeline.[12]

In addition to the operational characteristics of the various platforms/devices, it is also important to consider the performance of the platform, i.e. the ability of the technology to give accurate and reproducible results. Both the sensitivity and specificity of a quantitative test should be evaluated.[13] Platform performance is a significant driver in impact and health economic modelling, which is used to help justify purchase and use of these technologies.

[9] Same-day diagnosis, while desirable, is not always possible, as it usually takes approximately 2 hours to run samples and there is often a wait before samples can be processed, so the result may not be ready until the next day. In addition, frequently more than one test is ordered on the same patient and results are held and reported back only when the last result is available for the complete panel of tests ordered. Given batching/throughput/time to result and other factors that can vary across systems and assay types, this can lead to very significant reporting delays.

[10] It is also important that assays are selected that can be run on existing available equipment in the geographical setting.

[11] See Appendix 3 for more details on sensitivity and specificity.

[12] Operational charact eristics for pipeline technologies are not necessarily final.

[13] Note, however, that for a qualitative test, e.g. RDTs for HCV, accuracy and precision are not the relevant measures. Rather, sensitivity and specificity, as well as negative/positive predictive values, are needed.

Screening tests for HCV

Serological assays

Serology-based assays for screening of HCV infection can detect the presence of anti-HCV antibodies, HCV antigen, or both simultaneously. The testing platforms include EIAs, CIAs and RDTs.

EIA- and CIA-based tests

The test principle in EIAs and CIAs is the same, but end-point detection in EIAs is measured as colour change or fluorescence, whereas in CIAs, chemiluminescence is measured. Both EIAs and CIAs can detect HCV antibody (anti-HCV IgG) in serum or plasma. An overview of available technologies is presented in Table 2.

Over the years, improvements in the performance of HCV assays, particularly of EIAs, have been delineated as "generations" of the assays. First-generation assays were based on a yeast-expressed recombinant protein containing an epitope from the NS4 region of the HCV genome and detected antibodies about 12–26 weeks following exposure, creating a long window period of "acute" infectivity prior to seroconversion. First-generation EIAs had both poor sensitivity and specificity [*63*]. Second-generation EIAs incorporated two more epitopes, one each from the core antigen and a non-structural HCV antigen (NS3). These assays reduced the window period of infectivity observed in first-generation assays and permitted HCV antibodies to be detected between 10 and 24 weeks after exposure. Finally, third-generation EIAs incorporated an additional antigen from the non-structural HCV antigen (NS5) and further reduced the window period of infectivity by about 1 week compared with second-generation EIAs [*64*].

Several EIA assays are available for use as in vitro diagnostics (IVDs) for HCV screening, the details of which are included in Appendix 1. There are also several companies providing enhanced CIAs. CIAs and third-generation EIAs have been reported to have similar sensitivity and specificity [*65*]. In addition to the antibody-only tests, combination fourth-generation antigen-antibody EIAs for detection of HCV have also been introduced. These fourth-generation assays detect two markers of the same infection simultaneously; antibodies produced by the immune response to the virus and antigens from the virus

itself, whereas previous generations detected only antibodies. Although these assays are not as sensitive as HCV antigen-specific assays, they have demonstrated improved sensitivity over HCV Ab-only assays for the detection of HCV infection, especially in the window period, when antibodies are undetectable [*66*]–[*68*] . Although these combination assays are laboratory based and not ideally suited to resource-limited settings, it has been suggested that they could be a reasonable alternative for blood screening or detection of HCV when a NAT cannot be used for reasons such as affordability, feasibility, emergency or logistical challenges [*66*][*69*]. Despite the availability of fourth-generation EIAs, and CIAs, and the fact that the specificity of EIA assays is reported to be greater than 99% in high-risk populations [*70*], low- and middle-income settings may still rely on less specific, older but more affordable technologies.

Fourth-generation EIAs that can detect HCV antigen (p22) as early as 2-weeks post-infection as well as the antibodies that appear later, offer superior sensitivity and are now widely available in high-income settings [*71*]. With all generations of tests, both false-positive and false-negative results are possible. False-positives are more likely to occur when testing in low-prevalence HCV settings; false-negatives are more likely to occur in the presence of HCV-HIV coinfection [*70*][*34*].[14]

[14]In addition to EIAs, more specific supplemental tests for anti-HCV, namely recombinant immunoblot assays (RIBA), were developed to deal with false positives, particularly in low-prevalence settings. However, in resource-limited settings, reflex testing using RIBA was not widely implemented due to assay complexity, long turnaround time of test results and cost. In addition, because the specificity of third-generation EIAs is quite high, and given the availability of very sensitive and specific NAT, the role of such assays virtually disappeared, and in 2013 the licensed manufacturer of the RIBA notified the FDA that its production had been discontinued [*25*] [*121*].

TABLE 2.

Serological tests available for HCV screening

Company	Name of test (device)	Sample type	Storage temperature (°C)	Test type	Test target	Regulatory status
Abbott Diagnostics*	PRISM HCV assay (Abbott PRISMnEXT)	Serum, plasma	2–8 and 15–30	CIA	HCV Ab	FDA approved CE marked
Abbott Diagnostics*	AxSYM HCV3.0 (AxSYM Plus 5.0)	Serum, plasma	2–8	EIA	HCV Ab	FDA approved CE marked
Abbott Diagnostics*	ARCHITECT Anti-HCV (Abbott ARCHITECT i System)	Serum, plasma	2–8	CMIA	HCV Ab (IgG and IgM)	FDA approved CE marked
AccuBioTech Co. Ltd	Accu-Tell® HCV ELISA Test Kit	Serum, plasma	2–8	EIA	HCV Ab	TBC
Autobio Diagnostics	Anti-HCV	TBC	TBC	EIA	HCV Ab	IVD
BHAT Biotech India	Hepa-Scan® HCV ELISA	Serum, plasma	2–8	EIA	HCV Ab	CE marked
Biokit S.A.*	Bioelisa HCV 4.0	Serum, plasma	2–8	EIA	HCV Ab	CE marked WHO prequalified
Bio-Mérieux*	VIDAS® Anti-HCV	Serum, plasma	TBC	EIA	HCV Ab	CE marked
Bio-Rad Laboratories*	Monolisa® Anti-HCV PLUS Assay Version 3	Serum, plasma	2–8	EIA	HCV Ab	CE marked
Bio-Rad Laboratories*	Deciscan® HCV PLUS	Serum, plasma	2–8	Immuno-blot	HCV Ab	CE marked
Bio-Rad Laboratories*	Monolisa® HCV Ag-Ab ULTRA V2 Assay	Serum, plasma	2–8	EIA	HCV Ab and capsid Ag	CE marked
Biosynex*	recomLINE® HCV IgG	Serum, plasma	2–8	Immuno-blot	HCV IgG	CE marked
CTK Biotech*	RecombiLISA HCV Ab ELISA Test	Serum, plasma	TBC	EIA	HCV Ab	TBC
CTK Biotech*	RecombiLISA HCV IgG ELISA test	Whole blood, serum, plasma	TBC	EIA	HCV IgG	TBC
Cypress Diagnostics*	Anti-HCV test	Serum, plasma	2–8	EIA	HCV Ab	TBC
DIALAB	HCV Ab sensitive	Serum, plasma	2–8	EIA	HCV Ab	CE marked
DiaSorin	Murex anti-HCV	TBC	TBC	EIA	HCV Ab	CE marked WHO prequalified
DiaSorin	Murex HCV Ag/Ab combination	TBC	TBC	EIA	HCV Ag/Ab	CE marked
Fujirebio	INNOTEST® HCV Ab IV	Serum, plasma	2–8	EIA	HCV Ab	CE marked
Fujirebio	INNO-LIA HCV Score	Serum, plasma	2–8	EIA–LIA	HCV Ab	CE marked WHO prequalified
Green Cross Medical Science Corp.*	HCV EIA 3.0	Serum, plasma	TBC	EIA	HCV Ab	TBC
HUMAN Diagnostics Worldwide	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno)	Serum, plasma	TBC	EIA	HCV Ab	CE marked
InTec® Products Inc.	HCV Elisa Test Kit	Serum, plasma	2–8	EIA	HCV Ab	CE marked

Company	Name of test (device)	Sample type	Storage temperature (°C)	Test type	Test target	Regulatory status
J. Mitra & Co Pvt. Ltd	HCV Microlisa	Serum, plasma	2–8	EIA	HCV Ab	RUO
Maccura	anti-HCV	Serum, plasma	2–30	CIA	HCV Ab	Chinese FDA
MP Diagnostics*	HCV BLOT 3.0	Serum, plasma	2–8	EIA	HCV Ab	CE marked
MP Diagnostics *	HCV ELISA 4.0	Serum, plasma	2–8	EIA	HCV Ab	CE marked
Ortho-Clinical Diagnostics*	Anti-HCV (VITROS® ECi/ECiQ)	Serum, plasma, urine, amniotic fluid, blood	2–8	Enhanced CIA	HCV Ab	FDA approved
Ortho-Clinical Diagnostics*	Anti-HCV (VITROS® 5600)	Serum, plasma, urine, amniotic fluid, blood	2–8	Enhanced CIA	HCV Ab (IgG)	FDA approved
Ortho-Clinical Diagnostics*	Anti-HCV (VITROS® 3600)	Serum, plasma, urine, amniotic fluid, blood	2–8	Enhanced CIA	HCV Ab (IgG)	FDA approved
Qualpro Diagnostics	Qualisa™ HCV	Serum, plasma	2–8	ELIA	HCV Ab	RUO
Qualpro Diagnostics	Electra™ HCV	Serum, plasma	2–8	CLIA	HCV Ab	RUO
Roche Molecular Diagnostics*	Elecsys® Anti-HCV II Immunoassay and Elecsys® PreciControl Anti-HCV (COBAS® e 411/601/602, MODULAR ANALYTICS E170, Elecsys® 2010)	Serum, plasma	2–8	ECLIA	HCV Ab	FDA approved CE marked
Siemens Healthcare Diagnostics	Enzygnost® Anti-HCV 4.0 (BEP® III System, BEP® 2000 Advance® System, Quadriga BeFree® System)	Serum, plasma	2–8	EIA	HCV Ab (IgG and IgM)	FDA approved CE marked
Standard Diagnostics Inc.*	SD HCV ELISA 3.0	Serum, plasma	2–8	EIA	HCV Ab (IgG)	TBC
Sysmex*	Automated Immunoassay System HISCL-5000/HISCL-800 (compact analyser)	TBC	TBC	CIA	HCV Ab	TBC

*Details not confirmed by the manufacturer.

Rapid diagnostic tests (RDTs)

Despite the accuracy and availability of anti-HCV tests, EIAs and CIAs generally require specialized instrumentation (e.g. incubators, mechanical washing, optical reading devices) and well-trained laboratory technicians. While these tests may be implemented by most laboratories in intermediate referral facilities, the tests are relatively expensive and do not provide same-day results. Given the limitations of EIAs and CIAs, and the need for more timely testing and provision of HCV results, rapid diagnostic HCV tests have been developed. There are several HCV RDTs available, which use immunochromatography, immunofiltration or agglutination principles to detect the presence of anti-HCV in the test

specimen. The testing process begins by mixing a specimen (whole blood, plasma, serum or oral fluid) with a developing solution such as colloidal gold labelled with protein-A [*72*]. Some tests require the mixing step to be done before adding the specimen to the device, while others allow the direct addition of the specimen to the RDT. The device contains an absorbent membrane, which contains immobilized HCV antigens (such as core, NS3 and NS4 antigens) in the test area of the assay. As the sample fluid moves through the test area, a coloured line or dot appears if anti-HCV antibodies from the sample react in the test area. Tests also have an internal control area, which contains a monoclonal antibody and confirms that the test sample has adequately passed through the test area by showing another coloured line or dot [*73*]. If there is no coloured control line or dot, then the test is invalid. If there is only a control line or dot, then the test is valid and negative. Some HCV RDTs require serum or plasma samples (Table 3). This means that a centrifuge may be required to separate plasma or serum from the patient blood specimen before testing (although other methods are available such as size exclusion membranes and filtration devices) [*74*]. Some of the RDTs also require cold-chain storage of test kits. However, equipment for plasma separation, refrigerators and electricity may not be available in resource-limited settings, particularly at the POC. What is most needed in such settings are RDTs that use capillary blood or oral fluid specimens and require no electricity or cold-chain storage. There are a number of such assays available for HCV screening on the market. Table 3 lists some of these HCV RDTs, along with their basic specifications.

TABLE 3.

RDTs available for HCV screening

Company	Name of test	Sample type	Storage temperature (°C)	Test type	Regulatory status
ABON Biopharm*	HCV antibody test product	Whole blood, serum, plasma	4–30	Chromatographic immunoassay	CE marked
AccuBioTech Co. Ltd*	Accu-Tell® Rapid serum/ whole blood Anti-HCV Test	Whole blood, serum	2–30	Immunochromatographic	TBC
Alfa Scientific Designs*	Instant-view™ HCV serum Test	Serum, plasma	15–30	Chromatographic immunoassay (lateral flow)	CE marked
ALL.Diag/ BioSynex*	HCVTOP™	Serum, plasma	2–30	Chromatographic immunoassay	CE marked
Artron Laboratories*	HCV antibody test	Whole blood, serum, plasma	TBC	TBC	CE marked
Artron Laboratories*	Artron Detect 3 HIV/HCV/ HBV combo test kit	Serum, plasma	TBC	TBC	TBC
AT First Diagnostics**	HCV Rapid test – CE strip or cassette	Whole blood, serum, plasma	TBC	Chromatographic immunoassay	TBC
Atlas Link	One Step HIV/HBsAg/ HCV	Serum	2–30	Immunochromatographic	CE marked
Atlas Link*	One Step HCV test strip/ cassette	Serum	2–30	Immunochromatographic	TBC

Company	Name of test	Sample type	Storage temperature (°C)	Test type	Regulatory status
Atlas Link*	One Step HCV test strip/ cassette	Whole blood	2–30	Immunochromatographic	TBC
Autobio Diagnostics Co. Ltd*	Anti-HCV rapid test	TBC	1–30	Colloidal gold sandwich assay (cassette/strip)	IVD
Axiom Diagnostic*	HCV Card serum/plasma test	Whole blood, serum, plasma	TBC	TBC	CE marked
BHAT Biotech India	HEPA-SCAN® HCV Rapid Card Test	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	CE marked
Bionike**	Advanced Quality™ One Step HCV Test	Serum, plasma	2–30	Chromatographic immunoassay	TBC
BioSynex*	IMMUNOQUICK® HCV	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	CE marked
BioSynex*	Triplex HIV/HCV/HBsAg	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	TBC
Boditech*	ichroma™ – HCV cartridge	Whole blood, serum, plasma	4–30	Chromatographic immunoassay (with automatic reader)	CE marked
Boditech*	AFIAS – HCV cartridge	Whole blood, serum, plasma	4–30	Chromatographic immunoassay (with automatic reader)	CE marked
Boson	HBsAg/HIV/HCV Panel Test	Whole blood, serum, plasma	4–30	Immunochromatographic	Chinese FDA
Boson*	HCV Antibody Self Test Kit	Whole blood, serum, plasma	4–30	Immunochromatographic	TBC
Boson*	HCV Antibody Test Strip/ Card	Whole blood, serum, plasma	4–30	Immunochromatographic	TBC
Core Diagnostics*	ImmunoFlow HCV	Serum	4–30	Chromatographic immunoassay	CE marked
Core Diagnostics*	CoreHCV	Serum	4–30	Sandwich immunoassay	TBC
Core Diagnostics*	Core Combi HIV-HBsAg-HCV	Whole blood, serum, plasma	TBC	Sandwich immunoassay	TBC
CTK Biotech*	OnSite HCV Ab Plus Rapid Test	Serum, plasma	4–30	Chromatographic immunoassay	TBC
CTK Biotech*	HBsAg/HCV Ab Rapid Test	Whole blood, serum, plasma	TBC	Chromatographic immunoassay	TBC
CTK Biotech*	Recombinant HCV Core-NS3-NS4-NS5 Fusion Antigen	Serum, plasma	TBC	Chromatographic immunoassay	RUO
Cypress Diagnostics*	Anti HCV Card/Strip	Serum, plasma	10–30	Immunochromatographic assay	TBC
DIALAB	Diaquick HCV Ab Cassette	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	CE marked
Euro Genomas*	HCV rapid test (strip)	Whole blood, serum, plasma	TBC	Chromatographic immunoassay	CE marked
Euro Genomas*	Rapid HBsAg/HCV/HIV/ Syphilis Combo Test (Cassette)	Serum, plasma	TBC	Chromatographic immunoassay	CE marked

Company	Name of test	Sample type	Storage temperature (°C)	Test type	Regulatory status
Euro Genomas*	HBsAg/HCV Combo Rapid Test (Cassette)	Serum, plasma	TBC	Chromatographic iimunoassay	CE marked
EY Laboratories	HCVSCAN	Serum, plasma	2–8	Chromatographic immunoassay	TBC
Fujirebio	SERODIA®-HCV	Serum, plasma	2–10	Particle agglutination test	RUO
Genelabs Diagnostic**	TBC	TBC	TBC	TBC	TBC
Guangzhou Wondfo Biotech*	HCV rapid test	Whole blood, serum, plasma	Room temperature	Chromatographic immunoassay	TBC
Green Cross Medical Science Corp.*	Genedia HCV Rapid LF	Whole blood, serum, plasma	2–30	Immunofiltration	TBC
Hangzhou Biotest Biotech*	RightSign HCV Test Cassette	Serum, plasma	TBC	TBC	CE marked
Hangzhou Biotest Biotech*	RightSign HCV Test Cassette	Whole blood, serum, plasma	TBC	TBC	TBC
HUMAN Diagnostics Worldwide	Hexagon HCV	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	TBC
Intec® Products Inc.	Advanced Quality™ Rapid Anti-HCV test	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	CE marked
Jal Innovation	iCARE Multi-STD Diseases (HBsAg/HCV/ HIV/TP) Rapid Screen Test	Whole blood, serum, plasma	2–30	Immunochromatographic assay	TBC
Jal Innovation	iCARE One Step Anti-HCV Rapid Test	Whole blood, serum, plasma	2–30	Immunochromatographic assay	TBC
J. Mitra & Co Pvt Ltd*	Diagnos HCV Bi-Dot	Serum, plasma	2–8	Immunofiltration	TBC
J. Mitra & Co Pvt. Ltd*	HCV TRI-DOT	Serum, plasma	2–8	Immunofiltration	TBC
Laboratorium Hepatika Mataram**	TBC	TBC	TBC	TBC	TBC
Lumiquick Diagnostics*	Quick Profile™ HCV Ab Test Strip or Card	Whole blood, serum, plasma	TBC	Chromatographic immunoassay	TBC
Maccura	Hepatitis C Virus (HCV) Antibody Assay Kit	Serum, plasma	2–30	CIA	Chinese FDA
Maternova*	HIV/HBsAg/HCV combination rapid test	TBC	TBC	Immunochromatographic	CE marked
MedMira	Multplo rapid HBV/HIV/ HCV antibody test	Whole blood, serum, plasma	2–30	Immunochromatographic	TBC
MP Diagnostics	MULTISURE HCV	Whole blood, serum, plasma	2–28	Immunochromatographic	CE marked
MP Diagnostics	Multisure™ HIV/HCV/ Anti-HBc Rapid Test	TBC	2–8	Immunochromatographic	RUO
MP Diagnostics	ASSURE HCV Rapid Test	Serum, plasma	2–30	Chromatographic immunoassay	TBC

Company	Name of test	Sample type	Storage temperature (°C)	Test type	Regulatory status
NewScen Coast Bio-Pharmaceutical Co. Ltd	HCV Rapid Test Kit	Whole blood, serum, plasma	4–30	Chromatographic immunoassay	Saudi FDA
OraSure Technologies Inc	OraQuick® HCV Rapid Antibody Test	Oral fluid, whole blood, serum, plasma	2–30	Chromatographic immunoassay	WHO prequalified CLIA waived CE marked FDA approved
Qualpro Diagnostics	Combiquic® HIV/HCV	Serum, plasma	2–8	Immuno-concentration assay	RUO
Qualpro Diagnostics	Flavicheck® HCV WB	Whole blood, serum, plasma	4–30	Immunochromatographic	RUO
Qualpro Diagnostics	Flaviscreen HCV Plus™	Serum, plasma	4–30	Immunochromatographic	RUO
Qualpro Diagnostics	Slim HCV™	Serum, plasma	4–30	Immunochromatographic	RUO
Reckon Diagnostics	HCV Card Test (whole blood)	Whole blood, serum, plasma	4–40	Chromatographic immunoassay	TBC
Reckon Diagnostics	HCV Card Test/Strip Test	Serum, plasma	4–40	Chromatographic immunoassay	TBC
ReLIA*	HIV/HCV dual test	Whole blood, serum, plasma	TBC	Colloidal gold-based immunoassay (with automatic reader)	RUO
SERO-Med**	SM-HCV rapid test	Whole blood, serum	2–8 before opening, <30 after	Cassette-enclosed test card	TBC
Span Biotech*	One step HCV Ab fourth-generation rapid test	Whole blood, serum, plasma	2–8	Chromatographic immunoassay	TBC
Span Diagnostics*	Signal HCV	TBC	TBC	TBC	CE marked
Spectrum*	HBsAg/HCV Ab Rapid Test	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	TBC
Standard Diagnostics Inc.*	SD Bioline HCV	Whole blood, serum, plasma	1–30	Chromatographic immunoassay	WHO prequalified
Turklab*	Anti-HCV test	Whole blood, serum, plasma	4–30	TBC	CE marked
Wama Diagnóstica*	Imuno-Rápido HCV	Whole blood, serum, plasma	2–30	Chromatographic immunoassay	TBC

In 2015, a meta-analysis of studies of 30 HCV RDTs using serum and plasma samples, as well as blood (whole blood or capillary blood) or oral fluid specimens, which are best suited to use in resource-limited settings, found that performance varied widely among individual tests and this should be taken into consideration by physicians [*75*]. This is not necessarily reflective of all RDTs, merely of those included in the meta-analysis. However, it should be noted that a patient's HIV coinfection status

*Details not confirmed by the manufacturer.
**Company website no longer available.

can influence the diagnostic accuracy of screening tests. Since data are limited on this issue, it has been suggested that research studies stratified by HIV coinfection are needed to determine test accuracy in the presence of such coinfection [*76*]. In general, more affordable, quality-assured RDTs for HCV screening are needed for use in resource-limited settings. These tests should be easy to use and robust, with high temperature/humidity tolerance and no cold-chain requirements. Furthermore, their performance in the presence of HIV coinfection should be proven.

HCV screening tests in the pipeline

Table 4 provides an overview of screening tests in the pipeline and not yet available in the market.

TABLE 4.
Screening tests in the pipeline

Company	Name of test	Sample type	Storage temperature (°C)	Test type	Status
BioSynex	HIV+Crypto+HCV	TBC	TBC	TBC	Pipeline – expected date TBC
Chembio Diagnostic Systems*	DPP® HCV assay, HIV/HCV assay, HIV/HCV/TP assay	Oral fluids, whole blood, serum, plasma	TBC	Chromatographic immunoassay	Pipeline – expected date TBC
MBio Diagnostics*	mBio System	Whole blood, serum or plasma	TBC	Multiplexed immunoassays	Pipeline – expected date TBC
McGill University	Paper-based electrochemical platform	Whole blood, serum or plasma	2–30	Chromatographic immunoassay	Expected ~5 years
MedMira	Miriad Rapid TP/HBV/HIV/HCV quadruple multiplexed test	Whole blood, serum or plasma	TBC	Chromatographic immunoassay	Pipeline – expected date TBC

*Details not confirmed by the manufacturer.

Confirmation of viraemic HCV infection and treatment monitoring

All positive HCV serologic tests require confirmation of active HCV infection. An HCV RNA NAT is the gold standard assay for this purpose, as these assays verify the result of the serological test and establish the presence of viraemic HCV infection. HCV RNA molecular tests are either quantitative or qualitative assays (See Table 5 for an overview of available tests). A quantitative NAT can measure levels of HCV RNA, although this is no longer required based on the latest WHO guidance, whereas a qualitative test can only determine the presence or absence of HCV RNA, [28].

Quantitative HCV assays

Today, the most widely used quantitative HCV assays measure HCV RNA using NAT technologies. NAT-based RNA assays are used in both developed countries and resource-limited settings. All such technologies incorporate amplification techniques, since levels of nucleic acids are otherwise too low to be detected directly. Amplification methods either increase the number of target molecules (viral nucleic acids) to a level that permits detection (target amplification methods), or increase the signal generated by the method (signal amplification methods) [77]. Whether an assay is based on target amplification or signal amplification, it will consist of the following common steps: (i) sample preparation and/or viral nucleic acid extraction; (ii) the actual amplification step that is either target amplification based or signal amplification based; and (iii) detection and/or quantification of the amplified viral nucleic acids.

Pre-amplification methods (sample preparation and/or viral nucleic acid extraction) are critical to the testing process. For each sample to be analysed correctly and to achieve

an accurate result, the nucleic acid must be both available for the reaction and purified. Protocols for the pre-amplification steps include the use of purification methods for cells, and virion centrifugation or a capture step for RNA in plasma, followed by an extraction step to free the target viral nucleic acid [*77*]. Molecular detection methods require prompt processing of samples (generally within 6 hours of collection), a rapid extraction method and appropriate storage of plasma or cells prior to analysis.

There are several amplification methods used to detect viral RNA after preparation of samples. In target amplification, many copies of a portion of the viral nucleic acid are synthesized via an amplification reaction; in effect, this method enhances the ability to detect very low levels of nucleic acids that occur naturally in the blood. This technique includes reverse transcriptase polymerase chain reaction (RT-PCR).

In signal and probe amplification methods, a probe or a reporter molecule attached to a probe is detected and the signal generated by this reaction is amplified/increased; in effect, these methods increase the "marker" that shows that the target is present. Signal amplification techniques include branched DNA (bDNA).

Finally, post-amplification methods require the detection and/or quantification of either the amplification products (in target amplification methods) or the increased detection of signals that have been amplified (in signal amplification methods) [*77*]. Detection can be achieved using any one of several processes – e.g. colourimetric, radioactive or fluorescence. Detection can either be done at the endpoint of the process (completion of the run) or in "real time" (during the production of results as they occur). Real-time techniques, in which amplification and detection occur simultaneously, are now commonly used.

In general, in addition to their superior sensitivity, the advantages of NAT-based approaches include that many of the assays using these approaches have been evaluated and are well validated, the assays are available in quality-assured kits, some technologies can test for multiple diseases, and clinicians are comfortable interpreting the results. The assays vary in terms of sample preparation and amplification/detection methodologies, among other things.

Qualitative HCV assays

HCV assays require: RNA isolation; cDNA synthesis; PCR amplification; and detection of PCR amplicons. Qualitative NATs detect HCV in the blood and the test remains one of the most sensitive methods to detect active viraemia. As HCV is an RNA virus, reverse transcription PCR is used to detect viral RNA [*78*]–[*80*]. Most of the commercial PCR amplification strategies target the 5'UTR as there is >90% sequence identity between different genotypes [*78*][*81*]. The core and the 3'UTR region are also targeted for PCR-based detection of HCV [*82*].

TABLE 5.

Qualitative and quantitative NAT tests

Company	Test (equipment test can be run on)	Test target	Regulatory status
Abbott Molecular*	RealTi*me* HCV viral load assay (Abbott *m*2000 RealTi*me* System)	HCV RNA (quantitative)	FDA approved CE marked
Analytik Jena	RoboGene® HCV RNA Quantification Kit	HCV RNA (quantitative)	CE-IVD
Beckman Coulter	VERIS MDx system and HCV assay	HCV RNA (quantitative)	CE marked
Biocentric*	Generic HCV Charge Virale	HCV RNA (quantitative)	TBC
Bioneer	ExiStation™ Universal System	HCV RNA (quantitative)	RUO
BioSynex	RealLine HCV Qualitative and Quantitative Test	HCV RNA (quantitative/ qualitative)	TBC
Coyote Bioscience*	One-step detection kit for HCV (Mini Real-time PCR System)	HCV RNA (quantitative/ qualitative)	RUO
Euro Genomas*	viGen RNA HCV – 1/2/3	HCV RNA (qualitative)	TBC
GenePath Dx*	HCV RNA Qualitative and Quantitative Test	HCV RNA (quantitative/ qualitative)	TBC
Hologic®/Grifols	Aptima® HCV RNA Qualitative Assay (Leader System)	HCV RNA (qualitative)	CE marked FDA approved
Hologic®	Aptima® HCV Quant Dx Assay (Panther® System)	HCV RNA (quantitative)	CE marked
HUMAN Diagnostics Worldwide	HCV real-time PCR (HumaCycler)	HCV RNA (quantitative)	CE marked
Primerdesign	Genesig® q16 HCV	HCV RNA (quantitative)	RUO
QIAGEN N.V.	artus™ HCV RG RT-PCR (Rotor-Gene™ Q) artus™ HCV QS-RGQ (QIAsymphony® RGQ)	HCV RNA (quantitative)	CE marked
QIAGEN N.V.	careHCV RT-PCR Assay v2	HCV RNA (quantitative)	TBC
Roche Molecular Systems*	COBAS® AmpliPrep/COBAS® TaqMan® HCV Qualitative Test v2.0	HCV RNA (qualitative)	CE-IVD US-IVD
Roche Molecular Diagnostics*	COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test v2.0	HCV RNA (quantitative)	CE-IVD US-IVD
Roche Molecular Diagnostics*	COBAS® AmpliPrep/COBAS® TaqMan® HCV Test	HCV RNA (quantitative)	CE-IVD US-IVD
Roche Molecular Diagnostics*	COBAS® HCV for use on the COBAS® 6800/8800 Systems	HCV RNA (quantitative)	CE-IVD US-IVD
Roche Molecular Diagnostics*	COBAS® TaqMan® HCV Quantitative and Qualitative Test v2.0 for use with the High Pure System	HCV RNA (quantitative/ qualitative)	CE-IVD US-IVD
Sacace Biotechnologies	HCV Real-TM Qual Test (SaCycler-96™)	HCV RNA (qualitative)	RUO
Sacace Biotechnologies	HCV Real-TM Quant Dx Assay (SaCycler-96™)	HCV RNA (quantitative)	CE-IVD
Sacace Biotechnologies	HCV Real-TM Quant Assay* SaCycler-96™)	HCV RNA (quantitative)	RUO
Sacace Biotechnologies	HCV 240/440 IC (SaCycler-96™)	HCV RNA (qualitative)	RUO
Siemens Healthcare Diagnostics	VERSANT® HCV 1.0 Assay (VERSANT® kPCR Molecular System)	HCV RNA (quantitative)	CE-IVD

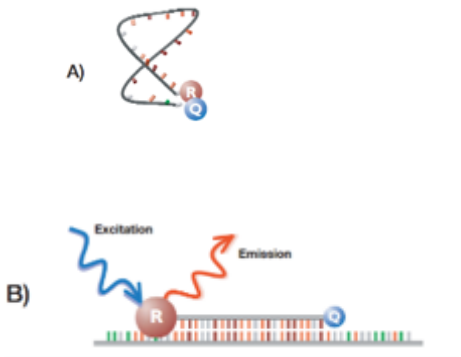
*Details not confirmed by the manufacturer.

Specifications of available qualitative and quantitative NAT assays/devices

RealTi*me* HCV Viral Load Assay (Abbott Molecular)

The Abbott RealTi*me* HCV assay is an in vitro RT-PCR assay for use with the Abbott mSample Preparation System reagents and with the Abbott *m*2000*sp* and *m*2000*rt* instruments for the quantitation of HCV RNA in human serum or EDTA plasma. The assay can be used to confirm active HCV infection after a positive serological test and also to predict SVR response to HCV therapy. The assay's performance characteristics have been established for individuals treated with PEGylated interferon alpha-2a or -2b and ribavirin; no information is available on the assay's predictive value with other regimens. The Real*Time* HCV assay uses RT-PCR technology combined with homogeneous real-time fluorescent detection for the quantitation of HCV RNA. The selection of a conserved region of the HCV genome, the 5'UTR region, and the primers are designed to hybridize to the 5'UTR region with the fewest possible mismatches among HCV genotypes 1 to 6. The probe used in the assay is illustrated in Figure 2. Abbott's RealTi*me* HCV assay is CE marked and FDA approved, as are a number of other assays for the system, including an HIV-1 qualitative assay that is also WHO prequalified; the system has already been adopted by a number of low- and middle-income countries [*83*][*84*].

FIGURE 2.
PROBE ACTION IN ABBOTT REALTI*ME* HCV ASSAY



The company states that the external calibration curve is a key design feature of the Abbott RealTi*me* HCV assay that enables it to achieve high precision. The use of different primers for the HCV target and the internal control minimizes competitive effects in the PCR reaction. The stored calibration curve reduces the variability of the viral load calculation compared to an internal calibration design. The Abbott RealTi*me* HCV assay has an LLOD of 12 IU/mL, for a 0.5 mL sample volume and an LLOD of 30 IU/mL for a 0.2 mL sample volume.

RoboGene® HCV RNA Quantification Kit (Analytik Jena)

The RoboGene® HCV RNA Quantification Kit is intended for real-time quantification of HCV RNA in human plasma or serum samples. The level of HCV RNA in serum and plasma can be used in conjunction with other clinical markers and clinical findings to distinguish between acute and chronic HCV infection and to assess the viral response to antiviral treatment.

During sample preparation, a synthetic internal control is included to control RNA extraction and to indicate for inhibitory effect on detection. Amplification of HCV RNA in samples and standards, and of control RNA, is measured independently at different wavelengths due to probes labelling with different fluorescence reporter dyes. Detection takes approximately 3 hours with a standard qPCR cycler and has a lower detection limit of 68 IU/mL. The test is CE-IVD marked.

VERIS MDx system and HCV assay (Beckman Coulter)

In 2014, Beckman Coulter introduced a fully automated random-access molecular diagnostics system, the VERIS MDx (Figure 3). This laboratory-based platform is a sample-to-answer system for the quantitative/qualitative analysis of molecular targets. The VERIS MDx system integrates the extraction, purification, quantification and results interpretation of infectious disease nucleic acid targets using PCR. This includes one-step sample introduction, proprietary bead extraction/purification, eluate transfer and reaction set-up, industry-standard RT qPCR amplification and detection, and results calculation and reporting.

FIGURE 3.
VERIS MDX SYSTEM

The VERIS MDx accepts several sample containers for plasma, serum and culture tubes; 48 samples can be lined up on 12 racks of 4 samples each. The time to result for RNA tests is approximately 115 minutes. For multiplex analysis, five different detection colours are available with a bandwidth from 505 to 720 mm. The onboard capacity consists of 96 extraction and purification cartridges, and reagents are covered for 20 assays with 48 tests per a ssay. Reagents are stable for up to 30 days from opening. Depending on the assay, the VERIS MDx can process up to 450 samples in 24 hours. The system features walk-away time of at least 2 hours. The system also includes a touchscreen user interface and has laboratory information system (LIS) interface capabilities. The VERIS HCV assay is CE marked and under assessment for WHO prequalification.

Aptima® HCV RNA Qualitative Assay (Leader System) (Hologic®/Grifols)

The Aptima®HCV RNA Qualitative Assay is an FDA-approved in vitro nucleic acid amplification assay for the detection of HCV RNA in human plasma (EDTA, sodium heparin, sodium citrate, and ACD) or serum. The assay requires the Leader HC+ luminometer to obtain results from the assay. The Aptima® HCV RNA Qualitative Assay is indicated for use with fresh or frozen specimens from the following populations: individuals with antibody evidence of HCV infection with evidence of liver disease; individuals suspected to be actively infected with HCV with antibody evidence; and individuals at risk for HCV infection with antibodies to HCV. It is not known if performance is affected by the state of HCV infection (acute or chronic) or by the presence or absence of liver disease. Performance has not been demonstrated for monitoring HCV-infected patients. This assay has not been FDA-approved for the screening of blood or plasma donors.

Aptima® HCV Quant Aassay (Real-Time Transcription Mediated Amplification) for the Panther® System (Hologic®)

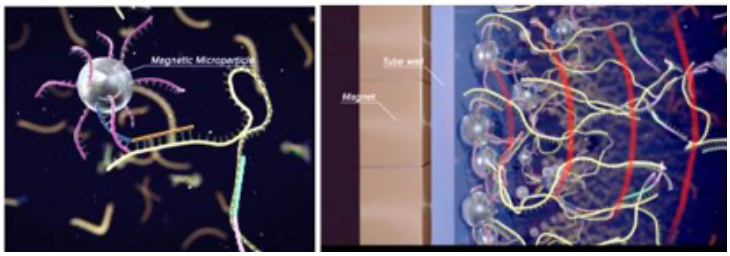
Hologic offers the Panther® System (Figure 4), a fully integrated and automated molecular diagnostic platform with random-access testing capability. The Panther® System is CE marked and FDA approved whereas the Aptima® HCV Quant Dx Assay is CE marked.

FIGURE 4.
PANTHER® SYSTEM

The Aptima® HCV Quant Assay requires three main processing steps, all of which take place in a single tube on the Panther® System: (i) target capture; (ii) target amplification by transcription-mediated amplification (TMA); and (iii) detection of the amplification products (amplicon) by fluorescent-labelled probes (torches).

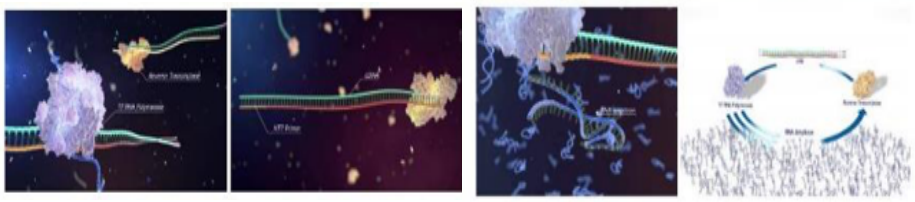
Target capture: During target capture, viral RNA is isolated from samples. The sample is treated with a detergent to release viral genomic RNA. Oligonucleotides hybridize to highly conserved regions of HCV RNA, if present, in the sample. As illustrated in Figure 5, the hybridized target is then captured on magnetic microparticles that are separated from the sample in a magnetic field. Finally, wash steps remove extraneous components from the reaction tube.

FIGURE 5.
TARGET CAPTURE



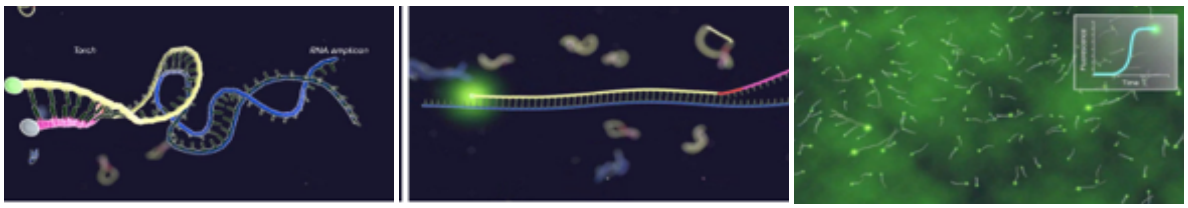
Target amplification: TMA is a transcription-based nucleic acid amplification method that utilizes two enzymes, RT and T7 RNA polymerase. The RT generates a DNA copy of the target sequence (containing a promoter sequence for T7 RNA polymerase). T7 RNA polymerase then produces multiple copies of RNA amplicon from the DNA copy template. The Aptima® assay utilizes TMA to amplify the 5'UTR region of the HCV genome. The primer design ensures accurate detection and quantitation of HCV (Figure 6).

FIGURE 6.
TARGET AMPLIFICATION



Detection of amplicon: Detection is achieved using single-stranded fluorescent probes (torches) that are present during the amplification and hybridize specifically to the amplicon in real time. The torches consist of a fluorophore and a quencher. When the torch binds to the amplicon, the fluorophore is separated from the quencher and will then emit fluorescence at a specific wavelength. As more torches hybridize to more amplicon, the fluorescent signal increases. The time taken for the fluorescent signal to reach a defined threshold is proportional to the starting HCV concentration. Each reaction also has an internal calibrator/internal control that controls for variations in sample processing, amplification and detection. The concentration of HCV in the sample is determined automatically by the Panther® System software using the HCV and internal control signals for each reaction and comparing them to stored calibration information (Figure 7).

FIGURE 7.
DETECTION OF AMPLICON

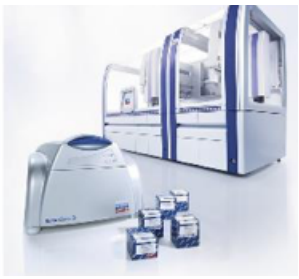


All nucleic acid testing steps, from primary sample tube to final results, are fully automated within the Panther® System, with the first reportable results available within 3 hours after loading samples and five results every 5 minutes thereafter. Samples can be continuously loaded, with up to 120 samples on the Panther® System at a time. Reagent controls and calibration are valid for 24 hours. More than 300 samples can be run during an 8-hour shift, or 550 in a 12-hour period using the continuous loading system. Four reagent lanes allow for up to four Aptima® reagent kits to be onboard and randomly accessed at any time (e.g. four kits of the Aptima® HCV Quant Dx Assay, or any combination of the other molecular diagnostic assays available e.g. HIV-1 Quant Dx Assay). A low-volume dilution option allows quantitative results to be obtained from 240 µL of specimen.

artus™ HCV RG/QS-RGQ RT-PCR System (QIAGEN N.V.)

QIAGEN N.V. manufactures a CE-IVD marked, RT-PCR-based assay for HCV: the artus™ HCV RG/QS-RGQ kit. The assay targets the conserved 5´UTR and core regions of the genome. The kits can be used in combination with an automated extraction and sample preparation system (QIAsymphony® SP/AS). The assay must then be run on one of the QIAGEN Rotor-Gene™ Q thermocyclers for amplification and detection. An example of a complete QIAsymphony® RGQ system is pictured in Figure 8.

FIGURE 8.
QIASYMPHONY® RGQ SYSTEM



The artus™ HCV RG/QS-RGQ assay has a linear range from 35 IU/mL to 17.7 million IU/mL (using automated extraction), and in combination with the Rotor-Gene™ Q can detect HCV down to an LLOD of 21 IU/mL (95% CI of 16–33 IU/mL). The time to result is about 5–6 hours for 24 samples. Performance of the artus™ assay has been evaluated against the CTM HCV assay from Roche Molecular Diagnostics and good correlation was found between the two assays, although sensitivity of the artus™ assay was lower than that of the CTM HCV assay [*85*] and when compared alongside five other quantitative assays had the highest LOD and LLOQ [*86*].

QIAsymphony® SP/AS (QIAGEN N.V.)

Sample preparation for the artus™ HCV assay may be conducted on the fully integrated automated sample preparation, and assay setup is also available using the QIAsymphony® SP/AS instruments. The QIAsymphony® SP can process from 1 to 96 samples (in batches of 24) with sample volumes up to 1 mL. It is a ready-to-run instrument that requires minimal installation. The SP can be combined with the QIAsymphony® AS device in a fully integrated system that can automate the entire workflow. To reduce manual handling and minimize the risk of sample contamination, samples processed on the SP can be transferred automatically to the AS, or the two instruments can be operated independently. The SP/AS system includes touchscreen controls, barcode-labelled sample tubes containing prefilled reagents, and allows for continuous loading in batches of up to 24 samples plus internal controls. The QIAsymphony® SP/AS instruments can also be integrated in laboratory information management systems (LMIS). In addition to HCV, the artus™ panels for QIAsymphony® Rotor-Gene™ Q (RGQ) include assays for the HBV and HIV virus, among others.

QIAsymphony® Rotor-Gene™ thermocycler (QUIAGEN N.V.)

The artus™ HCV assay can be run on the real-time PCR thermocycler RGQ. The RGQ has a centrifugal rotary design whereby each sample tube spins in a chamber of moving air, which keeps all samples at precisely the same temperature. As each tube aligns with the detection

optics in the device, the sample is illuminated and a fluorescent signal is collected. QIAGEN indicates that this results in sensitive, precise and fast real-time PCR analysis and eliminates sample-to-sample variations and edge effects. The Rotor-Gene™ Q can be ordered with the Rotor-Gene™ AssayManager software for molecular diagnostics that automatically analyses real-time PCR data of artus™ assays.

careHCV RT-PCR Assay v2 (QIAGEN N.V.)

In addition to the artus™ HCV RG/QS-RGQ assay described above, QIAGEN's Shenzhen subsidiary in China manufactures the careHCV RT-PCR Assay v2. The assay, which was approved by the State Food and Drug Administration of China in 2011, is for quantitative detection of HCV and viral load monitoring. The assay uses membrane technology for the binding and purification of RNA. It is an RT-PCR assay that uses fluorescent probes for the detection and quantification of HCV RNA; it also includes an internal control for result validation and detection of all key HCV subtypes. The LLOD of the assay is 500 IU/mL, and the linear dynamic range is from 1000 IU/mL to 50 million IU/mL.

The careHCV RT-PCR Assay v2 can be used in conjunction with automated sample technology products, such as QIAGEN's QIAcube, but also can accommodate manual sample preparation with the QIAGEN viral RNA mini-kit. The QIAcube enables automated mid- to high-throughput nucleic acid purification using silica membrane technology. The assay can be run on the RGQ thermocycler from QIAGEN, described above, or can be run on other instruments, including the 7000/7300 or 7500 (ABI), the iCycler iQ™ (Bio-Rad Laboratories), the LC480 (Roche Molecular Diagnostics), the Opticon Real Time Cycler (Bio-Rad Laboratories) or the LineGeneK™ (Bioer Technologies).

COBAS® AmpliPrep/COBAS® TaqMan® System HCV Qualitative Test v2.0 (CAP/CTM Qual Test) (Roche Molecular Diagnostics)

Roche Molecular Diagnostics manufactures a single real-time PCR assay, the COBAS® AmpliPrep/COBAS® TaqMan® HCV Qualitative Test v2.0 (CAP/CTM Qual Test). The assay uses the AmpliPrep instrument for automated viral nucleic acid extraction and the COBAS® TaqMan® 48 analyser, both of which are described below, for automated amplification and detection of the viral nucleic acid target.

The CAP/CTM Qual Test is a qualitative in vitro NAT for the detection of HCV RNA genotypes 1 to 6 in human serum or EDTA plasma. The company reports an LLOD of 15 IU/mL.[15] The assay is based on three major processes: (i) specimen preparation to isolate HCV RNA; (ii) reverse transcription of the target RNA to generate complementary DNA (cDNA); and (iii) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labelled oligonucleotide detection probes specific to the target.

More specifically, the CAP/CTM Qual Test utilizes automated specimen preparation on the COBAS® AmpliPrep instrument by a silica-based capture technique. The sample input volume is 650 µL of serum or plasma. The test then uses reverse transcription of HCV RNA to cDNA and PCR amplification of cDNA using primers that define a sequence within the highly conserved region of the 5'UTR of the HCV genome. Furthermore, the use of dual-labelled fluorescent

probes (HCV RNA and HCV internal control RNA) allows for real-time detection of PCR product accumulation by monitoring the emission intensity of fluorescent reporter dyes released during the amplification process. This increases the emission intensity of the individual reporter dyes and permits independent identification of HCV RNA and HCV internal control RNA. The HCV internal control serves as an extraction and amplification control for each independently processed specimen. The CAP/CTM Qual Test is CE-IVD marked. At least one peer-reviewed evaluation of the assay has been published [*87*]. The evaluation demonstrated that the CAP/CTM Qual Test performs significantly better than its predecessor.

The COBAS® AmpliPrep System (Roche Molecular Diagnostics)

The COBAS® AmpliPrep instrument is an automated sample preparation technology (Figure 9) for use in conjunction with the Roche COBAS® TaqMan® analysers discussed below.

FIGURE 9.
COBAS® AMPLIPREP SYSTEM

The instrument is large, weighing over 308 kg. The run size for the instrument is 24 specimens, but it can process up to 72 samples at any given time. The first 24 samples take 2 hours to process. However, because the instrument allows for parallel processing, subsequent batches of 24 can be completed every hour as one rack of specimens will begin processing before the previous rack processing has been completed. The system is closed and requires the use of test-specific, barcoded, ready-to-use COBAS® AmpliPrep kits.

FIGURE 10.
COBAS® TAQMAN® 48

The COBAS® TaqMan® 48 Analyser is a fully automated, closed-tube system. The TaqMan® 48 (Figure 10) is relatively compact and can run 6–48 samples at a time. The instrument is equipped with two thermal cyclers that operate independently and provide run times of 3 hours.

COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test v2.0 (CAP/CTM Quan HCV Test) (Roche Molecular Diagnostics)

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test v2.0 (CAP/CTM Quan HCV Test) is a NAT for the quantitation of HCV RNA in human serum or EDTA plasma. The test is based on three major processes: (i) specimen preparation to isolate HCV RNA; (ii) reverse transcription of the target RNA to generate cDNA; and (iii) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labelled oligonucleotide detection probes specific to the target.

The CAP/CTM Quan HCV Test uses magnetic silica bead-based nucleic acid extraction on the COBAS® AmpliPrep platform, followed by amplification with primers specific to the 5'UTR of the HCV genome and detection with a fluorescently labelled hydrolysis probe performed on the COBAS® TaqMan® thermal cycler to detect the target and a quantitative standard (QS).

The CAP/CTM Quan HCV Test is a second-generation assay that uses a dual-labelled fluorescent probe, which allows for real-time detection of PCR product accumulation by monitoring the emission intensity of fluorescent reporter dyes released during the amplification process. The test also uses an additional reverse primer to improve genotype 4 inclusivity and performance with known samples that are difficult to quantify [*88*]. Additional assay features include: (i) changes in the elution and lysis buffers that improve sample preparation; (ii) higher temperature RT step and shorter overall PCR cycles; and (iii) reduced sample input volume (650 µL sample requirement with 500 µL processed by the instrument).

The CAP/CTM Quan HCV Test has an LLOQ of at least 15 IU/mL to an upper limit of quantitation of at least 100 million IU/mL (linear range). The assay reports HCV RNA levels of 1–14 IU/mL as "HCV RNA detected, below the LLOQ". Performance of the assay has been evaluated and the assay is considered to exhibit very good sensitivity, reproducibility and dynamic range [*88*][*89*].

The CAP/CTM Quan HCV Test is CE-IVD marked and FDA approved.

COBAS® HCV for use on the COBAS® 6800/8800 Systems (Roche Molecular Diagnostics)

The COBAS® HCV test is a quantitative NAT for use on the COBAS® 6800/8800 Systems (Figure 11) and is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease; individuals suspected to be actively infected with HCV antibody; and individuals at risk for HCV infection with antibodies to HCV. It is able to detect genotypes 1 to 6 in human plasma or serum of HCV-infected individuals.

The test, which is US-IVD and CE-IVD marked, is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of SVR early during a course of antiviral therapy, and to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels in serum or EDTA plasma. The results must be interpreted within the context of all relevant clinical and laboratory findings.

FIGURE 11.
COBAS® 6800/8800 SYSTEMS

COBAS® TaqMan® HCV Quantitative Test v2.0 (High Pure System) (Roche Molecular Diagnostics)

The COBAS® TaqMan® HCV Quantitative Test v2.0 for use with the High Pure System (CTM HCV test) is a second-generation assay that uses a dual-labelled fluorescent probe and is similar to the CAP/CTM Quan HCV Test described above. However, rather than automated sample preparation, the High Pure System Viral Nucleic Acid Kit allows manual specimen preparation followed by automated amplification and detection on the COBAS® TaqMan® 48 Analyser. The CTM HCV test has a sensitivity (LLOD across all genotypes) of 20 IU/mL and a linear range from 25 IU/mL to 390 million IU/mL. Specimens containing HCV genotypes 1 to 6 have been validated for quantitation by the assay. The assay's performance characteristics have been established for individuals treated with peg-IFN-riba; no information is available on the assay's predictive value with other regimens. The CTM HCV Test is CE-IVD marked and FDA approved.

TaqMan® HCV Quantitative Test v2.0 (COBAS® AmpliPrep/COBAS® TaqMan® System) (Roche Molecular Diagnostics)

Roche Molecular Diagnostics manufactures the real-time PCR assay, the COBAS® AmpliPrep/COBAS® TaqMan® HCV quantitative Test version 2 (CAP/CTM Quan Test). The assay uses the AmpliPrep instrument for automated viral nucleic acid extraction and the COBAS® TaqMan® 48 analyser for automated amplification and detection of the viral nucleic acid target. The CAP/CTM Quan Test is a quantitative in vitro NAT for the detection of HCV RNA genotypes 1 to 6 in human serum or EDTA plasma. The company reports an LLOD of 15 IU/mL.[16] The assay is based on three major processes: (i) specimen preparation to isolate HCV RNA; (ii) reverse transcription of the target RNA to generate complementary

[16] The LLOD is defined as the lowest amount of HCV RNA concentration that can be detected with 95% probability to determine presence or absence.

DNA (cDNA); and (iii) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labelled oligonucleotide detection probes specific to the target.

More specifically, the CAP/CTM Quan Test utilizes automated specimen preparation on the COBAS® AmpliPrep instrument by a silica-based capture technique. The sample input volume is 650 µL of serum or plasma. The test then uses reverse transcription of HCV RNA to cDNA and PCR amplification of cDNA using primers that define a sequence within the highly conserved region of the 5'UTR of the HCV genome. Furthermore, the use of dual-labelled fluorescent probes (HCV RNA and HCV internal control RNA) allows for real-time detection of PCR product accumulation by monitoring the emission intensity of fluorescent reporter dyes released during the amplification process. This increases the emission intensity of the individual reporter dyes and permits independent identification of HCV RNA and HCV internal control RNA. The HCV internal control serves as an extraction and amplification control for each independently processed specimen. The CAP/CTM Qual Test is CE-IVD and US-IVD marked. At least one peer-reviewed evaluation of the assay has been published [*87*]. The evaluation demonstrated that the CAP/CTM Qual Test performs significantly better than its predecessor (the version 1 test).

In 2014, Roche Molecular Diagnostics – in partnership with the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Clinton Health Access Initiative (CHAI), the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to fight AIDS, Tuberculosis and Malaria – launched a Global Access Program for HIV viral load testing. Through a special pricing scheme for eligible countries, the company has committed to expanding access to its HIV assays that run on the COBAS® AmpliPrep, COBAS® 4800 and/or the COBAS® 6800/8800 systems [*90*]–[*92*]. As a result, many COBAS® systems have already been adopted in low- and middle-income countries [*93*].

HCV Real-TM Qual Test (SaCycler-96™) (Sacace Biotechnologies)

HCV Real-TM Qual is a real-time test for the qualitative detection of HCV in human plasma. The process begins with HCV RNA extraction from plasma. The RNA is amplified using RT-amplification and detected using fluorescent reporter dye probes specific for HCV or HCV internal control, which serves as an extraction and amplification control for each individually processed specimen and to identify possible reaction inhibition. Monitoring the fluorescence intensities during real time allows the detection of the accumulating product without having to reopen the reaction tube after the amplification (see below for details of SaCycler-96™).

HCV Real-TM Quant Dx Assay (Sacace Biotechnologies)

Sacace manufactures the CE marked, HCV Real-TM Quant Dx Assay, for the quantitative detection of HCV in human plasma and the simultaneous detection of an HCV-specific internal control, by dual colour detection. The assay extracts HCV RNA from plasma, amplifies it using real-time amplification and detects it using fluorescent reporter dye probes specific for HCV or HCV internal control. Amplification of both targets takes place simultaneously in the same reaction. Monitoring the fluorescence intensities in real time allows for the detection and quantification of the accumulating product without having to reopen the reaction tube after amplification.

The HCV-specific internal control, which represents a recombinant RNA-containing-structure, is carried through all steps of the analysis from nucleic acid extraction to PCR amplification and detection. The presence of this quantitative internal control allows the operator not only to monitor the extraction procedure and to check possible PCR inhibition, but also to verify possible losses of RNA during the extraction procedure. This enables precise calculation of the HCV viral load.

The target sequence for the HCV Real-TM Quant Dx Assay is the 5'UTR region of the HCV genome, which is highly conserved. The LLOD of the assay is 13 IU/mL with a 1.0 mL sample preparation procedure.

The assay can be run on the SaCycler-96™ manufactured by Sacace Biotechnologies and described earlier in this report. However, the test is platform independent and can also be run on the Rotor-Gene™ 6000/Q (QIAGEN N.V.). No peer-reviewed publications have been found assessing this assay.

HCV 240/440 IC Test (SaCycler-96™) (Sacace Biotechnologies)

HCV 240/440 IC is based on four major processes: isolation of HCV RNA from specimens; reverse transcription of the RNA; nucleic acid amplification; and detection of the amplified products on agarose gel. The kit contains the internal control, which may be used in the isolation procedure and serves as an amplification control for each individually processed specimen and to identify possible reaction inhibition (see below for details of SaCycler-96™).

SaCycler-96™ Diagnostic Device (Sacace Biotechnologies)

The two assays above, provided by Sacace Biotechnologies, can be processed on the SaCycler-96™ (Figure 12), an instrument for real-time amplification and melting analysis, suitable for diagnostics applications. The device features two thermoelectric Peltier elements which are designed to regulate the temperature. Loading of test samples can be done in an automated fashion.

FIGURE 12.
SACYCLER-96™

Like most RT-PCR platforms, the SaCycler-96™ is a laboratory-based instrument. It uses a standard 96-well format that is suited to standard PCR microplates, test tubes and strips, and contains 4- or 5-channel multiplexing for discrimination of up to five targets in a single reaction well. There is a separate light emitting diode (LED) source for each channel and a matrix charge-coupled device (CCD) camera. The platform has a wide dynamic range of detection using a multiple exposure method, which simplifies or even eliminates the need for fluorescence settings.

VERSANT® kPCR Molecular System and HCV 1.0 Assay (Siemens)

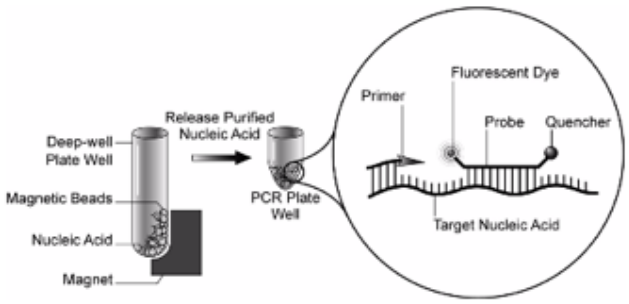
The VERSANT® kPCR Molecular System and the VERSANT® HCV 1.0 Assay (kPCR) are manufactured by Siemens Healthcare Diagnostics. Because they are CE-IVD marked, but not FDA approved, they are only available outside of the United States. The Siemens HCV assay is a real-time kinetic polymerase chain reaction (kPCR) assay for quantitative detection of HCV RNA in plasma or serum of infected individuals. The system (Figure 13) is an automated amplification method based on reverse transcription and real-time PCR technology and consists of two modules: the Sample Preparation Module used to extract nucleic acids from plasma, as well as a wide variety of other samples, and the Amplification Detection Module, along with VERSANT® kPCR software. The system is a "one-room" technology with no need for clean room operations due to closed-tube processing and other physical and chemical contamination controls.

FIGURE 13.
VERSANT® KPCR MOLECULAR SYSTEM

The VERSANT® kPCR Sample Preparation module along with the VERSANT® Mare used to extract RNA from plasma. The reagents kit includes proprietary magnetic silica beads that provide for efficient and high-quality extraction of nucleic acids. Extraction consists of a lysis step that utilizes proteinase K and a chaotropic buffer, and several washes to remove non-nucleic acid components of the sample and elution. The VERSANT® kPCR Sample Preparation module also pipettes the purified RNA to a PCR plate containing HCV primer/probe mix and HCV enzyme mix. The wells are then sealed and transferred to the Amplification Detection Module where the HCV and internal control RNA molecules are reverse transcribed to make cDNA and then simultaneously amplified and detected using the kPCR technique. The RT-PCR step uses primers and probes that target the highly conserved HCV 5'UTR region of the

gene and detects all 6 HCV genotypes within the range from 15 IU/mL to 1 x 108 IU/mL. A schematic representation of the assay principle is shown in Figure 14. The VERSANT® HCV 1.0 Assay (kPCR) is CE-IVD marked.

FIGURE 14.
VERSANT® HCV 1.0 ASSAY (KPCR) PRINCIPLE



The VERSANT® kPCR Molecular System provides the flexibility to process samples in batch sizes of 1–96 tests per run. The HCV assay provides patient results for up to 89 samples per run with a total time to result of less than 6 hours. The assay has an LLOD of 15 IU/mL (64.5 copies/mL) and a linear range between 15 IU/mL and 100 million IU/mL (64.5–430 million copies/mL). The VERSANT® HCV 1.0 assay is CE-IVD marked. Peer-reviewed publications regarding the performance of the assay found that it demonstrated good correlation with the CTM HCV assay [*86*] [*94*].

POC HCV NAT platforms on the market and in the pipeline

Each of the NAT-based HCV RNA viral load systems described above requires testing to be done in a laboratory setting, usually at a central or national reference laboratory, by well-trained technicians. Each requires dedicated space, a clean room or rooms and other specialized and sophisticated infrastructure to prevent contamination. HCV viral load testing that could be conducted at or near the POC would reduce the need for such infrastructure and would reduce the level of training required. In addition, the availability of quality POC HCV viral load testing would ensure that patients in remote areas would have access to appropriate diagnostic and monitoring tools with same-day test results, which can minimize lost to follow-up.

GeneXpert® System (Cepheid)

The Cepheid GeneXpert® system is a fully automated and integrated system for PCR-based NATs, with a variety of 14 FDA-cleared and 14 CE-IVD assays. Any of these tests can be run on virtually all of the GeneXpert® systems. The GeneXpert® HCV viral load assay is now available on the market. The quantitative HCV assay uses 1 mL of plasma or serum. The assay targets

the 5'UTR region of the HCV genome. The LLOD of the assay is 4.0 IU/mL in plasma and 6.1 IU/mL for serum for all HCV genotypes and has a linear range from 10 IU/mL to 100 million IU/mL. The workflow for the quantitative assay works by: (i) collecting 5 mL of whole blood in an EDTA plasma or serum tube; (ii) separating plasma or serum from whole blood; (iii) transferring 1 mL of plasma or serum into the cartridge via transfer pipette; (iv) scanning the cartridge barcode; and (v) loading the cartridge into the GeneXpert® module and closing the door. The time to result is ~105 minutes. The price per cartridge is available upon request. The list price for the GeneXpert® 1 is US$ 24 000.

Cepheid's Gene Xpert® HIV-1 Qual Assay received WHO prequalification in 2016, and the company's assays for HCV viral load, HPV and HIV-1 viral load are under WHO prequalification assessment. In addition, the use of the Xpert® MTB/RIF (rifampicin resistant *Mycobacterium* tuberculosis) assay has been recommended by WHO since 2010 [*95*]. As such, a growing number of countries have already adopted national algorithms positioning the GeneXpert® MTB/RIF as the initial diagnostic test for all people suspected of having pulmonary TB, meaning that the system has already been adopted by a number of low- and middle-income countries.

FIGURE 15.
GENEXPERT® 1 (LEFT) AND CARTRIDGE (RIGHT)

The GeneXpert® system integrates and automates sample preparation, amplification and detection in a single-use, self-contained cartridge (shown in Figure 15, on the right). Most liquids and dry reagents along with enzymes are prefilled so that pre-analytical steps are minimized, greatly reducing opportunities for sample mix-ups and operational errors. GeneXpert® cartridges can handle a variety of sample volumes (millilitre range) within macrofluidic chambers and then concentrate the target material down to microfluidic volumes, which can increase the sensitivity of the assays, if needed. The GeneXpert® HCV Viral Load cartridge along with the Xpert® HCV Viral Load, GeneXpert® Dx, GeneXpert® Infinity-48s and GeneXpert® Infinity-80s have been WHO prequalified.

Furthermore, the GeneXpert® System is modular. Individual modules contain solid state circuitry that control temperature, pressure, rotation of the valve that moves the liquid between reservoirs, and the detection software. These individual modules are packaged in units of 1, 2, 4, 16, 40, 48 or 80, and the latter two systems are fully automated, walk-away robotic instruments developed for high-throughput laboratory applications. Additionally, the modules can be removed and replaced individually so that the entire system is not incapacitated if one module fails. The GeneXpert® system is sufficiently simple that training can usually be completed within half a day. Furthermore, although the system was designed to use AC power, its low wattage requirements allow it to be powered by a 12 VDC/120 VAC voltage converter in mobile laboratories, and it has also been installed in remote clinic sites powered by solar panels. The GeneXpert® software comes pre-installed on a desktop or laptop computer and results can be displayed for each module in real time or uploaded via an internet connection to a central database. Wireless data connections via satellite phone networks are in development, as is a cloud-based system for remote access, online system calibration and interfacing with the LIS.

GeneXpert® is also developing the Omni, which will be a battery powered machine and is likely to further improve POC testing of RNA.

Mini8 Plus Real-Time PCR system (Coyote Bioscience)

Coyote Bioscience has developed a Mini8 Plus Real-Time PCR system that can be used with its One-Step RT-PCR Detection Kit for HCV (QPCR-Probe), but as an open system it is compatible with most commercial reagents (Figure 16). It is on the market but is currently research use only (RUO) and, therefore, is included in the pipeline section of this report. It is powered by either a 12 V DC power supply or a battery pack can be purchased. The device weighs only 2.1 kg thus is extremely portable and currently the only portable RT-PCR system available.

FIGURE 16.
COYOTE BIOSCIENCE MINI8 PLUS REAL-TIME PCR SYSTEM

Genedrive® HCV ID kit (Epistem Ltd)

Epistem Ltd, a biotechnology company headquartered in the United Kingdom, has developed a new molecular diagnostic platform called Genedrive® (Figure 17), which uses end-point PCR-based detection. Genedrive® is a highly portable, POC platform weighing about 550 grams. The platform accommodates both electric (110–240 V AC) and battery (12 V DC) power.

FIGURE 17.
GENEDRIVE® PLATFORM (LEFT) AND TEST CARTRIDGE (RIGHT)

The Genedrive® platform is integrated with a simple extraction process based on an advanced composite paper technology that allows extraction and decontamination in a single step and is suitable for use in low-resource settings. The sample is manually transferred with one pipetting step into the Genedrive® reaction cartridge. Epistem's Genedrive® HCV ID kit, a qualitative assay that detects HCV RNA by real-time PCR from fresh or frozen plasma (requires centrifugation), gained CE marking in October 2017. In addition, the company announced in March 2018 that it had commenced commercial sales and shipments of the kit into the EMEA (Europe, Middle East and Africa) region, with an initial focus on Africa; through its distributor Sysmex, distribution to the Asia Specific region is also expected to follow shortly [*96*] [*97*].

The current viral load POC pipeline is described in Table 6 and Appendix 2.

TABLE 6.
POC HCV RNA platforms in the pipeline[17]

Company	Machine/assay	Test target
Alere	Alere™ q	HCV RNA
Cepheid	GeneXpert® Omni	HCV RNA
Molbio Diagnostics Pvt. Ltd	Truenat™ (previously Truelab™ Real Time micro PCR) HCV viral load	HCV RNA
Ustar Biotechnologies	RT CPA HCV Viral Load Test	HCV RNA

[17] There are many more POC NAT systems under development that could potentially run HCV tests and may be in development, but which have not listed HCV in the pipeline.

HCV cAg assays

In addition to using either a qualitative or quantitative NAT to confirm chronic infection, it is also possible to use assays that measure the HCV cAg in serum, which have the potential to be cheaper and simpler tests in some clinical settings [*98*]. The WHO guidelines allow for the use of HCV cAg assays as an alternative NAT to diagnose viraemic infection as it is recognized that the cost of NAT assays in resource-limited settings is an important barrier to antiviral treatment [*28*]. A study in 1999 found that circulating HCV cAg could be detected via an enzyme-linked immunosorbent assay (ELISA) sandwich antigen test [*99*], but, until relatively recently, the test procedures were complex, and a number of barriers have remained [*100*]. For example, developing conditions that can disrupt the virus and Ab-Ag complexes, while permitting the assay to be performed, as well as developing core antibodies that will work in processed samples have been significant challenges to date. However, test methodologies are evolving and there are now several commercially available tests for HCV cAg detection. A recent systematic review identified that current HCV cAg tests can have similar diagnostic accuracy to NATs for identification of active HCV infection at viral loads greater than 3000 IU/mL and, therefore, HCV cAg assays may provide a cheaper and simpler alternative to NATs in high-HCV prevalence settings [*7*]. Still, in order to truly compete with NATs, there is a need for HCV cAg assays in inexpensive formats that have a lower limit of detection (LLOD)/lower limit of quantification (LLOQ) than existing standard assays [*101*].

Specifications of HCV cAg tests on the market and in the pipeline

Several HCV cAg assays are currently available or are in development, as profiled in Table 7.

TABLE 7.

cAg assays that are commercially available or in development

Company	Machine/assay	Technology	Test target	Regulatory status
Abbott Diagnostics	i2000SR Platform/ ARCHITECT HCV cAg Assay	CIA	HCV cAg	CE marked
Daktari Diagnostics Inc.	Daktari™ System	Biosensor technology	HCV cAg	TBC
Fujirebio*	Lumipulse G1200/ Lumipulse Ortho HCV Ag Test	CLEIA	HCV cAg	TBC
EIKEN	Lumispot HCV Ag	CLEIA	HCV cAg	TBC
Hunan Jynda Bioengineering Group*	HCV Core Ag	ELISA	HCV cAg	TBC
Ortho*	HCV ELISA-Ag	ELISA	HCV cAg	TBC

*HCV assay not listed on the company website.

ARCHITECT HCV cAg Assay (Abbott Diagnostics)

Abbott Diagnostics has developed the ARCHITECT HCV cAg Assay, which is a CIA that detects HCV cAg using microparticles coated with anti-HCV. The assay can be used as a reflex test to definitively diagnose individuals with active infection following a positive screening test for HCV, but it can also be used to detect HCV during the early window period of the disease. Moreover, because the assay is quantitative, it can be used to monitor the effectiveness of antiviral therapy as a complement to NAT-based testing, or in the light of all-DAA regimens, as a standalone assay for monitoring the clearance and cure of antiviral therapy.[18]

The ARCHITECT HCV cAg Assay is a two-step immunoassay using CIA technology, with flexible assay protocols referred to as CHEMIFLEX, for the quantitative determination of core antigen of HCV. The assay includes a sample pretreatment step. Afterwards, the pretreated sample, an assay-specific diluent and anti-HCV microparticles are combined. The objectives of the pretreatment step (which is automated) are to: (i) dissociate antibody-bound core antigen; (ii) lyse viral particles and expose core antigen; and (iii) inactivate antibody. The HCV cAg present in the pretreated sample binds to the anti-HCV coated microparticles in the first step. After washing, acridinium-labelled anti-HCV conjugate is added in the second step. Following another wash cycle, with Pre-Trigger (containing 1.32% hydrogen peroxide) and Trigger (containing 0.35N sodium hydroxide) solutions, the resulting chemiluminescent reaction is measured as relative light units. A direct relationship exists between the amount of HCV cAg in the sample and the relative light units detected by the ARCHITECT optical system.

The concentration of hepatitis cAg in the specimen is determined using a previously generated ARCHITECT HCV cAg calibration curve. If the concentration of the specimen is ≥3.00 fmol/L, then the specimen is considered reactive for HCV cAg.

There are several performance studies of the ARCHITECT HCV cAg Assay [*102*]–[*104*] , that found the assay to be highly specific and easy to perform [*102*], and to have utility for reflex testing on an anti-HCV positive individual to confirm or exclude an active HCV infection [*103*] and for screening for acute HCV infection [*104*].

It remains to be seen whether cAg assays are sensitive enough to be used for HCV treatment monitoring. Although the ARCHITECT assay is not as sensitive as HCV RNA assays, it has demonstrated good correlation with such assays regardless of the HCV genotype [105] [106]. Chevaliez et al. concluded that the ARCHITECT HCV cAg Assay is a valuable screening, diagnostic and monitoring tool, especially in the era of new all-oral IFN-free antiviral strategies that do not require high analytical sensitivity [*102*].

i2000SR Platforms (Abbott Diagnostics)

The ARCHITECT HCV cAg Assay can be performed on the i2000SR (Figure 18), a laboratory-based analyser from Abbott.

[18] The concentration of cAg of a patient specimen is expressed in fmol/L, which has a non-linear correlation with HCV RNA. The level of HCV cAg can be calculated as an RNA-equivalent viral load. For example, 3 fmol/L of cAg corresponds to between 700 and 1100 IU/mL of HCV RNA.

FIGURE 18.
ARCHITECT I2000SR

The i2000SR analyser uses CHEMIFLEX, and includes a robotic sample handler and immediate "STAT" processing. The i2000SR accommodates 200 tests per hour and can be integrated with a chemistry analyser to consolidate clinical chemistry and immunoassays on a single platform. The price of the analyser is available from Abbott.

Lumipulse Ortho HCV Ag Test (Fujirebio)

Fujirebio's Ortho HCV Ag Test is an automated chemiluminescent enzyme immunoassay (CLEIA) that can be run on the company's Lumipulse G1200 platform (Figure 19). The Lumipulse G1200 is a mid-sized fully automated immunoassay instrument that utilizes a mono-test cartridge and can perform 120 tests per hour. One study of 80 participants demonstrated 95% sensitivity, however, the data were insufficient to determine specificity [*107*].

FIGURE 19.
LUMIPULSE G1200

Lumispot HCV Ag (EIKEN)

Similar to Fujirebio's Lumipulse Ortho HCV Ag test, EIKEN's Lumispot is also a CLEIA. The diagnostic accuracy of the Lumispot HCV cAg test for active HCV infection, compared with NAT, showed that the Lumispot HCV Ag had a sensitivity range of 97.5–98.1%, however, the data were insufficient to determine specificity [*7*].

Hunan Jynda Bioengineering Group HCV Core Ag

The Hunan Jynda Bioengineering Group's HCV Core Ag test is an ELISA. A recent bivariate meta-analysis of four studies involving this test determined the sensitivity to be 59.5% and the specificity to be 82.9% [7].

HCV ELISA-Ag (Ortho)

The Ortho HCV ELISA-Ag is intended for identifying HCV cAg in plasma and serum samples from blood donors and organ donors. Bivariate meta-analysis of four studies identified that the Ortho HCV ELISA-Ag had a sensitivity of 59.5% and a specificity of 82.9% [7].

Freiman et al. concluded that a well-performing HCV cAg test can have a similar diagnostic accuracy compared to a NAT, but the viral load needs to be greater than 3000 IU/mL. The Abbott ARCHITECT HCV Ag test and Ortho ELISA-Ag had similar sensitivity and specificity, but the greater number of consistent data sets for the ARCHITECT allows for the greatest precision out of the platforms compared in this analysis [7].

HCV cAg assays in the pipeline

Daktari™ System (Daktari Diagnostics Inc.)

Daktari Diagnostics Inc. has developed a portable (battery powered) and robust diagnostic device. The company is currently developing an HCV cAg assay for diagnosis of HCV as well as for quantitative determination of HCV cAg (Figure 20). At present, there is no firm launch date for the HCV assay.

FIGURE 20.
DAKTARI™ SYSTEM

Intended for use at the point of patient care, the Daktari™ System eliminates sample preparation using a technology known as "microfluidic immunochromatography", which isolates cells (or viruses) in a miniature sensing chamber. No pipetting, labels or reagents are required; the only user step is to apply a drop of whole blood to the cartridge. Similarly, the Daktari™ device does not require fragile and expensive optical sensors, but rather uses a second group of innovations in electrochemical spectroscopy, which provides 1010-fold signal amplification, on a par with PCR-based detection methods, and requires only a simple sensor to interpret the electrical signal, and quantify cell counts or viral load

Genotyping

Pan-genotypic DAAs continue to simplify the testing continuum. However, where pan-genotypic DAAs are not available or not recommended, genotyping could still be required prior to starting patients on HCV therapy. For this reason, genotyping is still included in this report.

There are several laboratory-based genotyping assays on the market based on either real-time PCR, or LiPA (Table 8). Laboratory-based molecular systems require the operator to have a thorough knowledge of the applications run on the instrument (and on the sample preparation instrument) and must follow good laboratory practices when operating them

TABLE 8.

Genotyping assays available on the market

Company	Name of assay (and machine)	Sample type	Volume of sample	Technology	Test target	Regulatory status
Abbott Molecular*	RealTi*me* Genotype II (Abbott *m*2000 RealTi*me* System)	Serum, plasma	200–500 µL	RT-PCR	HCV RNA	FDA approved
Roche Molecular Diagnostics*	COBAS® HCV GT (COBAS® 4800 System)	EDTA serum, plasma	400 µL	qRT-PCR	HCV RNA	CE-IVD
Sacace Biotechnologies	HCV Genotype Plus Real-TM (SaCycler-96™)	Plasma (recommended), serum	400–1000 µL	qPCR and qRT-PCR	HCV RNA	RUO
Sacace Biotechnologies	HCV1/2/3 Real-TM Genotype (SaCycler-96™)	Plasma (recommended), serum	400–1000 µL	qPCR and qRT-PCR	HCV RNA	RUO
Siemens Healthcare Diagnostics	VERSANT® HCV Genotype 2.0 Assay (LiPA)	Serum, plasma	200 µL	LPA	HCV RNA	CE-IVD FDA approved

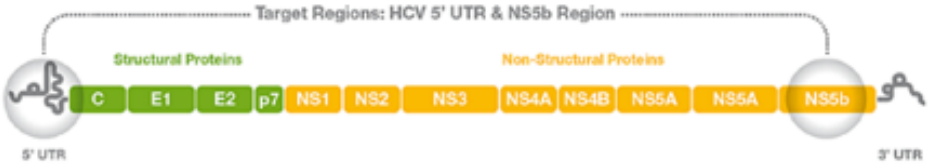
*Details not confirmed by the manufacturer.

RT-PCR genotyping

RealTime HCV Genotype II (m2000 System) (Abbott Molecular)

The Abbott RealTi*me* Genotype II is an RT-PCR assay for the identification of genotypes of HCV in plasma or serum from individuals with chronic HCV infection (Figure 21). The Abbott RealTi*me* HCV Genotype II detects genotypes 1, 1a, 1b, and 2–5 using genotype-specific fluorescent-labelled oligonucleotide probes. It targets the 5'UTR for the classification of HCV genotypes 1, 2, 3, 4, 5 and 6, and the NS5b region to accurately subtype HCV genotypes 1a and 1b. Further details can be found in Appendix 1.

FIGURE 21.
ABBOTT REALTI*ME* HCV GENOTYPE II ASSAY USES 5'UTR AND NS5B FOR BROADER SUBTYPE DEFINITION



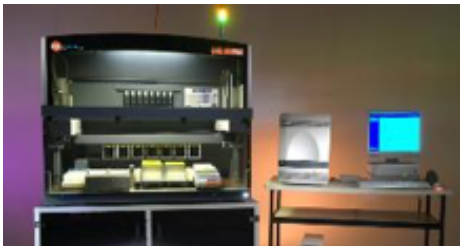
The Abbott RealTi*me* HCV Genotype II assay is CE-IVD marked. Two independent, peer-reviewed performance evaluations of the assay have been published demonstrating somewhat mixed results. Sohn et al. [*108*] concluded that the assay needs improvement to decrease cross-reactivity among genotypes and to improve the ability to detect minor genotypes in mixed infections, while Yang et al. [*69*] found that the assay failed to identify some genotype 6 subtypes. Sample preparation with the *m*2000 System: the Abbott RealTi*me* Genotype II assay is designed to be used with the *m*2000*rt* amplification and detection instrument as well as with one of three methods of sample preparation: (i) manual (for laboratories with low-throughput requirements); (ii) the *m*24*sp* instrument (for laboratories with low- to medium-throughput requirements); or (iii) the *m*2000*sp* instrument (for laboratories with medium- to high-throughput requirements), although the use of these assays is generally not based on throughput, but on automation. It should be noted that in addition to the HCV Genotype II assay, the Abbott *m*2000 System can also be used to perform both qualitative and quantitative HCV viral load assays, whereas the Roche Molecular Diagnostics and Siemens Healthcare Diagnostics genotype assays must be performed on instruments that are different from those used for their respective viral load assays.

The *m*24*sp* (Figure 22) is a bench-top sample preparation and extraction device with a small footprint that is generally appropriate for facilities with medium-throughput requirements. It provides a variable extraction system (extraction output can be stored either in deep-well trays or 1.5 mL tubes) with ready-to-use and reusable reagents as well as flexible batch size capabilities.

FIGURE 22.
M24SP INSTRUMENT

The *m*2000*sp* by Abbott (pictured in the centre of the image in Figure 23) is a larger and more automated sample preparation device than its sibling, the *m*24*sp*. With complete automation comes increased walk-away time for the operator. It is a high-throughput system with a maximum batch size of 96 samples per run. When combined with the Abbott *m*2000*rt*, an amplification and detection instrument, the system can provide automation from barcoded laboratory tube through patient result.

FIGURE 23.
***M*2000*SP* INSTRUMENT**



The Abbott *m*2000*rt* is the amplification and detection platform for use with manual extraction, the *m*24*sp* and the *m*2000*sp* instruments, as described above. It is relatively compact, weighing in at just over 34 kg. The *m*2000*rt* can run 96 samples at a time in about 3 hours of cycling time (not including time for sample preparation). The system will run both quantitative and qualitative analyses and offers validity parameters such as maxRatio.

FIGURE 24.
***M*2000*RT* INSTRUMENT**

COBAS® HCV GT for use on the COBAS® 4800 System (Roche Molecular Diagnostics)

COBAS® HCV GT is a highly sensitive real-time PCR-based test for the qualitative identification (it is not intended as a screening test for the presence of HCV) of HCV genotypes 1 to 6 and genotype 1 subtypes a and b in human plasma or serum from individuals with chronic HCV infection, using the COBAS® 4800 System (a fully automated sample preparation with real-time PCR technology for amplification and detection). COBAS® HCV GT uses three different target regions in the HCV genome (5'UTR, Core, NS5B) to achieve increased accuracy of genotyping and subtyping of HCV, compared to sequencing (Figure 25).

FIGURE 25.
COBAS® 4800 SYSTEM

HCV Genotype kits (Sacace Biotechnologies)

Sacace Biotechnologies manufactures two HCV genotype kits: HCV1/2/3 Real-TM and HCV Genotype Plus Real-TM. Both kits utilize real-time PCR to distinguish HCV genotypes. Further Information can be found in Appendix 1.

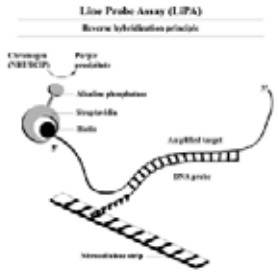
Like all of the company's assays, the test is platform-independent, or open-system, meaning that the assay can be used on a variety of platforms, either manual or automated, e.g. the Rotor-Gene™ (QIAGEN N.V.) and the LineGeneK™ (Bioer Technologies). In addition, the company also manufactures the RT-PCR platform, the SaCycler-96™, which is detailed elsewhere in this report.

Line probe assays (LiPAs)

VERSANT® HCV Genotype 2.0 LiPA (Siemens Healthcare Diagnostics)

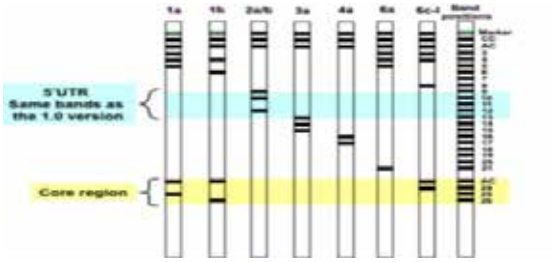
The VERSANT® HCV Genotype 2.0 Assay (LiPA) is a LiPA for IVD use, which identifies HCV genotypes 1 to 6 and 15 subtypes (including 1a vs. b and subtypes 6 c-l) in human serum or EDTA plasma samples.The VERSANT® HCV Genotype 2.0 Assay uses the 5'UTR region of the genotype, which contains multiple genotype-specific motifs distributed over seven small variable regions, to provide accurate genotyping information for genotypes 1 to 6. However, the assay uses sequence motifs from the core region in addition to the 5'UTR to identify genotype 6, subtypes c to l. Additional core motifs are included to improve the accuracy of the identification of 1a and 1b. The VERSANT® HCV Genotype 2.0 Assay (LiPA) utilizes reverse hybridization (Figure 26). Biotinylated DNA PCR product, generated by RT-PCR amplification of the 5'UTR and core regions of HCV RNA, is hybridized to immobilized oligonucleotide probes. The probes, which are bound to a nitrocellulose strip by a poly(dT) tail, are specific for the 5'UTR and core region of different HCV genotypes. After the hybridization step, unhybridized PCR product is washed from the strip, and alkaline phosphatase-labelled streptavidin (conjugate) is bound to the biotinylated hybrid. BCIP (5-bromo-4-chloro-3-indolu-phosphate)/NBT (nitro blue tetrazolium) chromogen (substrate) reacts with the streptavidin-alkaline phosphatase complex forming a purple/brown precipitate, which results in a visible banding pattern on the strip.

FIGURE 26.
REVERSE HYBRIDIZATION LIPA



The VERSANT® HCV Genotype 2.0 Assay (LiPA) strips have three control lines and 22 parallel DNA probe lines (Figure 27) containing sequences specific for HCV genotypes 1 to 6. The conjugate control (CONJ CTRL) line monitors the colour development reaction. The amplification control (AMPL CTRL 1) at line 2 contains universal probes that hybridize to the PCR product from the 5'UTR. The amplification control (AMPL CTRL 2) at line 23 contains universal probes that hybridize to the PCR product from the core region. HCV genotypes are determined by aligning the assay strips with the VERSANT® HCV Genotype 2.0 Assay (LiPA) Reading Card and comparing the line patterns from the assay strips with the patterns shown on the VERSANT® HCV Genotype 2.0 Assay (LiPA) Interpretation Chart.

FIGURE 27.
VERSANT® HCV GENOTYPE 2.0 ASSAY STRIPS



The assay must be used with the VERSANT® HCV Amplification 2.0 Kit (LiPA), which provides all reagents for reverse transcription and amplification of the 5'UTR and core region of the HCV genome. The HCV amplification procedure begins with viral RNA extracted from human serum or plasma. The QIAGEN N.V. QIAamp DSP Virus Kit has been evaluated for purification of viral nucleic acids from plasma/serum for use in conjunction with the LiPA. In addition, the assay must be performed on an Applied Biosystems thermal cycler model GeneAmp PCR System 9700 or equivalent, which is not provided by Siemens Healthcare Diagnostics. The VERSANT® Genotype 2.0 Assay (LiPA) is CE-IVD marked. There are several published performance evaluations of the assay [*69*] [*109*]–[*111*] . While Yang et al. concluded that the LiPA 2.0 may not be able to distinguish some genotype 3b samples from genotype 6 samples [*69*] and, as mentioned earlier, some 1b subtypes are classified as 1a [*109*] [*110*] . Verbeeck et al. found the assay to be sensitive, accurate and reliable for HCV genotyping [*111*].

Future directions for HCV testing

This report details the current continuum of testing for HCV, including screening and confirmation of viraemic infection, genotyping, assessing liver fibrosis, and treatment monitoring. The testing continuum remains complex and costly and, in resource-limited settings, few have access to testing, resulting in HCV remaining undiagnosed until patients present at health-care facilities with symptoms that occur in incidences of serious liver disease, including liver cancer.

Despite this, hepatitis testing and the monitoring of treatment responses have been greatly enhanced by advances in HCV detection technology, and important future directions for HCV testing are also being set in motion to improve this further, such as: simplifying testing; near-patient/POC assays for NAT and cAg; improved and more widespread use of DBS sampling and hub-and-spoke networks; expanded use of multi-disease platforms; implementation of multiplex testing; self-testing; and oral testing [*28*] [*112*].

Importantly, developers need continuous guidance from the stakeholder community, with respect to the key market requirements for HCV screening/diagnosis, as well as clearance/cure testing. Stakeholder-vetted target product profiles are being developed by FIND [*113*] and will be useful in this respect.

Important future directions in HCV testing and treatment include:

1. Adopting WHO guidelines into national testing and treatment strategies, which will help to improve the identification and treatment of people infected with HCV [*22*] [*28*] [*112*].

2. Making affordable, quality-assured diagnostic services or tests readily available for all people who need them, especially in low-income settings.

3. Assuring that effective laboratory provisions are made to ensure that high-quality testing and treatment monitoring are provided, that an appropriately trained health workforce is available, and that affected communities are actively involved in improving outcomes for their community.

4. Improving access to DAAs by increasing awareness among medical professionals and patients, and reducing the cost of this class of drugs so that they are accessible in low- and middle-income countries [*114*].

Ultimately, the technology pipeline for HCV detection is set to simplify the testing algorithm and allow for improved outcomes, particularly with the use of POC NATs, multiplex testing, self-testing and improved service delivery through innovations such as DBS sampling [*112*].

References

1. New hepatitis data highlight need for urgent global response. Geneva: World Health Organization; 2017.
2. Guidelines on hepatitis B and C testing. Geneva: World Health Organization; February 2017. [Online-acccessed 15 August 2018] (http://www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/).
3. Lemoine M, Nayagam S, Thursz M. Viral hepatitis in resource-limited countries and access to antiviral therapies: current and future challenges. Future Virol. 2013;8(4):371–80.
4. The silent pandemic: tackling hepatitis C with policy innovations. Economic Intelligence Unit, The Economist. 2012;1–28.
5. Hathorn E, Elsharkawy AM. Management of hepatitis C genotype 4 in the directly acting antivirals era. BMJ Open Gastroenterol. 2016;3(1):e000112.
6. Trucchi C, Orsi A, Alicino C, Sticchi L, Icardi G, Ansaldi F. State of the art, unresolved issues, and future research directions in the fight against hepatitis C virus: perspectives for screening, diagnostics of resistances, and immunization. J Immunol Res. 2016. [Epub 24 October 2016]
7. Freiman JM, Tran TM, Schumacher SG, White LF, Ongarello S, Cohn J et al. Hepatitis C core antigen testing for diagnosis of hepatitis C virus infection: a systematic review and meta-analysis. Ann Intern Med. 2016;165(5):345–55.
8. Busch MP. Insights into the epidemiology, natural history and pathogenesis of hepatitis C virus infection from studies of infected donors and blood product recipients. Transfusion Clinique et Biologique. 2001;8(3):200–06.
9. Grebely J, Page K, Sacks-Davis R, Schim van der Loeff M, Rice T, Bruneau J et al. The effects of female sex, viral genotype, and IL28B genotype on spontaneous clearance of acute hepatitis C virus infection. Hepatology. 2014;59(1):109–120.
10. Aparna R, Schwarz K. Chapter 19: Hepatitis C in Children. Caring Ambassadors Hepatitis C Choices: 4th Edition, 2008.
11. Terilli RR, Cox AL. Immunity and hepatitis C: a review. Curr HIV/AIDS Rep. 2013;10(1):51–8.
12. Thomson EC, Fleming VM, Main J, Klenerman P, Weber J, Eliahoo J et al. Predicting spontaneous clearance of acute hepatitis C virus in a large cohort of HIV-1-infected men. Gut. 2011;60(6):837–45.
13. Gerlach JT, Diepolder HM, Zachoval R, Gruener NH, Jung MC, Ulsenheimer A et al. Acute hepatitis C: high rate of both spontaneous and treatment-induced viral clearance. Gastroenterology. 2003;125(1):80–8.
14. Hajarizadeh B, Grebely J, Dore GJ. Epidemiology and natural history of HCV infection. Nat Rev Gastroenterol Hepatol. 2013;10(9):553–62.
15. Grebely J, Raffa JD, Lai C, Mel K, Conway B, Tyndall MW. Factors associated with spontaneous clearance of hepatitis C virus among illicit drug users. Can J Gastroenterol. 2007;21(7):447–51.
16. Thomas DL, Seeff LB. Natural history of hepatitis C. Clinics in Liver Disease. 2005;9(3):383–98.
17. Operskalski EA, Kovacs A. HIV/HCV co-infection: pathogenesis, clinical complications, treatment, and new therapeutic technologies. Current HIV/AIDS Reports. 2011;8(1):12–22.
18. Murphy DG, Sablon E, Chamberland J, Fournier E, Dandavino R, Tremblay CL. Hepatitis C virus genotype 7, a new genotype originating from Central Africa. J Clin Microbiol. 2015;53(3):967–72.
19. Smith DB, Bukh J, Kuiken C, Muerhoff AS, Rice CM, Stapleton JT et al. Expanded classification of hepatitis C virus into 7 genotypes and 67 subtypes: updated criteria and genotype assignment web resource. Hepatology. 2014;59(1):318–27.
20. Messina J, Humphreys I, Flaxman A, Brown A, Cooke GS, Pybus OG et al. Global distribution and prevalence of hepatitis C virus genotypes. Hepatology. 2015;61(1):77–87.

21. Mohd Hanafiah K, Groeger J, Flaxman AD, Wiersma ST. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. Hepatology. 2013;57(4):1333–42.

22. Guidelines for the screening care and treatment of persons with chronic hepatitis C infection. Geneva: World Health Organization; 2016.

23. [23] Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection. Genever: World Health Organization; 2018.

24. Toshikuni N. Therapy with direct-acting antiviral agents for hepatitis C-related liver cirrhosis. Gut Liver 2016;1–14.

25. Ghany MG, Strader DB, Thomas D L, Seeff LB. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1335–74.

26. Rockey DC, Bissell DM. Noninvasive measures of liver fibrosis. Hepatology. 2006;43(2 Suppl. 1).

27. Guidelines for the screening, care and treatment of persons with hepatitis C infection. Geneva: World Health Organization; April 2014.

28. Global hepatitis report 2017. Geneva: World Health Organization; 2017.

29. Ghany MG, Nelson DR, Strader DB, Thomas DL, Seeff LB. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guidelines by the American Association for the Study of Liver Diseases. Hepatology. 2011;54(4):1433–14.

30. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of hepatitis C virus infection. J Hepatol. 2011;55(2):245–64.

31. Vermehren J, Susser S, Berger A, Perner D, Peiffer K-H, Allwinn R et al. Clinical utility of the ARCHITECT HCV Ag assay for early treatment monitoring in patients with chronic hepatitis C genotype 1 infection. J Clin Virol. 2012;55(1):17–22.

32. Ford N, Kirby C, Singh K, Mills EJ, Cooke G, Kamarulzaman A et al. Chronic hepatitis C treatment outcomes in low- and middle-income countries: a systematic review and meta-analysis. Bull World Health Organ. 2012;90(7):540–50.

33. Lomtadze N, Kupreishvili L, Salakaia A, Vashakidze S, Sharvadze L, Kempker RR et al. Hepatitis C virus co-infection increases the risk of anti-tuberculosis drug-induced hepatotoxicity among patients with pulmonary tuberculosis. PLoS One. 2013;8(12):e83892.

34. Thio CL, Nolt KR, Astemborski J, Vlahov D, Nelson KE, Thomas DL. Screening for hepatitis C virus in human immunodeficiency virus-infected individuals. J Clin Microbiol. 2000;38(2):575–7.

35. George SL, Gebhardt J, Klinzman D, Foster MB, Patrick KD, Schmidt WN et al. Hepatitis C virus viremia in HIV-infected individuals with negative HCV antibody tests. J Acquir Immune Defic Syndr. 2002;31(2):154–162.

36. Bonacini M, Lin HJ, Hollinger FB. Effect of coexisting HIV-1 infection on the diagnosis and evaluation of hepatitis C virus. J Acquir Immune Defic Syndr. 2001;26(4):340–4.

37. Mullis CE, Laeyendecker O, Reynolds S, Ocama P, Quinn J, Boaz I et al. High frequency of false-positive hepatitis C virus enzyme-linked immunosorbent assay in Rakai, Uganda. Clin Infect Dis. 2013;57(12):1747–50.

38. Fonjungo PN, Alemnji GA, Kebede Y, Opio A, Mwangi C, Spira TJ et al. Combatting global infectious diseases: a network effect of specimen referral systems. 13 February 2017. [Epub ahead of print]

39. Shepherd SJ, Kean J, Hutchinson SJ, Cameron SO, Goldberg DJ, Carman WF et al. A hepatitis C avidity test for determining recent and past infections in both plasma and dried blood spots. J Clin Virol. 2013;57(1)29–35.

40. McCarron B, Fox R, Wilson K, Cameron S, McMenamin J, McGregor G et al. Hepatitis C antibody detection in dried blood spots. J Viral Hepat. 1999;6(6):453–6.

41. Lukacs Z, Dietrich A, Ganschow R, Kohlschutter A, Kruithof R. Simultaneous determination of HIV antibodies, hepatitis C antibodies, and hepatitis B antigens in dried blood spots: a feasibility study using a multi-analyte immunoassay. Clin Chem Lab Med. 2005;43(2):141–5.

42. Tuaillon E, Mondain AM, Meroueh F, Ottomani L, Picot MC. Nagot N et al. Dried blood spot for hepatitis C virus serology and molecular testing. Hepatology. 2010;51(3):752–8.

43. Parker SP, Cubitt WD, Ades AE. A method for the detection and confirmation of antibodies to hepatitis C virus in dried blood spots. J Virol Methods. 1997;68(2):199–205.

44. Chevaliez S, Soulier A, Poiteau L, Pawlotsky J-M. Dried blood spots (DBS), a promising tool for large-scale hepatitis C screening, diagnosis and treatment monitoring. J Hepatol. 2014;60(1 Suppl. 1):S325–S326.

45. Waterboer T, Dondog B, Michael KM, Michel A, Schmitt M, Vaccarella et al. Dried blood spot samples for seroepidemiology of infections with human papillomaviruses, Helicobacter pylori, hepatitis C virus, and JC virus. Cancer Epidemiol Biomarkers Prev. 2012;21(2):287–93.

46. Marques BL, Brandão CU, Silva EF, Marques VA, Villela-Nogueira CA, Do KM et al. Dried blood spot samples: optimization of commercial EIAs for hepatitis C antibody detection and stability under different storage conditions. J Med Virol. 2012;84(10):1600–7.

47. Croom HA, Richards KM, Best SJ, Francis BH, Johnson EI, Dax EM et al. Commercial enzyme immunoassay adapted for the detection of antibodies to hepatitis C virus in dried blood spots. J Clin Virol. 2006;36(1):68–71.

48. O'Brien JM, Kruzel KE, Wandell MG, Vinogradov IV, Sheagren JN, Frank AP et al. Detection of hepatitis C antibody with at-home collection kits using an innovative laboratory algorithm. Infect Dis Clin Pract. 2001;10(9):474–80.

49. Brandão CPU, Marques BL, Marques VA, Villela-Nogueira CA, Do KM, de Paula MT et al. Simultaneous detection of hepatitis C virus antigen and antibodies in dried blood spots. J Clin Virol. 2013;57(2):98–102.

50. Lee CE, Sri Ponnampalavanar S, Syed Omar SF, Mahadeva S, Ong LY, Kamarulzaman A. Evaluation of the dried blood spot (DBS) collection method as a tool for detection of HIV Ag/Ab, HBsAG, anti-HBs and anti-HCV in a Malaysian tertiary referral hospital. Ann Acad Med Singapore. 2011;40(10):448–53.

51. Kania D, Bekalé AM, Nagot N, Mondain AM, Ottomani L, Meda N et al. Combining rapid diagnostic tests and dried blood spot assays for point-of-care testing of human immunodeficiency virus, hepatitis B and hepatitis C infections in Burkina Faso, West Africa. Clin Microbiol Infect. 2013;19(12):E533–E541.

52. Dokubo EK, Evans J, Winkelman V, Cyrus S, Tobler LH, Asher A et al. Comparison of Hepatitis C Virus RNA and antibody detection in dried blood spots and plasma specimens. J Clin Virol. 2014;59(4):223–27.

53. Tejada-Strop A, Drobeniuc J, Mixson-Hayden T, Forbi JC, Le NT, Li L et al. Disparate detection outcomes for anti-HCV IgG and HCV RNA in dried blood spots. J Virol Methods. 2015;212:66–70.

54. Larrat S, Bourdon C, Baccard M, Garnaud C, Mathieu S, Quesada JL et al. Performance of an antigen-antibody combined assay for hepatitis C virus testing without venipuncture. J Clin Virol. 2012;55(3):220–5.

55. Nandagopal P, Iqbal HS, Saravanan S, Solomon SS, Mehta S, Selvakumar M et al. Evaluation of dried blood spot as an alternative specimen for the diagnosis of anti-HCV in resource-limited settings. J Med Microbiol. 2014;32(2):208–10.

56. Ross RS, Stambouli O, Grüner N, Marcus U, Cai W, Zhang W et al. Detection of infections with hepatitis B virus, hepatitis C virus and human immunodeficiency virus by analyses of dried blood spots – performance characteristics of the ARCHITECT system and two commercial assays for nucleic acid amplification. Virol J. 2013;10:1–8.

57. Solmone M, Girardi E, Costa F, Pucillo L, Ippolito G, Capobianchi MR. Simple and reliable method for detection and genotyping of hepatitis C virus RNA in dried blood spots stored at room temperature. J Clin Microbiol. 2002;40(9):3512–14.

58. Santos C, Reis A, Dos Santos CV, Damas C, Silva MH, Viana MV et al. The use of real-time PCR to detect hepatitis C virus RNA in dried blood spots from Brazilian patients infected chronically. J Virol Methods. 2011;179(1):17–20.

59. Soulier A, Poiteau L, Rosa I, Hézode C, Roudot-Thoraval F, Pawlotsky JM et al. Dried blood spots: a tool to ensure broad access to hepatitis C screening, diagnosis, and treatment monitoring. J Infect Dis. 2016;213(7)1087–95.

60. De Crignis E, Re MC, Cimatti L, Zecchi L, Gibellini D. HIV-1 and HCV detection in dried blood spots by SYBR Green multiplex real-time RT-PCR. J Virol Methods. 2010;165(1):51–6.

61. Bennett S, Gunson RN, McAllister GE, Hutchinson SJ, Goldberg DJ, Cameron SO et al. Detection of hepatitis C virus RNA in dried blood spots. J Clin Virol. 2012;54(2);106–9.

62. Abe K, Konomi N. Hepatitis C virus RNA in dried serum spotted onto filter paper is stable at room temperature. J Clin Microbiol. 1998;36(10):3070–2.

63. Barrera JM, Bruguera M, Ercilla MG, Sánchez-Tapias JM, Gil MP. Costa J et al. Incidence of non-A, non-B hepatitis after screening blood donors for antibodies to hepatitis C virus and surrogate markers. Ann Intern Med. 1991;115(8):596–600.

64. Marwaha N, Sachdev S. Current testing strategies for hepatitis C virus infection in blood donors and the way forward. World J Gastroenterol. 2014;20(11):2948–54.

65. Hepatitis C diagnostic testing [Online] (http://www.hepatitisc.uw.edu/pdf/screening-diagnosis/diagnostic-testing/core-concept/all, accessed 31 July 2018).

66. Laperche S, LeMarrec N, Girault A, Bouchardeau F, Servant-Delmas A, Maniez-Montreuil M et al. Simultaneous detection of hepatitis C virus (HCV) core antigen and anti-HCV antibodies improves the early detection of HCV infection. J Clin Microbiol. 2005;43(8):3877–83.

67. Yang J-F, Lin YY, Hsieh MH, Tsai CH, Liu SF, Dai CY et al. Performance characteristics of a combined hepatitis C virus core antigen and anti-hepatitis C virus antibody test in different patient groups. Kaohsiung J Med Sci. 2011;27(7):258–63.

68. Lambert N. Value of HCV antigen-antibody combined HCV assay in hepatitis C diagnosis. Dev Biol (Basel). 2007;127(113–21).

69. Yang R, Cong X, Du S, Fei R, Rao H, Wei L. Performance comparison of the VERSANT HCV genotype 2.0 assay (LiPA) and the Abbott Realti*me* HCV genotype II assay for detecting hepatitis C virus genotype 6. J Clin Microbiol. 2014;52(10):3685–92.

70. Colin C, Lanoir D, Touzet S, Meyaud-Kraemer L, Bailly F, Trepo C. Sensitivity and specificity of third-generation hepatitis C virus antibody detection assays: an analysis of the literature. J Viral Hepat. 2001;8(2):87–95.

71. Tan WS, Chow EPF, Fairley CK, Chen MY, Bradshaw CS, Read TRH. Sensitivity of HIV rapid tests compared to fourth generation enzyme immunoassays or HIV RNA tests – a systematic review and meta-analysis. AIDS. April 2016.

72. Lee SR, Yearwood GD, Guillon GB, Kurtz LA, Fischil M, Friel T et al. Evaluation of a rapid, point-of-care test device for the diagnosis of hepatitis C infection. J Clin Virol. 2010;48(1):15–17.

73. Yuen MF, Hui CK, Yuen JC, Young JL, Lai CL. The accuracy of SM-HCV rapid test for the detection of antibody to hepatitis C virus. Am J Gastroenterol. 2001;96(3):838–41.

74. Liu C, Mauk M, Gross R, Bushman FD, Edelstein PH, Collman RG et al. Membrane-based, sedimentation-assisted plasma separator for point-of-care applications. Anal Chem. 2013;85(21):10463–70.

75. Khuroo MS, Khuroo NS, Khuroo MS. Diagnostic accuracy of point-of-care tests for hepatitis C virus infection: a systematic review and meta-analysis. PLoS One 2015;10(3):e0121450.

76. Shivkumar S, Peeling R, Jafari Y, Joseph L, Pai NP. Accuracy of rapid and point-of-care screening tests for hepatitis C: a systematic review and meta-analysis. Ann Intern Med. 2012;157(8):558–66.

77. Constantine N, Saville R, Dax E. Retroviral testing and quality assurance: essentials for laboratory diagnosis. College Park MD: University of Maryland; 2005.

78. Yanagi M, St Claire M, Emerson SU, Purcell RH, Bukh J. In vivo analysis of the 3' untranslated region of the hepatitis C virus after in vitro mutagenesis of an infectious cDNA clone. Proc Natl Acad Sci USA. 1999;96(5):2291–5.

79. Bukh J, Purcell RH, Miller RH. Sequence analysis of the 5' noncoding region of hepatitis C virus. Proc Natl Acad Sci. 1992;89(11):4942–6.

80. Moradpour D, Penin F. Hepatitis C virus proteins: from structure to function. Curr Top Microbiol Immunol. 2013;369:113–42.

81. Choo QL, Richman KH, Han JH, Berger K, Lee C, Dong C et al. Genetic organization and diversity of the hepatitis C virus. Proc Natl Acad Sci USA. 1991;88(6):2451–5.

82. Firdaus R, Saha K, Biswas A, Sadhukhan PC. Current molecular methods for the detection of hepatitis C virus in high risk group population: a systematic review. World J Virol. 2015;4(1):25–32.

83. Hajna M, Metcalf C, Rumaney M, Khunga R, Ndlovu Z, Ortuno et al. Diagnostic accuray validation of Abbott *m*2000 for HIV viral load testing on DBS samples (version1.0). Biomed Journal, Zimbabwe. 2017;1(3):3.

84. Zeh C, Ndiege K, Inzaule S, Achieng R, Williamson J, Chang J et al. Evaluation of the performance of Abbott *m*2000 and Roche COBAS Ampliprep/COBAS Taqman assays for HIV-1 viral load determination using dried blood spots and dried plasma spots in Kenya. PLoS One 2017;12(6):e0179316.

85. Schønning K. Comparison of the QIAGEN artus HCV QS-RGQ test with the Roche COBAS Ampliprep/COBAS TaqMan HCV test v2.0 for the quantification of HCV-RNA in plasma samples. J Clin Virol. 2014;60(4):323–7.

86. Wiesmann F, Naeth G, Sarrazin A, Berger A, Kaiser R, Ehret R et al. Variation analysis of six HCV viral load assays using low viremic HCV samples in the range of the clinical decision points for HCV protease inhibitors. Med Microbiol Immunol. 2015;204(4):515–25.

87. Pas S, Molenkamp R, Schinkel J, Rebens S, Copra C, Seven-Deniz et al. Performance evaluation of the new Roche Cobas AmpliPrep/Cobas TaqMan HCV test, version 2.0, for detection and quantification of hepatitis C virus RNA. J Clin Microbiol. 2013;51(1):238–42.

88. Taylor N, Haschke-Becher E, Greil R, Strasser M, Oberkofler H. Performance characteristics of the COBAS Ampliprep/COBAS TaqMan v2.0 and the Abbott RealTi*me* hepatitis C assays: implications for response-guided therapy in genotype 1 infections. Antivir Ther. 2014;19(5):449–54.

89. Zitzer H, Heilek G, Truchon K, Susser S, Vermehren J, Sizmann D et al. Second-generation cobas ampliprep/cobas taqman HCV quantitative test for viral load monitoring: a novel dual-probe assay design. J Clin Microbiol. 2013;51(2):571–7.

90. Roche expands Global Access Program to include the first fully automated CE marked nucleic acid HIV-1/HIV-2 qualitative diagnostic test [Online] (https://molecular.roche.com/news/roche-expands-global-access-program-to-include-the-first-fully-automated-ce-marked-nucleic-acid-hiv-1hiv-2-qualitative-diagnostic-test/, accessed 8 May 2018).

91. Roche launches global access program for HIV viral load testing [Online] (https://molecular.roche.com/news/roche-launches-global-access-program-for-hiv-viral-load-testing/, accessed 8 May 2018).

92. Roche News. HIV Global Access Program expands [Online] (https://molecular.roche.com/news/roche-hiv-global-access-program-expands-to-include-next-generation-automated-platform-solutions, accessed 8 May 2018).

93. Roche – HIV testing in developing countries [Online] (https://www.roche.com/sustainability/access-to-healthcare/clinton-health-care-initiative.htm, accessed 8 May 2018).

94. Kessler HH, Hübner M, Konrad PM, Stelzl E, Stübler MM. Baser MH et al. Genotype impact on HCV RNA levels determined with the VERSANT HCV RNA 1.0 Assay (kPCR). J Clin Virol. 2013;58(3):522–7.

95. Xpert MTB/RIF implementation manual implementation manual: technical and operational "how-to": practical considerations. Geneva: World Health Oranization; 2014.

96. Genedrive gains European CE certification for Hep-C diagnostic [Online] (https://www.calculuscapital.com/genedrive-gains-european-ce-certification-for-hep-c-diagnostic, accessed 8 May 2018).

97. Genedrive PLC commences HCV ID Kit sales to EMEA region, reveals first commercial Asia-Pacific sales [Online]

98. Khan H, Hill A, Main J, Brown A, Cooke G. Can hepatitis C virus antigen testing replace ribonucleic acid polymearse chain reaction analysis for detecting hepatitis C virus? A systematic review. Open Forum Infect Dis. 2017;4(2).

99. Aoyagi K, Ohue Chiharu, Iida K, Kimura T, Tanaka E, Kiyosawa K et al. Development of a simple and highly sensitive enzyme immunoassay for hepatitis C virus core antigen. J Clin Microbiol. 1999;37(6):1802–8.

100. Dawson G. The potential role of HCV core antigen testing in diagnosing HCV infection. Antiviral Therapy. 2012;17(7 Part B):1431–5.

101. Ivanova Reipold E, Easterbrook P, Trianni A, Panneer N, Krakower D, Ongarello S et al. Optimising diagnosis of viraemic hepatitis C infection: the development of a target product profile. BMC Infect Dis. 2017;17(Suppl. 1):707.

102. Chevaliez S, Soulier A, Poiteau L, Bouvier-Alias M, Pawlotsky J-M. Clinical utility of hepatitis C virus core antigen quantification in patients with chronic hepatitis C. J Clin Virol. 2014;61(1):145–8.

103. Medici MC, Furlini G, Rodella A, Fuertes A, Monachetti A, Calderaro A et al. Hepatitis C virus core antigen: analytical performances, correlation with viremia and potential applications of a quantitative, automated immunoassay. J Clin Virol. 2011;51(4):264–9.

104. Cresswell FV, Fisher M, Hughes DJ, Shaw SG, Homer G, Hassan-Ibrahim MO. Hepatitis C core antigen testing: a reliable, quick, and potentially cost-effective alternative to hepatitis C polymerase chain reaction in diagnosing acute hepatitis C virus infection. Clin Infect Dis. 2015;60(2):263–6.

105. Ottiger C, Gygli N, Huber AR. Detection limit of architect hepatitis C core antigen assay in correlation with HCV RNA, and renewed confirmation algorithm for reactive anti-HCV samples. J Clin Virol. 2013;58(3):535–40.

106. Mederacke I, Wedemeyer H, Ciesek S, Steinmann E, Raupach R, Wursthorn K et al. Performance and clinical utility of a novel fully automated quantitative HCV-core antigen assay. J Clin Virol. 2009;46(3):210–15.

107. Murayama A, Sugiyama N, Watashi K, Masaki T, Suzuki R, Aizaki H et al. Japanese reference panel of blood specimens for evaluation of hepatitis C virus RNA and core antigen quantitative assays. J Clin Microbiol. 2012;50(6):1943–9.

108. Sohn YH, Ko SY, Kim MH, Oh HB. Performance evaluation of the Abbott RealTi*me* HCV genotype II for hepatitis C virus genotyping. Clin Chem Lab Med. 2010;48(4):469–74.

109. Chueca N, Rivadulla I, Lovatti R, Reina G, Blanco A, Fernandez-Caballero JA et al. Using NS5B sequencing for hepatitis C virus genotyping reveals discordances with commercial platforms. PLoS One. 2016;11(4):e0153754.

110. Guelfo JR, Macias J, Neukam K, Di Lello FA, Mira JA, Merchante N et al. Reassessment of genotype 1 hepatitis C virus subtype misclassification by LiPA 2.0: implications for direct-acting antiviral treatment. J Clin Microbiol. 2014;52(11):4027–9.

111. Verbeeck J, Stanley MJ, Shieh J, Celis L, Huyck E, Wollants E et al. Evaluation of the VERSANT hepatitis C virus genotype assay (LiPA) 2.0. J Clin Microbiol. 2008;46(6):1901–6.

112. Easterbrook PJ, Roberts T, Sands A, Peeling R. Diagnosis of viral hepatitis. Curr Opin HIV AIDS. 2017;12(3):302–14.

113. High-priority target product profile for hepatitis C diagnosis in decentralized settings: report of a consensus meeting. Geneva: FIND; April 2015.

114. Easterbrook P, Johnson C, Figueroa C, Baggaley R. HIV and hepatitis testing: global progress, challenges, and future directions. AIDS Rev. 2016;18(1):3–14.

115. Martin Bland J, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;327(8476):307–10.

116. Hadziyannis SJ, Sette H Jr, Morgan TR, Balan V, Diago M, Marcellin P et al. Peginterferon-alpha-2a and ribavirin combination therapy in chronic hepatitis C: a randomized study of treatment duration and ribavirin dose. Ann Inter Med. 2004;140(5):346–55.

117. Dieterich D, Asselah T, Guyader D, Berg T, Schuchmann M, Mauss S et al. SILEN-C3, a phase 2 randomized trial with faldaprevir plus pegylated interferon α-2a and ribavirin in treatment-naive hepatitis C virus genotype 1-infected patients. Antimicrob Agents Chemother. 2014;58(6):3429–36.

118. Wynberg E, Cooke G, Shroufi A, Reid SD, Ford N. Impact of point-of-care CD4 testing on linkage to HIV care: a systematic review. J Int AIDS Soc. 2014;17(1).

119. Guidelines on HIV self-testing and partner notification. Geneva: World Health Organization; December 2016.

120. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. PLoS Med. 2015;12(9):e1001873.

121. Analysis of HCV RIBA shortage and need to obtain an FDA variance – updated May 2014 [Online] (http://www.aabb.org/advocacy/regulatorygovernment/donoreligibility/hepatitis/Pages/hepatitisanalysis092712.aspx, accessed 8 May 2018).

Appendix 1.
Operational characteristics of diagnostic devices and assays

*Throughput: low = <50 samples/hour, medium = 51–100 samples/hour, high = >100 samples/hour
TBC = To be confirmed N/A = Not applicable

Abbott (information not verified by company)	
PRISM HCV assay, PRISMnEXT (device)	
Marketing status	On the market
Type of technology	CLIA
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	FDA approved, CE marked
Sensitivity	100%
Specificity	99.73%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	Device: TBC Assay: 12 months
Type of sample required	Serum, plasma
Volume of sample required	350 µL
Turnaround time	TBC
Throughput*	High
Dimensions (W x H x D)	Device: 1.73 x 2.33 x 0.84 m
Power requirements	Single-phase 200–240 VAC ±10%
Connectivity	TBC
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	VGA-compatible colour monitor with keyboard
Image of device(s)	Unavailable

Abbott (information not verified by company)	
AxSYM HCV V3.0 (assay), AxSYM Plus 5.0 (device)	
Marketing status	On the market
Type of technology	Microparticle enzyme immunoassay (MEIA)
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	Assay: FDA approved, CE marked
Sensitivity	100%
Specificity	99.6%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Serum, plasma
Volume of sample required	83–150 µL
Turnaround time	Time to first result 8–30 minutes
Throughput*	Medium to high (80–120 tests/hour)
Dimensions (W x H x D)	Device: 63 x 60.5 x 24 inches
Power requirements	AC
Connectivity	TBC
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	None
Image of device(s)	Unavailable
Abbott (information not verified by company)	
ARCHITECT HCV cAg assay, ARCHITECT i2000SR (device)	
Marketing status	On the market
Type of technology	Device: Fully automated immunoassay analyser using CHEMIFLEX Assay: Chemiluminescent microparticle immunoassay (CMIA)
POC	No
Infections the device(s) can test for and regulatory approval status	HCV cAg
	CE marked
Sensitivity	99.1%

Specificity	99.6%
Multiplex	No
Storage temperature of the device(s)/reagents	Device: TBC Reagents: 2–8 °C
Shelf life of the device(s)/reagents	Device: TBC Assay: 12 months
Type of sample required	Plasma, serum
Volume of sample required	150 µL
Turnaround time	First result in 36 minutes
Throughput*	Medium to high (up to 200 tests per hour)
Dimensions (W x H x D)	Device: Ranges from 124.5 x 149.9 x 76.2 cm (smallest system) to 121.9 x 322.6 x 124.5 cm (largest system)
Power requirements	Device: AC 180–264 V, 47–63 Hz
Connectivity	Uses Abbottlink
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	Moderately complex Steps include vortexing (internal control, calibrators and specimens), pipetting, centrifuge, etc. Fully trained laboratory technician required
Supporting instrumentation/sample preparation required	Pipettes, vortex mixer and refrigerator; freezer
Image of device(s)	Unavailable
Abbott Molecular	
***m*2000 System (*m*2000*sp* (extraction) and *m*2000*rt* (amplification), RealTi*me* Genotype II, RealTi*me* HCV viral load assay**	
Marketing status	All on the market
Type of technology	qPCR and qRT-PCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HCV (viral load), HCV (genotyping)
	FDA approved: HCV (viral load), HCV (genotyping)
Sensitivity	RealTi*me* Genotype II: 500 IU/mL for 0.5 mL prep RealTi*me* HCV viral load assay: 12 IU/mL for 0.5 mL sample, 30 IU/mL for 0.2 mL sample
Specificity	RealTi*me* Genotype II: 100% RealTi*me* HCV viral load assay: 100%
Multiplex	Yes, maxCycle assays allow two assays in a single run maxCycle for Abbott RealTi*me* HIV-1/HCV (CE marked)
Storage temperature of the device(s)/reagents	*m*2000 System: 60 °C Reagents: Amplification, control and calibrations kits ≤-10 °C (some amplification kits from -15 to -25 °C); sample preparation kits 15–30 °C

Shelf life of the device(s)/reagents	System: TBC Reagents: Amplification, control, and calibration kits 18 months upon manufacture; sample preparation kits 12 months
Type of sample required	For HCV: serum or plasma
Volume of sample required	Assay and sample type dependent: 0.2–1 mL
Turnaround time	Assay dependent: 4.5–6.3 hours for 24 samples; 6.2–9.5 hours for 96 samples (extraction and amplification)
Throughput*	Low: 6.2–9.5 hours for 96 samples (extraction and amplification)
Dimensions (W x H x D)	*m*2000*sp*: 145 x 138 x 79.5 cm *m*2000*rt*: 34 x 49 x 45 cm
Power requirements	*m*2000*sp*: 1200 VA *m*2000*rt*: 860 VA
Connectivity	AbbottLink and *m*View are optional features that allow remote diagnostics and performance monitoring, respectively, available using a secured internet connection
Marketing price per instrument/test	Contact the local Abbott Molecular representative for prices
Complexity/training requirements	2 days of instructor-led training for the system, including one assay; 1 day per assay thereafter
Supporting instrumentation/sample preparation required	*m*Plus (Amplification Reagent Extended Use) has the capability of reusing the amplification reagent one more time or more often (depending on the assay), allowing the reuse of the 24-test pack in order to run batch sizes smaller than 24 for higher efficiency *m*Plus gives laboratories flexibility and added efficiency that allows for customized workflow, and faster results Supporting instruments required is minimal; automated extraction and amplification Abbott also has the *m*24*sp* instrument for mid-volume extraction, but not all assays are available on this system *m*2000*sp* is for mid- to high-volume throughput; *m*24*sp* for low- to mid-volume throughput
Image of device(s) ***m*2000sp and *m*2000*rt***	

ABON Biopharm (limited information available/not verified by company)	
ABON HCV Rapid Test Device and Test Strip	
Marketing status	On the market (ABON now owned by Abbott)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	CE marked
Throughput	Low
Image of device(s)	Unavailable
AccuBioTech Co. Ltd (information not verified by company)	
Accu-Tell® HCV serum/whole blood Test Kit, Accu-Tell® HCV ELISA Test Kit	
Marketing status	Accu-Tell® HCV serum/whole blood Test Kit: On the market Accu-Tell® HCV ELISA Test Kit: On the market
Type of technology	Accu-Tell® HCV serum/whole blood Test Kit: Chromatographic immune assay (cassette/strip) Accu-Tell® HCV ELISA Test Kit: EIA
POC	Accu-Tell® HCV serum/whole blood Test Kit: Yes Accu-Tell® HCV ELISA Test Kit: No
Infections the device(s) can test for and regulatory approval status	Accu-Tell® HCV serum/whole blood Test Kit: HCV Accu-Tell® HCV ELISA Test Kit: HCV Accu-Tell® HCV serum/whole blood Test Kit: FDA pre-market approval – TBC Accu-Tell® HCV ELISA Test Kit: TBC
Sensitivity	Accu-Tell® HCV serum/whole blood Test Kit: 100% Accu-Tell® HCV ELISA Test Kit: 57.8–91.12%
Specificity	Accu-Tell® HCV serum/whole blood Test Kit: 97–99% Accu-Tell® HCV ELISA Test Kit: 99.5–99.7%
Multiplex	No
Storage temperature of the device(s)/reagents	Accu-Tell® HCV serum/whole blood Test Kit: 2–30 °C Accu-Tell® HCV ELISA Test Kit: 2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	AvailableAccu-Tell® HCV serum/whole blood Test Kit: Whole blood/serum Accu-Tell® HCV ELISA Test Kit: Serum, plasma

Volume of sample required	Accu-Tell® HCV serum/whole blood Test Kit: 1 drop/10 µL Accu-Tell® HCV ELISA Test Kit: 1 drop/10 µL
Turnaround time	Accu-Tell® HCV serum/whole blood Test Kit: 1 minute Accu-Tell® HCV ELISA Test Kit: >60 minutes
Throughput*	Accu-Tell® HCV serum/whole blood Test Kit: Low Accu-Tell® HCV ELISA Test kit: Low
Dimensions (W x H x D)	TBC
Power requirements	Accu-Tell® HCV ELISA Test kit: Refrigerator
Connectivity	TBC
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	Accu-Tell® HCV serum/whole blood Test Kit: Minimal Accu-Tell® HCV ELISA Test Kit: Depends on level of education or experience, but knowledge of molecular biology and basic laboratory skills required
Supporting instrumentation/sample preparation required	Accu-Tell® HCV serum/whole blood Test: None Accu-Tell® HCV ELISA Test Kit: a. Bring the conjugate and conjugate diluent to room temperature before use b. Make sure that the container for mixing the preparation is clean c. Dilute the conjugate to the needed volume with a 1 : 20 ratio of conjugate diluent; swirl gently to mix thoroughly without foaming d. Refrigerate the unused portion at 2 to 8 °C and use within 1 week e. General laboratory infrastructure required; pipettes, centrifuge, etc.
Image of device(s) **Accu-Tell® HCV ELISA Test Kit** **Accu-Tell® HCV serum/whole blood Test Kit**	Unavailable

Alere	
Alere™ q	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	Alere™ q HIV-1/2 Detect: WHO prequalification, CE marked HCV has been listed as a development target
Sensitivity	TBC
Specificity	TBC
Multiplex	Has the capability to be multiplex
Storage temperature of the device(s)/reagents	Alere™ q analyser to be stored at 2–50 °C Alere™ q HIV-1/2 Detect cartridges should be stored at ambient temperature 4–30 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	TBC
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	Low
Power requirements	Mains or battery powered
Connectivity	Yes, as standard Results can be printed immediately, but results are also stored in an onboard archive and can be viewed and printed as needed, exported to a USB memory stick or exported to a remote server via the use of an optional USB connectivity package using a GSM mobile telephone network infrastructure
Marketing price per instrument/test	TBC
Complexity/training requirements	Non-complex, minimal training required Actual hands-on time for the device is expected to be less than 3 minutes (i.e. sample collection, loading of the cartridge onto the analyser, and entering the operator and sample IDs on the analyser)
Supporting instrumentation/sample preparation required	Alere™ q analyser is factory calibrated and does not require any further calibrations No sample preparation required
Image of device(s)	

Alfa Scientific Designs (information not verified by company)	
Instant-View™ HCV Serum Test	
Marketing status	On the market
Type of technology	Immunochromatographic assay (lateral flow)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	CE marked
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	15–30 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	Serum, plasma
Volume of sample required	TBC
Turnaround time	TBC
Throughput	Low
Dimensions	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Contact company
Complexity/training requirements	TBC
Image of device(s)	Unavailable
ALL.DIAG/Biosynex (limited information available/not verified by company)	
HCVTOP ™	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
Infections the device(s) can test for and regulatory approval status	HCV
	CE marked
Sensitivity	99.1%
Specificity	99.6%
Multiplex	No
Storage temperature of the device(s)/reagents	2–30 °C

Shelf life of the device(s)/reagents	18 months
Type of sample required	Serum, plasma
Volume of sample required	1 drop (50 µL)
Turnaround time	10 minutes
Marketing price per instrument/test	TBC
Complexity/training requirements	None
Supporting instrumentation/sample preparation required	None
Image of device(s)	Unavailable
Analytik Jena	
TAdvanced, TRIO, TOne	
Marketing status	On the market
Type of technology	PCR thermocycler
POC	No
Infections the device(s) can test for and regulatory approval status	Assay dependent (see Robogene® HCV RNA quantification kit below)
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	No
Storage temperature of the device(s)/reagents	TAdvanced 96/96s, TRIO, TOne: 15–35 °C, 70% air humidity, maximum 2000 m NN
Shelf life of the device(s)/reagents	TAdvanced 96/96s, TRIO, TOne: 2-year warranty on device system
Type of sample required	Assay dependent (see below)
Volume of sample required	TAdvanced 96/96s, TRIO, TOne: 10–100 µL
Turnaround time	Assay dependent
Throughput*	TAdvanced 96/96s: 96 TRIO: 3 blocks: 30 x 0.5 mL; 3 blocks: 48 x 0.2 mL; 3 combi blocks for 18 x 0.5 mL or 48 x 0.2 mL tubes TOne: 96
Dimensions (W x H x D)	TAdvanced: 27.7 x 26.4 x 45.7 cm; or 27.7 x 41.1 x 45.7 cm TRIO: 30 x 41 x 25 cm TOne: 26 x 43 x 21 cm
Power requirements	TAdvanced: 850 watt; 100, 115, 230 Volt, 50–60 Hz TRIO: 1000 watt; 110, 115, 230 Volt, 50–60 Hz Tone: 550 watt; 100, 115, 230 Volt, 50–60 Hz

Connectivity	TAdvanced: USB A, Ethernet TRIO: USB A, Ethernet TOne: USB A, Ethernet
Marketing price per instrument/test	TAdvanced: €6690–7290 TRIO: €9990 TOne: €4990–5290
Complexity/training requirements	No
Supporting instrumentation/sample preparation required	Assay dependent
Image of device(s) **Top to bottom and left to right:** **TAdvanced/TOne/TRIO**	
Analytik Jena	
RoboGene® HCV RNA Quantification Kit	
Marketing status	On the market – not available in the United States
Regulatory approval status	CE-IVD
Type of technology	Real-time PCR
POC	No
Infections the device can test for	HCV RNA (genotypes 1 to 6)
Sensitivity	68 IU/mL
Specificity	TBC
Multiplex	Yes, target/IC
Storage temperature of the device/reagents	-20 °C
Shelf life of the device/reagents	Minimum 6 months
Type of sample required	Serum, plasma
Volume of sample required	150 µL for RNA extraction using INSTANT VIRUS RNA KIT
Turnaround time	120 minutes
Throughput	96 samples/2 hours from a single kit
Marketing price per instrument/test	€20/kit
Complexity/training requirements	No
Supporting instrumentation/sample preparation required	To be used in combination with INSTANT VIRUS RNA KIT General laboratory infrastructure and equipment
Product image	Unavailable

Artron Laboratories (information not verified by company)	
HCV Antibody Test, Detect 3 HIV/HCV/HBV Combo	
Marketing status	HCV Antibody Test: On the market Detect 3 HIV/HCV/HBV Combo: On the market
Type of technology	HCV Antibody Test: RDT Detect 3 HIV/HCV/HBV Combo: RDT
POC	HCV Antibody Test: Yes Detect 3 HIV/HCV/HBV Combo: Yes
Infections the device(s) can test for and regulatory approval status	HCV Antibody Test: HCV; CE marked Detect 3 HIV/HCV/HBV Combo: HCV, HIV, HBV; CE marked
Sensitivity	HCV Antibody Test: >99% Detect 3 HIV/HCV/HBV Combo: >99%
Specificity	HCV Antibody Test: TBC Detect 3 HIV/HCV/HBV Combo: >99%
Multiplex	HCV Antibody Test: No Detect 3 HIV/HCV/HBV Combo: Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	HCV Antibody Test: Whole blood, plasma or serum Detect 3 HIV/HCV/HBV Combo: Plasma or serum
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

Atlas Link (Beijing) Technology (some information not verified by company)	
One Step HIV/HCV/HBsAg Serum Test Panel, HCV Test in Serum, HCV Test in Whole Blood	
Marketing status	One Step HIV/HCV/HBsAg Serum Test Panel: On the market HCV Test in Serum: On the market HCV Test in Whole Blood: On the market
Type of technology	One Step HIV/HCV/HBsAg Serum Test Panel: RDT HCV Test in Serum: RDT HCV Test in Whole Blood: RDT
POC	One Step HIV/HCV/HBsAg Serum Test Panel: Yes HCV Test in Serum: Yes HCV Test in Whole Blood: Yes
Infections the device(s) can test for and regulatory approval status	One Step HIV/HCV/HBsAg Serum Test Panel: HIV/HCV/HBV; CE marked HCV Test in Serum: HCV HCV Test in Whole Blood: HCV
Sensitivity	HCV: >99%
Specificity	HCV: >99%
Multiplex	One Step HIV/HCV/HBsAg Serum Test Panel: Yes HCV Test in Serum: No HCV Test in Whole Blood: No
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	One Step HIV/HCV/HBsAg Serum Test Panel: Serum HCV Test in Serum: Serum HCV Test in Whole Blood: Whole Blood
Volume of sample required	Few drops
Turnaround time	10 minutes
Throughput*	Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	

Autobio Diagnostics Co. Ltd (information not verified by company)	
Anti-HCV, Anti-HCV Rapid Test	
Marketing status	Anti-HCV: On the market Anti-HCV: Rapid Test: On the market
Type of technology	Anti-HCV: EIA Anti-HCV Rapid Test: Colloidal gold sandwich assay (cassette/strip)
POC	Anti-HCV: No Anti-HCV Rapid Test: Yes
Infections the device(s) can test for and regulatory approval status	Anti-HCV: HCV Anti-HCV Rapid Test: HCV Anti-HCV: IVD Anti-HCV Rapid Test: IVD
Sensitivity	Anti-HCV: TBC Anti-HCV Rapid Test: 99.50%
Specificity	Anti-HCV: TBC Anti-HCV Rapid Test: 99.70%
Multiplex	Anti-HCV: No Anti-HCV Rapid Test: No
Storage temperature of the device(s)/reagents	Anti-HCV: 2–8 °C Anti-HCV Rapid Test: 1–30 °C
Shelf life of the device(s)/reagents	Anti-HCV: 12 months Anti-HCV Rapid Test: 24 months
Type of sample required	Anti-HCV: Serum (recommended) or plasma Anti-HCV Rapid Test: TBC
Volume of sample required	Anti-HCV: 10 µL Anti-HCV Rapid Test: ~80 µL
Turnaround time	Anti-HCV: 120 minutes Anti-HCV Rapid Test: 15 minutes
Throughput*	Anti-HCV: High Anti-HCV Rapid Test: Low
Power requirements	Anti-HCV: Refrigerator required and ELISA plate reader Anti-HCV Rapid Test: TBC
Connectivity	TBC
Marketing price per instrument/test	Available upon request from supplier

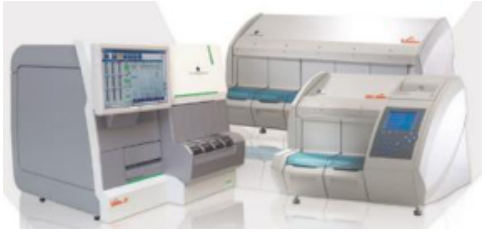
Complexity/training requirements	Anti-HCV: General laboratory skills and microbiology knowledge Anti-HCV Rapid Test: Minimal
Supporting instrumentation/sample preparation required	Anti-HCV: General laboratory infrastructure and equipment including: refrigeration, pipettes, vortex mixer and magnetic stirrer, and ELISA plate reader Anti-HCV Rapid Test: None
Image of device(s) **Anti-HCV** **Anti-HCV Rapid Test**	Unavailable
Axiom Diagnostic (information not verified by company)	
HCV Card Serum/Plasma Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV; CE marked
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	4–30 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum
Volume of sample required	~100 µL
Turnaround time	TBC
Throughput*	Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

Beckman Coulter	
DxN VERIS Molecular Diagnostics System	
Marketing status	On the market – not available in the United States/ all markets
Regulatory approval status	CE marked, currently under WHO prequalification (submission accepted)
Type of technology	RT-PCR (Taqman®) Magnetic particle separation (propriety)
POC	No
Infections the device can test for	HCV RNA (genotypes 1 to 6): See VERIS assay below
Sensitivity	≤0.4 log IU/mL for samples 12–<20 IU/mL ≤0.3 log IU/mL for samples 20–7.5x107 IU/mL
Specificity	≤0.2 log IU/mL
Multiplex	No
Storage temperature of the device/reagents	Device and general consumables: Room temperature Reagents: 4 °C Calibration adjusters: -20 °C Quality control: -20 or -70 °C for long-term storage (>6 months)
Shelf life of the device/reagents	Reagents 30 days from opening Device TBC
Type of sample required	K-EDTA plasma
Volume of sample required	1.0 mL
Turnaround time	Daily maintenance and setup: ≤10 minutes Walk-away time: ≥2 hours (replenish tips and samples)
Throughput	Low: ~100 results in 8 hours (RNA assay)
Dimensions (W x H x D)	43 (109.2) x 66 (167.7 x 81 (205.8) inches/cm Working footprint: 3.0 m2, 576 kg
Power requirements	Line voltage 200–240 VAC, 50/60 Hz, 16 A Class1
Connectivity	YES, LIS connectivity
Marketing price per instrument/test	Test volume dependent
Complexity/training requirements	Low complexity Very easy to use, fully automated after primary tube loading Ready to use reagents with onboard storage

Supporting instrumentation/sample preparation required	Single platform Fully automated platform Primary tube loading secondary tube option available
Product image	
Beckman Coulter	
VERIS HCV ASSAY	
Marketing status	On the market – not available in the United States/ all markets
Regulatory approval status	CE marked Under WHO prequalification
Type of technology	Real-time PCR (Taqman®)
POC	No
Infections the device can test for	HCV RNA (genotypes 1 to 6)
Sensitivity	12 IU/mL
Specificity	100% for HCV RNA and HCV IgG antibody negative samples
Multiplex	No
Storage temperature of the device/reagents	Device and general consumables: Room temperature Reagents: 4 °C Calibration adjusters: -20 °C Quality control: -20 or -70 °C for long-term storage (>6 months)
Shelf life of the device/reagents	30 days from opening, onboard storage
Type of sample required	K-EDTA plasma
Volume of sample required	1.0 mL
Turnaround time	115 minutes to first result, every 2.5 minutes; 100 test/8-hour shift
Throughput	Low: ~100 results in 8 hours for RNA assays

Marketing price per instrument/test	Test volume as well as placement business model dependent
Complexity/training requirements	Low complexity Very easy to use, fully automated after primary tube loading Ready-to-use reagents with onboard storage
Supporting instrumentation/sample preparation required	Single, fully automated platform (DxN VERIS Molecular Diagnostics System – see above) Primary tube loading, secondary tube option available
Product image **HCV reagent pack** **HCV extraction purification cartridge**	
BHAT Biotech (information not verified by company)	
Hepa-Scan® HCV ELISA, Hepa-Scan® HCV Rapid Card Test	
Marketing status	ELISA: On the market Rapid: On the market
Type of technology	ELISA: EIA Rapid: Immunochromatographic assay
POC	ELISA: No Rapid: Yes
Infections the device(s) can test for and regulatory approval status	ELISA: HCV Rapid: HCV
	ELISA: CE marked Rapid: HCV
Sensitivity	ELISA: >99% Rapid: >99%
Specificity	ELISA: >98% Rapid: >98%
Multiplex	ELISA: Yes Rapid: No
Storage temperature of the device(s)/reagents	ELISA: 2–8 °C Rapid: 2–30 °C
Shelf life of the device(s)/reagents	ELISA: 18 months Rapid: 24 months
Type of sample required	ELISA: Serum or plasma Rapid: Whole blood, serum or plasma

Volume of sample required	ELISA: 10 µL Rapid: 50 µL (serum or plasma), 25 µL (whole blood)
Turnaround time	ELISA: 90 minutes Rapid: 20 minutes
Throughput*	ELISA: High Rapid: Low
Marketing price per instrument/test	TBC
Complexity/training requirements	See the package insert
Supporting instrumentation/sample preparation required	ELISA: General laboratory infrastructure Rapid: Minimal
Image of device(s) **HCV ELISA Test** **HCV Rapid Card Test**	Unavailable
Biokit S.A. (information not verified by company)	
Bioelisa HCV 4.0	
Marketing status	On the market
Type of technology	EIA
POC	No
Infections the device(s) can test for and regulatory approval status	HCV Regulatory status: CE marked, WHO prequalified
Sensitivity	100%
Specificity	99.6–99.8%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma
Volume of sample required	200 µL
Turnaround time	10 minutes
Throughput*	High
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Depends on level of education or experience, but knowledge of molecular biology and basic laboratory skills required
Supporting instrumentation/sample preparation required	General laboratory infrastructure and equipment including: refrigeration, pipettes, vortex mixer and magnetic stirrer, and ELISA plate reader

Bio-Mérieux (information not verified by company)	
VIDAS-3 (device), miniVIDAS (device), VIDAS Anti-HCV (assay)	
Marketing status	On the market (CE marked)
Type of technology	Immunoassay
POC	No
Infections the device(s) can test for and regulatory approval status	HCV (others available)
	CE marked
Sensitivity	VIDAS Anti-HCV: 99.7%
Specificity	VIDAS Anti-HCV: >99.0%
Multiplex	VIDAS Anti-HCV: No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	VIDAS Anti-HCV: Serum, plasma
Volume of sample required	VIDAS Anti-HCV: 100 µL
Turnaround time	VIDAS-3: 17–90 minutes miniVIDAS: 17–90 minutes VIDA Anti-HCV: 40 minutes
Throughput*	VIDAS-3: Up to 36 tests per hour miniVIDAS: Up to 36 tests per hour
Dimensions (W x H x D)	VIDAS-3: TBC miniVIDAS: 45 x 57.5 x 55 cm
Power requirements	VIDAS-3: 100–240 VAC, 50–60 Hz, 50–60 W miniVIDAS: 100–240 VAC, 50–60 Hz, 50–60 W
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	VIDAS-3: TBC miniVIDAS comes with built in computer, keyboard and printer
Image of device(s) **VIDAS-3/miniVIDAS**	

BIONEER	
ExiStation™ Universal Molecular Diagnostic System (ExiPrep™ 16 Dx/ExiPrep™ 48 Dx (with or without ExiLT™ 48 BT/ST) in combination with Exicycler™ 96, or fully-automated ExiStation™ HT (with or without ExiLT™ 48 BT/ST))	
Marketing status	On the market: ExiPrep™ 16 Dx (nucleic acid extraction): CE marked, FDA approved, WHO prequalification Exicycler™ 96 Dx (5 colour qPCR system): CE marked, WHO prequalification ExiStation™ HT (integrated standalone platform for nucleic acid extraction and qPCR): CE marked ExiPrep™ 48 Dx (nucleic acid extraction): CE marked
	In development: ExiLT™ 48 BT (automated blood sample handler) ExiLT™ 48 ST (automated sputum, urine, faeces sample handler) (ExiLT™ 48 BT and ExiLT™ 48 ST dock with ExiPrep™ 48 Dx and Exicycler™ 96 Dx and automate the whole process of clinical sample tube loading and nucleic acid extraction and purification. Only user hands-on process is to seal PCR reaction tube and to load onto the PCR rack – together the system is called the ExiStation™ 48A, expected to launch soon.) ExiLT™ 48 BT and ExiLT™ 48 ST can also be used in combination with the ExiStation™ HT System
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: MTB, CT/NG, HPV, HSV-1, HSV-2, enterovirus, Trichomonas vaginalis, human herpes virus 6, FluA/B, ureaplasma, *Mycoplasma genitalium, Mycoplasma hominis, Chlamydophila pneumoniae*, Dengue virus, Ebola virus, Epstein-Barr virus, Zika virus multiplex (and others) Zika virus (Dengue virus, Chikungunya virus) multiplex assay also WHO prequalification and undergoing FDA submission
	RUO: HCV (viral load), HBV (viral load), HIV-1 (viral load)
Sensitivity	Assay dependent: HIV-1: 33.1 IU/mL (EDTA-plasma) MTB: 89.1 copies/mL HCV: 10.7 IU/mL (EDTA-plasma)

Specificity	Assay dependent HIV-1: 100% MTB: TBC HCV: 99.12%
Multiplex	Yes CE marked: AccuPower® STI8A-Plex, AccuPower® Zika virus (Dengue virus, Chikungunya virus and others) Entire ExiStation™ platform also WHO prequalification for AccuPower® Zika virus (Dengue virus, Chikungunya virus); this assay also undergoing FDA submission AccuPower® TB and XDR (Fluoroquinolone/ streptomycin/ethambutol resistance, MTB) – in development As well as having multiplex assays available, the ExiPrep System can automatically aliquot prepared sample into two separate reaction tubes for individual qPCR/RT-PCR analysis by Exicycler™ 96
Storage temperature of the device(s)/reagents	Instruments: 15–30˚°C ExiPrep™ Extraction Kits: 15–30 °C AccuPower® DNA/RNA Kits: -15 to -25 °C
Shelf life of the device(s)/reagents	Instruments: TBC ExiPrep™ Extraction Kits: 1 year AccuPower® DNA/RNA Kits: 1 year
Type of sample required	Assay dependant: DBS, plasma, serum, nasal swab, urine, etc.
Volume of sample required	Assay and instrument dependent: 200, 400 and 800 µL
Turnaround time	ExiStation™ 16: 3 hours plus 30 minutes hands-on time ExiStation™ 48: 2 hours 20 minutes plus 1 hour hands-on time ExiStation™ HT: First batch 3 hours, subsequent samples in 96 batch 1.5 hours
Throughput	Low to medium depending on the set-up: ExiPrep™ 16 Dx: 16 samples/90 minutes: 10.7 samples/hour ExiStation™: 48 samples/90 minutes: 32 samples/ hour
	Overall: 48 samples/180 minutes: 16 samples/hour ExiPrep™ 48 Dx: 48 samples/140 minutes: 20.6 samples/hour ExiStation™ HT: First batch 96 samples/3.0 hours (32 samples/hour); second batch 96 samples/1.5 hours (64.0 samples/hour)

Dimensions (W x H x D)	ExiPrep™ 16 Dx: 320 x 500 x 535 mm ExiPrep™ 48 Dx: 760 x 725 x 620 mm Exicycler™ 96: 355 x 540 x 470 mm ExiStation™ HT: 2182 x 1955 x 970 mm ExiLT™ 48 BT: 510 x 750 x 620 mm ExiLT™ 48 ST: TBC
Power requirements	ExiPrep™ 16 Dx: 100–240VAC via adopter ExiPrep™ 48 Dx: 100–240VAC Exicycler™ 96: 100–240VAC ExiStation™ HT: 110–120VAC or 220–240VAC with voltage selection switch on the back ExiLT™ 48 BT or ST: 100–240VAC
Connectivity	TCP/IP 2. USB protocol
Marketing price per instrument/test	ExiStation™ with one ExiPrep™ 16 Dx: US$ 50 000 ExiStation™ with two ExiPrep™ 16 Dx: US$ 66 000 ExiStation™ with three ExiPrep™ 16 Dx: US$ 80 000 Exicycler™ 96: US$ 32 000 ExiPrep™ 48 Dx US$ 48 000 ExiStation™ HT: US$ 390 000 ExiLT™ 48 BT or ST: US$ 15 000 Assays: US$ 10–25 (dependent on the assay)
Complexity/training requirements	Technicians with minimal skills can easily learn to operate ExiStation™ after 2 full days of education and training
Supporting instrumentation/sample preparation required	All configuration as priced include a notebook with ExiStation™ Management software pre-installed ExiPrep™ HT: Price includes a personal computer, monitor and printer In some cases, special samples such as sputum may require extra treatment prior to extraction
Image of device(s) **Top to bottom:** **ExiPrep™ 16 Dx and Exicycler™ 96**	
ExiPrep™ 48 Dx and Exicycler™ 96	

ExiPrep™ HT	
Bio-Rad Laboratories (information not verified by company)	
Monolisa® Anti-HCV PLUS Assay Version 3, Deciscan® HCV PLUS, Monolisa® HCV Ag-Ab ULTRA V2	
Marketing status	Monolisa® Anti-HCV PLUS Assay Version 3: On the market Deciscan® HCV PLUS: On the market Monolisa® HCV Ag-Ab ULTRA V2: On the market
Type of technology	Monolisa® Anti-HCV PLUS Assay Version 3: EIA Deciscan® HCV PLUS: EIA Monolisa® HCV Ag-Ab ULTRA V2: EIA
POC	Monolisa® Anti-HCV PLUS Assay Version 3: No Deciscan® HCV PLUS: No Monolisa® HCV Ag-Ab ULTRA V2: No
Infections the device(s) can test for and regulatory approval status	Monolisa® Anti-HCV PLUS Assay Version 3: HCV; CE marked Deciscan® HCV PLUS: HCV; CE marked Monolisa® HCV Ag-Ab ULTRA V2: HCV; WHO prequalified – active application, CE marked
Sensitivity	Monolisa® Anti-HCV PLUS Assay Version 3: 100% Deciscan® HCV PLUS: TBC Monolisa® HCV Ag-Ab ULTRA V2: 100%
Specificity	Monolisa® Anti-HCV PLUS Assay Version 3: 99.9% Deciscan® HCV PLUS: TBC Monolisa® HCV Ag-Ab ULTRA V2: ≥99.5%
Multiplex	No
Storage temperature of the device(s)/reagents	Monolisa® Anti-HCV PLUS Assay Version 3: 2–8 °C Deciscan® HCV PLUS: 2–8 °C Monolisa® HCV Ag-Ab ULTRA V2: 2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Monolisa® Anti-HCV PLUS Assay Version 3: Serum/plasma Deciscan® HCV PLUS: Serum/plasma Monolisa® HCV Ag-Ab ULTRA V2: Serum/plasma

Volume of sample required	Monolisa® Anti-HCV PLUS Assay Version 3: 20 µL Deciscan® HCV PLUS: 10 µL Monolisa® HCV Ag-Ab ULTRA V2: 50 µL
Turnaround time	Monolisa® Anti-HCV PLUS Assay Version 3: 120 minutes Deciscan® HCV PLUS: TBC Monolisa® HCV Ag-Ab ULTRA V2: TBC
Throughput*	Monolisa® Anti-HCV PLUS Assay Version 3: High Deciscan® HCV PLUS: TBC Monolisa® HCV Ag-Ab ULTRA V2: High
Dimensions (W x H x D)	TBC
Power requirements	Refrigeration and other general laboratory devices will need power
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Depends on level of education or experience, but knowledge of molecular biology and basic laboratory skills required
Supporting instrumentation/sample preparation required	General laboratory infrastructure and equipment including; refrigeration, pipettes, vortex mixer and magnetic stirrer, and ELISA plate reader
Image of device(s) **Monolisa® Anti-HCV PLUS Assay Version 3** **Deciscan® HCV PLUS** **Monolisa® HCV Ag-Ab ULTRA V2**	Unavailable
BioSynex (not confirmed by supplier)	
CarL, Autoblot 3000, AMPLIX-NG48/AMPLIX-NG96	
Marketing status	CarL: On the market Autoblot 3000: On the market AMPLIX-NG48/NG96: On the market
Type of technology	CarL: Automated Western-Blot Autoblot 3000: Automated strip processor for immunoLine and immuneBlot techniques AMPLIX-NG48/NG96: Real-time PCV machine
Infections the device(s) can test for and regulatory approval status	CarL: recomLINE® HCV IgG Immunoblot (see below), CE marked Autoblot 3000: recomLINE® HCV IgG Immunoblot (see below), CE marked AMPLIX-NG48/NG96: RealLine HCV Quantitative and Qualitative Test, RealLine HBV/HCV/HIV Test and HCV Quantitative PCR Kit Liquid (see below), CE marked

Sensitivity	TBC
Specificity	TBC
Multiplex	CarL: Yes Autoblot 3000: TBC AMPLIX-NG48/NG96: Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	recomLINE® HCV Immunoblot strips: Human serum or plasma Others: TBC
Volume of sample required	TBC
Turnaround time	CarL: TBC Autoblot 3000: 90 seconds AMPLIX-NG48/NG96: TBC
Throughput*	CarL: Capacity for 44 blots Autoblot 3000: Capacity for 20 blots AMPLIX-NG48: Capacity for 48 samples AMPLIX-NG96: Capacity for 96 samples
Dimensions (W x H x D)	CarL: 100 x 600 x 650 mm (weight: 60 kg) Autoblot 3000: 569 x 457 x 165 mm (weight: 13.6 kg) AMPLIX-NG48: 56 x 51 x 58 mm (weight: 60 kg)/210 x 480 x 310 mm (weight: 17 kg) AMPLIX-NG96: 56 x 51 x 58 mm (weight: 60 kg)/210 x 540 x 540 mm (weight: 17 kg)
Power requirements	CarL: TBC Autoblot 3000: TBC AMPLIX-NG48/NG96: 220 V
Connectivity	CarL: Yes, Laboratory information system (LIS)/ hospital information system (HIS) Autoblot 3000: TBC AMPLIX-NG48/NG96: LIS
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC

Image of device(s) **Top to bottom and left to right:** **CarL/Autoblot 3000**	
Biosynex (not confirmed by supplier)	
IMMUNOQUICK® HCV, Triplex HIV/HCV/HBsAg, recomLINE® HCV IgG, RealLine HCV Quantitative and Qualitative Test, HCV Quantitative PCV Kit Liquid, RealLine HBV/HCV/HIV	
Marketing status	All: On the market
Type of technology	IMMUNOQUICK® HCV: Chromatographic immunoassay Triplex HIV/HCV/HBsAg: Chromatographic immunoassay recomLINE® HCV IgG: Immuno-blot RealLine HCV Quantitative and Qualitative Test: Real-time PCR HCV Quantitative PCV Kit Liquid: Real-time PCR RealLine HBV/HCV/HIV: Real-time PCR
POC	IMMUNOQUICK® HCV: Yes Triplex HIV/HCV/HBsAg: Yes recomLINE® HCV IgG: No RealLine HCV Quantitative and Qualitative Test: No HCV Quantitative PCV Kit Liquid: No RealLine HBV/HCV/HIV: No
Infections the device(s) can test for and regulatory approval status	All: HCV All: CE marked
Sensitivity	IMMUNOQUICK® HCV: 99.1% Others: TBC
Specificity	IMMUNOQUICK® HCV: 99.6% Others: TBC
Multiplex	IMMUNOQUICK® HCV, Triplex HIV/HCV/HBsAg: No recomLINE® HCV IgG, RealLine HCV Quantitative and Qualitative Test, HCV Quantitative PCV Kit Liquid, RealLine HBV/HCV/HIV: Yes

Storage temperature of the device(s)/reagents	IMMUNOQUICK® HCV, Triplex HIV/HCV/HBsAg: 2–30 °C recomLINE® HCV Immunoblot strips: 2–8 °C RealLine HCV Quantitative and Qualitative Test: 4–8 °C HCV Quantitative PCR Kit Liquid: -20 °C RealLine HBV/HCV/HIV: 4–8 °C
Shelf life of the device(s)/reagents	IMMUNOQUICK® HCV: TBC Triplex HIV/HCV/HBsAg: 24 months recomLINE® HCV IgG: 12 months
	RealLine HCV Quantitative and Qualitative Test: 12 months HCV Quantitative PCV Kit Liquid: 12 months RealLine HBV/HCV/HIV: 12 months
Type of sample required	IMMUNOQUICK® HCV: Blood/serum/plasma Triplex HIV/HCV/HBsAg: Blood/serum/plasma recomLINE® HCV IgG: 12 months RealLine HCV Quantitative and Qualitative Test: TBC HCV Quantitative PCV Kit Liquid: TBC RealLine HBV/HCV/HIV: Serum/plasma
Volume of sample required	IMMUNOQUICK® HCV: Blood/serum – 1 drop (~25 µL) Others: TBC
Turnaround time	IMMUNOQUICK® HCV: 10 minutes Others: TBC
Throughput*	IMMUNOQUICK® HCV, Triplex HIV/HCV/HBsAg, recomLINE® HCV IgG, HCV Quantitative PCV Kit Liquid: Low RealLine HCV Quantitative and Qualitative Test, RealLine HBV/HCV/HIV: Medium
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Available upon request from the manufacturer
Complexity/training requirements	IMMUNOQUICK® HCV, Triplex HIV/HCV/HBsAg: Minimal Others: TBC
Supporting instrumentation/sample preparation required	None

Boditech (not confirmed by company)	
ichroma™ II reader and HCV Test, AFIAS-1/6 reader and HCV Test	
Marketing status	Ichroma™ II reader and HCV Test: On the market AFIAS-1/6 reader and HCV Test: On the market
Type of technology	Ichroma™ II reader and HCV Test: RDT and reader AFIAS-1/6 reader and HCV Test: RDT and reader
POC	Yes
Infections the device(s) can test for and regulatory approval status	Ichroma™ II reader and HCV Test: HCV, HBV, influenza A and B; CE marked AFIAS-1/6 reader and HCV Test: HCV, HBV; CE marked
Sensitivity	TBC
Specificity	TBC
Multiplex	TBC
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma or whole blood
Volume of sample required	TBC
Turnaround time	12 minutes
Throughput*	Low ichroma™ II reader: TBC AFIAS-1/6 reader: 10 tests per hour
Power requirements	Ichroma™ II reader: Can be battery powered AFIAS-1/6 reader: 100–240 V AC, 50–60 Hz, 1.5–1.8 A
Connectivity	Ichroma™ II reader: Built-in printer, wireless connectivity, LIS/HIS communication, USB hub chip supporting four USB ports AFIAS-1/6 reader: Built-in printer, wireless connectivity, LIS/HIS communication, USB hub chip supporting four USB ports
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s) **AFIAS-6** **ichroma II**	Unavailable

Boson (not all information confirmed by company)	
HBsAg/HIV/HCV Panel Test, HCV Antibody Self Test Kit, HCV Antibody Test Strip/Card	
Marketing status	HBsAg/HIV/HCV Panel Test: On the market HCV Antibody Self Test Kit: On the market HCV Antibody Test Strip/Card: On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBsAg/HIV/HCV Panel Test: HBV, HCV, HIV (China FDA approved) HCV Antibody Self Test Kit: HCV HCV Antibody Test Strip/Card: HCV
Sensitivity	HCV: 99.8%
Specificity	HCV: 99.6%
Multiplex	HBsAg/HIV/HCV Panel Test: Yes HCV Antibody Self Test Kit: No HCV Antibody Test Strip/Card: No
Storage temperature of the device(s)/reagents	4–30 °C
Shelf life of the device(s)/reagents	18 months
Type of sample required	HBsAg/HIV/HCV Panel Test: Serum, plasma or whole blood HCV Antibody Self Test Kit: Serum, plasma or whole blood HCV Antibody Test Strip/Card: Serum, plasma or whole blood
Volume of sample required	One drop
Turnaround time	20 minutes
Throughput*	Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	

Cepheid	
GeneXpert® I, II, IV and XVI, Infinity-48s, Infinity-80	
Marketing status	On the market
Regulatory approval status	RUO: In North America at only a few sites, WHO prequalified (Infinity-48s and Infinity-80), CE marked
Type of technology	RT-PCR
POC	Yes (depending on machine, GeneXpert® I can be considered POC)
Infections the device can test for	HCV viral load
Sensitivity	4 IU/mL in EDTA plasma, 6.1 IU/mL in serum
Specificity	100% in HCV negative blood donors
Multiplex	Yes
Storage temperature of the device/reagents	Devices: 15–30 °C Reagents: 2–28 ÅãC
Shelf life of the device/reagents	Reagents: 12 months Device (estimated to be): 60 months
Type of sample required	Plasma or serum
Volume of sample required	1 mL
Turnaround time	30–90 minutes
Throughput	GeneXpert® I: Low GeneXpert® II: Low GeneXpert® IV: Low GeneXpert® XVI: Medium GeneXpert® Infinity-48s: High GeneXpert® Infinity-80: High
Dimensions (W x H x D)	GeneXpert® I: 4 x 12 x 11.7 inches GeneXpert® II: 6.35 x 12 x 11.7 inches GeneXpert® IV: 11 x 12 x 11.7 inches GeneXpert® XVI: 22.75 x 25.8 x 13.25 inches GeneXpert® Infinity-48s: 85 x 78.5 x 35 inches GeneXpert® Infinity-80: 108 x 78.5 x 35 inches
Power requirements	GeneXpert®-I: 1.5A @ 100V~, 0.75 A @ 200V~ Rated GeneXpert®-II: 1.5A @ 100V~, 0.75 A @ 200V~ Rated GeneXpert®-IV: 1.9A @ 100V~, 0.95 A @ 200V~ Rated GeneXpert®-XVI: 8.24A @ 100V~, 4.12 A @ 200V~ Rated
	GeneXpert® Infinity-48s: 200–240 VAC, 20A. 50–60 Hz +/-0.5%

Connectivity	GeneXpert® Infinity-80: 200–240 VAC, 20A. 50–60 Hz +/-0.5%
Marketing price per instrument/test	GeneXpert® I (1 machine): US$ 24 900 GeneXpert® II (2 machines): US$ 37 900 GeneXpert® IV (2/4 machines): US$ 43 400/US$ 63 400 GeneXpert® XVI (4/8/16 machines): US$ 83 400/ US$ 113 400/US$ 173 400 GeneXpert® Infinity-48s (16/24/32 machines): US$ 199 000/US$ 239 000/US$ 279 000 GeneXpert® Infinity-80: 40/48/80 machines: US$ 330 000/US$ 370 000/US$ 530 000
Complexity/training requirements	All machines: 4 hours of end-user training
Supporting instrumentation/sample preparation required	GeneXpert® instrument components: laptop computer or desktop computer, monitor, keyboard, mouse, barcode scanner, UPS, printer Infinity instrument components: UPS, printer
Image of device(s) **Left to right:** **GeneXpert® I** **GeneXpert® II** **GeneXpert® IV** **GeneXpert® XVI** **GeneXpert® Infinity**	
Cepheid	
GeneXpert® Omni	
Marketing status	Pipeline (will update shareholders in July 2018 at the International AIDS conference in the Netherlands)
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	Assay dependent (see HCV viral load cartridge details below)
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes: Xpert® Carba-R, Xpert® MRSA/SA, Xpert® Xpress Flu/RSV, Xpert® MTB/RIF, Xpert® CT/NG (all CE marked and FDA approved)
Storage temperature of the device(s)/reagents	2–40 °C
Shelf life of the device(s)/reagents	60 months/5 years

Type of sample required	GeneXpert® Omni will utilize existing Cepheid cartridge technology: this technology remains a cornerstone of testing on any of the GeneXpert® Instrument System family members and will continue to deliver unsurpassed accuracy, speed and ease of use Type of sample varies depending on test
Volume of sample required	Varies depending on test and sample type
Turnaround time	30–90 minutes per sample on average
Throughput*	Low
Dimensions (W x H x D)	3 x 9.1 x 4.2 inches
Power requirements	Built-in integrated (up to 3 hours operation) and supplemental rechargeable batteries (up to 8 hours operation)
Connectivity	GeneXpert® Omni module, mobile device interface and Cepheid C360 support a broad set of communications protocols to enable connectivity: Cellular (e.g. SMS, GSM), local area networks (e.g. Wi-Fi), middleware (e.g. LIS connectivity), Bluetooth (e.g. device to device, mobile to printer), secure cloud-based connectivity (e.g. Cepheid C360) integrates timely data streams for greater productivity and performance
Marketing price per instrument/test	Cartridges ranging from US$ 10–17 on average Omni: TBC
Complexity/training requirements	Minimal: 4 hours
Supporting instrumentation/sample preparation required	Minimal
Image of device(s) **GeneXpert® Omni**	
Cepheid	
Xpert® HCV Viral Load	
Marketing status	On the market
Regulatory approval status	RUO: In North America only at a few sites WHO prequalified, CE marked
Type of technology	RT-PCR
POC	Yes

Infections the device can test for	HCV viral load
Sensitivity	4.0 IU/mL in EDTA plasma, 6.1 IU/mL in serum
Specificity	100% in HCV negative patients
Multiplex	No
Storage temperature of the device/reagents	2–28 °C
Shelf life of the device/reagents	Reagents: 12 months Device (estimated to be): 60 months
Type of sample required	Plasma or serum
Volume of sample required	1 mL
Turnaround time	105 minutes
Throughput	Depends on GeneXpert® system used (see table above)
Marketing price per instrument/test	Available upon request
Complexity/training requirements	4 hours of end-user training
Supporting instrumentation/sample preparation required	For use with GeneXpert® systems (details above)
Chembio Diagnostic Systems (not confirmed by company)	
DPP® HCV test	
Marketing status	Pipeline (expected date TBC)
Type of technology	Immunoassay; RDT (DPP® Technology)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV RUO
Sensitivity	97.8%
Specificity	>99.5%
Multiplex	No
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	24 months
Type of sample required	Whole blood (venepuncture or fingerstick), serum or plasma
Volume of sample required	10 µL
Turnaround time	15–30 minutes
Throughput*	Low; one test takes 15 minutes
Power requirements	TBC
Connectivity	TBC

Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	None
Image of device(s) **(representative image of the DPP® HCV test)**	
Core Diagnostics (not confirmed by company)	
ImmunoFlow HCV, Core HCV, Core Combo HIV-HBsAg-HCV	
Marketing status	ImmunoFlow HCV: On the market Core HCV: On the market Core Combo HIV-HBsAg-HCV: On the market
Type of technology	ImmunoFlow HCV: RDT Core HCV: RDT Core Combo HIV-HBsAg-HCV: RDT
POC	ImmunoFlow HCV: Yes Core HCV: Yes Core Combo HIV-HBsAg-HCV: Yes
Infections the device(s) can test for and regulatory approval status	ImmunoFlow HCV: HCV; CE marked Core HCV: HCV Core Combo HIV-HBsAg-HCV: HIV, HBV and HCV
Sensitivity	ImmunoFlow HCV: 100% Core HCV: 98.25% Core Combo HIV-HBsAg-HCV: TBC
Specificity	ImmunoFlow HCV: 99.8% Core HCV: 99.8% Core Combo HIV-HBsAg-HCV: TBC
Multiplex	ImmunoFlow HCV: No Core HCV: No Core Combo HIV-HBsAg-HCV: Yes
Storage temperature of the device(s)/reagents	ImmunoFlow HCV: 4–30 °C Core HCV: 4–30 °C Core Combo HIV-HBsAg-HCV: TBC
Shelf life of the device(s)/reagents	ImmunoFlow HCV: TBC Core HCV: TBC Core Combo HIV-HBsAg-HCV: TBC

Type of sample required	ImmunoFlow HCV: Serum Core HCV: Serum Core Combo HIV-HBsAg-HCV: Whole blood, serum or plasma
Volume of sample required	ImmunoFlow HCV: ~5 µL Core HCV: ~50 µL Core Combo HIV-HBsAg-HCV: TBC
Turnaround time	ImmunoFlow HCV: 15 minutes Core HCV: 15 minutes Core Combo HIV-HBsAg-HCV: TBC
Throughput*	ImmunoFlow HCV: Low Core HCV: Low Core Combo HIV-HBsAg-HCV: TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Not available
Image of device(s)	Not available
Coyote Bioscience	
Mini8 Real-Time PCR system, One-step MD-Box-Lab	
Marketing status	On the market (RUO/CE marked)
Type of technology	NAT: qPCR
POC	No
Infections the device can test for	Assay dependent, see below
Sensitivity	Assay dependent, see below
Specificity	Assay dependent, see below
Multiplex	No
Storage temperature of the device/reagents	10–60 ˚C
Shelf life of the device/reagents	Mini8 qPCR/One-step MD-Box-Lab: 8 years
Type of sample required	Assay dependent, see below
Volume of sample required	Assay dependent, see below
Turnaround time	Mini8 qPCR/One-step MD-Box-Lab: 60–120 minutes
Throughput	Mini8 qPCR/One-step MD-Box-Lab: 8 samples/hour

Dimensions (W x H x D)	Mini8 qPCR: 205 x 190 x 98 mm
Power requirements	Mini8 qPCR/One-step MD-Box-Lab: 12V DC, 10A or different alternating current
Connectivity	Mini8 qPCR/One-step MD-Box-Lab: USB 2.0
Marketing price per instrument/test	Mini8 qPCR: US$ 6900/unit One-step MD-Box-Lab: US$ 10 000/unit
Complexity/training requirements	1 hour training
Supporting instrumentation/sample preparation required	Laptop/computer WIN7,WIN8.1,WIN10 System
Product image	 
Coyote Bioscience	
One-step Detection Kit for Hepatitis C Virus (QPCR-Probe)	
Marketing status	On the market (RUO)
Type of technology	NAT: qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	RUO
Sensitivity	98%
Specificity	96%
Multiplex	No
Storage temperature of the device(s)/reagents	-20 °C
Shelf life of the device(s)/reagents	6 months
Type of sample required	Blood/serum/plasma
Volume of sample required	Blood: 50 µL Serum: 2 µL Plasma: 2 µL
Turnaround time	70 minutes
Throughput*	Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	One-Step HCV qPCR kit: US$ 10/test

Complexity/training requirements	1 hour training
Supporting instrumentation/sample preparation required	Mini8 qPCR/One-step MD-Box-Lab (see above)
Image of device(s)	Unavailable
CTK Biotech (information not verified by company)	
RecombiLISA HCV Ab/IgG ELISA, OnSite HCV Ab Rapid Test, HBsAg/HCV Ab Rapid Test, Recombinant HCV Core-NS3-NS4-NS5 Fusion Antigen	
Marketing status	RecombiLISA: On the market OnSite HCV: On the market OnSite HBsAg/HCV: On the market Recombinant HCV: On the market
Type of technology	RecombiLISA: EIA OnSite HCV: Immunochromatographic assay OnSite HBsAg/HCV: Immunochromatographic assay Recombinant HCV: Chromatographic assay
POC	RecombiLISA: No OnSite HCV: Yes OnSite HBsAg/HCV: Yes Recombinant HCV: No
Infections the device(s) can test for and regulatory approval status	RecombiLISA: HCV OnSite HCV: HCV Ab (IgG, IgM, IgA) OnSite HBsAg/HCV: HBsAg, HCV IgG, IgM, IgA HCV Ab Recombinant HCV: HCV
	RecombiLISA: TBC OnSite HCV: TBC OnSite HBsAg/HCV: TBC Recombinant HCV: RUO
Sensitivity	RecombiLISA: TBC OnSite HCV: TBC OnSite HBsAg/HCV: TBC Recombinant HCV: TBC
Specificity	RecombiLISA: TBC OnSite HCV: TBC OnSite HBsAg/HCV: TBC Recombinant HCV: TBC

Multiplex	RecombiLISA: Yes OnSite HCV: No OnSite HBsAg/HCV: No Recombinant HCV: No
Storage temperature of the device(s)/reagents	RecombiLISA: TBC OnSite HCV: TBC OnSite HBsAg/HCV: TBC Recombinant HCV: <-20 °C
Shelf life of the device(s)/reagents	RecombiLISA: 12 months OnSite HCV: 24 months OnSite HBsAg/HCV: 24 months Recombinant HCV: 24 months
Type of sample required	RecombiLISA: Serum or plasma (Ab), whole blood, serum or plasma (IgG) OnSite HCV: Whole blood, serum or plasma
	OnSite HBsAg/HCV: Whole blood, serum or plasma Recombinant HCV: TBC
Volume of sample required	RecombiLISA: TBC OnSite HCV: TBC OnSite HBsAg/HCV: TBC Recombinant HCV: TBC
Turnaround time	RecombiLISA: TBC OnSite HCV: 15 minutes OnSite HBsAg/HCV: 15 minutes Recombinant HCV: TBC
Throughput*	RecombiLISA: Medium OnSite HCV: Low OnSite HBsAg/HCV: Low Recombinant HCV: TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	RecombiLISA: TBC OnSite HCV: Simple to use, no training required OnSite HBsAg/HCV: Simple to use, no training required Recombinant HCV: TBC

Supporting instrumentation/sample preparation required	RecombiLISA: General laboratory infrastructure OnSite HCV: Simple test procedure, no equipment required OnSite HBsAg/HCV: Simple to use, no training required Recombinant HCV: TBC
Image of device(s) **OnSite Rapid Test**	Unavailable
Cypress Diagnostics (information not verified by company)	
Anti-HCV Test, Anti-HCV Card	
Marketing status	HCV Test: On the market HCV Card: On the market
Type of technology	HCV Test: EIA HCV Card: Immunochromatographic assay
POC	HCV Test: No HCV Card: Yes
Infections the device(s) can test for and regulatory approval status	HCV Test: HCV HCV Card: HCV
	HCV Test: None HCV Card: None
Sensitivity	HCV Test: TBC HCV Card: TBC
Specificity	HCV Test: TBC HCV Card: TBC
Multiplex	HCV Test: Yes HCV Card: No
Storage temperature of the device(s)/reagents	HCV Test: 2–8 °C HCV Card: 10–30 °C
Shelf life of the device(s)/reagents	HCV Test: TBC HCV Card: TBC
Type of sample required	HCV Test: Serum or plasma HCV Card: Serum or plasma
Volume of sample required	HCV Test: TBC HCV Card: TBC
Turnaround time	HCV Test: TBC HCV Card: TBC
Throughput*	HCV Test: Medium HCV Card: Low
Power requirements	TBC

Connectivity	TBC
Marketing price per instrument/test	HCV Test: TBC HCV Card: TBC
Complexity/training requirements	HCV Test: Standard laboratory training HCV Card: Simple to use
Supporting instrumentation/sample preparation required	HCV Test: General laboratory infrastructure HCV Card: None
Image of device(s)	Unavailable
Daktari Diagnostics Inc. (information not verified by company)	
Daktari Virology	
Marketing status	Pipeline
Type of technology	Biosensor technology: Microfluidics and electrochemical sensing
POC	Yes
Infections the device can test for	In development: HIV-1, HCV
Sensitivity	TBC
Specificity	TBC
Multiplex	TBC
Storage temperature of the device/reagents	TBC
Shelf life of the device/reagents	TBC
Type of sample required	Whole blood (fingerstick or venous collection)
Volume of sample required	TBC
Turnaround time	30 minutes
Throughput	Low: One sample takes 30 minutes
Dimensions (W x H x D)	TBC
Power requirements	Battery powered (portable)
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

Dialab GmbH	
DIAQUICK HCV Cassette, HCV Ab Sensitive (information not verified by company)	
Marketing status	On the market
Regulatory approval status	DIAQUICK HCV Cassette: CE marked HCV Ab Sensitive: CE marked
Type of technology	DIAQUICK HCV Cassette: Immunochromatography HCV Ab Sensitive: EIA
POC	DIAQUICK HCV Cassette: Yes HCV Ab Sensitive: No
Infections the device can test for	HCV
Sensitivity	DIAQUICK HCV Cassette: 99.1% HCV Ab Sensitive: TBC
Specificity	DIAQUICK HCV Cassette: 99.5% HCV Ab Sensitive: TBC
Multiplex	DIAQUICK HCV Cassette: No HCV Ab Sensitive: Yes
Storage temperature of the device/reagents	Room temperature
Shelf life of the device/reagents	DIAQUICK HCV Cassette: 24 months HCV Ab Sensitive: 15 months
Type of sample required	DIAQUICK HCV Cassette: Whole blood (fingerstick) HCV Ab Sensitive: Serum/plasma
Volume of sample required	DIAQUICK HCV Cassette: 25 µL serum or plasma; 50 µL whole blood HCV Ab Sensitive: TBC
Turnaround time	DIAQUICK HCV Cassette: 10 minutes HCV Ab Sensitive: TBC
Throughput	DIAQUICK HCV Cassette: Low HCV Ab Sensitive: Medium
Dimensions (W x H x D)	DIAQUICK HCV Cassette: 23.5 x 13 x 8 cm per kit (30 tests/kit) HCV Ab Sensitive: TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	DIAQUICK HCV Cassette: €0.73/test
Complexity/training requirements	DIAQUICK HCV Cassette: Minimal HCV Ab Sensitive: TBC
Supporting instrumentation/sample preparation required	DIAQUICK HCV Cassette: Specimen collection container, lancets, disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only), centrifuge (for plasma only), timer HCV Ab Sensitive: TBC

Image of device(s) **DIAQUICK HCV Cassette**	Unavailable
DiaSorin	
CLIA LIAISON® XL system	
Marketing status	On the market
Type of technology	CLIA with paramagnetic microparticle solid phase (MP) Random-access or batch immunoassay system with continuous loading of samples, reagents and consumables Disposable tips, 25 reagents onboard, 120 samples Radio frequency identification (RFID) technology STAT function Laboratory Automation System (LAS) version available
POC	No
Infections the device(s) can test for and regulatory approval status	System: CE marked, FDA approved
	Assays: HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, anti-HBe, HBeAg, anti-HAV, HAV IgM, anti-HCV, HIV Ag/Ab, Chagas, Epstein-Barr virus IgM, Borrelia IgM and IgG, Chlamydia trachomatis IgG and IgA, TP, varicella-zoster virus IgG and IgM, Mycoplasma pneumoniae IgG and IgM, measles IgG and IgM, mumps IgM and IgG, Bordetella pertussis toxin IgG and IgA, Helicobacter pylori IgG, Toxo IgM and IgG and Avidity, rubella IgG and IgM, CMV IgG and IgM and Avidity, HSV-1/2 IgG, HSV-2 IgG, HSV-1/2 IgM, HSV-1 IgG, parvovirus B19 IgG and IgM (and others)
Sensitivity	Depending on the specific assay (see HCV specific assays below)
Specificity	Depending on the specific assay (see HCV specific assays below)
Multiplex	No
Storage temperature of the device(s)/reagents	5–45 °C/2–8 °C
Shelf life of the device(s)/reagents	Depending on the specific assay
Type of sample required	Serum, plasma, urine, cerebrospinal fluid (CSF) and stool (as listed below)
Volume of sample required	Depending on the specific assay (range 10–200 µL)
Turnaround time	Depending on the specific assay and the routine; starting from 17 minutes
Throughput*	High: up to 180 tests/hour

Dimensions (W x H x D)	150 x 150 x 90 cm (standalone)
Power requirements	Voltage range: 90–240v Frequency: 50–60 Hz
Connectivity	Yes (LIS, LIMS)
Marketing price per instrument/test	TBC (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required
Supporting instrumentation/sample preparation required	IBM-compatible personal computer, 17-inch diagonal LCD touch sensitive screen, barcode scanners Sample preparation required only for assays to be performed on stool
Image of device(s)	
DiaSorin	
Murex anti-HCV (version 4.0)	
Marketing status	On the market
Type of technology	EIA
POC	No
Infections the device(s) can test for and regulatory approval status	Qualitative detection of antibodies to HCV in human serum or plasma
	CE marked, WHO prequalified
Sensitivity	100%
Specificity	≥99.5%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Serum, plasma
Volume of sample required	20 µL
Turnaround time	120 minutes
Throughput*	Low, medium or high depending on the system used

Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required
Supporting instrumentation/sample preparation required	Automated microplate strip washer, microplate reader or fully automated microplate processor (e.g. ETI-Max 3000 or Tecan Freedom EVOlyzer® 2-150/8); all instruments must be validated before use No sample preparation required
DiaSorin	
Murex HCV Ag/Ab Combination	
Marketing status	On the market
Type of technology	EIA
POC	No
Infections the device(s) can test for and regulatory approval status	Simultaneous qualitative detection of HCV core antigen and anti-HCV antibodies in human plasma or serum
	CE marked
Sensitivity	100%
Specificity	≥99.5%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Serum, plasma
Volume of sample required	50 µL
Turnaround time	150 minutes
Throughput*	Low, medium or high depending on the system used
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required

Supporting instrumentation/sample preparation required	Automated microplate strip washer, microplate reader or fully automated microplate processor (e.g. ETI-Max 3000 or Tecan Freedom EVOlyzer® 2-150/8); all instruments must be validated before use No sample preparation required
Image of device(s) **Murex HCV Ag/Ab Combination**	
EIKEN (not confirmed by company)	
Lumispot HCV Ag	
Marketing status	On the market
Type of technology	CLEIA
POC	No
Infections the device(s) can test for and regulatory approval status	TBC
Sensitivity	TBC
Specificity	TBC
Multiplex	TBC
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	TBC
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Not available

Euro Genomas (not confirmed by company)	
ViGen RNA HCV-1/2/3	
Marketing status	On the market
Type of technology	Real-time RT-PCR – detection of HCV RNA and differentiation of genotypes 1, 2 and 3
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
Sensitivity	15 IU/mL (400 IU/mL for HCV genotyping)
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	TBC
Type of sample required	Blood plasma or serum
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	Yes
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Not available
Euro Genomas (not confirmed by company)	
HCV Rapid Test Strip, Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette, HBsAg/HCV Combo Rapid Test Cassette	
Marketing status	HCV Rapid Test Strip: On the market Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: On the market
	HBsAg/HCV Combo Rapid Test Cassette: On the market
Type of technology	HCV Rapid Test Strip: RDT Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: RDT HBsAg/HCV Combo Rapid Test Cassette: RDT

POC	HCV Rapid Test Strip: Yes Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: Yes HBsAg/HCV Combo Rapid Test Cassette: Yes
Infections the device(s) can test for and regulatory approval status	HCV Rapid Test Strip: HCV; CE marked Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: HBV, HCV, HIV, TB; CE marked HBsAg/HCV Combo Rapid Test Cassette: HBV, HCV; CE marked
Sensitivity	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC
Specificity	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC
Multiplex	HCV Rapid Test Strip: No Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: Yes HBsAg/HCV Combo Rapid Test Cassette: Yes
Storage temperature of the device(s)/reagents	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC
Shelf life of the device(s)/reagents	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC
Type of sample required	HCV Rapid Test Strip: Whole blood, serum or plasma Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: Serum or plasma HBsAg/HCV Combo Rapid Test Cassette: Serum or plasma
Volume of sample required	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC
Turnaround time	HCV Rapid Test Strip: TBC Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: TBC HBsAg/HCV Combo Rapid Test Cassette: TBC

Throughput*	HCV Rapid Test Strip: Low Rapid HBsAg/HCV/HIV/Syphilis Combo Test Cassette: Low HBsAg/HCV Combo Rapid Test Cassette: Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Not available
Genedrive plc. (an Epistem company)	
Genedrive® HCV ID Kit	
Marketing status	On the market
Type of technology	NAT; Detection of DNA or RNA targets by fluorescent end-point PCR
POC	No
Infections the device(s) can test for and regulatory approval status	MTB, MTB/RIF: CE marked
	HCV (qualitative and pan-genotypic): CE marked
Sensitivity	99.8%
Specificity	100%
Multiplex	Current Genedrive® tests are singleplex; note: the Genedrive® technology does allow for multiplexing with a maximum 9–12 targets
Storage temperature of the device(s)/reagents	Genedrive® Platform: 5–50 °C Genedrive® HCV: 2–28 °C
Shelf life of the device(s)/reagents	Genedrive® HCV: 12–18 months (expect 6 months at launch)
Type of sample required	Genedrive® HCV: fresh or frozen EDTA plasma
Volume of sample required	Genedrive® HCV: 25 µL
Turnaround time	Genedrive® HCV: 90 minutes per test
Throughput*	Low, single sample throughput
Dimensions (W x H x D)	Genedrive® Platform: 12 x 18 x 10 cm
Power requirements	Genedrive® Platform Standard mains PSU: 100–240VAC 1.2A 50/60Hz input to 12VDC/8.33A output UPS: 11.1VDC 7400 mAh (nominal) rechargeable battery sufficient for 2–3 test executions per charge cycle (test type/duration dependent) No requirement for an external charging station

Connectivity	Each Genedrive® ID test programme is loaded onto the instrument using radio frequency identification (RFID) technology Genedrive® supports the use an external thermal printer for printing of test results Future expansion of connectivity features for Genedrive® may include Bluetooth connectivity to external information technology (IT)/mobile devices
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	Minimal user training and single-button operation (press/hold executions)
Supporting instrumentation/sample preparation required	Genedrive® platform is required for use with all Genedrive® tests No other supporting instrumentation or sample preparation is required once plasma/serum has been processed
EY Laboratories (information not verified by company)	
HCVSCAN	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV Regulatory status TBC
Sensitivity	100%
Specificity	93.7%
Multiplex	No
Storage temperature of the device(s)/reagents	-10 to 26° C
Shelf life of the device(s)/reagents	15 months
Type of sample required	Serum/plasma
Volume of sample required	45 µL per test
Turnaround time	Immediate
Throughput*	Low
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	None

FujireBio Diagnostics Inc	
INNO-LIA HCV Score, INNOTEST HCV Ab IV. HCV, SERODIA®-HCV	
Marketing status	INNO-LIA HCV Score: On the market INNOTEST HCV Ab IV: On the market SERODIA®-HCV: On the market
Type of technology	INNO-LIA HCV Score: Immunoassay INNOTEST HCV Ab IV: EIA SERODIA®-HCV: Particle agglutination
POC	INNO-LIA HCV Score: No INNOTEST HCV Ab IV: No SERODIA®-HCV: No
Infections the device(s) can test for and regulatory approval status	INNO-LIA HCV Score: HCV INNOTEST HCV Ab IV: HCV SERODIA®-HCV: HCV
	INNO-LIA HCV Score: Regulatory approval status: WHO prequalified, CE marked INNOTEST HCV Ab IV: Regulatory approval status: CE marked SERODIA®-HCV: RUO
Sensitivity	INNO-LIA HCV Score: 100% INNOTEST HCV Ab IV: 100% SERODIA®-HCV: TBC
Specificity	INNO-LIA HCV Score: Blood donors: 94.5%/clinical samples: 93.7% INNOTEST HCV Ab IV: 99.8% SERODIA®-HCV: TBC
Multiplex	INNO-LIA HCV Score: No INNOTEST HCV Ab IV: No SERODIA®-HCV: TBC
Storage temperature of the device(s)/reagents	INNO-LIA HCV Score: 2–8 °C INNOTEST HCV Ab IV: 2–8 °C SERODIA®-HCV: 2–10 °C
Shelf life of the device(s)/reagents	INNO-LIA HCV Score: 12 months INNOTEST HCV Ab IV: 15 months SERODIA®-HCV: 12 months
Type of sample required	INNO-LIA HCV Score: Human serum or plasma INNOTEST HCV Ab IV: Human serum or plasma SERODIA®-HCV: Human serum or plasma
Volume of sample required	INNO-LIA HCV Score: 10 µL for 16-hour incubation; 20 µL for 2–3-hour incubation INNOTEST HCV Ab IV: 20 µL SERODIA®-HCV: TBC

Turnaround time	INNO-LIA HCV Score: 5 hours for 3-hour incubation; 18 hours for 16-hour incubation INNOTEST HCV Ab IV: 3 hours SERODIA®-HCV: TBC
Throughput*	INNO-LIA HCV Score: 13.6 x 12 x 16 cm INNOTEST HCV Ab IV: 13.6 x 16.4 x 18.7 cm SERODIA®-HCV: TBC
Dimensions (W x H x D)	INNO-LIA HCV Score: None for manual procedure With AUTO-LIA, the instrument is auto-sensing thus no need to set to the correct voltage; connect the instrument only to a grounded electric supply system INNOTEST HCV Ab IV: None SERODIA®-HCV: None
Power requirements	INNO-LIA HCV Score: None for manual procedure With AUTO-LIA, the instrument is auto-sensing thus no need to set to the correct voltage; connect the instrument only to a grounded electric supply system INNOTEST HCV Ab IV: None SERODIA®-HCV: None
Connectivity	INNO-LIA HCV Score: N/A INNOTEST HCV Ab IV: N/A SERODIA®-HCV: N/A
Marketing price per instrument/test	INNO-LIA HCV Score: <€34/test (average advised user price) INNOTEST HCV Ab IV: <€2/test (average advised user price) SERODIA®-HCV: TBC
Complexity/training requirement	INNO-LIA HCV Score: Net (training) time to achieve assay competence is approximately
	1–2 hours INNOTEST HCV Ab IV: Estimated training time is 1–2 hour SERODIA®-HCV: TBC
Supporting instrumentation/sample preparation required	INNO-LIA HCV Score: For manual procedure: precision pipettes, orbital shaker or rocker, vortex mixer or equivalent, computer + screen + scanner + printer for using LiRAS (interpretation software) INNOTEST HCV Ab IV: precision pipettes, multichannel pipette (optional), microplate shaker, incubator at 37 °C, microplate washer, photometric reader SERODIA®-HCV: TBC
Image of device(s) **Left to right:** **INNO-LIA HCV Score** **INNOTEST HCV Ab IV**	

EY Laboratories (information not verified by company)	
HCVSCAN	
Marketing status	On the market
Type of technology	NAT; RT-PCR
POC	No
Infections the device(s) can test for and regulatory approval status	HCV, HBV, HIV-1, MTB/RIF, CMV, Epstein-Barr virus, Paro virus B19, BK virus, various multiplex panels
Sensitivity	TBC
Specificity	TBC
Multiplex	Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Blood in EDTA/EDTA plasma
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Not available
Green Cross Medical Science Corp. (not confirmed by company)	
Genedia® HCV Rapid, HCV EIA 3.0	
Marketing status	Genedia® HCV Rapid: On the market HCV EIA 3.0: On the market
Type of technology	Genedia® HCV Rapid: Immunofiltration HCV EIA 3.0: EIA
POC	Genedia® HCV Rapid: Yes HCV EIA 3.0: No
Infections the device(s) can test for and regulatory approval status	Genedia® HCV Rapid: HCV HCV EIA 3.0: HCV
	Genedia® HCV Rapid: Regulatory status TBC HCV EIA 3.0: Regulatory status TBC
Sensitivity	Genedia® HCV Rapid: 98.5% HCV EIA 3.0: 99.9%

Specificity	Genedia® HCV Rapid: 98.4% HCV EIA 3.0: 100%
Multiplex	Genedia® HCV Rapid: No HCV EIA 3.0: No
Storage temperature of the device(s)/reagents	Genedia® HCV Rapid: 2–30 °C HCV EIA 3.0: TBC
Shelf life of the device(s)/reagents	Genedia® HCV Rapid: TBC HCV EIA 3.0: 15 months
Type of sample required	Genedia® HCV Rapid: Serum, plasma HCV EIA 3.0: Serum, plasma
Volume of sample required	Genedia® HCV Rapid: 40 µL HCV EIA 3.0: TBC
Turnaround time	Genedia® HCV Rapid: 2 minutes HCV EIA 3.0: TBC
Throughput*	Genedia® HCV Rapid: Low HCV EIA 3.0: TBC
Dimensions (W x H x D)	Genedia® HCV Rapid: TBC HCV EIA 3.0: TBC
Power requirements	Genedia® HCV Rapid: TBC HCV EIA 3.0: TBC
Connectivity	Genedia® HCV Rapid: TBC HCV EIA 3.0: TBC
Marketing price per instrument/test	Genedia® HCV Rapid: Available from supplier HCV EIA 3.0: Available from supplier
Complexity/training requirements	Genedia® HCV Rapid: Minimal HCV EIA 3.0: TBC
Supporting instrumentation/sample preparation required	Genedia® HCV Rapid: None HCV EIA 3.0: TBC
Guangzhou Wondfo Biotech (not confirmed by company)	
HCV Rapid Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
Sensitivity	99%
Specificity	99.8%
Multiplex	No

Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum
Volume of sample required	TBC
Turnaround time	15 minutes
Throughput*	Low
Power requirements	TBC
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	
Hangzhou Biotest Biotech (not confirmed by company)	
RightSign HCV Test Cassette	
Marketing status	RightSign HCV Test Cassette: On the market RightSign HCV Test Cassette: On the market
Type of technology	RightSign HCV Test Cassette: RDT RightSign HCV Test Cassette: RDT
POC	RightSign HCV Test Cassette: Yes RightSign HCV Test Cassette: Yes
Infections the device(s) can test for and regulatory approval status	RightSign HCV Test Cassette: HCV; CE marked RightSign HCV Test Cassette: HCV
Sensitivity	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC
Specificity	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC
Multiplex	RightSign HCV Test Cassette: No RightSign HCV Test Cassette: No
Storage temperature of the device(s)/reagents	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC
Shelf life of the device(s)/reagents	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC
Type of sample required	RightSign HCV Test Cassette: Serum or plasma RightSign HCV Test Cassette: Whole blood, serum or plasma
Volume of sample required	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC

Turnaround time	RightSign HCV Test Cassette: TBC RightSign HCV Test Cassette: TBC
Throughput*	RightSign HCV Test Cassette: Low RightSign HCV Test Cassette: Low
Power requirements	TBC
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	
Hologic	
Panther® System, Aptima® HCV Quant Dx Assay	
Marketing status	Panther® System: On the market Aptima® HCV Quant Dx Assay: On the market
Type of technology	Target capture; target amplification by transcription-mediated amplification (TMA); and detection of the amplification products (amplicon) by fluorescent-labelled probes (torches)
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	Panther® System: CE marked, FDA approved Aptima® HCV Quant Dx Assay: CE marked
Sensitivity	Panther® System: Assay dependent Aptima® HCV Quant Dx Assay: 4.3 IU/mL for plasma and 3.9 IU/mL for serum
Specificity	Panther® System: Assay dependent Aptima® HCV Quant Dx Assay: 100%
Multiplex	Panther® System: Assay dependent Aptima® HCV Quant Dx Assay: No
Storage temperature of the device(s)/reagents	Panther® System: Systems: Room temperature Aptima® HCV Quant Dx Assay: Unopened storage: 2–8 °C/from -15 to -35° C Opened Kit (reconstituted): 2–8 °C/15–30 °C
Shelf life of the device(s)/reagents	Panther® System: TBC Aptima® HCV Quant Dx Assay: 24 months

Type of sample required	Panther® System: Assay dependent Aptima® HCV Quant Dx Assay: Fresh and frozen human serum and plasma
Volume of sample required	Panther® System: 500 µL Aptima® HCV Quant Dx Assay: Reaction volume = 500 µL Note: a volume of 240 µL of plasma or serum can be used with the Panther® automated 1 : 3 dilution protocol
Turnaround time	Panther® System: 161 minutes to first results Aptima® HCV Quant Dx Assay: 161 minutes to first results; five results every 5 minutes for each thereafter
Throughput*	Panther® System: Low – up to 320 samples processed in 8 hours Aptima® HCV Quant Dx Assay: Low
Dimensions (W x H x D)	Panther® System: 122 x 175 x 81.5 cm Aptima® HCV Quant Dx Assay: TBC
Power requirements	Panther® System: AC 100–230 +/- 10% vac, 50–60 Hz, single-phase Aptima® HCV Quant Dx Assay: N/A
Connectivity	Panther® System: N/A Aptima® HCV Quant Dx Assay: N/A
Marketing price per instrument/test	Panther® System: Pricing will be variable and dependent upon a variety of elements including instrument purchase, reagent rental and test volume
Complexity/training requirements	Panther® System: 3 days
Supporting instrumentation/sample preparation required	Panther® System: Fully automated sample-to-answer instrument, it automates all aspects of nucleic acid testing on a single, integrated platform
Image of device(s) **Panther® System** **Aptima® HCV Quant Dx Assay**	 

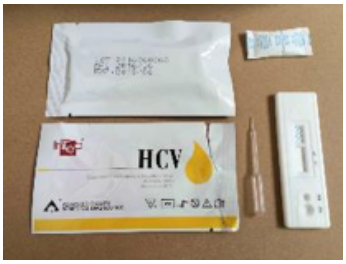
Hologic	
Leader System, Aptima® HCV Qualitative Dx assay	
Marketing status	Leader system: On the market Aptima® HCV Qual Dx Assay: On the market
Type of technology	Leader system:Luminometer to detect chemiluminescent emissions Aptima® HCV Qual Dx Assay: Nucleic acid amplification assay
POC	Leader system: No Aptima® HCV Qual Dx Assay: No
Infections the device(s) can test for and regulatory approval status	
	Aptima® HCV Qual Dx Assay: FDA IVD only
Sensitivity	99.6%
Specificity	7.5 IU/mL
Multiplex	No
Storage temperature of the device(s)/reagents	Leader system: TBC Aptima® HCV Qual Dx Assay: Unopened storage: -15 to –35 °C, or 2 to 8° C, or 15 to 30 °C depending on the different components
Shelf life of the device(s)/reagents	Leader system: TBC Aptima® HCV Qual Dx Assay: TBC
Type of sample required	Plasma, serum
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Pricing will be variable and dependent upon a variety of elements including instrument purchase, reagent rental and test volume
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	N/A

Human Diagnostics Worldwide	
Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno), Hexagon HCV, HCV Real-Time PCR (HumaCycler)	
Marketing status	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): On the market Hexagon HCV: On the market HCV Real-Time PCR kit (HumaCycler): On the market
Type of technology	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): EIA Hexagon HCV: Immunochromatographic HCV Real-Time PCR kit (HumaCycler): qPCR (real-time PCR)
POC	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): No Hexagon HCV: Yes HCV Real-Time PCR kit (HumaCycler): No
Infections the device(s) can test for and regulatory approval status	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): HCV Hexagon HCV: HCV HCV Real-Time PCR kit (HumaCycler): HIV-1, HBV, HCV, CMV – all already on the market and CE marked
	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno: CE marked Hexagon HCV: For IVD use but not CE marked HCV Real-Time PCR kit (HumaCycler): CE marked
Sensitivity	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 100% Hexagon HCV: >99.3% HCV Real-Time PCR kit (HumaCycler): 9.5 IU/mL
Specificity	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 99.75% Hexagon HCV: >99.5% HCV Real-Time PCR kit (HumaCycler): 100%
Multiplex	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): No Hexagon HCV: No HCV Real-Time PCR kit (HumaCycler): Device can be used for multiplexing with up to four parameters per tube

Storage temperature of the device(s)/reagents	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 2–8 °C Hexagon HCV: 2–30 °C HCV Real-Time PCR kit (HumaCycler): Device: 20–50 °C (transport and storage), 10–30 °C (operating temperature) Reagents: freezer from -25 to -15 °C
Shelf life of the device(s)/reagents	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): <18 months Hexagon HCV: <24 month from production HCV Real-Time PCR kit (HumaCycler): Device: 10 years Reagents: 12 months from production
Type of sample required	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): Serum and plasma with the anticoagulants citrate, heparin or EDTA Hexagon HCV: Whole blood, serum, plasma HCV Real-Time PCR kit (HumaCycler): Serum or EDTA-plasma for nucleic acid purification
Volume of sample required	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 100 µL Hexagon HCV: 10 µL HCV Real-Time PCR kit (HumaCycler): 150 µL serum or EDTA-plasma for nucleic acid purification; 10 µL of the extracted RNA for the qPCR reaction
Turnaround time	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 2 hours Hexagon HCV: 5–20 minutes HCV Real-Time PCR kit (HumaCycler): On sample number, run time is around 3 hours (including sample preparation)
Throughput*	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): Depends on reader used, see below: Low – HumaReader Single Plus, HumaReader HS, Elisys Uno Medium – Elisys Duo High – Elisys Quattro Hexagon HCV: Low HCV Real-Time PCR kit (HumaCycler): Low to medium
Dimensions (W x H x D)	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): 24 x 34 x 13 cm Hexagon HCV: 20 x 4 x 70 mm HCV Real-Time PCR kit (HumaCycler): 43 x 39.5 x 35.2 cm

Power requirements	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): N/A Hexagon HCV: N/A HCV Real-Time PCR kit (HumaCycler): AC
Connectivity	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): N/A Hexagon HCV: N/A HCV Real-Time PCR kit (HumaCycler): Bluetooth
Marketing price per instrument/test	On request (dependent on country and purchase amount)
Complexity/training requirements	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): TBC Hexagon HCV: Simple/low HCV Real-Time PCR kit (HumaCycler): 1–3 days training required (dependent on background)
Supporting instrumentation/sample preparation required	Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno): Plate reader Hexagon HCV: N/A HCV Real-Time PCR kit (HumaCycler): Requires prior DNA/RNA isolation, which can be done manually (VIRAL NUCLEIC ACID ISOLATION KIT ([REF] 87300) oder VIRAL RNA ISOLATION KIT ([REF] 87320), computer/laptop
Image of device(s) **Top to bottom:** **Anti-HCV ELISA (Elisys Quattro, Elisys Duo, Elisys Uno)** **Hexagon HCV** **HCV Real-Time PCR (HumaCycler)**	 
InTec® Products Inc.	
HCV Elisa Test Kit, Advanced Quality™ Rapid Anti-HCV Test	
Marketing status	HCV Elisa Test Kit: On the market Advanced Quality™ Rapid Anti-HCV Test: On the market
Type of technology	HCV Elisa Test Kit: EIA Advanced Quality™ Rapid Anti-HCV Test: Chromatographic immunoassay
POC	HCV Elisa Test Kit: No Advanced Quality™ Rapid Anti-HCV Test: Yes

Infections the device(s) can test for and regulatory approval status	HCV Elisa Test Kit: HCV Advanced Quality™ Rapid Anti-HCV Test: HCV
	HCV Elisa Test Kit: CE marked Advanced Quality™ Rapid Anti-HCV Test: CE marked
Sensitivity	HCV Elisa Test Kit: 99% Advanced Quality™ Rapid Anti-HCV Test: 99.7%
Specificity	HCV Elisa Test Kit: 99.8% Advanced Quality™ Rapid Anti-HCV Test: 99.8%
Multiplex	HCV Elisa Test Kit: No Advanced Quality™ Rapid Anti-HCV Test: No
Storage temperature of the device(s)/reagents	HCV Elisa Test Kit: 2–8 °C Advanced Quality™ Rapid Anti-HCV Test: 2–30 °C
Shelf life of the device(s)/reagents	HCV Elisa Test Kit: 12 months Advanced Quality™ Rapid Anti-HCV Test: 24 months
Type of sample required	HCV Elisa Test Kit: Serum, plasma Advanced Quality™ Rapid Anti-HCV Test: Whole blood, serum, plasma
Volume of sample required	HCV Elisa Test Kit: 10 µL Advanced Quality™ Rapid Anti-HCV Test: 10 µL
Turnaround time	HCV Elisa Test Kit: 120 minutes by semi-automated procedure Advanced Quality™ Rapid Anti-HCV Test: 15 minutes
Throughput*	HCV Elisa Test Kit: Low Advanced Quality™ Rapid Anti-HCV Test: Low
Dimensions (W x H x D)	HCV Elisa Test Kit: TBC Advanced Quality™ Rapid Anti-HCV Test: 8.2 x 2.5 x 0.5 cm (cassette only)
Power requirements	HCV Elisa Test Kit: N/A Advanced Quality™ Rapid Anti-HCV Test: N/A
Connectivity	HCV Elisa Test Kit: N/A Advanced Quality™ Rapid Anti-HCV Test: N/A
Marketing price per instrument/test	HCV Elisa Test Kit: US$ 1 Advanced Quality™ Rapid Anti-HCV Test: US$ 0.6
Complexity/training requirements	HCV Elisa Test Kit: Training required Advanced Quality™ Rapid Anti-HCV Test: Not required

Supporting instrumentation/sample preparation required	HCV Elisa Test Kit: Microplate washer and ELISA microplate reader (or fully automated ELISA reader) Advanced Quality™ Rapid Anti-HCV Test: Not required
Image of device(s) **Top to bottom:** **HCV Elisa Test Kit** **Advanced Quality™ Rapid Anti-HCV Test**	 
JAL INNOVATION	
iCARE One Step Anti-HCV Rapid Test, iCARE Multi-STD Diseases (HBSAG/HCV/HIV/TP) combo rapid test cassette	
Marketing status	Combo Rapid Test: On the market One Step Anti-HCV: On the market
Type of technology	Combo Rapid Test: Immunochromatography One Step Anti-HCV: Immunochromatography
POC	Combo Rapid Test: Yes One Step Anti-HCV: Yes
Infections the device(s) can test for and regulatory approval status	Combo Rapid Test: HCV, HIV-1, HIV-2, HBsAg, *Treponema pallidum* One Step Anti-HCV: HCV
	Combo Rapid Test: RUO One Step Anti-HCV: RUO
Sensitivity	Combo Rapid Test: >99.9% One Step Anti-HCV: 100%
Specificity	Combo Rapid Test: 99.7–99.8% One Step Anti-HCV: >99%
Multiplex	Combo Rapid Test: Yes One Step Anti-HCV: No
Storage temperature of the device(s)/reagents	Combo Rapid Test: Room temperature or cold chamber One Step Anti-HCV: 2–30 °C
Shelf life of the device(s)/reagents	Combo Rapid Test: 24 months One Step Anti-HCV: 24 months
Type of sample required	Combo Rapid Test: Whole blood, serum, plasma One Step Anti-HCV: Whole blood, serum, plasma

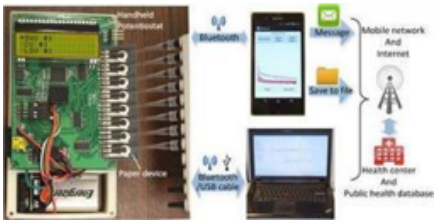
Volume of sample required	Combo Rapid Test: 50 µL One Step Anti-HCV: 30 µL
Turnaround time	Combo Rapid Test: 10 minutes One Step Anti-HCV: 15 minutes
Throughput*	Combo Rapid Test: Low One Step Anti-HCV: Low
Power requirements	None
Connectivity	None
Marketing price per instrument/test	Combo Rapid Test: US$ 3.0 One Step Anti-HCV: TBC
Complexity/training requirements	Combo Rapid Test: Follow package instructions One Step Anti-HCV: Follow package instructions
Supporting instrumentation/sample preparation required	Combo Rapid Test: Timer required One Step Anti-HCV: Timer required
Image of device(s)	Unavailable
J Mitra & Co Pvt. Ltd (information not verified by company)	
HCV TRI-DOT, Diagnos HCV Bi-Dot, HCV Microlisa	
Marketing status	HCV TRI-DOT: On the market DIAGNOS HCV BI-DOT: On the market HCV Microlisa: On the market
Type of technology	HCV TRI-DOT: Immunofiltration HCV DIAGNOS DI-DOT: Immunofiltration HCV Microlisa: ELISA
POC	HCV TRIDOT: Yes HCV DIAGNOS DI-DOT: Yes HCV Microlisa: No
Infections the device(s) can test for and regulatory approval status	HCV TRIDOT: HCV HCV DIAGNOS DI-DOT: HCV HCV Microlisa: HCV
	HCV TRIDOT: RUO HCV DIAGNOS DI-DOT: RUO HCV Microlisa: RUO
Sensitivity	HCV TRIDOT: 100% HCV DIAGNOS DI-DOT: 100% HCV Microlisa: 100%

Specificity	HCV TRIDOT: 98.9% HCV DIAGNOS DI-DOT: 99.8% HCV Microlisa: 97.4%
Multiplex	HCV TRIDOT: No HCV DIAGNOS DI-DOT: No HCV Microlisa: No
Storage temperature of the device(s)/reagents	HCV TRI-DOT: 2–8 °C HCV DIAGNOS BI-DOT: 2–8 °C HCV Microlisa: 2–8 °C
Shelf life of the device(s)/reagents	HCV TRI-DOT: 15 months HCV DIAGNOS BI-DOT: 18 months HCV Microlisa: 15 months
Type of sample required	HCV TRI-DOT: Whole blood, serum plasma HCV DIAGNOS BI-DOT: Whole blood, serum plasma HCV Microlisa: Whole blood, serum plasma
Volume of sample required	HCV TRI-DOT: 50 µL (1 drop) HCV DIAGNOS BI-DOT: 50 µL (1 drop) HCV Microlisa: 10 µL
Turnaround time	HCV TRI-DOT: 3 minutes HCV DIAGNOS BI-DOT: Immediate HCV Microlisa: ~2 hours
Throughput*	HCV TRI-DOT: Low HCV DIAGNOS BI-DOT: Low HCV Microlisa: Low
Marketing price per instrument/test	HCV TRI-DOT: Available from supplier HCV DIAGNOS BI-DOT: Available from supplier HCV Microlisa: Available from supplier
Complexity/training requirements	HCV TRI-DOT: Low HCV DIAGNOS BI-DOT: Low HCV Microlisa: General knowledge of microbiology required in addition to general laboratory infrastructure; pipettes, centrifuge, etc.
Supporting instrumentation/sample preparation required	HCV TRI-DOT: Refrigeration HCV DIAGNOS BI-DOT: Refrigeration HCV Microlisa: General laboratory infrastructure; pipettes, centrifuge, platereader, etc.

Lumiquick Diagnostics (not confirmed by company)	
Quick Profile™ HCV Ab Test Strip or Card	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	N/A
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Not available
Maccura (most information verified by supplier)	
Hepatitis C Virus (HCV) Antibody Assay Kit	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	Chinese FDA
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	18 months

Type of sample required	Serum, plasma
Volume of sample required	10 µL
Turnaround time	20 minutes
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	General microbiology skills required
Supporting instrumentation/sample preparation required	Matched with IS 1200 Automatic Chemiluminescence analyser, general laboratory equipment required (centrifuges, refrigerators, pipettes, etc.).
Image of device(s)	Unavailable
Maternova (not confirmed by company)	
HIV/HBsAg/HCV Combination Rapid Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HBV, HCV; CE marked
Sensitivity	TBC
Specificity	TBC
Multiplex	Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	TBC
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	Low
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable

mBio Diagnostics (not confirmed by company)	
mBio System	
Marketing status	In development (launch TBC)
Type of technology	Immunoassay/NAT integrated technology
POC	Yes
Infections the device(s) can test for and regulatory approval status	Research studies in malaria and HCV ongoing
Sensitivity	TBC
Specificity	TBC
Multiplex	Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	TBC
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

McGill University	
Paper-based electrochemical platform	
Marketing status	Pipeline (expected in ~4 years from 2018)
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1, HCV RUO
Sensitivity	The limits of detection of the platform for HIV-1 and HCV are 0.3 ng/µL and 0.75 ng/µL, respectively
Specificity	TBC
Multiplex	Yes
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Blood/serum/plasma
Volume of sample required	3 µL per test
Turnaround time	20 minutes
Throughput*	Low (8 samples analysed in 20 minutes)
Dimensions (W x H x D)	8 x 12 x 3 cm
Power requirements	Battery
Connectivity	Bluetooth, USB
Marketing price per instrument/test	US$ 200 per instrument; US$ 0.5 per test
Complexity/training requirements	Low; only training on solution pipetting is required
Supporting instrumentation/sample preparation required	Pipettes and tips
Image of device(s)	

MedMira	
MULTIPLO Rapid HBC/HIV/HCV Antibody Test	
Marketing status	On the market
Type of technology	Immunochromatography – Rapid Vertical Flow Assay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV, HBV, HIV
	TBC
Sensitivity	99.1%
Specificity	99.7%
Multiplex	Yes
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	18 months
Type of sample required	Whole blood (fingerstick and venous blood), serum, plasma
Volume of sample required	1 drop (40 µL)
Turnaround time	3 minutes
Throughput*	Medium
Dimensions (W x H x D)	12 x 17 x 1.8 cm (dimensions of one POC test pouch)
Marketing price per instrument/test	Pricing for Multiplo HBc/HIV/HCV ranges depending on local market conditions and order volumes
Complexity/training requirements	No special training required and the same procedure applies across any testing application on this platform
Supporting instrumentation/sample preparation required	No additional equipment is required to run and read the fingerstick and whole blood samples; a centrifuge is needed if using serum or plasma
Image of device(s)	

Molbio Diagnostics Pvt. Ltd	
Trueprep™ Auto sample preparation device, Truelab™ Uno Dx Real Time Micro PCR Analyser	
Marketing status	Trueprep™ Auto sample preparation device: On the market Truelab™ Uno Dx Real Time Micro PCR Analyser: On the market March 2017
Type of technology	Trueprep™ Auto sample preparation device: RT-PCR/qPCR Truelab™ Uno Dx Real Time Micro PCR Analyser: RT-PCR/qPCR
POC	Trueprep™ Auto sample preparation device: Yes Truelab™ Uno Dx Real Time Micro PCR Analyser: Yes
Infections the device(s) can test for and regulatory approval status	Trueprep™ Auto sample preparation device: N/A Truelab™ Uno Dx Real Time Micro PCR Analyser: HCV in development
	Trueprep™ Auto sample preparation device: CE marked Truelab™ Uno Dx Real Time Micro PCR Analyser: RUO
Sensitivity	Trueprep™ Auto sample preparation device: N/A Truelab™ Uno Dx Real Time Micro PCR Analyser: 100% (94–100%)
Specificity	Trueprep™ Auto sample preparation device: N/A Truelab™ Uno Dx Real Time Micro PCR Analyser: 100% (85–100%)
Multiplex	Trueprep™ Auto sample preparation device: Yes Truelab™ Uno Dx Real Time Micro PCR Analyser: Yes
Storage temperature of the device(s)/reagents	Trueprep™ Auto sample preparation device: 2–30 °C Truelab™ Uno Dx Real Time Micro PCR Analyser: 2–30 °C
Shelf life of the device(s)/reagents	microPCR chips, sample preparation kits and reagents are stable for 2 years at room temperature
Type of sample required	Whole blood (fingerstick or venous blood), plasma or serum for HCV Autoprep can also process sputum, stool and swabs
Volume of sample required	Trueprep™ Auto sample preparation device: Trueprep™ Auto requires 0.25/0.5 mL of whole blood/plasma/serum Truelab™ Uno Dx Real Time Micro PCR Analyser: 6 µL of purified DNA

Turnaround time	Trueprep™ Auto sample preparation device: ~20 minutes for sample preparation on Trueprep™ Auto Truelab™ Uno Dx Real Time Micro PCR Analyser: 35–40 minutes for RT/qPCR on Truelab™ Uno DX
Throughput*	Trueprep™ Auto sample preparation device: Low throughput (<50 samples/hour) Truelab™ Uno Dx Real Time Micro PCR Analyser: Low throughput (<50 samples/hour)
Dimensions (W x H x D)	Trueprep™ Auto sample preparation device: 115 x 215 x 235 mm Truelab™ Uno Dx Real Time Micro PCR Analyser: 112 x 248 x 185 mm
Power requirements	Trueprep™ Auto sample preparation device: Rechargeable lithium ion battery pack – sufficient backup for 1 day of testing; input to AC/DC adaptor: single-phase 100–240V; 50/60Hz; 1500 mA; output from AC/DC adaptor: 10 V; 4500mA; 45VA Truelab™ Uno Dx Real Time Micro PCR Analyser: Rechargeable lithium ion battery pack – sufficient back up for 1 day of testing; input to AC/DC adaptor: single-phase 100–240V; 50/60Hz; 1500 mA; output from AC/DC adaptor: 10 V; 4500mA; 45VA
Connectivity	Trueprep™ Auto sample preparation device: Bluetooth, GSM and Wi-Fi Truelab™ Uno Dx Real Time Micro PCR Analyser: Bluetooth, GSM and Wi-Fi
Marketing price per instrument/test	Trueprep™ Auto sample preparation device: Trueprep™ Auto and Truelab™ Uno Dx combo: US$ 12 000; per test: US$ 18
Complexity/training requirements	Trueprep™ Auto sample preparation device: Minimal training, less than 1 day Truelab™ Uno Dx Real Time Micro PCR Analyser: Minimal training, less than 1 day
Supporting instrumentation/sample preparation required	Trueprep™ Auto sample preparation device: No computer required – all data entry and analysis are done on the devices Truelab™ Uno Dx Real Time Micro PCR Analyser: No computer required all data entry and analysis are done on the devices
Image of device(s) **Left to right:** **Trueprep™ Auto sample preparation device** **Truelab™ Uno Dx Real Time Micro PCR Analyser**	

Molbio Diagnostics Pvt. Ltd	
Truenat™ HCV Viral Load	
Marketing status	Pipeline
Type of technology	qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	RUO
Sensitivity	100% (94–100%)
Specificity	100% (85–100%)
Multiplex	No
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Blood, serum, plasma, body fluids
Volume of sample required	250–500 µL
Turnaround time	60 minutes
Throughput*	Low
Marketing price per instrument/test	US$ 18 per Truenat™ chip
Complexity/training requirements	Minimal training required (<1 day)
Supporting instrumentation/sample preparation required	Truenat™ HCV is a chip-based PCR test that runs on Molbio's Truelab™ Uno Dx microPCR device Molbio's Trueprep™ Auto Sample preparation device is required for extraction of nucleic acids from sample; an aliquot of the extracted nucleic acids is loaded onto the Truenat™ HCV chip
Image of device(s)	Unavailable

MP Diagnostics (information not verified by company)	
HCV-SPOT (discontinued), ASSURE HCV Rapid Test, MULTISURE HCV ANTIBODY ASSAY, HCV BLOT 3.0, HCV ELISA 4.0	
Marketing status	HCV-SPOT: Discontinued ASSURE HCV Rapid Test: On the market MULTISURE HCV ANTIBODY ASSAY: On the market HCV BLOT 3.0: On the market HCV ELISA 4.0: On the market
Type of technology	ASSURE HCV Rapid Test: Chromatographic immunoassay MULTISURE HCV ANTIBODY ASSAY: Chromatographic immunoassay HCV BLOT 3.0: EIA HCV ELISA 4.0: EIA
POC	ASSURE HCV Rapid Test: Yes MULTISURE HCV ANTIBODY ASSAY: Yes HCV BLOT 3.0: No HCV ELISA 4.0: No
Infections the device(s) can test for and regulatory approval status	ASSURE HCV Rapid Test: HCV MULTISURE HCV ANTIBODY ASSAY: HCV HCV BLOT 3.0: HCV HCV ELISA 4.0: HCV
	ASSURE HCV Rapid Test: RUO MULTISURE HCV ANTIBODY ASSAY: CE marked HCV BLOT 3.0: CE marked HCV ELISA 4.0: CE marked
Sensitivity	ASSURE HCV Rapid Test: 98.13% MULTISURE HCV ANTIBODY ASSAY: 99.68% HCV BLOT 3.0: 99.9% HCV ELISA 4.0: TBC
Specificity	ASSURE HCV Rapid Test: 98.13% MULTISURE HCV ANTIBODY ASSAY: 98.85% HCV BLOT 3.0: 96.5% HCV ELISA 4.0: TBC
Multiplex	ASSURE HCV Rapid Test: No MULTISURE HCV ANTIBODY ASSAY: No HCV BLOT 3.0: No HCV ELISA 4.0: TBC
Storage temperature of the device(s)/reagents	ASSURE HCV Rapid Test: 2–30 °C MULTISURE HCV ANTIBODY ASSAY: 2–28 °C HCV BLOT 3.0: 2–8 °C HCV ELISA 4.0: TBC

Shelf life of the device(s)/reagents	ASSURE HCV Rapid Test: According to label MULTISURE HCV ANTIBODY ASSAY: According to label HCV BLOT 3.0: According to label HCV ELISA 4.0: According to label
Type of sample required	ASSURE HCV Rapid Test: Serum, plasma MULTISURE HCV ANTIBODY ASSAY: Serum, plasma, whole blood HCV BLOT 3.0: Serum, plasma HCV ELISA 4.0: Serum, plasma
Volume of sample required	ASSURE HCV Rapid Test: 5 µL MULTISURE HCV ANTIBODY ASSAY: 25 µL HCV BLOT 3.0: 20 µL HCV ELISA 4.0: TBC
Turnaround time	ASSURE HCV Rapid Test: 10 minutes MULTISURE HCV ANTIBODY ASSAY: 15 minutes HCV BLOT 3.0: ~120 minutes HCV ELISA 4.0: TBC
Throughput*	ASSURE HCV Rapid Test: Low MULTISURE HCV ANTIBODY ASSAY: Low HCV BLOT 3.0: Medium to high HCV ELISA 4.0: Medium to high
Dimensions (W x H x D)	ASSURE HCV Rapid Test: TBC MULTISURE HCV ANTIBODY ASSAY: 26.68 x 72.4 x 5.2 mm HCV BLOT 3.0: TBC HCV ELISA 4.0: TBC
Power requirements	HCV BLOT 3.0: General laboratory infrastructure including refrigeration, centrifuges, vortex mixers, etc.
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	ASSURE HCV Rapid Test: Minimal MULTISURE HCV ANTIBODY ASSAY: Minimal HCV BLOT 3.0: Training required HCV ELISA 4.0: Training required
Supporting instrumentation/sample preparation required	ASSURE HCV Rapid Test: N/A MULTISURE HCV ANTIBODY ASSAY: N/A HCV BLOT 3.0: General laboratory infrastructure including refrigeration, centrifuges, vortex mixers, ELISA plate reader, etc.
Image of device(s) **MULTISURE HCV ANTIBODY ASSAY**	Unavailable

Newscen Coast Bio-Pharmaceutical Co. Ltd (information not verified by company)	
HCV Rapid Test Kit	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	RUO: Saudi Arabia FDA
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	4–30 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, serum, plasma
Volume of sample required	35 µL (whole blood) or 70 µL (plasma/serum)
Turnaround time	5–15 minutes (whole blood) or 20 minutes (plasma/serum)
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	Available upon request from supplier
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	None
Image of device(s)	Unavailable
OraSure Technologies Inc	
OraQuick® HCV Rapid Antibody Test	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	WHO prequalified, CLIA waived, CE marked, FDA approved

Sensitivity	Oral fluid 98.1%
	Whole blood (fingerstick and venepuncture) 99.7%
	Plasma and serum 99.9%
Specificity	Oral fluid 99.6%
	Whole blood (fingerstick and venepuncture) 99.9%
	Plasma and serum 99.9%
Multiplex	No
Storage temperature of the device(s)/reagents	2–30 °C (controls 2–8 °C)
Shelf life of the device(s)/reagents	18 months from date of manufacture (controls 12 months from date of manufacture)
Type of sample required	Oral fluid, whole blood (fingerstick and venepuncture), serum, plasma
Volume of sample required	5 µL
Turnaround time	20 minutes
Throughput*	Low
Dimensions (W x H x D)	Approximately 2.1 x 11.9 x 0.6 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	$16/test, volume discounts available
Complexity/training requirements	Simple with a low risk for erroneous results Training performed by sales representative/ distributor
Supporting instrumentation/sample preparation required	For fingerstick and venepuncture specimens: antiseptic wipe, sterile lancet or venepuncture supplies, disposable gloves, sterile gauze pads, centrifuge.
Image of device(s)	
Ortho (not confirmed by company)	
HCV ELISA-Ag	
Marketing status	On the market
Type of technology	ELISA
POC	TBC
Infections the device(s) can test for and regulatory approval status	HCV

Sensitivity	TBC
Specificity	99.95%
Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, serum or plasma
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Can be used in a fully manual mode, in semi-automated mode using the ORTHO Summit Sample Handling System, or in automated mode with the ORTHO Summit System (OSS)
Supporting instrumentation/sample preparation required	TBC
Image of product(s)	Unavailable
Ortho-Clinical Diagnostics (information not verified by company)	
VITROS® ECi/ECiQ/3600/5600 anti-HCV	
Marketing status	On the market
Type of technology	Enhanced chemiluminescence using microwell technology
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	Anti-HCV assay is FDA approved across VITROS® ECi, VITROS® 3600 and 5600 machines
Sensitivity	100%
Specificity	99.75%
Multiplex	Yes, up to 2000 assays
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma
Volume of sample required	10–80 µL

Turnaround time	Up to 90 reportable patient results per hour
Throughput*	Medium
Dimensions (W x H x D)	44 x 51.25 x 29 inches
Power requirements	Line voltage: dedicated, single-phase AC power line, North America 120 V AC, continental Europe 200–240 V AC Line Frequency: 50–60 Hz
Connectivity	e-Connectivity® with Predictive Technology operations provide highly secure access to system data for immediate diagnostic and performance analysis
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Easy to train and cross-train operators
Supporting instrumentation/sample preparation required	General laboratory infrastructure required
Image of device(s)	Unavailable
Ortho-Clinical Diagnostics (information not verified by company)	
VITROS® 3600	
Marketing status	On the market
Type of technology	Enhanced chemiluminescence using Microwell technology
POC	No
Infections the device(s) can test for and regulatory approval status	Many including HCV
	Anti-HCV assay is FDA approved across VITROS® ECi, VITROS® 3600 and 5600 machines
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes, up to 3100 assays
Storage temperature of the device(s)/reagents	15–30 °C
Shelf life of the device(s)/reagents	Onboard stability up to 84 days Shelf life stability up to 12 months
Type of sample required	Assay dependent
Volume of sample required	Per assay: 10–80 µL, dead volume: minimum 35 µL
Turnaround time	For single result: ~16–73 minutes
Throughput*	
Dimensions (W x H x D)	83.5 x 64.5 x 33.5 inches

Power requirements	One dedicated 20-amp power line or one dedicated 30-amp power line with UPS, nominal: 200–240 V Ac Line frequency: 47–63 Hz
Connectivity	TBC
Marketing price per instrument/test	US$ 334 994.63 (Fisher Scientific website accessed 1 March 2017)
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	General laboratory infrastructure required
Image of device(s)	Unavailable
Ortho-Clinical Diagnostics (information not verified by company)	
VITROS® 5600 Anti-HCV	
Marketing status	On the market
Type of technology	Colourimetric, potentiometric, immune-rate, turbidimetric, enhanced chemiluminescence
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	Anti-HCV assay is FDA approved across VITROS® ECi, VITROS® 3600 and 5600 machines
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes, allows over 100 assays to be onboard at once
Storage temperature of the device(s)/reagents	15–30 °C
Shelf life of the device(s)/reagents	Onboard stability, up to 84 days Shelf life stability up to 18 months (gentamicin 24 and caffeine 36 months)
Type of sample required	Assay dependent
Volume of sample required	2–80 µL
Turnaround time	For single result: Potentiometric: ~2.5 minutes, colourimetric: ~6 minutes, immuno-rate: ~8 minutes, MicroTip: 8–16 minutes, MicroWell: 16–73 minutes
Throughput*	High, maximum theoretical throughput is up to 945 tests per hour
Dimensions (W x H x D)	110 x 68 x 34.9 inches
Power requirements	Two dedicated 20-amp power lines or one dedicated 30-amp power line with UPS, nominal: 200–240 V Ac Line frequency: 47–63 Hz
Connectivity	TBC

Marketing price per instrument/test	US$ 465 585.75 (Fisher Scientific website accessed 1 March 2017)
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	General laboratory infrastructure required
Image of device(s)	Unavailable
Primerdesign	
Genesig® q16	
Marketing status	On the market
Type of technology	qPCR and qRT-PCR
POC	No
Infections the device(s) can test for and regulatory approval status	HCV (others available)
	RUO
Sensitivity	RUO
Specificity	RUO
Multiplex	Yes
Storage temperature of the device(s)/reagents	Device: Room temperature Reagents: Freezer
Shelf life of the device(s)/reagents	Device: TBC Reagents: 18 months lyophilized, 6 months once reconstituted
Type of sample required	Any sample type is usable, an extraction solution is offered
Volume of sample required	10 µL per well
Turnaround time	90–-120 minutes
Throughput*	Low
Dimensions (W x H x D)	Device 12 x 16 x 12 cm
Power requirements	AC power supply (provided)
Connectivity	Lan cable/USB
Marketing price per instrument/test	£5.00 per reaction
Complexity/training requirements	Basic laboratory training, simply step-by-step operations
Supporting instrumentation/sample preparation required	Prior DNA/RNA extraction required Computer required
Image of device(s)	

QIAGEN N.V.	
artus™ HCV RG RT-PCR (Rotor-Gene™ Q), artus™ HCV QS-RGQ (QIAsymphony® RGQ)	
Marketing status	On the market
Type of technology	qRT-PCR
POC	No
Infections the device(s) can test for and regulatory approval status	HCV
	CE marked
Sensitivity	21 IU/mL
Specificity	99.4%
Multiplex	No
Storage temperature of the device(s)/reagents	-20 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	1200 µL
Volume of sample required	Plasma
Turnaround time	5–20 minutes
Throughput*	Medium to high
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	artus™ HCV RG RT-PCR: (24) £641 to (96) £2431
Complexity/training requirements	HCV QS-RGQ: (24) £669 to (72) £1971
Supporting instrumentation/sample preparation required	Manual
	For use with QIAsymphony® SP/AS and Rotor-Gene™ Q Instruments
Image of device(s)	

Qualpro Diagnostics	
Combiquic® HIV/HCV	
Marketing status	On the market
Type of technology	Rapid immunoconcentration assay for simultaneous detection of HIV1 and 2 and HCV
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HCV
	FDA approved
Sensitivity	HIV1 and 2: 100% HCV: 100%
Specificity	HIV1 and 2: 100% HCV: 99.6%
Multiplex	Yes
Storage temperature of the device(s)/reagents	Unopened kit: 2–8 °C for 12 months
Shelf life of the device(s)/reagents	12 months
Type of sample required	Serum, plasma
Volume of sample required	25 µL
Turnaround time	5 minutes
Throughput*	Low
Dimensions (W x H x D)	33.5 x 7 x 11 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	N/A
Complexity/training requirements	Follow procedure as in product insert
Supporting instrumentation/sample preparation required	No instrumentation required Sample preparation mentioned in the product insert
Image of device(s)	

Qualpro Diagnostics	
Combiquic® HIV/HCV, Flavicheck® HCV WB, Flaviscreen HCV Plus™, Slim HCV™, Qualisa™ HCV, Electra™ HCV	
Marketing status	Combiquic® HIV/HCV: On the market Flavicheck® HCV WB: On the market Flaviscreen HCV Plus™: On the market Slim HCV™: On the market Qualisa™ HCV: On the market Electra™ HCV: On the market
Type of technology	Combiquic® HIV/HCV: Rapid test for the detection of total antibodies to HCV in serum/plasma/whole blood Flavicheck® HCV WB: Immunochromatographic assay Flaviscreen HCV Plus™: Immunochromatographic assay Slim HCV™: Immunochromatographic assay Qualisa™ HCV: EIA Electra™ HCV: CIA
POC	Combiquic® HIV/HCV: Yes Flavicheck® HCV WB: No Flaviscreen HCV Plus™: Yes Slim HCV™: Yes Qualisa™ HCV: No Electra™ HCV: No
Infections the device(s) can test for and regulatory approval status	Combiquic® HIV/HCV: HIV, HCV Flavicheck® HCV WB: HCV Flaviscreen HCV Plus™: HIV Slim HCV™: HCV Qualisa™ HCV: HCV Electra™ HCV: HCV
	Combiquic® HIV/HCV: FDA approved Flavicheck® HCV WB: RUO Flaviscreen HCV Plus™: RUO Slim HCV™: RUO Qualisa™ HCV: RUO Electra™ HCV: RUO
Sensitivity	Combiquic® HIV/HCV: HCV: 100% Flavicheck® HCV WB: 100% Flaviscreen HCV Plus™: 100% Slim HCV™: 100% Qualisa™ HCV: 100% Electra™ HCV: TBC

Specificity	Combiquic® HIV/HCV: HCV: 100% Flavicheck® HCV WB: 99.61% Flaviscreen HCV Plus™: 99.61% Slim HCV™: 99.6% Qualisa™ HCV: 100% Electra™ HCV: TBC
Multiplex	Combiquic® HIV/HCV: No Flavicheck® HCV WB: No Flaviscreen HCV Plus™: No Slim HCV™: No Qualisa™ HCV: Yes Electra™ HCV: Yes
Storage temperature of the device(s)/reagents	Combiquic® HIV/HCV: 4–30 °C Flavicheck® HCV WB: 4–30 °C Flaviscreen HCV Plus™: 4–30 °C Slim HCV™: 4–30 °C Qualisa™ HCV: 2–8 °C Electra™ HCV: 2–8 °C
Shelf life of the device(s)/reagents	Combiquic® HIV/HCV: 24 months Flavicheck® HCV WB: 24 months Flaviscreen HCV Plus™: 24 months Slim HCV™: 24 months Qualisa™ HCV: 12 months Electra™ HCV: 12 months
Type of sample required	Combiquic® HIV/HCV: Serum, plasma, whole blood Flavicheck® HCV WB: Serum, plasma, whole blood Flaviscreen HCV Plus™: Serum, plasma Slim HCV™: Serum, plasma Qualisa™ HCV: Serum, plasma Electra™ HCV: Serum, plasma
Volume of sample required	Combiquic® HIV/HCV: 50 µL Flavicheck® HCV WB: 50 µL Flaviscreen HCV Plus™: 10 µL Slim HCV™: 25 µL Qualisa™ HCV: 10 µL Electra™ HCV: 10 µL
Turnaround time	Combiquic® HIV/HCV: 15 minutes Flavicheck® HCV WB: 15 minutes Flaviscreen HCV Plus™: 15–20 minutes Slim HCV™: 30 minutes Qualisa™ HCV: 90 minutes Electra™ HCV: 90 minutes

Throughput*	Combiquic® HIV/HCV: Low Flavicheck® HCV WB: Low Flaviscreen HCV Plus™: Low Slim HCV™: Low Qualisa™ HCV: Medium to high Electra™ HCV: Medium to high
Dimensions (W x H x D)	Combiquic® HIV/HCV: 20 x 13.0 x13.2 cm Flavicheck® HCV WB: 137 x 218 mm Flaviscreen HCV Plus™: 137 x 218 mm Slim HCV™: 137 x 218 mm Qualisa™ HCV: 274 x 218 mm Electra™ HCV: TBC
Power requirements	Combiquic® HIV/HCV: N/A Flavicheck® HCV WB: N/A Flaviscreen HCV Plus™: N/A Slim HCV™: N/A Qualisa™ HCV: N/A Electra™ HCV: N/A
Connectivity	Combiquic® HIV/HCV: N/A Flavicheck® HCV WB: N/A Flaviscreen HCV Plus™: N/A Slim HCV™: N/A Qualisa™ HCV: N/A Electra™ HCV: N/A
Marketing price per instrument/test	Combiquic® HIV/HCV: TBC Flavicheck® HCV WB: TBC Flaviscreen HCV Plus™: TBC Slim HCV™: TBC Qualisa™ HCV: TBC Electra™ HCV: TBC
Complexity/training requirements	Combiquic® HIV/HCV: Follow procedure as in product insert Flavicheck® HCV WB: Follow procedure as in product insert Flaviscreen HCV Plus™: Follow procedure as in product insert Slim HCV™: Follow procedure as in product insert Qualisa™ HCV: Follow procedure as in product insert Electra™ HCV: Follow procedure as in product insert

Supporting instrumentation/sample preparation required	Combiquic® HIV/HCV: No instrumentation required; sample preparation mentioned in the product insert Flavicheck® HCV WB: No instrumentation required; sample preparation mentioned in the product insert
	Flaviscreen HCV Plus™: No instrumentation required, sample preparation mentioned in the product insert Slim HCV™: No instrumentation required, sample preparation mentioned in the product insert Qualisa™ HCV: General laboratory infrastructure required, sample preparation mentioned in the product insert Electra™ HCV: General laboratory infrastructure required, sample preparation mentioned in the product insert
Image of device(s) **Top to bottom:** **Combiquic® HIV/HCV** **Flavicheck® HCV WB** **Flaviscreen HCV Plus™** **Slim HCV™ (no image)** **Qualisa™ HCV** **Electra™ HCV**	

Reckon Diagnostics (not confirmed by company)	
HCV Card Test, HCV Strip Test, HCV Card Test (whole blood)	
Marketing status	HCV Card Test: On the market HCV Strip Test: On the market HCV Card Test (whole blood): On the market
Type of technology	HCV Card Test: RDT HCV Strip Test: RDT HCV Card Test (whole blood): RDT
POC	HCV Card Test: Yes HCV Strip Test: Yes HCV Card Test (whole blood): Yes
Infections the device(s) can test for and regulatory approval status	HCV Card Test: HCV HCV Strip Test: HCV HCV Card Test (whole blood): HCV
Sensitivity	HCV Card Test: TBC HCV Strip Test: TBC HCV Card Test (whole blood): TBC
Specificity	HCV Card Test: TBC HCV Strip Test: TBC HCV Card Test (whole blood): TBC
Multiplex	HCV Card Test: No HCV Strip Test: No HCV Card Test (whole blood): No
Storage temperature of the device(s)/reagents	HCV Card Test: 4–40 °C HCV Strip Test: 4–40° C HCV Card Test (whole blood):
Shelf life of the device(s)/reagents	HCV Card Test: TBC HCV Strip Test: TBC HCV Card Test (whole blood): TBC
Type of sample required	HCV Card Test: Serum or plasma HCV Strip Test: Serum or plasma HCV Card Test (whole blood): Whole blood, serum or plasma
Volume of sample required	HCV Card Test: ~30 µL HCV Strip Test: ~30 µL HCV Card Test (whole blood): ~30 µL
Turnaround time	HCV Card Test: 15 minutes HCV Strip Test: 15 minutes HCV Card Test (whole blood): 15 minutes
Throughput*	HCV Card Test: Low HCV Strip Test: Low HCV Card Test (whole blood): Low

Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable
ReLIA Diagnostics (not confirmed by company)	
ReLIA Multi-Functional Immunoassay Instrument, HIV-HCV Dual Test	
Marketing status	On the market
Type of technology	RDT and reader
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HCV; RUO
Sensitivity	TBC
Specificity	TBC
Multiplex	Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	TBC
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable

Roche Molecular Diagnostics (information not verified by company)	
Elecsys® PreciControl Anti-HCV II, Elecsys® Anti-HCV PreciControl Anti-HCV	
Marketing status	On the market
Type of technology	Electrochemiluminescense immunoassay (ECLIA)
POC	No
Infections the device(s) can test for and regulatory approval status	HCV antibodies
	FDA approved CE marked
Sensitivity	100%
Specificity	99.84% (blood samples); 99.66% (hospitalized patients)
Multiplex	No
Storage temperature of the device(s)/reagents	2–8° C
Shelf life of the device(s)/reagents	31 days onboard stability
Type of sample required	Li-heparin, Na-heparin, K2-EDTA, K3-EDTA, serum gel separation, plasma gel separation, sodium citrate plasma
Volume of sample required	50 µL
Turnaround time	18 minutes per assay
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	COBAS® e 411 analyzer, Elecsys® 2010 analyzer or COBAS® e 601/e 602 modules
Image of device(s)	Unavailable
Roche Molecular Diagnostics (information not verified by company)	
COBAS® AmpliPrep/COBAS® TaqMan®HCV Qualitative Test v2.0	
Marketing status	On the market
Type of technology	RNA detection of HCV antibody-positive specimens
POC	No
Infections the device(s) can test for and regulatory approval status	HCV genotypes 1 to 6
	CE-IVD, US-IVD

Sensitivity	15 IU/mL
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Human EDTA plasma or serum
Volume of sample required	650 µL
Turnaround time	TBC
Throughput*	High
Dimensions (W x H x D)	TBC
Power requirements	Refrigeration
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	To be used with COBAS® AmpliPrep Instrument, COBAS® TaqMan® Analyzer and COBAS® TaqMan® 48 Analyzer
Image of device(s)	Unavailable
Roche Molecular Diagnostics (information not verified by company)	
COBAS® AmpliPrep/COBAS® TaqMan®HCV Quantitative Test v2.0	
Marketing status	On the market
Type of technology	RNA detection of HCV genotype
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV (genotypes 1 to 6)
	COBAS® AmpliPrep: IVD only COBAS® TaqMan®HCV Quantitative Test v2.0: CE-IVD, US-IVD
Sensitivity	15 IU/mL
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma
Volume of sample required	650 µL
Turnaround time	TBC

Throughput*	TBC
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	COBAS® AmpliPrep System for sample preparation; COBAS® TaqMan® 48 for amplification and detection
Image of device(s)	Unavailable
Roche Molecular Diagnostics (information not verified by company)	
TaqMan HCV test v2.0 for use with the High Pure System	
Marketing status	On the market
Type of technology	Real-time PCR for COBAS® TaqMan® 48 Analyzer
POC	No
Infections the device(s) can test for and regulatory approval status	HCV RNA quantification
	CE-IVD, US-IVD
Sensitivity	CE-IVD: Sensitivity (LOD; genotype 1) – plasma: 9.3 HCV RNA IU/mL, serum: 8.8 HCV RNA IU/mL FDA-IVD: Sensitivity (LOD; across all genotypes) – 20 IU/mL
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	High Pure System: 15–25 °C Taqman® HCV test: 2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma
Volume of sample required	TBC
Turnaround time	TBC
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	TBC

Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable
Roche Molecular Diagnostics (information not verified by company)	
COBAS® HCV GT/COBAS® 4800 system	
Marketing status	On the market
Type of technology	Automated real-time PCR
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV genotypes 1 to 6
	COBAS® HCV GT: CE-IVD COBAS® 4800 system: IVD
Sensitivity	Serum: 50–125 IU/mL (genotypes 1a, 1b, 2, 3, 4 and 6); 500 IU/mL (genotype 5) Plasma: 125–250 IU/mL (genotypes 1a, 1b, 2, 3, 4 and 6); 1000 IU/mL (genotype 5)
Specificity	For identification of HCV genotypes 1 to 6: 99.7% For identification of HCV genotype 1 subtypes 1a and 1b: 100%
Multiplex	Yes
Storage temperature of the device(s)/reagents	COBAS® HCV GT: 2–8 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	EDTA plasma, serum
Volume of sample required	400 µL
Turnaround time	Up to 384 samples a day
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

Roche Molecular Diagnostics (information not verified by company)	
COBAS® HCV/COBAS® 6800 System and COBAS® 8800 System	
Marketing status	On the market
Type of technology	Automated sample preparation and analysis using real-time PCR
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV nucleic acid detection and quantification
	COBAS® HCV: CE-IVD, US-IVD
Sensitivity	15 IU/mL
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	COBAS® HCV: 2–8 °C COBAS® 6800: 15–28 °C COBAS® 8800: 15–28 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	Human EDTA plasma or serum
Volume of sample required	650 µL
Turnaround time	COBAS® 6800: 384 tests in 8-hour shift COBAS® 8800: 960 tests in 8-hour shift
Throughput*	COBAS® 6800: Low COBAS® 8800: High
Dimensions (W x H x D)	COBAS® 6800: 292 x 216 x 129 cm COBAS® 8800: 429 x 216 x 129 cm
Power requirements	200–240 V Ac ±10%, 50/60 Hz ±5%, maximum power COBAS® 6800: 3500 VA, COBAS® 8800: 8200 VA
Connectivity	Installation category II, functions as central server when interconnecting and operating multiple systems
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	Fully trained laboratory technician required; dedicated training on instrument
Supporting instrumentation/sample preparation required	TBC
Image of device(s)	Unavailable

Roche Molecular Diagnostics (information not verified by company)	
COBAS® AmpliPrep/COBAS® Taqman® HCV test	
Marketing status	On the market
Type of technology	In vitro nucleic acid amplification test
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV nucleic acid quantification
	CE-IVD, US-FDA, Japan-IVD, Canada-IVD
Sensitivity	43 IU/mL
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	Temperature: 15–32 °C (59–89 °F) Humidity: <80% (for temperatures up to 32 °C) Maximum altitude: 2000 metres (6500 feet)
Shelf life of the device(s)/reagents	TBC
Type of sample required	Plasma or serum
Volume of sample required	Sample needed varies by assay (200 µL for qualitative assay; 650 µL for quantitative assay; 500 µL for quantitative assay with High Pure) Plasma can be transported/stored at 2–8 °C for five days or frozen at -70 °C
Turnaround time	Three racks of 24 specimens in approximately 5 hours; with 216 seconds processing time per specimen
Throughput*	Low – up to 168 specimens per 8-hour shift, based on testing combinations and laboratory workflow
Dimensions (W x H x D)	165 (65) x 95 (37.4) x 75 (29.5) cm/inches
Power requirements	100–125 V AC mains and 200–240 V AC mains (+10, -15%) 50–60 Hz
Connectivity	TBC
Marketing price per instrument/test	Available from supplier
Complexity/training requirements	Fully trained laboratory technician required; dedicated training on instrument
Supporting instrumentation/sample preparation required	COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan®Analyzer or the COBAS® TaqMan® 48 Analyzer for automated amplification and detection
Image of device(s)	Unavailable

Sacace Biotechnologies	
SaCycler-96i™	
Marketing status	On the market
Regulatory approval status	CE marked (device and some assays)
Type of technology	RT-qPCR
POC	No
Infections the device can test for	HCV (and others)
Sensitivity	HCV Real-TM Quant Dx: 13 IU/mL (sample input 1000 µL); 30 µL when using SaMag extraction HCV Genotype Plus Real-TM sensitivity: 1000 IU/mL
Specificity	HCV Real-TM Quant Dx specificity: 100% HCV Genotype Plus Real-TM specificity: 100%
Multiplex	Yes
Storage temperature of the device/reagents	HCV Dx (lyophilized reagents) are stored at 2–8 °C, shipped at room temperature Other liquid format reagent kits (e.g. HCV genotype) stored at -20 °C and shipped at 2–8 °C
Shelf life of the device/reagents	Liquid reagent kits (HCV genotype): 6–9 months Lyophilized reagents (HCV Dx quantitative viral load): 12 months Extraction kit reagents: 12 months
Type of sample required	Plasma (recommended) and serum
Volume of sample required	Up to 400 µL of plasma/serum when using SaMag extraction kit Up to 1000 µL of plasma when using manual extraction kit (Sacace MagnoVirus extraction kit)
Turnaround time	3.5–4 hours
Throughput	Low (<50 samples/hour), but at full theoretical capacity (with two SaMag-24 extraction systems plus one SaCycler-96™ PCR instrument) ~280 tests per day (8-hour work day) could be performed with HCV Real TM Quant Dx kit
Dimensions (W x H x D)	210 x 540 x 540 mm
Power requirements	10A, 250V power cable
Connectivity	USB

Marketing price per instrument/test	US$ 18 645 (for the version that comes with a notebook computer, but only works with Sacace test kits); or ~US$ 21 750 (for the version that does not include a notebook computer, but can also be used with non-Sacace test kits)
Complexity/training requirements	Requires prior DNA/RNA extraction, but extraction can be automated using the SaMag-12 or SaMag-24 Systems PCR setup can be automated when using SaMag instrument, which will elute DNA/RNA directly in the HCV Dx PCR tube with lyophilized reagents; the user must close the PCR tube cap and transfer directly into SaCycler-96™ instrument to perform PCR (this applies only to HCV Dx lyophilized kit)
Supporting instrumentation/sample preparation required	To work, SaCycler-96™ Real Time PCR instrument requires a personal computer notebook with Microsoft Windows Other instrumentation required are normal for molecular biology laboratories (e.g. micropipettes, filter tips, spin centrifuge)
Image(s) of device(s) **SaCycler-96i™**	
Sacace Biotechnologies	
HCV1/2/3 Real-TM Genotype, HCV Genotype Plus Real-TM	
Marketing status	HCV1/2/3 Real-TM Genotype: On the market HCV Genotype Plus Real-TM: On the market
Infections the device can test for and regulatory approval status	HCV1/2/3 Real-TM Genotype: HCV 1, 2, 3 HCV Genotype Plus Real-TM: HCV 1a, 1b, 2, 3, 4, 5a and 6
	HCV1/2/3 Real-TM Genotype: RUO HCV Genotype Plus Real-TM: RUO
Type of technology	HCV1/2/3 Real-TM Genotype: Real-time PCR HCV Genotype Plus Real-TM: Reverse transcription and real-time PCR amplification test
POC	HCV1/2/3 Real-TM Genotype: No HCV Genotype Plus Real-TM: No

Infections the device can test for	HCV1/2/3 Real-TM Genotype: HCV HCV Genotype Plus Real-TM: HCV
Sensitivity	HCV1/2/3 Real-TM Genotype: 50–500 IU/mL depending on sample volume for isolation HCV Genotype Plus Real-TM: 1000 IU/mL
Specificity	HCV1/2/3 Real-TM Genotype: 100% HCV Genotype Plus Real-TM: 100%
Multiplex	HCV1/2/3 Real-TM Genotype: Yes HCV Genotype Plus Real-TM: Yes
Storage temperature of the device/reagents	HCV1/2/3 Real-TM Genotype: 2–8 °C for kit/-20°C for some reagents HCV Genotype Plus Real-TM: 2–8 °C for kit/-20°C for some reagents
Shelf life of the device/reagents	HCV1/2/3 Real-TM Genotype: Liquid reagent kits (HCV genotype) 6–9 months HCV Genotype Plus Real-TM: Liquid reagent kits (HCV genotype) 6–9 months
Type of sample required	HCV1/2/3 Real-TM Genotype: Plasma (recommended), serum HCV Genotype Plus Real-TM: Plasma (recommended), serum
Volume of sample required	HCV1/2/3 Real-TM Genotype: Up to 400 µL of plasma/serum when using SaMag Viral extraction kit Up to 1000 µL of plasma when using manual extraction kit HCV Genotype Plus Real-TM: Up to 400 µL of plasma/serum when using SaMag Viral extraction kit Up to 1000 µL of plasma when using manual extraction kit
Turnaround time	HCV1/2/3 Real-TM Genotype: 3.5–4 hours HCV Genotype Plus Real-TM: 3.5–4 hours
Throughput	HCV1/2/3 Real-TM Genotype: Low (<50 samples/hour), but at full theoretical capacity (with two SaMag-24 extraction systems plus one SaCycler-96™ PCR instrument) ~280 tests per day (8-hour work day) could be performed with HCV Real TM Quant Dx kit HCV Genotype Plus Real-TM: Low (<50 samples/hour), but at full theoretical capacity (with two SaMag-24 extraction systems plus one SaCycler-96™ PCR instrument) ~280 tests per day (8-hour work day) could be performed with HCV Real TM Quant Dx kit
Dimensions (W x H x D)	HCV1/2/3 Real-TM Genotype: TBC HCV Genotype Plus Real-TM: TBC

Power requirements	HCV1/2/3 Real-TM Genotype: N/A HCV Genotype Plus Real-TM: N/A
Connectivity	HCV1/2/3 Real-TM Genotype: N/A HCV Genotype Plus Real-TM: N/A
Marketing price per instrument/test	HCV1/2/3 Real-TM Genotype: Available on request according to volumes requested HCV Genotype Plus Real-TM: Available on request according to volumes requested
Complexity/training requirements	HCV1/2/3 Real-TM Genotype: Technician must be proficient in molecular biology good laboratory practices for nucleic acids extraction and amplification (real-time PCR)
	HCV Genotype Plus Real-TM: Technician must be proficient in molecular biology good laboratory practices for nucleic acids extraction and amplification (real-time PCR)
Supporting instrumentation/sample preparation required	HCV1/2/3 Real-TM Genotype: Real-time Thermalcycler (4 channel), workstation, pipettes (adjustable), sterile tips with filters, tube racks, RNA extraction kit HCV Genotype Plus Real-TM: Disposable powder-free gloves and laboratory coat, automatic adjustable pipettes (from 5–20 µL and from 20–200 µL), disposable tips with aerosol barriers (100 or 200 µL) in tube racks, tube racks, vortex mixer/desktop centrifuge, PCR box, real-time PCR instrument, disposable polypropylene microtubes for PCR or PCR-plate, refrigerator for 2–8 °C, deep-freezer for ≤-16 °C, waste bin for used tips, RNA isolation kit
Sacace Biotechnologies	
HCV Real-TM Quant Dx CE, HCV Real-TM Quant, HCV Real-TM Qual, HCV 240/440 IC	
Marketing status	HCV Real-TM Quant Dx CE: On the market HCV Real-TM Quant: On the market HCV Real-TM Qual: On the market HCV 240/440 IC: On the market
Infections the device can test for and regulatory approval status	HCV Real-TM Quant Dx CE: CE marked HCV Real-TM Quant: RUO HCV Real-TM Qual: RUO HCV 240/440 IC: RUO
Type of technology	HCV Real-TM Quant Dx CE: Real-time PCR (lyophilized reagents) HCV Real-TM Quant: Real-time PCR HCV Real-TM Qual: Real-time PCR HCV 240/440 IC: Reverse-transcription and nucleic acid amplification test

POC	HCV Real-TM Quant Dx CE: No HCV Real-TM Quant: No HCV Real-TM Qual: No HCV 240/440 IC: No
Sensitivity	HCV Real-TM Quant Dx CE: 13 IU/mL HCV Real-TM Quant: 13 IU/mL HCV Real-TM Qual: 20 IU/mL HCV 240/440 IC: 500 copies/mL
Specificity	HCV Real-TM Quant Dx CE: 100% HCV Real-TM Quant: 100% HCV Real-TM Qual: 100% HCV 240/440 IC: 100%
Multiplex	HCV Real-TM Quant Dx CE: Two fluorescence channels HCV Real-TM Quant: Two fluorescence channels HCV Real-TM Qual: Two fluorescence channels HCV 240/440 IC: No
Storage temperature of the device/reagents	HCV Real-TM Quant Dx CE: 2–8 °C for kit/-20 °C for some reagents HCV Real-TM Quant: 2–8 °C for kit/-20 °C for some reagents HCV Real-TM Qual: 2–8 °C for kit/-20 °C for some reagents HCV 240/440 IC: 2–8 °C for kit/-20°C for some reagents
Shelf life of the device/reagents	HCV Real-TM Quant Dx CE: 12 months HCV Real-TM Quant: 6–9 months HCV Real-TM Qual: 6–9 months HCV 240/440 IC: 6–9 months
Type of sample required	HCV Real-TM Quant Dx CE: Plasma (recommended), serum HCV Real-TM Quant: Plasma (recommended), serum HCV Real-TM Qual: Plasma (recommended), serum HCV 240/440 IC: Plasma (recommended), serum
Volume of sample required	HCV Real-TM Quant Dx CE: Up to 400 µL of plasma/serum when using SaMag Viral extraction kit; up to 1000 µL of plasma when using manual extraction kit HCV Real-TM Quant: Up to 400 µL of plasma/serum when using SaMag Viral extraction kit; up to 1000 µL of plasma when using manual extraction kit HCV Real-TM Qual: Up to 400 µL of plasma/serum when using SaMag Viral extraction kit, up to 1000 µL of plasma when using manual extraction kit HCV 240/440 IC: 100 µL

Turnaround time	HCV Real-TM Quant Dx CE: 3.5–4 hours HCV Real-TM Quant: 4 hours HCV Real-TM Qual: 4 hours HCV 240/440 IC: 6 hours
Throughput	HCV Real-TM Quant Dx CE: Low HCV Real-TM Quant: Low HCV Real-TM Qual: Low HCV 240/440 IC: Very low
Dimensions (W x H x D)	Not provided
Power requirements	Not provided
Connectivity	Not provided
Marketing price per instrument/test	Available on request according to volumes requested
Complexity/training requirements	Technician must be proficient in molecular biology good laboratory practices for nucleic acids extraction and amplification (PCR) and agarose gel electrophoresis detection
Supporting instrumentation/sample preparation required	HCV Real-TM Quant Dx CE: RNA isolation kit (see RNA isolation), desktop micro centrifuge for “Eppendorf” type tubes, vortex mixer, disposable gloves (powderless), biohazard waste container, refrigerator and freezer, real-time thermal cycler, biological safety cabinet approved for working with infectious materials, pipettes (adjustable), sterile pipette tips with filters, tube racks HCV Real-TM Quant: RNA isolation kit (only ref. V1-100/2FRT), biological cabinet, desktop micro centrifuge for “Eppendorf” type tubes (RCF maximum 16 000 x g) – Eppendorf 5415D or equivalent, 60 °C ±2 °C dry heat block, vortex mixer, pipettors (capacity 5–40 µL, 40–200 µL, 200–1000 µL) with aerosol barrier, 1.5 mL polypropylene sterile tubes (Sarstedt, QSP, Eppendorf), disposable gloves (powderless), tube racks, biohazard waste container, 70% ethanol (freshly prepared mixture of reagent grade 96% ethanol and distilled water), acetone, refrigerator, real-time thermal cycler, freezer

	HCV Real-TM Qual: RNA isolation kit (only ref. V1-100FRT), biological cabinet, desktop micro centrifuge for “Eppendorf” type tubes (RCF maximum 16 000 x g) – Eppendorf 5415D or equivalent, 60 °C ±2 °C dry heat block, vortex mixer, pipettors (capacity 5–40 µL, 40–200 µL, 200–1000 µL) with aerosol barrier, 1.5 mL polypropylene sterile tubes (Sarstedt, QSP, Eppendorf), disposable gloves (powderless), tube racks, biohazard waste container, 70% ethanol (freshly prepared mixture of reagent grade 96% ethanol and distilled water), acetone, refrigerator, real-time thermal cycler, freezer contents HCV 240/440 IC: Thermal cycler, workstation, pipettors (capacity 0.5–10 µL, 5–40 µL) with aerosol barrier, tube racks, reagents not provided, RNA extraction kit, detection agarose kit
Siemens Healthcare Diagnostics	
BEP® 2000 Advance® System/BEP® III System	
Marketing status	On the market
Type of technology	Automated microtiter plates(MTP) (ELISA processing)
POC	No
Infections the device(s) can test for and regulatory approval status**	More than 100 validated Siemens CE marked assays on BEP® system for viruses including HIV, hepatitis, bacteria such as syphilis, borreliosis, fungi, worms, parasites are available
	CE marked; registration in other countries – contact Siemens for detailed information
Sensitivity	Assay specific – contact Siemens for detailed information
Specificity	Assay specific – contact Siemens for detailed information
Multiplex	BEP® 2000 Advance® System: Yes, up to four MTPs, up to 12 tests/plate frame (Enzygnost® and Novagnost® Assays), 100 tubes BEP® III System: Yes, 10 MTPs in parallel
Storage temperature of the device(s)/reagents	Data provided in IFU for 2–8 °C/15–25 °C
Shelf life of the device(s)/reagents	Assay specific: Typically 12–24 months; contact Siemens for detailed information
Type of sample required	Assay specific: Serum and/or plasma
Volume of sample required	Assay specific: Typically 100 µL
Turnaround time	Assay specific: 1–2 hours
Throughput*	BEP® 2000 Advance® System: 4 plates per run BEP® III System: 10 plates per run

Dimensions (W x H x D)	BEP® 2000 Advance® System: 44.8 x 39.4 x 61.4 inches BEP® III System: 13.8 x 9.8 x 23.6 inches
Power requirements	BEP® 2000 Advance® System: 100–260 V Ac, 47–63 Hz, typically maximum 500 VA BEP® III System: Operating unit: 100–240 V Ac, 50/60 Hz; supply unit: 110V 90–125 V (50/60 Hz), 230V: 205–245 V (50/60 Hz)
Connectivity	Yes
Marketing price per instrument/test	Contact the local Siemens for information
Complexity/training requirements	Siemens offers training in European training centres Customer-specific training in individual countries is available on request
Supporting instrumentation/sample preparation required	Siemens offers support either in the country or from global organization
Image of device(s) **Left to right:** **BEP® 2000 Advance® System** **BEP® III System**	
Siemens Healthcare Diagnostics (information not verified by supplier)	
Enzygnost® Anti-HCV 4.0	
Marketing status	On the market
Type of technology	EIA
POC	No
Infections the device(s) can test for and regulatory approval status	HCV IgG and IgM antibodies
	CE marked FDA approval
Sensitivity	100%
Specificity	99.92%
Multiplex	Yes
Storage temperature of the device(s)/reagents	2–8 °C
Shelf life of the device(s)/reagents	Check dates given on labels
Type of sample required	Serum or plasma
Turnaround time	Variable on which system used
Throughput	Low
Dimensions (W x H x D)	TBC

Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	Supporting instrumentation/sample preparation required
Image of device(s)	Unavailable
Siemens Healthcare Diagnostics	
VERSANT® HCV Genotype 2.0 Assay (LiPA)	
Marketing status	On the market
Type of technology	Reverse hybridization, LPA
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV genotypes 1 to 6 and subtypes 1a and 1b
	CE-IVD and FDA approved
Sensitivity	Assay LOD: 400 IU (plasma) and 650 IU (serum)
Specificity	Not applicable
Multiplex	Not applicable
Storage temperature of the device(s)/reagents	2–8° C (genotyping kit); -25 to -15 °C (amplification kit)
Shelf life of the device(s)/reagents	12 months from date of manufacture
Type of sample required	Serum or plasma
Volume of sample required	Depends on extraction method
Turnaround time	Depends on workflow (8–10 hours for 48 tests)
Throughput*	Auto-LiPA Instrument: 48 tests/run, Autoblot 3000H (20 tests/run)
Dimensions (W x H x D)	Autoblot 3000H: 22 x 18 x 7.5 inches Auto-LiPA 48: 804 x 460.2 x 459.8 mm
Power requirements	100–240 V, 50 or 60 Hz
Connectivity	
Marketing price per instrument/test	Country and volume dependent
Complexity/training requirements	Minimal complexity for molecular diagnostic laboratories; free training provided for new customers
Supporting instrumentation/sample preparation required	Full manual process or semi-automated options

Image of device(s)	
Siemens Healthcare Diagnostics	
VERSANT® kPCR Molecular System	
Marketing status	On the market
Type of technology	Extraction of nucleic acids, PCR plate set-up and amplification/detection by kPCR
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV (and others)
	CE-IVD
Sensitivity	Not applicable for system
Specificity	Not applicable for system
Multiplex	SP module: Up to six assays simultaneously; Amplification-detection module: five channels for up to five targets
Storage temperature of the device(s)/reagents	Ambient
Shelf life of the device(s)/reagents	Not applicable for system
Type of sample required	Plasma, serum, urine, whole blood, stool, transport media from urogenital swabs, breast milk, cerebrospinal fluid, semen, buccal swab, saliva/sputum, cell culture, ascites, PBMC, amniotic fluid, tears/eye swab, bronchial aveolar lavage, ThinPrep collection media, SurePath collection media
Volume of sample required	Up to 500 µL (HIV-1, HBV, HCV, kPCR PLX assays, ZIKV), 250 µL (CT/NG); not including dead volume requirements, which are sample tube type dependent
Turnaround time	96 tests in about 6 hours
Throughput*	Low; 96 tests per run
Dimensions (W x H x D)	SP module: 1.124 x 0.903 x 1.006 metres (depth includes autoload tray), no plumbing or drainage required AD module: 0.368 x 0.534 x 0.457 metres

Power requirements	SP and AD modules: 100 V to 120 V alternating current at 50 or 60 Hz ±5% or 200 V to 240 V alternating current at 50 or 60 Hz ±5%
Connectivity	Bidirectional LIS
Marketing price per instrument/test	Country and volume dependent
Complexity/training requirements	Minimal complexity for molecular diagnostic laboratories; free training provided for new customers
Supporting instrumentation/sample preparation required	VERSANT® kPCR Molecular System includes both sample preparation and amplification-detection modules VERSANT® Sample Preparation 1.0 Reagents kit required for extraction Automated PCR plate set-up included
Image of device(s)	
Siemens Healthcare Diagnostics	
VERSANT® HCV 1.0 Assay (kPCR)	
Marketing status	On the market
Type of technology	Real-time kPCR
POC	No
Infections the device(s) can test for and regulatory approval status**	HCV
	CE-IVD FDA approved
Sensitivity	15 IU/mL
Specificity	100% with a 95% lower one-sided confidence limit of 99.7%
Multiplex	HCV target and internal control

Storage temperature of the device(s)/reagents	HCV: -30 to -10 °C Sample preparation reagent: Room temperature/4 °C
Shelf life of the device(s)/reagents	12 months from date of manufacture
Type of sample required	Serum, plasma
Volume of sample required	500 µL (not including dead volume that is tube dependent)
Turnaround time	For 96 tests (full plate): 6 hours 15 minutes
Throughput*	Low; 96 tests
Dimensions (W x H x D)	SP module: 1.124 x 0.903 x 1.006 metres (depth includes autoload tray), no plumbing or drainage required AD module: 0.368 x 0.534 x 0.457 metres SP and AD: 100 V to 120 V alternating current at 50 or 60 Hz ±5% or 200 V to 240 V alternating current at 50 or 60 Hz ±5%
Power requirements	SP and AD: 100 V to 120 V alternating current at 50 or 60 Hz ±5% or 200 V to 240 V alternating current at 50 or 60 Hz ±5%
Connectivity	Bidirectional LIS
Marketing price per instrument/test	Country and volume dependent
Complexity/training requirements	Minimal complexity for molecular diagnostic laboratories; free training provided for new customers
Supporting instrumentation/sample preparation required	VERSANT® kPCR Molecular System includes both sample preparation and amplification-detection modules VERSANT® Sample Preparation 1.0 Reagents kit required for extraction Automated PCR plate set-up included
Image of device(s)	

Span Biotech (not confirmed by company)	
One-Step HCV Ab 4th Generation Rapid Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
Sensitivity	100%
Specificity	100%
Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum
Volume of sample required	TBC
Turnaround time	10 minutes
Throughput*	Low
Power requirements	TBC
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable
Span Diagnostics (not confirmed by company)	
Signal HCV	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV; CE marked
Sensitivity	TBC
Specificity	TBC
Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum

Volume of sample required	TBC
Turnaround time	TBC
Throughput*	Low
Power requirements	N/A
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable
Spectrum (not confirmed by company)	
HBsAg/HCV Ab Rapid Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBV, HCV
Sensitivity	HCV: 98.7%
Specificity	HCV: 99.6%
Multiplex	Yes
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Serum, plasma or whole blood
Volume of sample required	1 drop
Turnaround time	15 minutes
Throughput*	Low
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable

Standard Diagnostics Inc. (information not verified by company)	
SD Bioline HCV, SD HCV ELISA 3.0	
Marketing status	SD Bioline HCV: On the market SD HCV ELISA 3.0: On the market
Type of technology	SD Bioline HCV: Chromatographic immunoassay SD HCV ELISA 3.0: EIA
POC	SD Bioline HCV: POC – Yes SD HCV ELISA 3.0: Laboratory – No
Infections the device(s) can test for and regulatory approval status	SD Bioline HCV: HCV SD HCV ELISA 3.0: HCV
	SD Bioline HCV: WHO prequalified SD HCV ELISA 3.0: TBC
Sensitivity	SD Bioline HCV: 100% SD HCV ELISA 3.0: 99.5%
Specificity	SD Bioline HCV: 99.4% SD HCV ELISA 3.0: 99.5%
Multiplex	SD Bioline HCV: No SD HCV ELISA 3.0: No
Storage temperature of the device(s)/reagents	SD Bioline HCV: 1–30 °C SD HCV ELISA 3.0: 2–8 °C
Shelf life of the device(s)/reagents	SD Bioline HCV: 24 months SD HCV ELISA 3.0: 12 months
Type of sample required	SD Bioline HCV: Whole blood, serum, plasma SD HCV ELISA 3.0: Plasma, serum
Volume of sample required	SD Bioline HCV: 10 µL SD HCV ELISA 3.0: TBC
Turnaround time	SD Bioline HCV: 5–20 minutes SD HCV ELISA 3.0: ~2 hours
Throughput*	SD Bioline HCV: Low SD HCV ELISA 3.0: Low
Dimensions (W x H x D)	SD Bioline HCV: TBC SD HCV ELISA 3.0: TBC
Power requirements	SD Bioline HCV: TBC SD HCV ELISA 3.0: TBC
Connectivity	SD Bioline HCV: TBC SD HCV ELISA 3.0: TBC
Marketing price per instrument/test	Available upon request
Complexity/training requirements	SD Bioline HCV: Minimal SD HCV ELISA 3.0: TBC

Supporting instrumentation/sample preparation required	SD Bioline HCV: None SD HCV ELISA 3.0: ELISA plate reader
Image of device(s) **SD Bioline HCV**	Unavailable
Sysmex (not confirmed by company)	
Automated Immunoassay System HISCL-500 and HISCL-800 (compact analyser)	
Marketing status	On the market
Type of technology	CLIA
POC	No
Infections the device(s) can test for and regulatory approval status	HCV, HBV, HIV, HTLV
Sensitivity	TBC
Specificity	TBC
Multiplex	TBC
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Blood in EDTA/EDTA plasma
Volume of sample required	TBC
Turnaround time	17 minutes
Throughput*	Medium
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/sample preparation required	TBC
Image of device(s) **HISCL-800**	Unavailable
Turklab (not confirmed by company)	
Anti HCV Test	
Marketing status	On the market
Type of technology	RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV; CE marked
Sensitivity	100%
Specificity	100%

Multiplex	No
Storage temperature of the device(s)/reagents	TBC
Shelf life of the device(s)/reagents	TBC
Type of sample required	Whole blood, plasma or serum
Volume of sample required	TBC
Turnaround time	5–15 minutes
Throughput*	Low
Power requirements	N/A
Connectivity	No
Marketing price per instrument/test	TBC
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	Minimal
Image of device(s)	Unavailable
Ustar Biotechnologies	
RT-CPA HCV Viral Load Test	
Marketing status	Pipeline (expected 2019)
Regulatory approval status	RUO: Yes CLIA waived, WHO prequalified, CE marked, FDA approved: No
Type of technology	CPA-based, integrated molecular test
POC	Yes
Infections the device can test for	HCV, TB, HIV (all in development)
Sensitivity	TBC
Specificity	TBC
Multiplex	Yes
Storage temperature of the device/reagents	Room temperature
Shelf life of the device/reagents	2 years
Type of sample required	Whole blood (fingerstick)
Volume of sample required	100 µL
Turnaround time	1 hour
Throughput	Low (<50 samples/hour), four samples at once
Dimensions (W x H x D)	380 x 280 x 350 mm

Power requirements	AC, rechargeable batteries available
Connectivity	WiFi
Marketing price per instrument/test	US$ 5000/US$ 5
Complexity/training requirements	Minimal – instrument will be fully integrated (RNA extraction and analysis)
Supporting instrumentation/sample preparation required	Printer
Image of device and cartridge	
Wama Diagnóstica (information not verified by company)	
Imuno-Rápido	
Marketing status	On the market
Type of technology	Chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HCV
	RUO, WHO prequalified, CLIA waived, FDA approved: TBC CE marked: No
Sensitivity	100%
Specificity	99.8%
Multiplex	No
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	TBC
Type of sample required	10 µL
Volume of sample required	Whole blood, serum
Turnaround time	10–5 minutes
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Minimal
Supporting instrumentation/sample preparation required	None
Image of device(s)	Unavailable

Unitaid Secretariat

www.unitaid.org

Unitaid is a hosted partnership of the World Health Organization

Unitaid Secretariat
Global Health Campus
Chemin du Pommier, 40
1218 Le Grand-Saconnex, Switzerland
T +41 22 791 12 00
F +41 22 791 48 90
unitaid@who.int

Unitaid
Innovation in Global Health