Truenat®

HCV

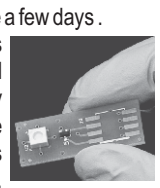
Chip-based Real Time PCR Test for Hepatitis C Virus

1. INTENDED USE

Truenat® HCV (REF 601180005 / 601180020 / 601180025 / 601180050 / 601180100 / 601180200) is an automated point-of-care or near patient Chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the quantitative detection of Hepatitis C virus (HCV) RNA in human plasma, serum and whole blood (venous) samples. **Truenat® HCV** aids in the diagnosis and confirmation of HCV infection (in conjunction with HCV antibody test) and in estimation of viral load. It is not intended as a blood donor screening test. **Truenat® HCV** runs on the **Truelab®** Real Time Quantitative micro PCR Analyzer. **Truenat® HCV** is a single-use *in vitro* diagnostics test meant for professional use in near-patient, laboratory or any healthcare settings, by healthcare professionals or any user appropriately trained by a representative of Molbio Diagnostics.

2. INTRODUCTION

The positive-sense single-stranded ribonucleic acid (RNA) virus, Hepatitis C Virus (HCV), belongs to the genus Hepacivirus, a member of the family Flaviviridae. The core genetic material (RNA) is surrounded by an icosahedral protective shell of protein and further encased in a lipid envelope of cellular origin. The Hepatitis C Virus is classified into six major genotypes (1-6) with several subtypes within each genotype. It is the cause of Hepatitis C and some cancer lymphomas in humans. Unlike Hepatitis A and B, there is no vaccine as yet that protects against contracting Hepatitis C. As per WHO reports, 130–150 million people globally have chronic hepatitis C infection. For a small percentage of people, Hepatitis C is a short-term illness but for an estimated 70%–85% of people who become infected with Hepatitis C, it becomes a long-term, chronic infection. Approximately half a million people die each year from complications and liver diseases related to Hepatitis C. Globally genotype 1 (specifically subtypes 1a and 1b) is the most prevalent, causing almost half of all HCV infections. Nucleic acid amplification tests (NAAT) for the detection of HCV RNA is recommended to be performed directly following a positive HCV serological test to establish the diagnosis of chronic HCV infection. This is because a portion of the infected population spontaneously clears the infection by a strong immune response and without any treatment. They will continue to test positive for anti-HCV antibodies despite clearing the infection. Quantitative NAATs are also important in order to make clinical decisions on starting treatment for HCV infection. Approximately half of all patients who undergo treatment with anti-viral medication for 24-48 weeks are cleared of the infection. Newer therapy that clears HCV infection in 12 weeks has recently been approved. Successful treatment decreases the risk of hepatocellular carcinoma by almost 75%. Success of treatment is indicated by sustained virologic response (SVR), defined as undetectable HCV RNA in the patient's blood 24 weeks after the end of treatment. NAAT tests are therefore crucial for diagnosis, treatment initiation and treatment monitoring of HCV. Unfortunately, the full benefits of diagnosis and treatment guidance using molecular tests have not yet reached the majority of HCV–infected patients who live in countries with limited resources because of the costs and technical constraints. Molecular/NAAT tests have so far been restricted to centralized reference laboratories as they require skilled manpower and elaborate infrastructure. Also the turnaround time for results could take a few days .



The **Truenat®** point-of-care real time PCR system enables decentralization and near patient diagnosis and viral load monitoring of HCV by making real time PCR technology rapid, simple, robust and user friendly and offering "sample to result" capability even at resource limited settings. This is achieved through a combination of lightweight, portable, mains / battery operated **Truelab®** Real Time Quantitative micro PCR Analyzer and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and room temperature stable **Truenat®** micro PCR chips and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit so that even the peripheral laboratories with minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour. Moreover, with these devices PCR testing can also be initiated in the field level, on site.

Truenat® HCV is a disposable, room temperature stable, Chip-based Real Time PCR test with dried $MgCl_2$ in reaction well and freeze dried RT-PCR reagents in microtube for performing Real Time RT-PCR test for detection of HCV and runs on the **Truelab®** Real Time Quantitative micro PCR Analyzer. All components of **Truenat®** pouch are nuclease-free. It requires only six (6) µL of purified RNA to be added to the reaction well for the analysis. The intelligent chip also carries test and batch related information. The **Truenat® HCV** chip also stores information of used chips to prevent any accidental re-use of the chip.

NOTE : Truelab®/ Truenat® / Trueprep® / Truepet® are all trademarks of Molbio Diagnostics Private Limited.

The Truelab® Real Time micro PCR Analyzer is protected by the following patents and patents granted: IN 2313/CHE/2007 (Patent No. 281573), WO2009/047804 and corresponding claims of any foreign counterpart(s) thereof.

The Truenat® micro PCR chip is protected by the following patents and patents pending: IN 2312/CHE/2007, WO 2009/047805 and corresponding claims of any foreign counterpart(s) thereof.

3. PRINCIPLE OF THE TEST

Truenat® HCV works on the principle of Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) based on Taqman chemistry. The patient sample (whole blood / plasma / serum) is first pre-treated using the **Trueprep® AUTO** Universal Sample Pre-treatment Pack. The RNA from the pre-treated sample is then extracted using **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit. The cartridge from the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit contains pre-loaded Internal Positive Control (IPC), composed of known concentration of DNA, trehalose, PBS buffer and amaranth dye, which is co-extracted along with sample nucleic acids, thereby validating the process from extraction to PCR run. The RNA extract is analyzed using the **Truenat® HCV** Chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test and the **Truelab®** Real Time Quantitative micro PCR Analyzer. **Truenat® HCV** chip is placed on the chip tray of the **Truelab®** Real Time Quantitative micro PCR Analyzer. Six (6) µL of the purified RNA is then dispensed using the provided calibrated micropipette and tip into the microtube containing freeze dried RT-PCR reagents and allowed to stand for 30-60 seconds to get a clear solution. ⚠ No mixing by tapping, shaking or by reverse pipetting should be done. Six (6) µL of this clear solution is then pipetted out using the same pipette and tip and dispensed into the reaction well of the **Truenat® HCV** chip and the test is inserted in the **Truelab®** Real Time Quantitative micro PCR Analyzer where the RNA is first converted into complementary DNA (cDNA) by the RT enzyme and further thermal cycling takes place. A positive amplification causes the dual labeled fluorescent probe in the **Truenat® HCV** chip to release the fluorophores in an exponential manner which is then captured by the built-in opto-electronic sensor and displayed as amplification curve on the analyzer screen, on a real time basis during the test run. The Cycle threshold (Ct) is defined as the number of amplification cycles required for the fluorescent signal to cross the threshold (i.e. exceed the background signal). Ct levels are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the Ct level the greater is the amount of target nucleic acid in the sample). In the case of negative samples, amplification does not occur and a horizontal amplification curve is displayed on the screen during the test run. At the end of the test run, HCV "DETECTED" or "NOT DETECTED" result is displayed, and in positive cases, Ct values and viral load is also displayed on the screen. Based on the detection of the internal positive control (IPC), the validity of the test run is also displayed. The IPC is a full process control that undergoes all the processes the specimen undergoes – from extraction to amplification thereby validating the test run from sample to result. Absence of or shift of IPC Ct beyond a pre-set range in case of negative samples invalidates the test run. While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid. The results can be printed using the **Truelab®** micro PCR Printer or transferred to the lab computer/or any remote computer via Wifi network or 4G/3G/GPRS network. Upto 20,000 results in **Truelab® Uno Dx/Duo/Quattro** can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The target sequence for this assay is the 3' UTR region of the HCV genome.

5. CONTENTS OF THE Truenat® HCV KIT

A. Individually sealed pouches

B. Package insert

Each individually sealed pouch contains:

1. **Truenat® HCV** micro PCR chip (1 No.)
2. Microtube with freeze dried RT-PCR reagents (1 No.)
3. DNase & RNase free pipette tip (1 No.)
4. Desiccant pouch (1 No.)

Pack sizes of **Truenat® HCV KIT**

REF	601180005	601180020	601180025	601180050	601180100	601180200
Σ	5T	20T	25T	50T	100T	200T

6. CONTENTS OF THE Trueprep® AUTO Universal Sample Pre-treatment Pack

A. Lysis buffer.

B. Disposable transfer pipette (graduated).

C. Package insert.

Pack sizes of **Trueprep® AUTO Universal Sample Pre-treatment Pack**

REF	60205AB05	60205AB20	60205AB25	60205AB50	60205AB100	60205AB200
Σ	5T	20T	25T	50T	100T	200T

7. CONTENTS OF THE Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Kit

A. The reagent pack contains the following reagents

No.	Contents	Purpose
1.	Wash Buffer A	To wash inhibitors from the sample
2.	Wash Buffer B	To wash inhibitors from the sample
3.	Elution Buffer	To elute nucleic acids
4.	Priming Waste	To purge residual liquid from tubing

B. The cartridge pack contains the following:

No.	Contents	Purpose
1.	Cartridge	Cartridges containing immobilized internal control (IPC) for extraction
2.	Elute collection tube (ECT)	Capped tubes for collection and storage of extracted nucleic acids
3.	Elute collection tube (ECT) label	To label Elute Collection Tube (ECT)
4.	Disposable transfer pipette	To pierce the seal of elute chamber and to transfer extracted nucleic acids from elute chamber of cartridge into the Elute Collection Tube (ECT)

C. Disposable transfer pipettes (graduated) - 3 mL

D. Reagent reset card-1 No.

E. Package insert

Pack sizes of **Trueprep® AUTO Universal Cartridge Based Sample Prep Kit**

REF	60203AR05	60203AR25	60203AR50	60203AR100	60203AR200
Σ	5T	25T	50T	100T	200T

Pack sizes of **Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit**

REF	60207AR05	60207AR25	60207AR50	60207AR100	60207AR200
Σ	5T	25T	50T	100T	200T

8. STORAGE, HANDLING AND STABILITY

1. **Truenat® HCV** test is stable for two (2) years from the date of manufacture if stored between 2-30°C. It is also stable for one (1) month at temperatures up to 45°C. Avoid exposure to light or elevated temperatures (above recommended levels). Do not freeze.
2. **Trueprep® AUTO** Universal Sample Pre-treatment Pack is stable for two (2) years from the date of manufacture if stored between 2-40°C. It is also stable for one (1) month at temperatures upto 45°C. Do not freeze.
3. **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit is stable for two (2) years from the date of manufacture if stored between 2°C to 40°C. It is also stable for one (1) month at temperatures up to 45°C. Avoid exposure to light.
4. Do not open the pouch until ready to test. ⚠ Make sure to start the test promptly after 30-60 seconds of adding the elute to the microtube.
5. Do not use the pouch if torn.
6. Do not use pouches that have passed the expiration date.

9. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

Truelab® Real Time micro PCR Workstation (REF 623010001 / 633010001 / 643010001 / 653010001) consisting of

1. **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device (REF 603041001 / 603042001).
2. **Truelab® Uno Dx / Duo / Quattro** Real Time Quantitative micro PCR Analyzer (REF 603021001 / 603022001 / 603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Truepet®** SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. **Truelab®** Microtube Stand (REF 603070001).

Also required additionally are: **Trueprep® AUTO** Universal Sample Pre-treatment Pack (REF 60205AB05 / 60205AB20 / 60205AB25 / 60205AB50 / 60205AB100 / 60205AB200), **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit (REF 60203AR05 / 60203AR25 / 60203AR50 / 60203AR100 / 60203AR200) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF 60207AR05 / 60207AR25 / 60207AR50 / 60207AR100 / 60207AR200), **Truenat®** Positive Control Kit - Panel II (REF 801020008), powder free disposable gloves, waste disposal container with lid and sodium hypochlorite.

10. SPECIMEN PREPARATION FOR EXTRACTION WITH Trueprep® AUTO / AUTO v2

Truenat® HCV requires purified nucleic acids from whole blood (venous)/plasma collected in EDTA anticoagulant or serum specimen that are extracted using the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit. Sample must be pre-treated using **Trueprep® AUTO** Universal Sample Pre-treatment Pack. Transfer 250µl of whole blood (venous) or 500µl of plasma/serum specimen using the graduated transfer pipette provided into the lysis buffer tube provided and mix well (refer to the package insert of **Trueprep® AUTO** Universal Sample Pre-treatment Pack for further details).

Sample Storage and Transportation:

To ensure the integrity of collected samples, it is ideal to process them immediately. However, if immediate processing is not feasible, it is recommended to adhere to the following sample storage conditions:

Stability temperature	Stability period		
	Blood	Serum	Plasma
-80°C	07 weeks	07 weeks	07 weeks
-20°C	07 weeks	07 weeks	07 weeks
4°C	04 hours	08 hours	08 hours
35°C	04 hours	04 hours	04 hours

Note: These recommendations are based on internal laboratory findings.

Pre-treated Sample Storage and Transportation:

Sample pre-treatment decontaminates the specimen and makes it ready for storage / transportation / extraction. The specimen in this form is stable for:

Stability temperature	Stability period		
	Blood	Serum	Plasma
2°C to 8°C	09 days	03 days	03 days
Room temperature (22°C±2°C)	02 days	01 day	01 day
30°C	01 days	04 hours	04 hours

Nucleic acid extraction: Use entire content from the lysis buffer tube containing specimen for further procedure with the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit (refer to the user manual of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and the package insert of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit for details). Dispose off lysis buffer tube and transfer pipette after use, as per the section on "Disposal and Destruction" (Section 18).

11. SAFETY PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Bring all reagents and specimen to room temperature (20-30°C) before use.
3. Do not use kit beyond expiry date.
4. Carefully read the user manuals, package inserts and Material Safety Data Sheets (MSDS) of all the components of the **Truenat®** point-of-care real time PCR system before use.
5. Good laboratory practices are recommended to avoid contamination of specimens or reagents.
6. All materials of human origin should be handled as though potentially infectious.
7. Do not pipette any material by mouth.
8. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
9. Use protective clothing and wear disposable gloves when handling samples and while performing sample extraction.
10. Do not substitute assay components / reagents with any other components / reagents.
11. Each single-use **Truenat®** chip is used to process one test. Do not reuse chip.

12. PROCEDURAL PRECAUTIONS

1. Check all packages before using the kit. Damage to the packaging does not prevent the contents of the kit from being used. However, if the outer packaging is damaged the user must confirm that individual components of the kit are intact before using them.
2. Do not perform the test in the presence of reactive vapours (e.g. from sodium hypochlorite, acids, alkalis or aldehydes) or dust.
3. While retrieving the **Truenat® HCV** chip, microtube and the DNase & RNase free pipette tip from the pouch, ensure that neither bare hands nor gloves that have been used for previous tests run are used.
4. Ensure that the colour of the desiccant pouch is orange after opening a sealed **Truenat®** chip pouch. If the colour of the desiccant pouch changes from orange to white due to the absorption of moisture, do not use the contents of the **Truenat®** chip pouch.

13. PROCEDURAL LIMITATIONS

1. Optimal performance of this test requires appropriate specimen collection, handling, storage and transport to the test site.
2. Though very rare, mutations within the highly conserved regions of the target genome where the **Truenat®** assay primers and/or probe bind may result in the under-quantitation of or a failure to detect the presence of the concerned pathogen.
3. The instruments and assay procedures are designed to minimize the risk of contamination by PCR amplification products. However, it is essential to follow good laboratory practices and ensure careful adherence to the procedures specified in this package insert for avoiding nucleic acid contamination from previous amplifications, positive controls or specimens.
4. A specimen for which the **Truenat®** assay reports "Not Detected" cannot be concluded to be negative for the concerned pathogen. As with any diagnostic test, results from the **Truenat®** assay should be interpreted in the context of other clinical and laboratory findings.

14. CLEANING AND DECONTAMINATION

1. Spills of potentially infectious material should be cleaned up immediately with absorbent paper tissue and the contaminated area should be decontaminated with disinfectants such as 0.5% freshly prepared sodium hypochlorite [10 times dilution of 5% sodium hypochlorite (household bleach)] before continuing work.
2. Sodium hypochlorite should not be used on an acid-containing spill unless the spill-area is wiped dry first. Materials used to clean spills, including gloves, should be disposed off as potentially bio-hazardous waste e.g. in a bio-hazard waste container.

15. TEST PROCEDURE

(Please also refer the **Truelab®** Real Time Quantitative micro PCR Analyzer user manual).

1. Switch on the **Truelab®** analyzer.
2. Select Username and enter password.
3. For **Truelab® Uno Dx**, select the test profile for "HCV" to be run from the profiles screen on the analyzer screen. For **Truelab® Duo/Quattro**, select the bay (I/II) for **Duo** and (I/II/III/IV) for **Quattro** from the status screen to view the profiles screen. Select the test profile for "HCV" to be run from the profiles screen, on the analyzer screen.
4. Enter the patient details as prompted in the **Truelab®** analyzer screen.
5. Press start reaction.
6. For **Truelab® Uno Dx,** press the eject button to open the chip tray. For **Truelab® Duo/Quattro**, the chip tray opens automatically on tapping the

"Start Reaction" button.

7. Open a pouch of **Truenat® HCV** and retrieve the micro PCR chip, microtube and DNase & RNase free pipette tip. Do not open the pouch until ready to test.
8. Place the **Truenat® HCV** chip on the chip tray without touching the white reaction well. The reaction well should be facing up and away from the analyzer. Gently place the chip on the chip tray by aligning it in the slot provided.
9. Place the microtube containing freeze dried RT-PCR reagents in the microtube stand provided along with the **Truelab®** Real Time micro PCR workstation after ensuring that white pellet of freeze dried RT-PCR reagents remains at the bottom of the microtube. Remove the microtube cap and dispose it off as per the section on "Disposal and Destruction" (Section 18). Using the filter barrier tip provided in the pouch, pipette out six (6) µL of the purified RNA from the elute collection tube into the microtube. Allow it to stand for 30-60 seconds (in-use time) to get a clear solution. ⚠ Do not mix it by tapping, shaking or by reverse pipetting. Using the same filter barrier tip, pipette out six (6) µL of this clear solution and dispense into the centre of the white reaction well of the **Truenat® HCV** chip. Take care not to scratch the internal well surface and not to spill elute on the outside of the well. Dispose off the microtip as per the section on "Disposal and Destruction"(Section 18).
10. For **Truelab® Uno Dx**, slide the chip tray containing the **Truenat® HCV** Chip-based Real Time PCR test loaded with the sample into the **Truelab®** analyzer. Press "YES" on the "Please Load Sample" prompt. For **Truelab® Duo/Quattro**, select "YES" at the "Please Load Sample" prompt. Chip tray will close automatically and the reaction will start. ⚠ Make sure to start the test promptly after 30-60 seconds of adding the elute to the microtube.
11. Read the result from the screen.
12. After the reaction is completed, for **Truelab® Uno Dx,** push the eject button to eject the chip tray. For **Truelab® Duo/Quattro**, tap the "Open/Close Tray" button to eject the chip tray.
13. Take out the **Truenat® HCV** micro PCR chip at end of the test and dispose it off as per the section on "Disposal and Destruction" (Section 18).
14. Turn on **Truelab®** micro PCR printer and select print on the screen for printing out hard copy of the results. Test results are automatically stored and can be retrieved any time later. (Refer to **Truelab®** analyzer manual).
15. Switch off the **Truelab®** analyzer.

16. RESULTS & INTERPRETATIONS

Two amplification curves are displayed on the **Truelab®** analyzer screen to indicate the progress of the test. Both the target and the internal positive control (IPC) curves will take a steep, exponential path when the fluorescence crosses the threshold value in case of positive samples. The Cycle threshold (Ct) will depend on the number of target nucleic acids in the sample. The target curve will remain horizontal throughout the test duration and the IPC curve will take an exponential path in case of negative samples. In case the IPC curve remains horizontal in a negative sample, the test is considered as invalid. At the end of the test run, the results screen will display "DETECTED" for positive result or "NOT DETECTED" for Negative result. The result screen would also display the Ct value and the IU/mL for positive specimen. The result screen also displays the validity of the test run as "VALID" or "INVALID". Invalid samples have to be repeated with fresh specimen from the sample preparation stage. While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid.

17. QUALITY CONTROL PROCEDURES

To ensure that the **Truelab®** Real Time micro PCR Analyzer is working accurately, run positive and negative controls from time to time. The **Truenat®** Positive Control Kit-Panel II (REF 801020008) containing Positive Control and Negative Control must be ordered separately. It is advisable to run controls under the following circumstances: • Whenever a new shipment of test kits is received. • When opening a new test kit lot.• If the temperature of the storage area falls outside of 2-30° C.• By each new user prior to performing testing on clinical specimen.

18. DISPOSAL AND DESTRUCTION

1. Submerge the used **Truenat® HCV** chip, microtube, microtube cap, transfer pipette, pipette tips, lysis buffer tube etc. in freshly prepared 0.5% sodium hypochlorite solution for 30 minutes before disposal as per the standard medical waste disposal guidelines.
2. Disinfect the solutions and/or solid waste containing biological samples before discarding them according to local regulations.
3. Samples and reagents of human and animal origin, as well as contaminated materials, disposables, neutralized acids and other waste materials must be discarded according to local regulations after decontamination by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume of 5% sodium hypochlorite for 10 volumes of water).
4. Do not autoclave materials or solutions containing sodium hypochlorite.
5. Chemicals should be handled in accordance with Good Laboratory Practice and disposed off according to the local regulations.

19. SPECIFIC PERFORMANCE CHARACTERISTICS

Traceability to the WHO standard: The **Truenat® HCV** assay is standardized to the 6th WHO NIBSC International Standard for Hepatitis C virus for Nucleic acid amplification Techniques (NIBSC Code 18/184).

Analytical specificity/Cross reactivity:

The cross reactivity with other organisms unrelated to hepatitis C was determined by spiking negative plasma with concentration of 10^6 CFU/mL of bacterial and 10^6 $TCID_{50}$/mL of viruses and 10^6 copies/mL of nucleic acids respectively. Similarly positive specimens were prepared by spiking negative plasma with 3-4X LoD of HCV armored RNA along with 10^6 CFU/mL of bacterial and 10^6 $TCID_{50}$/mL of viruses and 10^6 copies/mL of nucleic acids of the respective organism. Both the HCV negative and positive samples were subjected to sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR was performed in triplicates for HCV negative and HCV positive samples containing the test organism for cross reactivity. The results showed no cross-reactivity of **Truenat® HCV** to any of the organisms listed.

Organisms	Organisms
Banzi virus	Ilheus virus
BK Human polyoma virus	Influenza B virus
Cytomegalovirus	Measles
Dengue virus Type 1	St. Louis encephalitis virus
Dengue virus Type 2	Vaccinia virus
Dengue virus Type 3	Varicella Zoster virus
Dengue virus Type 4	West Nile virus
Epstein Barr Virus	Yellow fever virus
Hepatitis A virus	Zika virus
Hepatitis B virus	*Candida albicans*
Hepatitis E virus	*Chlamydia trachomatis*
Herpes simplex virus 1	*Leishmania donovani*
Herpes simplex virus 2	*Maycobacterium tuberculosis*
Human herpes virus 6	*Mycobacterium gordonae*
Human herpes virus 8	*Mycobacterium smegmatis*
Human Immunodeficiency virus 1	*Neisseria gonorrhoeae*
Human Immunodeficiency virus 2	*Plasmodium falciparum*
Human papilloma virus 16	*Staphylococcus aureus*
Human papilloma virus 18	*Staphylococcus epidermidis*
Human T-cell lymphotropic virus I	*Trichomonas vaginalis*
Human T-cell lymphotropic virus II	

Linearity for different HCV Genotypes:

Genotype 1-6 for HCV were made in plasma, blood and serum and the nucleic acids were extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truelab®** Real Time Quantitative micro PCR Analyzer.

	Sample type	Dilution series	Linearity
Genotype 1	Plasma	1.76E+08 IU/mL to 1.76E+02 IU/mL	7 orders of magnitude
	Blood	2.35E+08 IU/mL to 2.35E+03 IU/mL	6 orders of magnitude
	Serum	1.76E+08 IU/mL to 1.76E+03 IU/mL	6 orders of magnitude
Genotype 2	Plasma	2.48E+08 IU/mL to 2.48E+02 IU/mL	7 orders of magnitude
	Blood	2.00E+08 IU/mL to 2.00E+03 IU/mL	6 orders of magnitude
	Serum	2.48E+08 IU/mL to 2.48E+02 IU/mL	7 orders of magnitude
Genotype 3	Plasma	2.10E+08 IU/mL to 2.10E+02 IU/mL	7 orders of magnitude
	Blood	1.80E+08 IU/mL to 1.80E+03 IU/mL	6 orders of magnitude
	Serum	2.10E+08 IU/mL to 2.10E+02 IU/mL	7 orders of magnitude
Genotype 4	Plasma	3.30E+08 IU/mL to 3.30E+02 IU/mL	7 orders of magnitude
	Blood	5.00E+08 IU/mL to 5.00E+03 IU/mL	6 orders of magnitude
	Serum	3.30E+08 IU/mL to 3.30E+02 IU/mL	7 orders of magnitude
Genotype 5	Plasma	5.50E+08 IU/mL to 5.50E+02 IU/mL	7 orders of magnitude
	Blood	7.00E+08 IU/mL to 7.00E+03 IU/mL	6 orders of magnitude
	Serum	5.50E+08 IU/mL to 5.50E+02 IU/mL	7 orders of magnitude
Genotype 6	Plasma	2.40E+08 IU/mL to 2.40E+02 IU/mL	7 orders of magnitude
	Blood	3.50E+08 IU/mL to 3.50E+03 IU/mL	6 orders of magnitude
	Serum	2.40E+08 IU/mL to 2.40E+02 IU/mL	7 orders of magnitude

Limit of detection:

LoD was estimated for plasma, blood and serum using NIBSC 6th WHO International Standard for Hepatitis C virus RNA with NIBSC code: 18/184 on two different lots of reagents.

Limit of detection for plasma and serum: A dilution series ranging from 8000, 4000, 2000, 1000, 500, 250, 125, 62.5 and 0 IU/mL of the NIBSC standard was made in negative plasma and serum matrix. Each dilution was extracted (3x8=24 runs) over a period of 3 different days using 2 lots of reagents. The number of runs accounted for 48 replicates for each dilution using both the lots (lot 1 & lot 2) comprising of sample prep on **Trueprep® AUTO** and PCR using **Truenat® HCV** test. The data obtained was analyzed by probit analysis. The LoD for the plasma was determined to be 204.71 IU/mL with 95%CI of 178.26 to 247.84 IU/mL and the LoD for serum was determined to be 260.42 IU/mL with 95%CI of 229.68 to 307 IU/mL.

Limit of detection for blood: A dilution series ranging from 3000, 2500, 2000, 1500, 1000, 500, 250 and 0 IU/mL of the NIBSC standard was made in negative blood matrix. Each dilution was extracted (3x8=24 runs) over a period of 3 different days using 2 lots of reagents. The number of runs accounted for 48 replicates for each dilution using both the lots (lot 1 & lot 2) comprising of sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR using **Truenat® HCV** test. The data obtained was analyzed by probit analysis. LoD for the blood was determined to be 1153.94 IU/mL with 95%CI of 1019.44 to 1351.21 IU/mL.

Limit of detection for different HCV genotypes:

LoD for various HCV genotypes was estimated using quantified clinical samples obtained from Discovery Life Sciences.

Limit of detection for plasma and serum for genotypes 2 to 6: A dilution series ranging from 4000, 2000, 1000, 500, 250, 125, 62.5 and 0 IU/mL were made in plasma and serum matrix for genotypes 2 to 6. Each dilution was extracted (3x8=24 runs) over a period of 3 different days using 2 lots of reagents. The number of runs accounted for 48 replicates for each dilution using both the lots (Lot 1 & Lot 2) comprising of sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR using **Truenat® HCV** test. The data obtained was analyzed by probit analysis.

Limit of detection for blood: A dilution series ranging from 3000, 2500, 2000, 1500, 1000, 500, 250, and 0 IU/mL were made in negative blood matrix. Each dilution was extracted (3x8=24 runs) over a period of 3 different days using 2 lots of reagents. The number of runs accounted for 48 replicates for each dilution using both the lots (lot 1 & lot 2) comprising of sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR using **Truenat® HCV** test. The data obtained was analyzed by probit analysis.

Genotype	LoD Plasma	LoD Serum	LoD Blood
2	LoD: 166.61 IU/mL with 95% confidence interval of 144.28 - 203.35 IU/mL	LoD: 240.92 IU/mL with 95% confidence interval of 171.92- 503.41 IU/mL	LoD: 1281.78 IU/mL with 95% confidence interval of 1013.87-1870.40 IU/mL
3	LoD: 154.34 IU/mL with 95% confidence interval of 134.74 - 186.05 IU/mL	LoD: 275.07 IU/mL with 95% confidence interval of 237.80- 333.51 IU/mL	LoD:1269.98 IU/mL with 95% confidence interval of 1004.94-1849.57 IU/mL
4	LoD: 183.79 IU/mL with 95% confidence interval of 158.92 – 224.95 IU/mL	LoD: 291.33 IU/mL with 95% confidence interval of 210.14-580.30 IU/mL	LoD:684.84 IU/mL with 95% confidence interval of 500.81-1384.79 IU/mL
5	LoD: 191.56 IU/mL with 95% confidence interval of 165.91 - 233.85 IU/mL	LoD: 265.43 IU/mL with 95% confidence interval of 229.60 - 321.45 IU/mL	LoD: 1273.95 IU/mL with 95% confidence interval of 1019.63 – 1806.11 IU/mL
6	LoD: 183.69 IU/mL with 95% confidence interval of 158.67 - 225.02 IU/mL	LoD: 328.60 IU/mL with 95% confidence interval of 231.24 - 736.43 IU/mL	LoD: 1339.45 IU/mL with 95% confidence interval of 1025.70- 2129.29 IU/mL

Robustness:

The purpose of the study was to determine if there was a potential for carry-over between samples, which could be a source of contamination. This was tested on a single **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and a single **Truelab® Uno Dx** Real Time micro PCR Analyzer. Alternate positive and negative samples were subjected to sample prep followed by PCR. Devices were placed adjacent to each other to mimic a typical use case scenario. The results showed no carryover contamination under the tested conditions.

Reproducibility:

The purpose of the study is to determine the reproducibility of the **Truenat® HCV** assay. The study was performed on a sample panel comprising of 1 negative specimen, 1 low positive specimen (3 x LLOQ) and 2 specimens in the middle and upper range of the linearity span, respectively for all the claimed specimen types. The study was spread over a period of 5 days. Every day each sample panel member was tested which included nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using one lot of reagents, at three different sites, using 1 operator/site. Testing was conducted by operator's representative of intended users in addition to members of manufacturer's staff unassisted. The reproducibility for the **Truenat® HCV** assay performed at 3 study sites showed reproducible results. For Plasma specimens %CV values for Inter site, Inter user and Inter day study were in the range of 1.34 to 20.27. For Blood specimens %CV values for Inter site, Inter user and Inter day study were in the range of 1.48 to 13.31. For Serum specimens %CV values for Inter site, Inter user and Inter day study were in the range of 1.44 to 14.18.

Interference:

a) Effect of endogenous substances: The interference of endogenous substances on the performance of **Truenat® HCV** was performed by spiking the endogenous substances at abnormally high levels to 5 different negative plasma as well as 5 different plasma spiked with HCV sample concentration at 3 x LoD. Further both the HCV negative and positive samples were subjected to sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR was performed by **Truenat® HCV** test. The endogenous substances tested were:

A. Albumin (9.6g/dL)
B. Triglycerides (3186mg/dL)
C. Bilirubin (62 mg/dL)
D. Hemoglobin (472mg/dL)

The performance of the **Truenat® HCV** assay was not affected by the endogenous substances mentioned under the stated experimental conditions. The observed variation with regard to the HCV viral load was within the accepted range of ≤0.5 log IU/mL in comparison to the positive control samples.

b) Effect of added autoimmune disease markers: 3x LoD HCV sample was spiked into plasma samples containing the autoimmune disease markers for systemic lupus erythematosus, rheumatoid factor and anti-nuclear antibody and the performance of **Truenat® HCV** assay tested. Under the experimental conditions the performance of **Truenat® HCV** assay was not affected. The observed variation with regard to the HCV viral load was within the accepted range of ≤0.5 log IU/mL in comparison to the positive control samples.

c) Effect of interfering drugs: The interference of exogenous substances (respective drugs) on the performance of **Truenat® HCV** was performed by spiking the exogenous substances >3 times the peak plasma levels (3 times C max concentration) to 5 different negative plasma as well as 5 different plasma spiked with HCV RNA concentration at 3 x LoD. Further both the HCV negative and positive samples were subjected to sample prep on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and PCR was performed by **Truenat® HCV** test.

List of drugs and concentration used	List of drugs and concentration used
Stavudine (2.05µg/mL)	Ritonavir(44.4 µg/mL)
Zidovudine (6.87µg/mL)	Efavirenz (12.21µg/mL)
Ribavirin (11.04 µg/mL)	Nevirapine (17.22µg/mL)
Ganciclovir (27µg/mL)	Valacyclovir HCL (24.06µg/mL)
Abacavir sulfate (12.9µg/mL)	Lamivudine(35.52 µg/mL)
Indinavir sulfate (35.52 µg/mL)	Entecavir (4.2ng/mL)
Saquinavir mesylate (15.62µg/mL)	Ciprofloxacin(2.4 µg/mL)
Nelfinavir mesylate (12µg/mL)	Sofosbuvir (0.71µg/mL)
Clarithromycin (30µg/mL)	Daclatasvir(1.5µg/mL)
Azithromycin (15.62µg/mL)	Interferon Alpha 2B (820 IU/mL)
Tenofovir (0.98µg/mL)	Acyclovir (62.1µg/mL)
Enfuvirdite (13.8µg/mL)	Fosamprenavir(6.08 µg/mL)
Valganciclovir HCL (20.19µg/mL)	Lopinavir(42µg/mL)

Determination of carry-over contamination:

To determine whether the **Truenat® HCV** Chip-based Real Time PCR test showed any signs of carryover of PCR products between runs, alternate runs of positive high titre samples and negative samples were run on **Truelab®**. For this study blood was utilized as the sample type. Blood was spiked with a high positive >1.00E+06 IU/mL armored RNA of Hepatitis C virus genotype 2b from Asuragen. One lot of reagents was used for this study. This was tested on a single **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and a single **Truelab®** device by 2 users for 3 days. Alternate positive and negative samples were subjected to sample prep followed by PCR by user 1 and user 2 over a span of 6 days. Devices were placed adjacent to each other to mimic a typical use case scenario. User 1 performed the runs for the first 3 days followed by user 2 for the next 3 days. Each user ran 20 negatives and 20 positives. The total number of runs between the 2 users was 80 runs which comprised of 40 positives and 40 negatives. The results showed no carryover contamination under the tested conditions.

Truenat® HCV performance on different genotype panels:

To determine the performance of **Truenat® HCV** on different genotype panels a sample panel comprising of all possible HCV genotypes (ten numbers each of genotype 1, 3, 4 and three numbers each of genotypes 2, 5 and 6) was tested. **Truenat® HCV** test was able to detect all the HCV genotypes.

Determination of sample equivalence:

Sample equivalence was demonstrated for the plasma, serum, venous and finger prick blood specimens. The panel comprised of 25 positive and 25 negative specimens for each claimed specimen type. Each sample was subjected for nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using **Truenat® HCV** test using one lot of reagents. The **Truenat® HCV** test was able to detect HCV in each of the 25 HCV positive specimens of plasma, serum, venous and finger prick blood specimens as positive and each of the 25 HCV negative specimens of plasma, serum, venous and finger prick blood specimens as negative.

Precision:

Precision for blood: The purpose of this study is to determine the repeatability of **Truenat® HCV** test. The study was performed on a sample panel comprising of 1 negative specimen, 1 low positive specimen with a viral load of (3xLLOQ) and 2 specimens in the middle and upper range of linearity of one HCV genotype spiked into blood as the sample matrix. The study was spread over a period of 20 consecutive days. Every day each sample panel member was tested in replicates of 2 including nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using three different lots of reagents, at one site, by single user. The analysis of the CV values obtained between the 3 reagent lots is within the accepted range of ≤15%.

Precision for plasma: The purpose of this study is to determine the repeatability of **Truenat® HCV** test. The study was performed on a sample panel comprising of 1 negative specimen, 1 low positive specimen with a viral load of (3xLLOQ) and 2 specimens in the middle and upper range of linearity of one HCV genotype spiked into plasma as the sample matrix. The study was spread over a period of 20 days. Every day each sample panel member was tested in replicates of 2 including nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using three different lots of reagents, at one site, by single user. The analysis of the CV values obtained between the 3 reagent lots is within the accepted range of ≤15%.

Precision for serum: The purpose of this study is to determine the repeatability of **Truenat® HCV** test. The study was performed on a sample panel comprising of 1 negative specimen, 1 low positive specimen with a viral load of (3xLLOQ) and 2 specimens in the middle and upper range of linearity of one HCV genotype spiked into serum as the sample matrix. The study was spread over a period of 20 days. Every day each sample panel member was tested in replicates of 2 including nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using three different lots of reagents, at one site, by single user. The analysis of the CV values obtained between the 3 reagent lots is within the accepted range of ≤15%.

Whole system failure: Whole system failure rate was performed utilizing blood sample spiked at 3X LoD with NIBSC 6th WHO International Standard for Hepatitis C virus RNA. The study was performed on a sample panel of 100 numbers spread over 5 consecutive days. Every day 20 samples were utilized for nucleic acid isolation on **Trueprep® AUTO** followed by PCR on **Truelab®** using **Truenat® HCV** test using one lot of reagents and by single user. Since the study had to be performed on high viscosity sample, blood was chosen as

the sample matrix. No runs showed false results. The observed standard deviation across the 100 runs was 0.35 with a %CV of 11.30.

IVD **Trueness of measurement:** Trueness of the IVD was demonstrated by comparison of the performance of the **Truenat® HCV** test with Abbott Real-time HCV Genotype II Assay. A total of at-least 100 specimens positive for HCV RNA, with viral loads covering the entire linear range of the IVD covering relevant and as many different genotypes with all claimed specimen types. Two lots of reagents were utilized for the study. The entire sample panels which were positive by comparator Abbott Real-time HCV Genotype II Assay was positive by the **Truenat® HCV** test also.

IVD **Stability of samples (blood/plasma/serum):**
The study was performed as per the WHO PQ requirement document (TSS-10 (Draft) *In vitro* diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of hepatitis C RNA). Stability of samples was tested on various sample types consisting of whole blood, plasma and serum as sample types on a 10 member sample panel prepared by spiking 3xLoD of confirmed HCV positive sample into 10 different confirmed respective negative specimens.

Stability at -80°C: The samples were stored at -80°C at different time periods of 0hrs, week 1, week 2, week 3, week 4, week 5, week 6 and week 7 respectively in a -80°C freezer placed in a room having relative humidity ranging from 57 to 69% and temperature of the room ranging from 18.4 to 23.9°C. The samples were processed on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truenat® HCV** test. The 10 member sample panel of plasma, blood and serum was found to be stable till week 7 at -80°C.
Stability at -20°C: The samples were stored at -20°C at different time periods of 0 hrs, week 1, week 2, week 3, week 4, week 5, week 6 and week 7 respectively in a freezer placed in a room having relative humidity ranging from 57 to 69% and temperature of the room ranging from 18.4 to 23.9°C. The samples were processed on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truenat® HCV** test. The 10 member sample panel of plasma, blood and serum was found to be stable till week 7 at -20°C.

Stability at 4°C: The samples were stored at 4°C at different time periods of 0hr, 4hrs, 8hrs, 24hrs, 48hrs, 72hrs, 96hrs and 5 days in a refrigerator placed in a room having relative humidity ranging from 56 to 60% and temperature of the room ranging from 22 to 24.5°C. The samples were processed on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truenat® HCV** test. The 10 member sample panel of plasma and serum were found to be stable till 8hrs at 4°C, whereas blood was stable till 4hrs at 4°C.

Stability at 35°C: The samples were stored at 35°C at different time periods of 0hr, 4hrs, 8hrs, 24hrs, 48hrs, 72hrs respectively in an incubator placed in a room having relative humidity ranging from 51 to 59% and temperature of the room ranging from 23.6 to 25.9°C. The samples were processed on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truenat® HCV** test. The 10 member sample panel of plasma, blood and serum was found to be stable till 4hrs at 35°C.

Stability of samples after freeze thaw: Stability of samples after freeze thaw was tested on various sample types consisting of whole blood, plasma and serum as sample types on a 10 member sample panel prepared by spiking 3xLoD of confirmed HCV positive sample into 10 different confirmed respective negative specimens. The samples were frozen at -20°C and subjected to 5 freeze thaw cycles. The samples were processed on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device followed by PCR on **Truenat® HCV** test to determine the effect of freeze thaw process on stability of HCV RNA. The 10 member sample panel of plasma, blood and serum was stable even after 5 freeze thaw cycles.

Clinical validations:
a) Clinical validation 1:
A panel of 100 plasma samples comprising of 69 negatives and 31 positive specimen were tested on three different manufacturing lots of **Truenat® HCV** assay at AIIMS (All India Institute of Medical Sciences, New Delhi) against the AIIMS inhouse HCV PCR assay which is validated against 3rd HCV WHO International Standard. All the positive samples were also run in parallel with AIIMS in house PCR assay and Sacace- Real Time PCR kit for the quantitative detection of HCV (REF- V1-96/3FRT- a CE-IVD kit) for comparing the viral loads obtained by these **Truenat® HCV** lots.
Specificity: All 69 negative specimens by AIIMS assay were also found to be negative by the 3 lots of **Truenat® HCV** assay, showing a **100%** specificity.
Sensitivity: All 31 positive specimen results correlated between the methods giving a sensitivity of **100%** for the 3 different manufacturing lots of **Truenat® HCV** assay.

Concordance of viral loads:
The viral loads obtained by the **Truenat® HCV** assay on the 31 positive samples were compared with the loads obtained by the AIIMS in house PCR and Sacace-Real Time PCR kit. The viral loads of the samples ranged from ~ 200 IU/mL to 4500000 IU/mL. Satisfactory concordance well within the acceptable deviation of 0.5 log IU/mL was observed showing a good correlation between the assays and good lot to lot consistency of the **Truenat® HCV** assay.

b) Clinical validation 2:
A blind panel of 318 plasma samples pre-analyzed by FIND using the Roche HCV assay was provided for verification of the **Truenat® HCV** Assay. The final results, upon unblinding by FIND showed a concordance of 98.4% between the 2 assays.

2X2 Table			
	Roche Positive	**Roche Negative**	**Total**
Truenat® HCV Positive	**119**	**5**	**124**
Truenat® HCV Negative	**0**	**194**	**194**
			318

All the 5 **Truenat® HCV** positive and Roche negative samples also tested positive with Altona HCV CE-IVD kit.

c) Multicentric clinical evaluation study for Truenat® HCV test:
FIND conducted a multicentric prospective diagnostic clinical study to evaluate the performance of the **Truenat® HCV** test using samples collected from 1527 participants from clinical sites located in Georgia, Ukraine, Ethiopia, Thailand and Denmark. The study was conducted on plasma, serum and whole blood (venous) specimens. Fingerstick whole blood (venous) was also included as a specimen type in this study to check feasibility and compare with whole blood / plasma / serum. Respective samples were collected freshly from intended use population which included individuals presenting at a healthcare facility for HCV confirmatory testing following a positive HCV serology test result or exposure to risk factors, and individuals who completed anti-HCV treatment and present for a test of cure. Additionally, to confirm clinical specificity, the **Truenat® HCV** RNA test was conducted on 500 freshly collected venous blood specimens from healthy blood donors in Denmark. Specimens from each participant were tested by the **Truenat® HCV** RNA test. Sensitivity, specificity and quantitative accuracy of the **Truenat® HCV** RNA test was evaluated using the Abbott RealTime HCV assay as a reference method.

Results: The sensitivity and specificity of **Truenat® HCV** RNA test in fingerstick whole blood (venous) samples was 91.13% and 98.40%, respectively. In plasma samples, the sensitivity of the **Truenat® HCV** RNA test was 93.20%, while the specificity was same as that of the capillary blood specimens. In serum specimens the sensitivity and specificity were 97.83% and 100%. In venous blood specimens sensitivity and specificity was 96.77% and 98.68% respectively. Further the specificity in healthy blood donor populations was 99.6%.

Specimen Type	Sensitivity	Specificity
Plasma	93.20% (95% CI 90.74 - 94.75)	98.40% (95% CI 96.56 - 99.27)
Serum	97.83% (95% CI 92.42 - 99.4)	100% (95% CI 97.54 - 100)
Venous Blood	96.77% (95% CI 90.94–98.9)	98.68% (95% CI 95.33 - 99.64)
Fingerstick whole blood	91.13% (95% CI 88.63 - 93.23)	98.40% (95% CI 96.56 - 99.27)

Conclusions: The diagnostic accuracy of the **Truenat® HCV** RNA test is high in all specimen types used, confirming that the assay can be used for diagnosis and confirmation of active hepatitis C virus infection at point-of-care settings thus facilitating access to testing.

20. REFERENCES

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SYMBOL KEYS

Consult Instruction for use.	In vitro Diagnostic Medical device	Batch number/ Lot number.	Catalogue number	Unique Device Identifier.	This way up.	Manufacturer.	Caution.	Device for near-patient testing	Non sterile.
Contains sufficient for <n> tests	Temperature limitations.	Date of manufacture.	Date of expiry.	For single use only.	Keep Dry.	Keep away from sunlight.			