CE

Truenat®

HAV

Chip-based Real Time PCR Test for Hepatitis A Virus

1. INTENDED USE

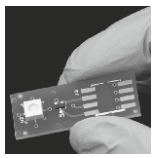
Truenat® HAV (REF601320005 / 601320020 / 601320025 / 601320050 / 601320100 / 601320200) is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Hepatitis A Virus in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis A Virus. This test is also intended for qualitative detection and diagnosis of Hepatitis A virus in stool sample. **Truenat® HAV** runs on the **Truelab®** Real Time Quantitative micro PCR Analyzers.

2. INTRODUCTION

Hepatitis A is an infectious disease of the liver caused by Hepatitis A virus (HAV). HAV is a nonenveloped RNA virus 27 to 32 nm diameter in size, with an icosahedral symmetry, which belongs to the genus Hepatovirus of the Picornaviridae family. HAV demonstrates little antigenic variability and isolates taken from different parts of the world belong to a single serotype. Hepatitis A virus (HAV) infection occurs worldwide and globally, an estimated 1.4 million cases occur each year. Hepatitis A can occur sporadically or in an epidemic form.

Transmission occurs by the fecal-oral route, either by direct contact with an HAV-infected person or by ingestion of HAV-contaminated food or water. The clinical manifestations of hepatitis A begins with symptoms such as fever, anorexia, nausea, vomiting, diarrhea, myalgia and malaise. Jaundice observed in the mucous membranes, conjunctiva and skin; dark-colored urine or light-colored stools might be present at onset or might follow constitutional symptoms within a few days. Physical findings can include abdominal tenderness, hepatomegaly or splenomegaly. In children, HAV infection can often lead to nonspecific symptoms, although in over 70% cases infection is asymptomatic while in adults, over 70% of cases are symptomatic showing that the clinical manifestation and severity of the disease is closely related to age. Fulminant hepatitis leading to acute liver failure is a rare complication of Hepatitis A.

Serological testing plays a pivotal role in distinguish hepatitis A from other forms of viral hepatitis. Diagnostically, IgM anti-HAV has been used as the primary marker of acute infection. However, the current commercially available IgM assays also detect low levels of antibodies present even after infection is resolved and for a short period of time antibody in persons recently administered hepatitis A vaccine. Also, interpretation of a positive IgM anti-HAV test result is problematic in asymptomatic cases where there is no other laboratory evidence of acute hepatitis and no epidemiologic link to other cases. Isolation of Hepatitis A Virus in cell cultures is difficult and not practical for diagnostic use. Molecular methods involving nucleic acid detection techniques are more sensitive than immunoassays for viral antigen to detect HAV in samples of different origins (e.g. clinical specimens, environmental samples or food). Amplification of viral RNA by RT-PCR is currently the most sensitive and widely used method for detection of HAV RNA and for screening clinical specimens. Studies show that the PCR detection of HAV RNA has an important role in the early diagnosis of infection, especially in the window period during outbreaks and in cases of acute hepatitis with unknown etiology. Detection of HAV RNA before IgM anti-HAV seroconversion may be used as an early diagnosis method during hepatitis A outbreaks. HAV RNA testing can also be helpful in elucidating acute hepatitis cases of unknown etiology. However, molecular 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 to weeks leading to high losses to follow-up.



The **Truelab®** Real Time Quantitative micro PCR System enables decentralization and near patient detection and viral load monitoring of **HAV** 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 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** Sample Prep kits 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® HAV is a disposable, room temperature stable, micro 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 HAV virus and runs on the **Truelab®** Real Time Quantitative micro PCR Analyzer. 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® HAV** chip also stores information of used chips to prevent any accidental re-use of the chip.

3. PRINCIPLE OF THE TEST

Truenat® HAV works on the principle of Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) based on Taqman chemistry. The RNA from the patient sample is first extracted using **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge based sample prep kit. The **Truenat® HAV** chip is placed on the chip tray of the **Truelab®** Real Time micro PCR Analyzer. Six (6) µL of the purified RNA is then dispensed using the provided 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® HAV** 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 labeled fluorescent probes in the **Truenat® HAV** 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, HAV "DETECTED" or "NOT DETECTED" result is displayed and in positive cases, Ct values and copies per milliliter (cp/ml) is 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 3G/GPRS network. Upto 20000 results in **Truelab® UnoDx/Duo/Quattro** can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The gene target sequences for this assay is *5'NCR* of HAV genome.

5. CONTENTS OF THE Truenat® HAV KIT

A. Individually sealed pouches, each containing
   1. **Truenat® HAV** micro PCR chip.
   2. Microtube with freeze dried RT PCR reagents.
   3. DNase & RNase free pipette tip.
   4. Desiccant pouch

B. Package Insert.

REF	601320005	601320020	601320025	601320050	601320100	601320200
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.

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

7. STORAGE AND STABILITY

Truenat® HAV chip 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.

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.

8. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

Truelab® Real Time micro PCR Workstation (REF623010001 / 633010001 /

643010001 / 653010001) consisting of,

1. **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device (REF603041001/603042001)
2. **Truelab® Uno Dx / Truelab® Duo / Truelab® Quattro** Real Time 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 (REF60205AB05 / REF60205AB20 / REF60205AB25 / REF60205AB50 / REF60205AB100 / REF60205AB200), **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit (REF60203AR05 / REF60203AR25 / REF60203AR50 / REF60203AR100) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF60207AR05 / REF60207AR25 / REF60207AR50 / REF60207AR100)**, Truenat®** Positive Control Kit - Panel IV (REF 801040008), Powder free disposable gloves, waste disposal container with lid.

9. SPECIMEN PREPARATION FOR EXTRACTION WITH Trueprep® AUTO

A. Blood/Serum/Plasma specimen:

Truenat® HAV requires purified nucleic acids from whole blood/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 or 500µl of plasma/serum specimen using the transfer pipette provided into the Lysis buffer tube provided and mix well.

B. Stool specimen:

Transfer Stool sample (approximately 100-150 mg) using a nylon flock swab into the lysis buffer tube. Mix the swab contents by vortexing for 1 minute. Allow the contents of tube to settle at room temperature for 5 minutes. Transfer 2 ml of the clear suspension to cartridge for further procedure. **Note:** Ensure that while transferring the suspension to cartridge, no particulate matter is transferred. ⚠ Dispose off nylon flock swab as per the section on "Disposal and Destruction" (Section 17). (Refer to package insert of **Trueprep® AUTO** Universal Sample Pre-treatment pack for details).

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 up to three (3) days at 40ºC and one (1) week at 30ºC.

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 17).

10. 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 **Truelab® Real Time micro PCR System** before use.
5. All materials of human origin should be handled as though potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
8. Use protective clothing and wear disposable gloves when handling samples and while performing sample extraction.

11. 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® HAV** chip, microtube and the DNase and RNase free pipette tip from the pouch, ensure that neither bare hands nor gloves that have been used for previous tests run are used.

12. 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.

13. 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 biohazard waste container.

14. TEST PROCEDURE

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

1. Switch on the **Truelab®** Analyzer.
2. Select user and enter password.
3. For **Truelab® Uno Dx**, select the test profile for "HAV" to be run from the Profiles Screen on the Analyzer screen. For **Truelab® Duo/Quattro**, select the Bay (Idle1/2) for **Duo** and (Idle1/2/3/4) for **Quattro** from the Status Screen to view the Profiles Screen. Select the test profile for "HAV" 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® HAV** and retrieve the chip-based Real Time PCR test and the microtube.
8. Place the **Truenat® HAV** chip on the chip tray without touching the white reaction well. The reaction well should be facing up and away from the Analyzer. Gently press the chip to ensure that it has seated in the chip tray properly.
9. Place the microtube containing freeze dried PCR reagents in the microtube stand provided along with the **Truelab®** Real Time micro PCR workstation **after ensuring that white pellet of dried 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 17). Using the filter barrier tip provided in the pouch, pipette out six (6) µL of the purified RNA from the Elute Collected Tube into the microtube. Allow it to stand for 30-60 seconds 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® HAV** 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 17).
10. For **Truelab® Uno Dx,** slide the chip tray containing the **Truenat® HAV** chip-based Real Time PCR test loaded with the sample into the **Truelab®** Analyzer. Press Done on the "Please Load Sample" Alert message. For **Truelab® Duo/Quattro**, select "YES" at the Please load Sample prompt. Chip tray will close automatically and the reaction will start.
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® HAV** chip-based Real Time PCR test at end of the test and dispose it off as per the section on "Disposal and Destruction" (Section 17).
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 the **Truelab®** Analyzer manual).
15. Switch off the **Truelab®** Analyzer.

15. 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 time taken (Ct) of the specimen will depend on the number of target RNA in the sample. The 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 copies per ml (cp/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.

16. QUALITY CONTROL PROCEDURES

To ensure that the **Truelab®** Real Time Quantitative micro PCR Analyzer is working accurately, run positive and negative controls from time to time. **Truenat®** Positive Control Kit - Panel IV (REF 801040008) 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.

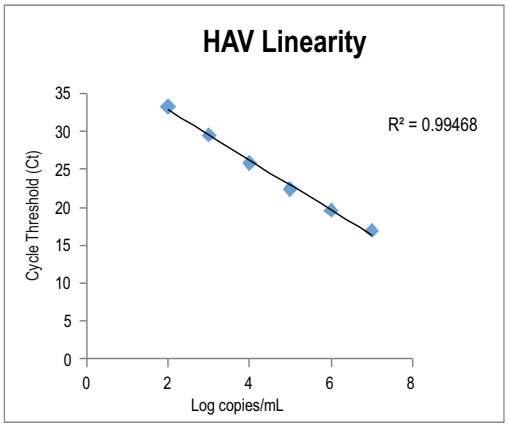
17. DISPOSAL AND DESTRUCTION

1. Submerge the used **Truenat® HAV** chip, microtube, microtube cap, transfer pipette, pipette tips, lysis buffer tube, nylon flock swab 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.

18. SPECIFIC PERFORMANCE CHARACTERISTICS

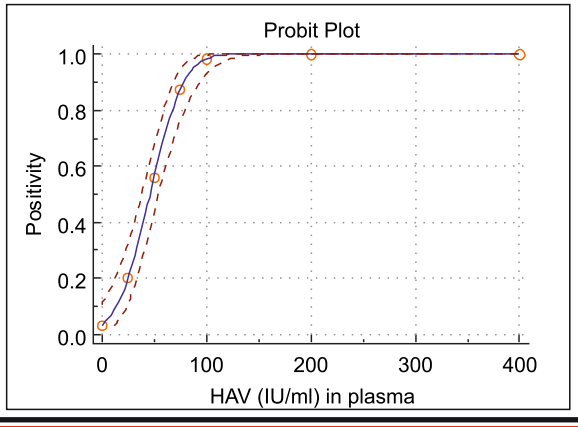
Linearity and Assay range:

The linearity analysis was performed according to CLSI Guidelines. Serial dilutions of *HAV IVT* RNA from 4.88E+07 to 4.88E+02 copies/mL were made and each dilution was tested in triplicates using the **Truenat® HAV** test on **Truelab®** Real Time micro PCR Analyzer. The assay is found to be linear over 6 orders of magnitude (from 4.88E+07 to 4.88E+02 copies/mL) for HAV RNA.



Limit of detection (Analytical Sensitivity):

The LOD was determined by testing dilutions (200 IU/mL, 100IU/mL, 75 IU/mL,50 IU/mL, 25 IU/mL, 0 IU/mL) of HAV viral suspension (NIBSC Standard:15/276). Each dilution was extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device with 50 µl of HAV viral suspension spiked in 450 µl negative plasma for 24 times followed by PCR on **Truelab® Uno Dx/Duo/Quattro** Real Time micro PCR analyzer for the respective dilution. Probit analysis of the data was used to determine the concentration of respective RNA with 95% probability. The LoD was found to be 87.7 IU/mL of Plasma (1IU corresponds to 3.28 copies) for **Truenat® HAV** assay.



Robustness:

To determine whether the **Truenat® HAV** chip-based Real Time PCR test showed any signs of carryover between the runs, alternating runs of positive and negatives samples were performed. 20 positive samples and 20 negative samples were used for the study. The **Truenat® HAV** test did not exhibit detectable carryover between positive and negative PCR runs.

Reproducibility:

The reproducibility of **Truenat® HAV** assay was determined between three different users, three different devices and five consecutive days. Three different titres of samples (1.0E+05 copies/mL,1.0E+04 copies/mL and 1.0E+03 copies/mL) were extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device and the RNA elutes were tested for inter user, inter device and inter day study using **Truelab® Uno Dx** Real Time micro PCR analyzer. Mean %CV values for all titres has been calculated for Inter User (1.69), Inter day (1.90) and Inter Device (1.39) which were in the accepted range of ≤15% CV for **Truenat® HAV** assay.

Precision of Truenat® HAV assay:

Precision was tested by performing **Truenat® HAV** assay of High (1.0E+05 copies/mL), Medium (1.0E+04 copies/mL) and Low (1.0E+03 copies/mL) titre RNA for five consecutive days. Every day PCR for each titre of RNA was run in triplicates. The %CV values obtained for High titre (2.56), Medium titre (3.26) and low titre (3.55) were within the accepted range of ≤15% CV for **Truenat® HAV** assay.

Clinical validation:

Total 100 samples comprising of 70 negative and 30 positive specimens were tested on three different lots of **Truenat® HAV** assay at NIV (ICMR- National Institute of Virology, Pune) against the NIV in-house HAV RT-qPCR assay. Positive samples containing viral loads ranging from ~ 3,080 copies/mL to 1,41,00,000 copies/mL were tested.

Specificity: 70 negative runs correlated between the methods, depicting **100%** specificity for **Truenat® HAV** assay.

Sensitivity: 30 out of 30 positive runs correlated between the methods giving a sensitivity of **100%** for **Truenat® HAV** assay.

Concordance of viral loads:

Satisfactory results were seen in the specificity and sensitivity of the **Truenat® HAV** assay and overall concordance of viral load estimation was in agreement with the NIV in-house HAV assay.

19. REFERENCES

1. Centers for Disease Control and Prevention(1999). Prevention of hepatitis A through active or passive immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morb. Mortal. Wkly. Rep. 48(RR-12):1–37.
2. Ryan KJ, Ray CG (editors) (2004). Sherris Medical Microbiology, 4th ed., McGraw Hill, 541– 544. ISBN 0838585299.
3. Centers for Disease Control and Prevention(1997). Hepatitis A vaccination programs in communities with high rates of hepatitis A. Morb. Mortal. Wkly. Rep. 46:600–603.
4. Brown EA, Day SP, Jansen RW and Lemon SM (1991). The 5' nontranslated region of hepatitis A virus: secondary structure and elements required for translation *in vitro*. J. Virol. 65:5828-5838.
5. https://www.cdc.gov/hepatitis/hav/index.htm
6. http://www.who.int/mediacentre/factsheets/fs328/en

SYMBOL KEYS

Consult instructions for use	IVD *In vitro* Diagnostic Medical Device. Not for medicinal use.	Temperature Limitation	REF Catalogue Number	For single use only	This Side Up	Manufacturer
Date of Manufacture	Date of Expiry	LOT Batch Number / Lot Number	Caution	Contains sufficient for <n> tests	EC REP Authorised Representative in the European Community	

Molbio Diagnostics Private Limited

Registered Office & Manufacturing Unit - I:
Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403 722, INDIA

Manufacturing Unit - II:
Plot No. L-42, Phase II B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA

www.molbiodiagnostics.com Email: sales@molbiodiagnostics.com

EC REP Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium

TNHA/11021V-03