



Truenat[®]

HEV

Chip-based Real Time PCR Test for Hepatitis E Virus

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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.

1. INTENDED USE

Truenat[®] HEV (REF 601330005 / 601330020 / 601330025 / 601330050 / 601330100 / 601330200) is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Hepatitis E virus in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis E Virus. This test is also intended for qualitative detection and diagnosis of Hepatitis E virus in stool sample. Truenat[®] HEV runs on the Truelab[®] Real Time Quantitative micro PCR Analyzers.

2. INTRODUCTION

Hepatitis E is a liver disease caused by the hepatitis E virus (HEV). Hepatitis E occurs around the world both as outbreaks and as sporadic cases. Every year, there are an estimated 20 million HEV infections worldwide, leading to an estimated 3.3 million symptomatic cases of hepatitis E. Waterborne outbreaks of hepatitis E are common in most parts of Asia and Africa. HEV is classified in the genus Hepevirus in the Hepeviridae family. HEV is a nonenveloped virus with an icosahedral capsid and a size of 27 to 34 nm. The virus has a positive-sense, single-stranded, 7.2-kb RNA genome. The virus has at least 4 different types: genotypes 1, 2, 3 and 4. Genotypes 1 and 2 infect only humans and are responsible for the majority of human disease caused by infection with this virus globally. In contrast, genotypes 3 and 4 primarily circulate among mammalian animals, including pigs, wild boar, deer and only occasionally infect humans.

The hepatitis E virus is transmitted mainly through the faecal-oral route due to faecal contamination of drinking water. The major clinical symptoms of hepatitis E virus include:

an initial phase of mild fever, reduced appetite (anorexia), nausea and vomiting, lasting for a few days; some persons may also have abdominal pain, itching (without skin lesions), skin rash or joint pain.

jaundice (yellow discoloration of the skin and sclera of the eyes) with dark urine and pale stools

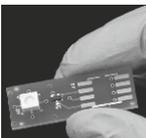
a slightly enlarged, tender liver (hepatomegaly).

These symptoms are often indistinguishable from those experienced during other liver illnesses and typically last between 1–6 week. In rare cases, acute hepatitis E can be severe and results in fulminant hepatitis (acute liver failure); these patients are at risk of death.

HEV infection can be diagnosed either indirectly by detecting serum anti-HEV antibodies or directly by detecting the HEV genome in blood or other bodily fluids. Detection of IgM anti-HEV antibodies in serum indicates recent HEV infection and is used for individual case diagnosis and confirmation of an outbreak of hepatitis. Due to the limitations of HEV serologic testing especially in immunosuppressed patients, molecular testing (e.g. RT-PCR assay) for HEV RNA in serum or plasma is an increasingly important tool in the diagnosis of acute or chronic HEV infection in these patients. Monitoring of HEV RNA levels in serum or plasma is used to assess response to antiviral therapy. The nucleic acid of HEV (HEV RNA) can be detected in a fair proportion of serum or plasma specimens collected during the first two weeks of acquiring acute hepatitis E using reverse transcription and PCR or a real-time-based PCR. These tests are highly specific. Further, the viral nucleic acids from specimens testing positive can be sequenced to determine the viral genotype to answer questions related to the epidemiology and pathogenesis of the disease. 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 micro PCR System enables decentralization and near patient detection and viral load monitoring of HEV 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[®] HEV is a disposable, room temperature stable, micro PCR test with dried MgCl₂ in reaction well and freeze dried RT PCR reagents in microtube for performing Real Time RT PCR test for HEV 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[®] HEV chip also stores information of used chips to prevent any accidental re-use of the chip.



3. PRINCIPLE OF THE TEST

Truenat[®] HEV 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 Sample Prep Device and Trueprep[®] AUTO/AUTO v2 Universal Cartridge based sample prep kit. The Truenat[®] HEV 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[®] HEV 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[®] HEV 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, HEV "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[®] Uno Dx/ Duo/Quattro can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The gene target sequences for this assay is ORF 1 poly protein gene of HEV genome.

5. CONTENTS OF THE Truenat[®] HEV KIT

- Individually sealed pouches, each containing
 - Truenat[®] HEV micro PCR chip.
 - Microtube with freeze dried RT PCR reagents.
 - DNase & RNase free pipette tip.
 - Desiccant pouch.
- Package Insert .

REF	601330005	601330020	601330025	601330050	601330100	601330200
▽	5T	20T	25T	50T	100T	200T

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

- Lysis buffer.
- Disposable transfer pipette (graduated).
- Package Insert.

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

7. STORAGE AND STABILITY

Truenat[®] HEV 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** 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/AUTO v2

A. Blood/Serum/Plasma specimen:

Truenat® HEV 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 40°C and one (1) week at 30°C.

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® HEV** chip, microtube, 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 "HEV" 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 "HEV" 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® HEV** and retrieve the chip-based Real Time PCR test and the microtube.
8. Place the **Truenat® HEV** 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® HEV** 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® HEV** 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® HEV** 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 valid.

negative PCR runs.

Reproducibility:

The reproducibility of **Truenat® HEV** 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 (2.35), Inter day (2.81) and Inter Device (1.40) which were in the accepted range of ≤15% CV for **Truenat® HEV** assay.

Precision of Truenat® HEV assay:

Precision was tested by performing **Truenat® HEV** 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 (2.92), Medium titre (2.22) and low titre (3.63) were within the accepted range of ≤15% CV for **Truenat® HEV** assay.

Clinical validation:

Total 100 samples comprising of 70 negative and 30 positive specimens were tested on three different lots of **Truenat® HEV** assay at NIV (ICMR- National Institute of Virology, Pune) against the NIV in-house HEV RT-qPCR assay. Positive samples containing viral loads ranging from ~ 170 copies/mL to 16,00,00,000 copies/mL were tested.

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

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

Concordance of viral loads:

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

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.

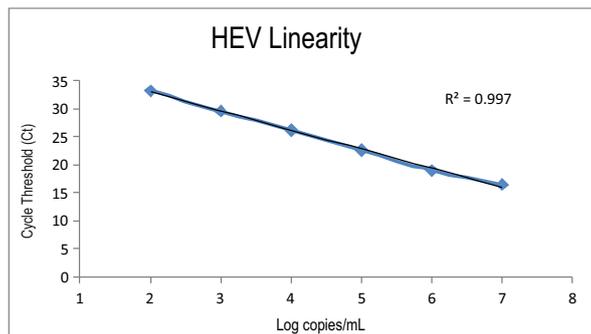
17. DISPOSAL AND DESTRUCTION

1. Submerge the used **Truenat® HEV** 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

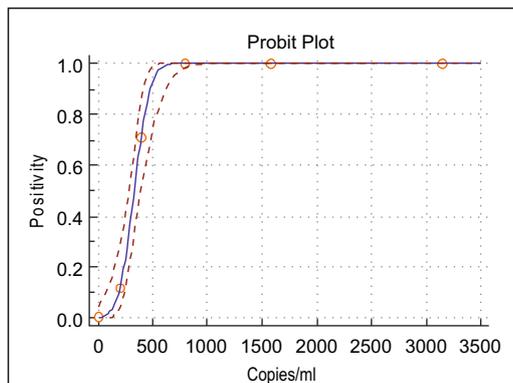
Linearity and Assay range:

The linearity analysis was performed according to CLSI Guidelines. Serial dilutions of **HEV IVT** RNA from 5.5E+07 to 5.5E+02 copies/mL were made and each dilution was tested in triplicates using the **Truenat® HEV** test on **Truelab®** Real Time micro PCR Analyzer. The assay is found to be linear over 6 orders of magnitude (from 5.5E+07 to 5.5E+02 copies/mL) for HEV RNA.



Limit of detection (Analytical Sensitivity):

The LOD was determined by testing dilutions (1500 copies/mL, 750 copies/mL, 375 copies/mL, 187.5 copies/mL, 93.5 copies/mL, 0 copies/mL) of *in vitro* transcribed HEV RNA. 24 replicates of each dilution was tested 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 516 copies/mL of **HEV IVT** RNA for **Truenat® HEV** assay.



Robustness:

To determine whether the **Truenat® HEV** 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® HEV** test did not exhibit detectable carryover between positive and

19. REFERENCES

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4. Ryan KJ, Ray CG (editors) (2004). Sherris Medical Microbiology, 4th ed., McGraw Hill, 541–544. ISBN 0838585299.
5. <http://www.who.int/mediacentre/factsheets/fs328/en/>
6. <https://www.cdc.gov/hepatitis/hev/index.htm>

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