INTENDED USE
Wanted Hepatitis E ELISA is an enzyme-linked immunosorbent assay for qualitative determination of IgM-class antibodies to hepatitis E virus in human serum or plasma samples. The assay is intended to be used in clinical laboratories for diagnosis and management of patients related to infection with hepatitis E virus.

SUMMARY
Hepatitis E (HEV) is a non-encephalitic, single-stranded RNA virus identified in 1990. Infection with HEV induces acute or sub-acute liver diseases similar to hepatitis A. HEV infections, endemic and frequently epidemic in developing countries, is seen as a zoonosis that affects both man and animals in form or with no history of traveling to endemic area. The overall case-fatality is 0.5-3%, and much higher (15-20%) among pregnant women. A hypothesis that HEV infection in a zoonosis was presented in 1995. Then a new HEV and later an avian HEV were identified and sequenced separately in 1997 and 2001. Since then, HEV infection can include anti-HEV in humans and faeces infection of HEV was seen in a wide variety of animals, i.e., swine, rodents, wild monkeys, deer, cows, dogs, goats and chicken in both the developing and developed countries. A direct testified was reported that the consumption of undercooked deer meat infected with HEV in human. And HEV genome sequences can be detected in pork livers available in the supermarkets in Japan.

PRINCIPLE OF THE TEST
This kit is a two-step incubation, solid-phase antibody capture ELISA assay in which polyethylene microwell strips are pre-coated with antibodies directed to human immunoglobulin M (anti-lgM). The patient’s serum/plasma sample is added to the microwell strips, where the microwell strips are coated with antibodies to capture the target protein. The complexes of the antibody bound antigen are measured using the substrate, 3,3’,5,5’-tetrachloro-4-iodophenol (TMB) solution. Readout is obtained by using a microplate reader that measures the absorbance at 450nm.

STORAGE AND STABILITY
The components of the kit will remain stable through the expiration date indicated on the label and package when stored at 2-8°C. Do not store below 2°C or above 8°C, do not freeze. WANTED HEPI ELISA, during storage, protect the reagents from contamination with microorganism or chemicals.

PRECAUTIONS AND SAFETY
To be used only by qualified professionals.

THE ELISA assays are time and temperature sensitive. To avoid incorrect result, strictly follow the procedure steps not to modify it.

1. Do not exchange reagents from different kits or lots reagents from other commercially available kits. The components of the kits are precisely matched for optimal performance of the tests.
2. Make sure that all reagents are used fresh and the same lot name. Never use reagents beyond their expiry date stated on labels or boxes.
3. Calculate CRITICAL: correct incubation times to reach room temperature (18-20°C) before use. Shake reagent gently before use. Store at 2-8°C after use. Use according to the manufacturer’s instruction. Avoid long-term storage at room temperature.
4. Do not touch the bottom exterior of the wells; fingerprints or scratches may interfere with the reading. When reading results, the plate bottom is not dry, and there are no bubbles and air bubbles in the wells.
5. Avoid the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the light of air bubbles when putting down the microwell strips.
6. Avoid assay steps long time interruptions. Assure same working conditions for all wells.
7. Calibrate the pipette to deliver the proportional volume of solution.
8. Using different disposable pipette tips for each specimen and reagents in order to avoid cross-contaminations.
9. Assure that the incubation temperature is 37°C when working with the plates in the incubator.
10. When adding specimens, do not touch the well’s bottom with the pipette tip.
11. Add reagents in the order of the protocol, i.e., reagents are added in the order that the reagents appear in the protocol.
12. The enzymatic activity of the HRP-conjugate might be affected from dust and reactive chemical and reactive materials. Therefore, do not perform the assay in the presence of these substances.
13. If using fully automated equipment, during incubation, do not cover the plates with the plate cover.
14. The concentration of the standard and sample should be determined spectrophotometrically.
15. In case of manual washing, we suggest to carry out 5 washing cycles, dispensing 350-400 μl/well and final washing cycle, turn down the plate onto blotting paper or clean towel and tap it to remove any remainders. Place 100 μl/pipette tips before each washing.
16. In case of manual washing, we suggest to carry out 5 washing cycles, dispensing 350-400 μl/well.
17. In case of manual washing, we suggest to carry out 5 washing cycles, dispensing 350-400 μl/well.
18. The pipette tips, vials, strips and specimen containers should be collected and autoclaved for not less than 2 hours. Disposed laboratory waste should be disposed of for 30 minutes to decontaminate before any further steps of disposal.
19. Contact the author should be considered separately when calculating and interpreting the results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each specimen absorbance value to the absorbance values of the respective standard curves. When the sample value is above the cut-off, the result is expressed as a percentage of the cut-off value. The standard curve is calculated from the average of 20 samples.
20. The results should be expressed as a percentage of the cut-off value. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples. The standard curve is calculated from the average of 20 samples.

RAW TEXT END
SUMMARY OF THE MAJOR COMPONENTS OF THE KIT:
Use this summary only as a reference and always follow the detailed method sheet when performing the assay.

<table>
<thead>
<tr>
<th>Item</th>
<th>Code 5</th>
<th>Code 6</th>
<th>Code 7</th>
<th>Code 8</th>
<th>Code 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wash Buffer</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop Solution</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Sample Diluent</td>
<td>6</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRP-Conjugate</td>
<td>8</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SUMMARY OF THE ASSAY PROCEDURE:
Use this summary only as a reference and always follow the detailed method sheet when performing the assay.

1. Quality Control
2. Positive Control
3. Sample Diluent
4. HRP-Conjugate
5. Wash Buffer
6. Chromogen A
7. Chromogen B
8. Stop Solution

CE MARKING SYMBOLS:

In Vitro Diagnostic Medical Device
-2°C~+4°C Storage Conditions

EU Authorized Representative
Use By
Purchased Date
Catalog Number
Manufacturer

REFERENCES