H. pylori Test Reagent

For the Qualitative Determination of H. pylori Antibodies in Serum and Plasma on Automated Chemistry Analyzers

**Cat. No. KAI-240**

**INTENDED USE**

The **K-ASSAY®** H. pylori Test Reagent is for the qualitative determination of anti-Helicobacter pylori antibodies in human serum and plasma by immunoturbidimetric assay on automated clinical chemistry analyzers. The **K-ASSAY®** H. pylori Test Reagent is used as an aid in the diagnosis and treatment of H. pylori infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

**WARNINGS AND PRECAUTIONS**

For research use only in the U.S. Not for use in diagnostic procedures in the U.S. Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed. Do not mix or use reagents from one test kit with those from a different lot number. Do not use reagents past their expiration date stated on each reagent container label. Do not pipette by mouth. Avoid ingestion and contact with skin.

Reagents in this kit contain less than 0.1 w/v% sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water. For further information, refer to “Decontamination of Laboratory Sink Drains to Remove Azide Salts,” in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Reagents are ready to use and do not require reconstitution. Do not shake the reagent bottles when putting on the analyzer.

**STORAGE AND HANDLING**

All reagents should be stored refrigerated (2-8°C). Unopened reagents can be used for 12 months from the date of manufacture as indicated on the expiration date on the package and bottle labels.

**REAGENT STABILITY**

Opened reagents can be used for 8 weeks if stored at 2-8°C. Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) is cause to discard.

**SPECIMEN COLLECTION AND PREPARATION**

Serum Blood should be collected from a patient and the serum separated as soon as possible. Soon after the blood is drawn, it should be allowed to clot, centrifuged, and the serum separated from the clot tube. It is recommended that the specimen collection be carried out in accordance with the NCCLS document M29-A2. After sampling, the specimen should be immediately stored at 2-8°C and assayed as soon as possible. If the assay cannot be performed immediately, then the sample should be tightly capped and frozen at -20°C or below. Avoid more than 2 freeze-thaw cycles.

Plasma Whole blood is collected in potassium EDTA (EDTA-2K or EDTA-3K) or sodium heparin anticoagulant. After collection, immediately centrifuge. In the U.S., follow NCCLS guideline H3-A2. If the assay cannot be performed immediately, then the sample should be capped and frozen at -20°C or below. Avoid more than 2 freeze-thaw cycles.

**AUTOMATED ANALYZER APPLICATION**

Suitable for two-reagent automated analyzers that use a multi-point calibration method.

**PROCEDURE**

**MATERIALS SUPPLIED**

Reagent 1 (R-1) Buffer Solution 1 x 60 mL
Reagent 2 (R-2) Latex Suspension 1 x 12 mL

**MATERIALS REQUIRED BUT NOT SUPPLIED**

Calibrators: **K-ASSAY®** H. pylori Calibrator, Cat. No. KAI-241C.
Controls: **K-ASSAY®** H. pylori Control, Cat. No. K242C-2M or K242-4M.
2 levels: Level 1 = Negative, Level 2 = Positive

**CALIBRATION**

A six-point calibration curve should be made using the **K-ASSAY®** H. pylori Calibrator and saline (0 U/mL). It is recommended that each laboratory determine calibration frequency, as this would depend on the analyzer in use as well as the types and number of other assays being run. A new calibration curve should be made at least once every two weeks or when a new lot of reagent is used.

**ASSAY PROCEDURE**

Note: Allow all reagents and specimens to warm to room temperature. Mix all reagents gently before using.

An example of automated application (Hitachi 917):

**Sample**

3.5 µL

R1 (Buffer Reagent) 200 µL
37° 5 min.
R2 (Reagent) 40 µL
37° 5 min.

**Endpoint** 570 nm (main) / 800 nm (secondary)

**Automated Method (Example)**

Chemistry Parameters for Automatic Analyzer

**INSTRUMENT FACTOR**

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**SALINE**

Saline (0.9% w/v NaCl)

**Two Reagent Clinical Chemistry Analyzer Capable of**

Accurate absorbance readings at approx. 570 nm
Accurately dispensing the required volumes
Maintaining 37°C

**INSTRUMENT**

Measurement of absorbance is to be made with an instrument able to accurately read absorbance at approximately 570 nm. Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and/or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information
QUALITY CONTROL
A quality control program is recommended for all clinical testing laboratories. It is recommended the K-ASSAY® H. pylori Control containing both negative and positive controls be run with each batch of samples to monitor the procedure. QC intervals and limits should be adapted to each laboratory’s individual requirements. Each laboratory should establish corrective measures if values fall outside the limits.

LIMITATIONS OF PROCEDURE
The measurable range for this H. pylori test kit is between 3 to 100 U/mL. If the H. pylori antibody concentrations are greater than the highest calibrator value, dilute the sample with isotonic saline and re-assay. Multiply the result by the dilution factor to compensate for the dilution.

PERFORMANCE
Precision
(Within Run)
Serum control samples were assayed 10 times on the same day.

<table>
<thead>
<tr>
<th>Control (Negative)</th>
<th>Control (Positive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 10</td>
<td>N = 10</td>
</tr>
<tr>
<td>Mean = 5.1</td>
<td>Mean = 20.6</td>
</tr>
<tr>
<td>SD = 0.1</td>
<td>SD = 0.3</td>
</tr>
<tr>
<td>CV = 2 %</td>
<td>CV = 1 %</td>
</tr>
</tbody>
</table>

Accuracy / Correlation
A comparison of the K-ASSAY® H. pylori Test Reagent and another H. pylori antibody test was performed with the following results.

<table>
<thead>
<tr>
<th>Other H. pylori Test</th>
<th>Positive</th>
<th>Negative</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-ASSAY® H. pylori Test Reagent</td>
<td>59</td>
<td>6</td>
<td>65</td>
</tr>
<tr>
<td>Positive</td>
<td>54</td>
<td>54</td>
<td>108</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>57</td>
<td>60</td>
</tr>
<tr>
<td>Overall agreement</td>
<td>113/122</td>
<td>95.2%</td>
<td></td>
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The 6 samples judged as positive by the K-ASSAY® H. pylori Test Reagent and negative by the other H. pylori Test were analyzed by a rapid urease test and endoscopy. The results show that 4 of these 6 samples were actually positive. 2 of these 6 samples were indeterminable.

The 3 samples judged as negative by the K-ASSAY® H. pylori Test Reagent and positive by the other H. pylori Test were analyzed by a rapid urease test and endoscopy. The results show that 2 of these 3 samples were actually negative. 1 of these 3 samples was indeterminable.

MATRICES OF RESULTS
10 U/mL should be used as the cutoff value.

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REFERENCES

LABELING SYMBOLS
LOT: Lot Number
Reagent
Expiration or “Use By” Date
Catalog Number
Temperature Limitation. Store between 2 and 8 degrees C
Manufacturer
Consult Package Insert for Instructions for Use
Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE
Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

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