Instructions for Use

380240-B

English

LZ H.pylori Antibody

REF V-IY05

INTENDED USE
For detection of *Helicobacter pylori* antibodies in serum or plasma. (Including support for the diagnosis of *Helicobacter pylori* infection.)

INTRODUCTION
Helicobacter pylori (*H. pylori*) is a gram-negative microaerophilic bacterium found in a gastric mucosa, and was found and identified by Warren and Marshall.[1] *H. pylori* is known by bringing about chronic inflammation of the gastric mucosa epithelium.
"LZ H.pylori Antibody" is a reagent developed for sensitive and accurate measurement of *H. pylori* antibody. This measurement utilizes a latex agglutination reaction, and the change in turbidity caused by this reaction is measured optically to determine the antibody concentration.

PRINCIPLE OF THE METHOD
This method is an optical measurement method by using the latex agglutination reaction and automated analyzer.
The latex reagent is prepared by binding *H. pylori* antigens to the surface of the latex particles. When this reagent is mixed in a cell to react with the sample, *H. pylori* antigens which are bounded to the latex particles react with *H. pylori* antibodies in the sample, and cause agglutination.
This reaction is then measured as a change in the turbidity, with the amount of the change increasing in proportion to higher antibody concentration of *H. pylori* in the sample.
Measurement using LZ H.pylori Antibody applies this principle to find a calibration curve from calibrator of known antibody concentration. The amount of *H. pylori* antibodies in the sample is then found relative to this calibrator.

CONTENTS OF THE KIT
1. Reagent-1 ·····60mL, 1 vial
   (Contains 50mmol/L of Good's buffer)
2. Reagent-2 ····· 20mL, 1 vial
   (Contains 50 vol% of latex sensitized with *H. pylori* antigens)

WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use only.
2. Use the fresh serum or plasma. When samples are stored, they should be kept at -20°C. Repeated freezing and thawing of sample should be avoided.
3. Store the reagents under the designated conditions. Do not use reagents that have passed their expiration date.
4. Mix the latex reagent before using by gently inverting the vial several times.
5. Measurement errors may result if bubbles are present on the surface of the sample after it is dispensed into the sample cup. Therefore remove all bubbles. If fibrin is present in the sample cup, remove it. Fibrin can cause clogging of the sample nozzle.
6. Create a calibration curve for each day of measurement. Also be sure to create a new calibration curve when a reagent from a different vial or lot is used.
7. The test sample may be contaminated with the HB virus, HCV, HIV, or other pathogens. Therefore use caution when handling.
8. If the sample antibody concentration exceeds the measurement range, dilute with a normal saline solution or similar solution and perform measurement again.
9. If a reagent enters eye or mouth, rinse it out with large volumes of running water, and perform other required first aid. If necessary, seek medical attention.
10. Use the reagents as quickly as possible after they are opened. If they are to be stored, be sure to close the caps and store them using the prescribed method.
11. There is the danger of infection from all tools, reagents, and reagent containers that contact the sample. Disinfect them using an autoclave or other means, or soak them in hypochlorous acid or other disinfectant solution.
    Example of treatment: Soak for 60 minutes or longer in a sodium hypochlorite solution (available chlorine concentration 1000 ppm or greater). (Neutralize any substances that contain acids before soaking.) Alternatively, treat in an autoclave at 121°C for 20 minutes. (Do not treat in this way any items to which sodium hypochlorite has adhered.)
12. Dispose of used reagents and containers should be performed as medical waste in accordance with applicable regulations.
13. If the product is used in any way other than that specified here, the reliability of measurement results cannot be guaranteed. Be sure to follow the procedure.
14. A clinical diagnosis based on the measurement results must be a comprehensive judgment made by the attending physician, including factors such as clinical symptoms and other test results.

SAMPLE COLLECTION
1. Use serum or plasma as test sample (specimen).
2. Collect samples in usual manner and test them while fresh.
3. If test samples are to be stored over a long period of time, preserve them frozen at -20°C or lower (avoid repeated freezing and thawing).
4. If a frozen stored test sample is to be used, thaw it at room temperature and then mix it by inversions before running the test.
5. Dialyzed blood-derived serum samples, in which fibrin is likely to be separated, should be defibrinated before used in the test.

TEST PROCEDURE
1.Preparation of reagents
   1) Reagent-1: Use the Reagent-1 as-is.
   2) Reagent-2: Use the Reagent-2 as-is.
   3) Calibrators: Separately obtain the LZ H.pylori Antibody Calibrator (REF V-IY83) as the calibrators.

2. Measurement procedure
   1) Follow the instructions in the instruction manual to operate the automated analyzer.
   2) Dispense the sample and standards into sample cups, and set them in the designated positions.
   3) Set Reagent-1 and Reagent-2 in the designated positions.
   4) Enter the parameters into the analyzer.
   5) Press the analyzer "Start" key to begin analysis and output the measurement results (by printout or other means).

EXPECTED REFERENCE VALUES
Negative < 10 U/mL, Positive ≥ 10 U/mL

INTERFERING SUBSTANCES
Almost no effect on the measurement value was found from conjugated bilirubin (20mg/dL), free bilirubin (20mg/dL), hemoglobin (500mg/dL), chyle (2,000 formazine turbidity units), and rheumatoid factor (RF positive sample 550 IU/mL). As an anticoagulant almost no effect on the measurement value was found from EDTA・2Na (500mg/dL), sodium citrate (1,000mg/dL) and heparin sodium (50mg/dL).

INTERNAL QUALITY CONTROL
A quality control program to monitor the performance of LZ H.pylori Antibody is recommended to each laboratory.
The following relevant products are being recommended for the quality control program.
   H.pylori Antibody Control Low (REF V-IY84)
   H.pylori Antibody Control High (REF V-IY85)

PERFORMANCE CHARACTERISTICS
1. Sensitivity
   When the positive control sample (H.pylori Antibody Control High) is measured, it is judged as positive.
2. Accuracy
   The negative control sample (H.pylori Antibody Control Low) is judged as negative, and positive control samples are judged as positive when they are measured.
3. Within-run reproducibility
   When the same specimens are measured 5 times simultaneously, the negative control ones are all judged as negative, and the positive control ones are judged as positive.
4. Measurement range
   3.0 – 100.0 U/mL

PRODUCT CODE, PRODUCT NAME & STORAGE

Product code	Product name	Contents	Storage
V-IY05	LZ H.pylori Antibody	1 × 60mL 1 × 20mL	2-10°C
V-IY83	LZ H.pylori Antibody Calibrator	6 × 1mL	2-8°C
V-IY84	H.pylori Antibody Control Low	2 × 3mL	2-8°C
V-IY85	H.pylori Antibody Control High	2 × 3mL	2-8°C

REFERENCE
1. Warren JR, et al.: Lancet, 321: 1273-1275, 1983

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