INTRODUCTION

EzDx Helicobacter Pylori (H. pylori) antibody test is a rapid Chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in serum, plasma, whole blood to aid in the diagnosis of H. pylori infection.

CLINICAL SIGNIFICANCE

H. pylori is a small, spiral shaped Gram-negative bacterium that lives in the surface of the stomach and duodenum. H. pylori was initially isolated by Warren and Marshall from biopsy sample taken from patients suffering from active chronic gastritis. In fact, it is now clear that H. pylori is the principle etiologic agent in type B gastritis (Chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Sample dependent and costly invasive diagnostic method includes gastric or duodenal biopsy. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individual infected with H. pylori develops serum antibodies which correlate strongly with histologically confirmed H. pylori infection.

The EzDx Helicobacter Pylori (H. pylori) test is a simple test that utilizes a combination of H. pylori antigens coated particles and human IgG to qualitatively and selectively detect H. pylori antibodies in serum, plasma, whole blood in ten minutes. The test is intended for professional use and must be used by trained personnel.

PRINCIPLE

EzDx Helicobacter Pylori (H. pylori) test is an In-vitro immunochromatographic, one step assay designed for qualitative determination of Helicobacter pylori antibodies in human serum, plasma, whole blood.

MATERIALS PROVIDED

EzDx Helicobacter Pylori (H. pylori) antibody kit contains following items to perform the assay:

1) EzDx Helicobacter Pylori (H. pylori) antibody Test device individually foiled pouch with a desiccant.
2) Sample Applicator
3) Product Insert

WARNING & PRECAUTIONS

1. For In-vitro diagnostic use only.
2. All specimen should be handled as being potentially infectious.
3. Do not open or remove test cassette from the individually sealed pouches until immediately before their use. Perform the test immediately after removing the test cassette from the foil pouch.
4. Do not re-use test cassette.
5. All reagents must be at room temperature before running the assay.
6. Do not use reagents beyond the stated expiration date marked on the package label.
7. The components in this kit have been tested in quality control as standard batch unit. Do not mix components (test cassette and sample diluent) from different lot numbers.
8. Do not use the test kit if the pouch is damaged or the seal is broken.
9. Dispose all the samples and kits properly as per the instructions after the test in accordance with GLP.
SPECIMEN COLLECTION, STORAGE & PRECAUTIONS

1. Whole blood specimen collection:
   - Venipuncture Whole blood specimen collection: Collect an anticoagulated blood specimen. Whole blood specimen must be tested within 24 hours of drawing.
   - Finger-puncture Whole blood specimen collection: Disinfect finger with alcohol and dry. Pierce finger with lancet, and fill the capillary tube.
2. Plasma/serum specimen collection:
   - Centrifuge whole blood to get plasma /serum specimen.
   - If specimens are not immediately tested they should be refrigerated at 2-8°C.
   - For storage periods greater than three days, freezing is recommended.
   - The specimen should be brought to room temperature prior to use.
3) Plasma or serum specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

TEST PROCEDURE

The instruction must be followed exactly to get accurate results.
1. Remove the test device from the foil, and place it on a flat, dry surface.
2. Transfer the specimen by a pipette or a dropper, add 2 drops (100μl) of serum / plasma or whole blood into the sample well of the test device and start the timer.
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Interpret test results at 10 minutes. A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the result can be read at 20 minutes.

Note: Specimens with high concentrations of *H. pylori* antibodies may produce positive result before 1 minute. Confirm negative result in 20 minutes.

INTERPRETATION OF RESULTS

Negative

The presence of only one color line at control line (C), within the result window, indicates a negative result.

Positive:

The presence of two color bands (T) line and (C) line within the result window regardless of which band appears first indicates a positive result.

Note: The shade of color / intensity of band may vary, but should be considered positive whenever, there is even a faint line.

Invalid:

If the color band is not visible at the control line (C) within result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated beyond the expiration date. It is recommended to repeat the test using a fresh device, and follow test procedure exactly.

LIMITATIONS OF THE TEST

1. A negative result does not preclude the possibility of infection with *H. pylori*. Other clinically available tests are required if questionable results are obtained.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND EXPIRATION

1. Test device in the sealed pouch should be stored at 2-30°C (36 - 86°F) DO NOT FREEZE.
2. The test device should be kept away from direct sunlight, moisture and heat.
3. Expiry date of this kit is as indicated on the kit cartons as well as on individual Pouches.

QUALITY CONTROL

The control line is an internal control of the test reagents and procedures. It will appear if the test has been performed correctly and the reagents are reactive.

REFERENCES

tion of a new immunodiagnostic assay for *Helicobacter pylori* antibody detection: Correlation with histopathological and micro

DISCLAIMER:

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. This product is used outside of the control of the manufacturer and the distributor and the results may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING:

The Manufacturers and Distributors of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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