**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle as specimens as well as test and control infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens or test materials.
- The used test should be discarded according to local regulations.
- Humidity and temperature can affect results.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date. Do not use if the test has been exposed to room temperature or refrigeration. The test remains in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- **H. pylori Antibody Rapid Test Cassette**
  - Can be used with whole blood, serum or plasma.
  - For professional use only. Do not use in non-professional laboratories.
  - The test is intended for in vitro diagnostic use.
  - The test is intended for use by healthcare professionals who have received training in the use of the test.

**INVESTIGATION OF RESULTS**

- **Positive**: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). The intensity of the color in the test line region (T) will vary depending on the concentration of H. pylori antibodies in the specimen. See illustration below.
- **Negative**: One colored line appears in the control region (C). No apparent colored line appears in the test region (T). See illustration below.
- **Invalid**: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit and immediately contact your local distributor.

**QUALITY CONTROL**

- A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control results are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

- The H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only.
- The test should be used for the detection of H. pylori antibodies in whole blood, serum, or plasma specimens only. Neither the quantitative nor the rate of increase in H. pylori antibody concentration over time should be interpreted by this diagnostic test.
- The H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of H. pylori antibodies in the specimen and should not be used as the sole criterion for the diagnosis of H. pylori infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available on the patient.
- All tests should be performed by healthcare professionals who have received training in the use of the test kit.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of H. pylori infection.

**EXCEPTED VALUES**

The H. pylori Antibody Rapid Test Cassette (Whole Blood/Plasma) has been compared with histology/histology/RUT and has demonstrated a sensitivity of 94.6%.

**PERFORMANCE CHARACTERISTICS**

- **Clinical Sensitivity**, **Specificity and Accuracy**:
  - The H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who provided informed consent. Histology and a Rapid Urine Test (RUT) were performed. The negative culture individuals were considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The result shows that the sensitivity of the H. pylori Antibody Rapid Test Cassette (Whole Blood/Plasma) is 98.3% and the specificity is 98.9% relative to Histology/RUT.

The H. pylori Antibody Rapid Test Cassette (Whole Blood/Plasma) has a high degree of specificity for antibodies to H. pylori and is designed for use with whole blood, serum, or plasma.

**BIBLIOGRAPHY**

3. H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, non-positive, and positive specimens. The sera were from individuals who were negative, low positive, medium positive, and high positive.
4. H. pylori Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The sera were from individuals who were negative, low positive, medium positive, and high positive.