INTENDED USE

The Clearview® H. pylori test is a rapid immunochromatographic immunoassay for the detection of IgG antibodies to H. pylori in whole blood. The test is intended for use with asymptomatic patients. It is not intended for use with symptomatic patients.

The Clearview® H. pylori test is for in vitro use only. It should be used for the detection of IgG antibodies to H. pylori in whole blood samples only. The qualitative nature of the test and the concentration of IgG antibodies can be determined by this qualitative test.

The qualitative test is for in vitro diagnostic use only. It should not be used for the detection of IgG antibodies to H. pylori in whole blood samples. If the sample does not contain IgG antibodies to H. pylori in the sample, the test should be used and performed as directed in the instructions for use.

The test is intended to be used in the diagnosis of infection in adults 18 years of age and older. The test is not intended for the diagnosis of infection in children under 18 years of age.

The Alere Logo, Alere and Clearview are trademarks of the Alere group of companies.

REFERENCES

INTENDED USES

The Clearview H. pylori test is a rapid, chromatographic immunochromatographic test for the qualitative detection of H. pylori specific IgG antibodies in whole blood, serum or plasma samples.

PRECAUTIONS

- The Clearview H. pylori test is intended for professional use only. The test is not for use by non-professional individuals.
- The test is not intended for use with samples from individuals known to be carriers of H. pylori.
- The test is intended for use in whole blood, serum, or plasma samples only.
- The test is not intended for use with fresh, whole blood samples.
- The test is not intended for use with urine or other body fluids.
- The test is not intended for use with samples from individuals who are allergic to any component of the test kit.

REAGENTS

- The Cassette is a plastic device that contains a test control line (C) and a test line (T) on a membrane strip.
- The Buffer is a solution of phosphate buffered saline (PBS) and sodium azide.

PROCEDURE

1. Collect a sample of whole blood, serum, or plasma.
2. Place the sample on the test cassette and allow it to dry.
3. Allow to dry.
4. Examine the result area of the test cassette.
5. Read the results after 10 minutes.

RESULTS

- A positive test result is indicated by a red line appearing in the test area (T).
- A negative test result is indicated by no red line appearing in the test area (T).
- An invalid test result is indicated by no red line appearing in the control area (C) and no red line appearing in the test area (T).

NOTE: Low levels of background should be clear before the result is read.

INTERPRETATION OF RESULTS

- A positive result indicates the presence of H. pylori specific IgG antibodies in the sample.
- A negative result indicates the absence of H. pylori specific IgG antibodies in the sample.
- An invalid result should be disregarded and a new test performed.

LIMITATIONS

- The test is not intended for use with samples from individuals known to be carriers of H. pylori.
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REFERENCES

- USE REFERENCES ON REPRINT: CLEARVIEW H. PYLORI WHOLE BLOOD, SERUM, PLASMA.

NOTE: The results of the archived clinical samples were also tested pending publication of a correlating study. (24% - 85%) (20% - 100%)*

ACCURACY = 130/150 = 87% (80% - 92%)*

SPECIFICITY = 107/122 = 88% (84% - 92%)*

Sensitivity = 84/97 = 87% (80% - 94%)*

Specificity = 76/88 = 86% (77% - 93%)*

Overall Agreement = 145/162 = 90% (84% – 94%)*

Negative Agreement = 91/93 = 98% (92% – 100%)*

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