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RAPID H-PYLORI TEST – Lateral Flow (*Serum or Plasma*) **(Helicobacter Pylori)**

FOR *IN VITRO* DIAGNOSTIC USE ONLY

INTENDED USE

THE RAPID H-PYLORI TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES OF H.PYLORI IN HUMAN SERUM OR PLASMA. THIS TEST IS A SCREENING TEST AND ALL POSITIVES MUST BE CONFIRMED USING AN ALTERNATE TEST SUCH AS WESTERN BLOT. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE ONLY.

SUMMARY

The Rapid H-pylori Test is a simple, visual qualitative test that detects antibodies in human serum or plasma. The test is based on immunochromatography and can give a result within 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well and add provided sample diluent immediately. The H-pylori antigens-colloidal gold conjugate embedded in the sample pad reacts with the H-pylori antibody present in serum or plasma sample forming conjugate/H.pylori antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/ H-pylori antibody complex is captured by an antibody-binding protein A immobilized on a membrane forming a colored test band in the test region. A negative sample does not produce a test line due to the absence of colloidal gold conjugate/ H-pylori antibody complex. The antigens used in the test are recombinant proteins corresponding to highly immunoreactive regions of H-pylori. A colored control band in the control region appears at the end of test procedure regardless of test result. This control band is the result of colloidal gold conjugate binding to an anti- H-pylori antibody immobilized on the membrane. The control line indicates that the colloidal gold conjugate is functional. The absence of the control band indicates that the test is invalid.

REAGENTS AND MATERIALS SUPPLIED

- Test cards/test strips individually foil pouched with a desiccant
- Plastic dropper.
- Sample Diluent
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls

STORAGE AND STABILITY

- The kit must be stored at 2 - 30°C.

WARNINGS AND PRECAUTIONS

1. ALL positive results must be confirmed by an alternative method.
2. Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
3. Devices used for testing should be autoclaved before disposal.
4. Do not use kit materials beyond their expiration dates.
5. Do not interchange reagents from different lot of kit.

SAMPLE COLLECTION AND STORAGE

1. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using. 0.1% of sodium azide can be added to specimen as preservative without affecting the results of the assay.

BEFORE TESTING

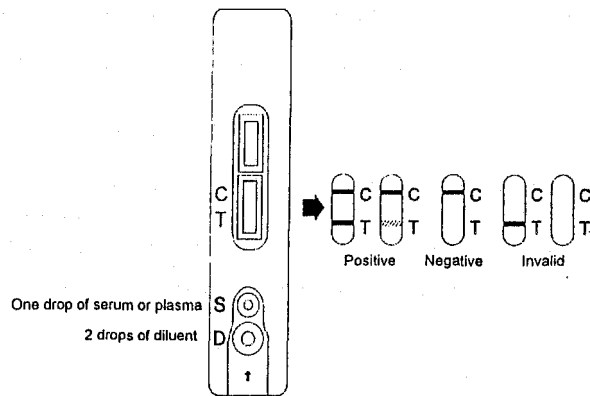
1. Bring the device, sample diluent, and specimens to room temperature.
2. Remove test card from the sealed pouch.

ASSAY PROCEDURE

For test cards:

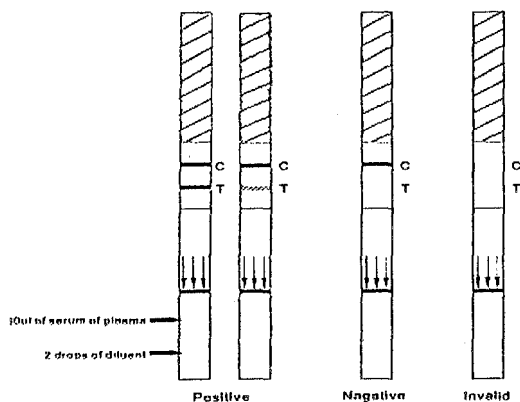
1. Dispense 1 drop (10µl) of serum or plasma to the circular sample well of the test card using the plastic dropper provided according to the figure.

- Add two (2) drops of Sample Diluent to the sample well immediately after the specimen is added.
- Interpret test results at 15 minutes.



For test strips:

- Dispense 1 drop (10 μ l) of serum or plasma to the upper edge of the sample pad of the test strip using the plastic dropper provided according to the figure.
- Add two drops of Sample Diluent to the lower edge of the sample pad after the specimen is added.
- Interpret test results at 15 minutes.



Notes:

- The positive results could appear as soon as 1 minute for a sample with high levels of *H-pylori* antibodies.
- Do not interpret result after 20 minutes.

READING THE TEST RESULTS

- Positive:** Both purplish red test band and purplish red control band appear on the membrane. The lower the antibody concentration, the weaker the test band.

2. *Negative:* Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3. *Invalid:* There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

ACCURACY

1. The accuracy of Rapid H-pylori test was evaluated in comparison to biopsy results of human specimens. Out of the three hundred and fifty-seven (357) samples, three hundred and twenty-three (323) test results agreed with the biopsy result. Thirty-four (34) samples gave different results.
2. Out of the thirty four (34) different test results, eighteen (18) samples obtained positive results with Rapid H-pylori test and positive biopsy results. A commercial EIA kit was used to reanalyze the discrepant samples. Out of the eighteen (18) positive, three (3) were negative. Out of sixteen (16) H-pylori negative test results, one (1) was negative, four (4) were indeterminate and eleven (11) were positive when tested in comparison with an EIA kit. The biopsy sample comparison results are summarized in table.

	Positive	Negative	Total
Biopsy Positive	219	16	235
Biopsy Negative	18	104	122
Total	217	120	357

- This comparison study results gave a sensitivity of 93.2% (219/235), a specificity of 85.2%(104/122), and a total agreement of 90.5%(323/357).
- The relatively low specificity of the serological test results in comparison to the biopsy results may be partially attributed to a sampling error of the biopsy test.

LIMITATIONS

1. Only samples that are clear and with good fluidity can be used in this test.
2. Fresh samples are best, but frozen samples can be used. If a sample has been frozen, it should be allowed to thaw in a vertical position.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

BIBLIOGRAPHY

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4. Parsonnet, J., Friedman, G. D. Daniel, M.S., et al. (1991) *Helicobacter pylori* infection and the risk of gastric carcinoma. *New Engl J Med* 325:1127-1131.
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