Ana-Chek® H. PYLORI ANTIBODY (IgG/IgM)

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC11

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

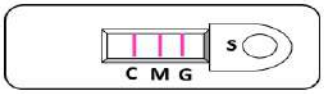
INTENDED USE: Test for qualitative detection of Helicobacter pylori IgG/IgM in human serum and plasma.

CLINICAL SIGNIFICANCE

Gastritis and peptic ulcers are one of the most common human diseases. Since the discovery of H. pylori, many reports have suggested that this organism is one of the main causes of ulcer diseases and stomach cancer. The eradication of H. pylori has been associated with elimination of ulcer diseases. The detection of the specific IgG antibodies to H. pylori has been shown to be an accurate method for detection of H. pylori infection in symptomatic patients.

PRINCIPLE

Ana-Chek® H. pylori IgG/IgM Rapid Test has 3 pre-coated lines on the surface of the membrane. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.



Anti-IgG and Anti-IgM antibodies coated on the test line 1 & 2 respectively. If sample contains antibody, it reacts with gold conjugated nanoparticle and flow on the membrane, where it will be captured by membrane coated antibodies depend on IgG or IgM type by developing purple colour on test line.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Instructions for use.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from sealed pouch just before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance to GLP.
6. Follow the testing procedure exactly as mentioned in the insert.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8 °C for up to 3 days. For long-term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/plasma specimen into the sample well marked "S".
3. Add 2 drop of assay buffer to the sample well.
4. As the test begins to work, you will see red color move across the result window in the center of the test device.
5. Interpret test results at 15-20 minutes.

Note: Do not interpret the result after 30 minutes.

INTERPRETATION OF THE RESULTS

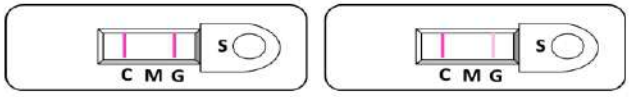
NEGATIVE RESULT:

One colour line appears in the control region (C). No apparent coloured line appears in the IgG and IgM region. Retest in 3-5 days if H. pylori bacteria is suspected.

POSITIVE RESULT:

IgG Positive:

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to H.pylori. This is indicative of secondary or previous infection of H.pylori bacteria.

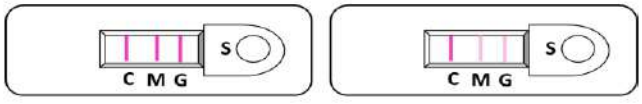


IgM Positive:

The control line (C) and the IgM line (M) are visible on the test device. This is positive for IgM antibodies to H.pylori. This is an indication of a primary infection of H.pylori bacteria.

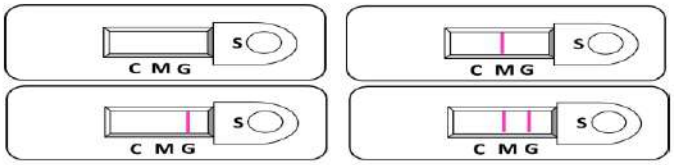
IgG and IgM Positive:

The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary infection of H. pylori bacteria.



INVALID TEST:

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.



LIMITATIONS OF THE TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to H. pylori bacteria in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Ana-Chek® H. pylori IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to H. pylori bacteria in human serum or plasma. The intensity of the test band does not correlate with antibody titre of the specimen.
3. A negative result for an individual subject indicates absence of detectable H. pylori bacteria antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with H. pylori bacteria.
4. This test is for single use only. Do not reuse the test.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required. Control standards 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.

BIBLIOGRAPHY

1. Anderson, L.P., Nielsen, H. (1993) Peptic ulcer: an infectious disease? Ann. Med. 25, 563 - 568.

2. Evans, D.J., Evans, D.G., Graham, D.Y., Klein, P.D. (1989) A sensitive and specific serologic test for detection of Campylobacter pylori infection. Gastroenterology 96, 1004 - 1008.

3. Hunt, R.H., Mohamed, A.H. (1995) The current role of Helicobacter pylori: eradication in clinical practice. Scan. J. Gastroenterol. 30 suppl 208, 47 - 52.

4. Lambert, J.R., Lin, S.K., Aranda-Michel, J. (1995) Heliocobacter pylori. Scan. J. Gastroenterol. 30 suppl 208, 33 - 46.

Symbol	Explanation	Symbol	Explanation
	Manufactured By	IVD	In Vitro Diagnostic Use
LOT	Lot Number		Read Instructions Before Use
REF	Catalogue Number		Storage Temperature
	Manufacturing Date	Σ	Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE