ImmunoScience INDIA

ImmunoQuick

H.Pylori

Rapid H.Pylori Antibodies Detection Test– Device

A test for detection of H. Pylori Antibodies Test in Serum/plasma/ whole blood

For Self - Testing &*In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

Helicobacter pylori are a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.

INTENDED USE

The H. Pylori Ab. test is a rapid chromatographic immunoassay for the qualitative detection of antibody to Helicobacter pylori in serum or plasma or whole blood. This is for healthcare professional use only.

PRINCIPLE

The product consists of recombinant H. pylori Antigen immobilized in the test line region of the device and a colloidal gold conjugate pad containing recombinant H. Pylori Ag conjugated to gold nanoparticles. When sample and buffer is applied, the positive sample reacts with H. pylori antigen-coated particles that have been applied to the conjugate pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized H. pylori Antigen coated on NCM. If the sample contains H. pylori antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain H. pylori antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS OF KIT

1. Test Device with desiccant
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. StopWatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C.Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be takeninternally.
8. Do not eat the desiccant in thepackage.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to anincorrectdiagnosis.

SPECIMEN COLLECTION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted or contaminated blood samples should not be used for performing the test.

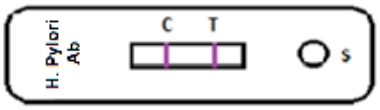
TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.30µl) serum/plasma or two drops (Approx.60µl) whole blood sample in sample 'S' well by using dropper.
5. Add 1 drop of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: If only colored line appears at control region 'C' and no line appears at test region T, then sample is H. PYLORI Ab negative.

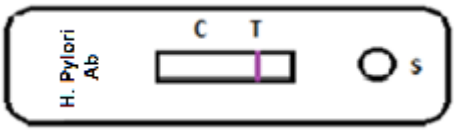
Positive: A distinct colored line appears at control region 'C' and at the test region 'T', then specimen is H. PYLORI Ab positive.

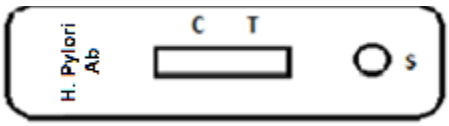


Invalid: Test should be considered invalid and repeat the test using fresh test if

No line appears at control side 'C' and line appears only at test side 'T'.

No line appears at control side 'C' and test side 'T'.





NOTE:

The intensity of the color in the test line region (T) will vary depending on the levels of the antibody in the specimen. However, neither the quantitative value nor the rate of increase in level of antibody in the specimen can be determined by this qualitative test. Positive results may appear as early as five minutes. Negative results must be confirmed only at the end of 15 minutes.

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LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

PERFORMANCE CHARACTERISTICS

Total 172 samples were evaluated for specificity& sensitivity. sensitivity was found to be 100% (51/51) and relative specificity was found 100% (121/121).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with tested samples.

Sample	Rapid H.Pylori Ab.Detection Test- Device		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	51	0	51	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	21	0	21	No cross reactivity observed			
Total	51	121	51	121	-			

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product.Thisproduct is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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