AG-H.PYLORI ANTIBODY RAPID TEST KIT

INTENDED USE

AstraGene's H. Pylori antibody Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in human whole blood, serum, or plasma to aid in the diagnosis of *H. pylori* infection.

PRINCIPLE

AstraGene's H. Pylori antibody Rapid Test Kit is a qualitative membrane-based immunoassay for the detection of H. pylori antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with H. pylori antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains H. pylori antibodies, a coloured line will appear in the test line region indicating a positive result. If the specimen does not contain H. pylori antibodies, a coloured line will not appear in this region indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette and Desiccant	10 Cassette	Cassette
Dropper	10 Nos	1 No.
Buffer	1 No.	1 No.
Instruction for use	1 Nos	1 No.

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/HPYAb/24/01	AG/RTK/HPYAb/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Centrifuge
- Lancet
- Pipette
- Latex gloves

STORAGE &STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- The H. pylori Antibody Rapid Test can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.

To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
- Touch the end of the capillary tube to the blood until filled to approximately 75 uL. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
- Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
- Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.

2. Place the cassette on a clean and level surface.

For Serum or Plasma specimen:

- Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 uL) to the specimen well of test Cassette and start the timer. See illustration below.

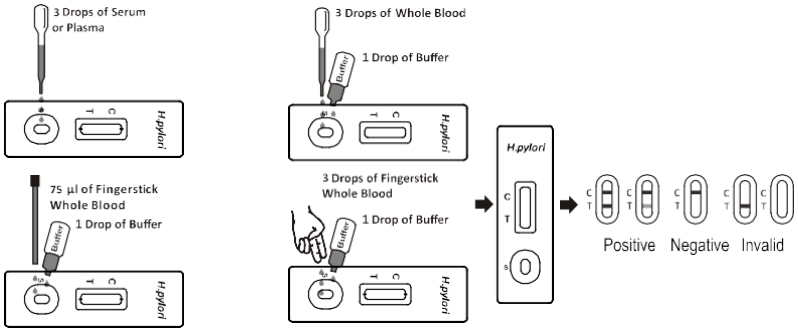
For Venipuncture Whole Blood specimen:

- Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 uL) to the specimen well, then add 1 drop of buffer (approximately 40 uL), and start the timer. See illustration below.

For Fingerstick Whole Blood specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 75 uL of fingerstick whole blood specimen to the specimen area of test cassette, then add 1 drop of buffer (approximately 40 uL) and start the timer. See illustration below.
- To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 ul) to fall into the specimen area of test cassette, then add 1 drop of buffer (approximately 40 uL) and start the timer. See illustration below.

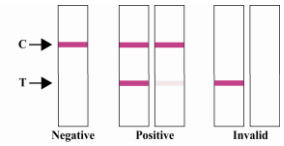
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



RESULT INTERPRETATION

Positive

A clear control band (C) and a detectable test band (T) appears, indicating a positive result.



Negative:

A band appears only at the control region (C), indicating a negative result

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number

SPECIFICITY & SENSITIVITY

The sensitivity of the AstraGene's H.Pylori antibody Rapid Test Kit is 97.1% and the specificity is 99.0% relative to ELISA.

LIMITATION OF THE PROCEDURE

- AstraGene's H. Pylori antibody Rapid Test Kit 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 value nor the rate of increase in H. pylori antibody concentration can be determined by this qualitative test.
- AstraGene's H. Pylori antibody Rapid Test Kit will only indicate the presence of H. pylori antibodies in the specimen and should not be used as the sole criteria for the diagnosis of H. pylori infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.

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WARNING AND PRECAUTION

- 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 all specimens as if they contain 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 specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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