Rapid Urease Test

IVD CE

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【For the qualitative detection of the presence of HP from the biopsy of the gastric mucosa】

INTENDED USE

The Rapid Urease Test kit is used to detect Helicobacter pylori in the gastric mucosa or tartar. Helicobacter pylori Hp is one of the common pathogenic bacteria that enters the digestive tract through the mouth and is a major causative factor in chronic gastritis and peptic ulcers. Detection of this bacterium for the diagnosis, treatment and prevention of chronic gastritis, peptic ulcer has become a clinical need.

PRINCIPLE

Helicobacter pylori can secrete a large amount of highly active urease, urease decomposes urea in the matrix, the pH value increases, and the indicator discoloration is used to detect Helicobacter pylori in gastric mucosal tissue or tartar.

COMPONENTS

MATERIALS PROVIDED

Rapid Urease Test Strip
Package Insert

PRECAUTIONS

1. Do not use after expiration date.
2. Test strip should remain sealed until ready for use. Do not use if pouch is damaged or opened.
3. Read this package insert carefully before performing the test.
4. Do not re-use the test strip.
5. Do not touch the membrane.
6. Do not eat the desiccant in the pouch.

STORAGE AND STABILTY

*The kit should be stored at 2-30℃ until the expiry date printed on the sealed pouch. Expiration date of this kit is 24 months after its manufacture date.
*The test must remain in the sealed pouch until use.
*Do not freeze.
*Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMENS COLLECTION

In the gastroscopy room, small pieces of gastric mucosal tissue are taken with a gastroscope or a mung bean-sized amount of tartar is taken before food and before brushing

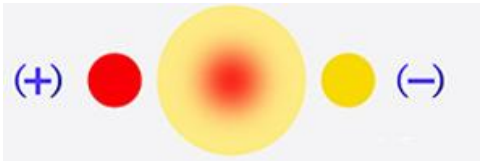
ASSAY PROCEDURE

1. Tear open the aluminum foil bag, take out the test strip, and find the position of the color block;
2. Fresh biopsy of gastric mucosal tissue or tartar is placed in a reaction region.;
3. Observe the discoloration degree of the color block after 5 minutes;
4. Compare with the standard color card to judge the result.

The color block

INTERPRETATION OF RESULTS

1. **Negative**: the test strip has no obvious color change, keep yellow-brown.
2. **Positive**: The color of the strip around the sample changes from yellowish brown to red or purplish red.



Positive Negative

Background Negative Weakly positive Positive Strong positive

During the operation, when there is acid and alkali pollution, it has an impact on the test results, and the operation and inspection should be carried out under clean conditions. When in doubt about test results, microbial culture identification should be performed.

PERFORMANCE

1. Appearance: Reaction area should be yellow-brown.
2. Repeatability: 10 tests were performed on the detection strip, and the results were all positive.
3. Blank test: When the blank test is performed on the detection strip, the reagent should have no color change.
4. Sensitivity test: 78mg/L urease was used to detect the reagent, and the reagent was positive and red.
5. The compliance rate of negative reference products is 100%.
6. Stability: The stability of the detection reagent is 24 months.

LIMITATIONS

1. The color change should be subject to 5 minutes, more than 5 minutes will cause many false positives
2. The test strip is one-time and cannot be used repeatedly.
3. The test strip is easy to fail in humidity and high temperature, and should be used as soon as possible after taking it out.
4. When the indoor temperature is lower than 10 °C, it should be placed for 10 minutes for observation, and if it is weakly positive, it can be extended to 30 minutes after observation.

MANUFACTURER

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EC REP EUROPEAN REPRESENTATIVE

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between	LOT	Batch number
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests
EC REP	European representative	CE	CE Mark

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