USERS INSTRUCTIONS

UU TUBE

by INDICAID™ 妥析™

Helicobacter Pylori Antigen Test

(LATEX MICROSPHERES)

CE

Read all instructions carefully before performing the test.

Failure to follow the instructions may result in inaccurate test results.

INTENDED USE

The Helicobacter Pylori Antigen Test is used for qualitative detection of the Helicobacter pylori antigen in human stool specimens in vitro. This product is used for diagnosis of Helicobacter pylori infection.

TEST PRINCIPLE

The Helicobacter Pylori Antigen Test (Latex Microspheres) uses double antibody sandwich method. The reagent contains the mouse anti-Hp antibody (VacA antigen epitope) pre-immobilized in the test region (T) of the membrane. The sheep anti-mouse IgG and streptavidin are pre-immobilized in the control region (C), as well as the latex-labeled mouse anti-Hp antibody and latex-BSA-biotin conjugates coated on the polyester membrane.

During the test, the liquid flows into the tube and then is chromatographed upwards due to the capillary effect. If the specimen contains Hp antigen, it will first form the antigen-antibody complexes with latex-labeled mouse anti-Hp antibody coated on the polyester membrane, and then it will be captured by the mouse anti-Hp antibody immobilized in the test region (T) when passing through, a red line will appear in the test region (T), which is identified as positive. If the specimen does not contain Hp antigen, the double-antibody sandwich complex will not be formed in the test region (T) and therefore no red line will appear in the test region (T), which is identified as negative. Regardless of the presence of Hp antigen in the specimen, the latex-BSA-biotin will be bound by the streptavidin immobilized on the membrane during chromatography and a red line will appear in the control region (C). The red line appearing in the control region (C) is the criterion for determining whether the chromatography process is normal, and also serves as the internal control criterion of the reagent.

PACKAGING SPECIFICATIONS

1 test/kit

Contained in Box

1x Individually-wrapped Test Device, Stool Collection Paper, English User Instructions, and Chinese User Instructions

PERFORMANCE INDICATORS

Positive percent agreement (PPA)

The percentage agreement of the positive reference is 100%.

Negative percent agreement (NPA)

The percentage agreement of the negative reference is 100%.

Limit of detection (LoD)

The LoD should not be higher than $3x10^4$ CFU/ml.

Positive detection rate

The clinical strain/clinical specimens of Helicobacter pylori from different regions are tested, and the positive detection rate is 100%.

Accuracy

Ten positive references, twenty negative references and thirteen clinical specimens from different regions are tested, and the accuracy is 100%.

LoD for protein

The LoD for detection of the antigenic protein of the epitope corresponding to the antibody is 125 ng/ml.

Precision

The intra/inter-batch, intra/inter-test day, inter-operator and inter-laboratory precision are evaluated. The negative detection rate of the precision negative reference is 100%, the positive detection rate of the precision low positive reference is over 95%, the positive detection rate of the precision moderate positive reference is 100%, and the difference of color line intensity is ≤1 grade color difference.

Hook effect:

In case of Hp≤ $1x10^8$ CFU/ml, the test result obtained with this product does not have the hook effect.

Analytical specificity

1. Interfering substance

The following substances in the specimen do not influence the test result when their final concentrations are lower than the corresponding values shown in the table below.

Name	Final concentration
Ascorbic Acid	20mg/dl
Fat	500 mg/ml
Bilirubin	60mg/dl
Ranitidine	2mg/g
Omeprazole	2mg/g
Bismuth Potassium Citrate	3 mg/g (equivalent to 1.1 mg/g bismuth)
Mucin	2000 mg/dL
Sodium hydroxide aluminium	20mg/g
White blood cell	10000 cells/ml
Famotidine	2mg/g
Hemoglobin	20 mg/g

2. Cross reaction

This reagent does not cross-react with the following substances at a final concentration of $1x10^7$ CFU/ml.

Pathogen	Strain number	Final concentration
Proteus vulgaris	ATCC6896	$1x10^7$ CFU/ml
Campylobacter je juni	ATCC33291	$1x10^7$ CFU/ml
Escherichia coli	ATCC8739	$1x10^7$ CFU/ml
Candida albicans	ATCC10231	$1x10^7$ CFU/ml
Enterococcus faecalis	ATCC19433	$1x10^7$ CFU/ml
Enterobacter aerogenes	CMCC45103	$1x10^7$ CFU/ml
Klebsiella pneumoniae	CMCC46117	$1x10^7$ CFU/ml
Bacillus subtilis	ATCC6633	$1x10^7$ CFU/ml
Acinetobacter calcoaceticus	ATCC23055	$1x10^7$ CFU/ml
Pseudomonas aeruginosa	ATCC9027	$1x10^7$ CFU/ml
Staphylococcus aureus	ATCC6538	$1x10^7$ CFU/ml
Proteus mirabilis	ATCC35659	$1x10^7$ CFU/ml
Shigella flexneri	ATCC12022	$1x10^7$ CFU/ml
Salmonella choleraesuis	ATCC13312	$1x10^7$ CFU/ml

Clinical Performance

Data from 744 clinical specimens with urea breath test (UBT) results demonstrated that the sensitivity and specificity of the reagent are 96.53% and 99.12% respectively.

Helicobacter Pylori Antigen Test (Latex Microspheres)	Urea breath test (UBT)		
	Positive	Negative	Total
Positive	278	4	282
Negative	10	452	462
Total	288	456	744

Sensitivity(95% CI) 96.53%(0.9371, 0.9832)
Specificity(95% CI) 99.12% (0.9777, 0.9776)
Overall agreement (95% CI) 98.12% (0.9686, 0.9897)

LIMITATIONS OF THE TEST

- This kit is a qualitative test and cannot be used to determine the amount of Helicobacter pylori antigen in the specimen.
- If the human stool specimen is not collected as required, the test result may be inaccurate.
- The test result cannot be used as the only evidence for diagnosis, diagnosis should be made based on the test result and other clinical examination. It is recommended reviewing the suspicious negative test result using other methods.
- The negative test result cannot completely rule out the possibility of a Helicobacter pylori infection.

For any questions, please contact Customer Service at +852 3700 8888 or email to cs@indicaid.com

WARNINGS AND PRECAUTIONS

- Use only the contents provided in the test kit.
- Do not use test kit beyond it's expiration date.
- Do not touch the sampling stick tip.
- Do not reuse. Test components are for single-use.
- Do not use if any of the test kit content or packaging is damaged or opened.
- Leave test device sealed in its pouch until just before use. Once opened, the test device should be used within 1 hour.
- Incorrect operations or insufficient specimen may lead to inaccurate results.
- The test result of this kit should be identified visually. In order to ensure an accurate test result, please do not identify the test result in dim light condition.
- Store at 2-30°C and the shelf life is 12 months. Do not freeze. Avoid direct sunlight.
- The test device should be used at 15-30°C and humidity 20%-90%. The result should be read after 10-20 minutes. Results after 20 minutes are regarded as invalid.
- This test is single-use. The used test device and samples may be potentially infected, and should be properly disposed of in accordance with relevant regulations.
- The package contains desiccant, please do not take it.
- Keep test kit and kit components away from children. There is a risk of chocking or cutting injury if the removable parts (such as sampling stick, the limit block) are swallowed.
- Pregnant women are not recommended to purchase and use this product without the advice of a doctor.
- After the test is completed, it is strictly forbidden to take medicine by yourself based on the test results.
- The test device cannot be tilted during the test process and should always be kept in an upright position.

HOW TO USE

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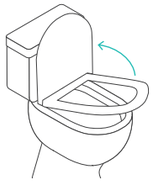
Helicobacter Pylori Antigen Test

(LATEX MICROSPHERES)

CE

Stool samples collection (use of stool collection paper)

1. Lift the toilet seat.



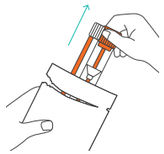
2. Unfold the stool collection paper, tear the double-sided tapes on both ends of the stool collection paper, and stick it onto both sides of the toilet body (ensure that the middle of the stool collection paper hangs above the water surface in the toilet).

3. Put down the toilet seat and carefully press the stool collection paper. Defecate onto the stool collection paper.

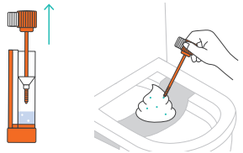
- Specimen type: fresh stool specimen
- Stool sample collected from the same person only
- Both formed and unformed stool can be used
- No requirement for the collection time
- Collected specimens shall not be mixed with water, urine, disinfectants or sewage

Performing your test

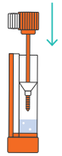
1. After defecation, take out the test device from the packaging



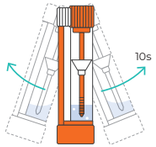
2. Pull off the orange cap on the top of the test device, insert the sampling stick into the stool at 5 different points to collect specimens. The threaded end of the sampling stick must be fully inserted into the stool.
   After collecting the stool, stool collection paper can be washed away directly.



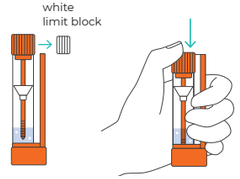
3. Insert the sampling stick back into the test device after sample collection is completed.



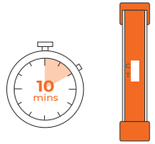
4. Shake the test device leftward and rightward for about 10seconds to fully mix the stool sample into the diluent.



5. Break off the white limit block from the cap, keep the test device in the upright position, press the cap down to the lowest level, and then start timing.



6. Keep the device in room temperature and read the result after 10minutes. (Read the result after 20minutes is invalid).



Refer to the “Interpreting Your Results” section on the right.

INTERPRETING YOUR RESULTS

Positive

A line appears in regions (C) and (T)

Interpretation: The result indicates the presence of Helicobacter Pylori Antigen in the sample. Please contact your doctor, report your test report and receive relevant treatments.

Negative

A line appears in region (C)

Interpretation: The result indicates that no Helicobacter Pylori Antigen is detected in the sample. A negative result does not rule out a Helicobacter Pylori infection, please seek follow-up with your doctor if necessary.

Invalid

No line appears in region (C)

Interpretation: The test could not test whether or not you have the Helicobacter Pylori infection. The test needs to be repeated with a new test kit and a freshly collected sample.

EXPLANATION OF SYMBOLS

- IVD — In vitro diagnostic medical device
- Consult Instructions for use
- CE registration
- Temperature limit
- Keep away from sunlight
- Contains sufficient for <n> tests
- Caution—consult accompanying documents
- Date of manufacture
- Keep away from moisture
- Do not reuse
- LOT — Batch code
- Use-by date
- Manufacturer
- Do not use if package is damaged
- EC REP — Authorized representative in the European Community / European Union

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