Uni-Gold™ H. pylori Antigen

20 Tests
Store Kit at +2 to +30°C

REF 1206650

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

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INTENDED USE

The Trinity Biotech Uni-Gold™ H. pylori Antigen test is a rapid in vitro qualitative assay for the detection of *Helicobacter pylori* antigens in human stool. The detection of stool antigen is intended to aid in the diagnosis of *H. pylori* infection and to monitor response post-therapy in adult patients. Conventional medical practice recommends that tests intended to monitor the *H. pylori* post therapy response should be done at least four weeks after the completion of therapy. As with other *H. pylori* tests, results should be considered in conjunction with the patient history and other laboratory findings.
For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Helicobacter pylori is a gram negative, non-spore forming helical microaerophilic bacterium, found in either the stomach, duodenum or hepatobiliary tract. Cells are motile with either single or multiple flagella. Possible routes of transmission are oral (person to person), animals and contaminated water.[1] *H. pylori* is an important cause of gastritis and peptic ulcers. In North America and Europe, prevalence is 15% in children and 60% in adults. In developing countries infection occurs early in life and most children are infected by the age of 10, while prevalence in adulthood rises to 90%. Infection by *H. pylori* is recognized as the main cause of peptic and duodenal ulcers and a major risk factor for gastric cancer. Acute gastritis may develop within 2 weeks of infection. Many patients have recurrent abdominal symptoms without a peptic ulcer involvement. Over 80% of infected individuals are asymptomatic[2] and have a 10-20% lifetime risk of developing peptic ulcers and a 1-2% risk of stomach cancer[3].

Diagnostic tests for *H. pylori* are categorized as either invasive (endoscopy, biopsy) or non-invasive (urea breath test, serology and stool antigen test). Invasive tests detect active infection, provide high specificity and positive predictive values. However, they have associated (a) risk, (b) patient discomfort, (c) false negative results as infected areas are random and can be missed, and (d) delays, as culture is time consuming[4-8]. Of the non-invasive tests, the urea breath test (UBT) detects the highly active urease of *H. pylori*. Although UBT is highly sensitive and specific, its drawbacks are it (a) is time consuming, (b) requires specialized detection equipment, (c) involves the ingestion of isotopically labeled urea by the patient,[8,9] and (d) drugs that affect urease activity give false negatives with the urea-based tests.

The stool antigen test has been evaluated extensively and is accepted as an accurate non-invasive test both before and after treatment. Conventional medical practice recommends that testing by any method to confirm loss of antigen be done at least four weeks following completion of therapy. The recent Maastricht 4 Consensus Report recommends the use of the stool antigen and UBT tests as an aid in the diagnosis of *H. pylori* disease in the primary care setting.[10]

PRINCIPLE OF THE TEST

Uni-Gold™ H. pylori Antigen rapid test was designed as a rapid lateral flow immunoassay to detect the presence of *H. pylori* antigen in fresh and frozen human stool specimens.

Uni-Gold™ H. pylori Antigen rapid test consists of anti-*H. pylori* antigen antibody coated onto the test line region of the nitrocellulose zone of the test strip and anti-species specific antibodies coated onto the control line region. Anti-*H. pylori* antigen antibody is also conjugated to red latex particles and dried onto inert glass fibre that is inserted into the test strip below the nitrocellulose zone.

H. pylori antigen present in the sample combines with the antibody/latex to form a complex. As this complex migrates up the nitrocellulose strip, it binds to the antibodies in the test region forming a visible pink/red band.

Excess conjugate forms a second pink/red band in the control region of the device. The control line should always appear as a pink/red band in the control region of the device to indicate that the test device is functioning correctly.

REAGENTS

MATERIALS SUPPLIED

- 1206650-D Test devices: 20 devices, each containing a membrane striped with anti-*H. pylori* and anti-species specific antibodies, and pads with dried latex conjugated to anti-*H. pylori* antibodies.
- 1206650-B Dilution buffer: 20 sample diluent vials, each containing 1 mL of buffered solution containing surfactants and preservatives.
- 90-1755 Disposable transfer pipettes: 20 disposable single use pipettes, used to add sample to the sample diluent vial.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Stool specimen collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves
- Uni-Gold™ H. pylori Antigen Control (Cat.# 1206651)

STORAGE AND STABILITY

- Store all components at 2-30˚C.
- Do not freeze or overheat.
- This product should not be used beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Test devices are for single use only. Do not reuse.
- Do not use the test device if the pouch is opened or damaged.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation. Liquid waste should be disposed of in a 1% sodium hypochlorite solution or in accordance with local requirements for disposal of infectious material.
- Dilution buffer solution contains ≤0.1% Azide.
- Do not concentrate specimens before testing.
- Stool specimens preserved in fixatives are not suitable for use.

The safety data sheet is available upon request.
Some components of this kit contain < 0.1% sodium azide.
H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H335: May cause respiratory irritation.
P264: Wash thoroughly with plenty of soap and water after handling.
P270: Do not eat, drink or smoke when using this product.
P280: Wear protective gloves / protective clothing / eye protection / face protection.
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: If swallowed, rinse mouth.
P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
P501: Dispose of contents and container in accordance to local, regional, national and international regulations.

SPECIMEN COLLECTIONS AND TRANSPORT

Human stool specimens collected for routine examination can be used with the Trinity Biotech Uni-Gold™ H. pylori Antigen. Stool specimens should be collected in clean, leak-proof, plastic containers.

- Fresh, untreated stool specimen should be stored at 2-8˚C and tested within 72 hours of collection
- If fresh untreated stool specimens will not be tested within 72 hours of collection, the sample should be stored at -10˚C or lower and tested within 1 month of collection. For longer term storage, please store the sample at -70˚C.
- Avoid multiple freeze-thaw cycles. Stool specimens preserved in fixatives are not suitable for use.

QUALITY CONTROL

Good Laboratory Practice (GLP) recommends the use of control specimens to ensure proper device performance at least once daily. Uni-Gold™ H. pylori Antigen Controls (Cat.# 1206651) are available separately for use only with the Uni-Gold™ H. pylori Antigen. These controls are used to verify correct device performance, operator procedure and result interpretation. The positive control will produce a reactive test result and the negative control will produce a non-reactive test result (refer to the Interpretation of Results section).

It is recommended that positive and negative controls are run:

- By all new operators performing testing on patient specimens.
- With each new kit lot and whenever a new shipment of test kits is received.
- At periodic intervals as specified in the laboratory Quality Assurance program.

Uni-Gold™ H. pylori Antigen Controls must give the expected reactive or non-reactive results. If the test results are not valid repeat the test with a new device. Refer to the Uni-Gold™ H. pylori Antigen Controls package insert (1206651-29EN) for instructions on the use of these reagents. It is the

responsibility of each laboratory using the Uni-Gold™ H. pylori Antigen to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Contact Trinity Biotech should unexpected results occur.

Each Uni-Gold™ H. pylori Antigen device has a built in procedural control that demonstrates assay validity. When a pink/red line appears at the control line position this indicates the device has performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

LIMITATIONS

- Uni-Gold™ H. pylori Antigen must be used in accordance with the instructions in this package insert to obtain an accurate result.
- A negative test result does not exclude the possibility of the presence of *H. pylori* antigen. This may occur when the antigen level in the sample is below the detection level of the test.
- Correlation between the amount of antigen in a sample and clinical presentation has not been established.
- Uni-Gold™ H. pylori Antigen detects *H. pylori* antigen in stool samples. The test cannot be used to derive a relationship between the intensity of the specific visible bands and the occurrence or severity of clinical symptoms.
- The results obtained are intended to aid in diagnosis only. All *in vitro* diagnostics tests must always be interpreted by the clinician in combination with the clinical evaluation, medical history, and/or other laboratory results to properly diagnose patients.
- Reading test results before or after the 15 minute read time may give incorrect results.
- Proper specimen collection and processing are essential to achieving optimal performance of the assay.
- Stool specimens preserved in fixatives are not suitable for use.
- Use one sample preparation per device. Do not "re-run" from the same diluted sample vial. If a sample needs to be "re-run" for any reason, make up another diluted sample preparation.
- Use device immediately after removing from pouch.

TEST PROCEDURE

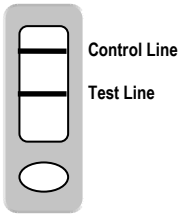
1. Ensure the Uni-Gold™ H. pylori Antigen device and sample diluent are at room temperature (15-30˚C).
2. Sample preparation
   - Ensure all stool specimens are at room temperature (15-30°C) prior to testing.
   - Mix all stool samples thoroughly before removing a portion for testing.
3. Label each sample diluent vial with appropriate patient information.
4. Unscrew the top from the supplied sample diluent vial.
5. Sample addition:
   - Using the top of the sample diluent vial, collect approximately 5-6 mm portion of stool on the end of the applicator stick.
   - For a liquid stool, collect 100 µL with the supplied disposable transfer pipette by filling to the first graduation mark.
   - Note: Too much or too little specimen can lead to erroneous or invalid results.
6. Screw the top with the applicator stick back into the sample diluent vial. If using the disposable transfer pipette add sample from the transfer pipette (total volume from first graduation mark) to the sample diluent vial and then screw on the top.
7. Thoroughly homogenize the sample by vortexing for 15 seconds or manually mixing (stir applicator stick until sample is evenly distributed, screw on top, and homogenize by flicking and/or shaking sample diluent vial).
8. Remove the required number of devices from their individual foil pouches and lay on a clean, flat surface.
9. Label each test device with appropriate patient information.
10. Break off the top of the sample diluent vial and apply 4 free-falling drops of diluted sample to the sample port of the test device. Time the assay from this point.
11. Read assay results immediately at the end of the 15 minute incubation. Do not read results before or after 15 minutes as they may be inaccurate.

INTERPRETATION OF RESULTS

- **Positive Result:**

  Two pink/ red lines of any intensity appear in the device window; at the test line and control line positions. This indicates a reactive result that is interpreted as positive for *H. pylori* antigen.

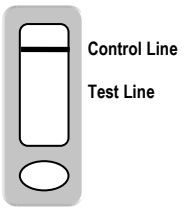
Postive Image



- **Negative Result:**

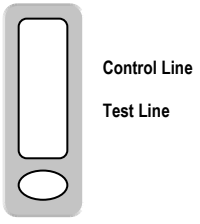
  A single pink/red line of any intensity appears in the device window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for *H. pylori* antigen.

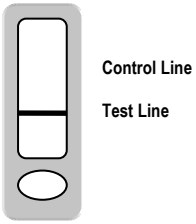
Negative Image



- **Invalid Result:**

  No line appears in the device window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the device window at the test line position. If either condition below occurs, the test should be repeated with a new device.





PERFORMANCE CHARACTERISTICS

The performance of Uni-Gold™ H. pylori Antigen was evaluated on 468 retrospective stool samples at a clinical laboratory and an in-house site.

Clinical Sensitivity & Specificity

Retrospective Study
The sensitivity and specificity of the test was compared against a commercially available EIA test with retrospective samples as shown in the following table.

Uni-Gold™ H. pylori Antigen		*H. pylori* Antigen EIA	
		(+) Positive	(-) Negative
Uni-Gold™	(+) Positive	218	12
	(-) Negative	16	222
	Total	234	234

Sensitivity: 93% (218/234) 95%CI 88.9-95.9%
Specificity: 95% (222/234) 95%CI 90.5-96.9%

Concordance Study
Uni-Gold™ H. pylori Antigen was compared to a commercially available lateral flow test on 468 retrospective stool samples. The percent agreement of Uni-Gold™ H. pylori Antigen versus the commercially available comparator device was as follows:

Uni-Gold™ H. pylori Antigen		Comparator Device	
		(+) Positive	(-) Negative
Uni-Gold™	(+) Positive	201	29
	(-) Negative	6	232
	Total	207	261

Overall Agreement: 93%
Of the 35 samples, where there wasn't agreement between Uni-Gold™ H. pylori Antigen and the comparator device, Uni-Gold™ H. pylori Antigen agreed with the confirmatory EIA result for 26 of the 35 samples.

Expected Values
The performance of the Uni-Gold™ H. pylori Antigen was evaluated at internal and external laboratories. Samples were collected from Hospitals in the Southwest of the US and Western Europe and consisted of both male and female patients, of all ages, who were suspected of gastritis and/or *H. pylori* infections. The retrospective study included 234 positive samples and 234 negative samples confirmed by EIA. There were no differences observed in clinical performance between males or females.

Analytical Sensitivity:
The limit of detection was determined by spiking serial dilution of whole cell lysate of *H. pylori* (ATCC strain 43504) into stool to determine the lowest concentration that produced a positive result. A limit of detection of 137.5 ng/mL was determined for Uni-Gold™ H.pylori Antigen.

Cross Reactivity.
No cross-reactivity was observed with negative samples containing the following organisms at a concentration of 10^7 cfu/mL or more for bacteria and 10^6 pfu/mL or more for viruses:

Adenovirus serotype 40	*Enterobacter cloacae*	*Pseudomonas aeruginosa*
Adenovirus serotype 3	*Enterococcus Faecalis*	*Rotavirus*
Aeromonas hydrophila	*Enterococcus faecium*	*Serratia liquefaciens*
Bacillus cereus	*Escherichia coli(2)*	*Shigella boydii*
Bacillus substilis	*Escherichia coli Ser026*	*Shigella flexneri*
Campylobacter coli	*Escherichia coli H10407*	*Shigella sonnei*
Coxsackievirus Strain B3	*Escherichia fergusonii*	*Staphylococcus aureus (2)*
Cytomegalovirus Strain AD169	*Klebsiella pneumoniae (2)*	*Staphylococcus epidermis*
Echovirus Serotype 20	*Proteus penneri*	

Interfering Substances

The analytical specificity of the test was determined in stool samples containing potentially interfering substances at clinically relevant concentrations. Compounds were respectively spiked into positive and negative samples at medically relevant dosages (treatment). All treatments, including the unspiked (neat) positive and unspiked (neat) negative samples were tested across multiple samples with Uni-Gold™ H.pylori Antigen. The following compounds were tested:

Human whole blood (50% v/v)	Mucin (3.5% w/v)
Imodium A-D (Loperamide HCl) (5% v/v)	Barium Sufphate (5%w/v)
Kaopectate (Attapugite) (5% v/v)	Sennosides (5% w/v)
Pepto-Bismol (Bismuth) (5% v/v)	Aspirin (5% w/v)
Hydrocortizone (5% w/v)	Ibuprofen (5% w/v)
Phenylephrine (5% w/v)	Acetaminophen (5% w/v)
PBS (5% v/v)	Tums (Calcium Carbonate) (0.5% w/v)
Stool fat (Stearic Acid 5% w/v)	Mylanta (Al & Mg Hydroxide) (0.5% v/v)
Hemoglobin (12.5% w/v)	Naproxen Sodium (0.05% w/v)
Leukocytes (3.5% w/v)	

No test interference was observed by any of the compounds at the concentrations tested above.

Reproducibility Study
Reproducibility testing was carried out at three sites on twelve blinded samples (varying positive and negative samples) by two operators, twice daily for three days. 99.7% of the samples tested for *H. pylori* produced the expected results.

REFERENCES

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9. Graham DY, Malaty HM, Evans DG et al. Epidemiology of *Helicobacter pylori* in an asymptomatic population in the United States. Effect of age, race, and socioeconomic status. Gastroenterology 1991;100:1495-1501.
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ORDERING INFORMATION

Cat. No.	Item	Quantity
1206650	Uni-Gold™ H.pylori Antigen	20 test devices
1206651	Uni-Gold™ H.pylori Antigen Control	1 Positive and 1 Negative

GUIDE TO SYMBOLS

	Consult Instructions for Use
REF	Product Number
LOT	Lot Number
IVD	*In Vitro* Diagnostic Medical
	Use By
	Caution, consult accompanying documents
	Temperature limitation
	Manufacturer

EC REP Trinity Biotech plc.
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