



QuickVue[®] TLI

H. pylori Stool Antigen TEST

CLIA Complexity: MODERATE

For *in vitro* diagnostic use.

IVD

Rx ONLY

For Canadian Users: For Laboratory Use Only

A symbols glossary can be found at quidel.com/glossary.



INTENDED USE

The QuickVue TLI H. pylori Stool Antigen Test is a rapid membrane enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in a single use cassette. It is intended for use with human fecal specimens to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* antigen following treatment. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media from patients suspected of *H. pylori* infection. Testing of patients to demonstrate loss of *H. pylori* antigen following treatment should be performed no sooner than 4 weeks after completion of the treatment regimen. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms. **Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.**

EXPLANATION

It is estimated that half of the global population is infected with *H. pylori*.¹ The majority of those infected remain asymptomatic and do not require treatment (colonized individuals). A minority of infected individuals develop gastritis, and a fraction of those further develop gastric ulcers or gastric cancer.² The diagnosis of *H. pylori* infection is endoscopy with biopsy – the biopsied tissue is tested for the presence of *H. pylori* by culture, histology, or rapid urease test. Under current guidelines, endoscopy is still recommended for the diagnosis of *H. pylori* infection in patients with alarm symptoms (e.g. GI bleeding, sudden weight loss, excessive vomiting, anemia), or patients over the age of 55. However, for younger patients not exhibiting alarm symptoms, non-invasive tests such as the urea breath test (UBT) or fecal antigen test are recommended for diagnosis of *H. pylori* infection.^{3,4} Following completion of a treatment regimen of antibiotics and a proton pump inhibitor (PPI), it is recommended that patients be tested to verify eradication of *H. pylori* infection.⁵ Serum antibody tests are also available, but these are unable to distinguish between past and current infection. By detecting antigen present in fecal specimens, the QuickVue TLI H. pylori Stool Antigen Test allows for the non-invasive detection of *H. pylori* when endoscopy is not required.

PRINCIPLE OF THE TEST

The QuickVue TLI H. pylori Stool Antigen Test utilizes antibodies specific for *H. pylori* antigen. The *Membrane Device* contains a *Reaction Window* with two vertical lines of immobilized antibodies. The test line (“T”) contains antibodies specific for *H. pylori* antigen. The control line (“C”) contains antibodies to horseradish peroxidase (HRP). The *Conjugate* consists of antibodies to *H. pylori* antigen coupled to horseradish peroxidase. To perform the test, the sample is added to a tube containing a mixture of *Diluent* and *Conjugate*. The diluted sample-conjugate mixture is added to the *Sample Well* and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, any *H. pylori* antigen in the sample

binds to the antibody-peroxidase conjugate. The antigen-antibody-peroxidase complexes migrate through a filter pad to a membrane where they are captured by the immobilized anti-*H. pylori* antigen antibodies in the test line. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10-minute incubation period, the *Reaction Window* is examined visually for the appearance of vertical blue lines on the “C” and “T” sides of the *Reaction Window*. A blue line on the “T” side of the *Reaction Window* indicates a positive result. A positive “C” reaction, indicated by a vertical blue line on the “C” side of the *Reaction Window*, confirms that the sample and reagents were added correctly, the reagents were active at the time of performing the assay, and that the sample migrated properly through the *Membrane Device*. It also confirms the reactivity of the other reagents associated with the assay.

MATERIALS PROVIDED

<i>Membrane Devices</i> – 25, each pouch contains 1 device	MEM DEV
<i>Conjugate</i> (2.5 mL) – Antibody specific for <i>H. pylori</i> antigen coupled to horseradish peroxidase in a buffered protein solution (contains 0.05% ProClin® 300)*	CONJ ENZ
<i>Diluent</i> (22 mL) – Buffered protein solution with black graduated dropper assembly (contains 0.05% ProClin® 300)*	DIL SPE
<i>Positive Control</i> (2 mL) – <i>H. pylori</i> antigen in a buffered protein solution (contains 0.05% ProClin® 300)*	CONTROL +
<i>Substrate</i> (3.5 mL) – Solution containing tetramethylbenzidine	SUBS REAG
<i>Wash Buffer</i> (12 mL) – Buffered solution with white graduated dropper assembly (contains 0.05% ProClin® 300)*	WASH REAG
Disposable plastic transfer pipettes (50) – Graduated at 25 µL, 100 µL, 200 µL, 300 µL, 400 µL and 500 µL	
Wooden applicator sticks (50)	

*(contains 0.05% ProClin® 300)

Signal Word: Warning

H317: May cause an allergic skin reaction

P261, P272, P280, P302, P352, P333, P313, P321, P362, P364, P501



MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

- Small test tubes (e.g., plastic 2 mL conical microcentrifuge tubes)
- Vortex mixer
- Disposable gloves
- Timer

SHELF LIFE AND STORAGE

The expiration date of the kit is given on the kit box label. Expiration dates for each component are listed on the individual labels. Store the kit between 2°C and 8°C. Return the kit to the refrigerator as soon as possible after use.

PRECAUTIONS

1. Rx Only – Prescription Only
2. Each component in the kit should be inspected for any signs of leakage. Upon arrival, inspect the kit to ensure that components are not frozen or warm to the touch due to improper shipping conditions.
3. The *Substrate* reagent should be colorless. If the *Substrate* reagent changes to a dark blue/violet color, discard and call Technical Services for a replacement.
4. Reagents from different kits should not be mixed or interchanged. Do not use a kit past the expiration date.

5. Caps, tips and dropper assemblies are color-coded; do NOT mix or interchange!
6. Bring all components to room temperature before use to ensure proper kit reactivity. Remove the reagents from the foam insert to reduce the time needed to warm to room temperature.
7. Do not freeze the reagents. The kit should be stored between 2°C and 8°C.
8. The pouch containing the *Membrane Device* should be at room temperature before opening. Keep the *Membrane Devices* dry before use.
9. Hold reagent bottles vertically to dispense reagents to ensure consistent drop size and correct volume.
10. Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes if removing aliquots from reagent bottles.
11. *Membrane Devices* cannot be reused.
12. The test has been optimized for sensitivity and specificity. Alterations of the specified procedure and/or test conditions may affect the sensitivity and specificity of the test. Do not deviate from the specified procedure.
13. The validity of the test results using the QuickVue TLI H. pylori Stool Antigen Test is dependent upon the proper reaction of the internal and external controls. See the Quality Control section.
14. Fecal specimens and used membrane devices may contain potentially infectious agents and should be handled at “*Biosafety Level 2*” as recommended in the CDC/NIH Manual “*Biosafety in Microbiological and Biomedical Laboratories.*” Wear disposable gloves when performing the test.
15. Reagents contain 0.05% ProClin® 300 as a preservative. Although the concentration is low, ProClin® 300 is known to be harmful. If skin irritation or rash occurs, get medical advice/attention. Take off contaminated clothing and wash it before reuse. Handle reagents according to existing regulations for laboratory safety and good laboratory practice.
16. Follow your national, regional, and local ordinances accordingly for waste disposal regulations. Do not place in trash, dispose of as hazardous waste.
17. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) available from Technical Support at technicalsupport@quidel.com.

COLLECTION, HANDLING, AND STORAGE OF FECAL SPECIMENS

Acceptable Sample Type	Do Not Use
Fresh Fecal Specimens	Fecal Specimens in Formalin-based fixative (e.g., sodium acetate formalin, 10% formalin)
Frozen Fecal Specimen	Fecal Specimens in alcohol-based fixative (e.g., polyvinyl alcohol)
Specimens in Transport Media (Cary Blair, C&S)	Concentrated Fecal Specimens

Storage Condition	Recommended Storage Time
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 2°C and 8°C	96 hours
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 20°C and 25°C	96 hours
Frozen Unpreserved Samples Stored at ≤ -10°C	14 days

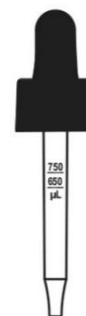
1. Use standard in-house collection and handling procedures for fecal specimens. Collect fecal specimens in clean, leak-proof containers.
2. Fecal specimens that are stored frozen may be thawed up to 2 times. If using frozen specimens, thaw at room temperature.

- Do not store fecal specimens in the *Diluent*.
- Do not allow the fecal specimens to remain in the *Diluent/Conjugate* mixture for >2 hours.

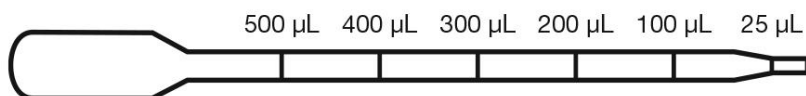
TEST PROCEDURE

- Be attentive to the total assay time when testing more than one fecal specimen.
- Bring all reagents and devices to room temperature before use. Remove the reagents from the foam insert to reduce the time needed to warm to room temperature.
- Set up and label one small test tube for each specimen and optional external control.**
- Using the black graduated dropper assembly, add 750 μL of *Diluent* to each tube for fresh and frozen specimens, and external controls. For specimens in Transport Media (Cary Blair, C&S), add 650 μL of *Diluent* to each tube.**

Sample Type	Volume of <i>Diluent</i>
Fresh Fecal Specimens	750 μL (2 nd graduation from tip)
Frozen Fecal Specimens (frozen undiluted)	750 μL (2 nd graduation from tip)
External Controls (positive and negative)	750 μL (2 nd graduation from tip)
Specimens in Transport Media (Cary Blair, C&S)	650 μL (1 st graduation from tip)



- Add one drop of *Conjugate* (red capped bottle) to each tube.** Gently mix the *Conjugate* in the bottle by inverting several times prior to addition. Hold the dropper bottle vertically to ensure proper drop size. The *Diluent* and *Conjugate* should be added to all tubes prior to adding the specimens.
- Obtain one disposable plastic transfer pipette (supplied with the kit) for each sample.
Graduated Transfer Pipette:



- For Liquid/Semi-Solid Specimens** – Mix specimen thoroughly. Using a transfer pipet, add 25 μL of specimen to the *Diluent/Conjugate* mixture in the tube.

For Formed/Solid specimens – Mix specimen thoroughly using a wooden applicator stick and transfer a small portion (approximately 2 mm diameter, the equivalent of 25 μL) of the specimen into the *Diluent/Conjugate* mixture. Emulsify the specimen using the applicator stick.

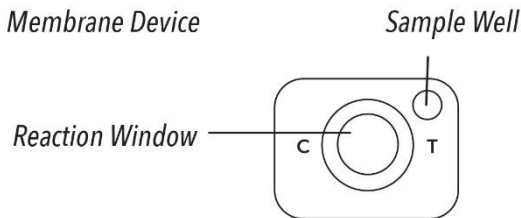
For specimens in transport media (Cary Blair or C&S) – Using a transfer pipette, transfer 100 μL of specimen into the *Diluent/Conjugate* mixture.

Note: Transferring too little sample, or failure to mix and completely suspend the sample in the *Diluent/Conjugate* mixture, may result in a false-negative test result. The addition of too much sample may cause invalid results due to restricted flow.
- Optional External Controls:**

External Positive Control – add one drop of *Positive Control* (gray-capped bottle) to the appropriate test tube.

External Negative Control – add 25 μL *Diluent* to the appropriate test tube.

- For all test and control samples, close the tubes and mix thoroughly using a vortex mixer or by inverting the tube several times. Samples or controls diluted in the *Diluent/Conjugate* mixture may be incubated at room temperature up to 2 hours prior to addition to the *Membrane Device*.
- Open one room temperature *Membrane Device* pouch for each diluted specimen and external control (as necessary). Label each device appropriately and orient it on a flat surface so that the small *Sample Well* is located in the top right corner of the device.



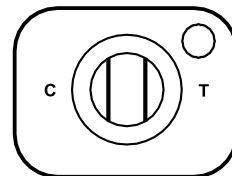
- Make sure that each diluted sample is thoroughly mixed (See Step 9) before adding to the *Membrane Device*. Using a new transfer pipette, transfer 500 μL (topmost graduation) from each tube into the *Sample Well* (smaller hole in the top right corner of the device) of a *Membrane Device*.** When adding the sample into the *Sample Well*, make sure that the tip of the transfer pipette is inside the *Sample Well* hole and angled towards the *Reaction Window*. Expel the diluted sample onto the wicking pad inside the *Membrane Device*.
- Incubate the device at room temperature for 15 minutes** – the sample will wick through the device and a wet area will spread across the *Reaction Window*. The 15-minute incubation step begins after the last diluted sample-conjugate mixture has been transferred to the last *Membrane Device*.
NOTE FOR SAMPLES THAT FAIL TO MIGRATE:
*Occasionally, a diluted sample fails to migrate properly and the Reaction Window does not fully wet. If the Reaction Window does not appear to be completely wet within 5 minutes of adding the sample to the Sample Well, then add 100 μL (4 drops) of Diluent to the *Sample Well* and wait an additional 5 minutes (for a total of 20 minutes). Continue with the next step of the Test Procedure.*
- After the incubation, add 300 μL of Wash Buffer to the central *Reaction Window* using the graduated white dropper assembly). Allow the Wash Buffer to be absorbed completely.**
- Add 2 drops of Substrate (white-capped bottle) to the central *Reaction Window*.**
- Incubate 10 minutes at room temperature. Read visually and record results after the incubation.

INTERPRETATION OF RESULTS

Interpretation of the test is most reliable when the device is read immediately at the end of the reaction, in a well-lit area, and from directly over the device at a normal working distance.

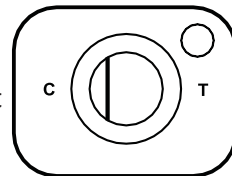
Positive Result

Two vertical blue lines are visible, the Control Line on the “C” (left) side of the *Reaction Window* and the test line on the “T” (right) side of the *Reaction Window*. The lines may appear faint to dark in intensity – any line on the “T” side is considered positive. Do not interpret membrane discoloration as a positive result. A positive result indicates the presence of *H. pylori* antigen, and that there is a properly reactive positive control Line.



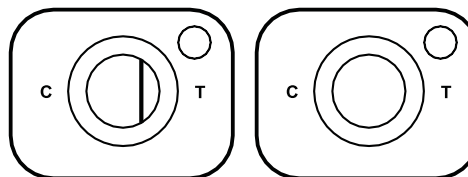
Negative Result

A single vertical blue line is visible on the “C” (left) side of the *Reaction Window* and no test line is visible on the “T” (right) side of the *Reaction Window*. A negative result indicates that *H. pylori* antigen is either absent in the sample or is below the detection limit of the test, and that there is a properly reactive positive control Line.



Invalid Result

A single line is visible on the “T” side of the *Reaction Window*, or no lines are visible in the *Reaction Window*. The test is invalid if a control Line is not present at the completion of the test reaction.



A positive result in the QuickVue TLI *H. pylori* Stool Antigen Test confirms the presence of *H. pylori* antigen in the sample; a negative result indicates the absence of antigen or insufficient levels of antigen for detection.

QUALITY CONTROL

The validity of the test results using the QuickVue TLI *H. pylori* Stool Antigen Test is dependent upon the proper reaction of the internal and external controls. If correct control results are not observed, contact Technical Support.

Internal

A vertical blue Control Line must be visible on the “C” (Control) side of the *Reaction Window* on every *Membrane Device* that is tested. The appearance of the blue control Line confirms that the sample and reagents were added correctly, that the sample migrated properly through the *Membrane Device*. It also confirms the reactivity of the other reagents associated with the assay. A uniform background in the result area is considered an internal negative control.

External

The reactivity of the QuickVue TLI *H. pylori* Stool Antigen Test should be verified on receipt using the *Positive Control* and negative control (*Diluent*). The *Positive Control* confirms the reactivity of the other reagents associated with the assay, and is not intended to ensure precision at the analytical assay cut-off. Additional tests can be performed with the controls to meet the requirements of Local, State and/or Federal regulations and/or accrediting organizations.

LIMITATIONS OF THE QUICKVUE TLI H. PYLORI STOOL ANTIGEN TEST

1. The QuickVue TLI H. pylori Stool Antigen Test is used to detect *H. pylori* antigen in fecal specimens. The test confirms the presence of *H. pylori* antigen in the sample, and this information should be taken under consideration by the physician in light of the clinical history and physical examination of the patient.
2. A negative test result does not preclude the possibility of the presence of *H. pylori* antigen in the specimen which may occur if the level of antigen is below the detection limit of the test.
3. False negative results may occur if a patient has used antibiotics, proton pump inhibitors (PPIs) or bismuth compounds in the 14 days prior to fecal sample collection, as these medications are known to inhibit *H. pylori*. In these cases, a new fecal sample should be collected and tested 14 days after treatment has stopped. Positive results from patients that have used antibiotics, PPIs, or bismuth compounds in the 14 days prior to fecal sample collection are still considered accurate.
4. Transferring too little sample, or failure to mix and completely suspend the sample in the *Diluent/Conjugate* mixture, may result in a false-negative test result. The addition of too much sample may cause invalid results due to restricted flow.
5. The QuickVue TLI H. pylori Stool Antigen Test is qualitative. The intensity of the color should not be interpreted quantitatively.
6. No data exists on the effects of colonic washes, barium enemas, laxatives, or bowel preparations on the performance of the QuickVue TLI H. pylori Stool Antigen Test. These procedures can result in extensive dilution or the presence of additives that may affect test performance.

EXPECTED VALUES

The QuickVue TLI H. pylori Stool Antigen Test detects the presence of *Helicobacter pylori* antigen in human fecal samples. *H. pylori* infection is a global phenomenon with reported prevalence rates in adults ranging from 20% to 95%.¹ In addition to geographical location, factors such as age, ethnicity, and socioeconomic status also affect the prevalence rate.^{6,7} *H. pylori* is purportedly the cause of 70%-85% of gastric ulcers and 90%-95% of duodenal ulcers.⁸ Historically, treatment regimens to eradicate *H. pylori* infection reported success rates ranging from 76%-94%, but the efficacy of standard treatment regimens has declined due to factors such as the increased prevalence of antibiotic resistant *H. pylori* strains.⁹ The effectiveness of eradication therapy can improve significantly when a tailored regimen is prescribed.¹⁰

PERFORMANCE CHARACTERISTICS

The performance of the QuickVue TLI H. pylori Stool Antigen Test was evaluated at 6 independent sites. Patients were recruited that were undergoing endoscopy as part of routine care. A composite reference method (CRM) comparison was used in the evaluation consisting of rapid urease and histology of the biopsy samples. The following table shows a summary of the clinical performance data. The results of the study show that the QuickVue TLI H. pylori Stool Antigen Test exhibited sensitivity of 97.0% and specificity 100% with CRM biopsy results.

Age and Gender Distribution

Age and gender information was available for 122 patients. The ages ranged from 19 to 82 years. Of the 122 patients tested, 68% were female and 32% were male. No difference in test performance was observed based on patient age or gender.

Initial Diagnosis QuickVue TLI H. pylori Stool Antigen Test versus Composite Reference Method (CRM)

N = 122	CRM Positive	CRM Negative
QuickVue TLI H. pylori Stool Antigen Test Positive	32	0
QuickVue TLI H. pylori Stool Antigen Test Negative	1*	89

		95% Confidence Limits
Sensitivity	97.0%	84.7% - 99.5%
Specificity	100.0%	95.9% - 100.0%

* Additional testing with an FDA cleared *H. pylori* stool antigen test provided an antigen negative result.

Post-Therapy

For Eradication (post-therapy), there were 9 samples from patients being tested post therapy. The results show that the QuickVue TLI H. pylori Stool Antigen Test exhibited a sensitivity of 100% with the composite reference method.

N = 9	CRM Positive	CRM Negative
QuickVue TLI H. pylori Stool Antigen Test Positive	9	0
QuickVue TLI H. pylori Stool Antigen Test Negative	0	0

		95% Confidence Limits
Sensitivity	100.0%	70.1% - 100.0%

Retrospective Sample Study

A supplemental retrospective sample study was performed comparing the QuickVue TLI H. pylori Stool Antigen Test to an FDA cleared commercial ELISA. For this study, 200 samples (96 positive and 104 negative by the commercial ELISA) were evaluated. There was 98.9% Positive Agreement and 97.2% Negative Agreement of results between the assays.

N = 200	FDA Cleared Commercial ELISA Positive	FDA Cleared Commercial ELISA Negative
QuickVue TLI H. pylori Stool Antigen Test Positive	93	3*
QuickVue TLI H. pylori Stool Antigen Test Negative	1**	103

		95% Confidence Limits
Percent Positive Agreement	98.9%	94.2% - 99.8%
Percent Negative Agreement	97.2%	92.0% - 99.0%

* *H. pylori* DNA was amplified from the samples with PCR

** No *H. pylori* DNA was amplified from the sample with PCR

REPRODUCIBILITY

The reproducibility of the QuickVue TLI H. pylori Stool Antigen Test was determined using 8 fecal specimens that were coded to prevent identification during testing. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The samples were tested in triplicate twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. The results were as expected among the different locations, and exhibited an overall percent agreement of 100%.

CROSS REACTIVITY

The QuickVue TLI H. pylori Stool Antigen Test was evaluated for cross-reactivity with common intestinal organisms and viruses listed below. None of the organisms or viruses were shown to interfere with the performance of the QuickVue TLI H. pylori Stool Antigen Test.

Acinetobacter baumannii
Bacillus cereus
Bacillus subtilis
Borrelia burgdorferi
Campylobacter coli
Campylobacter fetus
Campylobacter helveticus
Campylobacter hyointestinalis
Campylobacter jejuni
Campylobacter lari
Campylobacter upsaliensis
Candida albicans
Clostridium bifermentans
Clostridium difficile
Clostridium perfringens
Edwardsiella tarda
Enterobacter cloacae
Enterococcus faecalis
Escherichia coli

Adenovirus Types 2, 40
Human Coronavirus
Coxsackievirus B1, B2, B3, B6

Escherichia coli EIEC
Escherichia coli EPEC
Escherichia coli ETEC
Escherichia coli O157:H7 (non-toxigenic)
Escherichia coli O157:H7 (toxigenic)
Haemophilus influenzae
Lactobacillus acidophilus
Listeria monocytogenes
Peptostreptococcus anaerobius
Porphyromonas asaccharolytica
Prevotella melaninogenica
Proteus vulgaris
Pseudomonas aeruginosa
Pseudomonas fluorescens
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus aureus (Cowan's)
Streptococcus agalactiae
Yersinia enterocolitica

Echovirus 9, 22
Enterovirus 70
Human Rotavirus

INCLUSIVITY STUDY

The following strains, which include isolates representing described *H. pylori* populations, were tested for reactivity with the QuickVue TLI H. pylori Stool Antigen Test. All strains tested generated a positive result.

ATCC 700392	JP26
ATCC 43526	ATCC 43504
ATCC 700824	ATCC 43579

INTERFERING SUBSTANCES (U.S. FORMULATION)

The following substances had no effect on positive or negative QuickVue TLI H. pylori Stool Antigen Test results analyzed at the concentrations indicated:

Barium sulfate (5% w/v), Benzalkonium Chloride (1% w/v), Ciprofloxacin (0.25% w/v), Ethanol (1% w/v), Hog gastric mucin (3.5% w/v), Human blood (40% v/v), Hydrocortisone (1% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Leukocytes (0.05% v/v), Maalox® Advanced (5% v/v), Mesalazine (10% w/v), Metronidazole (0.25% w/v), MiraLax® (3350 PEG)(7% w/v), Mineral Oil (10% w/v), Mylanta® (4.2 mg/mL), Naproxen Sodium (5% w/v), Nonoxynol-9 (1% w/v), Nystatin (1% w/v), Palmitic Acid/Fecal Fat (40% w/v), Pepto-Bismol® (5% v/v), Phenylephrine (1% w/v), Prilosec OTC® (5 µg/mL), Sennosides (1% w/v), Simethicone (10% w/v), Stearic Acid/Fecal Fat (40% w/v), Tagamet® (5 µg/mL), TUMS® (50 µg/mL), Human Urine (5% v/v), and Vancomycin (0.25% w/v).

ANALYTICAL SENSITIVITY

The Limit of Detection (LoD) for the QuickVue TLI H. pylori Stool Antigen Test was established at 16.08 ng/mL in fecal matrix (0.24 ng/test) for *Helicobacter pylori* antigen using cell lysate antigen prepared from *H. pylori* strain ATCC 43526. For specimens in Protocol™ Cary Blair media, the LoD was established at 13.01 ng/mL (0.20 ng/test). For specimens in Protocol™ C&S media, the LoD was established at 19.96 ng/mL (0.31 ng/test).

FRESH VERSUS FROZEN SAMPLES

The effect of long-term frozen specimen storage on antigen stability was evaluated. For the analysis, a total of 32 fecal specimens was tested with the QuickVue TLI H. pylori Stool Antigen Test. The fecal specimens consisted of 2 negative fecal samples, 5 high negative fecal samples, 10 low positive fecal samples, and 15 positive fecal samples covering the range of the test (50 ng/mL – 1200 ng/mL). Samples were prepared and stored $\leq -10^{\circ}\text{C}$ and $\leq -70^{\circ}\text{C}$ and tested at 0, 5, 10, and 14 days. No conversion of positive-to-negative or negative-to-positive was observed in any of the samples at the specified time points.

PROZONE

To ensure that a high concentration of *H. pylori* antigen does not interfere with a positive reaction in the QuickVue TLI H. pylori Stool Antigen Test, high positive samples were prepared by spiking a negative fecal pool at concentrations up to 10 times the highest concentration of antigen observed in a positive clinical specimen. A total of 5 different dilutions of *H. pylori* antigen was prepared and tested in triplicate. The results demonstrated that there was no overall prozone effect, that elevated levels of antigen did not affect the detection of the antigen.

REFERENCES

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ASSISTANCE

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference quidel.com to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
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REF 20343 – QuickVue TLI H. pylori Stool Antigen Test – 25 Test U.S. Patent #8,343,726



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91-343-01 (12/19)

REF

Catalogue number



CE mark of conformity

EC REP

Authorized Representative
in the European Community

ITEM

Item number

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use

Rx ONLY

Prescription use only



Consult instructions for use

IVD

For *In Vitro* diagnostic use



Contains sufficient for 25 determinations
