This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10).

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

QuickVue TLI H. pylori Stool Antigen

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

Membrane Devices – 25, each pouch contains 1 device	MEM DEV
Conjugate (2.5 mL) **–** Antibody specific for *H. pylori* antigen coupled to horseradish peroxidase in a buffered protein solution (contains 0.05% ProClin® 300)*	CONJ ENZ
Diluent (22 mL) – Buffered protein solution with black graduated dropper assembly (contains 0.05% ProClin® 300)*	DIL SPE
Positive Control (2 mL) – *H. pylori* antigen in a buffered protein solution (contains 0.05% ProClin® 300)*	CONTROL +
Substrate (3.5 mL) – Solution containing tetramethylbenzidine	SUBS REAG
Wash Buffer (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.
3. Do not store fecal specimens in the *Diluent*.
4. Do not allow the fecal specimens to remain in the *Diluent/Conjugate* mixture for >2 hours.

TEST PROCEDURE

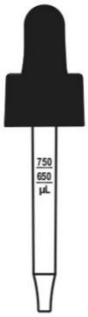
1. Be attentive to the total assay time when testing more than one fecal specimen.

2. 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.

3. **Set up and label one small test tube for each specimen and optional external control.**

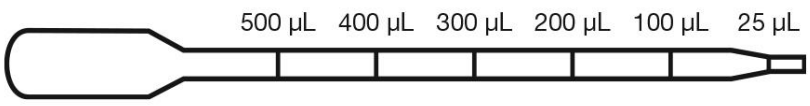
4. **Using the black graduated dropper assembly, add 750 µL of *Diluent* to each tube for fresh and frozen specimens, and external controls. For specimens in Transport Media (Cary Blair, C&S), add 650 µL of *Diluent* to each tube.**

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



5. **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.

6. Obtain one disposable plastic transfer pipette (supplied with the kit) for each sample.
   Graduated Transfer Pipette:



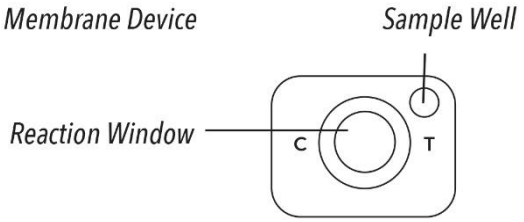
7. **For Liquid/Semi-Solid Specimens** – Mix specimen thoroughly. Using a transfer pipet, add 25 µL of specimen to the *Diluent/Conjugate* mixture in the tube.
   For Formed/Solid specimens – Mix specimen thoroughly using a wooden applicator stick and transfer a small portion (approximately 2 mm diameter, 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.

8. **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.

9. 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*.

10. 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.



11. **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*.

12. **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.

13. **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.

14. **Add 2 drops of *Substrate* (white-capped bottle) to the central *Reaction Window*.**

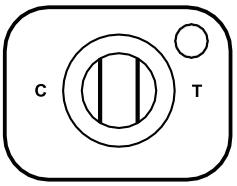
15. Incubate 10 minutes at room temperature. Read visually and record results after the incubation.

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.

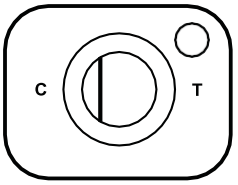
Positive Result

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.



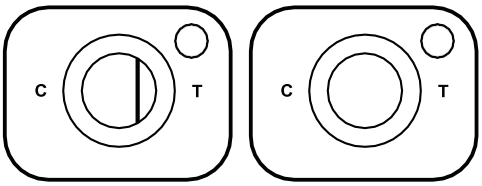
Negative Result

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 enterocoliticas

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
ATCC 43526
ATCC 700824
JP26
ATCC 43504
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 ≤ –10°C and ≤ –70°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

1. Hunt RH, Xiao SD, Megraud F, Leon-Barua R, Bazzoli F, van der Merwe S, Vaz Coelho LG, Fock M, Fedail S, Cohen H, Malfertheiner P, Vakil N, Hamid S, Goh KL, Wong BC, Krabshuis J, Le Mair A; World Gastroenterology Organization. 2011. *Helicobacter pylori* in developing countries. World Gastroenterology Organisation Global Guideline. J Gastrointestin Liver Dis. 20:299-304.
2. Wroblewski LE, Peek RM Jr., Wilson KT. 2010. *Helicobacter pylori* and gastric cancer: factors that modulate disease risk. Clin Microbiol Rev. 23:713-739.
3. Talley NJ, Vakil N. 2005. Practice Parameters Committee of the American College of Gastroenterology. Guidelines for the management of dyspepsia. Am J Gastroenterol. 100:2324-37.
4. Talley NJ. 2005. American Gastroenterological Association medical position statement: evaluation of dyspepsia. Gastroenterology. 129:1753-1755.
5. Chey WD, Wong BC, Practice Parameters Committee of the American College of Gastroenterology. 2007. American College of Gastroenterology guideline on the management of *Helicobacter pylori* infection. Am J Gastroenterol. 102:1808-1825
6. Moayyedi P, Axon AT, Feltbower R, Duffett S, Crocombe W, Braunholtz D, Richards ID, Dowell AC, Forman D; Leeds HELP Study Group. 2002 Relation of adult lifestyle and socioeconomic factors to the prevalence of *Helicobacter pylori* infection. Int J Epidemiol. 31:624-631.
7. Everhart JE, Kruszon-Moran D, Perez-Perez GI, Tralka TS, McQuillan G. 2000. Seroprevalence and ethnic differences in *Helicobacter pylori* infection among adults in the United States. J Infect Dis. 181:1359-1363.
8. Testerman TL, Morris J. 2014. Beyond the stomach: An updated view of *Helicobacter pylori* pathogenesis, diagnosis, and treatment. World J Gastroenterol. 20: 12781–12808.
9. Kim SY, Choi DJ, Chung J. 2015. Antibiotic treatment for *Helicobacter pylori*: Is the end coming? World J Gastrointest Pharmacol Ther. 6:183–198.
10. Chen H, Dang Y, Zhou X, Liu B, Liu S, Zhang G. 2016. Tailored Therapy Versus Empiric Chosen Treatment for *Helicobacter pylori* Eradication: A Meta-Analysis. Medicine (Baltimore). 95: e2750.

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	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	technicalsupport@quidel.com
Canada	437.266.1704 (main) 888.415.8764 (toll free)	technicalsupport@quidel.com
China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

CL91-343-01_EN_D (12/19)

Test Procedure Approval and Review Sheet

Prepared By:	
Date:	
Supervisor Review:	
Date:	
Laboratory Director or Designee Approval:	
Implementation Date:	
Supersedes Procedure Dated:	
Date Procedure Retired:	

Laboratory Director or Designee	Date Reviewed	Laboratory Director or Designee	Date Reviewed

QuickVue TLI H. pylori Stool Antigen Verification Form

Account Name: _____

Address: _____

_____

Telephone: _____

QuickVue TLI H. pylori Stool Antigen Lot #/Exp: _____

Date: _____

Supervisor Signature: _____

Record the results from reference samples below.

Record the Sample #, the **QuickVue TLI H. pylori Stool Antigen Test** results, Tester's Initials, and any comments. After the **QuickVue TLI H. pylori Stool Antigen Test** results have been recorded (positive or negative) then record the Expected Results (positive or negative).

Sample #	Expected Results	**QuickVue TLI H. pylori Stool Antigen Test** Result	Tester's Initials	Comments

QuickVue TLI H. pylori Stool Antigen Verification Form (page 2 of 2)

Sample #	Expected Results	**QuickVue TLI H. pylori Stool Antigen Test** Result	Tester's Initials	Comments

Review: _____ Date: _____

Laboratory Director Review and Approval for Clinical Use: _____

Date: _____

QuickVue TLI H. pylori Stool Antigen Test External Quality Control

There are two options for complying with CLIA's daily QC requirements for non-waived test systems under Section 493.1256 of the regulations:

- *Run two levels of external controls daily before patient testing OR*
- *Laboratories may develop and implement an IQCP for each non-waived test system.*

TECHLAB IQCP Support Documents may obtained upon request. The following listed conditions are also required as a minimum requirement:

External QC testing is recommended:

- When a new shipment of kits is received
- Additional tests can be performed with the controls to meet the requirements of local, state, and/or federal regulation and/or accrediting organizations

Date	**QuickVue TLI H. pylori Stool Antigen Test** Kit Lot/Exp	Positive Ctrl Lot/Exp	Negative Ctrl (Diluent) Lot/Exp	Positive Control Result	Negative Control Result	Tester's Initials	Comments

Reviewed by: _____ Date: _____

FOR EXTERNAL USE. PRINT AND DISTRIBUTION PERMITTED.

QuickVue TLI H. pylori Stool Antigen Test Quality Control Results and Patient Record

Lot Number _____ **Exp. Date** _____

Record the Date, Patient's Name, Patient's ID Number, Patient's Test Result, Procedure Control Results and the Tester's initials.

Date	Patient Name	Patient ID Number	**QuickVue TLI H. pylori Stool Antigen** Test Results	Are the Procedural Control Results Invalid or Valid?		Comments	Tester's Initials
				Invalid	**Valid**		

Reviewed by: _____ Date: _____

FOR EXTERNAL USE. PRINT AND DISTRIBUTION PERMITTED.

QuickVue TLI H. pylori Stool Antigen Test Lot to Lot Comparisons

Name of Facility: _____

External Quality Controls are required to test a new lot of reagents.

- When a new shipment or new lot of kit is received
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

	CURRENT QuickVue TLI H. pylori Stool Antigen Test In-Use Kit					**NEW QuickVue TLI H. pylori Stool Antigen Test Kit**					
Date	**QuickVue TLI H. pylori Stool Antigen Test** Kit Lot/Exp	Pos Control Lot/Exp	Neg Control Lot/Exp	Pos Control Result	Neg Control Result	**QuickVue TLI H. pylori Stool Antigen Test** Kit Lot/Exp	Pos Control Lot/Exp	Neg Control Lot/Exp	Pos Control Result	Neg Result	Tech's Initials

Reviewed by: _____ Date: _____

FOR EXTERNAL USE. PRINT AND DISTRIBUTION PERMITTED.

Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

Quality Assessment Activity	Comments	Date	Initials
Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality Control: Assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of Test Results: Review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of Patient Test Information to Test Results*:* Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with Patient's age, sex, diagnosis, and other test parameters.			
Personnel: Evaluate the effectiveness of policies and procedures for assuring employees' competence of testing and reporting test results.			
Communications: Evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint Investigation: Evaluate documented complaints and corrective actions.			
Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.			

Temperature Log

Equipment: _____

Name of Facility: _____

To be recorded at the beginning of each workday. Temperature Range: _____

Date	˚C	Initials	Adjustments	Date	˚C	Initials	Adjustments