

H. PYLORI QUIK CHEK™

A Rapid Membrane Enzyme Immunoassay for the Qualitative Detection
of *Helicobacter pylori* Specific Antigen in Human Fecal Specimens

Catalog No. T5050 (25 Tests)

IVD *In Vitro* Diagnostic Medical Device

For Canadian Users: For Laboratory Use Only

U.S. CLIA classification — Moderate

U. S. Patent #8,343,726

Made in the USA

Developed and Manufactured by:



TECHLAB®

TECHLAB, Inc.

2001 Kraft Drive

Blacksburg, VA 24060-6358, USA

www.techlab.com

H. PYLORI QUIK CHEK™

INTENDED USE

The TECHLAB® *H. PYLORI QUIK CHEK*™ 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 *H. PYLORI QUIK CHEK*™ test allows for the non-invasive detection of *H. pylori* when endoscopy is not required.

PRINCIPLE OF THE TEST

The *H. PYLORI QUIK CHEK*™ 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

MEM	DEV
CONJ	ENZ

Membrane Devices – 25, each pouch contains 1 device

Conjugate (2.5 mL) – Antibody specific for *H. pylori* antigen coupled to horseradish peroxidase in a buffered protein solution (contains 0.05% ProClin® 300)*

DIL	SPE
-----	-----

Diluent (22 mL) – Buffered protein solution with black graduated dropper assembly (contains 0.05% ProClin® 300)*

CONTROL	+
---------	---

Positive Control (2 mL) – *H. pylori* antigen in a buffered protein solution (contains 0.05% ProClin® 300)*

SUBS	REAG
------	------

Substrate (3.5 mL) – Solution containing tetramethylbenzidine

WASHBUF	20X
---------	-----

Wash Buffer (12 mL) – Buffered solution with white graduated dropper assembly (contains 0.05% ProClin® 300)*

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)

Disposable gloves

Vortex mixer

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.

- The validity of the test results using the *H. PYLORI QUIK CHEK™* test is dependent upon the proper reaction of the internal and external controls. See the Quality Control section.
- 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.
- 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. Safety Data Sheets for this product are available upon request, contact technical support.
- Follow your national, regional, and local ordinances accordingly for waste disposal regulations. Do not place in trash, dispose of as hazardous waste.

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 Specimens	Fecal Specimens in alcohol-based fixative (e.g., polyvinyl alcohol)
Specimens in Transport Media (Cary Blair, C&S)	Concentrated Fecal Specimens

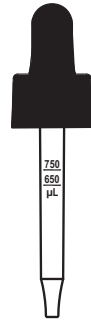
Storage Condition	Recommended Storage Time
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 2°C and 8°C	96 hours
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 20°C and 25°C	96 hours
Frozen Unpreserved Samples Stored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

- Use standard in-house collection and handling procedures for fecal specimens. Collect fecal specimens in clean, leak-proof containers.
- 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

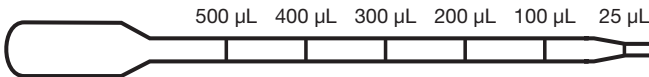
- Be attentive to the total assay time when testing more than one fecal specimen.
- Bring all reagents and devices to room temperature before use. Remove the reagents from the foam insert to reduce the time needed to warm to room temperature.
- Set up and label one small test tube for each specimen and 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 Diluent
Fresh Fecal Specimens	750 μ L (2 nd graduation from tip)
Frozen Fecal Specimens (frozen undiluted)	750 μ L (2 nd graduation from tip)
External Controls (positive and negative)	750 μ L (2 nd graduation from tip)
Specimens in Transport Media (Cary Blair, C&S)	650 μ L (1 st graduation from tip)



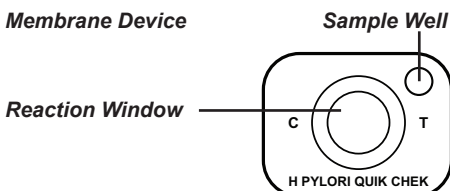
5. **Add one drop of Conjugate (red capped bottle) to each tube.** Gently mix the *Conjugate* in the bottle by inverting several times prior to addition. Hold the dropper bottle vertically to ensure proper drop size. The *Diluent* and *Conjugate* should be added to all tubes prior to adding the specimens.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

Graduated Transfer Pipette:



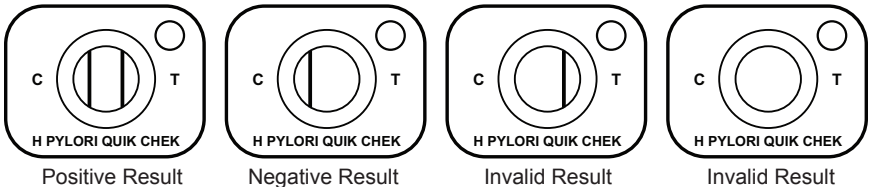
7. **For Liquid/Semi-Solid Specimens** - Mix specimen thoroughly. Using a transfer pipet, add 25 μ L of specimen to the *Diluent/Conjugate* mixture in the tube.
For Formed/Solid specimens - Mix specimen thoroughly using a wooden applicator stick and transfer a small portion (approximately 2 mm diameter, the equivalent of 25 μ L) 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 μ L 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 μ L *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 the "H. PYLORI QUIK CHEK" print is at the bottom of the device, and the small *Sample Well* located in the top right corner of the device.

Membrane 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 μ L (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 μ L (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 μ L 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* TEST

1. The *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* test. These procedures can result in extensive dilution or the presence of additives that may affect test performance.

EXPECTED VALUES

The *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* test versus Composite Reference Method (CRM)

N = 122	CRM Positive	CRM Negative
<i>H. PYLORI QUIK CHEK™</i> Positive	32	0
<i>H. PYLORI QUIK CHEK™</i> 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 *H. PYLORI QUIK CHEK™* test exhibited a sensitivity of 100% with the composite reference method.

N = 9	CRM Positive	CRM Negative
<i>H. PYLORI QUIK CHEK™</i> Positive	9	0
<i>H. PYLORI QUIK CHEK™</i> 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 *H. PYLORI QUIK CHEK™* 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
<i>H. PYLORI QUIK CHEK™</i> Positive	93	3*
<i>H. PYLORI QUIK CHEK™</i> 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* test.

<i>Acinetobacter baumannii</i>	<i>Escherichia coli</i> EPEC
<i>Bacillus cereus</i>	<i>Escherichia coli</i> ETEC
<i>Bacillus subtilis</i>	<i>Escherichia coli</i> O157:H7 (non-toxicogenic)
<i>Borrelia burgdorferi</i>	<i>Escherichia coli</i> O157:H7 (toxicogenic)
<i>Campylobacter coli</i>	<i>Haemophilus influenzae</i>
<i>Campylobacter fetus</i>	<i>Lactobacillus acidophilus</i>
<i>Campylobacter helveticus</i>	<i>Listeria monocytogenes</i>
<i>Campylobacter hyointestinalis</i>	<i>Peptostreptococcus anaerobius</i>
<i>Campylobacter jejuni</i>	<i>Porphyromonas asaccharolytica</i>
<i>Campylobacter lari</i>	<i>Prevotella melaninogenica</i>
<i>Campylobacter upsaliensis</i>	<i>Proteus vulgaris</i>
<i>Candida albicans</i>	<i>Pseudomonas aeruginosa</i>
<i>Clostridium bifermentans</i>	<i>Pseudomonas fluorescens</i>
<i>Clostridium difficile</i>	<i>Salmonella typhimurium</i>
<i>Clostridium perfringens</i>	<i>Staphylococcus aureus</i>
<i>Edwardsiella tarda</i>	<i>Staphylococcus aureus</i> (Cowan's)
<i>Enterobacter cloacae</i>	<i>Streptococcus agalactiae</i>
<i>Enterococcus faecalis</i>	<i>Yersinia enterocolitica</i>
<i>Escherichia coli</i>	
<i>Escherichia coli</i> EIEC	
Adenovirus Types 2, 40	Echovirus 9, 22
Human Coronavirus	Enterovirus 70
Coxsackievirus B1, B2, B3, B6	Human Rotavirus

INCLUSIVITY STUDY

The following strains, which include isolates representing described *H. pylori* populations, were tested for reactivity with the *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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 *H. PYLORI QUIK CHEK™* 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, Traika 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.

Technical Support

Further information can be obtained from contacting TECHLAB® Technical Support:

US + 1 800 TECHLAB
Phone (540) 953-1664
FAX (540) 953-1665

© 2018 TECHLAB, Inc. All rights reserved.

H. PYLORI QUIK CHEK, the TECHLAB Logo, and TECHLAB are trademarks of TECHLAB, Inc. ProClin is a trademark of Rohm and Haas Company. All other trademarks referenced are trademarks of their respective owners.