Serim® PYLORITEK®
FREQUENTLY ASKED QUESTIONS

1. **Is PyloriTek® CLIA-waived?**

   Yes, PyloriTek was granted a CLIA-waiver in February 1996. In fact, PyloriTek was the first Rapid Urease Test to receive CLIA-waived status.

2. **What is the CPT code for PyloriTek?**

   87077QW

3. **Are External controls available for PyloriTek?**

   Yes. Although the whole idea of building positive & negative controls into PyloriTek strips was to eliminate the extra labor of running separate controls, this didn't satisfy JCAHO or CAP regulations for "external" controls, so Serim created the PyloriTek Positive Control Papers.

   PyloriTek Positive Control Papers (Product Code 5146) consist of a small bottle containing 5 pieces of urease-impregnated paper. The product is stable for 1 year after opening (3 years unopened).

   Simply follow the "Test Procedure" in the PyloriTek product insert using the control paper in place of a gastric biopsy. If the PyloriTek test is working properly you will see an intense purple/blue color develop over both the Positive Control Paper and the built-in Positive Control Spot.

   For a Negative Control, run a PyloriTek test without any biopsy or external control. If the PyloriTek test is working properly, an intense purple/blue color will develop ONLY over the built-in Positive Control Spot; the rest of the Reaction Pad should remain yellow.

   Serim leaves it up to each facility to determine the frequency of quality control testing.

4. **Is there a Proficiency Program for PyloriTek?**

   Yes, a proficiency program is available through the American Proficiency Institute (800-333-0958). Ask for catalog **# 260 Rapid Urease Program.** Each proficiency test includes 2 simulated gastric biopsy samples for use with PyloriTek or similar methods. The annual program consists of three shipments per year (March, July & October) and costs approximately $100.

AMERICAN PROFICIENCY INSTITUTE (API)
1159 Business Park Drive
Traverse City, Michigan 49686
(800) 333- 0958

5. **How does PyloriTek detect *H. pylori* in a gastric biopsy?**

The dry Substrate Pad of the PyloriTek Reagent Strip contains urea which is rehydrated by adding 4 drops of Hydration Reagent (Tris buffer). The gastric biopsy is placed on the Reaction Pad and the moistened Substrate Pad is folded over onto the biopsy. The folded strip is then inserted into the Disposable Reaction Pouch to ensure sufficient contact between the Substrate Pad and the Reaction Pad, allowing a chemical reaction to begin. If *H. pylori* bacteria are present in the biopsy, urease produced by the bacteria will react with the urea in the Substrate Pad and produce ammonia gas. (Urease in the Positive Control spot also begins to react with urea in the Substrate Pad to generate ammonia.) The ammonia gas generated is sandwiched between the two pads, and since the white membrane of the Reaction Pad is permeable to gas (but not to liquids like tissue fluids, blood or Hydration Reagent), the ammonia is channeled through the membrane to the yellow Reaction Pad (pH indicator paper) on the front of the strip where an intense blue color forms.

6. **What does a positive reaction look like?**

A positive reaction appears as an intense blue/purple color directly over the specimen. The color may develop over the entire specimen or in stippled patches, but the color must be similar to that of the Positive Control.

The Positive Control will react within 60 minutes. However, there may be times when the patient's specimen yields a positive reaction ***before*** the control spot develops. In these cases, wait (allow the ***full 60 minutes*** if necessary) until the Positive Control spot develops before interpreting the final test results.

7. **What does a negative reaction look like?**

Negative specimens may develop no color at all over the biopsy (the reaction pad remains yellow except for the Positive Control spot) or a mottled, light gray or pale blue color (commonly called a "footprint" or "shadow") may appear over the biopsy. Refer to the "PyloriTek Quick Reference Guide"; a visual interpretation chart of typical reaction patterns.

8. Can I interpret the results of the test *before* 60 minutes have passed?

Yes, a result of "positive" can be interpreted before 60 minutes have passed ***only*** if an intense purple/blue color has developed over ***both*** the Positive Control ***and*** patient's biopsy.

If an intense purple/blue color has developed ***only*** over the Positive Control, but ***not*** over the patient's biopsy, ***wait the full 60 minutes*** to confirm that the patient's biopsy is truly "negative".

If an intense purple/blue color has developed ***only*** over the patient's biopsy but ***not*** over the Positive Control, wait until the Positive Control appears (allow the ***full 60 minutes*** if necessary). If the Positive Control does not appear at the 60-minute mark, the test is invalid and the results should not be reported. (The biopsy specimen(s) may be transferred once to a second PyloriTek Reagent Strip for repeat testing. See #9 below.)

9. **What should I do if the Positive Control does not react?**

If the Positive Control spot does not develop ***after waiting the full 60 minutes,*** the biopsy specimen(s) may be transferred once to a second PyloriTek Reagent Strip for repeat testing. This decision should be made by the attending physician based on the patient's history, symptoms and observations during endoscopy. Clean medical forceps, plastic or wooden applicator stick, needle or similar device should be used to make the transfer. (If the device used was disinfected in formaldehyde, rinse the tool with clean water prior to use in the transfer.) Care should be taken not to remove excess mucous from the specimen, as some of the *H. pylori* bacteria may be lost in the transfer.

An alternative method is to place the specimen(s) in formalin and send it to pathology for histological staining and pathological interpretation. While it is up to your institution whether or not to do this, a reference article (Evaluation of Handling Methods in the Histological Diagnosis of *Helicobacter pylori*: The Effect of Filter Paper, *Am J Gastroenterol* 1996; 91:2344-46) has reported that biopsies collected on filter paper are more likely to show a false negative in histological staining compared to those collected in non-absorbent containers due to loss of gastrointestinal mucous.

No studies have been done to determine whether mucous is lost when transferring gastric specimens from a PyloriTek Reagent Strip. However it is likely that mucous may adhere to the Substrate Pad/Reaction Pad of the PyloriTek Strip causing a loss of organisms.

10. What if I read the results of the PyloriTek Reagent Strip *after* the 60-minute reaction time?

Reading the results after the 60-minute reaction time can lead to "false positive" results caused by non-specific reactions occurring on the Reaction Pad. Therefore always read the results of the test within 60 minutes and disregard any color formed after 60 minutes.

11. What does the PyloriTek Hydration Reagent do?

The Hydration Reagent rehydrates the urea on the dry Substrate Pad and provides the optimum environment for the urease/urea chemical reaction to produce the ammonia gas. The test will not perform properly without the Hydration Reagent. (You can use Hydration Reagent from one kit with Reagent Strips from another kit. Just be sure that both components are within the expiration date printed on the label or bottom of the bottle.)

12. Can I add more or less than the prescribed 4 drops of PyloriTek Hydration Reagent and is the placement important?

No. Add only 4 drops of Hydration Reagent as stated in the insert. Adding too much Hydration Reagent may change the concentration of urea in the Substrate Pad, thereby altering the sensitivity and performance of the Reagent Strip. The drops should be placed roughly in the middle of each quadrant of the Substrate Pad to adequately and evenly moisten the dry pad.

It is important the Hydration Reagent is fully absorbed before folding the strip and placing it in the Reaction Pouch. The entire Substrate Pad may look wet, but if liquid still standing on the surface of the Substrate Pad, the incompletely absorbed Hydration Reagent may puddle near the Positive Control Spot and **slow down** or cause **diffuse or pale, watery color development of the control spot**.

13. If I add the Hydration Reagent to the Substrate Pad, but then the doctor decides not to test for *H. pylori*, can I still use the Reagent Strip?

No, discard the Reagent Strip. Do not place the strip back in the bottle, as the moisture will destroy the integrity of the other strips. Do not leave the strip out at room temperature to use later because:

a) The Hydration Reagent may evaporate which would inhibit the chemical reaction between the urea and urease
b) Adding more Hydration Reagent will change the concentration of urea in the Substrate Pad, thereby altering the sensitivity and performance of the Reagent Strip, and
c) The control spot may absorb humidity from the air, become sticky and dissolve, rendering the test invalid.

14. How do I dispose of unused or expired PyloriTek Hydration Reagent?

PyloriTek Hydration Reagent is a simple buffer (salt solution) that contains a small amount of the sodium azide as a preservative. Sodium azide has been used for decades as a preservative for chemical and biochemical solutions. The caution in the MSDS refers to the fact sodium azide can, over a long period of time; react with the metal in old pipes to form a potentially explosive compound. This is an extremely rare occurrence and requires the disposal of large quantities of sodium azide into lead pipes over a long period of time.

The universal precaution to prevent formation of this reaction compound is to flush the remaining PyloriTek Hydration Reagent down the drain with large amounts of running water. Another option is to empty the Hydration Reagent into a paper towel, allow it to evaporate and dispose of the towel in the medical waste.

Check your hospitals rules on disposal of chemicals containing sodium azide. There may be a specific recommendation for your hospital's clinical laboratory as sodium azide is a common preservative in clinical chemistry reagents.

15. Can we place more than 1 biopsy (from the same patient) on a PyloriTek Reagent Strip?

Yes, up to 3 biopsies from the same patient may be placed on the Reaction Pad of a PyloriTek Reagent Strip.

Biopsy-based methods for detecting *H. pylori* are liable to sampling error because infection is patchy. Therefore consensus guidelines recommend multiple biopsies be taken from the antrum and corpus to improve the sensitivity of the rapid urease test.

Remember to keep the biopsies ~1/4 inch away from the red Positive Control spot.

Note: To prevent adversely affecting the development and intensity of the Positive Control spot, ***do not close*** the Reagent Strip ***until the last biopsy is in place***. (If the first biopsy is placed on the Reaction Pad and the strip is closed, the urease in Positive Control spot will begin reacting with the urea in the moistened Substrate Pad and generate ammonia gas. If the strip is unfolded to add a second biopsy, any ammonia gas generated will take the path of least resistance; the gas will dissipate in the air instead of passing through the semi-permeable membrane to the yellow pH indicator on the front of the PyloriTek Reagent Strip. The dissipation of the ammonia whenever the strip is unfolded can result in a pale or undetectable Positive Control spot on the yellow Reaction Pad.)

16. **Sometimes it takes several minutes to place all three gastric biopsies on the strip. In order for the Substrate Pad to remain thoroughly wet, can I add the Hydration Reagent last?**

Yes, you can place the biopsies on the Reaction Pad first and then add the Hydration Reagent to the Substrate Pad. Just remember to let the Hydration Reagent fully absorb before folding the strip and placing it in the Reaction Pouch.

17. We have 10 gastroenterology suites in our facility. Can I leave a few PyloriTek strips laying out in each suite?

No. It is very important that PyloriTek strips remain in the bottle until immediately before use. Exposure to humidity can adversely affect the strip, especially the Positive Control spot. Depending on the volume of endoscopy procedures performed, we recommend keeping a kit at each station (each bottle of strips is good for three months after opening and Serim offers 20-test or 5-test kits) or moving the kit from suite to suite as needed. (It is okay to use Hydration Reagent from one kit with Reagent Strips from another kit. Just be sure that the components are within the expiration date printed on the labels.)

18. My doctors want to carry the strip in their coat pocket. Can they do this?

No. The test is designed to operate at room temperature (59°- 90°F) and must be kept in the Disposable Reaction Pouch during the reaction to insure proper results. Also, as any rapid urease test containing biopsy tissue is potentially infectious, it is not a good idea to carry the test in personal clothing.

19. **Why do you have to use the Disposable Reaction Pouch? Can't I just tape or clip the strip together?**

No. The Disposable Reaction Pouch is designed to provide evenly dispersed pressure and optimum contact between the moistened Substrate Pad and the Reaction Pad/biopsy/Positive Control Spot. Pressing the two pads together initiates the reaction and channels the ammonia gas (generated by the reaction) through the semi-permeable membrane to the pH indicator. Taping or clipping the strip together may result in uneven, inadequate contact, causing false negative results.

20. **How do we dispose of the biopsy specimen and PyloriTek strip once the test is complete?**

Follow established hospital practices or procedures and local, state and federal regulations for disposal of medical materials contaminated with human blood, tissue or body fluids.

Visit Serim's website (http://www.serim.com/technical_tips_diagnostic_support.cfm for additional "Customer Support Materials" such as:

- 10-question Competency Test
- Troubleshooting Guide
- Electronic version of the PyloriTek procedure in NCCLS-format
- Log sheets

PYLORITEK TECHNICAL TIPS

- Store unopened PyloriTek Test Kits in the refrigerator until needed.
- Allow the components of the PyloriTek Test Kit to come to room temperature prior to use.
- Once opened, do not return the PyloriTek Test Kit to the refrigerator. Placing a warm bottle of strips back in the refrigerator allows condensation to build up inside the bottle resulting in degradation of the test.
- Always check the expiration dates on PyloriTek Reagent Strips and Hydration Reagent before use. (Lot number and expiration dates can be found on the bottom of the bottle or printed on the bottle label.)
- PyloriTek Reagent Strips and the Hydration Reagent are not lot specific; Hydration Reagent from one kit can be used with Reagent Strips from another kit. Just be sure that both components are within the expiration date printed on the label or bottom of the bottle.)
- Always check to make sure the red Positive Control Spot is present on the PyloriTek Reaction Pad before using it.
- Do not use a strip if the PyloriTek Reaction Pad displays atypical purple, blue or gray areas ***prior*** to use. (Some strips do have Reaction Pads with a yellow or yellow-orange "mottled" or "spotted" appearance. This slight variation in color is a normal characteristic of the membrane and can vary from lot to lot. It does not affect performance of the PyloriTek test.)
- Once a strip has been removed from the bottle, do not replace it in the bottle. Humidity can make the red Positive Control Spot slightly sticky. If it is returned to the bottle, it may stick to another strip.
- Do not lay a PyloriTek Reagent Strip on a wet counter.
- Do not handle the strip with wet gloved hands as the Positive Control Spot could be smeared or rubbed off.
- Make sure the PyloriTek Hydration Reagent is added to the Substrate Pad. Place 1 drop of Hydration Reagent on each quadrant of the Substrate Pad.
- Do not add more than 4 drops of Hydration Reagent.
- Make sure the Hydration Reagent is fully absorbed and the Substrate Pad is evenly moistened before folding the strip and placing it in the Disposable Reaction Pouch.
- Place the biopsy directly on the Reaction Pad of the PyloriTek Reagent Strip as soon as possible so that the urease activity is not lost. Avoid placing the biopsy on a gauze sponge or a specimen pad as the mucus, where *H. pylori* bacteria tend to be found, will stick to the gauze reducing the sensitivity of the test.

PYLORITEK TECHNICAL TIPS (CON'T)

- Applicator sticks or plastic picks can be used to transfer the specimen from the forceps to the Reagent Strip to assist in preventing needle sticks.

- If adding more than one biopsy to the Reaction Pad, ***do not fold the strip until all biopsies are in place.*** (If the first biopsy is placed on the Reaction Pad and the strip is closed, the urease in Positive Control spot will begin reacting with the urea in the moistened Substrate Pad and generate ammonia gas. If the strip is unfolded to add a second biopsy, any ammonia gas generated will take the path of least resistance; the gas will dissipate in the air instead of passing through the semi-permeable membrane to the yellow pH indicator on the front of the PyloriTek Reagent Strip. The dissipation of the ammonia whenever the strip is unfolded can result in a pale or undetectable Positive Control spot on the yellow Reaction Pad.)

- Never transfer PyloriTek Reagent Strips from one bottle to another. The desiccant packets inside an "old" bottle can become saturated and will no longer effectively absorb moisture. Moisture adversely affects the Positive Control Spot and deteriorates the reagents in the Substrate and Reaction pads. Also, traceability of the product is lost when strips from one lot number are transferred to a bottle with a different lot number.

- Always use the Disposable Reaction Pouch to hold the folded PyloriTek Reagent Strip. Do ***not*** use tape or paper clips.

- The patient's specimen may yield a positive reaction ***before*** the control spot develops. In these cases, wait until the PyloriTek Positive Control spot develops (allow the ***full 60 minutes*** if necessary) before interpreting the final test results.

- If the Positive Control spot does not develop ***after waiting the full 60 minutes,*** the biopsy specimen(s) may be transferred once to a second PyloriTek Reagent Strip for repeat testing.

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