

# PyloPlus

Ultra Rapid Urease Test (RUT)

## GASTROENTEROLOGY

PyloPlus Rapid Urease Test (RUT) offers significant improvements that make the task of detecting H. Pylori infections in gastric mucosal biopsies faster, easier, less expensive, and more accurate than ever before.



# Frequently Asked Questions

## When replacing HP Fast with PyloPlus RUT, how is it validated?

- The serial dilution will be manufactured within a specific time frame for use.
- Prepare the serial dilution to get down to an approximate equivalent of 90% sensitivity.
- The serial dilution will be in a small glass jar with small squares of filter paper in the urease solution to simulate an actual biopsy.
- Place the squares inside each test as if performing a normal biopsy for a positive result.

## How many test slides come in a box?

- PyloPlus RUT is packaged in boxes of 50 test slides

## What needs to be done to complete the internal validation?

- If validating performance: Use the bottle of positive and negative control solutions that have been calibrated at 90%.
- Test the positive and negative solution on 5 separate tests.
- If validating proficiency: Test 3 blind samples labeled A - B - C and record which ones produced a positive result.
- A proficiency certificate will be provided at the end of the testing.

## When validating the new PyloPlus RUT each organism test yielded a positive result. Why would this happen?

- PyloPlus RUT is a dry test and is designed to work with minimal moisture content. If too much moisture is contained in the biopsy specimen, a false positive will be indicated.
- If used correctly, a false positive is unlikely due to the pH neutral solution used when controls are manufactured.

## Are the College of American Pathologist (CAP) samples the same as HP Fast?

- There have not been any reports from users that the CAP samples do not work, but there is a substantial difference in the operation of the PyloPlus RUT test from that of HP Fast.

- If CAP is used, the user must blot the specimen so that only a minimal amount of moisture is present. If not, this may cause an issue with the test.

## Are there any issues with reading these tests past 60 minutes?

- PyloPlus RUT is validated as a 1-Hour test.
- It is possible a specimen at 1-hour tests negative and that same specimen at 24 hours tests positive. This is not a failure, but rather an indication, if positive, that there is a low level of urease present. If this occurs, the patient should be treated as negative and/or brought back in 1-2 months for testing by a non-invasive method.

## Can PyloPlus RUT results be read 1-2 days later?

- Reading results after 24 hours is not recommended.

## How should PyloPlus RUT be stored?

- PyloPlus RUT should be stored at room temperature away from direct light.

## What could cause a false negative PyloPlus RUT result?

- False negative results may occur when there are low numbers of *H. pylori* present or the bacterium has a patchy distribution.
- To reduce the occurrence of false negatives, two PyloPlus RUT tests should be performed, one with a sample from the antrum and one from the body of the stomach.

## Where should the biopsy be placed?

- The biopsy should be placed directly on the yellow pad and not the mesh. You should not see the mesh if the test stays intact.
- The yellow pad should not come up with the label. If the pad comes up with the label, it is safe to put it back in or you can just use a different test.

Laborie Medical Technologies is an authorized distributor of PyloPlus for ARJ Medical, Inc.

**Laborie**<sup>1</sup>

USA

T +1 800 522 6743

E [gis-gisupplyinfo@laborie.com](mailto:gis-gisupplyinfo@laborie.com)  
W [laborie.com](http://laborie.com)



Learn more