

SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

		No.	<u>LAB-23F</u>
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Subject:	<u>POC – RAPID UREASE TEST</u> <u>Helicobacter Pylori Urease Test</u>	Original Issue Date	<u>08/04</u>
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PRINCIPLE:

Also known as CLO test for “Campylobacter-Like Organism”, is a rapid urease test (RUT) that accurately detects the urease enzyme of *Helicobacter pylori* in gastric mucosal biopsies. The test consists of a well of urease indicator gel sealed inside a plastic slide. The gel contains urea, phenol red (a pH indicator), buffers and bacteriostatic agent to prevent the growth of contaminating organism. If the urease from *H. pylori* is present in the tissue sample, it changes the gel from yellow to bright magenta (purple-red). The chemical reaction of urea + water + acid in the presence of urease, gives ammonium + bicarbonate changing the color of the indicator.

LEVEL OF FUNCTION: Unit Physician in collaboration with Laboratory staff.

LEVEL OF PERSONNEL: Physicians
Physicians Assistants
Laboratory staff

PRODUCT STORAGE: The CLO test RUT kits should be stored at 2°-8°C (36°-48°F). Shelf life and expiration must be noted and taken into account when stored and when placed in use. Do not use the product if the gel is not yellow, if seal is damaged and gel appears dehydrated, or if the expiration date has passed.

PATIENT PREPARATION:

Patient should discontinue the use of antibiotics and bismuth preparations three weeks before the biopsy. These agents may suppress but not eradicate the presence of *H. pylori* making the organism difficult to detect by any means. The patient should not have ingested proton pump inhibitors two weeks prior to the test as these drugs have been shown to inhibit growth of the organism in some persons.

SPECIMEN COLLECTION, ACCEPTABILITY AND HANDLING:

Biopsy: The recommended gastric area biopsy is at least 2cm away from the pylorus along the lesser or greater curve of the antrum. Avoid tissue that is eroded or ulcerated as *H. pylori* may be smaller around those areas. A **standard biopsy forceps** should render a specimen of sufficient size for the test. If an additional sample is inserted into a single CLO test well, do not contaminate the second specimen with blood from the first biopsy site.

TEST PROCEDURE:

1. After removing the CLOtest ® rapid urease test slide from refrigeration, lift the label far enough to expose the yellow gel. For faster test results allow the gel to reach room temperature before inserting the biopsy (usually 7-10 minutes).
2. With a clean applicator device, push the entire sample from the forceps beneath the surface of the gel to expose as much of the specimen to the gel as possible. Make sure that the biopsy specimen is completely immersed in the gel.
3. Re-seal the pressure-sensitive label on the slide and **record the patient name, date and time the biopsy was inserted.**
4. To accelerate reaction time, the CLO test slide may be placed on a warming plate at a temperature between 30°-40°C (86°-104°). This will not affect the test accuracy but slide should be heated no more than three hours, then it should be stored at room temperature until the final reading.
Record a positive reaction as soon as the gel changes color [from yellow to magenta (purple-red)]. This **change of color will be within 20 minutes.** Once a positive reaction has occurred, no further reading is necessary.
5. After first reading, all test slides will be kept in the Endoscopy suite for 24 hrs and then must be sent to the main Laboratory (Hematology) for final reading and result placed in the LIS.

INTERPRETATION OF RESULTS:

1. A specimen contaminated with blood may stain the gel around the edge of the tissue. This is NOT a positive test. If the biopsy contains urease, the change first appears around the sample and eventually colors all of the gel.
2. The pH change in a positive test is first seen at the interface of the gel and the biopsy. If a significant amount of urease is present, the visible change is rapid. Any color change of the whole gel to a shade other than yellow (e.g., red, magenta, pink, deep orange) indicates the presence of *H. pylori*.
3. A negative test remains yellow after imbedding the tissue into the gel. If the color of the gel is yellow at 24hrs, the test is negative. If unable to be read at 24 hours, the test will remain valid for 72 hrs after insertion of the biopsy into the gel medium.

QUALITY CONTROL PROTOCOL:

Whenever a kit with new lot # is received and with each negative test slide, the laboratory will perform the following positive control to ensure the CLO test is working properly:

1. Insert a urease tablet (Kimberly-Cark Catalog #60407) into the CLO test gel and re-seal the slide.
2. After five minutes inspect the gel for a positive color change (re-magenta).
3. If the gel does not turn red or magenta, notify the P.O.C coordinator for a change of Kit.

LIMITATION OF RAPID UREASE TEST :

Possible causes for False Negative:

- Very low numbers of H. pylori in the tissue sample.
- Irregular H. pylori distribution so that the organism is not captured in the tissue sample.
- A sample of intestinal Metaplasia (H. pylori does not colonize intestinal mucosal).
- Recent ingestion of antibiotics, bismuth, or proton pump inhibitors, which can inhibit the organism.
- Formalin contamination of sample.

Possible causes for False Positive:

- ♦ When test is properly performed, false positives are rare. Late false positive reaction (>12 hrs) may be caused by failure to completely insert the biopsy into the gel having that contaminating organism grow in the tissue.
- ♦ Could occur in patients who have achlorhydria (Absence of hydrochloric acid in the gastric secretions of the stomach) due to bacteria overgrowth.

REPORTING RESULTS:

Slide must be sent to the Laboratory within 24 hrs of tissue insertion, for final reading and placement of result in the LIS computerized system.

NORMAL EXPECTED RESULTS:

In the presence of Helicobacter pylori, slide gel will turn from yellow to red **within 20minutes**. If bacteria is **absence**, the slide will remain yellow and at 24hrs, the test is confirmed negative. If unable to be read at 24 hours (e.g. week-ends), the test will remain valid for 72 hrs after insertion of the biopsy into the gel medium.

REFERENCE:

1. CLO Test * Rapid Urease Test Slide Kit package insert; Ballard Medical, Kimberly-Clark Manufacturing Co, Inc.

ATTACHMENTS

1. Helicobacter Pylori Urease Test - Negative Test Control Log
2. Helicobacter Pylori Urease Test - New Kit Control Log

Date Reviewed	Revision Required		Responsible Staff Name and Title
	Yes	No	
	Yes	No	

[illegible]



SUNY DOWNSTATE MEDICAL CENTER HELICOBACTER PYLORI UREASE TEST NEW KIT CONTROL LOG

DATE	KIT LOT #	EXIRATION DATE	POSITIVE RESULT	NEGATIVE RESULT	TECH.