PROCEDURE: CLO TEST

ISSUE DATE: October 2003

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Principle:

The CLOtest rapid urease test accurately and conveniently detects the urease enzyme of *Helicobacter pylori* in gastric mucosal biopsies. Its use is intended for the presumptive diagnosis of *H. pylori* infection.

H. pylori was first cultured from antral biopsies in 1982 and was originally called Campylobacter-like organism. Subsequently, the genus was named *Helicobacter*, meaning spiral or helical bacteria.

CLOtest is a well of urease indicator gel sealed inside a plastic slide. The gel contains urea, phenol red, buffers and a bacteriostatic agent to prevent the growth of contaminating urease-positive organisms. If the urease from *H. pylori* is present in the tissue sample, it changes the gel from yellow to bright magenta.

Specimen:

Specimens are collected in the Ambulatory Procedure Center, SDS, OR or the CSCC. The recommended gastric area to biopsy is at least 2 cm away from the pylorus along the lesser or greater curve of the antrum. Tissue should be excised that appears normal. Avoid tissue that is eroded or ulcerated as *H. pylori* may be present in smaller numbers around those areas. The 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.

Materials:

2-3mm tissue sample obtained by endoscopist
CLOtest device stored at 2 - 8°C
CLOtest Reagent Urease Type III
Forceps

Quality Control:

Quality control must be performed on all new shipments and new lot numbers of the CLOtest. The lot number, expiration date and QC results will be documented on the CLO test Quality Control form in the Microbiology Lab. Two slides are removed from the package and allowed to come to room temperature. Inoculate one gel with one capsule of the CLOtest Reagent Urease Type III and leave the other gel uninoculated to serve as the negative control. Incubate at room temperature for 24 hours. Interpret and record results after 24 hours.

CLOtest Reagent Urease Type III = POSITIVE (red to magenta color)	**Uninoculated =NEGATIVE (yellow)**

If expected results are not obtained, notified Technical Supervisor or designee.

Procedure:

Ambulatory Procedure Center/SDS/OR/CSCC

1. Before use, the CLOtest should be inspected to make sure that the well is full and is a yellow color.

2. Immediately before endoscopy, the CLOtest should be warmed to room temperature 7-10 minutes.

3. Peel back the label of the CLOtest exposing the gel.

4. With a sterile needle, remove the specimen from the biopsy forceps and push the tissue into the CLOtest gel. Make certain the tissue is completely immersed so that there is maximum contact with the gel.

5. Reseal the CLOtest. Record or use the label, identification must include the name of the patient, DOB and account number and the date and time specimen was inserted on the CLOtest slide.

6. Send the device to the lab.

In the SLCH Core/POC Laboratory:

1. Confirm the name on the requisition and specimen match. Log the specimen into the SLC DEC l Cerner.

2. Incubate the CLOtest at room temperature in the wire basket in processing area of the Core lab.

3. Specimens are then stored in the POC room until read.

4. If urease is present in the tissue, and expanding pink zone will be noted around the biopsy Specimen. A positive reaction can be recorded as soon as the entire gel changes color. Once a Positive reaction has occurred, no further reading is necessary. 75% of positive tests change color within 20 minutes of collection.

5. A negative result is indicated when the gel remains yellow after 24 hours. If the gel is still Yellow at 24 hours, follow the Fail-Safe protocol below.

Results:

Positive test: The pH change in a positive test is first seen at the interface of the gel and biopsy. 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*.

A specimen contaminated with blood may stain the gel around the edge of the tissue. This is NOT a positive test.

Negative test: If the color of the gel is yellow at 24 hours, the test is negative. If unable to read at 24 hours, the test will remain valid for 72 hours after insertion of the biopsy into the gel medium.

Fail-Safe Protocol: With each negative test read at 24 hours, perform the following positive control to ensure the CLOtest is working properly.

1. Peel off the back of label far enough to expose the yellow gel. Using forceps, inoculate the gel with a capsule of CLOtest Reagent Urease type III. Stab the capsule into the medium.

2. Reseal the label on the device.

3. After 5 minutes, inspect the gel for a positive color change (red or magenta).

4. If the gel does not turn red or magenta, notify the Supervisor or Technical Specialist immediately. Do not report patient results.

5. If the gel does turn red or magenta, the fail-safe protocol has been verified and the CLOtest is working properly. In the work card portion of CERNER, enter the biochemical 'CLOVER'—"Fail-safe protocol confirms this negative test to be working properly."

6. Specimens are stored refrigerated for 7 days.

Reporting:

Results are entered into Accession Result Entry.

Enter FINAL into the ENTRY box. Enter POSITIVE or NEGATIVE into the response box and verify.

Limitations of the Test:

Possible causes of False Negatives:

- Very low numbers of *H. pylori* in the tissue sample
- Patchy *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 mucosa
- Recent ingestion of antibiotics, bismuth, proton pump inhibitors, or sucralfate which can inhibit the organism
- Formalin contamination of the sample

Possible causes for False Positives:

- Patients who have achlorhydria from bacterial overgrowth could exhibit false positives. This condition could result from the following: pernicious anemia, previous gastric surgery, or recent use of proton pump inhibitor drugs. However, other bacteria produce much less urease than *H. pylori* and should not cause a rapid color change.

References:

CLOtest Rapid Urease Test package insert. Halyard Health Inc. 2015

Written By: Revised By: Donna Walck

Laboratory Medical Director and Microbiology Medical Director _____ Date _____

Technical Supervisor _____ Date _____

Annual Review: Medical Director/Designee Date

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Location of hard copy location(s): SLC Core lab

Date Archived: _____