UnityPoint Health Pekin
Department of Pathology
Pekin, IL 61554

Effective Date: 11-16-18
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RAPID UREA TEST

I. PRINCIPLE

Rapid urease test, also known as the CLO test (Campylobacter-like organism test), is a rapid test for diagnosis of *Helicobacter pylori*. The basis of the test is the ability of *H. pylori* to secrete the urease enzyme, which catalyzes the conversion of urea to ammonia and bicarbonate. The test is performed at the time of gastroscopy. A biopsy of mucosa is taken from the antrum of the stomach and is placed into a medium containing urea and an indicator phenol red. The urease produced by *H. pylori* hydrolyzes urea to ammonia, which raises the pH of the medium, and changes the color of the specimen.

II. CLINICAL SIGNIFICANCE

UnityPoint Health Pekin laboratory personnel will utilize this procedure to perform the rapid urea test.

III. SPECIMEN

A. Patient Preparation:
   1. 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.
   2. 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.

B. Biopsy
   1. The recommended gastric area to biopsy is at least 2 cm away from the pylorus along the lesser or greater curve of the antrum. Excise tissue that appears normal – avoid tissue that is eroded or ulcerated. H. pylori may be present in smaller numbers around those areas. A standard biopsy forceps should render a specimen of sufficient size for the test.

V. QUALITY CONTROL:

A. Each new lot or shipment of Selected Rapid Urea is tested with:
   1. *Proteus mirabilis* ATCC12453 = Positive
   2. *Escherichia coli* ATCC25922 = Negative
   3. *All Qc is provided by Methodist Microbiology Department*

B. Immerse a Culti-loop® of each organism into butt of agar; leave loop in agar and wait for appropriate reaction. Incubate for 24 hours.

C. All is documented on monthly QC log (UPPK SER-0503.01).

IV. PROCEDURE:

A. Insert the biopsy specimen into the agar butt once product has equilibrated to room temp.
B. A sterile loop may be used to push the specimen into the agar.
C. Incubate the tube aerobically at 35-37° C.
D. Observe for a pink color developing around the biopsy specimen, frequently within 30 minutes. This reaction may also be observed at room temperature incubations.
E. Continue incubation of negative test for a maximum of 24 hours. If urease enzyme is present, a pink color will develop.
F. Log patient result on log sheet (UPPK SER-0503.02)

V. REPORTING RESULTS/INTERPRETATION

A. Positive Test - a pink color developing in the media around the biopsy specimen.
B. Negative Test - no color change in the medium around the biopsy specimen.

VI. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. An improperly transported specimen may not result in an accurate test.
B. A false-positive reaction could result should the medium become contaminated with a urease-producing organism.
C. A false-negative reaction could result from an insufficient number of organisms present at the biopsy site. NOTE: A negative rapid urease test does not rule out the possibility of *Helicobacter pylori* colonization.

VII. REFERENCES

A. Remel Selective Rapid Urea package insert, 12076 Sante Fe Drive, Lenexa, KS 66215, General Information (800) 255-6730. Revised September 3, 2009.

POLICY CREATION :		***Date***
Author:	***Gretchen Norton, MT (ASCP)***	***03/14/1996***
Medical Director:	***Sheikh, MA, MD***	***03/14/1996***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
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REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Reviewed by

Lead	**Date**	**Coordinator/ Manager**	**Date**	**Medical Director**	**Date**