Accutest *Helicobacter pylori* Urease Test

Purpose

This procedure provides instructions for Acutest *Helicobacter pylori* Urease Test.

Principal and Clinical Significance

The Acutest *H. pylori* Urease Test is intended for the qualitative detection of the urease enzyme in gastric mucosal biopsies for the presumptive determination of *H. pylori* in symptomatic patients.

H. pylori has been shown to cause active chronic gastritis and has been implicated as a primary etiologic factor in duodenal ulcer disease, gastric ulcer and non-ulcer dyspepsia. *H. pylori* infection is a risk factor for gastric cancer and mucosal-associated lymphoid-type lymphoma (MALT). By causing chronic inflammation *H. pylori* may weaken the mucosal defenses and allow acid and pepsin to disrupt the epithelium.

H. pylori produces large amounts of urease enzyme.

Although *H. pylori* can be detected with histology or culture of gastric tissue, simple tests for the presence of urease enable more rapid and convenient diagnosis. Tests for gastric urease are more specific for *H. pylori* because mammalian cells do not produce urease and, except for *H. pylori,* the stomach is usually sterile.

Acutest test is a reactive pad of urease indicator sealed inside a plastic slide. The pad 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 pad from yellow to bright magenta.

This procedure applies to Microbiologists who perform culture plate reading.

Test Code

HPU

Materials

Supplies
• Accutest test slides (supplied to Surgery by the Microbiology department)

Specimen

A. Acceptable specimens
- Tissue, gastric mucosal biopsy

B. SDES codes/Specimen type
- GANT (gastric antrum)
- ANT (antrum)

C. Specimen Collection, Transport and Rejection Criteria
- Refer to Lab Test Directory – *Helicobacter pylori* Urease Test

Special Safety Precautions

Microbiologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology Procedure Manual***.**
- *Biohazard Containment*
- *Biohazardous Spills*
- *Safety in the Microbiology Laboratory*

Storage

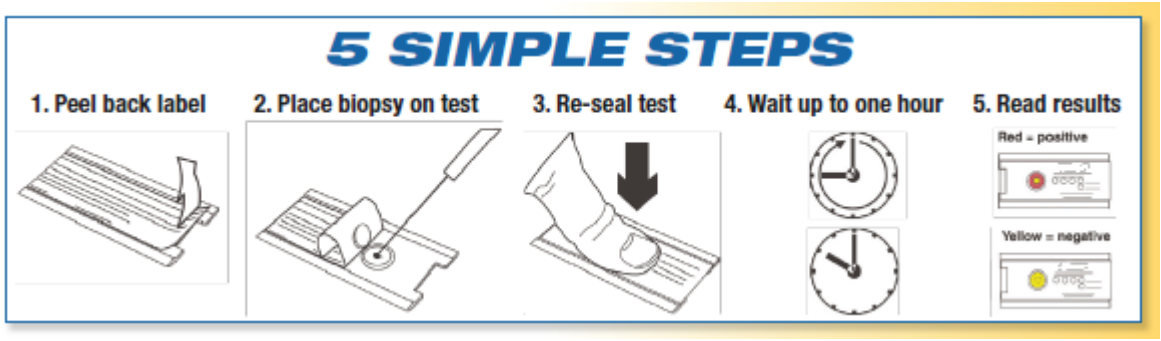
1. Store at room temperature away from direct light until expiration date.
2. Discard slide if the media is not yellow or appears dehydrated.
3. Discard slide if the seal is damaged.

Quality Control

1. **Positive control**: *Proteus mirabilis* (ATCC 7002) {a heavy inoculum}
2. **Negative control:** *E. coli* (ATCC 25922)
3. Perform QC with each new lot or shipment before put into service. Record results in QC manual.
4. If there is a QC failure, document observation and corrective action. Report QC problems that cannot be resolved to the microbiology technical specialist. Call Jant Pharmacal Corporation Customer Service at 800-676-5565. Do not report patient results until problem is resolved.

Procedure

A. Inoculation (Performed by Surgery)
   1. Peel back the label of the Accutest test far enough to expose the yellow reactive pad.
   2. With a clean applicator device (i.e. sterile needle), remove the specimen from the biopsy forceps and place it onto the reactive yellow pad. Make sure the tissue is positioned to have maximum contact with the reactive pad.
   3. Re-seal the test. Press the label over the reactive pad lightly with your finger to squeeze the tissue contents out of the specimen. Accurate resealing is important to prevent the biopsy specimen from drying up.
   4. Label slide(s) properly with the patient's name, medical record number and date/time.
   5. Transport to microbiology laboratory immediately.



B. Incubation (Performed by microbiology technologists)
   1. Results of Accutest test can be read over 1 hour at the following intervals:
      - 5 minutes
      - 30 minutes
      - 1 hour
   2. Record a positive reaction as soon as the reactive pad changes color. Once a positive reaction has occurred no further reading is necessary.
   3. If *H. pylori* is present, an expanding red color zone will be noted around the biopsy specimen, or the Accutest will gradually change to a deep orange, then red color. The red reactive pad anytime within an hour is considered positive reaction.
   4. A negative result is when the Accutest *H. pylori* test reactive pad is still yellow 1 hour after insertion of the specimen.

Interpretation

- **Positive**: Red, magenta, pink, deep orange
- **Negative**: Yellow

Limitations

A. Possible causes for false negatives:
   1. Very low numbers of *H.pylori* in the tissue sample.
   2. Patchy distribution so that the *H.pylori* is missed in the biopsy.
   3. A sample of intestinal metaplasia, (*H.pylori* does not colonize intestinal mucosa)
   4. Recent ingestion of antibiotics or bismuth which can inhibit the organism.
   5. Formalin contamination of the sample.

B. Possible causes for false positives:
   1. Theoretically, a false positive could occur in patients who have achlorhydria from bacterial overgrowth. This could be the result of the following conditions: 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.

Method Performance Specifications

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, as *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.

Result Reporting

1. Record results in Sunquest MRE Culture Entry tab. An example displaying the possible results is as follows:

   Observations: 1. POSITIVE: *Helicobacter pylori* urease enzyme detected
   2. NEGATIVE: No *Helicobacter pylori* urease enzyme detected

2. Sunquest Reporting Codes:
   - **PCLO**: *Helicobacter pylori* urease enzyme detected
   - **NCLO**: No *Helicobacter pylori* urease enzyme detected

3. If a culture requires a correction, the code **CORR** (corrected report) must be reported on an observation line in the Culture Entry tab. Refer to the procedure MCVI 5.1 Mislabeled and Unlabeled Specimens for additional information.

References

1. Accutest Rapid Urease Test for *H. pylori* Jant Pharmacal Corporation 16530 Ventura Blvd, Suite 512 Encino CA 91436 Rev B
2. Leber, Amy. *Clinical Microbiology Procedures Handbook*, 4th edition. Vol. 1-3 (Section 3.8.4). 2016. American Society for Microbiology, Washington D.C., 20036.

Training Plan/ Competency Assessment

Training Plan	Initial Competency Assessment
1. Employee must read the procedure. 2. Employee will observe trainer performing the procedure. 3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer.	1. Direct observation.

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1.0	Becky Carlson	01/20/1994	Initial Version

1.1	Becky Carlson/ Pat Ackerman	06/25/2007	Updated into procedure format and Sunquest 6.2 recording. Added correction information. Added worklabel information.
1.2	Jessica Craig	05/21/2010	Updated into online format.
2	Becky Carlson	4/19/2015	Re-numbered from MC 910 for CMS load. Retired old formatted procedure.
3	Susan DeMeyere/ Andrew Fangel	7/30/2018	Added room air for incubation.
4	Susan DeMeyere	1/2/2025	Changed from Avanos CLOtest to Jant Accutest.