



### CLOtest

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**Kettering Health Network (KHN) Organization-Wide Policy**  
 KHN adopts this policy for Kettering Medical Center, Sycamore Medical Center, Grandview Hospital and Medical Center/Southview Hospital, Greene Memorial Hospital, Inc., Soin Medical Center, Fort Hamilton Hospital, Troy Hospital, Kettering Physician Network, all hospital off-sites, and KHN Support Services.

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## I. PRINCIPLE

CLOtest® Rapid Urease Test (RUT) accurately detects the urease enzyme of *Helicobacter pylori* in gastric mucosal biopsies. Its use is intended for the presumptive diagnosis of a *H. pylori* infection. *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* produces large amounts of urease which can be detected in gastric biopsies. Tests for gastric urease are specific for *H. pylori* because mammalian cells do not produce urease, and, except for *H. pylori*, the stomach is usually sterile.

CLOtest® is a sealed plastic slide holding an agar gel, which contains urea, phenol red, buffers and bacteriostatic agents. If the urease enzyme of *H. pylori* is present in an inserted tissue sample, the resulting degradation of urea causes the pH to rise and the color of the gel turns from yellow, to a bright magenta color.

## II. SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

A. Biopsy specimens from endoscopy inoculated into the CLOtest® gel will be submitted. The usual biopsy site is the sump of the antrum, along the greater curve. It is better to biopsy normal tissue because the organism is present in smaller numbers if the epithelium is eroded or the mucus layer is denuded. Biopsy specimens will be inoculated into the CLOtest® gel at the bedside and then submitted to the laboratory.

## III. MATERIALS

- A. CLOtest plastic slide
- B. CLOtest urease tablet
- C. Inoculation loop or an applicator stick
- D. Non-CO<sub>2</sub>, incubator, 35°C

## IV. STORAGE AND STABILITY

A. The CLOtest RUT is stable for 18 months when stored at 2-8°C and expires on the last day of the month indicated on the package. Unopened CLOtest® should be yellow in color.

## V. QUALITY CONTROL

- A. Control reference cultures should be run with each new lot and each new shipment of CLOtest slides received into the laboratory.
- B. **Performing QC**
  - 1. Visually inspect the CLOtest slide and ensure that the uninoculated kit is yellow.
  - 2. Peel back the label on CLOtest slide so that the yellow gel is visible.
  - 3. Using an inoculation loop, take some of the QC organism and stab into the yellow gel.
  - 4. Put the label back into place and follow the procedure steps in Section VI for incubation and result interpretation.

Organism	Expected Result
<i>Klebsiella pneumoniae</i> ATCC 700603	Positive
<i>Escherichia coli</i> ATCC 25922	Negative
<i>Sterility</i>	Negative

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## VI. PROCEDURE

- A. Upon arrival in the laboratory, the CLOtest® slide is placed in the 35°C non-CO<sub>2</sub> incubator for three hours. Periodically examine the specimen over the three hours and note any change in color from yellow to pink or red.
- B. After three hours in the incubator, the CLOtest® is removed from the incubator and placed on the bench for 24 hours. Note the color of the gel, if the color of the gel is yellow proceed to the next step. If the color of the gel is a shade other than yellow (magenta, pink, deep orange) this is considered a positive test and no further incubation is required.
- C. After the 24-hour room temperature incubation, note the color of the gel. If the color of the gel is yellow at 24 hours, the test is negative and you should proceed to the next step.
  1. The “CLOtest Positive Control” must be performed to ensure the CLOtest slide is working properly. The positive control confirms that the negative result is due to the absence of *H. pylori* and not a defective CLOtest slide.
    - a. Peel back the Clotest Slide so that the yellow gel is visible.
    - b. Insert one Clotest urease tablet into the CLOtest gel and re-seal the slide.
    - c. After ten minutes, inspect the gel for a positive color change from yellow, to red or magenta.
    - d. If the gel turns red or magenta, the test is valid and the patient maybe reported out as negative.
    - e. If the gel does not turn red or magenta, the test is invalid and the patient result should not be reported out. If this occurs, repeat the test and contact the manufacturer.

## VII. INTERPRETATION

1. If at any time the entire gel turns to a shade other than yellow (magenta, pink, deep orange), this indicates the presence of *H. pylori* and is considered a positive test.
2. A negative test remains yellow after imbedding the tissue into the gel. If the color of the gel is yellow at 24 hours, and the positive control passes, the test is considered negative.
3. When first inserted in the gel, specimens may have a very slight pink tinge. Only if the pink area is deepening in color and expanding in size will the CLOtest® be positive.
4. If only a small number of organisms are present in the specimen, then instead of a seeing a red color around the biopsy, the color of the whole CLOtest® gel will gradually change.

## VIII. REPORTING RESULTS

- A. **Resulting in Epic Beaker**
  1. Select result entry and enter the specimen number.
    - a. Verify patient information matches patient information of the organism being tested.
  2. Click on “Edit”
  3. Enter in the CLOtest result as either positive or negative on Line 1 in the Value box.
  4. Enter the CLOtest QC result in Line 2.
    - a. If the QC passed, type in the number “84” or select the magnifying glass to select the “External QC passed after addition of the urease tablet” comment.

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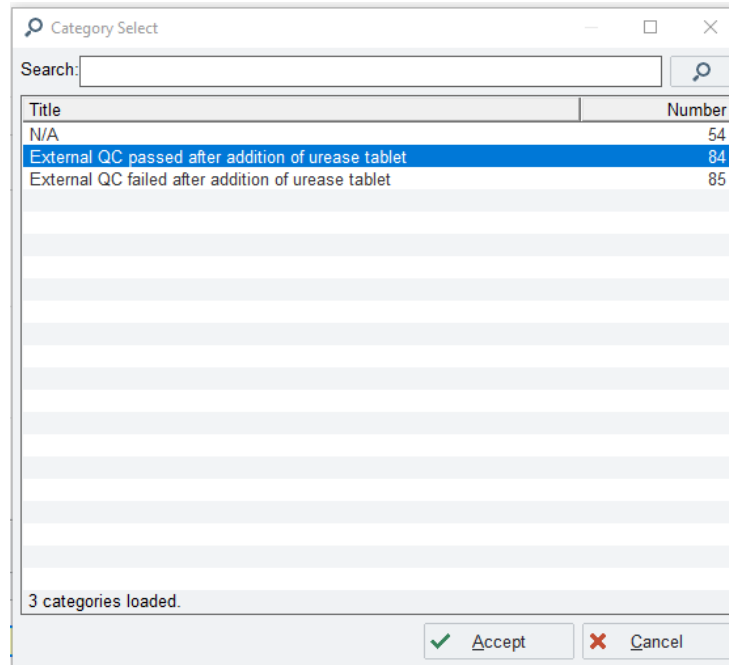
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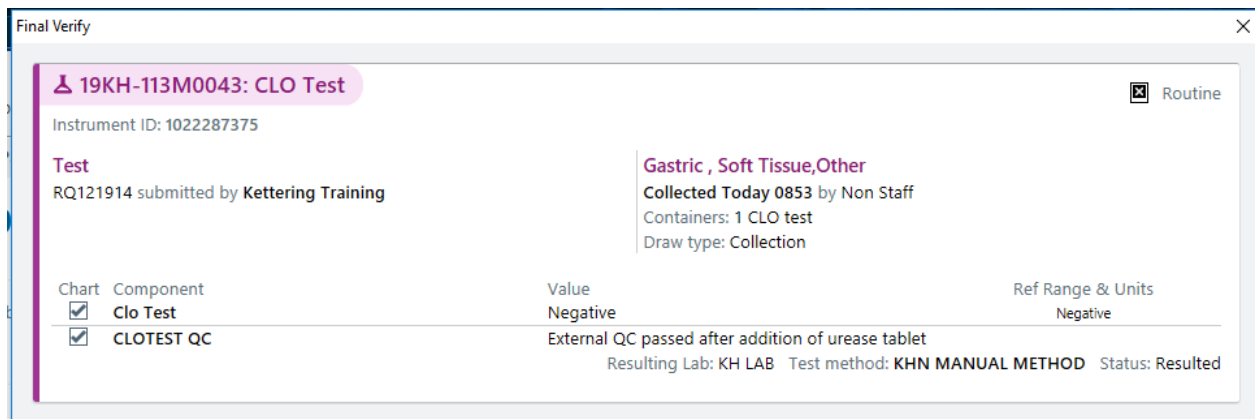
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- b. If the QC failed, type in the number “85” or select the magnifying glass to select the “External QC failed after addition of the urease tablet” comment.
5. Final verify the results.



### IX. CRITICAL DETERMINANTS

- A. False negative CLOtest results can occur when: the organism is present in very low numbers in the tissue sample, if the patient has recently taken antibiotics or bismuth, and if the sample is taken from the intestinal metaplasia.
- B. False positive CLOtest results may occur when there is bacterial overgrowth of the stomach.

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## **X. REFERENCES**

- A. Halyard CLOtest Rapid Urease Test Instructions for Use (2015).
- B. Halyard Reagent Urease Type III Instructions for Use.

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