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| **St. Anthony**  **Regional Hospital**  POLICY/PROCEDURE | Lab Director |  |
| Lab Manager |  |
| Laboratory | Department: Serology | |
| **Title: SOP.SER.005 CloTest 20240714** | | |

**Policy**

To detect preformed urease enzyme activity in gastric mucosal biopsies which indicate the presence of Helicobacter pylori. 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.

**Storage**

CloTest should be stored at 2-8 ºC until used. Allow product to come to room temperature before use.

**Preparation**

Before use the CloTest should be inspected to make sure that the well is full and a yellow color. If a CloTest has an orange color it should not be used.

Surgery will obtain a CloTest device from the laboratory when needed. Surgery will obtain the specimen and place in the CloTest package and return it to the lab.

**Procedure**

The CloTest specimen should be kept at room temperature for 24 hours.

**Interpretation of Results**

When first inserted into the gel, specimens may have a very slight pink tinge, particularly if blood or alkaline bile is present. Only if the pink area is deepening in color and expanding in size will the CloTest be called positive. If urease is present in the tissue, then an expanding magenta zone will be noted around the biopsy specimen. The CloTest may also gradually change to a deep orange and then a magenta color.

**Positive:** Any color change of the whole gel to a shade other than yellow (red , magenta, pink, orange) indicated the present of a H. Pylori. Read within 24 hours. Test device may be held up to 72 hours before reading.

**Negative:** Yellow color within 24 hours.

Positive Control: All negative tests will have a positive control test done.

1. Peel back the label on the CloTest slide until the yellow gel is exposed.
2. Put the CloTest Positive Control tablet into the gel.
3. Reseal the CloTest label over the gel.
4. Wait 5 minutes.
5. Observe the gel for a positive magenta color change.

Alternative Positive Control: Alternative positive control may be used when unable to obtain the CloTest Positive Control tablet.

1. Peel back the label on the CloTest slide until the yellow gel is exposed.
2. Use a green 10 µL loop to add Proteus vulgaris ATCC 49132 by puncturing the gel with the loop.
3. Reseal the CloTest label over the gel.
4. Incubate for 3 hours at 35-37°C.
5. Observe the gel for a positive magenta color change.

**Results**

Report CloTest results and positive control if performed in Meditech according to the Serology LIS Policy.

**Reference**

CloTest package insert and positive control tablet vial.