



CLO Test SOP/CRF

CLO Test Preparation	
CHAIN ID (Write CHAIN ID #. Affix barcode if available)	[3] [0] [0] [0] [1] [] [] []
Specimen Kit ID # (Write Specimen Kit ID #. Affix barcode if available)	MC- 0 _ _
<i>During MITs Set-Up and Preparation SOP, remove CLO test from mortuary refrigerator and lift the label far enough to expose the yellow gel. Allow it to reach room temp before inserting biopsy (at least 7-10 Do not use if seal is damaged, if gel appears dehydrated or is not yellow, or if expiration date passed.</i>	

Stomach Biopsy	
<i>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.</i>	
Biopsy Location	<input type="checkbox"/> Antral curve <input type="checkbox"/> Other: _____
Were samples contaminated by blood?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Sample Handling			
<i>With a clean applicator device, push the entire sample beneath the surface of the gel to expose as much of the specimen to the gel as possible. Make sure that the biopsy is completely immersed in the gel.</i>			
<i>Re-seal the pressure-sensitive label on the slide.</i>			
Date sample inserted	___ / ___ / ___ DD / MM / YYYY	Time sample inserted	___ : ___ 24 hour

CLO Test Reading			
<i>Contamination by blood may stain the gel around the edge of the tissue. This is NOT a positive test. If the biopsy contains urease, the change first appears around the sample and eventually colors all of the gel. 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 (positive test result).</i>			
<i>If the color of the gel is yellow at 24 hrs, the test is negative. The test will remain valid for 72 hrs after insertion of the biopsy into the gel. If the gel is yellow between 4-24 hours, it should be re-read at 24-72 hours to confirm a negative result. A positive result at any point before 72 hours is positive and does not need to be re-read.</i>			
CLO Test Result	<input type="checkbox"/> Positive <input type="checkbox"/> Negative		
Date CLO test read	___ / ___ / ___ DD / MM / YYYY	Time CLO test read	___ : ___ 24 hour
Location CLO test read	<input type="checkbox"/> CHAIN lab <input type="checkbox"/> Dr. Peter Finch's office		

Name of person who recorded CLO test result	_____
<p><i>If the CLO test is negative, perform the following positive control to ensure test is working properly:</i></p> <p><i>1) Insert a urease tablet into the gel and re-seal the slide.</i></p> <p><i>2) After 5 min, inspect the gel for a positive color change (red or magenta).</i></p> <p><i>3) If gel does not turn to red or magenta, make note below.</i></p>	
Positive Control Test	<input type="checkbox"/> Turns red/magenta <input type="checkbox"/> Remains yellow <input type="checkbox"/> N/A, test positive <input type="checkbox"/> N/A, urease tablet unavailable

Comments on CLO Test Procedure (Optional)
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Document History				
Version	Owner	Approved By	Date	Change Log
V.1 CLO Test SOP/CRF	Donna Denno	Anstead Kankwatira, Peter Finch, Phil Tarr	1-Aug-18	Original version
V.2 CLO Test SOP/CRF			1-May-19	1. Changed name of control test to 'positive control test' 2. added space for HMIS