## **MITS in CHAIN**



## **CLO Test SOP/CRF**

CHAIN ID  (Write CHAIN ID #. Affix barcode if available)  Specimen Kit ID # (Write Specimen Kit ID #. Affix barcode if available)  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.  Stomach Biopsy  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.  Biopsy Location  Mere samples contaminated by blood?  Yes No  Sample Handling  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.  Re-seal the pressure-sensitive label on the slide.  Time  sample  j / _ /	CLO Test Preparation							
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Date sample inserted/ / sample : : : 24 hour CLO Test Reading	the specimen to the gel	as possible. Make sure that th	ne biopsy is completel	y immersed in the gel.				
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		DD / MM / YYYY	inserted	24 hour				
	CLO Test Reading							
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)	Any color change of the w	hole gel to a shade other than	yellow (e.g. red, mag	enta, pink, deep orange)				
indicates the presence of H. pylori (positive test result) .								
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.								
CLO Test Result  Positive  Negative	CLO Test Result	Positive		T				
Time			Time					
Date CLO test read / /   CLO test : :	Date CLO test read	/ /	CLO test	:				
DD / MM / YYYY read 24 hour		DD / MM / YYYY	read	24 hour				
Location CLO test read CHAIN lab Dr. Peter Finch's office		CHAIN lab Dr.	Peter Finch's office					

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

Document History						
Version	Owner	Approved By	Date	Change Log		
		Anstead Kankwatira,				
V.1 CLO Test SOP/CRF	Donna Denno	Peter Finch, Phil Tarr	1-Aug-18	Original version		
V 2 3 1 2 7 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2				Changed name of control test to 'positive control test'     added space for HMIS		
V.2 CLO Test SOP/CRF			1-May-19	2. added space for frivins		