

## H. Pylori Rapid Stain Kit

**Description:** The H. Pylori Rapid Stain Kit is designed for demonstrating Helicobacter Pylori infected tissue. Kit may be used on formalin fixed, paraffin-embedded tissue as well as frozen sections.

**Uses/Limitations:** Not to be taken internally.  
 For In-Vitro Diagnostic use only.  
 Histological applications.  
 Do not use if reagents become cloudy.  
 Do not use past expiration date.  
 Use caution when handling reagents.  
 Non-Sterile.

**Control Tissue:** Helicobacter Pylori infected stomach.



**Results:** Helicobacter Pylori: Blue  
 Mucin: Yellow  
 Background: Light Blue

### Kit Contents:

<u>Item #</u>	<u>Kit Contents</u>	<u>Volume</u>	<u>Storage</u>
SSC-PAQ500	Periodic Acid Solution	500 ml	2-8° Centigrade
SSC-SME125	Sodium Metabisulfite Solution	125 ml	Room Temperature
SSC-ANY125	Alcian Yellow Solution	125 ml	Room Temperature
SSC-TQF006	Toluidine Blue Solution	6 ml x 2	Room Temperature
SSC-SHC008	Sodium Hydroxide Solution (3%)	8 ml	Room Temperature

### Mixed Storage Conditions. Separate Contents.

**Note:** Individual components are designed to be interchangeable with StatLab kits when both are produced by StatLab and have identical catalog numbers (e.g. SSC-PAQxxx may be ordered as an individual component to replace Periodic Acid Solution that is supplied with kit).

For information regarding ordering individual components, please contact us at: 800-442-3573.

**Control Slides Available.** Catalog: CS-HELI/25, Helicobacter, 25/pack

**Precautions:** Avoid contact with skin and eyes.  
 Harmful if swallowed.  
 Follow all Federal, State, and local regulations regarding disposal.

**Procedure:**

1. Deparaffinize sections if necessary and hydrate to distilled water.
2. Incubate slide in Periodic Acid Solution for 10 minutes (Note: Do Not Reuse Periodic Acid Solution).
3. Rinse thoroughly in distilled water.
4. Incubate slide in Sodium Metabisulfite Solution for 5 minutes.
5. Rinse thoroughly in distilled water.
6. Incubate slide in Alcian Yellow Solution for 5-10 minutes.

**Prepare Toluidine Blue Working Solution (Immediately prior to use):**

Distilled Water	50 ml
Toluidine Blue Solution	10 drops
Sodium Hydroxide Solution	3 drops

7. Rinse slide thoroughly in distilled water.
8. Incubate slide in freshly prepared Toluidine Blue Working Solution for 3-5 minutes  
(Note: Do Not Reuse Toluidine Blue Working Solution).
9. Rinse thoroughly in distilled water.
10. Air dry slides for 8-10 minutes or until completely dried.
11. Dehydrate quickly in 2 changes of absolute alcohol.
12. Clear, and mount in synthetic resin.

**References:**

1. Leung, K., Gibbon, K.J. A Rapid Staining Method for Helicobacter Pylori in Gastric Biopsies, Journal of Histochemistry, Volume 19, Pages 131-132. 1996
2. Vartanian, R.K., Leung, J.K., Davis, J.E., Kim, Y.B., Owen, D.A. A novel Alcian yellow-toluidine blue (Leung) stain for Helicobacter species: comparison with standard stains, a cost-effectiveness analysis, and supplemental utilities. Modern Pathology, January 1998, Volume 11(1); pages 72-78.



Lot-to-Lot Validation Form  
H. Pylori Rapid Stain Kit Catalog: SSK-HELI

Kit Lot Number: \_\_\_\_\_  
Kit Expiration Date: \_\_\_\_\_  
Date Tested: \_\_\_\_\_  
Control Tissue (#) \_\_\_\_\_  
Approved for Use: Y/N \_\_\_\_\_  
Date put into use: \_\_\_\_\_

If not approved,  
corrective actions  
taken: \_\_\_\_\_

Approved by: \_\_\_\_\_

**Kit Component****Lot #**

Periodic Acid Solution	_____
Sodium Metabisulfite Sol.	_____
Alcian Yellow Solution	_____
Toluidine Blue Solution	_____
Sodium Hydroxide (3%)	_____

Replacement Component if used	Replacement Date	Lot #	Accepted Y/N	Comments
Periodic Acid Solution				
Sodium Metabisulfite Sol.				
Alcian Yellow Solution				
Toluidine Blue Solution				
Sodium Hydroxide (3%)				
Approved By: _____				

StatLab is providing this form to assist with reagent lot validation as stated in CLIA'88 Standard 493.1256-For reagent(s), the laboratory must do the following: Check each batch (prepared in-house), lot number (commercially prepared) and



Instructions For Use **IFU-052**

## SSK-HELI

Rev. Date: Aug. 17, 2016 **Revision: 4** Page 4 of 4

shipment of reagents, stains, and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, if applicable.