

H. Pylori Rapid Stain Kit

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Intended Use

For In Vitro Diagnostic Use

Summary and Explanation

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.

Helicobacter Pylori: Blue

Mucin: Yellow

Background: Light Blue

Control Tissue

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding. Consult references (Kiernan, 1981; Sheehan & Hrapchak, 1980) for further details on specimen preparation.

1. Cut sections, usually 3 to 5 μ m and pick the sections up on glass slides.
2. Bake the slides for at least 30 minutes at approximately 70°C.
3. Allow to cool.

Recommended Positive Control

1. *Helicobacter Pylori* infected stomach

Reagents Provided

Kit Contents	Volume	Storage
Periodic Acid Solution	500 mL	2-8°C
Sodium Metabisulfite Solution	125 mL	15-30°C
Alcian Yellow Solution	125 mL	15-30°C
Toluidine Blue Solution	6 mL X 2	15-30°C
Sodium Hydroxide Solution (3%)	8 mL	15-30°C

Storage and Handling

Do not use product after the expiration date printed on vial. If reagents are stored under conditions other than those specified here, they must be verified by the user. Diluted reagents should be used promptly.

Prepare the Following Solutions Immediately Before Use

- i. Prepare Toluidine Blue Working Solution (Immediately Prior to Use)
- ii. Distilled Water 50 mL
- iii. Toluidine Blue Solution 10 drops
- iv. Sodium Hydroxide Solution 3 drops

Staining Procedure

1. Deparaffinize sections if necessary and hydrate to distilled water.
2. Incubate slide in Periodic Acid Solution for 10 minutes.
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.
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. Dehydrate quickly in 2 changes of absolute alcohol.
11. Clear, and mount in synthetic resin.

Limitations of the Procedure

1. Histological staining is a multiple step diagnostic process that requires specialized training in the selection of the appropriate reagents, tissue selections, fixation, processing, preparation of the slide, and interpretation of the staining results.
2. Tissue staining is dependent on the handling and processing of the tissue prior to staining.
3. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts or false negative results.
4. The clinical interpretation of any positive staining, or its absence, must be evaluated within the context of clinical history, morphology and other histopathological criteria. It is the responsibility of a qualified pathologist to be familiar with the special stain and methods used to produce the slide.
5. Staining must be performed in a certified licensed laboratory under the supervision of a pathologist who is responsible for reviewing the stained slides and assuring the adequacy of positive and negative controls.

Precautions

1. Consult local and/or state authorities with regard to recommended method of disposal.
2. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
3. Avoid microbial contamination of reagents. Contamination could produce erroneous results.
4. This reagent may cause irritation. Avoid contact with eyes and mucous membranes.
5. If reagent contacts these areas, rinse with copious amounts of water.
6. Do not ingest or inhale any reagents.
7. Use in a chemical fume hood whenever possible.

Troubleshooting

If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem is suspected, contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2 or techsupport@dbiosys.com.

References

- i. Leung, K., Gibbon, K.J. A Rapid Staining Method for *Helicobacter Pylori* in Gastric Biopsies, *Journal of Histochemistry*, Volume 19, Pages 131-132. 1996.

