



**Diagnostic
BioSystems**

Instructions For Use KT 019-IFU

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H. Pylori Rapid Stain Kit

Description and Principle

The H. Pylori Rapid Stain Kit is designed for demonstrating Helicobacter Pylori infected tissue. Kit may be used on formalin fixed, paraffin-embedded tissue.

Mucins are oxidized by Periodic Acid and selectively stained by Alcian Yellow. H. pylori is stained by a Toluidine Blue working solution resulting in blue bacteria on a yellow background.

Expected Results

Helicobacter pylori:	Blue
Mucin:	Yellow
Background:	Light Blue

Kit Contents

1. Periodic Acid Solution	Storage 2-8°C
2. Sodium Metabisulfite Solution	15-30°C
3. Alcian Yellow Solution	15-30°C
4. Toluidine Blue Solution	15-30°C
5. Sodium Hydroxide Solution (3%)	15-30°C

Suggested Controls (not provided)

Helicobacter Pylori infected stomach.

Uses/Limitations

For In-Vitro Diagnostic use only.

Do not use if reagents become cloudy or precipitate

Do not use past expiration date.

Use caution when handling reagents.

Non-Sterile

Intended for FFPE sections cut at 5-10µm.

This procedure has not been optimized for frozen sections.

Frozen sections may require protocol modification.

Storage

Mixed storage conditions. Store according to individual label instructions.

Safety and Precautions

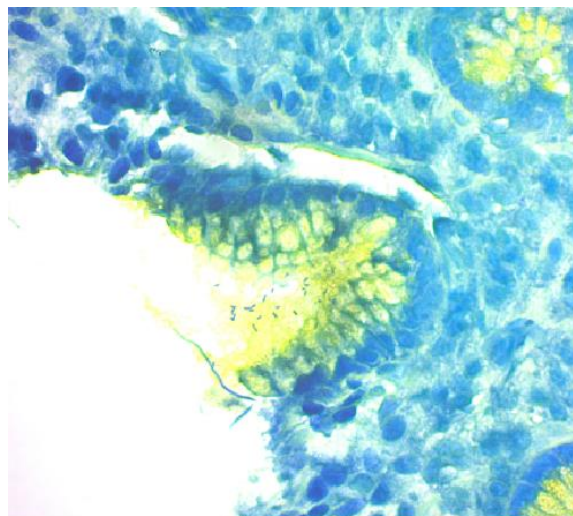
Please see current Safety Data Sheets (SDS) for this product and components GHS classification, pictograms, and full hazard/precautionary statements. If there is any serious incident that has occurred in relation to the device, please contact the manufacturer: Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2 or techsupport@dbiosys.com. If required, please report to the Competent Authority of the Member State in which the user and/or patient is established.

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.

7. Rinse slide thoroughly in distilled water. Leave in water until ready for next step.



H. pylori infection in Human Stomach mucin

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

Distilled Water	50 ml
Toluidine Blue Solution	20 drops
Sodium Hydroxide Solution	3 drops

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.

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.

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