



Instructions For Use KT 036-IFU

Document #: DS-3028-C

Release Date: 07/02/2024

6616 Owens Drive, Pleasanton, CA 94588 U.S.A. - Tel. (925) 484-3350 - Fax (925) 484-3390 - www.dbiosys.com

Warthin-Starry Stain Kit

Description and Principle

The Warthin-Starry Stain Kit is intended for use in the visualization of Spirochetes, *Helicobacter pylori*, *Legionella pneumophila*, and Cat Scratch Fever bacteria. This kit may be used on formalin-fixed, paraffin-embedded sections.

Bacteria bind silver ions from a solution of silver nitrate. Silver is reduced to a visible metallic form by a reducer solution containing hydroquinone.

Expected Results

| | |
|---------------------------------|-------------|
| <i>Helicobacter pylori</i> : | Black |
| <i>Legionella pneumophila</i> : | Black |
| Spirochetes: | Black |
| Cat Scratch Fever Bacteria: | Black |
| <i>Klebsiella</i> : | Brown/Black |
| Nuclei: | Brown |
| Background: | Yellow |

Kit Contents

1. SpiroPrep
2. Gelatin (4%), Acidulated
3. Silver Nitrate Solution (0.5%), Acidulated
4. Hydroquinone Solution (0.1%), Acidulated
5. Silver Nitrate Solution (2%), Acidulated

Storage

- 15-30°C
- 2-8°C
- 2-8°C
- 2-8°C
- 2-8°C

Suggested Controls (not provided)

Any spirochete infected tissue, *H. Pylori* infected tissue.

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.

Important Notes:

1. All glassware used in this procedure should be chemically cleaned with dilute bleach or acid and rinsed thoroughly in distilled water.
2. Do not use metal forceps to remove slides from reagents. Use plastic forceps only.

3. Equilibrate all reagents to room temperature prior to use.

4. Coatings on some control slides are more prone to binding silver than others. This can cause background staining and stain the glass a characteristic grey color.



Helicobacter pylori infection in Human Stomach stained with Warthin-Starry Stain Kit

Preparation of Reagents Prior to Beginning:

1. Warm Gelatin (4%), Acidulated to liquify prior to beginning.
2. Prepare Reducing Solution in unused or chemically cleaned plastic stain jar by combining:

| | |
|-------------|--|
| 12.5 ml | Gelatin (4%), Acidulated |
| 20-30 Drops | Silver Nitrate Solution (2%), Acidulated |
| 7.5 ml | Hydroquinone Solution (0.1%), Acidulated |

Procedure:

1. Deparaffinize sections if necessary and hydrate to distilled water.
2. For spirochete staining only, place slide in room temperature SpiroPrep for 5 minutes (Omit this step for other listed bacteria). Note: Use of SpiroPrep will not affect staining of *Helicobacter pylori*, *Legionella pneumophila*, or Cat Scratch Fever bacteria.
3. Pour 20ml of Silver Nitrate Solution (0.5%), Acidulated in an unused plastic staining jar and place in a waterbath at 65-70°C for 5 minutes.
4. Place slide in warmed Silver Nitrate Solution (0.5%), Acidulated and incubate for 3-5 minutes with repeated agitation.
5. Transfer slide into previously prepared Reducing Solution and agitate. Place staining jar in a waterbath at 65-70°C with frequent agitation until tissue section is a "paper bag" brown (5-20 min).



Diagnostic BioSystems
6616 Owens Drive
Pleasanton, CA, 94588
Tel: (925) 484 3350
www.dbiosys.com



CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland



MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

6. Rinse slide carefully in hot tap water for 2 minutes.
7. Dehydrate slide through 3 changes of fresh Absolute Alcohol.
8. Clear and mount in synthetic resin.

References

1. Kerr, D.A. Improved Warthin-Starry method for tissue sections; American Journal of Clinical Pathology, 1938, Vol. 8: pages 63-67.
2. Pounder, D.J. Warthin-Starry for Legionella. American Journal of Clinical Pathology, August 1983, Volume 80(2): page 276.
3. Ohtani, Y., Yoshirio, T., Akagi, T. Ultrastructure of Warth-Starry Stain-Positive Bacteria in Abscess-Forming Reticular Lymphadenitis. Pathology – Research and Practice, April 1992, Volume 188, Issue 3, pages 314-317.
4. Field, A.S., Marriott, D.J., Hing, M.C. The Warthin-Starry stain in the diagnosis of small intestinal microsporidiosis in HIV-infected patients. Folia Parasitology (Praha), 1993, Volume 40(4): pages 261-266.



Diagnostic BioSystems
6616 Owens Drive
Pleasanton, CA, 94588
Tel: (925) 484 3350
www.dbiosys.com



CH REP 
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland



MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands