

Instructions For Use KT 036-IFU

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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

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

Helicobacter pylori: Black Legionella pneumophila: Black Spirochetes: Black Cat Scratch Fever Bacteria: Black Brown/Black Klebsiella: Nuclei: **Brown** Background: Yellow

Kit Contents	Storage
1. SpiroPrep	15-30°C
2. Gelatin (4%), Acidulated	2-8°C
3. Silver Nitrate Solution (0.5%), Acidulated	2-8°C
4. Hydroquinone Solution (0.1%), Acidulated	2-8°C
5. Silver Nitrate Solution (2%), Acidulated	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 5-10 μ m.

This procedure has not been optimized for frozen sections. Frozen sections may require protocol modification.

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:

Diagnostic BioSystems

Pleasanton, CA, 94588

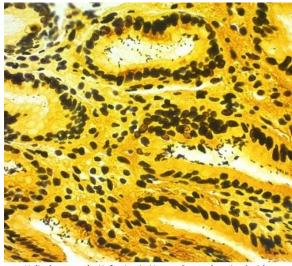
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Tel: (925) 484 3350

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- 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 Hydroquinone Solution (0.1%), Acidulated 7.5 ml

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).





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- 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
- Kerr, D.A. Improved Warthin-Starry method for tissue sections; American Journal of Clinical Pathology, 1938, Vol. 8: pages 63-67.
 Pounder, D.J. Warthin-Starry for Legionella. American Journal of Clinical Pathology, August 1983, Volume 80(2): page 276.
 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.
 Field, A.S., Marriott, D.J., Hing, M.C. The Warthin-Starry stain in the diagnosis of small intestinal microsportificsis in HIV-infected nationts. Folia Pagasitology (Praha)
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