

## Instructions For Use IFU-075 SSK-WARTHSTARR

Rev. Date: Aug. 17, 2016 Revision: 3 Page 1 of 4

**Control Tissue:** 

### Warthin-Starry Stain Kit

**Description:** 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 or frozen sections.

**Uses/Limitations:** For In-Vitro Diagnostic use

only. Histological

applications. Do <u>not</u> use past expiration date. Use caution when handling

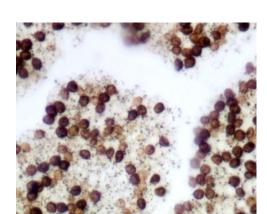
these reagents.

**Results:** Helicobacter pylori: Black

Legionella pneumophila: Black Spirochetes: Black Cat Scratch Fever Bacteria: Black

Klebsiella: Brown/Black

Nuclei: Brown Background: Yellow



Any well fixed tissue.

#### **Kit Contents:**

<u>ltem #</u>	Kit Contents	<u>Volume</u>	<u>Storage</u>
SSC-SSE125	SpiroPrep	125 ml	18-25°C
SSC-GSA065	Gelatin (4%), Acidulated	2x65 ml	2-8°C
SSC-SNB125	Silver Nitrate Solution (0.5%), Acidulated	125 ml	2-8°C
SSC-HSA030	Hydroquinone Solution (0.1%), Acidulated	2x30 ml	2-8°C
SSC-SNA030	Silver Nitrate Solution (2%), Acidulated	30 ml	2-8°C

For information regarding ordering individual components, please contact us at: 800-442-3573. Control Slides Available. Catalog: CS-SPIRO/25, Spirochete, 25/box and CS-HELI/25, Helicobacter Pylori, 25/box

**Precautions:** Keep away from open flame.

Avoid contact with skin and eyes.

Harmful if swallowed.

Follow all Federal, State, and local regulations regarding disposal.

Use in chemical fume hood whenever possible.



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Rev. Date: Aug. 17, 2016 Revision: 3 Page 2 of 4

### Preparation of Reducing Solution Prior to Beginning:

1. Warm Gelatin (4%), Acidulated to liquify prior to beginning. Prepare Reducing Solution in an unused plastic Slide Jar.

2. Combine: 12.5 ml Gelatin (4%), Acidulated

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

### Procedure (Standard):

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 brown (approximately 1-5 minutes).
- 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.



# Instructions For Use IFU-075 SSK-WARTHSTARR

Rev. Date: Aug. 17, 2016 Revision: 3 Page 3 of 4

#### Rapid Procedure (Microwave Oven):

- 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 microwave at full power for 30 seconds. Invert several times to equalize temperature.
- 4. Place slide in warmed Silver Nitrate Solution (0.5%), Acidulated and incubate for 5 minutes with repeated agitation.
- 5. Warm previously prepared Reducing Solution in microwave at full power for 20 seconds. Invert several times to equalize temperature.
- 6. Transfer slide into warmed Reducing Solution and with frequent agitation until tissue section is brown (approximately 2-5 minutes).
- 7. Rinse slide carefully in hot tap water for 2 minutes.
- 8. Dehydrate slide through 3 changes of fresh Absolute Alcohol.
- 9. 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.



Kit Lot Number:

### Instructions For Use IFU-075 SSK-WARTHSTARR

Rev. Date: Aug. 17, 2016 Revision: 3 Page 4 of 4

### Lot-to-Lot Validation Form Warthin-Starry Stain Kit Catalog: SSK-WARTHSTARR

Kit Lot Number:	ıt Lot Number:			Kit Component	Lot #
Kit Expiration Date:			<del></del>	SpiroPrep Gelatin (4%) Acidulated	
Date Tested:					
Control Tissue (#)		<del></del>	Silver Nitrate (0.5%)		
Approved for Use: Y/N Date put into use:				Acidulated Hydroquinone (0.1%)	
				Acidulated Silver Nitrate (2%)	
If not approved,					
corrective actions				Acidulated	
taken:					
Approved by:					
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Danlaramant	Danlerannant	10+#	Accorded	Companyonto	
Replacement	Replacement	Lot #	Accepted	Comments	
Component if used	Date		Y/N		
SpiroPrep					
Gelatin (4%) Acidulated					
Silver Nitrate (0.5%)					
Acidulated					
Hydroquinone (0.1%)					
Acidulated					
Silver Nitrate (2%)					
Acidulated					
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 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.