

Warthin Starry*Kit to highlight Spirochaetes on tissue sections***Manufacturer: Diapath S.p.A.****Use**

Reagent for in vitro diagnostic use

Code	Test	Reagents	Code	Packaging
		Citric acid	PMT0006	1.6g
		Silver nitrate	PMT0007	10g
010270	12 preparations for 4 slides	Silver nitrate 2%	G087AA	2x75 ml
		Gelatine 5%	G088AA	3x75 ml
		Hydroquinone 0.15%	G089AA	2x75 ml

Description

The kit is intended for use in histological visualization of *Spirochaetes* on tissue sections using stainings of Warthin Starry protocol.

Specimen and preparation kind

- Preparation: paraffin section
- Suggested fixative: formalin
- Control: Known positive case (*Spirochaetes*)
- Storage temperature: +4°/+8°C
- Procedure time: 1 h 20 min
- Critical step: pH of solution temperature. Do not use metal, use well cleaned laboratory glassware. Pay attention to protect reagents from the sunlight

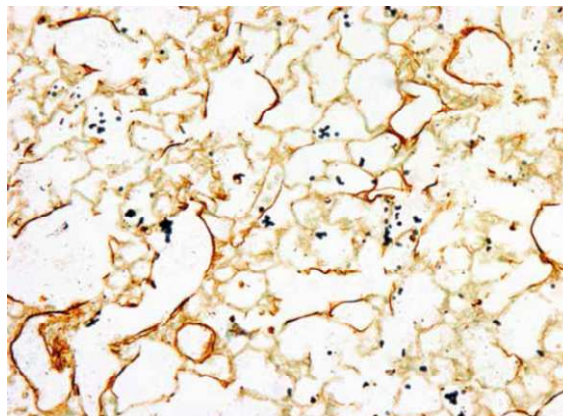
Staining protocol

Drain reagent directly on section in a way to cover it completely.
To avoid section excessive drying, use an incubator box.

1. Deparaffinize and hydrate to distilled water
2. Melt **Citric Acid** in 1 liter of bidistilled water. Stir up to complete melting. Check if the pH value is between 3.6-4.0
3. Dip **Silver nitrate** into the already prepared solution. Mix with a glass row (Note: NOT use metals, use always well cleaned glassware)
4. Pour some solution already prepared in a histological jar and protect it from the sunlight
5. Dip the slides into the prepared solution for 40 minutes at 50°C, into the darkness
6. Setting of Developing solution:
 - i. 7 ml of **Silver nitrate 2%**, heat at 50°C for 10 minutes
 - ii. 18 ml of **Gelatine 5%**, heat at 50°C for 10 minutes
 - iii. 10 ml of **Hydroquinone 0.15%**, heat at 50°C for 10 minutes
7. Mix the heat reagent with the following order: **Silver nitrate 2% + Gelatine 5% + Hydroquinone 0.15%** (mix with a glass row)
8. Pour the already prepared solution into an histological jar
9. Dip the slides for 3-4 minutes (up to the solution turns into brown)
10. Wash in heat running water
11. Dehydrate quickly, clarify and mount with balsam

Results

Spirochaetes: Black
Background: Gold brown



Quality control

The products and the raw materials are entered and constantly monitored by computer systems that allow traceability between batch number of each single product and batches of their raw materials.

Instructions of use

To avoid mistakes, the product should be used by qualified and trained staff. Professional use product. The guidelines concerning safety on the workplace must be applied according to current regulations. The tools used for diagnosis must be suitable for diagnostic use in laboratory. The diagnosis should be performed only by authorized, trained and competent staff. Control sections should be used during each test to avoid incorrect results.

Storage








Store the product according to the specifications listed on the label. The product, if opportunely stored and integrally packed, is stable up to the expiry date reported on the label. Do not use after expiration date.

If the reagent is not stored as recommended, its performance may change and must be validated by the user. After opening, the reagent is stable up to expiration date but only if stored in its container and in accordance with the specifications listed on the label. It is recommended to close the container tightly after the use.

Disposal instruction

The expired and/or unused product must be disposed according to local waste regulations, based on danger classification on the label and after possible contaminations evaluation. In some cases it may be necessary an analytical evaluation to determine the correct waste classification and the danger features.

Labeling legend

 LOT	Batch n.	 Manufacturer	 Storage temperature limits
 REF	Product code	 Expiry date	 In vitro diagnostic medical device
 Photosensitive			

For more information see the MSDS.