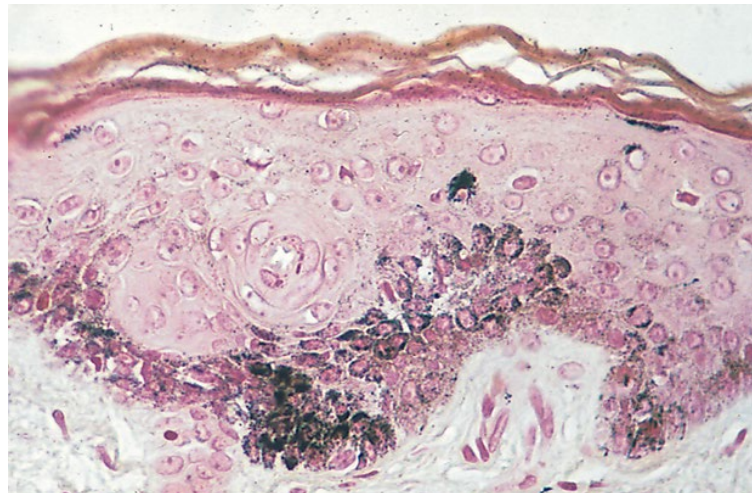




MASSON FONTANA



Skin

CODE	DESCRIPTION	TESTS NUMBER
04-041822	Masson Fontana	100 test

IVD

In Vitro Diagnostic – medical device
IVD in **Class A**, Reg. UE 2017/746
UDI-DI: 08033976230739
Basic UDI: 080339762W01030799Y5



Manufacturer: Bio-Optica Milano S.p.A.

Product for the preparation of cyto-histological samples for optical microscopy.
Recommended method to show melanin in histologic sections.

PRINCIPLE

Argentaffine reaction is based on the intrinsic capacity of some tissue components to reduce silver in an ammoniacal solution to metallic silver. To point out false positive results, this kit includes reagents for depigmentation of melanin (Mallory's bleach). Depigmentation has to be effected on control section before silver impregnation.

WARNING

For good results, follow these rules:

- Always use excellent and chlorine-free distilled or deionized water.
- Use only perfectly clean glassware.
- Avoid deposit of dust on sections. Never touch solutions with metallic objects (tweezers etc.)
- Fixatives containing heavy metal salts (mercury chloride, potassium dichromate) should be avoided since deposits of such salts may cause false positive results. It is necessary to use distilled water for all the washings and perfectly clean glassware.

METHOD

- 1) Bring two slides of the same preparation to distilled water.
- 2) Select slide as control. Only for control section, execute 3 and 4 steps.
- 3) Put on control slide 10 drops of reagent B and 10 drops of reagent C: leave to act 20 minutes and wash in distilled water.
- 4) Put on control slide 10 drops of reagent D: leave to act 5 minutes and wash in distilled water.
- 5) Prepare the incubation box and lay down the two slides (specimen and control); put 10 drops of reagent A on each section and close the incubation box: leave to act overnight.
- 6) Wash in distilled water and put 10 drops of reagent E: leave to act 5 minutes.
- 7) Wash in distilled water.
- 8) Put on control slide and on the specimen 10 drops of reagent F: leave to act 10 minutes.
- 9) Wash in distilled water.
- 10) Dehydrate through ascending alcohols, clear in xylene and mount.



The picture is for illustrative purposes only

Technical details

Method specifications	Procedure time	45 minutes + overnight	
	Complementary equipment	Not requested	
	Results	Melanin:	Black in specimen, absent in control (The presence of black precipitates is due to false positive).
Nuclei:		Red	
Components	A) Ammoniacal solution	30 ml	
	B) Potassium permanganate solution	18 ml	
	C) Activation acid buffer	18 ml	
	D) Oxalic acid solution	30 ml	
	E) Sodium thiosulfate solution	30 ml	
	F) Mayer's Carmalum	30 ml	
Storage	Storage	Store the preparation at 2-8°C. Keep the containers tightly closed	
	Storage temperature	2-8°C	
	Stability	After the first opening, the product is reusable until the expiry date, if correctly stored.	
	Validity	1 year	
Warning	Product classification	<p>The product is intended for professional laboratory use for healthcare professionals.</p> <p>Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged.</p> <p>In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.</p>	
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.	

REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022