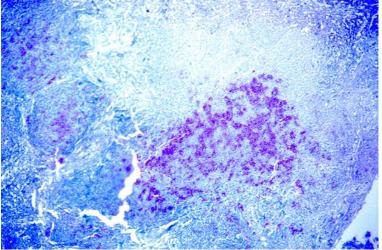


Data Sheet

(6

ZIEHL – NEELSEN FITE



Lung

CODE	DESCRIPTION	TESTS NUMBER	
04-111802	Ziehl Neelsen Fite	100	



In Vitro Diagnostic – medical device IVD in **Class A**, Reg. UE 2017/746 UDI-DI: 08033976231132 Basic UDI: 080339762W01030799Y5



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

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano Phone +39 02.21.27.13.1 - Fax Italia +39 02.21.53.000 - Fax Export +39 02.21.54.155 www.bio-optica.it – info@bio-optica.it – claims@bio-optica.it



Product for the preparation of cyto-histological samples for optical microscopy. To show pathogenic mycobacteria (especially Koch's bacillus and Hansen's bacillus) in histologic sections, sputum smears and culture smears.

PRINCIPLE

Acid resistance is a particular dyeing feature of myco-bacteria. Once they have been stained with carbol fuchsin, they have the capacity to remain red even if they undergo strong decolourizations. Acid resistance is usually ascribed to the special composition of mycobacteria's cell walls, which are very rich in lipids.

METHOD

- 1) Bring section to distilled water.
- 2) Put on the section 10 drops of reagent A: leave to act 10 minutes.
- 3) Rinse in distilled water.
- 4) Put on the section 10 drops of reagent B: leave to act 30 minutes.
- 5) Wash in distilled water and dry the slide with filter paper.
- 6) Put on the section 10 drops of reagent C: leave to act 1 minute.
- 7) Rinse 3 minutes in tap water.
- 8) Put on the section 10 drops of reagent D: leave to act 1 minute.
- 9) Wash in distilled water.
- 10) Dehydrate through ascending alcohols, clear in xylene and mount.



The picture is for illustrative purposes only



3

Technical details

Method specifications	Procedure time	45 minutes	
	Complementary equipment	Not requested	
	Results	Koch' s bacillus and other acid resistant elements:	Red
		Background:	Blue
Components	A) Periodic acid solution	30 ml	
	B) Carbolfuchsin solution	30 ml	
	C) Acid differentiation buffer	30 ml	
	D) Methylene blue solution	30 ml	
Storage	Storage	Store the preparation at room temperature. Keep the containers tightly closed.	
	Storage temperature	15-25°C	
	Stability	After the first opening, the product is reusable until the expiry date, if correctly stored.	
	Validity	2 years	
Warning	Product classification	The product is intended for professional laboratory use for healthcare professionals. 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. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.	
	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