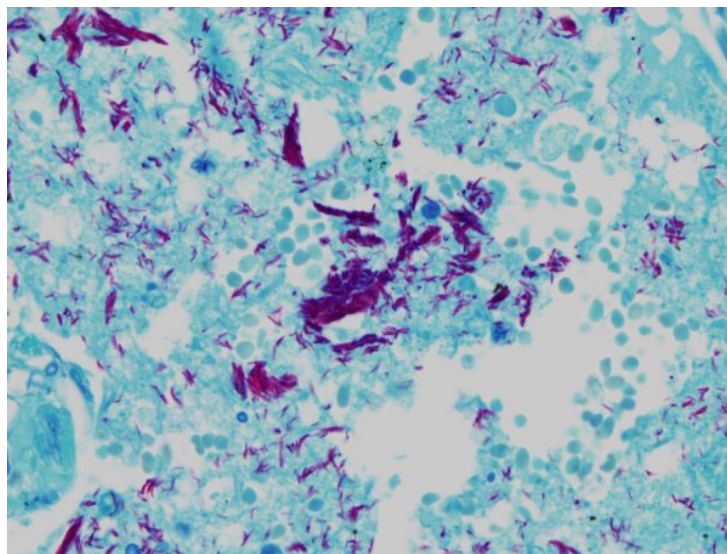




ZIEHL – NEELSEN FITE

For microbiology



Koch's Bacilli

CODE	DESCRIPTION	TESTS NUMBER
04-111803	Ziehl Neelsen for microbiology	N.A.



In Vitro Diagnostic – medical device
IVD in **Class A**, Reg. UE 2017/746
Basic UDI: 080339762W01030799Y5
UDI-DI: 08033976231156



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

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

PRINCIPLE

Acid resistance is a particular dyeing feature of mycobacteria. 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) Put on the smear the reagent A for 10 minutes
- 2) Wash in tap water.
- 3) Add on the smear the reagent B for 1minute
- 4) Wash in tap water
- 5) Put on the smear the reagent C for 30 seconds
- 6) Wash in tap water
- 7) Dehydrate through ascending alcohols, clear in xylene and mount.



The picture is for illustrative purposes only

Technical details

Method specifications	Procedure time	12 minutes	
	Complementary equipment	Not requested	
	Results	Koch' s bacillus and other acid resistant elements:	Red
Background:		Blue	
Components	A) Carbol fuchsin solution	500 ml	
	B) Decolorizing solution	2 x 500 ml	
	C) Methylene blue solution	500 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