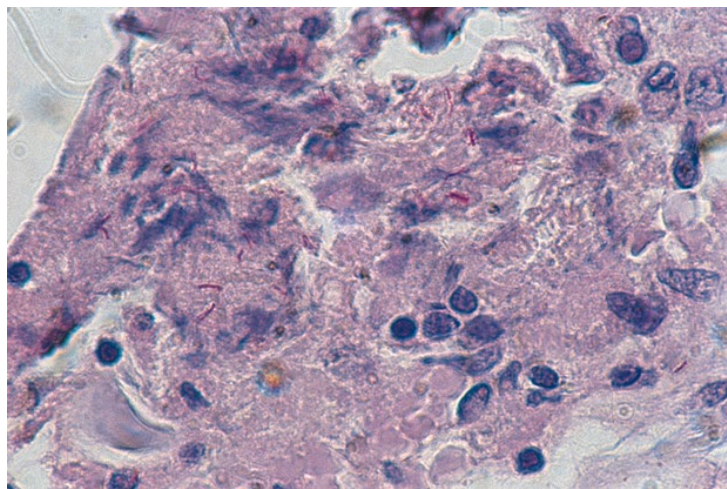




ZIEHL - NEELSEN



Lung

| CODE | DESCRIPTION | TESTS NUMBER |
|-----------|---------------|--------------|
| 04-110802 | Ziehl Neelsen | 100 |



In Vitro Diagnostic – medical device
IVD in **Class A**, Reg. UE 2017/746
UDI-DI: 08033976231101
Basic UDI: 080339762W01030799Y5



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 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 2 minutes.
- 9) Wash in distilled water and blue in running tap water for 5 minutes.
- 10) Dehydrate through ascending alcohols, xylene and mount.



The picture is for illustrative purposes only

Technical details

| | | | |
|-----------------------|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Method specifications | Procedure time | 50 minutes | |
| | Complementary equipment | Not requested | |
| | Results | Koch' s bacillus and other acid resistant elements: | Red |
| | | Nuclei: | Blue |
| Components | A) Periodic acid solution | 30 ml | |
| | B) Carbofuchsin solution | 30 ml | |
| | C) Acid differentiation buffer | 30 ml | |
| | D) Mayer's Hemalum | 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 | <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 | <p>Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.</p> | |

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