

MYCOBACTERIUM TUBERCULOSIS FLUORESCENT STAINING REAGENT (TB FLUORESCENT STAIN)

Catalog No. 09B0401

3 × 100 mL

INTENDED USE

This assay is intended to apply a chemical dye to acid-fast bacteria such as *Mycobacterium tuberculosis*, acting as an important aid in the diagnosis of *Mycobacterium tuberculosis* infections.

INTRODUCTION

Mycobacterium tuberculosis (MTB) is a pathogenic bacterial species in the genus *Mycobacterium* and the pathogen of most cases of tuberculosis (TB)¹.

Globally, the TB disease is an enormous problem. TB is the world's most significant infectious disease from a single infection agent².

Hence, the early screening and detection of MTB infection is of great benefit to the control of this disease.

The identification of MTB is still the most specific method for TB diagnosis. Among various MTB identification protocols, fluorescent staining technology has the advantages of simple operational procedures, reasonable cost, and rapid results, etc³.

BIOLOGICAL PRINCIPLE OF THE PROCEDURE

When the acid-fast bacteria are stained by fluorescent dye auramine O, bright orange-yellow fluorescence with a black background can be easily detected by UV-fluorescence microscope under low magnification. It is faster to screen acid-fast bacteria using this fluorescence kit than the carbolfuchsin stain.

MATERIALS PROVIDED

1. Auramine O Dye Reagent: a reagent containing auramine O dye and phenol (1 vial, 100 mL)
2. Decolorization Reagent: a reagent containing ethanol and hydrochloric acid (1 vial, 100 mL)
3. Counterstain Reagent: a reagent containing potassium permanganate (1 vial, 100 mL)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Microscope slides
2. Inoculation loop

STORAGE OF TEST KIT AND INSTRUMENTATION

1. Unopened test kits should be stored at room temperature and under good ventilation conditions upon receipt. The test kit may be used throughout the expiration date of the

kit (12 months from the date of manufacture). Refer to the package label for the expiration date.

SPECIMEN COLLECTION, PREPARATION, TRANSPORT AND STORAGE

1. Specimens collected with right medical techniques such as sputum, urine and pleural effusion may be used.

PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. For professional use only.
2. This package insert must be fully understood prior to operation. The operation must be stringently in accordance with the instruction for use.
3. The Auramine O dye included in this kit is very stable and will not precipitate. As a result, the fluorescence would not disappear.
4. For kit storage, avoid exposure to extreme high or low temperature and sunlight.
5. Wear disposable gloves when dealing with specimens and reagents. Wash hands after operations. All specimens must be regarded as potentially infectious materials. Waster material must be disposed of safely according to relevant local and national requirements.
6. Components with different lot numbers are not allowed to be exchanged.

ASSAY PROCEDURE

1. Pick the specimens with a inoculation loop. Smear to an ellipse shape with a size of 2.0 × 2.5 cm. Fix the smear with an alcohol lamp.
2. Add Auramine O Dye Reagent onto the smear to stain for 15 minutes at room temperature or under mild flame for 5 minutes.
3. Rinse with tap water gently. Air dry or dry with bibulous paper.
4. Decolorize for 1~2 minutes with Decolorization Reagent. Rinse with water.
5. If yellow color is still present, decolorize again until no yellow color is coming off the specimen.
6. Apply Counterstain Reagent for 2 minutes. Rinse with water gently and air dry. Bake to dry with mild flame.
7. Examine the finished slide under a microscope.



INTERPRETATION OF RESULTS







The acid-fast mycobacteria appear bright orange yellow against a black background. Occasionally, the debris in the background displays light yellow.

LIMITATIONS

Some other bacteria such as *Mycobacterium leprae* also display a bright orange yellow color.

SYMBOLS


	BATCH CODE
	USE BY

	MANUFACTURER
	CONTAINS SUFFICIENT FOR <n> TESTS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION
	CATALOGUE NUMBER
	CONSULT INSTRUCTIONS FOR USE

REFERENCES

1. Kenneth James Ryan, C. George Ray, John C. Sherris *Sherris Medical Microbiology : An Introduction to Infectious Diseases*; McGraw-Hill Professional: 2003;
2. Barry R. Bloom *Tuberculosis: pathogenesis, protection, and control*; ASM Press: 1994;
3. Zhuang Y. *Chinese Journal of Laboratory Medicine* 2001, 24, 69.

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