TMS 07 – TUBERCULOSIS FIRST LINE KIT

PRODUCT INFO

Contains five antitubular drugs (Isoniazide, Streptomycin, Ethambutol, Rifampicin, Pyrazinamide) +2 controls

PRODUCT SUMMARY AND EXPLANATION.

Anti-tuberculosis drugs have been used for many decades and resistance to them is now widespread. *M. tuberculosis* may be resistance to one or more drugs. Anti-tuberculosis drug resistance is a major public health problem which arises due to improper and irrational use of anti-tuberculosis drugs in chemotherapy of drug-susceptible tuberculosis patients. This improper use is a result of a number of actions including administration of improper treatment regimens, and failure to ensure that patients complete the whole course of treatment. A patient who develops active disease with a drug resistant tuberculosis strain can transmit this form of tuberculosis to other individuals.

Based on invitro correlation between the clinical response to antimicrobial agent and the result of invitro susceptibility testing kit helps in diagnosing the sensitivity pattern of *M. tuberculosis* affected patient and accordingly provide treatment, drug therapy for the patients.

Mycobacteria susceptibility test can be inoculated either directly from digested and concentrated smear positive sputum (direct test) or from a pure culture of Mycobacteria isolated from a clinical specimen (indirect test). The direct test is usually done only on specimens showing Mycobacteria on smear and give the best results when large no. of Mycobacteria are present. The advantage of the direct test is that a much earlier report of susceptibility studies (3 to 4 weeks) can be made than with indirect test which may take up to 5 to 7 weeks, but can be frequently be complicated by over growth with other bacteria that have survived.

COMPOSITION

Proprietary

PRINCIPLE

The five anti tubular drug slants help in determining resistance of the pathogen against the first line of antibiotics, which are Isoniazide, Streptomycin, Ethambutol, Rifampicin and Pyrazinamide.

INSTRUCTION FOR USE

Perform all work in Biological safety cabinet. Follow good laboratory procedures when working with Mycobacteria cultures and specimens. For inoculations use calibrated loop or micropipette. Ensure that all the specimen and used slants are immersed in suitable disinfectant or preferably 2% glutealdehyde for minimum two hours before disposal. The Drug Susceptibility Test is carried out for:

1. Either sputum sample previously subjected to decontamination and concentration process. Inoculate 10- of the processed specimen on slants. OR
2. Pure culture of Mycobacteria isolated from a clinical sample.

Preparation of inoculum:

1) Inoculum is taken from the M. tuberculosis growth, primarily isolated on L. J. medium slant.
2) Take a loopful of inoculum (aseptically).
3) Prepare a suspension of the sample in 1.0ml of sterile distilled water in a screw capped bottle.
4) Use the glass beads of 3.0mm diameter for better homogenization and declumping of cells.
5) Homogenize the mixture on a vortex mixture up to 10 minutes.
6) Make sure the suspension is evenly dispersed.
7) Keep the tubes for standing about 10 minutes, before opening the bottle.

8) Find out the Optical density of suspension to match McFarland 0.5 standard with saline giving approximately 1.5x 108 cfu/ml.
9) Later, dilute this suspension to 1:10000.

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Pale bluish green colored, smooth slants containing five antitubular slants.
Sterility Check	:	Passes release criteria

INTERPRETATION

Cultural characteristics observed after Incubation with 5-10% CO_2.

Microorganism	ATCC	Inoculum	Growth on control slant pH 6.8	Growth on control slant pH 5.5	Colony characteristics on control slants	Growth on slant w/ antibiotic	Incubation Temperature	Incubation Time
Mycobacterium tuberculosis H37RV	25618	Standardized inoculum giving approximately 1000000 cfu/ml	Luxuriant	Luxuriant	Granular, rough, warty, dry, friable colonies	Inhibited	35-37°C	2-4 weeks

PACKAGING:

In pack size of 1 kit containing 10 slants.

STORAGE

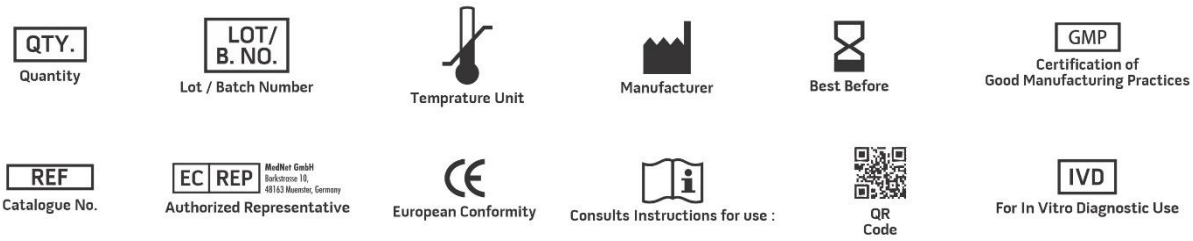
On receipt, store vials in the dark at 2-8° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Vials from unopened packages can be used up to the expiration date. Opened vials must be used immediately.
Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, or any other signs of deterioration.

DISPOSAL

After use, prepared media, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1. Guidelines for Drug Susceptibility Testing for second - line Antituberculosis drugs for Dots- Plus. WHO/CDS/TB/2001.288.
2. Tuberculosis in Canada, 2002, Drug Resistant Tuberculosis Among the foreign- born in Canada. Public Health Agency, Home Publications, Canada.
3. Canetti, G.;. Smelev, N.A et al. 1968 Bull., Org. Mnd. Sante, Bull. Wld Hlth. Org.: Advances in techniques of testing Mycobacterial drug sensitivity, and the use of sensitivity tests in tuberculosis control programmes , 41, 21-43.
4. Isenberg, H.D., 2004, Clinical Microbiology Procedures Handbook, 2nd edition, Vol. 2, ASM Press, Washington, DC.
5. Lorian, V. 2005, Antibiotics in Laboratory Medicine, 5th edition, Lippincott Williams & wilkins, USA.
6. Joklik W.K., Zinsser, H and. Willet, H.P, 1976, Zinsser Microbiology, 16th edition, Norwalk,CT: Appleton-Century-Croft.
7. Koneman , E.W et.al.,1992, Color Atlas and Text book of Diagnostic Microbiology, 4th edition, p: 736, J.B. Lippincott Company, Philadelphia.
8. John Bernard Henry (ed). 1984, Clinical Diagnosis and Management by Laboratory Methods, Todd, Sandord, Davidsohn, 17th ed., W.B. Saunders, Philadelphia.
9. Lutwick L.I. 1995, Tuberculosis; A Clinical Handbook, 1st Edition, Chapman & Hall Medical, New York. 10. Collee J.G. Marmin, B.P., Fraser, A.G and Simmons A (eds) Mackie and McCartney, Practical Medical Microbiology, (1996) 14th ed., Churchill Livingstone, New York.



NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**

Revision: 17 March., 2022