Lyfectol®

Intended Use
Lyfectol ® is a mucolytic, disinfectant, specimen pretreatment and buffering system for AFB staining and culture.

Summary
Infection with *Mycobacterium tuberculosis* remains a major public health problem. The epidemic of Tuberculosis and Multi Drug Resistant Tuberculosis reflects the failure of public health and social program's towards prompt treatment of infected cases and screening of high-risk population. Culture, isolation and sensitivity of *Mycobacterium tuberculosis* from patient groups using standard culture methods remain the gold standard for *Mycobacterium tuberculosis* detection and effective and swift treatment worldwide.

Principle
Proper decontamination and concentration of specimen containing normal microbial flora such as sputum are crucial in detecting *Mycobacterium tuberculosis*. Lyfectol® provides a liquefaction-decontamination and specimen buffering procedure that maintains the viability and pathogenecity of *Mycobacterium tuberculosis*, simultaneously eliminating all unwanted microorganisms. Since mucous is sticky, Acid Fast Bacilli trapped in mucoid portion of sputum are released by mucolytic action of N-Acetyl-L-cysteine. NaOH decontaminates other microorganisms, and final wash with phosphate buffer ensures that specimen is at optimum pH for staining and culturing. Specimen pretreatment and disinfection with Lyfectol® increases relative Acid Fast Bacilli concentration and ensures its more sensitive detection during Acid Fast Bacilli staining and culture.

Reagent
Microxpress® Lyfectol® is a reagent for laboratory use only.
Lyfectol® is provided as a three component reagent.
1. Lyfectol® Reagent A (2 % NaOH solution)
2. Lyfectol® Reagent B (N-Acetyl-L-Cysteine)
3. Lyfectol® Reagent C (Phosphate Buffer)

Accessories: Spatula for approximate weighing (12 mg) and transfer of Reagent B.
Lyfectol® is used for decontamination and concentration of specimen containing normal microbial flora such as sputum as per international recommendation.

Additional Material Required
Sterile plating loops (10 µL), biosafety hood with Bunsen burner, centrifuge at 3000-4000 rpm, activated 2% glutaraldehyde solution, 5 mL measuring cylinder, vortex mixer, 1 mL micropipette, 15-25 mL universal container.

Specimen Collection
Collect specimen prior to use of antimicrobial agent. Wherever possible, indicate clearly that patient is on antitubercular drugs.
Sputum: Collect 5 to 10 mL in a sterile container from an early morning specimen of deep productive cough. For induced specimen use sterile saline. Have patients rinse mouth with water to minimize specimen contamination with food particles, mouthwash, or oral drugs.

Directions
The procedure mentioned below is for 2.5 mL of the sputum sample. In case of variation in quantity of specimen used, process using proportionate amounts of reagent, mucolytic and disinfection reagent.

Preparation of Mucolytic Reagent
The mucolytic reagent must be prepared just prior to use.
1. Bring the reagents to room temperature.
2. Add one scoop full (≈12 mg) of Reagent B to 2.5 mL of Reagent A with the provided spatula.
3. Mix to dissolve.
4. The mucolytic reagent can be used within 24 hours of preparation, if stored at 2°C-8°C.

Processing of Specimen
1. Take approximately 2.5 mL of the specimen in a clean sterile 15-25 mL universal container.

2. Add 2.5 mL of the mucolytic reagent and close the container tightly with a screw cap fitted with an intact liner.
3. Mix well by gently vortexing at every 5 minutes interval for 20 minutes.
4. After 20 minutes, unscrew the cap of the container carefully and add 5 mL of Reagent C.
5. Close again the container tightly as in step 2.
6. Mix well and centrifuge for 25 minutes at 3000-4000 rpm.
7. After centrifugation unscrew the cap of the container with the content carefully and discard the supernatant gently in an activated 2% glutaraldehyde solution, taking care as not to disturb the pellet at the bottom.
8. To the pellet at the bottom add 0.1 mL of sterile distilled water or 5% Bovine albumin solution and re-suspend the contents.
9. Use this suspended material for microscopy (Acid Fast Bacilli), Acid Fast Bacilli culture or Polymerase Chain Reaction.

Quality Control

Appearance:

Lyfectol® Reagent A (2% NaOH Solution)- Clear, colourless liquid.
Lyfectol® Reagent B (N-Acetyl-L-Cysteine)- White crystalline powder.
Reagent C (Phosphate Buffer)- Clear, colourless liquid.

Liquification Test:

Test	Result
2.5 mL of thick mucoid sputum specimen added to a mixture of 12 mg of Reagent B and 2.5 mL of Reagent A, mix well by gently vortexing at every 5 minutes interval for 20 minutes.	Thin liquified sputum obtained

Remarks

1. Treat the unused specimen and contaminated containers by immersing in 2% activated glutaraldehyde for atleast two hours before incineration and disposal.
2. Good laboratory practices and hazard precautions must be observed at all times.
3. Discoloured or contaminated reagent should not be used.
4. The reagent containing the phosphate buffer may appear turbid on prolonged storage at 2°C-8°C. Gently warm at 25°C-30°C before usage to remove such an appearance.

Storage and Stability

1. Store the Lyfectol® kit at 2°C-8°C, away from light.
2. Stability of the Lyfectol® kit is as per the expiry date mentioned on the label.

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

Clinical Diagnosis & Management by Laboratory Methods, Todd, Sanford & Davidsohn, 17th Edition 1998, Edited by John Bernard Henry.

1. Tuberculosis; A Clinical Handbook, 1st Edition 1995, Edited by L.I. Lutwick.
2. Practical Medical Microbiology, Mackie & McCartney, 13th Edition 1989, Edited by J.G. Collee, J.P. Duguid.
3. Microbiology, Zinsser, 16th Edition 1976, Edited by W.J. Joklik, H.P. Willet.
4. Cultural Detection of Mycobacteria, L. Naumann, Biotest Bulletin 5:177-180 (1995).
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat. No.	Product Description	Pack Size
203120350012	Lyfectol®	12 Tests

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.