

INTENDED USE

PRO-LAB Mucolyse PL.701 is a sputum liquefying agent used to digest and thin out the sputum, thus enhancing the isolation of organisms responsible for chronic lung disease.

SUMMARY AND EXPLANATION

Diagnosis and management of chronic lung disease has improved with the advent of sputum thinning agents. In the past iodides, Alevaire (Breon Laboratories, Inc. New York, N.Y.), and sodium salts, have clinically been used to help thin the thick bronchopulmonary secretions commonly associated with this disease, but with limited success.¹ A significant contribution to the cause was made by Sheffner in 1963 when he demonstrated that the reactive sulfhydryl groups in n-acetylcysteine were mucolytic.² Since then, Cleland has shown that the sulfhydryl reagent dithiothreitol is a superior reagent for the specific and total reduction of mucoprotein disulfide bonds.³ DTT as a liquefying agent is used routinely in the digestion of sputum prior to processing smears and cultures as it does not effect the morphology, growth or FA standing of the pathogens in the sputum.⁴

DESCRIPTION

Dithiothreitol (DTT) and phosphate buffer in accurate quantities are lyophilized and provided in individually labelled vials. Each vial is sufficient to make 100 ml of final product. The resultant pH will be 7.0.

FORMULA

Each vial contains:

Dithiothreitol 100 mg

PROCEDURE

To reconstitute each vial of PRO-LAB Mucolyse PL.701, add, aseptically, a volume of sterile distilled water (up to 10 ml). After closing the vial, gently agitate for complete reconstitution. The resultant solution should be clear and free from visible particulate matter. Add the contents of the vial to a volume of sterile distilled water so that the final volume is 100 ml.

IN USE

1. Overlay sputum samples with an equal volume of diluted Mucolyse in a centrifuge tube.
2. Vortex the sputum for 30 seconds.
3. Allow the mixture to stand at room temperature for 15 minutes.

Note: Prolonged standing will not inhibit floral multiplication.

For Predominant organisms:

1. Centrifuge the mixture for five minutes at 1500 rpm to sediment the cells.
2. Discard the supernatant and resuspend the sediment in a small amount of diluted Mucolyse. The amount of diluent used is dependent upon the volume of sediment and the final concentration desired. A dilution of 1:100 with an inoculum of 0.01 ml is recommended for colony counting. For a more accurate count serial dilutions are required.

For Acid Fast Bacilli:

1. Decontaminate the specimen by suspending the sediment in 5-10 ml of 1% NaOH (thorough mixing is required for the first minute).
2. Centrifuge the suspension for fifteen minutes at 3000 rpm and discard the supernatant.
3. Wash the sediment twice in 10 ml of mucolyse.
4. After the last centrifugation, suspend the sediment in 0.5 ml of diluted mucolyse.
5. Culture for Acid Fast Bacilli on appropriate media.

SAFETY PRECAUTIONS

1. PRO-LAB Mucolyse PL.701 is offered only as an *in vitro* material and is in no way intended for a curative or prophylactic purpose.
2. During and after use, handle all materials in a manner conforming to Good Laboratory Practices and consider at all times that material under test should be regarded as a potential biohazard if mishandled.

PRESENTATION

PRO-LAB Mucolyse PL.701 is supplied 10 vials per box (lyophilized).

STORAGE

PRO-LAB Mucolyse PL.701 (lyophilized) must be stored at 2° to 8°C. Kept under these conditions it may be used up to date of expiry shown on product label.

REFERENCES

1. Hirsh, S.R., Zastrow, J.E., and Kory, R.C. 1969. Sputum liquefying agents: a comparative "in vitro evaluation". J. Lab. & Clin. Med. 74: 346-352.
2. Shah, R.J. and Dye, W.E. 1966. Use of dithiothreitol to replace n-acetyl-l-cysteine for routine sputum digestion-decontamination for the culture of mycobacteria. Am. Rev. Respir. Dis. 94: 454.
3. Cleland, W.W. 1964. Dithiothreitol, a new protective reagent for SH groups. Biochemistry. 3: 480-482.

4. Reep, B.R., Kaplan, P.H, and Kaplan, W. 1972. The use of n-acetyl-l-cysteine and dithiothreitol to process sputa for mycological and fluorescent antibody examination. Health Lab Sci. 9: 118-124.

	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use

EU	 <p>Warning Hazardous ingredients: Na₂HPO₄ / Dithiothreitol Causes serious eye irritation. Causes skin irritation.</p> <p>Wear protective gloves. Wear eye or face protection. Wash hands thoroughly after handling. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>
United States and Canada	 <p>Warning Causes serious eye irritation. Causes skin irritation.</p> <p>Wear protective gloves. Wear eye or face protection. Wash hands thoroughly after handling. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.</p>