

INTENDED USE

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

SUMMARY AND EXPLANATION

Diagnosis and management of chronic lung disease have 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 before processing smears and cultures as it does not affect the morphology, growth, or FA standing of the pathogens in the sputum.⁴

PRINCIPLE OF THE TEST

DTT is a reducing agent that splits the disulphide bonds present in mucus glycoproteins and releases microorganisms for analysis.

REAGENTS / MATERIALS PROVIDED

Mucolyse™ is supplied as 10 vials per box (lyophilized). Each vial contains: Dithiothreitol 100 mg
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 the final product. The resultant pH will be 7.0.

MATERIALS REQUIRED BUT NOT PROVIDED

- Sterile distilled water
- Pipettes, graduated cylinders
- Culture media
- Inoculating loops, swabs, collection containers
- Vortex mixer

STORAGE AND STABILITY

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

PRECAUTIONS AND WARNINGS

1. Mucolyse™ is intended for in vitro diagnostic use only.
2. Do not use after the expiry date shown on the product label.
3. Do not use if the seal is damaged or if the pellet cannot be dissolved.
4. Universal precautions should be taken in handling, processing, and discarding all clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.

SPECIMEN COLLECTION AND PREPARATION

The specimen should be collected and handled following standard clinical laboratory sputum handling procedures.

PROCEDURE

To reconstitute each vial of Mucolyse™, aseptically add 10ml of sterile distilled water. Close the vial and 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™.
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.**
4. The liquefied/homogenized samples are ready to be used in downstream analyses.

QUALITY CONTROL PROCEDURES

Testing of control organisms should be performed as per the quality control procedures established by each laboratory following their state and local regulatory agencies.

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>

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