

# **QBC<sup>®</sup> Diagnostics** Innovative Solutions for a Healthier World



## QBC F.A.S.T.™ Sputum Digestion Solution

### Instruction Manual



4277-400-045 Rev. E  
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## English

# QBC F.A.S.T.™ Sputum Digestion Solution

### Intended Use

For processing sputum and other respiratory clinical specimens for recovery of mycobacteria such as *Mycobacterium tuberculosis*.

### Summary and Principles

Mycobacteria can be difficult to recover from mucoid clinical specimens due to their relatively slow growth characteristics, as well as the presence of normal flora that may contaminate culture media. QBC Diagnostics Sputum Digestion Solution is designed to facilitate the liquefaction of mucous and the inactivation of non-acid fast organisms in clinical specimens, which promotes optimum recovery of mycobacteria for subsequent diagnostic testing and culturing. N-Acetyl-L-Cysteine (NALC) in the solution acts to liquefy the specimen by disrupting the disulfide linkages that help to form mucin aggregates. Sodium hydroxide acts to both liquefy specimens and inactivate non-acid fast organisms. Trisodium citrate acts to chelate heavy metal contamination that would inhibit the effectiveness of NALC.

NALC is effective as a digesting agent only in a reduced (non-oxidized) form. For this reason, the Sputum Digestion Solution contains the NALC in a dry powder form sealed in a glass ampoule. The NALC will remain in a reduced state maintaining its potency until the ampoule is broken.

Included with the digestion solution are five packets of sodium phosphate powder that can be made up as a separate buffer

solution. The buffer is added to the digested specimen to quench the reaction and optimize the specimen pH for subsequent culture.

## **Contents**

- 9 - 75 mL bottles of Sputum Digestion Solution
- 4 Phosphate Buffer Powder packets (one packet makes 500 mL of buffer solution)
- 1 Product Insert

## **Warnings and Precautions**

For *in vitro* diagnostic use

Human clinical specimens can harbor infectious diseases such as the causative agents of tuberculosis, hepatitis, human immunodeficiency virus (HIV) and others. “Universal Precautions” and local guidelines and regulations should be followed when handling clinical specimens. All activities that could generate aerosols from clinical specimens should be performed in a biosafety cabinet. Activities that involve culturing of *Mycobacterium tuberculosis* should be performed using Biosafety Level 3 procedures and practices.

The chemicals in this kit are hazardous and can be harmful or fatal. Reagents contain strong alkali and can cause burns. Avoid eye and skin contact. In case of eye contact, flush immediately with copious amounts of water. If ingested, give milk, egg white or large amounts of water. In case of eye contact or ingestion call a physician immediately. Consult kit MSDS for additional information regarding safety and disposal.

This product is designed to aid in the detection of acid fast bacilli. Sputum smear microscopy and the procedures involved with sample preparation and processing for AFB detection should be

performed only by those trained in the techniques involved as well as general laboratory practices and procedures.

### **Storage Instructions**

The Sputum Digestion Solution is stable for 1 years at 15-25 °C provided that the NALC remains in the intact ampoule. Avoid extreme heat or cold. Do not use if the glass ampoule is broken prior to use or expiration date has passed. Do not open until ready to use. Store away from strong oxidizers.

The Phosphate Buffer packet is stable for 1 years at 15-25 °C. Once the Phosphate Buffer Solution is reconstituted, it should be sterilized immediately. Do not use beyond the expiration date. Do not open until ready to use.

### **Directions for Use**

**Note: Perform manipulation of patient specimens with proper biosafety practices.**

#### *Phosphate Buffer Preparation*

1. Pour contents of Phosphate Buffer Powder packet into a 500 mL volumetric flask or autoclavable bottle with a 500 mL gradation.
2. Add water to 500 mL and mix well.
3. If a volumetric flask was used, pour contents into an autoclavable bottle.
4. Autoclave buffer.

#### *Digestion procedure*

1. Prior to use, loosen but do not remove the screw-cap on the Sputum Digestion Solution plastic bottle.

2. Locate ampoule in bottle and squeeze bottle in the upright position until the ampoule breaks.
3. Close the lid and shake the bottle gently to dissolve the NALC; avoid foaming the solution.
4. In an aerosol-free sterile 50 mL centrifuge tube, add equal amounts of clinical specimen and NALC containing solution.
5. Cap the centrifuge tube and mix specimen until it is liquefied. Allow digestion reaction to take place for 15 minutes at room temperature. Avoid longer digestion times as mycobacteria will become inactivated with prolonged exposure to the digestion solution.
6. Add sterile phosphate buffer for a final volume of 50 mL and recap the centrifuge tube.
7. Centrifuge sample for 15 minutes at 2200 to 3000 x g.
8. Decant supernatant into appropriate biohazard container.
9. Resuspend sediment in 1 to 2 mL of phosphate buffer. Specimen should now be pH 6.8.
10. Specimen is now ready for diagnostic testing and culturing.

### **Expected Results**

The QBC F.A.S.T. Sputum Digestion Solution is used for the digestion and decontamination of clinical respiratory specimens (sputum or bronchial lavage) suspected to contain mycobacteria.

If procedures are followed correctly, viscous specimens will be liquefied and contamination by normal flora will be reduced or eliminated.

### **Limitations**

No one method of digestion-decontamination is suitable for all

clinical specimens in all situations. When selecting a procedure, choose the mildest procedure that will reduce contamination.

### **Equipment Required But Not Provided**

A centrifuge that is capable of spinning 50 mL centrifuge tubes at 2200-3000 x g.

### **References**

For additional information on the recovery of mycobacteria for diagnostic testing and culturing, consult the following references:

1. Essential Procedures for Clinical Microbiology. (1998) American Society of Microbiology. Washington, D.C.
2. Manual of Clinical Microbiology. (2007) Volumes 1 and 2. 9<sup>th</sup> Edition. American Society of Microbiology. Washington, D.C.

### **Ordering Information**

- QBC F.A.S.T.™ Sputum Digestion Solution, catalog number 427403
- QBC F.A.S.T.™ Centrifuge (115V, 60Hz), catalog number 427412
- QBC F.A.S.T.™ Centrifuge (220V, 50Hz), catalog number 427413
- QBC F.A.S.T.™ Sputum Prep Tubes, catalog number 427406



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Manufacturer



Authorized Representative in the European Community



Use By



Catalog Number



In Vitro Diagnostic Medical Device



Temperature Limitation



Batch Code (Lot)



Consult Instructions for Use



Caustic