K7625050 NAOH-NALC DIGESTANT 2.5% KIT 5 X 50ML
K7625200 NAOH-NALC DIGESTANT 2.5% KIT 5 X 200 ML
K7640050 NAOH-NALC DIGESTANT 4.0% KIT 5 X 50ML
K7640200 NAOH-NALC DIGESTANT 4.0% KIT 5 X 200 ML
K7670030 PHOSPHATE BUFFER 30 ML
K7670050 PHOSPHATE BUFFER 50 ML
K7670500 PHOSPHATE BUFFER 500 ML
K7680003 BOVINE SERUM ALBUMIN FRACTION V

INTENDED USE:
The recovery of mycobacteria is oftern difficult because mycobacteria generally grow much slower than other bacterial species and specimens containing mycobacteria also contain many other types of bacteria. N-Acetyl-L-Cysteine (NALC), when combined with NaOH, facilitates decontamination by digesting mucopurulent specimens which allows the NaOH to penetrate. Sodium citrate stabilizes the NALC by binding the heavy metals, allowing it to work properly. The final combined solution is only usable for 24 hours after adding the NALC. For this reason, the NALC is packaged separately, to allow mixing only as needed. Phosphate Buffer lowers the specific gravity of the specimen and gently neutralizes the specimen after decontamination. Bovine Serum Albumin is added to the sediment after centrifugation to enhance the growth of mycobacteria. Bovine Serum Albumin also assists in adhering the sediment material to the slide or solid media and increases the volume of material for culture.

APPROXIMATE FORMULATIONS:
NAOH-NALC DIGESTANT KIT : (5 sets included)
NaOH 2.5% or 4.0% Solution depending on catalog number. (50%)
Sodium Citrate 2.94 % (50%)
NALC- N-Acetyl-L-Cysteine to achieve a final dilution of 0.5 %
Final pH 13.5 +/-0.5 @ 25° C
PHOSPHATE BUFFER: **(see price list for packaging)**
Disodium Phosphate 9.47gm
Monopotassium Phosphate 9.07gm
Deionized Water 1000 ml
pH 6.8 +/- 0.2 at 25° C
BOVINE SERUM ALBUMIN:(sold separately)
Bovine Serum Albumin Fraction V 0.20gm
Sodium Chloride 0.8 gm
Deionized Water 100.0 ml
pH 7.2 +/- 0.2 at 25° C

STORAGE AND SHELF LIFE:
Do not use any of the material if there are any signs of discoloration, contamination, deterioration or if the expiration has passed. The expiration date applies to the product when stored as directed. The NAOH-NALC KIT and Bovine Albumin have an expiration date of 180 days from date of manufacture whereas Phosphate buffer has 365 days. The NAOH-NALC KIT and Phosphate buffer should be stored at 15-30 degrees C. Store Bovine Serum Albumin at 2-8 degrees C.

CAUTIONS:
This product is for in vitro diagnostic use only and should be used by adequately trained and qualified laboratory personnel only. All laboratory specimens should be considered infectious and handled according to approved laboratory guidelines for infectious material. Sterilize all biohazard waste before disposal.

PROCEDURE:
Specimens should be collected in a sterile container. Transport specimens to the lab without delay. The specimen should be refrigerated if processing will be delayed. Work within a biological safety cabinet and wear gloves and proper laboratory attire.
1. Prepare fresh digestant solution by adding the container of NALC powder to the bottle of the NAOH-NALC Base Digestant. Prepare only what can be used within 24 hours.
2. Transfer 5-10ml of sputum specimen and an equal amount of the activated digestant into a 50ml, aerosol-free, screw-capped centrifuge tube.
3. Vortex the centrifuge tube until the specimen is liquified. If specimen is extremely viscous, add a little more digestant.
4. Stand tube upright at room temperature (15-30 degrees C.) for 15 minutes. Do not exceed 20 minutes.
5 Without touching the lip of the centrifuge tube, add Phosphate Buffer to within 2cm of the top of the tube. Recap then gently mix.
6. Centrifuge at least 15 minutes at 3600Xg.
7. Asceptically decant the supernatant into a splash proof waste container containing a sterilant such as 5% phenol. Wipe the lip of the centrifuge tube with disinfectant. Do not allow the disinfectant to enter the tube.
8. Add to this sediment, using a separate sterile pipette for each tube, 1-2ml of 0.2% Bovine Serum Albumin fraction V (pH 6.8) or phosphate buffer. Mix with pipette, without creating an aerosol.
9. The suspension may then be used for smear prep, culture, or susceptability testing following protocol for mycobacterial cultures.
10. Follow CDC protocol for the interpretation of growth and more information on smears and/or susceptability testing.

LIMITATIONS:
Timing is important during the digestion process. A digestion time of longer than 15 minutes should not be used. Many Mycobacterium spp. are killed by over decontamination. Occasional specimens are so contaminated with resistant bacteria that the decontamination process is not effective and the contaminating bacteria will overgrow the slower growing mycobacteria. Sediment material may be redigested and a selective medium, with antibiotics such as Lowenstein Jensen or Middlebrook 7H11, can be used to decrease the growth of contaminating organisms. Consult CDC procedures for recommended culture media.

MATERIALS REQUIRED BUT NOT PROVIDED
Microbiological supplies and equipment such as vortex mixers, biological safety cabinets, centrifuge tubes, slides, media, loops, incinerators, incubators, pasteur pipets, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL:
NAOH-NALC Base Digestant is not a growth medium. The product is tested only for its ability to decontaminate. Do not use any of the material if there are any signs of discoloration, contamination, deterioration, or if the expiration date has passed.
Procedure:
1. Prepare a large test tube with 1 ml of suspension of *Pseudomonas aeruginosa* and *Staphylococcus aureus* adjusting to a 0.5 McFarland.
2. Add 1 ml of prepared NAOH-NALC digestant to this suspension and incubate aerobically @ 35C for 10 minutes.
3. Neutralize by adding 2 ml of Phosphate buffer ; vortex then streak 0.01 ml onto a Blood Agar plate.
4. Incubate aerobically at 35 degrees C for 24 hours. Both organisms should be partially to completely inhibited. Note: Some pH tolerant organisms may breakthrough (e.g. S. aureus ATCC® 25923) when the process sample is plated on non-selective media.

REFERENCES:
1. Murray, P.R., et al. 1995. Manual of Clinical Microbiology, 6th ed. American Society for Microbiology, Washington, D.C.
2. Forbes, B.A., et al. 1990. Bailey and Scott's Diagnostic Microbiology, 8th ed. C.V. Mosby Company, St. Louis, MO.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook, Vol. I & II. American Society for Microbiology, Washington, D.C.

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