

INTENDED USE

M/15 Phosphate Buffer is used in the N-acetyl-L-cysteine (NALC) digestion and decontamination procedure of clinical specimens for the recovery of acid-fast bacilli (AFB).

SUMMARY

A decontamination and digestion procedure, utilizing the mucolytic compound NALC, results in increased yields of tuberc bacilli. The NALC/NaOH procedure involves a digestion of the specimen and decontamination of non-acid-fast bacilli. The M/15 Phosphate Buffer should be used in accordance with the appropriate digestion/decontamination time.

FOR IN VITRO DIAGNOSTIC USE ONLY**STABILITY AND STORAGE**

M/15 Phosphate Buffer is stable until the stated expiration date when stored at the required temperature. Prior to opening, store at room temperature (15– 30°C). After opening, refrigerate between 2– 8°C.

USER QUALITY CONTROL

Each bottle of M/15 Phosphate Buffer contains the volume stated on the label. Any product showing cloudiness, turbidity, precipitation, or coloration should be discarded.

PROCEDURE

Materials Provided: M/15 Phosphate Buffer.

Materials Not Provided: Centrifuge, vortex mixer, AFB digestion reagents, pipettes, microscope slides, TB media, centrifuge tubes, and bovine albumin.

SPECIMEN PROCESSING

1. Line up specimens and centrifuge tubes in a biosafety hood.
2. Loosen specimen container caps. Work in sets equivalent to a centrifuge load.
3. Add an equal volume of NALC/NaOH reagent solution to a sterile 50 ml centrifuge tube containing the specimen to be digested. Do not use more than 10 ml of specimen. The NAC-PAC® Systems are a convenient method for digestion. **NOTE:** The amount of the specimen to be processed in the centrifuge must never exceed more than 1/5 the volume of the tube (i.e., for a 50 ml centrifuge tube, 10 ml of specimen is the maximum). If it is necessary to process the entire specimen, use more than one centrifuge tube and combine the sediments after centrifugation.
4. Tighten the caps on the centrifuge tubes. Mix each specimen on vortex until liquified—30 seconds per specimen.
5. Allow each specimen to stand for 15–20 minutes.
6. Fill each tube to the 50 ml mark with M/15 Phosphate Buffer. Tighten the cap and swirl by hand to mix.
7. Centrifuge the specimen tubes at 3000 xg for 15 minutes. It is recommended but not required to use a refrigerated centrifuge. Each laboratory must check the centrifuge head radius and use an appropriate nomogram for proper speed selection (rpm) to achieve the desired relative centrifugal field of 3000 xg.
8. Working in a biosafety hood, pour off **all** the supernatant into a splash-proof container holding an appropriate disinfectant. Use appropriate disinfectant to disinfect any contamination on the lip of the specimen tube. Do not allow any disinfectant to run inside the specimen tube.
9. Using a sterile pipette, add 1 or 2 drops of the 0.2% Bovine Albumin Fraction V Solution. Shake gently by hand to mix.
10. Place two drops of the undiluted albumin sediment onto the surface of each of the TB media used and inoculate according to your rapid broth diagnostic system's manufacturer's recommendations.
11. Make a smear of the albumin sediment. Spread one drop over an area of 1 x 2 cm on the microscopic slide. Place the slide on an electric slide warmer at 65–70°C for two hours or overnight.
12. Stain slides using Rapid TB Stain Set (#0003445) or other procedure of choice. Call Alpha-Tec for a complete list of AFB stains.

NOTE: A QC1™ AFB Slide (#0003240) should be stained in conjunction with the patient smears to verify the staining technique and components.

SPECIAL PROCEDURES

Specimens contaminated with *Pseudomonas* spp. will need additional treatment with 5% Oxalic Acid (#0003447). Refer to the Oxalic Acid Directions For Use for complete instructions.

BIBLIOGRAPHY

1. Kent, P, Kubica, GP. Public Health Mycobacteriology: A Guide for the Level III Laboratory. Center for Disease Control and Prevention (CDC). 1985.
2. Kubica, GP, et al. Sputum digestion and decontamination with N-acetyl-L-cysteine-Sodium Hydroxide for culture of mycobacteria. Am Rev Respir Dis. 1963. 87;775-779
3. Kubica, GP, et al. Comments on the use of the new mucolytic agent, N-acetyl-L-cysteine, as a sputum digestant for the isolation of mycobacteria. Am Respir Dis. 1964. 89;284-286.
4. Murray, P. Manual of Clinical Microbiology. American Society of Microbiology. 1985.
5. *Mycobacterium tuberculosis*: Assessing Your Laboratory. Centers for Disease Control and Prevention (CDC). March 1995.

CONTACT

Alpha-Tec Systems, Inc. offers a complete line of digestion systems, stains, and reagents for AFB specimen processing. For Technical Assistance contact Technical@AlphaTecSystems.com and for Customer Service, email Sales@AlphaTecSystems.com or call [+1] 800.221.6058 or [+1] 360.260.2779 between 8 am and 4 pm Monday through Friday, Pacific Time.

WARRANTY

Alpha-Tec Systems, Inc. warrants this product to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS

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PRODUCT CODES

0003440 M/15 Phosphate Buffer, 50 x 50 ml
0003442 M/15 Phosphate Buffer, 8 x 250 ml
0003449 M/15 Phosphate Buffer, 64 x 10 ml
0003451 M/15 Phosphate Buffer, 10 x 500 ml
0003496 M/15 Phosphate Buffer, 50 x 40 ml



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GLOSSARY OF SYMBOLS

LOT Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote

REF Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog number / Het aantal van de catalogus / Kataloška številka / Número de catálogo

IVD In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro

EC REP Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Germachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeo Autorizado



Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada



Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante



Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / laktag försiktighet / Previdno / Atenção



Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperatura comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas



Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenido suficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebinsa zadostuje za <n> testov / Contém quantidade suficiente para <n> testes



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