

Sulfuric Acid Solution 4%**INTENDED USE**

Sulfuric Acid Solution is used for decontamination and digestion of clinical urinary source specimens.

FOR IN VITRO DIAGNOSTIC USE ONLY**PRECAUTIONS**

Sulfuric Acid Solution is **POISONOUS**. If swallowed, dilute by drinking milk or water. Call a physician or local poison center IMMEDIATELY. Avoid contact with skin and eyes. Should contact occur, flush immediately with water. Contact physician if irritation develops. Observe ALL laboratory standards for the handling of patient specimens.

STABILITY AND STORAGE

Sulfuric Acid Solution is stable to the stated expiration date when stored at room temperature (15-30°C).

USER QUALITY CONTROL

Each bottle of Sulfuric Acid Solution should contain the quantity listed on labeling. Each bottle should be clear and free of precipitates. Discard if precipitates form.

SPECIMEN COLLECTION AND PREPARATION

Appropriate specimens should be collected according to prescribed standards and delivered to the laboratory in a safe and timely manner. Refer to local procedural guidelines for this information.

PROCEDURE

Materials Provided: Sulfuric Acid Solution 4%.

Materials Not Provided: Centrifuge, CO₂ incubator, NPC-67® Neutralizing Buffer, centrifuge tubes (50 ml), NAC-PAC® RED, coverslips, PRB™ Pellet Resuspension Buffer (#0004510), glass slides, CELL-BOND® Slides, sterile pipettes, AFB stains, TB media.

SPECIMEN PROCESSING

ATTENTION: Handle all specimens with extreme caution. Possible PATHOGENS. Wear gloves at ALL TIMES. Work in a biosafety cabinet.

1. Centrifuge the entire specimen for 15 minutes at 3000 xg. Several tubes may be required.
2. Decant supernatant fluid and pool sediments. If volume is small, add PRB to bring volume to 2 ml.
3. Add an equal volume of 4% Sulfuric Acid Solution to the sediment.
4. Mix and let stand for 15 minutes.
5. Add 8 ml of NAC-PAC RED to the solution. (The solution should be pink. If solution is not pink, add NAC-PAC RED drop-wise until pink color persists.)
6. Fill each centrifuge tube with NPC-67 until effective neutralization is indicated by a color change from red/pink to colorless. Once a colorless point has been reached, do not continue to add NPC-67 to the sample. Tighten cap and swirl by hand to mix.
7. Centrifuge the specimen tubes in a refrigerated centrifuge at 3000 xg for 15 minutes. (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 supernatant into a splash-proof container holding an appropriate disinfectant. Use an appropriate disinfectant or flame to disinfect any contamination on the lip of the specimen tube. Do not allow the disinfectant to run down inside the specimen tube.
9. Resuspend the pellet with 0.5 ml of PRB (do not resuspend the pellet with NPC-67 AFB Neutralizing Buffer).
10. Mix the sediment and PRB well and make smears for AFB staining. (Use adhesive CELL-BOND Slides or appropriate sterile albumin adhesive solutions to attach the specimen to the slide.) Dry the smears and proceed with AFB staining per the manufacturer's directions. **NOTE:** Good laboratory practice recommends more than one smear be prepared for staining. **NOTE:** A QC1™ AFB Slide should be stained in conjunction with the patient smears to

verify the staining technique and components (#0003240, QC1 AFB Slide).

11. Add an additional 1 - 2 ml (according to the laboratory's set-up procedure volume requirements) of PRB.
12. Place two drops of the sediment onto the surface of each of the TB media used and inoculate to rapid broth detection systems, per the manufacturer's recommendations. **NOTE:** A contamination control plate can be inoculated at this point – BAP or TSA, and incubated at 35-37°C for 48 hours. Add the remaining PRB to the pellet specimen and refrigerate at 2-8°C for further studies, or redecontamination if the cultures or rapid detection methods indicate that a contaminant is present.

BIBLIOGRAPHY

1. Lennette, E.H., et al., 1980. MANUAL OF CLINICAL MICROBIOLOGY. American Society for Microbiology Third Edition, Washington, D.C. pp 150-179.
2. Vestal, A.L., 1978. PROCEDURES FOR THE ISOLATION AND IDENTIFICATION OF MYCOBACTERIA. DHEW Publication No. CDC 79-8230, Atlanta, GA.

CONTACT

Alpha-Tec Systems, Inc. offers a complete line of reagents, stains, and QC1™ Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing, as well as O&P collection systems and concentration devices for Parasitology. For Technical Assistance, email Technical@AlphaTecSystems.com, and for Customer Service, email Sales@AlphaTecSystems.com, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY

This product is warranted by Alpha-Tec Systems, Inc. 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

0003439 4% Sulfuric Acid Solution, 1 x 125 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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