



Puritan® Sputum Solution

INTENDED USE

Puritan Sputum Solution is intended for use in the collection and liquefying of clinical sputum specimens for the isolation of bacteria and fungi that cause respiratory tract infections.

SUMMARY AND EXPLANATION

Lower respiratory tract infections are among the most common infectious diseases worldwide.¹ Liquefaction and homogenization of sputum specimens have been recommended to ensure accurate, representative bacterial and fungal cultures.² Puritan Sputum Solution is a nonnutritive phosphate buffered solution containing dithiothreitol (DTT) to act as a liquefying agent for sputum specimens prior to culture.

REAGENTS

Sodium Phosphate, monobasic
Sodium Phosphate, dibasic
Sodium Chloride
DL-Dithiothreitol (DTT)

PRECAUTIONS

For *in vitro* Diagnostic Use

- For single use only.
- Clinical specimens are considered biohazard and must be handled in manner to protect laboratory personnel.
- For use by trained qualified personnel using aseptic techniques.
- The sterile pipette is to be used for transferring biological specimens (sputum, mucus) from a container into the Sputum Solution. It must not be used for direct collection from the patient.
- Clinical samples may contain human pathogens including hepatitis virus and Human Immunodeficiency Virus. Institutional and universally recognized guidelines should be followed when handling items contaminated with blood and other body fluids.³
- Specimen vials and other contaminated materials must be sterilized by autoclave before discarding.
- Do not use if the vial is damaged or detected evidence of contamination, discoloration or leakage.
- Do not use beyond expiry date.
- Do not ingest the medium.

STORAGE

For optimum performance, store at 2-25°C (36-77°F). Avoid freezing and excessive heat.^{4,5} The packaging of the Sputum Solution comprises of barrier plastic film together with a modified atmosphere inside the package to maintain stability of the product. The Sputum Solution tubes should be used immediately or stored at 2-8°C and used within 24 hours after opening the package.

MATERIALS SUPPLIED

Puritan Sputum Solution is available in product configurations indicated in the table below:

Item Number	Product Descriptions	Pack Size
SP-100	Natural polypropylene screw-cap tube with 1 mL of Sputum Solution.	30 / Box
SP-100B		10 x 30 / Case
SP-100P	Natural polypropylene screw-cap tube with 1 mL of Sputum Solution and one sterile Pasteur pipette for sputum sample transfer.	20 / Box
SP-100PB		10 x 20 / Case

MATERIALS NOT PROVIDED

Appropriate materials for cultivation and isolation of bacteria and fungi. Refer to laboratory reference manuals for recommended protocols for culture and identification.

INSTRUCTIONS FOR USE

Sputum Solution with Sterile Pipette

1. Peel open one sterile pipette.
2. Open the plastic pack containing the vials of Sputum Solution and remove one vial.
3. Insert the pipette into the container of sputum specimen. Squeeze the bulb to obtain approximately 1mL of sputum.
4. Remove the cap of a vial and transfer the contents of the pipette into the Sputum Solution.
5. Replace cap on the Sputum Solution.
6. Leave the inoculated Sputum Solution at room temperature for at least 15 minutes. A prolonged contact time of up to 6 hours does not impair the survival of the bacteria or fungi in the specimen.
7. Vortex the inoculated Sputum Solution for 30 seconds at 2000-2500 rpm or until the mixture has liquefied.
8. Aseptically remove aliquots of the liquefied sputum specimen and inoculate onto appropriate bacteriology culture medium.

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection is critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals.^{6,7}

QUALITY CONTROL

All batches of Puritan Sputum Solution are tested prior to release for pH and further evaluated for their ability to promote growth for the following organisms:

CONTROL

Pseudomonas aeruginosa ATCC 27853
Haemophilus influenzae ATCC 10211
Staphylococcus aureus ATCC 6538
Streptococcus pneumoniae ATCC 6305
Streptococcus pyogenes ATCC 19615
Moraxella catarrhalis ATCC 25238
Candida albicans ATCC 10231

INCUBATION

Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature
Aerobic, 6 h@ Room Temperature

RESULTS

Good Recovery
Good Recovery
Good Recovery
Good Recovery
Good Recovery
Good Recovery
Good Recovery

LIMITATIONS

- Puritan Sputum Solution is not tested for acid resistant bacilli culture.
- Performance testing was conducted using laboratory strains spiked into the Sputum Solution tube. Human specimens were not used.

REFERENCES

1. Carroll, K. C. 2002. Laboratory Diagnosis of Lower Respiratory Tract Infections: Controversy and Conundrums. Journal of Clinical Microbiology. 40(9): 3115-3120.
2. Hammerschlag, M.R., L. Harding, A. Macone, A. L. Smith, D. A. Goldmann. 1980. Bacteriology of Sputum in Cystic Fibrosis: Evaluation of Dithiothreitol as a Mucolytic Agent. Journal of Clinical Microbiology. 11(6): 552-557.
3. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risk related exposure to biological agents at work. Official Journal of the European Communities. L 262/21-45.
4. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry, D.W. Warnock. 2011. Manual of Clinical Microbiology, 10th ed. American Society for Microbiology. Washington, DC.
5. Miller, J.M. 1996. A guide to specimen management in clinical microbiology. American Society for Microbiology. Washington, DC.
6. Forbes, B.A., D.F. Sahm, A.S. Weissfeld. 2007. Diagnostic Microbiology 12th ed. Mosby. St. Louis, MO.
7. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, R.H. Tenover. 2003. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology. Washington, DC.



207-876-3311 • puritanmedproducts.com
sales@puritanmedproducts.com
Puritan Medical Products Co. LLC
31 School Street, Guilford, Maine 04443-0149 USA
ISO 9001:2008 ISO 13485:2003 CE

