

Revisions

SO 0046-2

Rev From	Rev To	ECO #	Date	Appr.
1199	1003	2146-03		

Notes:

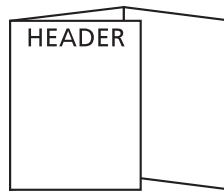
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- Style (see illustrations below): #1



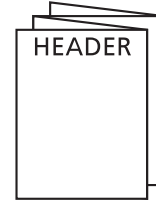
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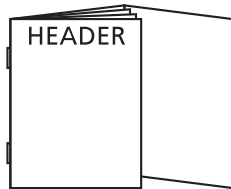


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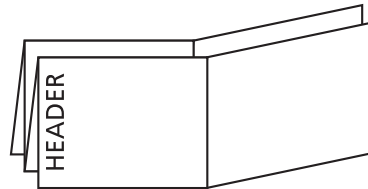
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- See Specification Control No. n/a for Material Information
- Ink Colors: Printed two sides Yes No
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Proofer	Date			
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Part Number: S1458JAA		Category and Description Package Insert Dubos Oleic Albumin Complex	Sheet: 1 of <hr/> Scale: 1:1	A


BD Difco™ Dubos Oleic Albumin Complex
S1458JAA
2003/10

See symbol glossary at end of insert. / Se symbolglossaret i slutningen af indlægssedlen. / Voir le glossaire des symboles à la fin de la notice. / Siehe Symbol-Erklärungen am Ende der Packungsbeilage. / Δείτε το γλωσσάριο των συμβόλων στο τέλος του ένθετου. / Vedere il glossario dei simboli alla fine del foglio illustrativo. / Consulte o glossário de símbolos no fim do folheto informativo. / Consulte el glosario de símbolos al final del prospecto. / Se symbolförteckningen vid slutet av bipacksedeln.

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INTENDED USE

Dubos Oleic Albumin Complex and penicillin are used to supplement Dubos Oleic Agar Base for the isolation and susceptibility testing of *Mycobacterium tuberculosis*.

SUMMARY AND EXPLANATION

Dubos and Middlebrook¹ described Dubos Oleic Medium Albumin as suitable for primary isolation and cultivation of the tubercle bacillus and for studying colony morphology. In comparative studies, Dubos Oleic Albumin Agar Medium was superior to other media studied for primary isolation.^{2,3}

PRINCIPLES OF THE PROCEDURE

Oleic acid is a carbon source. Albumin Fraction V is a growth factor.

REAGENTS**Dubos Oleic Albumin Complex**

A 0.05% solution of alkalized oleic acid in a 5% solution of albumin fraction V in normal saline (0.85%).

Warnings and Precautions:

For Laboratory Use.

Follow proper, established laboratory procedures in handling and disposing of infectious materials.

Biosafety Level 2 practices and procedures, containment equipment and facilities are required for non-aerosol-producing manipulations of clinical specimens such as preparation of acid-fast smears. All aerosol-generating activities must be conducted in a Class I or II biological safety cabinet. Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities in the propagation and manipulation of cultures of *M. tuberculosis* and *M. bovis*. Animal studies also require special procedures.⁴

Storage: Store at 2 – 8°C.

SPECIMEN COLLECTION AND PREPARATION⁵

1. Collect specimens in sterile containers and transport immediately to the laboratory following recommended guidelines.
2. Process each specimen as appropriate for that specimen.

PROCEDURE

Material Provided: Dubos Albumin Complex.

Materials Required But Not Provided: Dubos Oleic Agar Base, Penicillin, glassware, purified water, autoclave and incubator (CO₂, 35°C).

Method of Preparation

Dubos Oleic Agar

1. Suspend 4 g Dubos Oleic Agar Base in 180 mL purified water. Mix thoroughly.
2. Heat with frequent agitation and boil for 1 min to completely dissolve the powder.
3. Autoclave at 121°C for 15 min.
4. Cool to 50 – 55°C.
5. Aseptically add 20 mL Dubos Oleic Albumin Complex and 5,000 – 10,000 units of penicillin (25 – 50 units per mL medium).
6. Mix thoroughly.
7. Dispense into sterile tubes or plates.
8. Test samples of the finished product for performance using stable, typical control cultures.

Test Procedure⁵

1. Inoculate the specimen onto/into the medium and incubate tubes for up to eight weeks at 35 ± 2°C in a CO₂-enriched atmosphere.
2. Examine tubes for growth.

User Quality Control**Dubos Oleic Agar**

Prepare medium from Dubos Oleic Agar Base and Dubos Oleic Albumin Complex per label directions. Inoculate and incubate at 35 ± 2°C under 5 – 10% CO₂ for up to 3 weeks.

Organism	ATCC™	Inoculum CFU	Recovery
<i>Escherichia coli</i>	25922	1,000	partial inhibition
<i>Mycobacterium fortuitum</i>	6841	300	good
<i>Mycobacterium intracellulare</i>	13950	300	good
<i>Mycobacterium kansasii</i>	12478	300	good
<i>Mycobacterium scrofulaceum</i>	19981	300	good
<i>Mycobacterium tuberculosis</i> H37 Ra	25177	300	good

RESULTS

Mycobacteria grow on the medium.

LIMITATIONS OF THE PROCEDURE

- Negative culture results do not rule out active infection by mycobacteria. Some factors that are responsible for unsuccessful cultures are:
 - The specimen was not representative of the infectious material, i.e., saliva instead of sputum.
 - The mycobacteria were destroyed during digestion and decontamination of the specimen.
 - Gross contamination interfered with the growth of the mycobacteria.
- Mycobacteria are strict aerobes and growth is stimulated by increased levels of CO₂. Screw caps on tubes or bottles should remain loosened for at least one week to permit a free exchange of CO₂.

AVAILABILITY**Cat. No. Description**

237510 **Difco™** Dubos Oleic Albumin Complex, 20 mL, Pkg. of 12 tubes

REFERENCES

- Dubos, R.J., and G. Middlebrook. 1947. Media for tubercle bacilli. *Am. Rev. Tuberc.* 56:334-345.
- Roberts, Wallace and Erlich. A. *Rev. Tuberculosis.* 1950. 67:563.
- Byham. *Am. J. Clin. Path.* 1950. 20:678.
- U.S. Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. 1999. Biosafety in microbiological and biomedical laboratories, 4th ed. HHS Publication No. (CDC) 93-8395. U.S. Government Printing Office, Washington, D.C.
- Isenberg, H.D. (ed.). 1994. *Clinical microbiology procedures handbook*, vol. 1. American Society for Microbiology, Washington, D.C.



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