

## Revisions

SO 0191-5

Rev from	Rev to	ECO #
0405	0707	4502-07

**Notes:**

1. BD Cat. Number 297815, 221818, 221819, 297431, 295771, 297753
2. Blank (Sheet) Size : Length: 11"      Width: 8.5"  
 Number of Pages: 1      Number of Sheets: 1  
 Page Size: Length 11"      Width 8.5"      Final Folded Size: 4.25" x 1.375"
3. Style (see illustrations below): # 1




4. See Specification Control Number S1161 for Material Information
5. Ink Colors: Printed two sides  Yes     No  
 No. of Colors: 1      PMS# Black
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

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Part Number: 8806181JAA		Category and Description Package Insert, BBL Saline, Normal	Sheet: 1 of 3 <hr/> Scale: N/A	A

# **BD BBL™ Prepared Saline Solution**

## **Saline, Normal**

 8806181JAA  
2007/07

Pokyny vám poskytne miestní zástupce společnosti BD. / Kontakt den lokale BD repräsentant for at få instruktioner. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / A használati utasítást kérje a BD helyi képviselőjétől. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielem BD. / Contacte o seu representante local da BD para obter instruções. / Instrukcie získate u miestneho zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar. / Свържете се с местния представител на BD за инструкции. / Contactați reprezentantul dumneavoastră local BD pentru instrucțiuni. / Talimatlar için yerel BD temsilcilerinize danışın.

### **INTENDED USE**

Saline, Normal (physiological) is used in procedures that require the use of an isotonic diluent.

### **SUMMARY AND EXPLANATION**

An isotonic diluent may be used for dilution of bacterial cells to provide a concentration suitable for microscopic observation, determination of cell numbers, analysis for genetic or metabolic properties, washing cells preparatory to study, or preparation of standardized inocula.<sup>1-3</sup>

### **PRINCIPLES OF THE PROCEDURE**

Saline is routinely used as a diluent to adjust the turbidity of bacterial cell suspensions to help maintain cell integrity and viability.

### **REAGENTS**

#### **Saline, Normal**

Approximate Formula Per Liter Purified Water

Sodium Chloride .....8.5 g

#### **Warnings and Precautions:**

For *in vitro* Diagnostic Use.

Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass. Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, prepared tubes, specimen containers, and other contaminated materials must be sterilized by autoclaving.

**Storage Instructions:** Prepared tubed saline solution is ready to use with no additional preparation required. On receipt, store tubes at 2 to 25°C. Freezing and overheating must be avoided. Allow to warm to room temperature before use. Do not open until ready to use.

**Product Deterioration:** Do not use tubes if they show evidence of evaporation, microbial contamination, discoloration or other signs of deterioration.

### **PROCEDURE**

**Material Provided:** Saline, Normal

**Materials Required But Not Provided:** Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

#### **Test Procedure:**

Using a sterile pipette, adjust the turbidity of a culture to be equivalent to a standard, such as a McFarland (barium sulfate) turbidity standard.<sup>2,3</sup>

The diluted culture should be used within the time limit stated in the appropriate method or procedure.

**User Quality Control:** Examine tubes for signs of deterioration as described under "Product Deterioration."

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI (formerly NCCLS) guidance and CLIA regulations for appropriate Quality Control practices.

### **RESULTS**

Cell integrity and viability is maintained within the parameters of the particular procedure being employed.

### **LIMITATIONS OF THE PROCEDURE**

For critical or unusual situations, use a diluent suitable for the conditions.<sup>1</sup>

Although published procedures recommend adding saline to tissue specimens to maintain moisture during transport,<sup>4</sup> saline may be a source of nonviable organisms; therefore, caution should be exercised in reporting Gram stain results on tissue specimens processed with saline.

### **PERFORMANCE CHARACTERISTICS**

Prior to release, all lots of **BBL Normal Saline** are tested for performance characteristics. Representative samples of the lot are tested chemically by silver nitrate titration for sodium chloride content. The calculated percent sodium chloride is 0.8 to 0.95.

### **AVAILABILITY**

<b>Cat. No.</b>	<b>Description</b>
297815	<b>Saline, Normal</b> , 1 mL, Ctn. of 100 size K tubes
221818	<b>Saline, Normal</b> , 5 mL, Pkg. of 10 size K tubes
221819	<b>Saline, Normal</b> , 5 mL, Ctn. of 100 size K tubes
295771	<b>Saline, Normal</b> , 5 mL, Ctn. of 100 size C tubes
297753	<b>Saline, Normal</b> , 10 mL, Ctn. of 100 size D tubes

### **REFERENCES**

- Koch, A.L. (with P. Gerhardt). 1994. 11.3.1, Diluents, p. 255. *In* P. Gerhardt (ed.), *Methods for general and molecular bacteriology*. American Society for Microbiology, Washington, D.C.
- Clinical and Laboratory Standards Institute. 2006. Approved Standard: M2-A9. Performance standards for antimicrobial disk susceptibility tests. 9th ed. CLSI, Wayne, Pa.
- Clinical and Laboratory Standards Institute. 2006. Approved Standard: M7-A7. Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically, 7th ed. CLSI, Wayne, Pa.
- Thomson, Jr., R.B., and J.M. Miller. 2003. Specimen collection, transport, and processing: bacteriology, p. 286-330. *In* P.R. Murray, E.J. Baron, J.H. Jorgensen, M.A. Tenover, and R.H. Tenover (ed.), *Manual of clinical microbiology*, 8th ed., American Society for Microbiology, Washington, D.C.

