INTENDED USE

BD Phosphate Buffered Saline (pH 7.2) and BD Saline Solution (0.9%) are used in microbiological procedures that require an isotonic or buffered diluent. They are mainly used for the suspension and dilution of non-fastidious microorganisms.

PRINCIPLES AND EXPLANATION OF THE PROCEDURE

Microbiological method.

Isotonic diluents such as saline (0.75 to 0.9%) or Phosphate Buffered Saline are routinely used to prepare cell suspensions of microbial cells, e.g. for suspensions of bacteria in antimicrobial susceptibility procedures.\(^1\)\(^-\)\(^3\) The salts contained in these suspension fluids provide an isotonic medium to maintain cell integrity and viability. Additionally, a physiological pH (6.8 to 7.4) value may be important to maintain viability. Phosphate Buffered Saline (pH 7.2) and Saline Solution (0.9%) may also be used for rinsing and washing steps in various laboratory procedures.

In BD Phosphate Buffered Saline (pH 7.2), sodium chloride provides osmotic protection of microbial cells; additionally, phosphates provide a stable physiological pH value which is also important for the maintenance of cell viability. In BD Saline Solution (0.9%), sodium chloride provides osmotic protection of microbial cells.

REAGENTS

Formulas* Per Liter Purified Water

<table>
<thead>
<tr>
<th>BD Phosphate Buffered Saline (pH 7.2)</th>
<th>BD Saline Solution (0.9%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dipotassium Hydrogen Phosphate 1.1 g</td>
<td>Sodium Chloride 9.0 g</td>
</tr>
<tr>
<td>Potassium Dihydrogen Phosphate 0.32</td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride 8.5</td>
<td></td>
</tr>
<tr>
<td>pH 7.2 +/- 0.1</td>
<td></td>
</tr>
</tbody>
</table>

*Adjusted and/or supplemented as required to meet performance criteria.

PRECAUTIONS

IVD. For professional use only.

BD Phosphate Buffered Saline (pH 7.2) and BD Saline Solution (0.9%) are intended to be used only in laboratory procedures.

Warning: Do not use for injection or infusion!

Do not use vials if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Consult GENERAL INSTRUCTIONS FOR USE document for aseptic handling procedures, biohazards, and disposal of used product.

STORAGE AND SHELF LIFE

On receipt, store vials in the dark at 2 to 8° C until just prior to use. Avoid freezing and overheating. The vials may be inoculated up to the expiration date (see container or package label) and incubated for the recommended incubation times.

USER QUALITY CONTROL

Prepare suspensions of the strains mentioned below in BD Saline Solution or BD Phosphate Buffered Saline to produce a slight but visible turbidity. With a 10 µl loop, collect a sample from each tube and subculture onto BD Trypticase™ Soy Agar (=TSA). Keep the tubes containing the suspensions of the test strains for 2 hours at 18 - 23° C. Afterwards, collect a second 10 µl
sample from each tube and subculture again as described. Incubate the TSA plates for 18 to 24 hours for the bacteria, and for 24 to 42 hours for the Candida strain. To determine the survival of the strains, compare the intensity of growth on the first (=Time 0) and the second (=Time 2 hours) TSA plate. The growth on both plates should be equal on both plates or may be slightly stronger on the second than on the first plate.

If desired, the growth may be quantified by plating an appropriate dilution and volume onto TSA and counting the colonies after incubation.

<table>
<thead>
<tr>
<th>Test strain</th>
<th>Growth on TSA at time 0</th>
<th>Growth on TSA after 2 hours at 18 to 23°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candida albicans ATCC™ 10231</td>
<td>Good to excellent</td>
<td>Good to excellent</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 6538</td>
<td>Good to excellent</td>
<td></td>
</tr>
<tr>
<td>Escherichia coli ATCC 25922</td>
<td>Good to excellent</td>
<td></td>
</tr>
<tr>
<td>Bacillus subtilis ATCC 6633</td>
<td>Good to excellent</td>
<td></td>
</tr>
<tr>
<td>Uninoculated</td>
<td>Colorless, clear</td>
<td></td>
</tr>
</tbody>
</table>

PROCEDURE
Materials Provided
BD Phosphate Buffered Saline (pH 7.2) or BD Saline Solution (0.9%), provided in vials.

Materials Not Provided
Ancillary culture media, reagents and laboratory equipment as required.

Specimen Types
BD Phosphate Buffered Saline (pH 7.2) and BD Saline Solution (0.9%) are suspension, dilution and rinsing fluids used in laboratory procedures. If required, they may be used for suspending or diluting clinical specimens before cultivation. They do not contain nutrients and, therefore, cannot be used for cultivation of microorganisms.

Test Procedure
Prepare suspensions of the microorganisms and adjust the turbidity to the required density. Dilute in fresh tubes of the same fluid if required.

These products have many different uses. Refer to the appropriate procedures. Several procedures and applications are given in the references.1-3

PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE PROCEDURE
BD Phosphate Buffered Saline (pH 7.2) and BD Saline Solution (0.9%) are suspension, dilution, and rinsing fluids that do not contain nutrients and, therefore, do not allow growth of microorganisms.

Microbial suspensions prepared in these fluids should not be stored longer than several hours since viability of certain organisms may decrease due to starvation. Depending on the organisms suspended, this time may vary considerably. Therefore, the suitability of BD Saline Solution or BD Phosphate Buffered Saline for specific organisms should be tested before use.

BD Saline Solution and BD Phosphate Buffered Saline are not the appropriate suspension fluids for very fastidious or strictly anaerobic organisms.

REFERENCES
PACKAGING/AVAILABILITY

BD Saline Solution (0.9%): Ready-to-use medium in vials
Cat. No. 257255  cpu 50  10 ml in 15 ml screw-cap vials

BD Phosphate Buffered Saline (pH 7.2): Ready-to-use medium in vials
Cat. No. 257204  cpu 50  10 ml in 15 ml screw-cap vials

FURTHER INFORMATION

For further information please contact your local BD representative.

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