IFU

Instructions for Use

PHOSPHATE BUFFERED SALINE (PBS)

Cat. no. K146	Phosphate Buffered Saline (PBS), 16x125mm Tube, 9ml	20 tubes/box
Cat. no. K163	Phosphate Buffered Saline (PBS), 16x125mm Tube, 9.9ml	20 tubes/box
Cat. no. R201	Phosphate Buffered Saline (PBS), 13x100mm Tube, 1ml	20 tubes/box
Cat. no. U137	Phosphate Buffered Saline (PBS), 125ml Polypropylene Bottle, 100ml	1 each
Cat. no. U138	Phosphate Buffered Saline (PBS), 1L Polypropylene Bottle, 1000ml	10 bottles/box

INTENDED USE

Hardy Diagnostics Phosphate Buffered Saline (pH of 7.5) is recommended as a diluent for quantitative culturing or as a rinsing agent in microbiological, immunological, histological and molecular testing procedures.

SUMMARY

Commonly used in biological and biomedical research, Phosphate Buffered Saline (PBS) has many applications due to its isotonic nature. PBS can be used as a diluting agent in preparing decimal dilutions and as a rinsing agent for rinsing labware containing cells. Phosphate salts are nontoxic to living cells and have a high buffering capacity; pH maintenance is important in retaining cell viability and in the recovery and revitalization of injured or damaged cells during bacterial culture and analysis. Phosphate Buffered Saline is generally used as a 10mM working solution containing a mixture of sodium chloride and inorganic phosphate salts.

Phosphate Buffered Saline is recommended as a rinsing or diluting fluid by the Food and Drug Administration in the *Bacteriological Analytical Manual* (BAM), by the Association of Analytical Communities (AOAC) in the *Official Methods of Analysis*, by the United States Pharmacopeia in the *USP-NF*, and by the American Public Health Association (APHA) in the *Compendium of Methods for the Microbiological Examination of Foods* and *Standard Methods for the Examination of Water and Wastewater*.[1-3,8,9] PBS is also recommended in the *Clinical Microbiology Procedures Handbook* and other laboratory texts for diluting or rinsing specimens for microbiological, histological, immunological or molecular testing.[4-7,10]

FORMULA

A 10mM solution of Phosphate Buffered Saline.

Final pH 7.5 +/- 0.3 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store Cat. no. K146, K163, U137, and U138 at 2-30°C and Cat. no. R201 at 2-8°C away from direct light. These products should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

For Cat. nos. K146, K163, U137, and U138:

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

For Cat. no. R201:

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Consult listed references for information on specimen collection and specific standard methods.[1-5]

General Dilution Guidelines:

1:10 Serial Dilutions
1. Using a sterile pipet, aliquot 10mL of test suspension to 90mL of PBS diluent. Mix thoroughly. This yields a 1:10 dilution.

2. Use a second sterile pipet to aliquot 10mL of the 1:10 dilution prepared in step 1 into a second 90mL filled vessel of PBS diluent. Mix thoroughly. This yields a 1:100 dilution.

3. Continue aliquoting 10mL of subsequent dilutions into 90ml filled PBS diluent vessels until the desired concentration of test sample is obtained. Each succeeding dilution increases by a factor of 10. A separate sterile pipet should be used with each dilution.

1:100 Serial Dilutions
1a. Using a sterile pipet, aliquot 1ml of test suspension to 99ml of PBS diluent. Mix thoroughly. This yields a 1:100 dilution.

2a. Use a second sterile pipet to aliquot 1ml of the 1:100 dilution prepared in step 1a into a second 99mL filled vessel of PBS diluent. Mix thoroughly. This yields a 1:10,000 dilution.

3a. Continue aliquoting 1mL of subsequent dilutions into 99mL filled PBS diluent vessels until the desired concentration of test sample is obtained. Each succeeding dilution increases by a factor of 100. A separate sterile pipet should be used with each dilution.

INTERPRETATION OF RESULTS

Phosphate Buffered Saline is not a growth medium.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests Phosphate Buffered Saline for appearance, sterility, pH and fill volume only.

USER QUALITY CONTROL

* Refer to the document "Inoculation Procedures for Media QC" for more information.

PHYSICAL APPEARANCE

Phosphate Buffered Saline should appear clear and colorless.

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*. APHA, Washington, D.C.

2. American Public Health Association Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

3. Association of Official Analytical Communities. *Official Methods of Analysis*, AOAC, Washington, D.C.

4. Bullock, G.R. and Petrusz, P. 1989. Techniques in Immunocytochemistry, Volumes 1, 2, 3 and 4, Academic Press.

5. Cseke, L.J., P.B. Kaufman, G.K. Podila, and C.J. Tsai. 2004. *Handbook of Molecular and Cellular Methods in Biology and Medicine.* CRC Press. Taylor & Francis LLC. Boca Raton, FL.

6. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

7. Jorgensen et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

8. The Official Compendia of Standards. 2008. *USP27-NF22*. United States Pharmacopeial Convention, Rockville, MD.

9. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

10. Walker, J.M. 1984. *Methods in Molecular Biology*. The Humana Press Inc. Clifton, NJ.

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