Instructions for Use

Culbenez

IFU

PHOSPHATE BUFFERED SALINE

Cat. no. CG182BX	Phosphate Buffered Saline (PBS), 1X, pH 7.4, 1L PET Bottle, 1000ml	10 bottles/box
Cat. no. CG202	Phosphate Buffered Saline (PBS), 10X, pH 7.4, 1L PET Bottle, 1000ml	1 each
Cat. no. CG202BX	Phosphate Buffered Saline (PBS), 10X, pH 7.4, 1L PET Bottle, 1000ml	10 bottles/box

INTENDED USE

Hardy Diagnostics CulGenexTM Phosphate Buffered Salines are recommended for use in various procedures used in biological and molecular research.⁽¹⁻⁶⁾

This product is not intended to be used for the diagnosis of human disease.

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 contains sodium chloride, sodium phosphate, potassium phosphate and, in some formulations, potassium chloride, magnesium and calcium.

Hardy Diagnostics CulGenex™ Phosphate Buffered Saline products are available by the bottle or a box of ten.

FORMULA

Ingredients per liter of molecular grade water:*

Phosphate Buffered Saline (PBS), 1X (Cat. no. CG182BX):			
Sodium Chloride	9.0gm		
Disodium Phosphate	0.795gm		
Monopotassium Phosphate	0.144gm		

Final pH 7.4 to 7.6 +/- 0.1 at 25°C.

Ingredients per liter of molecular grade water:*

Phosphate Buffered Saline (PBS), 10X (Cat. no. CG202, CG202BX):		
Sodium Chloride	90.0gm	
Disodium Phosphate	7.95gm	
Monopotassium Phosphate	1.44gm	

Final pH 7.2 to 7.4 +/- 0.1 at 25°C.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30°C away from direct light. Buffers should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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

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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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

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

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

2. 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.

3. 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.

Consult additional references for information on specific standard protocols.⁽¹⁻⁶⁾

LIMITATIONS

Note: PBS containing calcium and magnesium is not recommended for enzymatic reactions due to its potential interaction with divalent cations and resulting precipitation.

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

QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics <u>Certificate of Analysis</u> website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

USER QUALITY CONTROL

Check for signs of contamination and deterioration. Users of commercially prepared culture media may be required to perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction (where applicable). Refer to the following documents on the Hardy Diagnostics website for more information on QC: "Introduction to Quality Control," "Finished Product Quality Control Procedures," or "The CLSI Standard and Recommendations for User Quality Control of Media."

PHYSICAL APPEARANCE

CulGenex[™] Phosphate Buffered Saline (PBS), 1X; and Phosphate Buffered Saline (PBS), 10X; should appear clear, and colorless.

REFERENCES

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5. Sambrook and Russell. *Molecular Cloning: A Laboratory Manual*. Cold Spring Harbor Laboratory Press. Woodbury, New York.

6. Walker, J.M. Methods in Molecular Biology. The Humana Press Inc. Clifton, NJ.

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Distribution Centers: California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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