IFU

Instructions for Use

BUTTERFIELD'S PHOSPHATE BUFFER

Cat. no. D125	Butterfield's Phosphate Buffer, Dilu-Lok II™ Vial, 25ml	50 vials/case
Cat. no. D590	Butterfield's Phosphate Buffer, Dilu-Lok II™ Vial, 90ml	50 vials/case
Cat. no. D599	Butterfield's Phosphate Buffer, Dilu-Lok II™ Vial, 99ml	50 vials/case
Cat. no. K109	Butterfield's Phosphate Buffer, 16x125mm Tube, 9ml	20 tubes/box
Cat. no. K119	Butterfield's Phosphate Buffer, 13ml Polypropylene Screw Cap Tube, 9ml	20 tubes/box
Cat. no. K208	Butterfield's Phosphate Buffer, 16x125mm Tube, 9.9ml	20 tubes/box
Cat. no. K209	Butterfield's Phosphate Buffer, 20x125mm Tube, 9ml	20 tubes/box
Cat. no. U123	Butterfield's Phosphate Buffer, 500ml Polycarbonate Bottle, 225ml	10 bottles/box
Cat. no. U150	Butterfield's Phosphate Buffer, 500ml Polycarbonate Bottle, 450ml	10 bottles/box
Cat. no. U154	Butterfield's Phosphate Buffer, 500ml Polycarbonate Bottle, 400ml	10 bottles/box
Cat. no. U190	Butterfield's Phosphate Buffer, 500ml Polycarbonate Bottle, 500ml	10 bottles/box
Cat. no. U290	Butterfield's Phosphate Buffer, 125ml Polypropylene Bottle, 100ml	12 bottles/box

INTENDED USE

Hardy Diagnostics Butterfield's Phosphate Buffer is used as a diluent for the preparation of dilutions in plate count and other laboratory processes.

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

SUMMARY

Butterfield's Phosphate Buffer is formulated according to the standard in the *Compendium of Methods for the Microbiological Examination of Foods*.[5] It is recommended as a general diluent in laboratory procedures by the Federal Drug Administration and in the *Bacteriological Analytical Manual*.[2] In addition, this product is described in *Standard Methods for the Examination of Water and Wastewater* for use in water testing.[1]

FORMULA

Ingredients per liter of deionized water:*

Monopotassium Phosphate	42.5mg

Final pH 7.2 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC. away from direct light. Products should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat 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 "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.[1-4]

General Dilution Guidelines:

1:10 Serial Dilutions
1. Using a sterile pipet, aliquot 10ml of test suspension to 90ml of the Dilu-Lok II™ 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 Dilu-Lok II™ diluent. Mix thoroughly. This yields a 1:100 dilution.

3. Continue aliquoting 10ml of subsequent dilutions into 90ml filled Dilu-Lok II™ diluents 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 the Dilu-Lok II™ 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 Dilu-Lok

II™ diluent. Mix thoroughly. This yields a 1:10,000 dilution.

3a. Continue aliquoting 1ml of subsequent dilutions into 99ml filled Dilu-Lok II™ diluents 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

See listed references for interpretation of growth. [2,5]

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, sterile pipets, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests Butterfield's Phosphate Buffer for sterility, toxicity, pH, and fill volume.

USER 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 Certificate of Analysis 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.

PHYSICAL APPEARANCE

Butterfield's Phosphate Buffer 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. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

3. Association of Official Analytical Chemists. *Official Methods of Analysis* ^{sm} , AOAC, Washington, D.C.

4. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

5. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods,* APHA, Washington, D.C.

IFU-10097[B]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

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.

HDQA 2207D [D]