IFU

Instructions for Use

PHOSPHATE BUFFER, PH 7.2

Cat. no. U438	Phosphate Buffer, pH 7.2, 500ml Polycarbonate Bottle, 500ml	10 bottles/box

INTENDED USE

Hardy Diagnostics Phosphate Buffer, pH 7.2 is recommended for use as a diluent in the preparation of solutions for plate counts and other laboratory processes for non-clinical samples. This product meets the harmonized *United States Pharmacopeia* (USP), *European Pharmacopoeia* (EP), and *Japanese Pharmacopoeia* (JP) performance specifications, where applicable.[5]

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

SUMMARY

Phosphate Buffer was originally specified by the American Public Health Association (APHA) for use in diluting test samples.[1] The formulation has also been described for use in diluting water, dairy, and food samples.[2-4] The *United States Pharmacopeia* (USP) general chapters <61> and <62> also mention the use of Phosphate Buffer, pH 7.2 in preparing dilutions of nonsterile pharmaceutical products when performing Microbial Enumeration Tests and Tests for Specified Microorganisms, as well as when making suspensions of microorganisms for testing purposes.[5]

FORMULA

Ingredients per liter of deionized water:*

Stock Buffer Solution:	
Potassium Dihydrogen Phosphate	34.0g

Final pH 7.2 +/- 0.2 at 25ºC.

Note: Phosphate Buffer, pH 7.2 is a mixture of purified water and Stock Buffer Solution (800:1 v/v).

* 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. Media 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 "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

Sample Collection: Consult reference methods for information on sample collection.[1-5] Samples should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the sample should be inoculated onto an appropriate transport medium and refrigerated until inoculation.

Method of Use: Allow medium to warm to room temperature prior to inoculation. Consult references for information concerning inoculation procedures.[1-5]

INTERPRETATION OF RESULTS

Consult listed references for appropriate interpretation of results.[1-5]

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.

Phosphate Buffer, pH 7.2 is not intended as a growth medium.

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, incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Phosphate Buffer, pH 7.2 is not a growth medium and is tested for sterility, pH, and fill volume only.

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

Phosphate Buffer, pH 7.2 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. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

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

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

5. *United States Pharmacopoeia and National Formulary* (USP-NF). Rockville, MD: United States Pharmacopeial Convention.

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

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