IFU

Instructions for Use

PEPTONE WATER, 0.1%

Cat. no. D290	Peptone Water, 0.1%, Dilu-Lok II™ Vial, 90ml	50 vials/case
Cat. no. D299	Peptone Water, 0.1%, Dilu-Lok II™ Vial, 99ml	50 vials/case

INTENDED USE

Hardy Diagnostics Peptone Water, 0.1% is recommended as a diluent for microbial enumeration purposes as described by the Food and Drug Administration and The *U.S. Pharmacopeia National Formulary* (USP-NF) for use in pharmaceutical and cosmetic testing and by the American Public Health Association and Environmental Protection Agency for food, dairy and water industries.

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

SUMMARY

Peptone Water, 0.1% is a minimal nutrient media designed to reduce multiplication of microorganisms; it is useful as diluent or for making suspensions of non-fastidious microorganisms for microbial enumeration procedures.[1-6] The medium is not well suited for the growth or maintenance of fastidious microorganisms due to its low nutrient content.

Peptone Water, 0.1% meets or exceeds the requirements set for by the *Food and Drug Administration-Bacteriological Analytical Manual* (FDA-BAM), the United States Pharmacopeia (USP), the Personal Care Products Council (formerly CTFA), the American Public Health Association (APHA) and the Environmental Protection Agency (EPA) for use in pharmaceutical, cosmetics, and water industries.[1-6]

FORMULA

Ingredients per liter of deionized water:*

Peptone	1.0gm

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. 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

For use as a diluting or rinsing fluid or in the preparation of suspensions for enumeration procedures, see appropriate references or regulatory guidelines for best practices.[1-6]

INTERPRETATION OF RESULTS

Consult listed references for interpretation criteria and for further testing.[1-6]

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 each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media.* The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms**	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	

Candida albicans ATCC® 10231	A	18-24hr	35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	A	18-24hr	35°C	Aerobic	Growth
Staphylococcus aureus ATCC® 25923	A	18-24hr	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922	A	18-24hr	35°C	Aerobic	Growth

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

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.

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. 2001. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. APHA, Washington, D.C.

4. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* Silver Springs, MD. www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

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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.

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