IFU

Instructions for Use

PEPTONE WATERS, 0.1%

Cat. no. K47	Peptone Water, 0.1% with 1% NaCl, 20x125mm Tube, 9ml	20 tubes/box
Cat. no. U201	Peptone Water, 0.1%, 500ml Polycarbonate Bottle, 500ml	10 bottles/box

INTENDED USE

Hardy Diagnostics Peptone Waters, 0.1% are recommended for use in food, water and wastewater, pharmaceutical and cosmetic testing as a diluent or rinsing solution and for microbial enumeration purposes.

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

SUMMARY

Peptone Waters, 0.1% are minimal nutrient media designed to reduce multiplication of microorganisms. The media are useful as diluent or rinsing solutions, or for making suspensions of non-fastidious microorganisms for microbial enumeration procedures.[2,3,5-11] Peptone Water, 0.1% with 1% sodium chloride helps to maintain osmotic balance and preserve sublethally injured cells. Peptone Waters, 0.1% are not recommended for the growth or maintenance of fastidious microorganisms.[2,3]

FORMULA

Ingredients per liter of deionized water:*

Peptone	1.0gm

Final pH 7.2 +/- 0.2 at 25ºC.

In addition, Peptone Water, 0.1% with 1% NaCl contains:

Sodium Chloride	10.0gm

Final pH 8.2 +/- 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.[2,3,5-11]

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.

Do not suspend bacteria in any peptone water for more than 30 minutes at room temperature because death or microbial multiplication may occur.

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 Peptone Waters, 0.1% for sterility, 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

Peptone Waters, 0.1% should appear clear, and colorless in color.

REFERENCES

1. Anderson, N.L., et al. 2005. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

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

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

4. *Quality Assurance for Commercially Prepared Microbiological Culture Media* , M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

5. American Public Health Association. 2012. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.

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

7. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF* . United States Pharmacopeial Convention Inc., Rockville, MD.

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

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

10. U.S. Food and Drug Administration. *Hazard Analysis and Critical Control Points (HACCP)* . Silver Spring, MD. http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm

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

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Ordering Information

Distribution Centers:

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

HDQA 2207D [D]