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Instructions for Use

DEIONIZED WATER

Cat. no. K253	Deionized Water, 20x150mm Tube, 25ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Deionized Water is recommended for the preparation of dilutions and suspensions.

SUMMARY

Diluent solutions such as deionized water are used for preparing microbial and antimicrobial suspensions when it is necessary to deliver a standardized inoculum of microbes or standard concentration of antimicrobial agents. Delivery of a standard inoculum of microbes and antimicrobials provides consistent test results and allows for a quantitative analysis of drug potencies and susceptibilities of microbes.

FORMULA

Contains deionized water.

Final pH 6.25 +/- 0.75 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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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

Method of Use: Solutions for inoculation should be prepared by inoculating the diluent with one to five isolated colonies of test organism from a purity plate. The suspension should be adjusted to the concentration of the appropriate McFarland inoculum Standard.

Refer to the Clinical and Laboratory Standards Institute (CLSI) publications "Standards for Antimicrobial Susceptibility Testing" for further details.[1,2]

INTERPRETATION OF RESULTS

Deionized Water lacks nutrients and, therefore, does not support microbial growth. However, nutrient carry-over during suspension preparation may occur and allow for growth to continue.

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.

Use caution when creating a suspension to prevent excessive transfer of nutrients from growth media.

Once inoculated, use immediately.

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, McFarland Standards, Wickerham Card, incinerators, incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Deionized Water is not a growth medium. It is tested for sterility 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

Deionized Water should appear clear and colorless.

REFERENCES

1. *Performance Standards for Antimicrobial Disk Susceptibility Tests*, M2-current edition. Clinical and Laboratory Standards Institute (CLSI), Villanova, PA

2. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*, 2nd ed., M7-current edition. Clinical and Laboratory Standards Institute (CLSI), Villanova, PA.

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

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

5. Tille, P.M., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

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

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

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