IFU

Instructions for Use

SALINE

Cat. no. D12	Saline, 0.45%, 11.75x75mm Tube, 1.8 - 2.2ml	100 tubes/box
Cat. no. U159	Saline, 0.45%, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
Cat. no. D185	Saline, 0.85%, 11.75x75mm Tube, 1.8 - 2.2ml	100 tubes/box
Cat. no. R45	Saline, 0.85%, 13x100mm Tube, 2ml	20 tubes/box
Cat. no. R55	Saline, 0.85%, 13x100mm EP Glass Tube, 2ml	20 tubes/box
Cat. no. R47	Saline, 0.85%, 13x100mm Tube, 4ml	20 tubes/box
Cat. no. K248	Saline, 0.85%, 16x100mm Tube, 1ml	20 tubes/box
Cat. no. K59	Saline, 0.85%, 16x100mm Tube, 5ml	20 tubes/box
Cat. no. K52	Saline, 0.85%, 16x100mm Tube, 9ml	20 tubes/box
Cat. no. K53	Saline, 0.85%, 16x125mm Tube, 9.9ml	20 tubes/box
Cat. no. K51	Saline, 0.85%, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. K58	Saline, 0.85%, 20x125mm Tube, 10ml	20 tubes/box
Cat. no. U155	Saline, 0.85%, 125ml Polypropylene Bottle, 100ml	12 bottles/box
Cat. no. U157	Saline, 0.85%, 1L Polycarbonate Bottle, 1000ml	10 bottles/box

INTENDED USE

Hardy Diagnostics Saline products are recommended for proceduresthat require the use of an isotonic diluent. It is also recommended foruse in preparing test suspensions of organisms.

SUMMARY

Saline is useful as a diluent to maintain cell integrity andviability because it lacks properties that may interfere withbiochemical reactions and/or antibiotic susceptibility tests. Theconcentration of sodium chloride in 0.85% (normal) Saline providesosmotic protection for microbial cells. Normal saline is used forpreparing microbial suspensions when it is necessary to deliver a setnumber of microbes to an identification test battery, to antimicrobialagents, or to growth media used for disk susceptibility testing. It isalso used in the preparing of stock solutions and serial dilutions ofantimicrobial agents. The Clinical and Laboratory Standards Institute(CLSI - formerly NCCLS) recommends the use of 0.85% Saline to adjustthe turbidity of bacterial suspensions to help maintain cell integrityand viability.[1,2] Saline, 0.45% is the isotonic diluent recommended for use with the Vitek® System.

FORMULA

Ingredients per liter of deionized water:*

Saline, 0.45%:	
Sodium Chloride	4.5gm

Saline, 0.85%:	
Sodium Chloride	8.5gm

Final pH of both solutions is 6.5 +/- 1.0 at 25ºC.**

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

** Final pH of K59 is 5.5-7.0 at 25ºC which is compatible with the API® and Micro ID® enteric bacterial identification strips.

** Final pH of D12 is 5.5-7.2 at 25ºC and is consistent with Vitek®/bioMerieux specifications for this product.

** Final pH of D185 is 5.5-7.2 at 25ºC.

** Final pH of K248 is 5.5-7.2 at 25ºC.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-30°C away from direct light. Saline should not be used if there are any signs of deterioration (evaporation, discoloration), contamination, or if the expiration date has passed. Protect from excessive heat.

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

Specimen Collection: Specimen collection is not applicable since saline is not used in the primary isolation of microbes

from clinical specimens.

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

See the Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS) publications "Standards for Antimicrobial Susceptibility Testing" for details on use of normal saline for Kirby-Bauer sensitivity standardization.[1,2]

Inoculation Procedure for Saline, 0.45% (Cat. no. D12) intended for Vitek®/bioMerieux System: It is recommended by the manufacturer of the luminometer to "blank" each tube prior to inoculation.

Quality and thickness of the glass may vary and cause differences int the luminometer's readings. For increased accuracy, after the inoculation of the tube, it is recommended to insert the tube back into the luminometer with the same orientation as when the tube was originally blanked.

LIMITATIONS

Saline lacks nutrient substances, and therefore does not support microbial growth. However, nutrient carry-over may allow growth to continue.

Failure to blank each tube individually before inoculation and orient the tube consistently after inoculation may lead to erroneous turbidity readings on the luminometer.

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

QUALITY CONTROL

Saline 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

Saline should appear clear and colorless.

Saline, 0.45%, 2mL (Cat. no. R45).

REFERENCES

1. *Performance Standards for Antimicrobial Disk Susceptibility Tests*, 6th ed., M2-A11, Vol. 33, No. 1. 2013. Clinical Laboratory Standards Institute (CLSI - formerly NCCLS), Villanova, PA.

2. *Methods for Dilution Antimicrobial Susceptibility Test For Bacteria That Grow Aerobically*, M7-current edition. Clinical Laboratory Standards Institute (CLSI - formerly NCCLS), 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. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

5. Tille, P., 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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