IFU

Instructions for Use

FLUID D WITH 1% TWEEN® 80

Cat. no. U413	Fluid D with 1% Tween® 80, 125ml Polypropylene Bottle, 100ml	12 bottles/box

INTENDED USE

Hardy Diagnostics Fluid D with 1% Tween® 80 is recommended for use as a rinsing and diluting fluid.

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

SUMMARY

Hardy Diagnostics Fluid D with 1% Tween® 80 is a 0.1% peptone solution containing 1% Tween® 80, instead of the traditional 0.1% Tween®, for use in diluting, neutralizing, dissolving and rinsing materials containing lecithin, oils, or preservatives. The modified formulation is extremely useful as a membrane filter wash solution when testing viscous materials such as ointments, creams, and oils.

FORMULA

Ingredients per liter of deionized water:*

Meat Peptone	1.0gm
Tween® 80	10.0ml

Final pH 7.1 +/- 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 in procedures involving rinsing or diluting of viscous samples, or when performing membrane filtration techniques. Follow standard laboratory aseptic methods or procedures, and consult specific regulatory or industry guidelines for use.

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, 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	
Bacillus subtilis ATCC® 6633	A	18-24hr	25-30°C	Aerobic	Growth when subcultured to Blood Agar, 5% and incubated for 24-48hr
Candida albicans ATCC® 10231	A	18-24hr	25-30°C	Aerobic	Growth when subcultured to Blood Agar, 5% and incubated for 24-48hr
Mirococcus luteus ATCC® 9341	A	18-24hr	25-30°C	Aerobic	Growth when subcultured to Blood Agar, 5% and incubated for 24-48hr

* 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.

PHYSICAL APPEARANCE

Fluid D with 1% Tween® 80 should appear clear and light to medium amber in color.

REFERENCES

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

2. Association of Official Analytical Chemists. *Official Methods of Analysis*, AOAC, Washington, D.C.

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

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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.

HDQA 2207F [D]