IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

HARDYVAL™ À LA CARTE

Cat. no. HVB10	Media Bag, Empty, Sterile, 100ml	10 bags/box
Cat. no. R35	Tryptic Soy Broth with Red Dye, USP, 5ml Ampoule, 3ml	20 ampoules/box
Cat. no. SV20	20ml Serum Vial, Empty	10 vials/box
Cat. no. SV100	100ml Serum Vial, Empty	10 vials/box
Cat. no. U100	Tryptic Soy Broth, Media Bag™, USP, 100ml	10 bags/box
Cat. no. U101	Tryptic Soy Broth, USP, 100ml Serum Vial, 100ml	10 vials/box
Cat. no. U130	Tryptic Soy Broth, Powder, 50ml Skirted Transport Vial, 3g	10 vials/box
Cat. no. U382	Tryptic Soy Broth, USP, 20ml Serum Vial, 15ml	10 vials/box

INTENDED USE

Hardy Diagnostics HardyVal™ à la carte products are recommended for routine use in the monitoring of aseptic procedures used in the preparation of Compounded Sterile Preparations (CSPs). HardyVal™ à la carte components can be purchased separately and used to create customized proficiency tests that most closely resemble the laboratory's procedures. In addition, Tryptic Soy Broth (TSB), also known as Soybean Casein Digest Broth, in HardyVal™ à la carte complies with the harmonized European, U.S. and Japanese Pharmacopoeias for determining the microbial quality of non-sterile products.[1]

These products are not intended to be used for the diagnosis of human disease.

SUMMARY

On January 1, 2004, Chapter <797> of the United States Pharmacopeia/National Formulary entitled "Pharmaceutical Compounding Sterile Preparations" became effective. USP <797> details the procedures and requirements for compounded sterile preparations, and sets standards applicable to all practice settings in which sterile preparations are compounded. Since USP <797> is considered a requirement, pharmacies may be subject to inspection for compliance with these standards by State Boards of Pharmacy, the FDA, and accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Accreditation Commission for Health Care, Inc. (ACHA) and the Community Health Accrediditation Program (CHAP). Compliance with these standards was required by January 1, 2006.

USP <797> provides general guidance on complexity or risk level assignment based upon compounding manipulations, types of ingredients and equipment used, compounding environment, and storage and use of the resulting preparation. *The ultimate determination of risk level is the responsibility of the licensed health care professionals who supervise compounding, using their professional judgement and experience.*

Training for personnel who compound sterile preparations is mandatory and should be comprehensive and include

thorough evaluation. Media-fill challenge testing (media-fill verification of aseptic technique) is used to verify that personnel have the necessary skills to compound sterile preparations. During media-fill challenge testing, personnel are instructed to prepare a CSP using sterile liquid culture medium. The solution is examined for evidence of microbial growth or turbidity during incubation and at the end of the incubation period. If there is evidence of turbidity, the challenge test has failed and it can be concluded that there was a breach in aseptic technique.

The compounding pharmacy is responsible for the proper packaging, handling, transport, and storage of all Compounded Sterile Preparations (CSPs) prepared or dispensed from the facility, whether the preparations are used within or transported outside of the institution. Sterile products must be transported to ensure they are protected from excesses of temperature and light, and pharmacists must ascertain that the end-user knows how to properly store products. A formal patient or caregiver training program is mandated. As part of the Quality Assurance Program, all CSP providers must have formal procedures to monitor, evaluate, correct, and improve the activities and processes outlined in USP.[1] Return product evaluation testing can be used to evaluate transportation, handling, and storage conditions of an expired product. These products can be used to detect gross contamination of products. This method is not adequate for use in "Sterility Testing" procedures as described in USP <71>.

The components in this Instruction for Use can be used to customize a procedure for media-fill challenge testing. Procedures should be determined by the laboratory per guidelines set forth in USP <797> regarding Method Suitability.

Tryptic Soy Broth, also known as Soybean Casein Digest Broth, used in media-fill challenge testing is widely used for the cultivation of a variety of microorganisms from environmental sources. Tryptic Soy Broth conforms to the formulation outlined by the U.S. Pharmacopeia.[1] This medium contains digest of soybean meal and casein, which provide amino acids and other nitrogenous substances, making it highly nutritious for a variety of bacteria and fungi. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is incorporated as an energy source. Dipotassium phosphate is included to maintain pH.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	17.0gm
Sodium Chloride	5.0gm
Papaic Digest of Soybean Meal	3.0gm
Dextrose	2.5gm
Dipotassium Phosphate	2.5gm

Final pH 7.3+/- 0.2 at 25ºC.

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

Formulated in accordance with USP <797>.[1]

STORAGE AND SHELF LIFE

Storage: Upon receipt, store Cat. no. R35, U100, U101, U382 at 2-25ºC away from direct light. Store Cat. no. U130 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. Protect from light, excessive heat, moisture, and freezing.

The expiration dating 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 quality control incubation times.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

To design a custom procedure for testing of CSPs, refer to the Method Suitability section of USP <797>.

When performing a media-fill challenge, use procedures and techniques that most closely resemble those used during routine compounding of CSPs in the laboratory. Once begun, the test must be completed without interruption.

For Cat. no. U130, follow the below procedure to reconstitute the non-sterile TSB Broth:

1. In an area outside of the Laminar Air Flow workbench or isolator, open the cap for Cat. no. U130.

2. Place the contents of Cat. no. U130 into a clean flask or beaker that can hold 100-200mL of water, or use a similar sized container.

3. Add 100mL of non-bacteriostatic water to the flask or beaker and place the container on a stir plate or mix well to completely dissolve.

4. Take the prepared non-sterile TSB broth to the Laminar Air Flow workbench or isolator and proceed with the challenge procedure that most closely matches laboratory routine compounding procedures.

INTERPRETATION OF RESULTS

Visible growth or turbidity observed on or before 14 days of incubation is a positive test for the presence of microorganisms. If positive, the test has failed and indicates a non-sterile technique was used.

No visible growth or turbidity observed in 14 days indicates a negative result and the technique used during the test was aseptic.

LIMITATIONS

Rare, fastidious microorganisms may not grow in Tryptic Soy Broth.

Sterile empty vials may contain a small amount of sterile condensation. This will not affect the results of the test.

Adding 100mL of water to the original container used to package Cat. no. U130 will result in insufficient space in the

container to reconstitute this product for use.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as transfer tube sets, syringes, needles, adhesive seals, thermometers, 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538	J	24-72 hrs	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24-72 hrs	20-25°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	3-5 days	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC®16404	J	5 days	20-25°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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

Tryptic Soy Broth (TSB), USP should appear clear, and light amber in color.

Tryptic Soy Broth (TSB) with Red Dye should appear clear, and red in color.

Tryptic Soy Broth (TSB), Powder should appear free flowing, and light beige in color. Once prepared, the broth should appear clear, and light amber in color.

***HardyVal™ à la carte may contain components items in the packaged kit which may have different lot numbers. The expiration date of the completed kit is based on the component with the shortest shelf life. Refer to the Certificate of Analyses for the component lot, where applicable.

Quality Control testing was performed on the kit lot components, as stated above.

REFERENCES

1.*United States Pharmacopoeia and National Formulary* (USP-NF). Rockville, MD: United States Pharmacopeial Convention.

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RESULTS LOG

Name: _____ Date Test Performed: _____

Signature: _____ Kit lot#: _____ Kit Expiration Date: _____

Date	Sample#	Initials	Hood/ Bench#	Sample/ Process Tested	TSB Bag Lot#	Inoc. Temp[1]	Results		
							Negative	Positive	Organism ID
							Initials/ Date	Initials/ Date	

1. Recommended incubation period is 14 days and incubation temperature is 20-25ºC and/or 30-35ºC per USP <797>.

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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 2207H [C]