

Instructions for Use

TAT BROTH MEDIA

Cat. no. D077	TAT Broth, Dilu-Lok II™ Vial, 90ml	50 vials/case
Cat. no. K179	TAT Broth with Lecithin and Tween® 80, 16x125mm Tube, 3ml	20 tubes/box
Cat. no. K251	TAT Broth, 20x125mm Tube, 9ml	20 tubes/box
Cat. no. U77	TAT Broth, 8oz. Wide Mouth Jar, 90ml	12 jars/box
Cat. no. U78	TAT Broth, 4oz. Glass Bottle, 99ml	20 bottles/box
Cat. no. U87	TAT Broth, 4oz. Glass Bottle, 90ml	20 bottles/box
Cat. no. U88	TAT Broth, 8oz. Wide Mouth Jar, 99ml	12 jars/box
Cat. no. U318	TAT Broth, 1 Liter Polypropylene Bottle, 490ml	10 bottles/box
Cat. no. U319	TAT Broth, 1 Liter Polypropylene Bottle, 1000ml	10 bottles/box
Cat. no. U399	TAT Broth, 125ml Polypropylene Bottle, 99ml	50 bottles/box

INTENDED USE

Hardy Diagnostics TAT (Tryptone-Azolectin-Tween®) Broth is recommended for use in cultivating microorganisms from highly viscous or gelatinous materials, such as salves and ointments. These media are especially adapted to the microbiological examination of non-sterile products from pharmaceutical, cosmetic and raw material or end-products, for the purpose of performing microbial enumeration studies.

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

SUMMARY

TAT (Tryptone-Azolectin-Tween®) Broth, also known as Casein-peptone Lecithin Polysorbate Broth, is recommended for sterility testing of viscous materials, such as salves, creams and ointments, and is especially suited to the sterility testing of cosmetics.⁽¹⁻³⁾ Cosmetics and topical pharmaceutical products are easily subjected to contamination during the manufacturing process and through continued use by consumers.^(2,3) Consequently, these products contain preservatives for self-sterilization against vegetative bacteria, yeast, and mold.

Hardy Diagnostics TAT Broth formulations are enriched to isolate and cultivate microorganisms from viscous materials. These media contain pancreatic digest of casein, which provides nitrogen, vitamins, amino acids, and carbon. Lecithin (azolectin) and Tween® 20 neutralize common preservatives in cosmetics or pharmaceutical products, thereby permitting the growth of contaminating flora. The relatively high casein content provides optimal conditions for spore germination and regeneration of damaged cells. Lecithin and polysorbate 20 inactivate many antimicrobial compounds.

Hardy Diagnostics TAT Broth with Lecithin and Tween® 80 contains additional lecithin and Tween® 80 to further neutralize germicidal or disinfectant residues on highly viscous materials. Neutralization of these residues reduces their

inhibitory effects. Quaternary ammonia compounds are neutralized by lecithin while phenolic disinfectants and hexachlorophene are neutralized by Tween[®]. Together, lecithin and Tween[®] 80 neutralize ethanol.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	20.0gm
Lecithin	5.0gm
Tween [®] 20	40.0ml

In addition, TAT Broth with Lecithin and Tween[®] 80 also contains:

Lecithin	0.7gm
Tween [®] 80	5.0ml

Final pH 7.2 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store Cat. no. K179 at 2-8°C. away from direct light. Upon receipt store Cat. nos. D077, K251, U77, U78, U87, U88, U318, U319, and U399 at 2-30°C. 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 a complete discussion on sterility testing and culture, consult the appropriate reference method.⁽¹⁻³⁾

1. Add 1.0gm or 1ml of an undiluted sample to 40ml of complete medium and agitate to obtain an even suspension.
2. Incubate at 35°C. for 18-48 hours.

INTERPRETATION OF RESULTS

Tubes or bottles exhibiting growth in the form of turbidity should be subcultured for further identification.

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.

Since the nutritional requirements of organisms vary, some strains may be encountered that fail to grow or grow poorly on this medium.

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 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	
TAT Broth & TAT Broth with Lecithin and Tween® 80:					
<i>Salmonella enterica</i> ATCC® 14028	A	18-48hr	35°C	Aerobic	Growth
<i>Pseudomonas aeruginosa</i> ATCC® 27853	A	18-48hr	35°C	Aerobic	Growth
<i>Bacillus subtilis</i> ATCC® 6633	A	18-48hr	35°C	Aerobic	Growth
<i>Staphylococcus aureus</i> ATCC® 25923	A	18-48hr	35°C	Aerobic	Growth
TAT Broth (Cat. no. U318 and U319):					
<i>Staphylococcus aureus</i> ATCC® 6538	J	3-5 days	30-35°C	Aerobic	Growth
<i>Pseudomonas aeruginosa</i> ATCC® 9027	J	3-5 days	30-35°C	Aerobic	Growth

<i>Bacillus subtilis</i> ATCC® 6633	J	3-5 days	30-35°C	Aerobic	Growth
<i>Escherichia coli</i> ATCC® 8739	J	3-5 days	30-35°C	Aerobic	Growth
<i>Salmonella enterica</i> ATCC® 14028	J	3-5 days	30-35°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 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

TAT Broth should appear slightly opalescent, and light amber in color with a slight precipitate. TAT Broth with Lecithin and Tween® 80 should appear slightly opalescent, and light to medium amber in color with a slight precipitate

REFERENCES

1. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, Rockville, MD.
2. Orth, D.S. 1993. Handbook of cosmetic microbiology. Marcel Dekker, Inc. New York, NY.
3. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA.
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>.

ATCC is a registered trademark of the American Type Culture Collection.
Tween is a registered trademark of ICI Americas, Inc.

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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]