INSTRUCTIONS FOR USE

ANAEROBIC TRANSPORT MEDIUM / DENTAL TRANSPORT MEDIUM (ATM, ATM-SP, and DTM)

PRODUCTS

AS-911	Anaerobic Transport Medium (ATM)	10 tubes / pkg
AS-914	Anaerobic Transport Medium – Surgery Pack (ATM-SP)	10 tubes / pkg
AS-920	Anaerobic Dental Transport Medium (DTM)	10 tubes / pkg

INTENDED PURPOSE

TruPRAS™ Anaerobic Culture Media is intended for the transport, preservation, or cultivation of a wide variety of microorganisms from specimens to aid in the isolation of bacteria for in vitro diagnostic and / or research / general laboratory purposes.

INTENDED USERS

Scientists, laboratory, and healthcare professionals trained in anaerobic microbiology techniques working in areas such as clinical, research, industrial, pharmaceutical and veterinary applications.

FORMULATION*

Anaerobic Transport Medium (ATM and ATM-SP) and Anaerobic Dental Transport Medium (DTM) are mineral salt-based, buffered semi-solid media containing reducing agents, designed to maintain the viability of both anaerobic and aerobic microorganisms during specimen collection, transport, and shipping. These media contain sodium thioglycolate and cysteine, which help create a reduced environment by scavenging excess oxygen. The formulation is designed to maintain the viability of most microorganisms without promoting significant multiplication and to dilute potential inhibitors present in the specimen. This medium meets the stringent viability requirements of obligate anaerobes. All tubes are supplied with a Hungate cap (a screw caps with a rubber septum), allowing for the direct injection of aspirated specimens or the introduction of tissue samples. Resazurin is included as a color indicator to signal significant oxygen exposure in the medium. This medium is prepared, dispensed, and packaged under oxygen-free conditions using TruPRAS™ Technology to prevent the formation of oxidized products prior to use. This product is supplied ready to use, with no pre-reduction step required.

Sodium thioglycolate	1.00	g
Sodium phosphate dibasic	1.15	g
Sodium chloride	3.00	g
Potassium chloride	0.20	g
Potassium phosphate monobasic	0.20	g
Magnesium sulfate heptahydrate	0.10	g
Gellan gum	4.00	g
L-cysteine hydrochloride	1.00	g
Resazurin	1.00	mg
DI Water	1.00	L

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

Final pH: 7.5 ± 0.5 at 25°C
Final volume: 6.0 mL ± 0.6 mL for AS-911 and AS-914
Final volume: 5.0 mL ± 0.5 mL for AS-920

PRECAUTIONS

For *IN VITRO DIAGNOSTIC USE* only. Utilize approved biohazard precautions and aseptic technique when using this product. This product is for use by properly trained and qualified personnel only. Sterilize all biohazard waste prior to disposal. This product is manufactured as a single use device.

Report serious incidents that occur in direct relation to this product to tech@biolog.com. As necessary, report serious incidents to the regulatory authority in which the user is established.

When working with anaerobic culture media, the potential for ergonomic hazards may exist due to repetitive motions, awkward postures, improper bench/chair heights or poor lighting. Although it is beyond the scope and provision of products by Anaerobe Systems, it should be recognized and mitigated by the end user in the laboratory environment.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at room temperature (15 – 25°C) in original package until used. Avoid overheating or freezing. Do not use media if there are signs of deterioration (discoloration due to oxidation of media), contamination, broken cap, or cracked glass. Do not use this product if a blue/purple/pink ring has formed at the surface of the media prior to opening the vial and exposing the media to oxygen. For AS-914 ATM-SP only, do not use this product if the barrier packaging paper is torn or separated from the plastic backing. The expiration date applies to the product in its original packaging and stored as directed. Do not use product past the expiration date shown on the label.

Shelf Life:	AS-911 (ATM)	1 year from date of manufacture.
	AS-914 (ATM-SP)	5 months from the date of manufacture.
	AS-920 (DTM)	1 year from the date of manufacture.

PROCEDURE

Specimen Collection: Protect specimens for anaerobic culture from oxygen during collection, transportation, and processing. Consult appropriate references for detailed instructions concerning collection and transportation of anaerobes. The selection of specimens for culture is made by physicians or scientists collecting the sample.

Methods for Use: ATM, ATM-SP, and DTM are suitable for use as a transport and holding medium for specimens collected as tissue samples or fluid specimens aspirated into syringes. With any specimen, this media should be inoculated using aseptic technique during collection. For tissue samples, open the screw cap and place tissue on the surface of the semi-solid medium; inserting the tissue into the gel is not necessary. Immediately close the tube. Oxygen contact within the medium should be minimized. For syringe specimens, the rubber septum in the cap should be disinfected with ethyl alcohol and the fluid specimen injected directly into the tube at a slow rate. Once tubes are inoculated, keep at room temperature, and deliver to the laboratory for processing as soon as possible. Swabs are not recommended for use as anaerobic specimen collection devices; however, this medium can accommodate swabs if necessary. Detailed instructions for processing anaerobic cultures can be found in the appropriate references.

ATM-SP (AS-914): The contents and outer surface of the tube have been decontaminated. To open, peel the envelope apart. While wearing sterile gloves, remove the tube from the packaging and take the tube into the sterile surgical area.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as specimen collection swabs or aspirate devices, loops, saline blanks, slides, staining supplies, microscope, incinerator / autoclave, incubators, anaerobic chamber / anaerobic jars, disinfectant, other culture media, and serological / biochemical reagents.

INTERPRETATION OF RESULTS

Results for the recovery of bacteria will largely depend on proper and adequate specimen collection, timely transport, and processing in the laboratory. If used properly, this medium should maintain the viability of microorganisms, anaerobic and aerobic, present in a specimen until transported and processed within the laboratory for up to 48 hours.

LIMITATIONS

ATM, ATM-SP, and DTM are designed as holding mediums to maintain the viability of microorganisms contained within a specimen during transport. This medium will not provide complete information for identification of bacterial isolates. Additional test procedures and media are required for complete identification. Specimens should be transported and processed in the laboratory in a timely manner as delays may result in overgrowth by one organism present in a specimen from polymicrobial infections. Consult reference materials for additional information.

QUALITY CONTROL

The following organisms are routinely used for quality assurance testing at Anaerobe Systems. To determine the holding capacity of ATM, ATM-SP, and DTM, an ATCC® isolate strain (listed below), from 24-hour growth, is inoculated into the transport aerobically and held for 48 hours at room temperature protected from light. After 48 hours, each organism is subcultured onto a Brucella Blood Agar (BRU, catalog #: AS-111) plate and placed in an anaerobic environment to obtain isolated colonies. Plates are incubated at 35 – 37°C for 48 hours then observed for growth.

Organism Tested	ATCC® #	Results
Bacteroides fragilis*	25285	Viable
Prevotella melaninogenica*	25845	Viable
Cutibacterium acnes*	6919	Viable
Fusobacterium nucleatum*	25586	Viable
Peptostreptococcus anaerobius*	27337	Viable

*Organisms specified by CLSI for quality control testing of anaerobic microbiological transport systems.

User Quality Control: The final determination to the extent and quantity of user laboratory quality control must be determined by the end user.

If the holding capacity of this medium is to be tested for performance, it is recommended that the following ATCC® organisms be evaluated for growth.

Organism	ATCC® #	Results
Bacteroides fragilis	25285	Viable
Prevotella melaninogenica	25845	Viable
Cutibacterium acnes	6919	Viable
Fusobacterium nucleatum	25586	Viable
Peptostreptococcus anaerobius	27337	Viable

Physical Appearance: ATM, ATM-SP, and DTM should appear as a clear to slightly hazy, colorless, semi-solid media with a pungent "rotten egg" smell. The medium is dispensed in a 16 mm x 100 mm glass tube (for AS-911 & AS-914) or a 19 mm x 40 mm glass tube (for AS-920) with a hungate-style cap.

REFERENCES

1. CLSI. *Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline*. CLSI document M56-A. Clinical and Laboratory Standards Institute; 2014

2. Leber AL, Burnham CA, eds. *Clinical Microbiology Procedures Handbook*. 5th ed. 4 vols. Washington, DC: ASM Press; 2023.

3. Carroll KC, Pfaller MA, eds. *Manual of Clinical Microbiology*. 13th ed. 4 vols. Hoboken, NJ: Wiley-Blackwell; 2023.

4. Jousimies-Somer HR, Sutter VL, eds. *Wadsworth-KTL Anaerobic Bacteriology Manual*. 6th ed. Belmont, CA: Star Publishing Company; 2002.

5. CLSI. *Quality Control for Commercially Prepared Microbiological Transport Systems; Approved Standard – Second Edition.* CLSI document M40-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

GLOSSARY OF SYMBOLS

SYMBOL	TITLE	DESCRIPTION	STANDARD	REF#
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1
	Lot number/ Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.4
	Authorized Representative	Indicates the Authorized Representative in the identified country or jurisdiction.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.2
	Do not re-use/ Single use only	Indicates a medical device that is intended for one single use only.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.2
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.3
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7
	In vitro diagnostic medical device	Indicates that a medical device is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.5.1
	CE Mark European Conformity	Designates that the product labeled Is authorized for sale in European countries.	EU IVDR (EU) 2017/746	

AUTHORIZED REPRESENTATIVE INFORMATION

Revision 4
Additions: Intended Use, Intended Users, Ergonomics Precautions, Serious Incident Report Contact Information, Glossary of Symbols
Changes: Title change from Product Insert to Instructions for Use. Room temperature from 20 – 25°C to 15 – 25°C. References updated. Contact information.
Deletions: None