



INSTRUCTIONS FOR USE

BOTULISM SELECTIVE MEDIUM (BSM)

PRODUCTS

AS-223 Botulism Selective Medium (BSM) 4 plate / 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*

BSM is a selective and differential medium used for growth of *Clostridium botulinum* from food or clinical samples. BSM contains cycloserine, sulfamethoxazole, and trimethoprim as selective agents to inhibit the growth of non-target organisms. A suspension of egg yolk is included to detect lecithinase, lipase, and proteolytic activity. Lecithinase activity results in an opaque precipitate surrounding the colonies due to lecithin degradation. Lipase activity produces an iridescent sheen on the colony surface as fats in the egg yolk are broken down. Proteolytic activity is indicated by a clear zone around the colonies 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.

Beef heart infusion	10.00	g
Tryptose	10.00	g
Sodium chloride	5.00	g
Cycloserine	0.25	g
Sulfamethoxazole	0.076	g
Trimethoprim	0.06	g
Thymidine phosphorylase	0.10	mL
Egg yolk suspension	40.00	mL
Agar	20.00	g
DI Water	1.00	L

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

Final pH: 7.4 ± 0.3 at 25°C

Final weight: 17.0 g ± 1.7 g mono plate

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.

This product may contain components of animal origin. All components of animal origin have been sourced from Bovine Spongiform Encephalopathy- (BSE-) free and Transmissible Spongiform Encephalopathy- (TSE-) free countries. Certified knowledge of the origin of animal derived components does not guarantee the absence of transmissible pathogenic agents. It is recommended that Universal Precautions be observed.

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 (shrinking, cracking, or discoloration due to oxidation of media) or contamination. 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: 90 days 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: BSM agar should be inoculated directly with a specimen or from a broth that has been inoculated from a specimen. Streak plates with inoculum to obtain isolated colonies and immediately place in an anaerobic atmosphere, incubating at 35 - 37°C for 18 - 48 hours. Extended periods of incubation may be required to recover some anaerobes. Extended incubation time may also result in loss of selectivity of the medium which can result in the overgrowth of organisms that should be inhibited. Detailed instructions for processing anaerobic cultures can be found in the listed references. As packaged, this medium constitutes a qualitative, manual method.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as 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

BSM supports the growth of *Clostridium botulinum* from food and clinical specimens. It also allows for the detection of typical lecithinase and lipase activity produced by certain *Clostridium* specimens. Lecithinase-positive organisms degrade lecithin in the egg yolk, resulting in an opaque precipitate surrounding the colonies. Lipase-positive organisms break down fats in the egg yolk, producing an iridescent sheen on the colony surface.

LIMITATIONS

BSM does not provide complete information for the identification of bacterial isolates. Additional test procedures and media are required for full identification. It is recommended that a non-selective medium, such as Brucella Blood Agar (BRU, catalog #: AS-111), also be inoculated from the same sample to ensure recovery of all organisms present. Consult reference materials for additional information.



QUALITY CONTROL

The following organisms are routinely used for quality control testing at Anaerobe Systems using the specifications outlined in the CLSI document M22-A3: Quality Control for Commercially Prepared Microbiological Culture Media.

Organism Tested	ATCC® #	Results	Special Reaction
Bacteroides fragilis	25285	No growth	
Prevotella melaninogenica	25845	Poor to no growth	
Fusobacterium necrophorum	25286	No growth	
Fusobacterium nucleatum	25586	No growth	
Clostridium perfringens	13124	Poor to no growth	Lecithinase-positive
Clostridioides difficile	9689	Poor to no growth	
Clostridium novyi	7659	No growth	
Clostridium sporogenes	3584	Growth	Lipase-positive
Cutibacterium acnes	6919	No growth	
Peptostreptococcus anaerobius	28337	No growth	
Escherichia coli	25922	No growth	
Staphylococcus aureus	25923	No growth	

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 nutritive/inhibitory 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	Special Reaction
Bacteroides fragilis	25285	No growth	
Fusobacterium necrophorum	25286	No growth	
Clostridium sporogenes	3584	Growth	Lipase-positive
Escherichia coli	25922	No growth	

Physical Appearance: BSM should appear opaque and pale yellow in color.

ATCC® is a registered trademark of American Type Culture Collection.

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 Culture Media; Approved Standard- Third Edition*. CLSI document M22-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.



6. Dezfulian M, McCroskey LM, Hatheway CL, Dowell VR. *Selective Medium for Isolation of Clostridium botulinum from Human Feces*. *J Clin Microbiol*. 1981;13(3):526-531.
7. U.S. Department of Agriculture, Animal and Plant Health Inspection Service. *Animal Health Status of Regions*. Published March 12, 2025. <https://www.aphis.usda.gov/regionalization-evaluation-services/region-health-status>
8. European Commission. *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3)*. Published March 5, 2011. <https://op.europa.eu/en/publication-detail/-/publication/3392e464-ba89-4ae4-955c-a07f617c8e06/language-en>

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, labelling, 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 3

Additions: Intended Use, Intended Users, Animal Origin Statement, 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.