INSTRUCTIONS FOR USE

CHOPPED MEAT MEDIUM (CM, CMG, and CMC)

PRODUCTS

AS-811	Chopped Meat Medium (CM) – 7 mL tube	10 tubes / pkg
AS-8111	Chopped Meat Medium (CM) – 100 mL bottle	1 bottle / pkg
AS-8112	Chopped Meat Medium (CM) – 250 mL bottle	1 bottle / pkg
AS-8115	Chopped Meat Medium (CM) – 500 mL bottle	1 bottle / pkg
AS-813	Chopped Meat Medium with Glucose (CMG) – 7 mL tube	10 tubes / pkg
AS-8131	Chopped Meat Medium with Glucose (CMG) – 100 mL bottle	1 bottle / pkg
AS-8132	Chopped Meat Medium with Glucose (CMG) – 250 mL bottle	1 bottle / pkg
AS-8135	Chopped Meat Medium with Glucose (CMG) – 500 mL bottle	1 bottle / pkg
AS-823	Chopped Meat Medium with Carbohydrates (CMC) – 7 mL tube	10 tubes / pkg
AS-8231	Chopped Meat Medium with Carbohydrates (CMC) – 100 mL bottle	1 bottle / pkg
AS-8232	Chopped Meat Medium with Carbohydrates (CMC) – 250 mL bottle	1 bottle / pkg
AS-8235	Chopped Meat Medium with Carbohydrates (CMC) – 500 mL bottle	1 bottle / 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*

Chopped Meat Media (CM, CMG, and CMC) are enriched, differential, non-selective media that support the growth of most non-spore forming and spore forming anaerobes associated with human and animal infections. CM, CMG, and CMC facilitate sporulation, proteolysis, and toxin production by certain *Clostridia* species, such as *Clostridium novyi* Type A. They are also suitable for preserving clostridial cultures by freezing. These media can initiate growth from minimal inoculum and maintain the viability of organisms over extended periods. They allow slower-growing organisms within mixed samples to proliferate alongside faster-growing species and are used to demonstrate clostridial toxin production, sporulation, and short-chain organic acid production detectable by gas chromatography. 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.

CM		
Lean ground beef	500.00	g
Sodium hydroxide solution	25.00	mL
Pancreatic digest of casein	30.00	g
Yeast extract	5.00	g
Potassium phosphate dibasic	5.00	g
L-cysteine hydrochloride	0.50	g

Hemin	5.00	mg
Vitamin K_1	10.00	mg
DI Water	1.00	L
CMG (CM + Glucose)		
Dextrose	3.00	g
CMC (CM + Carbohydrates)		
Dextrose	4.00	g
D-Maltose	1.00	g
D-Cellobiose	1.00	g
Soluble starch	1.00	g

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

Final pH: 7.1 ± 0.3 at 25°C
Final volume: 7.0 mL ± 0.7 mL

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 (discoloration due to oxidation of media or evaporation), contamination, broken cap, or cracked glass. 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: 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: CM, CMG, and CMC should be inoculated directly with a specimen or with isolated colonies. Immediately place into an anaerobic atmosphere and incubate at 35 - 37°C for 18 - 48 hours. Extended periods of

incubation may be required to recover slower growing anaerobes. 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

Chopped Meat Media (CM, CMG, and CMC) are highly nutritious media that support the growth of both non-spore forming and spore forming anaerobes associated with human and animal infections. These media support robust growth of *Clostridium tetani*, *Clostridium sporogenes, Prevotella melaninogenica,* and *Fusobacterium necrophorum* from a small inoculum (i.e. 0.01 ml of a 24 – 48-hour Lombard-Dowell [LD] Broth culture diluted to 3:1000). Both *C. tetani* and *C. sporogenes* typically produce characteristic spores, and *C. sporogenes* should exhibit typical proteolysis of the meat. Additionally, *C. septicum* and *C. tetani* are expected to produce typical toxins, as demonstrated by mouse toxicity and mouse toxin neutralization assays.

LIMITATIONS

CM, CMG, and CMC will not provide complete information for identification of bacterial isolates. Subcultures to obtain pure colonies of organisms are required for morphological, biochemical, and serological tests performed for complete identification. Direct gram stains are not recommended due to the presence of non-viable bacterial cells in the sterilized meat components of the product. 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
Bacteroides fragilis	25285	Growth
Prevotella melaninogenica	25845	Growth
Phocaeicola vulgatus	8482	Growth
Fusobacterium nucleatum	25586	Growth
Fusobacterium necrophorum	25286	Growth
Clostridium perfringens	13124	Growth
Clostridium novyi	7659	Growth
Peptostreptococcus anaerobius	27337	Growth
Cutibacterium acnes	6919	Growth
Staphylococcus aureus	25923	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 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	Growth
Prevotella melaninogenica	25845	Growth

Clostridium perfringens	13124	Growth
Fusobacterium necrophorum	25286	Growth
Staphylococcus aureus	25923	Growth

Physical Appearance: CM, CMG, and CMC should appear as a clear to slightly turbid, golden-yellow liquid with ground meat particles at the bottom of the tube.

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. 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

7. 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, 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 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.
Deletions: None