



## INSTRUCTIONS FOR USE

### CAMPYLOBACTER SELECTIVE AGAR (CAMPY)

#### PRODUCTS

AS-211 Campylobacter Selective Agar (CAMPY)

1 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\*

CAMPY agar is an enriched, selective blood agar used for the growth of *Campylobacter jejuni* subsp. *jejuni* from fecal or rectal swabs. This medium inhibits the growth of normal fecal flora to favor target organism development. Based on Skirrow's formulation, Brucella Blood Agar (BRU) serves as the nutritive base and is supplement with trimethoprim, vancomycin, and polymyxin B to suppress normal enteric bacteria. 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.

Pancreatic digest of casein	10.00	g
Soy peptone	3.00	g
Meat peptone	10.00	g
Yeast extract	2.00	g
Sodium chloride	5.00	g
Sodium bisulfite	0.10	g
Dextrose	1.00	g
Agar	15.00	g
L-cysteine hydrochloride	0.50	g
Vancomycin	10.00	mg
Polymyxin B	2500	Units
Trimethoprim	5.00	mg
Laked horse blood	70.00	mL
DI Water	1.00	L

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

Final pH: 7.4 ± 0.2 at 25°C

Final weight: 16.0 g ± 1.6 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](mailto: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:** Rectal swabs or swabs of fecal specimens are used to inoculate an area approximately 1" to 1¼" in diameter on the surface of the media. Streak the plate for isolated colonies. Incubate inoculated plates at 42 – 43°C in an anaerobic jar (catalyst removed) flushed with a microaerophilic gas mixture. For strain specific gas mixtures, consult the appropriate references. As packaged, this medium constitutes a qualitative, manual method.

NOTE: If facilities for gassing out an anaerobic jar are not available, a disposable hydrogen-carbon dioxide generator sachet may be substituted. Not all strains of *Campylobacter jejuni* subsp. *jejuni* grow as well when generators are used, and some may not grow at all. *Campylobacter jejuni* subsp. *jejuni* is a microaerophile, not a strict anaerobe.

Examine plates after 24, 48, and 72 hours of incubation. Colonies of *Campylobacter jejuni* subsp. *jejuni* are usually detected in 24 hours. The colonies vary from pinpoint, glossy appearing to those which spread over the entire surface of the agar.

*Campylobacter jejuni* subsp. *jejuni* is an oxidase positive organism, the oxidase test can be used to screen suspect colonies.

## 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

CAMPY agar will support good growth of *Campylobacter jejuni* subsp. *jejuni* isolated from a specimen. Normal bowel flora organisms such as *Proteus mirabilis*, *Escherichia coli*, *Enterococci* spp., and *Clostridium perfringens* should be inhibited.

## LIMITATIONS

CAMPY agar will not provide complete information for identification of bacterial isolates. Additional biochemical test procedures from a pure culture are necessary for complete identification. Consult appropriate 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
<i>Campylobacter jejuni</i> subsp. <i>jejuni</i> *	33291	Growth
<i>Campylobacter fetus</i> subsp. <i>fetus</i>	33246	Growth
<i>Staphylococcus aureus</i>	25923	No growth
<i>Enterococcus faecalis</i>	29212	No growth
<i>Escherichia coli</i> *	25922	Poor to no growth
<i>Proteus mirabilis</i>	12453	Poor to no growth

\* Organisms specified by CLSI for quality control testing of CAMPY.

**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
<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	33291	Growth
<i>Campylobacter fetus</i> subsp. <i>fetus</i>	33246	Growth
<i>Escherichia coli</i>	25922	Poor to no growth
<i>Staphylococcus aureus</i>	25923	No growth

**Physical Appearance:** CAMPY should appear translucent copper red in color.

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

## REFERENCES

1. Morbidity and Mortality Weekly Report. Waterborne *Campylobacter* Gastroenteritis – Vermont. Vol. 24, No. 25, June 23, 1978, pg. 207.
2. King, E. O. Human infections with *Vibrio fetus* and a closely related *Vibrio*.
3. Butzler, J. P., P. Dekeyser, M. Detrain and F. Dhaen. Related vibrio in stools. *J. Ped* 52:493-495, 1973.
4. Skirrow, M. R. *Campylobacter* enteritis: a "new disease. *Br. Med J* 2: 9-11, 1977.



5. Campylobacter enteritis. The Lancet, ii: 135-136, 1978.
6. Morbidity and Mortality Weekly Report. Campylobacter enteritis – Colorado. Vol. 27, No. 27, July 7, 1978, pg. 226.
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9. Smibert, R. M. The genus Campylobacter, An. Rev. Microbiol. 32: 673-709, 1978.
10. George, H. A., P. S. Hoffman, R. M. Smibert and N. R. Krieg. Improved media for growth and aerotolerance of Campylobacter fetus. J. of Clin Micro. 8: 36-41, 1978.
11. Blaser, M. J., P. Roesler, H. L. Hardesty, and W. L. Wang. Carriage of Campylobacter by dogs and cats in Denver, Co. CDC Vet. Pub. 11th, Notes, Feb 1979.
12. Blaser, M. J., J. Cravens, B. Powers, W. L. Wang. Campylobacter enteritis associated with canine infection. Lancet 2: 979-981, 1978.
13. 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.
14. 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>
15. 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

<b>EC</b>	<b>REP</b>	Casus Europe B.V. Lange Vliedstraat 2b 3511 BK Utrecht The Netherlands
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<b>CH</b>	<b>REP</b>	Casus Switzerland GmbH Hinterbergstrasse 49 6312 Steinhausen Switzerland
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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