

INSTRUCTIONS FOR USE

LAKED BRUCELLA BLOOD AGAR WITH KANAMYCIN AND VANCOMYCIN (LKV)

PRODUCTS

AS-112	Laked Brucella Blood Agar with Kanamycin and Vancomycin (LKV)	1 plate / pkg
AS-142	Laked Brucella Blood Agar with Kanamycin and Vancomycin (LKV)	4 plates / pkg

The following products contain LKV as one of multiple components

AS-212 BBE/LKV Biplate	1 plate / pkg
AS-242 BBE/LKV Biplate	4 plates / pkg
AS-302 BRU Mono / BBE-LKV Biplate	1 plate each / pkg
AS-303 BRU Mono / LKV Mono / PEA Mono	1 plate each / pkg
AS-323 BRU Mono / PEA Mono / BBE-LKV Biplate	1 plate each / pkg
AS-444 BRU Mono / PEA Mono / LKV Mono / BBE Mono	1 plate each / pkg

INTENDED PURPOSE

TruPRASTM 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*

LKV agar is an enriched, selective, and differential medium designed to support the growth of obligately anaerobic gram-negative bacilli. LKV agar is particularly useful for promoting the growth of *Prevotella* species. The nutritive base includes casein, soy peptone, meat peptone, yeast extract, and dextrose to support a broad range of anerobic bacteria. Selective agents kanamycin and vancomycin are included to inhibit the growth of most obligate gram-negative and gram-positive anaerobes, as well as most facultative anaerobic bacteria. Laked sheep blood and vitamin K_1 are added to support the recovery and pigment production of *Prevotella melaninogenica* and *Porphyromonas* species. This medium is prepared, dispensed, and packaged under oxygen-free conditions using TruPRASTM Technology to prevent the formation of oxidized products prior to use. This product is supplied ready to use, with no pre-reduction step required.

FORMULATION*

Pancreatic digest of casein	10.00	g
Soy peptone	3.00	g
Meat peptone	10.00	g
Dextrose	1.00	g
Yeast extract	2.00	g
Sodium chloride	5.00	g
Sodium bisulfite	0.10	g
Hemin	5.00	mg



Vitamin K ₁	10.00	mg
L-cysteine hydrochloride	0.50	g
Agar	15.00	g
Kanamycin sulfate	100.00	mg
Vancomycin hydrochloride	7.50	mg
Laked sheep blood	50.00	mL
DI Water	1.00	L

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

Final pH: 7.1 ± 0.4 at 25°C

Final weight: 16.0 g \pm 1.6 g mono plate Final weight: 8.0 g \pm 0.8 g biplate

PRECAUTIONS

For <u>IN VITRO DIAGNOSTIC USE</u> 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 <u>tech@biolog.com</u>. 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 $(15 - 25^{\circ}C)$ 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: LKV 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 inhibition 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

LKV agar will support good growth of some obligately anaerobic gram-negative bacteria (e.g. *Prevotella melaninogenica* and *Bacteroides fragilis*) and inhibit the growth of facultatively anaerobic bacteria (e.g. *Escherichia coli, Proteus mirabilis*, and *Staphylococcus aureus*) and gram-positive obligate anaerobes (e.g. *Clostridium perfringens* and *Peptostreptococcus anaerobius*). LKV agar will support the pigmentation of *Prevotella* and *Porphyromonas* species.

LIMITATIONS

LKV agar will not provide complete information for identification of bacterial isolates. Additional test procedures and media are required for complete identification. Some organisms that would normally grow on LKV medium may be inhibited. It is recommended that a non-selective medium, such as Brucella Blood Agar (BRU, catalog #: AS-111) also be inoculated from the same specimen to assure recovery of all species present. Some strains of facultative organisms (which should be inhibited) may grow on LKV. A test for aerotolerance should be performed to confirm that each colony type is an obligate anaerobe using Chocolate Agar (CHOC, catalog #: AS-214). 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	Growth	
Prevotella melaninogenica*	25845	Growth	Pigment ^t
Fusobacterium necrophorum	25286	Variable	
Fusobacterium nucleatum*	25586	Variable	
Clostridium perfringens*	13124	No growth	
Peptostreptococcus anaerobius*	27337	No growth	
Staphylococcus aureus	25923	Poor to no growth	
Enterococcus faecalis	29212	Poor to no growth	
Escherichia coli	25922	Poor to no growth	
Proteus mirabilis	12453	Poor to no growth	
Cutibacterium acnes	6919	No growth	
Clostridioides difficile	9689	No growth	

^{*} Organisms recommended by CLSI for quality control testing of anaerobic blood agars.

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.

^t Pigment production may require more than 48 hours of incubation

Organism	ATCC® #	Expected Results	Special Reactions
Bacteroides fragilis	25285	Growth	
Prevotella melaninogenica	25845	Growth	Pigment ^t
Peptostreptococcus anaerobius	27337	No growth	
Clostridium perfringens	13124	No growth	
Escherichia coli	27337	Poor to no growth	

^t Pigment production may require more than 48 hours of incubation

Physical Appearance: LKV should appear translucent red.

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#
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	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
\subseteq	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
XX REP	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



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
[]i	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
IVD	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	CE Mark European Conformity	Designates that the product labeled Is authorized for sale in European countries.	EU IVDR (EU) 2017/746	

AUTHORIZED REPRESENTATIVE INFORMATION

EC	REP	Casus Europe B.V. Lange Viestraat 2b 3511 BK Utrecht The Netherlands
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REVISION 2

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