1 plate each / pkg



INSTRUCTIONS FOR USE

BRUCELLA BLOOD AGAR (BRU)

AS-444 BRU Mono / PEA Mono / LKV Mono / BBE Mono

PRODUCTS

AS-111 Brucella Blood Agar (BRU) AS-141 Brucella Blood Agar (BRU) AS-614 Brucella Blood Agar (BRU) – 150 mm plates	1 plate / pkg 4 plates / pkg 1 plate / pkg
The following products contain BRU as one of the multiple components:	
AS-302 BRU Mono / BBE-LKV Biplate	1 plate each / pkg
AS-322 BRU Mono / BBE-PEA 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

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*

BRU agar is an enriched, non-selective medium designed to support the growth of obligate anaerobic bacteria from a wide range of specimens. When incubated under appropriate conditions, this medium also supports aerobic and microaerophilic bacteria. BRU is suitable for antibiotic differential disk testing and spot biochemical assays. The nutrient base includes casein, peptones, yeast extract, and dextrose. The medium is supplemented with vitamin K_1 and hemin to promote recovery and pigment production of *Prevotella melaninogenica* and other fastidious anaerobes. Defibrinated sheep blood is added to provide growth factors required by some anaerobic bacteria and to enable observation of hemolytic reactions, such as the characteristic double zone β -hemolysis produced by *Clostridium perfringens*. 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.

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
L-Tryptophan	0.20	g
Calcium lactate	0.50	g
Sodium acetate	0.50	g
Ascorbic acid	0.10	g



Hemin	5.00	mg
Vitamin K ₁	10.00	mg
L-Cystine	0.40	g
Sodium hydroxide	0.16	g
Agar	15.00	g
Defibrinated 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 ± 1.6 g

Final weight: $68.0 \text{ g} \pm 3.4 \text{ g}$; Fill depth: $4.0 \text{ mm} \pm 0.5 \text{ mm}$ for AS-614 only.

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: BRU 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 into an anaerobic atmosphere, incubating 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

BRU is a highly nutritious medium that supports the growth of obligate anaerobes and other fastidious microorganisms found in a specimen. In addition, this media should support typical pigment production by $Prevotella\ melaninogenica$ and typical double zone of β -hemolysis around colonies of $Clostridium\ perfringens$.

LIMITATIONS

BRU agar will not provide complete information for the identification of bacterial isolates. Additional test procedures and media are required for complete identification. In some cases, BRU agar may be overgrown with swarming *Proteus* spp. or *Clostridium* spp. It is recommended that a media such as Laked Brucella Blood Agar with Kanamycin and Vancomycin (LKV, catalog #: AS-112) and/or Phenylethyl Alcohol Agar (PEA, catalog #: AS-113) also be inoculated from a specimen to prevent such overgrowth and thus provide isolated colonies. 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 (tan color)
Fusobacterium necrophorum	25286	Growth	
Fusobacterium nucleatum*	25586	Growth	
Clostridium perfringens*	13124	Growth	Double zone of β-hemolysis
Peptostreptococcus anaerobius*	27337	Growth	
Staphylococcus aureus	25923	Growth	
Enterococcus faecalis	29212	Growth	
Escherichia coli	25922	Growth	
Proteus mirabilis	12453	Growth	
Cutibacterium acnes	6919	Growth	
Clostridioides difficile	9689	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.

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



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® #	Expected	Special Reactions
		Results	
Bacteroides fragilis	25285	Growth	
Prevotella melaninogenica	25845	Growth	Pigment ^t
Fusobacterium nucleatum	25586	Growth	
Clostridium perfringens	13124	Growth	Double zone of β-hemolysis
Peptostreptococcus anaerobius	27337	Growth	

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

Physical Appearance: BRU should appear opaque red in color. For AS-614, the media is in a 150 mm \times 15 mm plate with a fill depth of 4.0 mm \pm 0.5 mm. All other catalog numbers for BRU come in standard sized 100 mm \times 15 mm petri plates.

 $\label{eq:attack} {\sf ATCC}^{\scriptsize @} \ {\sf is a registered trademark of American Type Culture Collection}.$

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
<u> </u>	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





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.

<u>Deletions:</u> None