INSTRUCTIONS FOR USE

Anaerobe Systems BIOME-Preserve Collection and Transportation System (BIOME-Preserve)

PRODUCTS

AS-930 Anaerobe Systems BIOME-Preserve Collection and Transportation System (BIOME-Preserve) 1 tube / pkg

INTENDED PURPOSE

BIOME-Preserve Collection and Transportation System is intended for the transport, preservation, or cultivation of a wide variety of microorganisms from specimens to aid in the isolation of bacteria for *RESEARCH USE ONLY*.

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*

BIOME-Preserve is a microbiome collection kit designed to preserve live microbiota for the culture and isolation of anaerobic and facultative anaerobic microorganisms. It maintains microbial viability at room temperature for up to 120 hours, enabling reliable recovery of live organisms from downstream culturing and analysis. Samples collected in BIOME-Preserve may also be frozen directly for cryogenic storage. The medium is a pre-reduced, non-nutritive phosphate-buffered saline formulation containing mineral salts, oxygen scavengers, antioxidants, and a cryoprotectant to support the stability of diverse microbial communities. BIOME-Preserve is intended for the self-collection, storage, preservation, and transport of live microbiota samples such as stool. It supports the viability of microbes during transit from the collection site to the processing laboratory without requiring refrigeration. Each kit includes a foil pouch containing a collection tube pre-filled with BIOME-Preserve liquid medium. The tube cap features an integrated, defined-volume 1-gram scoop to facilitate easy and accurate sample collection. 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.

Magnesium sulfate heptahydrate	0.10	g
Potassium phosphate monobasic	0.20	g
Potassium chloride	0.20	g
Sodium phosphate dibasic	1.15	g
Sodium chloride	3.00	g
Sodium thioglycolate	1.00	g
L-cysteine hydrochloride	0.50	g
Antioxidant blend	5.00	mL
Glycerol	200.00	mL
DI Water	800.00	mL

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

Final pH: 7.5 ± 0.5 at 25°C
Final volume: 12.0 mL ± 0.5 mL

PRECAUTIONS

For *RESEARCH USE ONLY*. BIOME-Preserve is not intended to be used in the diagnosis or treatment of a disease or condition. Medical treatment should not be performed based on data or analysis from samples collected in BIOME-Preserve. 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. Appropriate review and consent should be obtained before collecting human samples.

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.

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. Do not use media if there are signs of deterioration (discoloration due to oxidation of media), contamination, or a broken cap. 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: 18 months 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.

Do not remove the BIOME-Preserve tube from its foil pouch until you are ready to collect the sample. Collect the stool sample using a suitable collection device such as a paper toilet accessory or commode-style container (not provided). Do not collect stool directly from the toilet bowl and avoid contamination with urine.

1. Remove the BIOME-Preserve tube from the foil pouch.
2. Produce a stool sample onto an appropriate collection device.
3. Unscrew the tube cap. Using the integrated scoop attached to the cap, collect one full scoop (approximately 1 gram) of stool.
4. Insert the scroop back into the tube and securely tighten the cap. Do not overtighten, but ensure the tube is fully sealed. Avoid leaving the tube open for more than 2 minutes.
5. Shake the tube vigorously for 10 seconds to mix the stool with the liquid medium.

Sample Transport and Storage: Samples should be transported and processed within 120 hours of collection. Store and transport at room temperature. Do not freeze for transport unless the sample remains frozen until final processing. Refrigeration is not required but may help minimize microbial metabolism during transport. Ensure compliance with local, state, and national regulations for labeling and shipping human stool samples.

Sample Processing: Upon receipt in the laboratory, process samples for culture recovery or freeze at -80°C as soon as possible. BIOME-Preserve tubes can be opened for sample processing. The remaining contents may be re-sealed and stored cryogenically. Avoid multiple freeze-thaw cycles. Once frozen, samples should not be thawed and re-frozen.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional supplies may be required for the individual providing the sample, such as detailed user instructions, a stool collection device, sample labels, a plastic isolation bag for shipping, a desiccant or absorbent pad, and a return shipping box.

Standard microbiological supplies and equipment such as specimen collection swabs or aspirate devices, loops, saline blanks, slides, staining supplies, microscope, incinerator / autoclave, incubators, anaerobic chamber / anaerobic jars, disinfectants, other culture media, and serological / biochemical reagents.

INTERPRETATION OF RESULTS

The recovery of bacteria is highly dependent on proper specimen collection, timely transport, and prompt processing in the laboratory. When used as directed, this medium is designed to maintain the viability of the majority of microorganism present in the sample for up to 120 hours prior to processing.

LIMITATIONS

BIOME-Preserve is intended solely as a specimen collection and transport device designed to maintain the viability of microorganisms during transit. It does not provide comprehensive information for microbial identification or population analysis. Additional tests and specialized media are necessary for full recovery, isolation, and identification of microbial isolates.

This medium is not designed to preserve the original bacterial population structure or relative abundance within the sample. For direct microbial community analysis, alternative collection kits may be required alongside BIOME-Preserve.

Specimens should be transported and processed promptly to minimize the risk of overgrowth by one or more organisms. Delays may affect the accuracy of culture results. For more detailed information, consult relevant reference materials.

QUALITY CONTROL

The following organisms are routinely used for quality assurance testing at Anaerobe Systems. To determine the holding capacity of BIOME-Preserve, an ATCC® isolate strain (listed below), from 24-hour growth, is inoculated into the transport aerobically and held for 72 hours at room temperature protected from light. After 72 hours, each organism is subcultured onto a Brucella Blood Agar (BRU, catalog #: AS-111) plate and placed in an anaerobic environment to obtain isolated colonies. Plates are incubated at 35 – 37°C for 48 hours then observed for growth.

Organism Tested	ATCC® #	Results
Bacteroides fragilis	25285	Viable
Prevotella melaninogenica	25845	Viable
Salmonella enterica subsp. enterica serovar Typhimurium*	14028	Viable
Shigella sonnei*	9290	Viable
Escherichia coli*	25922	Viable

*Organisms specified by CLSI for quality control testing of fecal transport devices

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 holding 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	Viable
Escherichia coli	25922	Viable

Physical Appearance: BIOME-Preserve should appear clear and colorless in a 16 x 100 mm polypropylene conical bottom vial and brown cap integrated with a 1 mL collection scoop.

Odor: BIOME-Preserve, when opened, will have a faint sulfur-like (rotten egg) odor.

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

REFERENCES

1. Clinical and Laboratory Standards Institute. Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline. CLSI document M56-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

2. Clinical and Laboratory Standards Institute. Quality Control of Microbiological Transport Systems; Approved Standard—Second Edition. CLSI document M40-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

3. Hyde ER, Lozano H, Cox S. BIOME-Preserve: A novel storage and transport medium for preserving anaerobic microbiota samples for culture recovery. PLoS One. 2022;17(1):e0261820.

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
	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

Revision 2
Additions: None
Changes: Changed shelf-life from 6 months to 18 months. Revised Intended Purpose to include research use only.
Deletions: None