Product Insert

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

Product

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

Intended Use

BIOME-Preserve is a microbiome collection kit that preserves live microbiota samples for growth and isolation of anaerobic and facultative anaerobic microorganisms. The product effectively preserves, for culture recovery, microorganisms at room temperature for up to 120 hours without substantial loss of viability. Samples may be directly frozen in BIOME-Preserve for cryogenic storage.

Summary

BIOME-Preserve is a pre-reduced non-nutritive phosphate buffered saline containing mineral salts, oxygen scavengers, antioxidants, and a cryopreservant. BIOME-Preserve is intended for the self-collection, storage, preservation, and transportation of live microbiota samples such as stool. BIOME-Preserve can maintain the viability of microorganisms contained within the sample for up to 120 hours at room temperature during transportation from the collection site to the processing laboratory. The collection kit consists of a foil pouch containing a tube filled with BIOME-Preserve liquid medium. The cap of the tube has an integrated 1-gram defined volume scoop to facilitate collecting and inserting the sample into the tube. This media is prepared, dispensed, and packaged under oxygen-free conditions to prevent the formation of oxidized products prior to use.

Formulation*

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

Final pH: 7.5 ± 0.2 at 25° C
Final volume: 12.0 mL ± 0.5 mL

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

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. Analysis of samples collected in this product is for use by properly trained and qualified personnel only. Sterilize all biohazard waste prior to disposal. Appropriate review and consent should be obtained before collecting human samples.

Storage and Shelf Life

Storage: Upon receipt, store at room temperature in its original packaging until used. Avoid overheating or freezing prior to use. Do not use media if there are signs of deterioration (discoloration or damage to packaging) 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: 6 months from date of manufacture.

Procedure

Specimen Collection: Do not remove BIOME-Preserve tube from the foil package until the time of sample collection. Collect the microbiota sample in a suitable container or toilet accessory (not provided). Do not collect samples directly from toilet bowl.

1. Remove the BIOME-Preserve tube from the foil package.
2. Produce a stool sample on to an appropriate stool collection device, such as a paper toilet accessory or commode bucket style container. Do not get urine mixed with the stool sample.
3. Unscrew the tube cap and collect 1 scoop of stool using the scoop attached to the BIOME-Preserve cap.
4. Place the scoop and cap back on the BIOME-Preserve tube, and tighten the cap. Do not overtighten cap, but ensure it is fully sealed. The BIOME-Preserve tube should not stay opened for longer than 2 minutes.
5. Shake the tube for 10 seconds to mix the stool in the scoop with the liquid inside.

Sample Transport and Storage: Transport samples to the laboratory and process samples within 120 hours of collection. Samples are intended to be stored and transported at room temperature. Samples should not be frozen for transport unless the sample will remain frozen until final processing. Refrigerating a sample is not necessary but may help slow potential growth and metabolism of organisms. Check local/state/country regulations for required labeling and packaging requirements for shipping stool samples.

Sample Processing: Samples contained in BIOME-Preserve should be processed for culture recovery or frozen at -80ºC as soon as possible upon receipt in the laboratory. BIOME-Preserve may be opened to process the contents for culture recovery or other analysis, and the remainder may be frozen for cryogenic storage with the cap re-sealed. Avoid multiple freeze-thaw cycles. Once BIOME-Preserve is frozen, it should not be thawed and re-frozen.

Materials Required, But Not Provided

Additional supplies may be necessary for the person providing the sample such as detailed user instructions, a device to catch the stool sample, sample labels, plastic isolation bag for sample shipping, desiccant or absorbent pad for shipping, and a return shipment box.

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

Results for the recovery of bacteria will largely depend on proper and adequate specimen collection, timely transport, and processing in the laboratory. If used properly, this medium should maintain the viability of the majority of microorganisms present within a sample until transported and processed within the laboratory for up to 120 hours.

Limitations

BIOME-Preserve is designed as a specimen collection and transport device to maintain viability of microorganisms contained within a specimen during transport. This medium will not provide complete information for identification of microbial isolates or microbial population. Additional test procedures and media are required for complete recovery, isolation, and/or identification. BIOME-Preserve is not intended to maintain the bacterial population distribution or abundance of microorganisms in the sample. Other kits may be required for direct analysis of the sample in addition to culture recovery. Specimens should be transported and processed in the laboratory in a timely manner as delays may result in overgrowth by one or more organism present in a specimen. Consult reference materials for additional information.

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 media aerobically and held for 72 hours at room temperature. Each organism is streaked onto Anaerobic Brucella Blood Agar (BRU, catalog #: AS-111) in an anaerobic environment to obtain isolated colonies. Plates are incubated in the appropriate conditions at 35–37°C for 48 hours and growth is observed.

Organism Tested	ATCC #	Results	Time
Bacteroides fragilis	25285	Growth	24 hrs
Prevotella melaninogenica	25845	Growth	24 - 48 hrs
Salmonella enterica subsp. enterica serovar Typhimurium	14028	Growth	24 - 48 hrs
Shigella sonnei	9290	Growth	24 hrs
Escherichia coli	25922	Growth	24 hrs

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 #	Growth in Hours
Bacteroides fragilis	25285	24 hrs
Prevotella melaninogenica	25845	48 hrs
Escherichia coli	25922	24 hrs

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 1mL collection scoop.

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

References

1. Clinical and Laboratory Standards Institute. Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline. (2014). CLSI document M56-A. *Clinical and Laboratory Standards Institute*, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087.

2. Clinical and Laboratory Standards Institute. Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard- Third Edition. (2004). CLSI document M22-A3. *Clinical and Laboratory Standards Institute*, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087.

3. Clinical and Laboratory Standards Institute. Quality Control of Microbiological Transport Systems; Approved Standard-Second Edition. (2014). CLSI document M40-A2. *Clinical and Laboratory Standards Institute*, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087.

4. Engelkirk, P. G., Duben-Engelkirk, J. and Dowell, V. R. 1992. Principles and Practices of Clinical Anaerobic Bacteriology. *Star Publishing Co.*, Belmont, CA 94002.

5. Jousimeis-Somer, H. R., Summanen, P., Citron, D. M., Baron, E. J., Wexler, H. M. and S. M. Finegold. 2002. Wadsworth – KTL Anaerobic Bacteriology Manual. *Star Publishing Co*., Belmont, CA 94002.