BD GasPak™ EZ Gas Generating Pouch Systems

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8010419(05)
2022-01
English

REF 260683 REF 260684 REF 260685

INTENDED USE

The BD GasPak™ EZ Gas Generating Pouch Systems are single-use systems that produce atmospheres suitable to support the primary isolation and cultivation of anaerobic, microaerophilic, or capnophilic bacteria by use of gas generating sachets inside single-use resealable pouches.

SUMMARY AND EXPLANATION

In 1965, Brewer and Allgeier introduced a disposable hydrogen generator envelope, which was later modified to include carbon dioxide generation and an internal catalyst.[1,2] The BD GasPak™ EZ Gas Generating Pouch Systems offer bio-performance and reliability without the need for a catalyst or an activation procedure. The BD GasPak™ EZ Gas Generating Sachets contain all the ingredients needed to create a specific atmosphere for specimen incubation. The sachet and specimens are placed in the BD GasPak™ EZ resealable pouch. The pouch is sealed and incubated.

PRINCIPLES OF THE PROCEDURE

The BD GasPak™ EZ Gas Generating Sachet consists of a reagent sachet containing inorganic carbonate, activated carbon, ascorbic acid and water. When the sachet is removed from the outer wrapper, the sachet becomes activated by exposure to air. The activated reagent sachet and specimens are placed in the resealable pouch and sealed. The sachet rapidly reduces the oxygen concentration within the pouch. At the same time, inorganic carbonate produces carbon dioxide.

For the cultivation of anaerobic bacteria, the BD GasPak™ EZ Anaerobe Pouch System with Indicator Sachets produce an anaerobic atmosphere within 2.5 hours with greater than or equal to 10% carbon dioxide within 24 hours.

For the cultivation of microaerophilic bacteria, the BD GasPak™ EZ Campy Pouch System Sachets produce an atmosphere with approximately 5–15% oxygen.

For the cultivation of carbon dioxide requiring organisms, the BD GasPak™ EZ CO_2 Pouch System Sachets produce an atmosphere with greater than 3% carbon dioxide. In this manual, qualitative procedure, organism growth may be used as an aid to diagnosis per the intended purpose of the media and required specimen types.

REAGENTS

Warnings and Precautions:

For in vitro diagnostic use. For use by Trained Laboratory Personnel.

Warning

H315 Causes skin irritation**. H319** Causes serious eye irritation.

P264 Wash face, hands and any exposed skin thoroughly after handling. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P321** Specific treatment (see supplemental first aid instructions on this label). **P332+P313** If skin irritation occurs: Get medical advice/attention. **P337+P313** If eye irritation persists: Get medical advice/attention. **P362+P364** Take off contaminated clothing and wash it before reuse.

Observe established precautions against microbiological hazards throughout all procedures. Prior to discarding, sterilize specimen containers and other contaminated material by autoclaving.

After use, the sachet may remain warm. Discard sachet after reaction is complete (when cool).

After use, discard pouch in a proper waste container. Do not reuse.

DO NOT use sachet if outer foil is damaged or open in any manner.

Avoid direct sunlight and excessive temperatures.

DO NOT open resealable pouch until incubation is complete.

BD GasPak™ EZ Pouch System Sachets are intended for use in BD GasPak™ EZ resealable pouches. Their use in other systems may yield misleading results.

BD GasPak™ EZ resealable pouches are designed for BD GasPak™ EZ Pouch System Sachets. Do not use with other gas generating envelopes (e.g., BD BBL™ GasPak™/BD GasPak™ Plus Envelopes).

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

Storage Instructions

On receipt, store sachets at 2–25 °C in a dry environment.

BD GasPak™ EZ Pouch System Sachets are ready to use. The expiration date is for unopened, intact and properly stored sachets. Do not open until ready to use.

BD GasPak™ EZ Dry Anaerobic Indicator should appear white before use. Do not use indicator if blue in color before use. Do not touch indicator tablet or open indicator package to remove tablet.

Product Deterioration

Do not use reagent sachets if outer package has been damaged or opened. Do not use resealable pouches that show rips or tears or other irregularities.

Active Ingredients

Ascorbic acid, activated carbon and water

PROCEDURE

Materials Provided

BD GasPak™ EZ Gas Generating Pouch System. Each system requires the use of a resealable pouch and sachet (See "Availability").

Materials Required But Not Provided

Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure:

1. Place the inoculated plates inside the resealable pouch. The BD GasPak™ EZ Campy Pouch System requires at least 2 Petri dishes and will hold up to 4 petri dishes. The BD GasPak™ EZ CO_2 Pouch System and the BD GasPak™ EZ Anaerobe Pouch System with Indicator can be used for 1–4 Petri dishes.

   Note: For optimum growth using the BD GasPak™ EZ Campy Pouch System, place a paper towel or cotton ball moistened with 5 mL of water inside the pouch.
2. One BD GasPak™ EZ Pouch System Sachet is used in each resealable pouch. Remove the BD GasPak™ EZ Pouch System Sachet from the carton. Remove the outer foil packaging.
3. Place the activated sachet in the BD GasPak™ EZ resealable pouch with the plates. The sachet should be placed between the plates and the pouch. If using the BD GasPak™ EZ Anaerobe Pouch System with Indicator, there is no need to add a separate anaerobic indicator.
4. Close the pouch by pressing the zipper part of the pouch together.
5. Incubate the BD GasPak™ EZ Pouch System at a temperature appropriate for the organism being cultured, but not to exceed 45 °C.
6. After incubation, open the pouch, remove the plates and dispose of the BD GasPak™ EZ Pouch System Sachet, indicator and pouch in the appropriate manner.

USER QUALITY CONTROL

Each BD GasPak™ EZ Gas Generating Pouch System should be tested periodically for its ability to provide adequate conditions for the growth of appropriate bacteria.

System	QC Organism
BD GasPak™ EZ Anaerobe Pouch System with Indicator	*Bacteroides fragilis* ATCC® 25285
BD GasPak™ EZ Campy Pouch System	*Campylobacter jejuni* ATCC 29428
BD GasPak™ EZ CO_2 Pouch System	*Neisseria gonorrhoeae* ATCC 19424

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

Anaerobic conditions are achieved rapidly within 2.5 hours, with greater than or equal to 10% carbon dioxide within 24 hours at 35 °C. Visible condensate should occur within 30 minutes of activation. Blood-containing agar plates appear reduced within 2–4 hours at 35 °C. The anaerobic indicator should appear reduced (white) within 2–4 hours at 35 °C.

Microaerophilic conditions are achieved rapidly with an oxygen concentration of 5–15% at 35 °C.

Carbon dioxide enriched conditions are achieved rapidly with a carbon dioxide concentration of greater than 3% at 35 °C.

PERFORMANCE CHARACTERISTICS

BD GasPak™ EZ Anaerobe Pouch System with Indicator

Prior to release, representative samples of each lot of BD GasPak™ EZ Anaerobe Pouch System with Indicator are tested for performance characteristics.

Each sample sachet of the BD GasPak™ EZ Anaerobe Pouch System with Indicator is placed in a resealable incubation pouch with 4 media filled Petri dishes. The sachet is activated and the pouch is sealed according to label directions and incubated at 35 ± 2 °C. After approximately 2.5 hours, a 22-gauge 1.5″ needle is inserted into the incubation pouch and a sample of the gas is removed, placed in a gas chromatograph, and analyzed for the amount of oxygen present in the incubation pouch. The percent oxygen for each pouch is less than or equal to 1% and the mean percent for all samples tested for oxygen is less than 0.7%. After approximately 24 hours incubation at 35 ± 2 °C, another sample is taken from the pouch and analyzed for the amount of carbon dioxide. The percent carbon dioxide for each pouch is greater than or equal to 10%. All anaerobic dry indicators are reduced.

BD GasPak™ EZ Campy Pouch System

Prior to release, representative samples of each lot of BD GasPak™ EZ Campy Pouch System are tested for performance characteristics.

Each sample sachet of the BD GasPak™ EZ Campy Pouch System is placed in a resealable incubation pouch along with 2 media filled Petri dishes. The sachet is activated and the pouch is sealed according to label directions and incubated at 35 ± 2 °C. After approximately 24 hours, a 22-gauge 1.5″ needle is inserted into the incubation pouch and a sample of the gas is removed, placed in a gas chromatograph, and analyzed for the amount of oxygen present in the incubation pouch. The percent oxygen for each pouch is 5–15%.

BD GasPak™ EZ CO_2 Pouch System

Prior to release, representative samples of each lot of BD GasPak™ EZ CO_2 Pouch System are tested for performance characteristics.

Each sample sachet of the BD GasPak™ EZ CO_2 Pouch System is placed in a resealable incubation pouch along with 2 media filled Petri dishes. The sachet is activated and the pouch is sealed according to label directions and incubated at 35 ± 2 °C. After approximately 24 hours, a 22-gauge 1.5″ needle is inserted into the incubation pouch and a sample of the gas is removed, placed in a gas chromatograph, and analyzed for the amount of carbon dioxide present in the incubation pouch. The percent carbon dioxide for each pouch is greater than 3%.

AVAILABILITY

Catalog Number	Description
260683	BD GasPak™ EZ Anaerobe Pouch System with Indicator (Containing 20 sachets, 20 resealable pouches and 20 Dry Anaerobic Indicators)
260685	BD GasPak™ EZ Campy Pouch System (Containing 20 sachets and 20 resealable pouches)
260684	BD GasPak™ EZ CO_2 Pouch System (Containing 20 sachets and 20 resealable pouches)

REFERENCES

1. Brewer, J.H. and D.L. Allgeier. 1966. Disposable hydrogen generator. *Science 147*:1033–1034.
2. Brewer, J.H. and D.L. Allgeier. 1966. Safe self-contained carbon dioxide-hydrogen anaerobic system. *Appl. Microbio*l. *16*:848–850.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Change History

Revision	Date	Change Summary
04	2019-07	Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling.
05	2022-01	Inserted Do not use if package is damaged, Do not reuse, Keep away from sunlight, and Keep dry symbols. Updated all symbols. Added Intended User and Disposal statement. Added SDS information. Added Serious Incident and Technical Information statement. Updated Symbols Glossary. Updated trademark statement. Updated EC REP symbol and address. Added CH REP symbol and address. Updated Australian sponsor address. Added New Zealand sponsor address. Added the following hazards identifications to the Warnings and Precautions section: H315, P302+P352, P332+P313, P362+P364, and P321. Added details regarding the use of organism growth as an aid to diagnosis to the Principles of the Procedure section.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
	Patient number
	This way up
	Do not stack
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

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