TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	4/16/2018
Department:	Core Lab	**Due Date:**	5/10/2018
		Implementation:	**5/1/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

GasPak EZ Anaerobe Pouch System SGAH.MI757 v1.2

Has been converted to system SOP

GasPak EZ Anaerobe Pouch Indicator QC AG.F58.1
GasPak EZ Anaerobe Pouch New Lot / Shipment QC AG.F59.1

Description of change(s):

Forms:

Added column on Pouch Indicator QC form for when new lot/shipment was done (reminder to staff that to do this)

Both forms were updated with current QD logo and SGMC name

SOP:

Note: changes are mostly format updates

Section	Reason
Header	Add WAH
3.1	Updated online collection manual title
4,6	Updated reagent labeling statement to current general BPT format
15	Updated to new standard wording
16	Added forms
17	Updated reference

The revised SOP and logs will be implemented on May 1, 2018

Document your compliance with this training update by taking the quiz in the MTS system.

Quest Diagnostics

☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

GasPak EZ Anaerobe Pouch Indicator QC

Month / Year _____

Daily upon use: Always include an anaerobic indicator in each pouch to visually monitor the atmospheric condition. Record visual result. If indicator is not white, remove the plates and place into a new pouch with a new indicator.

Corrective Action (record on reverse of this sheet if necessary)

Date	Lot Number	Indicator Color (white/blue)	Acceptable (Y/N)	Tech	Date of New Lot or Shipment QC
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
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30					
31					

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Quest Diagnostics

☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

GasPak EZ Anaerobe Pouch New Lot / Shipment QC

Month / Year _____

Each new lot / shipment: Subculture stock organism *Bacteroides fragilis* ATCC 25285 onto appropriate medium. Incubate at 35±2°C for 24-48 hours. This tests the system's ability to provide adequate conditions for growth of anaerobic bacteria. Always include anaerobic indicator.

Date	**Lot Number**	**Indicator Color (white/blue)**	***B. fragilis* (Growth / No growth)**	**Acceptable (Y/N)**	**Tech**	**Corrective Action** (record on reverse of this sheet if necessary)

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Technical SOP

Title	**GasPak™ EZ Anaerobe Pouch System**		
Prepared by	Gail Granillo, MT(ASCP)	Date:	11/14/2002
Owner/BPT Leader	Kathleen Carlson, S.M., MT(ASCP)	Date:	11/14/2002

Corporate Approval			
BPT Medical Advisor	Jeffrey L. Craver, M.D.		
Signature	*On file*	Date:	11/22/2002
Medical Director/Designee	William M. Miller, M.D.		
Signature	*On file*	Date:	01/06/2003
Corporate Issue Date	January 13, 2003		

Laboratory Approval	**Local Effective Date:**	
Print Name	**Signature**	**Date**
Refer to electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 10/31/02

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	QLS Order Code	Local Code
GasPak™ EZ Anaerobe System	Oxygen reduction / Gas generation	N/A	N/A

Synonyms/Abbreviations
ANA Pak, GasPak

Department
Microbiology

Form revised 10/31/02

2. ANALYTICAL PRINCIPLE

The BD GasPak™ EZ Pouch Systems are single-use gas-generating systems that produce atmospheres suitable for the primary isolation and cultivation of anaerobic microorganisms.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	Refer to Laboratory Test Directory on Adventist Hospital Intranet, Microbiology Specimen Collection Information.
Special Collection Procedures	Refer to Laboratory Test Directory on Adventist Hospital Intranet, Microbiology Specimen Collection Information.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	• Appropriately inoculated culture plates for recovery of organisms requiring anaerobic atmosphere. • Refer to specific culture SOP's utilizing these atmospheric systems for culture inoculation details.	
-Other Acceptable	Bacterial cultures in tubes.	
Collection Container	Refer to Microbiology Specimen Collection Chart.	
Volume - Optimum	All media plates appropriate for specimen source (Refer to related culture SOPs).	
- Minimum	One plate or tube	
Transport Container	Refer to related culture SOPs (Anaerobe, etc.) for further details	
Stability & Storage Requirements	**Ambient**:	Plates – dependent on organisms cultivated Swabs – up to 48 hours
	Refrigerated:	Not acceptable
	Frozen:	Not acceptable
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Refer to Specimen Acceptability, Microbiology procedure	
Compromising Physical Characteristics	Refer to Microbiology Specimen Collection Chart.	
Other Considerations	N/A	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits or reagents must be reviewed for any changes before the kit is used.

4.1 Reagent Summary

Systems / Kits	Supplier & Catalog Number	Stock Clerk Number	Quantity
BD GasPak EZ Anaerobic Pouch System (Includes sachets, pouches, & indicators)	BD 260683	126421	20

4.2 Reagent Preparation and Storage

Upon receipt, store GasPak™ sachets and indicators at 2-25°C in a dry environment.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

System	Quality Control / Organism
GasPak EZ Anaerobic Pouch System	• *Bacteroides fragilis* ATCC 25285 • Methylene blue or other appropriate anaerobic indicator

6.2 Control Preparation and Storage

- Refer to other specifically related test procedures for preparation, storage and handling instructions.

6.3 Frequency

- **GasPak™ EZ Anaerobic Pouch System**

- **Daily upon use**: Always include an anaerobic indicator in each pouch to visually monitor the atmospheric condition. Record visual result on appropriate Quality Control (QC) record / chart.
- **New lot / shipment**: Subculture stock organism *Bacteroides fragilis* ATCC 25285 onto appropriate medium. Incubate at 35±2°C for 24-48 hours. This tests the system's ability to provide adequate conditions for growth of anaerobic bacteria. Always include anaerobic indicator. Record on appropriate QC sheet.

6.4 Tolerance Limits and Criteria for Acceptable QC

- When working properly, the anaerobic indicator will turn from blue to white within 2 to 4 hours and remain white until the jar or bag is opened.
- Growth of appropriate QC organism dependent on system being tested. Adequate growth of organism must be demonstrated.

QC Failure / Corrective Action:

- If noted that the anaerobic indicator does not turn white after 4 hours, this would indicate a leak in the pouch or some other failure of the system. Remove the plates and place them into a new pouch with a new sachet with indicator. If more than 4 hours have passed since initial incubation of the pouches and the indicator is blue before opening the GasPak™ container, it will be necessary to re-set the culture from either the original specimen or the broth tube depending on the type and stability of the specimen received.
- All steps taken in response to QC failures must be documented, including: a description of the QC failure, the root cause of the problem, actions taken to correct the problem, how patient samples were handled, and the date and initials of the person recording the information.
- Supervisors may override rejection of partial or complete runs based on findings in the corrective-action investigation and based on established override criteria that have been approved by the Medical Director. The rationale for the override must be thoroughly documented.

6.5 Review of Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as unusual or unexpected isolates or lack of correlation with gram stain results.

6.6 Documentation

Refer to local policies and procedures for QC documentation and to Quest Diagnostics records management program for record retention requirements.

6.7 Quality Assurance Program

Refer to National and local policies and procedures for other quality assurance activities applicable to this procedure.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Not applicable.

7.2 Equipment

- Incubator, 35-37°C ambient air or CO_2
- Biological Safety Cabinet, Class II Type A

7.3 Supplies

- GasPak EZ Anaerobic Pouch System
- Inoculation loops and needles
- Sterile swabs
- Media appropriate to culture type
- Other supplies as required in specifically related culture SOP's.

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	GasPak™ EZ Gas Generating Pouch System
1.	Place the desired plates inside the resealable pouch.
2.	One GasPak™ Pouch System Sachet is used in each resealable pouch. Remove the GasPak™ EZ Pouch System Sachet from the carton. Remove the outer foil packaging to activate the sachet.
3.	Place the activated sachet in the GasPak™ EZ resealable pouch with the plates. The sachet should be placed between the plates and the outside of the pouch.
4.	Close the pouch by pressing the zipper part of the pouch together.
5.	Incubate the GasPak™ EZ Pouch System at the 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 GasPak™ EZ Pouch System Sachet, indicator, and pouch into an appropriate biohazard waste container.

	When systems are functioning properly, the following results should be achieved: • Anaerobic conditions are achieved within 2.5 hours with greater than 16% carbon dioxide within 24 hours at 35-37°C. Visible condensate should occur within 30 minutes of activation. Blood-containing agar plates should appear reduced (darkened) within 2-4 hours at 35-37°C. The anaerobic indicator should appear reduced (white) within 2-4 hours at 35-37°C.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

Refer to department procedures on related cultures for appropriate reporting and repeat criteria.

11. EXPECTED VALUES

11.1 Reference Ranges

Not applicable

11.2 Critical Values

Not applicable

11.3 Standard Required Messages

Not applicable

12. CLINICAL SIGNIFICANCE

Appropriate atmospheric conditions (along with other factors such as culture media, incubation temperature, and properly collected specimens) are necessary to allow certain organisms with pathogenic potential to be cultivated. The GasPak™ Anaerobic System provides the correct amount of oxygen to help ensure that anaerobic cultures are incubated in the appropriate atmosphere.

13. PROCEDURE NOTES

- **FDA Status:** Cleared
- **Validated Test Modifications:** N/A

- When properly stored, the sachets will retain their reactivity until the expiration on the outer box unless the foil wrapping has been damaged.
- Do not open until ready to use.
- Do not use a sachet if the outer foil is damaged or open in any manner prior to use.
- Do not open pouch until incubation is complete.
- Avoid direct sunlight and excessive temperatures.
- Discard sachets (when cool) after use into appropriate biohazard waste container.
- Use sachets and indicators only once.
- Indicator is sensitive to heat, light, oxygen, and CO_2.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Not applicable

14.2 Precision

Not applicable

14.3 Interfering Substances

Not applicable

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not applicable

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Quality Control Program, QA procedure
- Specimen Acceptability, Microbiology procedure
- Current package insert GasPak™ EZ Pouch System
- GasPak EZ Anaerobe Pouch Indicator QC (AG.F58)
- GasPak EZ Anaerobe Pouch New Lot / Shipment QC (AG.F59)

17. REFERENCES

Becton, Dickinson and Company; 2017/05; Package Insert

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1.0	6/10/10	Page 1	Update BU site.	R. Master	R. Master
		3.1 & 3.2	Update site specific collection manual		
		8.2	Delete section on products not used		
		11.2	Update title to Critical Values		
		13	Added FDA status and Modifications		
		14.1	Updated title terminology		
		16	Update to local documents		
1.0A	3/27/18	Header	Added WAH	L. Barrett	R. Master
		3.1	Updated online collection manual title	R. Master	
		4, 6	Updated reagent labeling statement to current general BPT format		
		11.3	Updated sub-section title to match current format		
		15	Updated to new standard wording		
		16	Added forms		
		17	Updated reference		
		Footer	New local version numbering adopted per corporate policy change.		

19. ADDENDA

Addendum 1: **BD Gaspak™ EZ Pouch System Procedure Overview**
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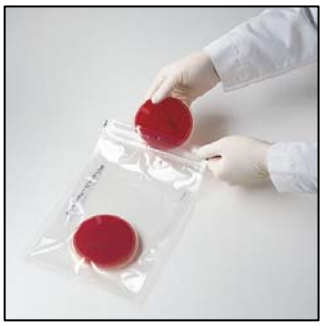
Addendum 1

BD Gaspak™ EZ Pouch System
Procedure Overview



1) Place the desired plates inside the resealable pouch.

2) One **GasPak EZ** Pouch System Sachet is used in each resealable pouch. Remove the **GasPak EZ** Pouch System Sachet from the carton. Remove the outer foil packaging.

3) Place the activated sachet in the **GasPak EZ** resealable pouch with the plates. The sachet should be placed between the plates and the outside of the pouch. If using the **GasPak EZ** Anaerobe Pouch System, add one of the dry anaerobic indicator strips to the pouch at this time.

4) Close the pouch by pressing the zipper part of the pouch together.

5) Incubate the **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 **GasPak EZ** Pouch Systems Sachet, indicator and pouch in the appropriate manner.

Form revised 10/31/02