**St. Elizabeth’s Medical Center**

**Department of Laboratory Services**

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|  **POLICY NO: SEMIC.01.0047.01****SUBJECT:** Pharmacy Sterility Testing  |
| **Effective Date: 11/16** |
| **Supersedes: none** |
| **Medical Director: David Ricklan, MD, PhD** |
| **Administrative Director: Nicholaos Tsaniklides, MT (ASCP) MSM** |
| **Written by: Lisa Zenkin MT(ASCP)** |
| **Reviewed by:****Note Annual Review on Last Page**  |

1. **PRINCIPLE**

 Per USP 797, pharmacies that prepare sterile compounds must perform competency evaluations of all Pharmacy personnel annually. Competency evaluations include Media-Fill and Gloved Fingertip tests.

1. **SAFETY**

All patient specimens should be treated using Standard Precautions. This includes the use of appropriate personal protective equipment, such as a lab coat and gloves. All microbiological cultures should be handled using aseptic technique.

1. **SPECIMEN REQUIREMENTS**

The laboratory will receive three specimens from each pharmacy employee. One GroMed bag and 2 Enviro Paddles, one from each hand. Each specimen will be labeled with the date and time collected and the employee’s identification. The paddles will also be labeled with the source of specimen (right or left hand).

1. **REAGENTS, EQUIPMENT AND MATERIALS**

GroMed bags filled with TSB broth Enviro Paddles containing Malt Agar, Yeast Extract, Dextrose, Lactic Acid, Lecithin and Polysorbate 80

1. **QUALITY CONTROL**
	1. Quality control is performed on each new lot/shipment.
	2. Each Lot of Bags and Paddles should be checked for sterility before use. A bag should be incubated for 14 days and a Paddle should be incubated for 7 days to insure sterility of the lot. (30-35c)
2. **PROCEDURE**
3. Following pharmacy procedures a bag will be prepared by each pharmacy employee. This bag will be labeled with the employee’s identification and date and time. During the procedure the pharmacy employee will inoculate the paddles, one for each hand. Each paddle will be labeled with the employee’s identification, date and time.
4. Upon arrival in the lab, under subdivisions, select Steward Lab Census, under HIM Dept select the same Steward Lab Census
5. The patient will be SEM, PHARMACY.
6. The GroMed bag and each paddle will be ordered as ENV.
7. The Source will be OTH (other).
8. On the SPECIMEN page, the pharmacy employee’s identification MUST be entered under comments.
9. GroMed bags will be incubated for 14 days and reported as either positive or negative. .
10. Enviro Paddles will be incubated for 7 days. Any growth should be reported as CFU (colony forming units). Identification will be as follows: Gram Negative Rods, Gram positive coag positive cocci, Yeast and Mold. The presence of any of these organisms should be reported to Pharmacy.
11. **LIMITATIONS**

 All GroMed bags should be negative. If positive the pharmacist has failed the test and it must be repeated. Calls of positive GroMed bags should be made to Pharmacy as soon as possible at extension 5139

1. **EXPECTED RESULTS AND REPORTING**

All results positive or negative, will be entered into Meditech.

1. **REFERENCES**
2. QI Medical Inc. Product insert DFU026 A 9/11
3. QI Medical Inc. Product insert DFU014 J 1/08
4. USP 35, Physical Test (797) Pharmaceutical Compounding- Sterile
5. D.USP 35, Physical Test (797) Pharmaceutical Compounding- Sterile

**St. Elizabeth’s Medical Center**

**Clinical Laboratory**

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| Standard Operating Procedure File #: **SEMIC.01.0047.01** | File Name:.doc Pharmacy Sterility Testing  |
| Title of Procedure: **:** Pharmacy Sterility Testing  |

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| Standard Operating Procedure Historical Record |

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| Review Date | Annual Review/Revision Summary | Supervisor Review | Laboratory Director/Approval |
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