Loyola University Chicago
Comparative Medicine Facility

# Standard Operating Procedure

SOP Number: **02-18-5601**
Service: **Research**
Operating Section: **Diagnostic Laboratory**
Unit: **CMF**
Title: **Sterilizer Quality Assurance Using Biological Indicators**

**Purpose:**
To describe quality assurance procedures for verifying adequacy of autoclave or ethylene oxide sterilization using biological indicators.

**Procedure:**

1) Biological indicators will be used in accordance with Husbandry SOP, "Autoclave Validation".
2) All biological indicators from all CMF autoclaves are processed at least weekly and brought to the CMF diagnostic laboratory.
3) All indicators are logged onto the "Biological Indicator Log Sheet for Autoclave QA":
   a) Date (sterilized)
   b) Load/run/pack type
   c) Sterilizer location
   d) Technician initials (person sterilizing)
4) Biological Indicators will be activated according to package insert and then placed into the heat block or incubator.
5) Indicators will be observed after 24-48 hours (for autoclave processing) or 48-72 hours (for ethylene oxide processing) and results recorded as "POSITIVE" or "NEGATIVE"

**Results:**

1) If adequate sterilization has been achieved, the liquid in the ampule will remain blue/purple in color. This is recorded as a NEGATIVE result.
2) If adequate sterilization has not been achieved, the liquid in the ampule will turn yellow indicating that sterilization was not adequate to kill the bacteria in the ampule. This is recorded as a POSITIVE result.
3) All results will be reviewed and analyzed by the Laboratory Coordinator in consultation with the Director of CMF.
   a) Records will be maintained by the Laboratory Coordinator on the shared laboratory drive.
   b) Unacceptable findings will be discussed with the CMF Director, Assistant Director, and Operations Manager.
   c) A plan of action will be devised for each individual case of unusual or unacceptable findings and may involve additional testing, revised sterilization procedures, equipment modifications, maintenance, or repairs if necessary.

**Discussion/Background:**

Sterilization is achieved using either pressurized steam (autoclaving) or ethylene oxide gas (gas sterilization). In order for sterilization to be adequately achieved, adequate heat or gas levels must

be reached and maintained for a specific period of time determined by specific cycle parameters. Also, the load must be packed appropriately to allow for adequate steam or gas circulation around the items in the load. A biological indicator is a good method to evaluate the efficacy of sterilization. Each ampule contains a disc inoculated with both *Geobacillus stearothermophilus* and *Bacillus atrophaeus* spores and culture media. These organisms cannot survive adequately achieved steam or ethylene oxide sterilization processes. Thus, if growth occurs in the ampule after the sterilization process, adequate sterilization has not been achieved.

**APPROVALS**

| **Responsible Official Signature** | | | **Date** |
|---|---|---|---|
| Jue Cua DVM, PhD | | | 3/01/18 |
| **QA Signature** | | | **Date** |
| | | | 03/01/2018 |
| **Version** | **Effective Date** | **Supersedes** | **Original Date** |
| #2 | | #1 | 02/22/10 |