Microbial Monitoring of GF Isolators

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Topics to Cover

- Sterility testing of the newly set up GF isolator prior to animal entry
- QC of materials entering the isolator
- Microbial monitoring of the isolator after animal entry
- Supplies for testing and outsourcing
New GF Isolator Sterility Testing

- Typically sterile supplies are already in the isolator (caging, racks, water bottles etc.) as well as feed and bedding

- 3 weeks of negative sterility testing:
  - **Week 1 testing**
    - Mold trap swabs
    - Moisten swabs with sterile water; swab interior walls, ceiling, gloves, around filter outlets, caging, feeders and floor area
  - **Week 2 testing**
    - As above with addition of mold trap samples
  - **Week 3 testing**
    - As above with the addition of mold trap samples

*Imperative that sterilant does not get on the swabs!!*
Vials are transported to the QC lab on the same site

Samples are processed the same day of receipt/collection

Cultured aerobically and anaerobically

Wet mounts prepared

Original vial is kept at least one week (BTC, mold, discrepancies)

Suspect findings must be confirmed by a second sampling taken on a separate day
  - If it does not confirm, an investigation takes place
  - Must have 3 consecutive weeks of negative results to be used
QC of Materials Entering the Isolators

- Autoclaving is the safest method to sterilize materials for GF isolators
  - Biological indicators- Verify
  - Chemical indicators- Sterigage

- Validated autoclave cycles
- Validated loads
- Ethylene oxide (Verify and Sterigages work)
- Irradiated materials (feed particular concern)
STERIS' Verify® Self-Contained Biological Indicators (SCBIs) are available as either single or dual species formats (Bacillus atrophaeus (BA) for ethylene oxide and dry heat sterilization and/or Geobacillus stearothermophilus (GS) for saturated steam sterilization).
Other Biological Indicators

Spore Strips
3M Comply SteriGage

These chemical integrators are used for pack control as a method for monitoring sterilization process conditions inside each pack. The 3M™ Comply™ Steam Chemical Integrators can also be used inside a process challenge device (PCD) to release processed items, excluding implants (load control). Use for this purpose, does not replace the use of biological indicators.

Steam enters the permeable topside of the device - the chemical pellet melts and migrates as a color along the paper wick; the distance or extent of migration depends on exposure to steam, time, and temperature.
Microbial Monitoring After Animal Entry

- **Weekly vial testing**
  - Swab of isolator interior surfaces (moisten with "dirty" water), swab caging, feed, feeders, floor area
  - Randomly sample 10-12 cages-collect fresh feces and soiled bedding
  - Add water from water bottles (several)
  - Transport to laboratory

- **Culture: aerobic, anaerobic, mold**
  - Trypticase soy agar with 5% sheep blood (37 degrees C)
  - Nutrient agar with dextrose (22 degrees C)
  - Brucella agar with 5% horse blood (anaerobic 37 degrees C)
  - Wet mount
  - Store original sample
Transport Media

- Viability of a wide variety of strict anaerobic, aerobic and microaerophilic organisms is maintained for up to 72 hours at 20 to 25 degrees C.
  - Tubes
  - Jars
  - Vials
  - BBL™ Port-A-Cul™ Transport Systems
- Validate the transport system works for your particular testing
Summary

- **Microbial monitoring of new GF isolators**
  - At least 3 weeks of negative results prior to animal entry

- **QC/monitoring of supplies**
  - Autoclaving is recommended
  - Validation of autoclave, runs, loads
  - Use of biological indicators/chemical indicators

- **Microbial monitoring after animal entry**
  - Weekly microbial monitoring
• Enviro-Tech Laboratories - Mail in laboratory testing service
http://www.sporestriptesting.com/services.htm

• Accugen Laboratories (independent contract microbiology laboratory)
http://www.accugenlabs.com/

• Microbac Laboratories, Inc.
http://www.microbac.com/index.php