

# Microbial Monitoring of GF Isolators

**Taconic**  
Smart Solutions To Improve Human Health



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- **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**



- **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



- **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)**





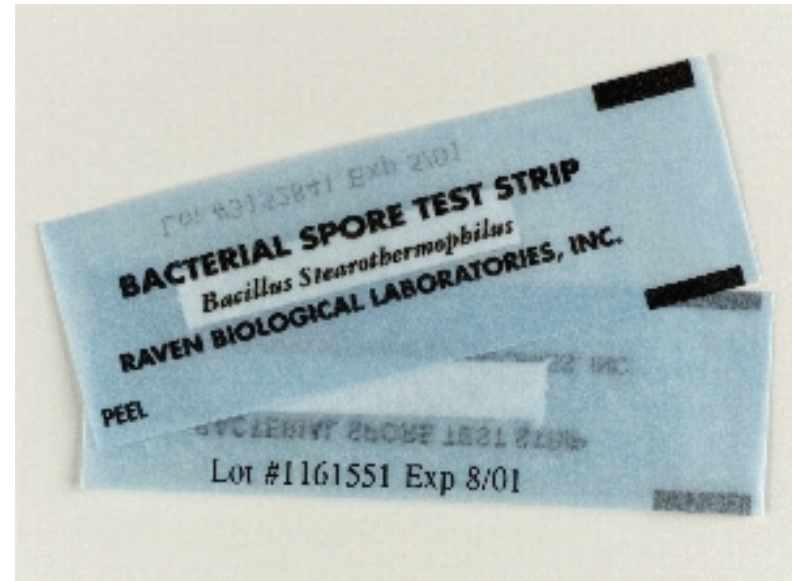
## Biological Indicators

**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.







- **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



- **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**





- **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.sporestriptest.com/services.htm>
- **Accugen Laboratories (independent contract microbiology laboratory)**  
<http://www.accugenlabs.com/>
- **Microbac Laboratories, Inc.**  
<http://www.microbac.com/index.php>