

VAL 200: Selection and Use of Biological Indicators during Validation Studies

Appendix 3: Biological Indicator Test Results Sheet – Spore Strips

Procedure

Fill out table and transfer sheet to Quality Control with all samples.

| | | | | | |
|-------------------------|-------------------------|--------|----------------------|----------------|----------------------|
| Cycle/Test Number: | <input type="text"/> | Run #: | <input type="text"/> | Initials/Date: | <input type="text"/> |
| QC Serial Number: | <input type="text"/> | | | | |
| Commenced Incubation at | <input type="text"/> °C | Time: | <input type="text"/> | Initials/Date: | <input type="text"/> |

1. All testing must be performed in a biological safety cabinet
2. On Return to the QC Lab BI's will be stored at room temperature and must be tested within 7 days from the end of the sterilisation process
3. Aseptically open glassine envelopes and withdraw spore strips with sterile forceps
4. Transfer spore strips to individual tubes containing 10 – 15mLs of sterile Trypticase Soy Broth (TSB)
5. Each tube must be clearly labelled with date and BI number.
6. Incubate Spore strips for seven days at 55°C - 60°C.
7. Observe tubes daily for growth and record the results on Table # 1.

Acceptance Criteria

Turbid = growth = non-sterile

Clear = no growth = sterile

| Table # 1 Test Results for Spore Strips | | | | | | | | |
|---|------------------|---------|---|---|------------------|---|---|---|
| BI No. | Received by Date | Results | | | | | | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
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| Control | | | | | | | | |
| Sign & Date | | | | | | | | |
| Test Result (Pass / Fail) | | | | | Tested By / Date | | | |
| Verified By / Date | | | | | Review By / Date | | | |