How to Audit to ... ?

Microbiology Fields of Accreditation

Bottom line ...

- Can the laboratory demonstrate the ability to grow the target organism if it is indeed present in samples?
- Can the laboratory demonstrate the absence of contamination or inhibiting substances if the target organism is indeed absent in samples?

Positive Controls

- Reference cultures traceable to national culture collections or certificates of analysis / purity (bacteria, viruses, protozoa, cell lines, PCR primers)
- Growth media (commercial lots or lab.-prepared batches) tested with positive culture controls, with the expected result observed.
- Acceptable method evaluation performed as required by NELAC.
  - PT's if available
  - 10 spiked samples in the quality system matrix
  - Comparison with test method already approved for use
  - Procedure specified in the test method

Positive Controls

- Confirmations of presumptive positive results performed as specified in the test method (completed test where needed).
  - Question: When do Colilert results require confirmation? (Quantitrays? P/A?)
  - Question: What confirmations are needed for Colisure, Readycult, Colitag, & other enzyme substrate medias?
- Colony count confirmations on the same plate monthly.
- Reference cultures are maintained and tested to verify purity and viability of cultures
  - Question: What types of tests are adequate to prove the organism is Escherichia, Pseudomonas, Enterococcus, etc.?

Negative Controls

- Growth media (commercial lots or lab.-prepared batches) tested with negative culture controls, with the expected result observed.

- Growth media (commercial lots or lab.-prepared batches) tested with un-inoculated controls, with no growth observed.

Sterility Checks

- Membrane filters, if used
- Sample bottles, if lab.-supplied
- Dilution-rinse water (each lab. batch or commercial lot)

Equipment Checks

- Autoclave used for sterilizations.
- Incubators (temperatures, tolerances)
- Refrigerators and freezers for storage
- Microscope maintenance, adjustments, calibrations, analyst observer logs
- Volumetric accuracy of all pipettes, marked containers, & others used to determine critical sample sizes and test results

Media & Reagents
(includes Antibiotics & Cell Passages)

- Preparation logs and traceability to neat, unexpired materials (and prepared according to method or manufacturer requirements)

- Use in specific tests is traceable to specific preparation entries.

Documentation

- History of sample readily understood through the documentation
  - Checks: temperature, lack of chlorine, holding time
  - Preparations: MF steps, dilutions, volumes, ID's
  - Incubations: temps., dates & times in & out
  - Results: Observational details, counts
    - WHAT does + or – MEAN?

Questions?

- Can any of these tests be performed by a subcontract laboratory or outside facility?