

# Bioburden Testing

Bioburden testing is known by many names, such as: Microbial Count, Viable Count, Total Count, Plate Count, Colony Count, Heterotrophic Count, and Mesophilic Count.

Under ISO/AAMI it is called Bioburden Determination and can be found in ISO 11737-1:2006. In the USP, bioburden testing is called Microbial Enumeration, per section <61>.

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## The Role of Bioburden Testing in Evaluating Healthcare Products

In the last few years bioburden testing has taken on an increasingly important role in evaluating the microbiological quality of health care products, including:

- ▶ Initial acceptance of incoming materials and components
- ▶ Evaluation of processes (assembly, cleaning, packaging, etc.)
- ▶ Assessment of microbial levels at manufacturing steps
- ▶ Evaluation of changes to a product or process
- ▶ Validation of a sterilization process (EO, radiation, steam)
- ▶ Development and assessment of aseptic operations
- ▶ Evaluation/validation of water systems (DI, RO, UV, etc.)



The type of bioburden test that should be performed depends on the information that is needed. The following are descriptions of the four most common types of bioburden tests. Performing all four tests will typically satisfy the “characterization” requirement of Bioburden Determination in ISO 11737-1:2006.

### AEROBIC COUNT

Enumerates the overall level of microorganisms that exist in an aerobic environment, typically most bacteria, fungi (mold) and yeast. Usually run for all bioburden determinations, with other selective tests added to supplement the data.

### ANAEROBIC COUNT

Selects for anaerobic organisms by growing them in an anaerobic (non-oxygen) environment. Typically performed when a product has a biologic/tissue component.

### FUNGI / MOLD COUNT

Selects for most fungi and yeast by inhibiting the growth of bacteria. Typically performed in conjunction with the aerobic count as an indication of the microbial load for these two most common categories.

### SPORE COUNT

Selects for bacterial spores by eliminating other bacterial cells using heat. Typically run in conjunction with aerobic count to determine the percent of spores in a microbial population, which can be a significant factor in sterilization validation.

### OTHER AVAILABLE BIOBURDEN TESTS INCLUDE:

- **Recovery Efficiency (Validation)**  
Usually required to validate the efficiency of a test procedure in extracting and culturing the bioburden organisms.
- **Selective Tests**  
Tests that may be necessary – depending on a product’s materials/components – to select for particular organisms or groups, such as Psuedomonas Count, Clostridium Count, Coliform Count, or Gram-Negative Count.

Contact us for more information on WuXi AppTec’s complete menu of microbiology services.

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