TECHTIP

BIOLOGICAL INDICATOR POPULATION VERIFICATION TEST

Purpose

In a sterilization process where biological indicator (BI) sterility results are used as part of product release criteria, the BIs shall be procured from an approved supplier with a minimum population of test organisms defined. The population of the test organisms upon receipt at the test facility should be verified per *ISO 11138-1 Sterilization of health care products - Biological indicators - Part 1: General requirements.*

In ethylene oxide and dry heat sterilization, the test organism used is typically the endospore-forming bacteria, *Bacillus atrophaeus, (ISO11138-2 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes and ISO11138-4 Biological indicators - Part 4: Biological indicators for dry heat sterilization processes)* with each unit having a minimum population of 1 x 106.

This spore population should be verified prior to use for routine sterilization purposes, to ensure that:

1. The spore population is as stated by the manufacturer on the certificate of analysis (COA)
2. The transit and storage conditions have not affected the spore population

Moist heat and vaporized hydrogen peroxide (VHP) modalities typically use a thermophilic endospore-forming bacteria, *Geobacillus stearothermophilus.*

Manufacturers are required by ISO 11138-1 to provide the name of the test organism; instructions for use, storage, testing, and disposal; and the nominal population and resistance information with each biological indicator batch.

How the Population Verification is Performed

To verify the spore population of the test organism, samples of biological indicators are selected from each distinct manufacturer batch per delivery received. ISO 11138-1 defines the minimum sample number of four biological indicators for population verification.

Biological indicators are assayed following manufacturer's instruction, usually involving extraction, and sometimes requiring maceration of a paper strip, heat-shocking, serial dilution, pour-plating, incubation, and enumeration. Manufacturer and biological indicator product methods may vary in extraction techniques, as well as heat-shocking and incubation temperatures of different test organisms, and appropriateness should be verified by end-user performing the test.

Following the incubation period, the colony forming units (CFUs) are enumerated and the results recorded.

Results are then compared to the manufacturer's certificate nominal population. Verification of the population is achieved if the test result is between 50% and 300% of the nominal certificate population.

Per Section 6.3.2 of ISO 11138-2, if the end-user population verification performed during the manufacturer's stated shelf-life results in a population below 1x106 but still falls between 50% to 300% criteria, the verification is acceptable.

FOR MORE INFORMATION

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