

Objective

To provide an organic and inorganic challenge that mimics what medical devices would be exposed to in the patient body, using artificial test soil (ATS). The composition of ATS is based on the worst-case levels of protein, carbohydrate, endotoxin, and hemoglobin detected from patient-used flexible endoscopes.

Microorganisms

Use test organisms such as *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Enterococcus faecalis* (ATCC 29212). These organisms are passaged on tryptic soy agar and incubated aerobically at 37°C. Follow ATCC guidelines for storage of organism stocks. (www.atcc.org)

Test soil and inoculation methods

Test organisms are suspended in ATS to provide a final concentration of 10^8 cfu/mL. The inoculation of the test carrier is performed by the use of a micropipette to place 10 or 50 μ L of the test suspension on the inner surface of a PVC test carrier. This provides an inoculum of 10^6 cfu/carrier. The test carrier consists of a 1-cm piece of PVC tubing with an inner diameter of 3 mm. Once inoculated, the test carrier is placed in a petri dish inside a biosafety cabinet and allowed to dry overnight at room temperature (RT). These inoculated dried test carriers are then used to assess the killing efficacy of various detergent formulations and represents a “worst-case” challenge to the detergent.

Test method and quantitation

Lumen test carrier:

The dried inoculated test carriers are exposed to the detergent when placed into a test tube that contains 1 mL of the detergent to be evaluated. The test carrier is exposed for the detergent manufacturer’s recommended time and temperature. Quantitation is based on the viable counts that are performed from serial dilutions of the original sample (limit of detection, 10 cfu/carrier) on the spread plate and filtration for quantitation of the original sample (limit of detection, 1 cfu/carrier). All inoculated plates are incubated aerobically at 35°C for 24 to 48 hours and subsequently the numbers of colonies are counted. All results may be presented as the number of viable organisms per test carrier. To assess the cleaning efficacy of the various detergents, the lumen test carrier method is used to assess soil parameters before and after treatment. The inoculation and processing method are the same as described above. To prevent loss of soil caused by exposure to fluid, the dried inoculum on the lumen carrier may be fixed by immersing in 1% glutaraldehyde for 1 minute at RT. The final sample is assayed to determine the level of hemoglobin, carbohydrate, protein, and endotoxin. The method for quantitation of each of these soil parameters is as described by Alfa et al. 1999.

Control:

To ensure that “wash-off” from fluid exposure is separated from the microbial killing ability, all experiments should include controls that consist of quantitative testing of the recoverable bioburden after exposure of the inoculated/dried carrier to phosphate buffered saline solution for the time and temperature equivalent to the detergent exposure conditions.

Study utilizing this method:

Alfa MJ, Jackson M. A new hydrogen peroxide-based medical device detergent with germicidal properties: comparison with enzymatic cleaners. *Am J Infect Control* 2001; 29:1-10.

Other relevant publications:

Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999;27:392-401.



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