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MICROBIAL CONTAMINATION OF MATERIALS AND THEIR PACKAGING BEFORE DISINFECTION

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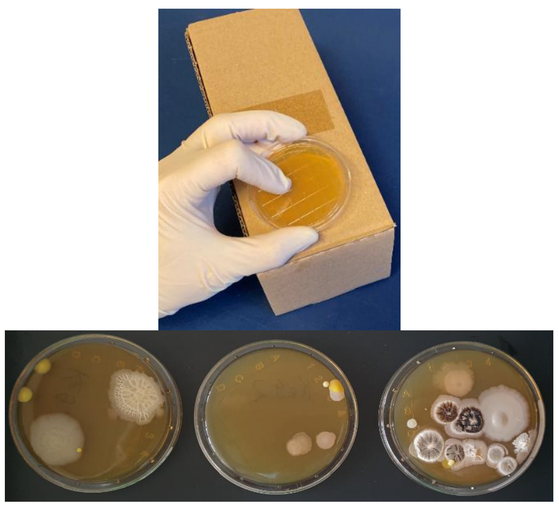
Background Materials used in aseptic production like medical devices (MD), infusion bags (IB), bottles (B), infusion vials (V) and ampoules (A) most widely undergo disinfection with alcohol 70%. Alcohol, however, is known not to eradicate all microbes, e.g. bacterial spores.

Purpose To explore the microbial contamination of materials and their packaging before disinfection.

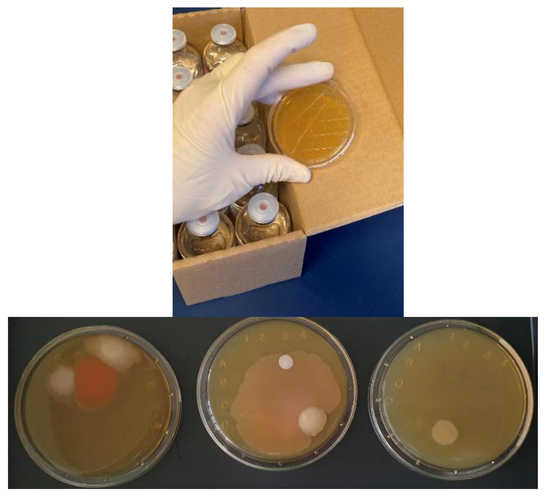
Materials and Methods For 12 materials and their cardboard packaging (MD, IB, B, V, A), three samplings each at the outer and inner side of the packaging and at the material surface were tested with contact plates (108 plates) applied for 5 sec. After incubation for ≥72 hours at 20 - 25 ° C and 30 - 35 ° C, respectively, contact plates were observed for colony forming units (CFU). Unpacked materials were additionally tested, three samplings each (36 contact plates), after sporicidal disinfection using High-Speed $H_2O_2^{TM}$ (wipes and foam).

Results Without disinfection, CFU appeared on 81% and 33% of contact plates referring to the outer and inner sides of the cardboard boxes. Surface of the materials showed contamination in 25% of plates. The microbes found on the plates included bacteria, aerobic spore-formers and Aspergillus. After sporicidal disinfection, in none of the plates microbial growth was seen.

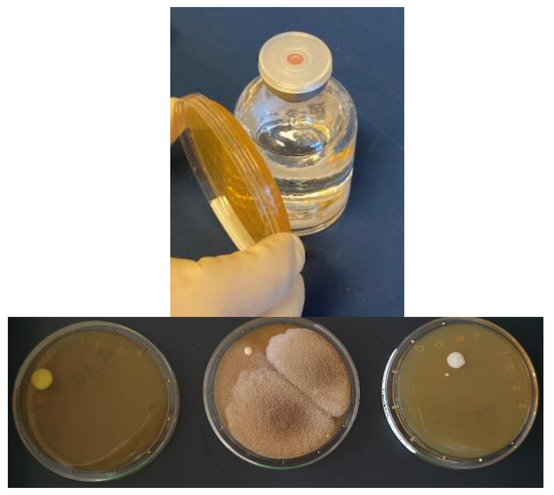
Picture 1.a – 1.c: Example Infusion Vials



1.a: Contaminated samples cardboard boxes outer side

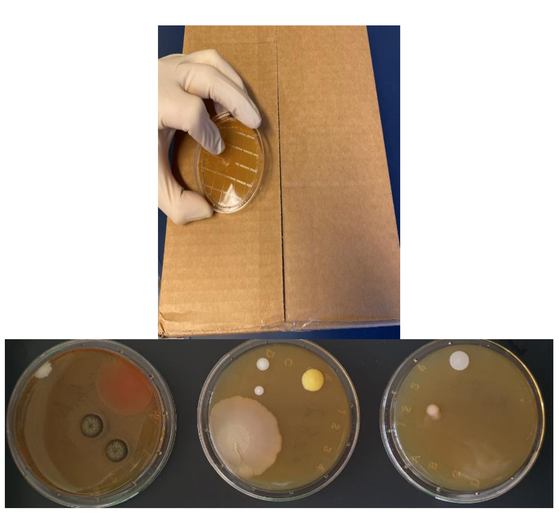


1.b: Contaminated samples cardboard boxes inner side



1.c: Contaminated Samples material surface

Picture 2.a – 2.c: Example Infusion Bottles



2.a: Contaminated Samples cardboard boxes outer side

2.b: Contaminated samples cardboard boxes inner side

2.c: Contaminated samples material surface

Conclusions Microbial contamination includes microbes that may not be eradicated by alcohol. Sporicidal disinfection, e.g. with H_2O_2, may further reduce microbial contamination risk and may not only be applied when materials are transferred to clean room classes B and A, but when materials already enter the production area (zone D).