

Method validation of surface sampling

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Various types of solid surfaces are used by the manufacturers to carry out packaging of their healthcare products. In order to control microbial hazards, these surfaces are subjected to de-contamination processes to avoid cross-contamination of the products and to improve product safety. The preventive approaches have resulted in the use of microbiological analysis of surfaces of the working areas as one of the tools to control the hygiene of products. The surface sampling method or their modifications are generally carried out for this purpose. The objective of this study is to validate a modified surface sampling method against the conventional method. The surface sampling method, i.e. conventional swabbing test was performed to assess the quality of the work areas. This method was used in specific locations in the work surfaces and microorganisms in the selected area (100 cm²) was taken, using a sterile swab. The swab test is based on the serial dilution technique (10⁻¹ to 10⁻⁷) and 1 ml of each dilution was plated with Tryptic Soy Agar (TSA). In the modified method, 1 ml from each prepared dilution was transferred to the selected area of the surface. After 2 minutes, the surface was rubbed with a sterile swab. Each swab was then transferred into a buffer solution contained in a universal bottle and 1 ml from each dilution was plated with TSA. All prepared plates were incubated at 32 °C for 3 days. Three trials were conducted for each method as stated before and the results were calculated as cfu/ml. The results were subjected to paired-samples t- test using MINITAB programme to compare the two methods. There was no significant difference in conventional swab sampling method (m= 192, SD = 129) and the modified method (m=190. SD = 130); t (6) = 2.08, p= 0.083 (Table T value = 2.45, p=0.05). Both surface sampling methods successfully swabbed all bacteria in the selected area to be tested. Therefore, both methods can be performed to analyse the microbiological quality of working surfaces.

Keywords: Modified swab test, Surface sampling, Validation