

TITLE: COMPARISON OF THE AUTOMATED *VERSUS* CONVENTIONAL METHODOLOGY OF MICROBIOLOGICAL CULTURES, IN A CARDIOVASCULAR TISSUES BANK

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ABSTRACT:

The Human Tissue Bank aims to process and make available human heart valves for therapeutic purposes. Therefore, to ensure safety and quality of tissues during all stages of processing is of paramount importance to mitigate disease transmission. The present study evaluated the performance of the automated *versus* conventional microbiological method on quality control during the stages of cardiac valve processing. The conventional methodology was performed according to the Brazilian Pharmacopoeia, using liquid media such as Thioglycolate Broth, Tryptic Soy Broth and Sabouraud Dextrose Broth. Microbial growth was detected by daily visual analysis of turbidity for up to 14 days. The automated methodology was performed on BD BACTEC® (FX40) equipment, using Plus Aerobic /F®, Plus Anaerobic /F® and Myco /F Lytic® (Becton Dickinson) media. Four types of samples were used: 1. Transport Solution (NaCl 0,9%), 2. Macerated Tissue with After Sterilization Solution (SE) composed of antibiotics (vancomycin, polymyxin B, cefoxitin and lincomycin), 3. Physiological solution used for tissue washing and 4. Macerated tissue from washing step. These samples were artificially contaminated with six different microbial concentrations (10^{-1} to 10^4 CFU / mL) of *Staphylococcus aureus* (ATCC 25923), *Pseudomonas aeruginosa* (ATCC 27853), *Escherichia coli* (ATCC 25922) and *Candida albicans* (ATCC 14053) strains, in triplicate. Out of 144 samples from the two first solutions (1 and 2), both methodologies had the same number of positive cultures (108), and the lower dilutions of the macerated tissue were negative. However, from the total of 144 samples post SE (3 and 4), 29.19% presented positivity in the automated method, while only 18.05% were positive in the conventional method. Regarding the time of positivity, 83.52% of the samples of the automated methodology were positive before the conventional ones, with an average time of 4 hours earlier. The partial results demonstrate that the automated methodology obtained superior performance (sensitivity and turnaround time) in relation to the conventional methodology.

Keywords: Automated culture, cardiovascular tissues, conventional method, microbiological cultures

Development Agency: Ministério da Saúde / Fundo Nacional de Saúde / Convênio nº814611/ 2014