ORT_15 - Comparison between different VITEK® 2 and MALDI Biotyper® for the identification of Bacillus subtilis group

Laís dos Santos Oliveira[1]; Amanda Silva Costa[1]; Luciana Veloso da Costa[1]; Rebeca Vitória da Silva Lage de Miranda[1]; Talita Bernardo Valadão[1]; Daniel da Silva Guedes Junior[1]; Marcelo Luiz Lima Brandão[1].
[1]Fiocruz/Bio-Manguinhos

Introduction: Contamination of products in the pharmaceutical industry can generate several complications, such as the risk for users, in addition to microbial degradation, leading to loss of efficacy and safety of the medicine. In an attempt to guarantee compliance with regulatory requirements and ensure microbiological quality, there is greater automation of processes, making them faster and less expensive, in relation to the limitations of the conventional methods. Bacillus subtilis group is composed by Gram-positive endospore forming bacteria frequently found in samples from the production chain of immunobiological. These species are difficult to be eliminated due to their high tolerance to extreme temperatures and common sanitizers. Due to parity between closely related species and considering their environmental origin, there is great difficulty in identifying it at the species level.

Objectives: This study aimed to compare two automated methodologies: VITEK®2 and MALDI Biotyper® for the identification of Bacillus subtilis group isolated from a immunobiological pharmaceutical facility.

Methodology: One hundred and twenty-nine strains isolated from different types of samples from the production chain of immunobiological from 2016 to 2022 had been previously identified by VITEK®2(bioMérieux) as Bacillus subtilis group. These strains were analyzed by Matrix□Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry (MALDI-TOF MS) through proteome profiling analysis with MALDI Biotyper®(Bruker).

Results: From the 129 strains previously identified by VITEK®2 as Bacillus subtilis group, (41,0%) were identified at species level; (31,0%) at genus level; (28,0%) were not identified by MALDI Biotyper®(Bruker) and (39,0%) were identified as belonging to the Bacillus subtilis group.

Conclusion: When comparing the two methodologies, MALDI Biotyper® provided results in less time and cost than VITEK®2 and was able to identify 17.2% of the strains at species level. However, it is necessary to build a robust database based on proteomic spectra, after identification at species level by genotypic methods, for better differentiation of the closely related species of the group thus contributing to the unit's contamination control strategy.

Keywords: Phenotypic characterization; Immunobiological facility; Bacillus subtilis group