

ORT 13 - Identification of isolates from an immunobiological industry: comparison between VITEK®2, MALDI-TOF MS and 16S rRNA gene sequencing

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Introduction: In the pharmaceutical industry, the presence of microorganisms is a major concern, especially in the manufacture of sterile medicines. To reduce the risk of product contamination, an environmental monitoring program is needed, with microbial identification as one of the objectives. Routine identification can use phenotypic methodologies such as VITEK®2 (a semi-automated system that performs several biochemical tests at once) and Matrix-Assisted Laser Desorption Ionization - Time of Flight / Mass Spectrometry - MALDI-TOF MS (based on the ionization of proteins); and genotypic methodologies such as 16S rRNA gene sequencing (considered the gold standard method for species delineation).

Objectives: This study aimed to compare bacterial identification using VITEK®2 and MALDI-TOF MS with the full 16S rRNA gene sequencing.

Methodology: Eighteen isolates were selected from the environmental monitoring program of an immunobiological producer in Rio de Janeiro, obtained between 2013 and 2020. The isolates were analyzed by VITEK®2, MALDI-TOF MS and full 16S rRNA gene sequencing, according to the instructions of the manufacturers and the MicroSEQTM Full Gene 16S rDNA kit. Full 16S rRNA gene sequencing was considered valid when the percentage of identification was $\geq 96\%$, and the isolate was considered identified to species level when the identification was $\geq 98.7\%$.

Results: The 16S sequencing identified 11 isolates (61.1%) at the species level and 7 (38.9%) at the genus level. MALDI-TOF MS identified 1 (5.55%) and 6 (33.3%) at the species and the genus level, respectively. VITEK®2 identified 3 (16.7%) at species level and 6 (33.3%) at genus level. When comparing the VITEK®2 identification with the sequencing, 1 (5.55%) isolate belonged to the same class, 2 (11.1%) to the same order and 8 (44.4%) to the same genus. However, no isolate was identified as the same species by both methodologies. Identification by MALDI-TOF MS arrived at the same genus as sequencing for 4 (22.2%) isolates and the same species for another 2 (11.1%).

Conclusion: Although VITEK®2 showed a higher number of isolates identified as the same genus than sequencing, MALDI-TOF MS was more specific and reached species-level identification.

Keywords: VITEK®2; MALDI-TOF MS; 16S rRNA gene sequencing

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