IVD_01 - Respiratory Virus Panel 1 (VR1) and Respiratory Virus Panel 2 (VR2) Bio-Manguinhos Molecular Typing Assay: tool for discriminatory diagnosis of respiratory infections

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Introduction: The Respiratory Virus Panels VR1 VR2 was developed in response to a request from the General Coordination of Public Health Laboratories / Ministry of Health. The assay detects Influenza A (INF-A), Influenza B (INF-B), SARSCoV-2(SC2), Respiratory Syncytial Virus (RSV), Human Metapneumovirus (HMPV), Adenovirus (ADV) and Rhinovirus (HRV). As a proof of concept before registration with National Health Surveillance Agency (ANVISA), the assay was made available to partner laboratories. The assay is intended for respiratory swab collection testing. A collaborative study was carried out with the Faculty of Medicine of São José do Rio Preto (FAMERP) city, at the beginning of February 2024. According to the city's epidemiological bulletin (February/2024), 62 cases of INF-A were recorded; 264 of SARS-Cov2; 178 of RSV; 44 of ADV; 4 of MPVh; 131of Rhinovirus RVH. Samples from the FAMERP were evaluated with previous testing for SARS-CoV2, using *in-house* methodology. Some patient samples, with previously undetected results, had other respiratory viruses detected when tested with the VR1/VR2 Assay. One patient presented detectable results for three different respiratory viruses in the same sample evaluated. The VR1/VR2 Assay constitutes an important discriminatory diagnostic tool, differentiating the causative agents of the main respiratory infections in multiplex assessment.

Objectives: Discriminatory detection of respiratory viruses causing illness in patients with respiratory infections.

Methodology: The VR1/VR2 Bio-Manguinhos Molecular Typing Assay is a qualitative and discriminatory multiplex test that uses the RT-PCR technique. It is divided in two reactions: INF-A / INF-B / SARS-Cov / MPVh / RNAseP and ADV / RSV / RVH / RNAseP.

Results: Nasal swab samples from 48 patients previously evaluated for SARS-CoV2 (FAMERP in-house methodology) were tested with the VR1/VR2 Typing Assay. 10 patients had results detected by both methodologies. 11 SARS-CoV2 patient's samples not detected by the in-house test had results detected for other respiratory viruses when tested with the VR1/VR2 assay. Among these 11 patient's samples, 1 male child, 9 months 2 days old, with symptoms of diarrhea, runny nose, fever and vomiting, was detected for 3 different viruses: SARS CoV-2, RSV, RVH.

Conclusion: The discriminatory detection of the VR1/VR2 Molecular Typing Assay is essential to determine the causative agent of respiratory syndromes. After registration with ANVISA, it can assist in the differential diagnosis, identifying the causing agent of infections. It could be used in epidemiological surveillance of respiratory epidemics in Brazil.

Keywords: Discriminatory; Diagnosis; Respiratory