Biomarker Development Trial to test the diagnostic accuracy of EUA approved RT-PCR assay and a Laboratory Developed LAMP SARS-CoV-2 test in paired nasopharyngeal, saliva, and urine samples

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Abstract

As the SARS-CoV-2 pandemic virus has spread throughout the world, millions of positive cases of COVID-19 have been registered and, even though there are millions of people already vaccinated against SARS-CoV-2, a large part of the global population remains vulnerable to contracting the virus. Given the difficulty of massive sample collection in Puerto Rico and the restrictions to perform the molecular test to detect SARS-CoV-2, this study aims to evaluate the diagnostic accuracy of the TaqPath RT-PCR COVID-19 kit and a LAMP SARS-CoV-2 Laboratory Developed Test in paired nasopharyngeal, saliva, and urine samples. Automated RNA extraction was performed in the KingFisher Flex instrument, whilst PCR quantification of SARS-CoV-2 on the 7500 Fast Dx RT-PCR instrument using the TaqPath RT-PCR COVID-19 molecular test. The PCR data was interpreted by the COVID-19 Interpretive Software from Applied Biosystems and statistically analyzed with Cohen's kappa coefficient (k). Cohen's kappa coefficient (k) for paired nasal and saliva samples was found to be 0.52, showing moderate agreement. Nasal and saliva samples displayed concordance and it was determined that saliva samples had a higher viral load. Another objective was to compare the positive or negative result of the RT-PCR with the positive or negative result of LifeGene-Biomarks SARS-CoV-2 Rapid Colorimetric LAMP LDT, which resulted in 90% concordance. Due to this, the use of saliva and LifeGene-Biomarks SARS-CoV-2 Rapid Colorimetric LAMP test is suggested for further evaluation as an alternative to nasal, urine, and RT-PCR tests for the detection of SARS-CoV-2, since it can be easily used in clinics, hospitals, the workplace, and at home, optimizing the surveillance and collection process, which helps mitigate the global public health and socioeconomic damage caused by airborne pandemics.

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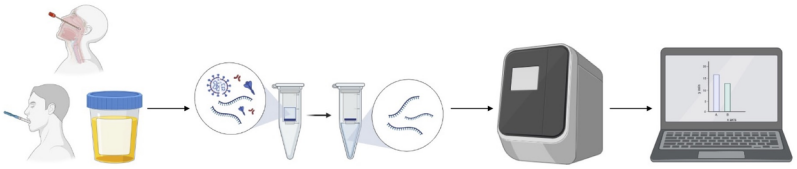
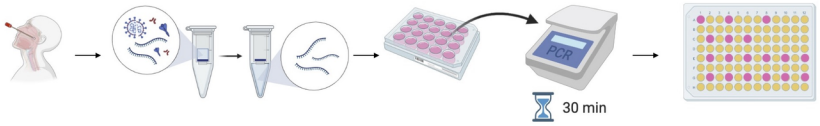


Collection of nasal, saliva, and urine samples

RNA extraction from inactivated SARS-CoV-2 virus

Quantification by RT-PCR

Test Result (Positive or Negative)



Collection of nasopharyngeal samples

RNA extraction from inactivated SARS-CoV-2 virus

Incubation at 65°C

Test Result (Positive or Negative)