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Immunoassay SARS Cov-2 Ag quantitative test in saliva v.s PCR test in nasopharyngeal swab for diagnosis of Covid-19.

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PURPOSE / OBJECTIVES

The 2019 novel coronavirus infection disease (COVID-19) is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since 2021, variants of the virus have emerged or become dominant in many countries, with the Delta, Alpha and Beta variants being the most virulent. As of 27 August 2021, more than 214 million cases and 4.47 million deaths have been confirmed, making it one of the deadliest pandemics in history.

Our goal is clinical assessment of CLEIA Lumipulse G600II SARS Cov-2 Ag quantitative test in saliva sample and reverse transcriptase polymerase chain reaction (RT-PCR) performed on a nasopharyngeal swab sample for diagnosis of infection with SARS Cov-2.

MATERIALS & METHODS

At the same time, we collected saliva sample and nasopharyngeal swab sample from 29 patients referred to lab for screening or diagnosis of SARS Cov-2 infection. Each patient was tested twice with the two different methods and respective samples. Patients were hospital staff and were examined at the onset of symptoms and 18 days thereafter. Laboratory Methods: Nucleic acid-based tests can detect SARS-CoV-2 gene – RT PCR method. Lumipulse G SARS-CoV-2 Ag is an assay system, including a set of immunoassay reagents, for the quantitative measurement of SARS-CoV-2 antigen in specimens (saliva) based on CLEIA technology by a specific two-step immunoassay method on the LUMIPULSE G System.

RESULTS

Method/results	Et once of symptoms	After 18 days
Number of patients (total)	29	29
RT-PCR test – positive results	23	0
RT- PCR test – negative results	6	29
Lumipulse SARS Cov-2 Ag results (pg/mL):		
0.09-0.45	4	24
0.46-0.67	2	4
0.68-29.90	4	1 (0.69 pg/ml)
30.00-129.99	15	0
130.00-1099.99	4	0
1100.00-5000.00	0	0

To detect the virus, lower respiratory tract specimen, nasopharyngeal swab fluid and saliva of the patient are shown to be reliable samples for the detection of the SARS-CoV-2 virus. In general, the diagnosis of SARS-CoV-2 infection is made by molecular detection of the SARS-CoV-2 genes. Although nucleic acid-based tests can detect SARS-CoV-2 gene with high sensitivity, it is restricted by the needs of special equipment and turnaround time. Lumipulse G SARS-CoV-2 Ag is useful as a diagnostic tool for the confirmation of a SARS-CoV-2 infection by detecting the SARS-CoV-2 antigen in saliva or nasopharyngeal swab.

LEG UP:

- Eid in early detection of SARS Cov-2 Virus from suspected Covid-19 cases.

- High-throughput quantitative antigen test with CLEIA platform Lumipulse G.

- Shorten the TAT and simplify operation procedure to improve the efficiency of clinical diagnosis.

RESULTS

RT-PCR test results are reported as positive or negative. The results of the antigen test are reported quantitatively. The cut-off value is 0.67 pg / mL. Above this value the patient is positive for the virus, and below this value he is negative. The range of results is from 0.00 to 5000 pg/mL. We found no differences in the end result with the two methods. RT-PCR results are reported like positive or negative. Saliva results are reported like quantitative concentrations with cut-off value and higher or lower. Quantitative concentrations are correlated with the amount of virus infection. Thus, the severity of the disease can be predicted.

Boundary results were obtained in two of the patients. This is acceptable for any immunological method. In these cases, in clinical practice, we repeat the analysis the next day in a new sample. Clinical logic suggests that such results be considered as no infection.

SUMMARY/CONCLUSION

To detect the virus, lower respiratory tract specimen, nasopharyngeal swab fluid and saliva of the patient are shown to be reliable samples for the detection of the SARS-CoV-2 virus. In general, the diagnosis of SARS-CoV-2 infection is made by molecular detection of the SARS-CoV-2 genes. Although nucleic acid-based tests can detect SARS-CoV-2 gene with high sensitivity, it is restricted by the needs of special equipment and turnaround time. Lumipulse G SARS-CoV-2 Ag is useful as a diagnostic tool for the confirmation of a SARS-CoV-2 infection by detecting the SARS-CoV-2 antigen. The research data of many authors show Lumipulse assay was highly sensitive in samples with low RT-PCR Ct values, implying repeated testing to reduce consequences of false-negative results. We recommend this method in the routine diagnosis of SARS Cov-2 infection like auxiliary because: it can be implemented in any laboratory; more easily accessible sample; faster result; assessment of viral load; ability to track infection.