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Comparison of a rapid antigen test with a point of care rtRT-PCR for the detection of SARS CoV-2

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Introduction and Objectives: Real time RT-PCR (rtRT-PCR) is the gold standard for the diagnosis of SARS-CoV-2 infection. It has high sensitivity and can detect low amounts of RNA. Testing for SARS-CoV-2 infection is a critical element of the public health response to COVID-19**.** However, there is an ongoing need for reliable assays for timely and easy detection of individuals with acute SARS-CoV-2 infection. Manufacturer-reported performance data on rapid antigen test kits seem convincing, but real-world data are limited, especially from low/middle income countries. The present study aimed to compare a rapid antigen detection test (RAT) with a rapid point of care real-time RT-PCR (POC-rtRT-PCR) assay approved by the Ministry of Health, Sri Lanka to determine the test indices of the antigen detection test for the detection of SARS CoV-2 infection.

Methods: Samples collected for routine SARS-CoV-2 diagnostic testing were used for this study. Fifty (n=50) nasopharyngeal swab samples analysed by POC-rtRT-PCR (Truenat^{TM} COVID-19 assay) at the Teaching Hospital Peradeniya were subjected to the RAT (SD-Biosensor rapid antigen assay) simultaneously, according to manufacturer's instructions. Sensitivity and the specificity for the RAT were calculated to evaluate the performance of RAT using the POC-rtRT-PCR results as reference. POC-rtRT-PCR used here for comparison has been validated with Taqman real time PCR system with 100% agreement as based on the manufacturers statement.

Results: The RAT had a sensitivity of 100% and a specificity 92.3 % for high viral load samples with a comparator PCR Ct value <20.3. The sensitivity decreased to 48% on tested samples with Ct values from 20.9 to 33. The sensitivity of 48% is lower than the sensitivity of >90% claimed by the manufacturer.

Conclusion: Rapid Ag tests appeared to be highly sensitive and specific in detecting SARS-CoV-2 infections with lower Ct values (high viral loads). The RAT may be a quick and easy to perform alternative to identify individuals with high SARS-CoV-2 loads.

Key words: Rapid antigen test, Point of care, Sensitivity, Specificity.

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