The Diagnostic Performance Of SARS-Cov-2 Nasal Antigen Test In Mildly Symptomatic Cases

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Introduction

COVID 19 has been vastly spreading since December 2019, and the medical teams worldwide are doing their best to limit its spread. Early detection and isolation of infected cases is essential to reduce the spread. Therefore, a readily available, rapid, and cost-effective test with high specificity and sensitivity for early detection of COVID 19 is required. This study aimed to assess the diagnostic performance of the rapid antigen detection test (RADT) in mildly symptomatic cases.

Methods

The study included 4183 patients who were mildly symptomatic. A nasal sample for the rapid antigen test and a nasopharyngeal sample was taken from each patient. The nasal sample for the RADT was compared to the gold standard test (nasopharyngeal sample by PCR). Statistical analysis was conducted to determine the diagnostic ability of the RADT.

Results

Using the PCR test, 17.5% (733/4183) of the study population were positive. The calculated sensitivity and specificity of the RADT were 82.1% and 99.1%, respectively. Kappa's coefficient of agreement between the rapid antigen test and RT-PCR was 0.859 ($p < 0.001$). Further stratified analysis was conducted and showed a significant improvement in the test's sensitivity with lowering the cutoff Ct value to 24 or time since onset of symptoms <5 days

Conclusion

The results of the diagnostic assessment of RADT with nasal swabs used in our study illustrate a potential benefit of using them as a screening tool in mildly symptomatic patients. The diagnostic ability was exceptionally high in cases with high viral load. The rapid antigen test is intended to be used alongside RT-PCR and not replace it. Applying such test in primary care health centers in patients with typical mild symptoms is necessary to isolate the positive cases until confirmed by PCR. Additionally, the RADT can be used at a community level to ease up the reopening process.

Table 1: The effect of symptoms onset time and Ct values on the diagnostic performance

No.	Model	N	Prevalence	Sensitivity	Specificity	Negative Predicted Value	Positive Predicted Value	Kappa (p<0.001)
1	Symptom onset within 7 days	1290	20% (18% - 22.8%)	82.6% (77.5% - 87%)	99.3% (98.6% - 99.7%)	95.7% (94.3% - 96.8%)	96.9% (93.7% - 98.7%)	86.6% (83.1% - 90.1%)
2	Symptom onset within 5 days	1252	20% (18% - 22.8%)	82.4% (77.2% - 86.9%)	99.3% (98.6% - 99.7%)	95.6% (94.2% - 96.8%)	96.8% (93.5% - 98.7%)	86.5% (82.9% - 90.1%)
3	Cases with Ct ≤ 30	4148	17% (16% - 18.1%)	84.5% (81.6% - 87.1%)	99.1% (98.8% - 99.4%)	96.9% (96.3% - 97.5%)	95.2% (93.2% - 96.7%)	87.5% (85.5% - 89.6%)
4	Cases with Ct < 24	3996	14% (13% - 15%)	87.9% (84.9% - 90.5%)	99.1% (98.8% - 99.4%)	98.1% (97.6% - 98.5%)	94.2% (91.8% - 96.1%)	89.5% (87.5% - 91.6%)
5	Symptom onset within 7 days with Ct ≤ 30	1274	20% (17% - 21.8%)	86.3% (81.4% - 90.4%)	99.3% (98.6% - 99.7%)	96.8% (95.5% - 97.8%)	96.8% (93.6% - 98.7%)	89.3% (86.1% - 92.5%)
6	Symptom onset within 7 days with Ct < 24	1220	16% (14% - 18.3%)	89.3% (84.2% - 93.3%)	99.3% (98.6% - 99.7%)	98% (96.9% - 98.7%)	96.2% (92.3% - 98.4%)	91.3% (88.1% - 94.5%)
7	Symptom onset within 5 days with Ct < 30	1236	19% (17% - 21.8%)	86.3% (81.3% - 90.4%)	99.3% (98.6% - 99.7%)	96.8% (95.5% - 97.8%)	96.7% (93.4% - 98.7%)	89.3% (86.0% - 92.5%)
8	Symptom onset within 5 days with Ct < 24	1184	16% (14% - 18.3%)	89.5% (84.2% - 93.5%)	99.3% (98.6% - 99.7%)	98% (96.9% - 98.8%)	96% (92% - 98.4%)	91.3% (88.1% - 94.5%)